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National cervical cancer prevention program in the Arab States: Strategies and cost-minimization study of the Tunisian case

R. Gamaoun

Faculty of Pharmacy, University of Monastir, Monastir, Tunisia

Epidemiology and Preventive Medicine Department, Fattouma-Bourguiba University Hospital, Monastir, Tunisia

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ABSTRACT

Background: The Arab states geographic region is marked by a low to moderate cervical cancer screening coverage rates and the absence of national human papillomavirus (HPV) vaccination programs, except for the United Arab Emirates. Knowing that the HPV prevalence among Tunisian woman is estimated to 4.9/100 000 according to the “HPV Center” data, this study aims to estimate the cost of a national cervical cancer prevention program in Tunisia using either the primary prevention method (the two-dose schedule anti-HPV vaccine according to the WHO recommendation for young adolescents) or the secondary prevention method (the Pap smear test according to three time-lapse periodicity).

Methods: The mean incremental cost of one avoided cervical cancer case was calculated for each prevention scenario.

Results: The ascending incremental costs by avoided cervical cancer case are: 1- the national vaccination program through the GAVI support (\$ 1803), 2- the cervical cancer screening according to 10-year periodicity (\$ 8219), 3- the cervical cancer screening according to 5-year periodicity (\$ 14,567), 4- the cervical cancer screening according to 3-year periodicity (\$ 20,479), 5- and finally the national vaccination program according to the manufacturer marketed price (\$ 36,854).

Conclusion: Currently, the anti-HPV national vaccination program combined with cervical cancer screening according to 5-year periodicity present the best cost-effective strategy for cervical cancer prevention in Tunisia. This study gives Tunisian decision makers a basis for structured planning and cost apportionment to ensure effective roll-out of the cervical cancer prevention strategies.

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1. Introduction

Cervical cancer is the fourth most common female cancer worldwide with an estimated incidence rate of 14/100,000, approximately 527,624 new cases and 265,672 deaths annually according to the HPV Center's 2017th world report [1]. Over the last two decades, it has been proven that human papillomavirus (HPV) is involved in the genesis of the majority of cervical cancer cases [2–4], and that between 15% and 25% of oncogenic HPV infection cases develop into cervical cancer within 2–4 years of persistent infection [5].

According to Lille consensus conferences (1990, 1994, 2004), the Pap Smear test is still the unique screening method with a proven efficacy for premalignant and malignant lesions of cervix screening with up to 85% sensitivity and specificity of detecting cervical intraepithelial neoplasia (CIN) [6,7]. By allowing an early detection of dysplastic lesions, the Pap Smear test gives the

opportunity to treat them at an early stage and avoid their evolution towards invasive cancer [8].

The mortality associated with cervical cancer has been profoundly influenced by organized cervical cancer screening and treatment programs for pre-neoplastic lesions in developed countries [9]. This was not the case in Tunisia where the cervical cancer screening coverage rate continues to be low (12–14%) despite the implementation of an anti-cancer plan since 2006 [10], especially when compared to coverage rates in some western countries such as France (73.6%) [11]. However, this rate is similar to most of the other Arab states coverage rates, with the exception of the United Arab Emirates (UAE) (40.6%) [12].

In Tunisia and most of the Arab states, the incidence of the cervical cancer is relatively low, and the means put in place to carry out a rigorous and systematic screening are still relatively weak. This relatively low cervical cancer incidence rate and the resource-limited economic context lead the health authorities not to consider the cervical cancer prevention methods as part of their priorities.

E-mail address: rihab.gamaoun@outlook.com<https://doi.org/10.1016/j.vaccine.2018.06.070>

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According to the current Tunisian Health Authorities recommendations, the target population for the Pap Smear test in Tunisia is all women aged between 35 and 59 years old; and the time-lapse between two subsequent screenings should be five-years for all women and three-years for women at a higher risk of cervical cancer (history of sexually transmitted infections, multiple abortions, early sexual contact) [13].

The cost of a Pap Smear test in Tunisia is estimated at 16 Tunisian dinars in 2015 according to the Pasteur Institute, the main public health and scientific research institution under the supervision of the Ministry of Health [14]. This fee is the direct cost of the Pap Smear test in the public sector including lab and medical staff fees. This cost represents also the amount endorsed by the public provider for the Pap Smear test since most of the eligible patients are covered by the social security program and receive medical health services free of charge in approximately 2303 public health facilities.

Due to the proven causal link between the oncogenic HPV infection and cervical cancer, the marketing of the first anti-HPV vaccine in 2006 was considered as an important scientific advance in the fight of cervical cancer and several other HPV related cancers [15]. The anti-HPV vaccine offers a protection against the development of cervical cancer, especially if administered before the onset of sexual activity. Despite the availability of the vaccine in most of the Arab states, no country has yet launched a national vaccination program except the United Arab Emirates (UAE) [16].

Only the bivalent vaccine has been authorized since 2011 on the Tunisian market and it was made available only in pharmacies. The vaccine dose fee is entirely out of the patient's pocket since it is not covered by the social security program. The selling price of one vaccine dose is estimated at 45.45 US dollars in 2015 since Tunisia does not benefit from the Global Alliance for Vaccines and Immunization (GAVI) support for the anti-HPV vaccination introduction [17]. This price represents more than one-third of the Tunisian monthly minimum wage which is estimated at 282 Tunisian dinars (113 US dollars) in December 2017 [18]. No additional physician visit fee will be added to the vaccine price if it is administrated in one of the public health facilities; however, an additional fee will be induced if carried out by a doctor in one of the private health facilities. The high cost of the vaccine has been highlighted by several studies as one of the main barriers explaining the slow introduction of the anti-HPV vaccine in developing countries [19–21].

No recommendation regarding the anti-HPV vaccine targeted population or the number of doses to be administered per patient has been issued by the Tunisian health authorities, and no cervical cancer primary prevention awareness campaigns targeting health professionals or young women took place in Tunisia since the introduction of the vaccine in 2011.

This lack of political will for the introduction of the anti-HPV vaccine has always been justified by the limited financial resources in low to middle-income countries such as Tunisia. Considering the current cervical cancer screening Tunisian authorities recommendations and the anti-HPV vaccination WHO recommendations of two-dose schedule for girls under the age of 15 [13,22], the objective of this study is to conduct a cost-effectiveness analysis of the different strategies to consider as part of a national cervical cancer prevention program (primary, secondary or combined prevention methods) in Tunisia. This economic analysis will allow the identification of the most suitable and feasible cervical cancer prevention modalities in the limited economic resources Tunisian context.

2. Methods

This study is a retrospective cost analysis considering **the total annual number of cervical cancer avoided cases** and **the incremental cost per avoided case** as the main study outcomes.

The outcomes are assessed for each prevention strategy (Pap-Smear test versus anti-HPV vaccination) and scenario (different efficacy and coverage rates) in order to identify the most cost-effective strategy/scenario.

The estimation of the vaccination strategy outcomes was based on the Papillomavirus Rapid Interface for Modelling and Economics (PRIME) and its most updated default data [23,24]. PRIME is a static model of HPV vaccination that uses proportional impact to estimate the cost-effectiveness of HPV vaccination in low- and middle-income countries. It was developed by The London School of Hygiene & Tropical Medicine (LSHTM) in collaboration with researchers from the World Health Organization, Laval University and Johns Hopkins University. It is meant to be used as a demonstration and decision support tool for analysts in low- and middle-income countries to examine the potential impact and cost-effectiveness of HPV vaccination. The Excel-based code with accompanying documentation is freely available online [25]. When more updated data was available, the PRIME tool default values were customized according to the data presented in the Table 1. Regarding the estimation of the cervical screening strategy outcomes, data was exclusively based scientific literature. For both strategies, all considered costs were actualized to 2017 according to an inflation rate of 3%.

Two vaccination strategies were considered: strategy 1 corresponds to the two-dose schedule according to the manufacturer marketed price, and strategy 2 corresponds to the two-dose schedule according to GAVI initiative price. Each strategy was assessed according to three scenarios: one conservative scenario that considers the lowest reported vaccine efficacy and the lowest expected vaccination coverage; one probabilistic scenario that considers the mean reported vaccine efficacy and the average expected vaccination coverage [26]; and finally one optimal scenario that considers the highest reported vaccine efficacy and a full vaccination coverage.

Three cervical cancer strategies were considered: strategy 1 corresponds to a Pap-Smear test to all eligible women (35–59 years) according to a 3-year interval periodicity; strategy 2 according to a 5-year interval periodicity; and strategy 3 according to a 10-year periodicity. Each of the strategies was assessed according to three coverage rate scenarios: 50%, 60% (the Tunisian Health Authorities goal), and 70%.

2.1. Variables definition, calculation or assumptions

To conduct the cost comparison of the different strategies, several input parameters and estimations had to be first documented or calculated. The definition of each variable is defined in Table 1.

3. Results

The results of the cervical cancer screening presented in Table 2 revealed that the incremental cost per avoided cervical case does not vary depending on the cervical cancer screening coverage, unlike the number of cervical cancer avoided cases that linearly increases with the screening coverage. Regarding the periodicity of the Pap Smear test, the current Tunisian recommendations (5-year interval, 60% screening coverage) are the most appropriate strategy, when both efficacy and affordability are considered, compared to the 3-year and 10-year intervals.

The results of the anti-HPV vaccination program presented in Table 2 revealed that the incremental cost per avoided cervical case varies considerably (ranges between \$ 1436 and \$ 45,551) depending on the considered anti-HPV vaccine dose price.

Regarding the lack of precision of the anti-HPV vaccine efficacy estimated at 76% CI (62–85%) and the different vaccination

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