

How can the results of Health Technology Assessment (HTA) evaluations applied to vaccinations be communicated to decision-makers and stakeholders? The ISPOR Rome Chapter Project

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Key words

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Summary

HTA is considered the most comprehensive and transparent method of supporting decision-makers in their choices in Public Health.

HTA on vaccines is being performed by many experts. However, they often present their studies to colleagues, but not to decision-makers, who should be the main target and current users. It is therefore crucial to improve the transfer of scientific data to decision-makers and all stakeholders.

The aims of the present project are: 1) to set up a team of experts to collect economic evaluations and HTA studies on vaccines and assess their actual use in decision-making processes; 2) to constitute regional working groups in order to identify the critical aspects of the communication process and identify the most appropriate method of data transfer.

Systematic reviews of economic evaluations and HTA on vaccines and their actual use in decision-making will be used to draw up the basic documents for discussion by the 3 regional working boards. The working groups will discuss the current scientific evidence and communication methods and will try to implement a model of technology assessment with well-defined and objective criteria, in order to better fit pharmaco-economic and HTA methods to the field of vaccinations.

Improving the transfer of HTA results to stakeholders, particularly decision-makers, will enable decisions to be taken on the basis of scientific evidence, and appropriate, sustainable actions to be undertaken.

Introduction

In accordance with the recommendations of the World Health Organization (WHO) (2005) [1], the current *Italian National Plan for Vaccination Prevention 2012-2014* (PNPV) [2] specifies that the choices made in the sector of prevention, such as those concerning vaccination, should be based on clear, robust, shared criteria. This need is due to the increasing availability of new vaccines, the introduction of new vaccination indications and the limited economic resources of health systems, even in developed countries. Only by prioritizing all possible preventive interventions can we rationalize the use of limited resources and maximize results in terms of health. As *Health Technology Assessment* (HTA) meets the above-mentioned criteria, it may constitute the best approach to this issue.

HTA is regarded as the most comprehensive and transparent method of supporting decision-makers in their choices concerning health technologies. This approach is even more important in the Public Health sector, particularly with regard to vaccine prevention [3]. As vaccination targets healthy individuals, its benefits (such as

absence of disease, reduced disease burden etc.) are often unapparent to both the population and decision-makers. Consequently, preventive interventions are viewed only as a considerable cost to the health system, rather than as fundamental investments that generate benefits in the short and long terms. These issues are even more evident today, in the current critical period of spending review in Italy. Indeed, the most debated issue related to the introduction of a new vaccine is that of economic sustainability. In order to verify economic sustainability, pharmaco-economic evaluations are needed. The first step in this process is to evaluate the costs that a disease generates for the National Health Service (point of view of the third-party payer) and the community (point of view of society). Pharmaco-economics offers several approaches. In the field of vaccinations, the most frequently used approach is cost-effectiveness analysis, whereby the cost of vaccination is compared with its clinical benefit (e.g. the number of cases avoided or the years of survival gained). Among cost-effectiveness analyses, cost-utility analysis is preferentially adopted, as benefits are measured in QALYs (quality-adjusted life-years). When comparing two or more alternatives which have different

costs and degrees of efficacy/effectiveness, it is important to obtain information in a single summary measure, i.e. considering both cost and effectiveness. The *Incremental Cost-effectiveness Ratio* (ICER) provides this information and expresses the additional cost of each unit of a health outcome (e.g. one QALY) obtained by one strategy compared with another. The ICER is a fundamental parameter for decision-makers. However, decision-makers must also consider other domains: the epidemiology of the disease in question; vaccine efficacy/effectiveness; the predicted clinical impact on the population, as assessed through mathematical modelling of possible vaccination strategies; ethical, social and legal aspects, and the impact of introducing a new vaccine on health organizations. HTA deals with all these aspects.

In Italy, as in other countries, the application of HTA to vaccines has increased in recent years. Many HTA reports and pharmaco-economic studies, including several in the Italian context, have been published [4-24]. Although the data from these studies are widely available, they are often underused by decision-makers, who may lack the knowledge and ability necessary to exploit them fully. Indeed, decision-makers often evaluate the implementation of new vaccines only on the basis of vaccination costs, without considering the clinical and economic benefits derived from the avoidance of cases of disease.

It is therefore essential to improve the transfer of scientific data to decision-makers and all stakeholders, in order to promote evidence-based decisions in the area of immunization. The introduction of a new vaccine can only be based on Evidence-Based Medicine (EBM), or rather Evidence-Based Prevention (EBP) [25]. To achieve this goal, it is necessary to create a communication network linking all subjects involved in the decisional process: researchers, decision-makers and stakeholders. In this perspective, the project "HTA for public health decision-makers in the area of vaccination" has been planned and endorsed by the ISPOR Rome Chapter.

The *International Society for Pharmacoeconomics and Outcomes Research* (ISPOR), founded in 1995, is a public non-profit educational and scientific association. It promotes pharmaco-economic and outcome research and facilitates the translation of the results of that research into useful information for decision-makers in order to encourage efficiency, effectiveness and equity in health and to improve the health of the population. The ISPOR Italy-Rome Chapter is a working group affiliated to ISPOR and sharing its mission and objectives. It involves healthcare professionals, providers of healthcare technologies, decision-makers and other pertinent subjects in issues of pharmaco-economics and outcome research in the Italian context.

Objectives

The objectives of the project are:

- 1) to organize a multidisciplinary working group composed of experts (the Project's founding group) in order to:

- carry out systematic reviews of economic evaluations and HTA reports on vaccines and vaccination strategies;
 - assess the current use of HTA and economic evaluations in decision-making processes;
 - implement a model of technology assessment with well-defined and objective criteria, in order to better fit pharmaco-economic and HTA methods to the field of vaccinations.
- 2) to constitute regional working groups composed of experts, decision-makers and stakeholders in order to:
 - identify and define critical points in communication from/to decision-makers and stakeholders and in data transfer processes, in order to identify the most appropriate method of data transfer;
 - increase decisions taken on the basis of scientific evidence in the field of vaccinations;
 - improve the culture of vaccination in the Italian population and counteract the spread of erroneous, confusing and outdated information.

Achievement of these objectives will lead to the identification of the best strategies for creating a "data bridge" between researchers, decision-makers and stakeholders.

Materials and methods

Two different main activities will be performed: systematic reviews of economic and HTA studies on vaccine/vaccination strategies, and organization of working boards. Table I shows the main activities of the ISPOR Rome Chapter Project.

The following specific activities will be carried out:

- systematic reviews of economic and HTA evaluations of vaccination strategies or of vaccines already included in the Italian vaccination schedule or still under discussion for inclusion in the current regional or national vaccination programs: for example, HPV vaccination in females and males, meningococcal C vaccine, pneumococcal vaccine in children and the elderly, varicella vaccine, quadrivalent conjugate meningococcal vaccine, meningococcal B vaccine, rotavirus vaccine, and herpes zoster vaccine. This systematic review will be performed on PubMed, Scopus and NIHR HTA databases; articles published at any time up to the end of 2015 will be included. PubMed and Scopus will be queried by means of a combination of MESH terms and keywords referring to vaccines/vaccinations and HTA/economic evaluations, while the search on NIHR HTA will be performed through the use of keywords related only to vaccines/vaccinations. Furthermore, a hand-search of the following journals will be carried out: *Global & Regional Health Technology Assessment*, *Pharmaco-Economics Italian Research Articles*, *Giornale Italiano di HTA*, *Politiche Sanitarie*, *HTA Focus – Pills of Clinical Governance*, *Pillole di Farmacoeconomia*, *Giornale Italiano di Farmacoeconomia e Farmacoutilizzazione*, *Italian Journal of Public*

Tab. I. The main activities of ISPOR Rome Chapter project.

Activities	Working boards
Systematic reviews on economic and HTA evaluations of vaccination strategies or vaccines already included in the vaccination schedule in Italy and Europe.	Project's founding group
Systematic reviews on economic and HTA evaluations for vaccination strategies or vaccines that are as yet under discussion for inclusion in the current regional or national vaccination programs in Italy and Europe.	Project's founding group
Report on the real use of economic and HTA studies in decision-making process in Italy.	Project's founding group
Development of mathematical models for compared some vaccination programmes with other health interventions.	Project's founding group
Identification of critical points in communication from/to decision-makers and stakeholders and in data transfer processes in order to identify the most appropriate method of data transfer.	Regional working groups
Increasing of decisions taken on the basis of scientific evidence in the field of vaccinations.	Regional working groups
Improving of the culture of vaccination in the Italian population and counteracting the spread of erroneous, confusing and outdated information.	Regional working groups
Implementation of a model of technology assessment with well-defined and objective criteria in order to better fit pharmaco-economic and HTA methods to the field of vaccinations.	Project's founding group
National event of working groups	

Health and Quaderni dell'Italian Journal of Public Health. Eligible articles will be identified through a two-step approach: screening of titles/abstracts and reading of full texts. Articles will be considered eligible if they report the results of an economic evaluation or of an HTA performed in Italy or one or more Italian Region;

- evaluation of the real use of economic and HTA studies in the decision-making process in Italy in recent years. This evaluation will be performed by comparing the results of the studies collected with the decisions taken at the national and regional levels in recent years, with regard to the inclusion of new vaccines or vaccination strategies in immunization programmes;
- some vaccination programmes will be compared with other health interventions (therapeutic interventions) by means of mathematical models, in order to increase decision-makers' awareness of the fact that investments in the field of vaccines generate significant benefits and are not only a cost for the health system. For example, HPV vaccination in females will be compared with therapeutic interventions in women with HPV-related lesions/cancer.

These activities will be carried out by the Project's "founding group", made up of researchers working on these subjects at the Universities of Florence, Genoa and Rome (Catholic University and Tor Vergata University). The founding group will also implement a model of technology assessment with well-defined and objective criteria, in order to better fit pharmaco-economic and HTA methods to the field of vaccinations.

Data acquired from these activities will be used to draw up the basic documents for discussion by the working boards that will be organized. The working boards will be composed of all relevant subjects involved in the decision-making process: researchers, decision makers and stakeholders. (Tab. II). The parties that have an interest are: citizens and their associations, health professionals and their associations, scientific societies, those

elected by citizens to the various levels of government, businesses and no-profit partners, academics, and volunteers and their associations [26].

The importance of involving as many stakeholders as possible stems from the need to improve the culture of vaccination in the Italian population and to counteract the spread of erroneous, confusing and outdated information. Indeed, the success of a vaccination campaign depends not only on the supply of a vaccine free of charge, but also on the acceptance of vaccination on the part of the target population. The acceptability of vaccination strongly influences vaccine coverage rates, and only high vaccine coverage enables the incidence of disease to be reduced, thereby achieving considerable savings in terms of both healthcare and socioeconomic costs. Opinion leaders and journalists will be involved in the working groups, on account of their significant influence on the choices of the population and decision-makers. In particular, journalists can support the improvement of communication between researchers and decision-makers by identifying the most appropriate method of data transfer. Journalists can also help to spread the culture of vaccination in the population and increase public awareness of the importance of prevention activities.

Tab. II. Multidisciplinary working groups of ISPOR Rome Chapter Project.

Researchers	University researchers Independent researchers
Decision-maker	Minister of Health Institute of Health Regions Minister of Economic Italian Medicine Agency Minister of University
Stakeholders	Vaccine manufacturers Scientific Societies Medical Federations Citizens associations Provident Institution Volunteers associations

Expected results and discussion

Two systematic reviews will be published: the first will focus on economic and HTA evaluations of vaccination strategies or vaccines already included in vaccination schedules in Italy and Europe; the second will focus on economic and HTA evaluations of vaccination strategies or vaccines that are as yet under discussion for inclusion in current regional or national vaccination programs in Italy and Europe.

A report on the real use of economic and HTA studies in the decision-making process in Italy in recent years will be made.

Three permanent regional working boards will be set up in Northern, Central and Southern Italy, coordinated by the Project's "founding group". These will discuss the current scientific evidence of cost-effectiveness and the cost-benefit profiles of vaccinations and will also investigate other domains relevant to the decisional process (such as ethical, social and legal aspects and the impact of introducing a new vaccine on health organizations). They will also identify and analyse critical points in the different kinds of communication, in order to pick out the most appropriate methods of communication and data transfer. Furthermore, they will discern the information needs of each subject involved and work out how to improve the transfer of knowledge from researchers to decision-makers and stakeholders. The information obtained by these permanent regional boards may be validated in other Italian Regions. Lastly, a national event will be organized in order to extend the indications and information obtained at the regional level to the national level.

The feasibility of the project is guaranteed by the participation of academics and researchers in the permanent regional working boards. However, the achievement of the above-mentioned objectives might be jeopardised by the potentially scant participation of decision-makers and stakeholders in the communication network. To avoid this eventuality, every effort will be made to convince decision-makers and stakeholders of the importance of developing a communication network with scientific experts in order to foster evidence-based decisions that meet the needs highlighted by the decision-makers and stakeholders themselves.

Finally, individuation of a model of technology assessment with well-defined and objective criteria could contribute to the development of new HTA reports according to the requirements and needs evinced by the decision-makers and stakeholders themselves in the future.

Conclusions

The success of the project will pave the way towards an interactive dialogue among all subjects involved in the decision-making process. In this way, decisions can be taken on the basis of scientific evidence, and appropriate, sustainable actions can be undertaken. Indeed, healthcare priorities can only be established through

broadly based, shared evaluations of health interventions. This approach will ensure a more appropriate use of limited resources and enable preventive activities that generate many benefits and not only costs.

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