

# THE OPPORTUNITY COST OF HPV9 VACCINATION IN ITALY

**THE OPPORTUNITY COST OF HPV9 VACCINATION IN ITALY**

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|---|--|--|
| <p><b>BACKGROUND</b></p> <p>Human papillomavirus (HPV) is the most common sexually transmitted virus and causes a substantial burden of disease in both men and women [1]. In 2013-2014, approximately 25% of men and 25% of women between the ages of 18 and 39 had genital HPV infection [2], a large proportion of which is preventable with vaccination.</p> <p>Since the first prophylactic vaccine against Human Papillomavirus (HPV) was licensed by WHO, the recommended vaccine schedule</p> <p style="text-align: center;">OPEN</p> | <p><b>METHODS</b></p> <p>A cost opportunity cost model was developed in order to estimate the HPV-related diseases averted from a hypothetical policy context of vaccine and drugs.</p> <p>The model considers the age ratio of hospitalizations for: genital warts (GW) (218.11), cervical intraepithelial neoplasia (CIN) (522.16, 677.52, 67.28, 67.28, 233.5), anal cancer (AC) (134.2, 234.8), oropharyngeal cancer (OC), oropharyngeal cancer (OCC), LAR, R) and basal, squamous cell cancers (175.0), genital cancer (GC), penis cancer (187.3, 187.3) and cervical cancer (208.2, 182.4).</p> <p>Other direct healthcare costs were estimated from the literature of the relevant areas (acute therapy for genital warts associated with incident patients, considering the data existing from the Italian National Institute of Statistical Demography (ISTAT)).</p> <p>Various efficacy data were taken from HPV9 vaccine trial C and literature.</p> <p>Different scenarios were compared based on the vaccination coverage rates (VCRs): No vaccination (0% of VCR for both male and female), low coverage (25% of VCR for female and 15% coverage for Male as observed for the (e.g. 2018) and Optimal Vaccination Strategy as required by the Italian National Immunization Programme (NIP) (50% of VCR for both male and female). All scenarios have a lifetime projection.</p> | <p><b>RESULTS</b></p> <p>The model estimates the total economic burden of the HPV-related diseases of about €226.8 million (20% attributable to indirect costs) in the absence of HPV vaccination (Figure 1).</p> <div style="text-align: center;"> <p style="text-align: center;">OPEN</p> </div> |
| <p><b>OBJECTIVE</b></p> <p>The analysis was aimed at estimating the opportunity cost attributable to an increase in coverage rate of an HPV vaccination in Italy.</p>   | <p><b>CONCLUSIONS</b></p> <p>To obtain in Italy the residual cost for related HPV diseases, necessary to reach about €226.8 million, will be saving due to primary prevention intervention amounting €76 million. By further increasing the vaccination coverage, an envisaged in the NIP, further savings of about €30 million could be obtained and a total number of avoided events that exceeds 20 thousand.</p> <p>The estimated cost of vaccinating 95% of the primary school would amount to about €26 million per year; it is concluded that the cost of vaccination is simply compensated already in an 8% coverage. Nevertheless, our results suggest the importance of complying with the NIP targets and suggests that increasing vaccination coverage rates could generate important advantages in terms of opportunity costs.</p>  |  |

ABSTRACT REFERENCES CONTACT AUTHOR GET POSTER

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## BACKGROUND

Human papillomavirus (HPV) is the most common sexually transmitted virus and causes a substantial burden of disease in both men and women [1]. In 2013-2014, approximately 45% of men and 40% of women between the ages of 18 and 59 had genital HPV infection [2], a large proportion of which is preventable with vaccination.

Since the first prophylactic vaccine against Human Papillomavirus (HPV) was licensed in 2006, the quadrivalent vaccine (which protects against high-risk HPV types 16 and 18, and low-risk types 6 and 11, which cause 90% of genital warts) or bivalent vaccine (targeting HPV types 16 and 18) have been implemented in more than 28 countries as part of their national immunization programmes [3]. In December 2014, a nonavalent vaccine (9vHPV), was developed. The 9vHPV gained marketing authorization throughout the EU in June 2015; in Italy it was approved in February 2017.

Primary prevention of HPV-related diseases in Italy started in 2008, and the vaccination programme consisted of active and free service for all 12-year-old girls. Since 2017, the Italian Ministry of Health extended the immunization programme to 12-year-old boys, even though some regions had already started in 2014. [4]

## OBJECTIVE

The analysis was aimed at estimating the opportunity cost achievable with an increased in coverage rate of anti-HPV vaccination in Italy.

## METHODS

A cost consequence model was developed in order to estimate the HPV-related diseases incurred from a hypothetical Italian cohort of women and boys.

The model considers the age risks of hospitalization for: 'genital warts (GW)' (078.11); 'cervical intraepithelial neoplasia (CIN)' (622.1x; 67.2; 67.32; 67.33; 67.39; 233.1); 'anal cancers' (AC) (154.2–154.8); oropharyngeal cancers (OC): 'oropharyngeal cancer' (146.0–146.9) and 'head, face and neck cancers' (171.0); genital cancers (GC): 'penis cancer' (187.1–187.9) and 'cervical cancer' (180.0–180.9).

Other direct healthcare costs were estimated from the literature while indirect costs (social security benefits) were associated with incident patients considering the data coming from the Italian National Institute of Social Security (INPS).

Vaccine Efficacy data were taken from HPV9 vaccine SmPC and literature.

Different scenarios were compared based on the vaccination coverage rates (VCRs): No vaccination (0% of VCR for both male and female), 'as is scenario' (62% of VCR for female and 19% coverage for Male as observed for the 1.a.y. 2018) and Optimal Vaccination Strategy as required by the Italian National Immunization Programme (NIP) (95% of VCR for both male and female). All scenarios have a lifetime projection.

## RESULTS

The model estimates a total economic burden of the Hpv related diseases of about € 226.8 million (55% attributable to indirect costs) in the absence of HPV vaccination (*Figure 1*).

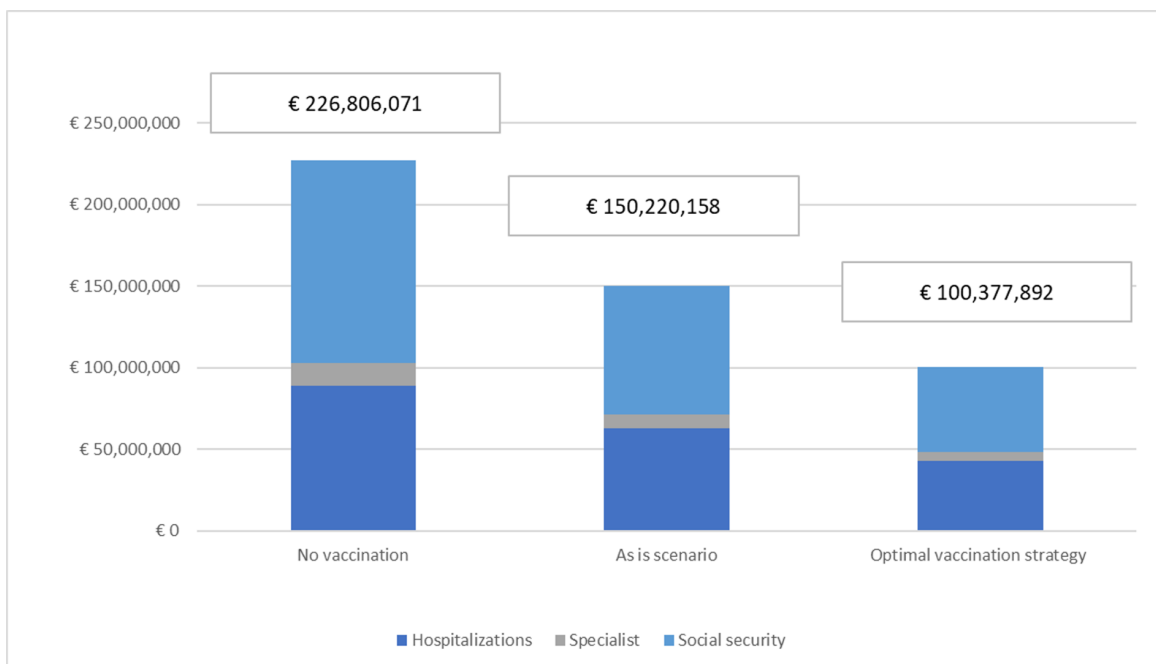


Figure 1: HPV related costs by scenarios

The 'as is' VCRs are likely to reduce € 31.4 million of direct healthcare costs and € 45.1 million of indirect costs. An Optimal Vaccination Strategy could reduce over € 126 million of direct and indirect cost if compared to the no Vaccination strategy and € 49.8 million if compared to the Standard Vaccination Strategy (*Figure 2*).

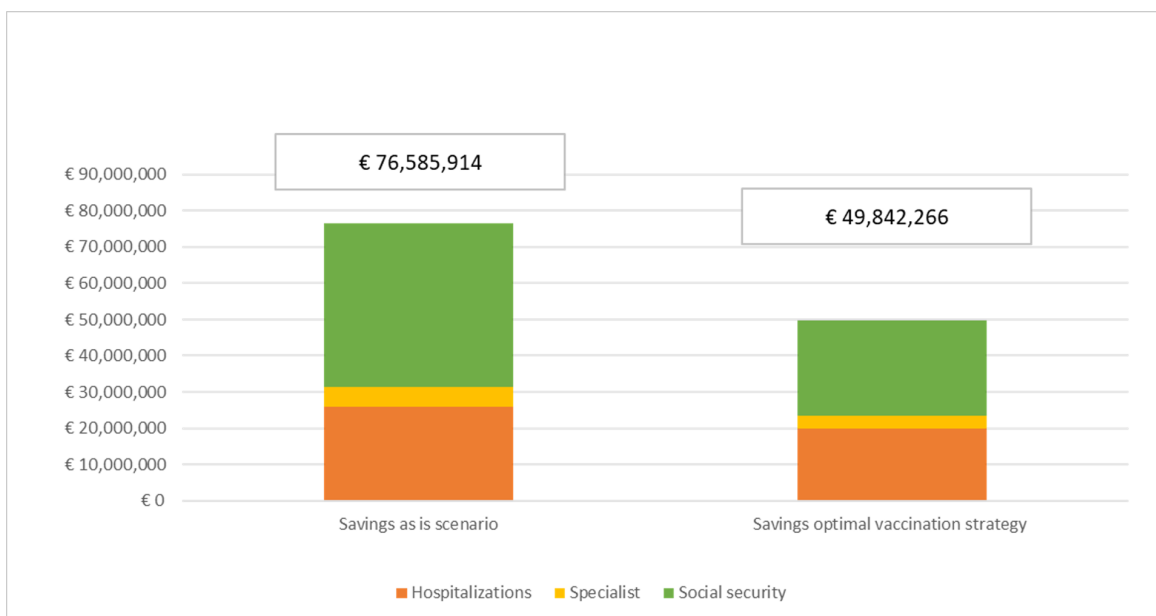


Figure 2: Costs avoided by 'as is' vaccination and avoidable costs with optimal coverage

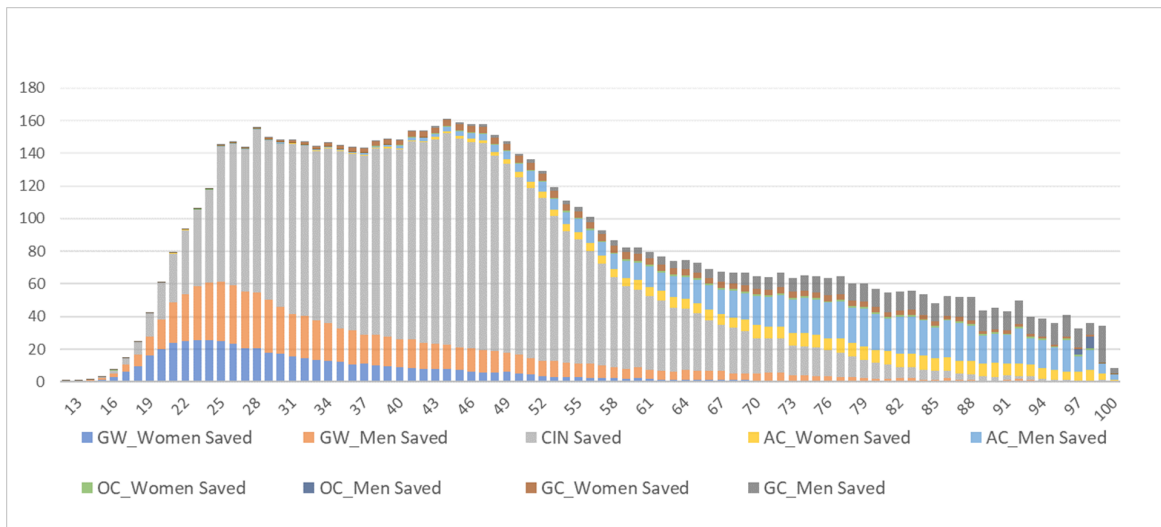


Figure 3: Events avoided with optimal coverage VS 'as is' vaccination

|   | GW Women | GW Men | CIN    | AC Women | AC Men | OC Women | OC Men | GC Women | GC Men | CC Women | Total  |
|---|----------|--------|--------|----------|--------|----------|--------|----------|--------|----------|--------|
| optimal VS 'as is'                        | 521      | 904    | 4,384  | 351      | 825    | 52       | 10     | 220      | 442    | 557      | 8,267  |
| 'as is' vs No vaccination                 | 988      | 230    | 8,318  | 665      | 210    | 99       | 3      | 418      | 113    | 1,058    | 12,101 |
| Tot. preventable events vs no vaccination | 1,509    | 1,134  | 12,702 | 1,016    | 1,036  | 151      | 13     | 638      | 555    | 1,615    | 20,368 |

Table 1: Avoided events

## CONCLUSIONS

To date, in Italy the residual cost for related HPV diseases amounts to more than **€ 150 million**, with a saving due to primary prevention interventions exceeding **€ 76 million**. By further increasing the vaccination coverage, as envisaged in the NIP, further savings of almost **€ 50 million** could be obtained and a total number of avoided events that exceeds **20 thousand**.

The estimated cost of vaccinating 95% of the primary cohort would amount to about € 66 million per year, it is understood that the cost of vaccination is amply compensated already in 'as is' coverage. Nevertheless, our results support the importance of complying with the NIP targets and suggests that increasing Vaccination coverage rates could generate important advantages in terms of opportunity costs.

## AUTHOR INFORMATION

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# ABSTRACT

## The opportunity cost of HPV9 vaccination in Italy

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### Abstract

**INTRODUCTION:** The objective of this study is to estimate the opportunity cost that are achievable with an increased coverage rate of anti-HPV9 vaccination in Italy.

**METHODS:** A cost consequence model was developed in order to estimate the HPV-related diseases incurred from a hypothetical Italian cohort of women and boys. The model considers the age risks of hospitalization for: 'cervical intraepithelial neoplasia (CIN)' (622.1x; 67.2; 67.32; 67.33; 67.39; 233.1); 'condyloma acuminatum' (GW) (078.11); 'anal cancers' (AC) (154.2–154.8); oropharyngeal cancers (OC): 'oropharyngeal cancer' (146.0–146.9) and 'head, face and neck cancers' (171.0); genital cancers (GC): 'penis cancer' (187.1–187.9) and 'cervical cancer' (180.0–180.9). Other direct healthcare costs were estimated from the literature while indirect costs (social security benefits) were associated with incident patients considering the data coming from the Italian National Institute of Social Security (INPS). Vaccine Efficacy data were taken from HPV9 vaccine RCP and literature. Different scenarios were compared based on the vaccination coverage rates (VCRs): No vaccination (0% of VCR for both male and female), 'as is scenario' (62% of VCR for female and 19% coverage for Male as observed for the I.a.y. 2018) and Optimal Vaccination Strategy (95% of VCR for both male and female). All scenarios have a lifetime projection.

**RESULTS:** The model estimates a total economic burden of the Hpv related diseases of about € 226.8million (55% attributable to indirect costs) in the absence of HPV9 vaccination. The 'as is' VCRs are likely to reduce € 31.4 million of direct healthcare costs and € 45.1 million of indirect costs. An Optimal Vaccination Strategy could reduce over € 126 million of direct and indirect cost if compared to the no Vaccination strategy and € 49.8 Mln if compared to the Standard Vaccination Strategy.

**CONCLUSIONS:** These results support the importance of primary prevention strategy in Italy and suggest that increasing Vaccination coverage rates could generate important advantages in terms of opportunity costs.

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