

Value in assessing new vaccines

Giuseppe La Torre

Clinical Medicine and Public Health Unit, Sapienza University of Rome

Correspondence to: Prof. Giuseppe La Torre, Clinical Medicine and Public Health Unit Sapienza University of Rome, Viale Regina Elena 324, 00161 Rome. E-mail: giuseppe.latorre@uniroma1.it

Abstract

Vaccination strategies are recognised as one of the most powerful interventions in the field of Public health worldwide, capable of reducing both morbidity and mortality. There is wide availability of new vaccines, at least in Developed Countries, that have the potential to control infectious diseases, while on the other hand there are new vaccines that will become available in the next few years. This paper aims to describe the different perspectives one could take into account in valuing particularly new vaccines.

The *epidemiological approach* has been one of underlying principles in setting priorities for immunization programs. The introduction in the health market of a new vaccine is based on the assessment of the related burden of infection/disease and the consequent impact on population health.

In the *economic evaluation approach* several types of analysis are available. The budget impact analysis is concerned more with the immediate impact; in this sense cost is considered instead of value as well as giving higher consideration to short-term effects, while cost-effectiveness or cost-utility analysis can be utilised to examine effects in the long term.

In the field of vaccinations a *public approach* through the use of media campaigns or non-profit organisations, might or might not push politicians and physicians to take action to address a perceived health problem via a vaccine.

A *Health Technology Assessment approach* has been developed in some European countries to examine, in a multidisciplinary way, the clinical, economic, organizational, ethical, juridical, social and cultural implications of the introduction or the implementation of a specific technology. The HTA approach in Italy was demonstrated to be a comprehensive tool in assessing the introduction of a new vaccine, giving insight to the issue to several stakeholders, i.e. decision makers, researchers, and patients.

Introduction

Vaccination strategies are one of the most powerful interventions in the field of Public Health worldwide, both in reducing morbidity and mortality. Vaccination implementation is a proven tool for controlling and even eradicating disease and World Health Organisation (WHO) estimates that immunization averted approximately two million deaths in 2002 [1]. At the global level it has been calculated that infectious diseases are still responsible for about one quarter of the overall mortality, particularly in children aged younger than 5 years [2].

Several new vaccines with major potential for controlling infectious diseases are now available, thanks to the development of new prophylactic vaccines against many acute infectious diseases that have an important burden of disease. Moreover, further vaccines will be available in the next few years, and this will be a critical point for decision makers, because of the large number of

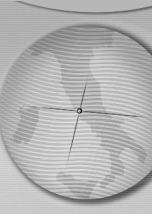
vaccines available by 2015 [3].

Despite the potential availability of vaccines, we are pretty sure that according to limited economic health resources, the Governments will not be able to finance all vaccines produced by drug companies. This issue implies that it will more and more important in the near future in deciding how to better allocate resources, especially in the field of public health interventions.

This paper aims to describe the different perspectives from which it is possible to evaluate vaccines, and in particular new vaccines. It considers the following approaches: a) epidemiological; b) health economic; c) public perspective; d) health technology assessment (HTA).

The Epidemiological approach

The decisions on the introduction of a new vaccine in the immunisation schedule of a certain country is first of all based on the assessment of



the related burden of infection/disease and the consequent impact on the population's health. Incidence rate of the infection/disease, mortality rate, permanent sequelae, complications and related hospitalisations are usually the main elements that are considered. [4].

Moreover, this approach aims to also take into consideration issues such as information on the vaccine safety and effectiveness that are topics to address in suggesting priorities for policy makers. The epidemiological approach has been seen for several years as one of the main factors in setting priorities for vaccines to be introduced into immunization programs [5]. The underlined idea is that the higher the burden, the more attractive a potential addition to the immunization schedule of a specific country would be in the view of decision makers.

Vaccine safety and performance in this context are also important issues. Most countries have mentioned safety, low rates of side effects and vaccine performance as fundamental elements to consider when introducing a new vaccine, especially in developing countries [6].

The economic evaluation approach

The economic impact of an infectious disease is another key issue to be considered in the evaluation of the implementation of a vaccine in a specific country. Information on the potential cost savings determined by vaccine coverage is critical in order to convince the decision makers of the opportunity of financing a vaccine campaign.

Based on this perspective, several types of economic evaluation are available. The Budget Impact analysis is concerned more about the immediate impact, in the sense that it considers cost instead of value. In this view, little consideration is given to long-term effects [7].

Decision makers now consider cost effectiveness analysis (CEA) as one of the key factors for adding a new vaccine into national immunization programmes versus an alternative use of the resources [8].

However, CEA is far from perfect, as there has been a number of times when an explicit statement on key elements of the analysis has not been given. A recent systematic review of the economic analyses of HPV vaccine was conducted in order to evaluate their quality according to BMJ referees's checklist [9] and it clearly showed that the quality of vaccine economic evaluations needs to be improved in terms of defining the viewpoint of the analysis, the justification of the choice of economic evaluation form, the explanation on the choice of model and its parameters, the sources of

effectiveness and methods to evaluate health state and other benefits and the justification of the choice of variables in the sensitivity analysis [10].

The public approach

In the field of vaccinations, the public, through media campaign or non-profit organisations, might or might not push politicians and physicians to take action to address a perceived health problem via a vaccine [6]. Generally speaking, the public is supportive of immunisation programs and recognises the potential health benefits to individuals and to the wider society of high rates of immunisation coverage. However, there is a lot of evidence to reinforce the fears of side-effects and concerns over the safety of particular vaccines and as such are factors associated with low immunisation coverage.

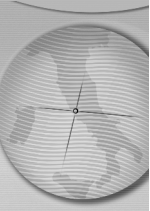
A study was conducted to explore European citizens' opinions on the extent to which childhood immunisation should be a matter of parental discretion or should be strictly enforced by the State. In this study, barriers to childhood immunisation include concerns over the risk of adverse side-effects, distrust of those advocating the vaccines, poor communication with health-care staff and a lack of awareness of the immunisation schedule [11].

The Health Technology Assessment (HTA) approach

This approach was recently developed in Europe mainly by the Danish Center for Evaluation and Health Technology Assessment (DACEHTA) and by the Health Technology Assessment Public Health Unit at the Catholic University in Rome. The starting point of this approach was to consider a vaccine as a technology. In this field 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. HTA in the field of vaccine has proved to be an innovative and effective approach in order to support decision-making processes, for the best allocation of economic resources [12].

As an example of the application of the HTA approach to the assessment of HPV vaccines [13-14], the following issues were considered:

1. Epidemiological evaluation of HPV infection and related diseases in Italy and in the world;
2. Study of health services utilisation from people affected by HPV infection/diseases;
3. Evaluation of current measures to prevent



- cervical cancer (screening- PAP test);
4. Evaluation of HPV vaccines effectiveness;
 5. Projecting a mathematical model to predict the effects of new vaccine introduction;
 6. Economical evaluation of vaccine introduction;
 7. Determination of organisational concerns;
 8. Study of ethical, social and legal impact.

This approach was confirmed very recently at the end of WHO European Region Ministerial Conference, when Health Ministers of 53 countries adopted the Tallinn Charter: Health Systems for Health and Wealth. HTA is identified as important means to create resources for health care systems: "...Fostering health policy and systems research and making ethical and effective use of innovations in medical technology and pharmaceuticals are relevant for all countries; health technology assessment should be used to support more informed decision-making." [15].

Conclusion

In recent years, vaccinology has been one of the scientific fields in which research has led to the planning and implementation of several biotechnological innovations. Now and more and more in the next future, there will probably be more vaccines on the market than those actually used in daily public health life, and the value of a new vaccine cannot be based only on epidemiological or health economical considerations. What is required is a useful tool capable of orientating not only decision makers, but also researchers and citizens, towards a better allocation of economic resources. HTA is a multidisciplinary and politically oriented tool that is capable of considering the clinical, economic, organizational, ethical, juridical, social and cultural implications of the introduction or the implementation of specific technologies, and, among these, vaccines.

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