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## LETTER TO THE EDITOR

## The future of best investing in vaccines: The Health Technology Assessment approach

## KEYWORDS

Health Technology Assessment;  
Vaccines;  
Decision-making process

**Summary** Over the past two decades, scientific research has led to the development of a huge number of new health technologies, among which new vaccines. The decision process underlying the introduction of a new vaccine will be of particular concern in the future and a useful tool is needed to orientate decision makers towards better allocation of economic resources. Health Technology Assessment (HTA) is a multidisciplinary tool that aims to examine the clinical, economic, organizational, ethical, juridical, social and cultural implications of the introduction or the implementation of a specific technology; it could so represent an innovative and effective approach in order to support decision-making processes.

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## Introduction

Over the past two decades, scientific research has led to the development of a huge number of new health technologies, among which new vaccines against many acute infectious diseases and for the first time against a neoplastic disease, that are already available or will be disposable by 2015 [1]. A vaccine has to be considered a “health technology” since this term internationally covers every instrument, device and method used to promote health, prevent and treat diseases and improve rehabilitation or long-term care [2].

Technologies offer great improvements in health conditions, however they result in a continuous increase of health care costs. Then, the decision process underlying the introduction of a new vaccine will be of particular concern in the future and needs to be developed and sustained.

Reducing the burden of infectious diseases, which are still responsible for about 25% of the global mortality – especially in children younger than 5 years – is actually one of the most important challenges in Public Health [3].

Notwithstanding, only a scant part of health expenditure is currently assigned to preventive medicine in most countries; on the other hand, limited economic resources will not allow governments to finance all the future available vaccines. Therefore a useful tool is needed to orientate decision makers towards better allocation of economic resources, not only according to safety, efficacy and effectiveness, appropriateness and costs of the new technology but also considering population health needs [4,5].

Health organizations need by now an instrument by which appraising all these aspects and Health Technology Assess-

ment (HTA) could represent an innovative and effective approach in order to address them and support decision-making processes [6].

HTA developed in '70 as a discipline and a systematic method to evaluate alternative technologies, both from the clinical and the economic point of view. The HTA can be defined as a multidisciplinary tool that aims to examine the clinical (effectiveness, emergency and indications of use), economic, organizational, ethical, juridical, social and cultural implications of the introduction or the implementation of a specific technology [7]. The HTA process comprised two phases: the first provides a synthesis of the results from systematic reviews and evidence-based medicine. The second phase consists of a synthesis of the evaluation findings and the formulation of conclusions and recommendations, based on the data gathered from scientific literature.

Therefore, HTA represents a bridge between the world of scientific research and the world of decision-making, particularly policy-making [2].

Currently the relation between HTA and vaccines is not yet developed but we firmly believe that applying HTA to the evaluation process of introducing new vaccines could be a useful strategy both to meet population health needs and best employ economic resources.

In order to elaborate an HTA report on a new vaccine we propose to address the following aspects, according to the typical HTA multidisciplinary approach:

1. evaluation of the epidemiology of infection and related diseases by a systematic review of scientific literature;

2. assessment of the disease burden in terms of morbidity (hospitalisations, drugs consumption, etc.) and mortality, through the consultation of National Discharge Cards and direct interviews of clinicians;
3. study of current preventive measures to avoid infection (immunisation, evidence of immunisation and immunisation in practice) and practices to treat the disease/infection;
4. evaluation of effectiveness and safety of the new vaccine through a systematic review of scientific evidences;
5. investigation of biotechnological aspects and analysis of manufacturers' view;
6. elaboration of a mathematical model predicting epidemiological and economic impact of vaccination;
7. economic evaluation of immunisation by a cost-effectiveness analysis with the computation of cost per QALY (quality adjusted life year gained);
8. evaluation of ethical, legal and social issues related to the infection and to the introduction of new vaccine;
9. study of organizational aspects and of vaccination impact on the health system, both at micro-, meso- and macro-level.

Very recently, a joint project promoted by the Institute of Hygiene, Catholic University of the Sacred Heart, and by the Glaxo–Smith–Kline Company has been concluded in order to produce an HTA report on the vaccine against the human papillomavirus (HPV). Applied method retraced the steps described above. The estimated pooled prevalence of HPV infection in Italy is 19.17% (95% CI: 10–30%) while yearly incidence and mortality rates of cervical cancers are respectively 9.8/100.000 and 3/100.000. Each year 5/6 million of Pap test are performed in Italy thus determining an expenditure between 125 and 150 million of euros. Health spending for CIN 1 and CIN 2–3 is estimated to range from 12 to 19 million of euros whereas expense for treating invasive cancers in 2003 was about 21.5 million of euros. Since the follow-up periods shortness of trials on vaccines available by now, we estimated vaccine efficacy in preventing persistent infections from HPV 16 and 18 and we relieved values of 87% (RR = 0.13; 95% CI: 0.09–0.20) and 78% (RR = 0.22; 95% CI: 0.13–0.38), respectively. According to the results of the mathematical model, the vaccination will be able to avoid 61% of cervical cancers with a coverage of 90% of 12 years old women; combining vaccination with regular screening every 3 years, we estimated a cost per QALY of 26.361,34€. Since this value, vaccine introduction will be cost-effective [8].

## Conclusions

We propose an HTA approach to evaluate the introduction of a new vaccine that potentially could have a great impact on

population health. Taking into account all the aspects of a new vaccine, a HTA report could represent a new important tool to support decision makers' choices in order to better allocate economic resources and maximise healthcare services. HTA approach needs however to be improved, in order to be systematically, transparently and widely applied.

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