



## Review

The role of health economic analyses in vaccine decision making<sup>☆</sup>Steven Black<sup>\*</sup>

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## ABSTRACT

Beginning in the 20th century with the consideration of the seven-valent pneumococcal conjugate vaccine in the US, the cost effectiveness became a topic of discussion when this vaccine was being considered for universal use by the US Advisory Committee on Immunization practices (ACIP). In 2008, the ACIP began using formal criteria for the presentation of such data and their inclusion in ACIP discussions. More recently, the US Institute of Medicine has recommended that health economic considerations play a primary role in the prioritization of future vaccine for development. However, such analyses can be biased towards vaccines that provide economic benefit rather than those that reduce severe morbidity and mortality. This is because the economic impact of minor common events that result in medical utilization or time lost from work for parents can outweigh the economic impact of severe morbidity and mortality. Thus diseases with a low mortality and morbidity but with a common clinical manifestation such as the common cold could be prioritized over vaccines against diseases such as meningococcal sepsis where the morbidity and mortality associated with each case is very high, but there is no associated common clinical syndrome. Thus the use of cost effectiveness analyses as a 'gating criteria' to decide which vaccines should be developed or routinely used runs the risk of transforming vaccines into primarily a tool for achieving cost savings within the health care system rather than a public health intervention targeting human suffering, death and disability. It is the purpose of this article to review the framework under which health economic evaluations can be undertaken, to review the experience with and reliability of such analyses, and to discuss the potential negative implications of the use of health economic analyses as a primary decision making tool.

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## 1. Introduction

At the time of the development of the smallpox vaccine by Jenner in 1796, the focus of the public was on high mortality of smallpox and on the safety and the efficacy of Jenner's vaccine. The cost effectiveness of his approach was not a consideration [1]. In fact, at the beginning of the modern vaccine era in the 1940s,

diseases were targeted based upon their morbidity and mortality rather than their cost saving potential leading to vaccines for diphtheria, pertussis, tetanus and later polio, measles, mumps and rubella. Beginning in the 20th century and with the consideration of the seven-valent pneumococcal conjugate vaccine in the US, the cost effectiveness of this vaccine became a topic of discussion when it was being considered for universal use by the US Advisory Committee on Immunization practices (ACIP). In 2008, the ACIP began using formal criteria for the presentation of such data and their inclusion in ACIP discussions [2]. More recently, the US Institute of Medicine has recommended that health economic considerations play a primary role in the prioritization of future vaccine for development [3]. It is the purpose of this article to review the framework under which health economic evaluations can be undertaken, to

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review the experience with and reliability of such analyses, and to discuss the potential negative implications of the use of health economic analyses as a primary decision making tool.

## 2. Types of health economic studies relevant to vaccine evaluation

The methods most commonly applied to the health economic evaluation of vaccines are cost-benefit, cost-effectiveness and cost-utility. While a full description of each of these methods is beyond the scope of this article, summaries of these methods have been prepared elsewhere so they will only be summarized here to put the later discussion in context [4].

A cost effectiveness analysis is a comparison of the costs and outcomes of two or more health interventions. For a new vaccine this is commonly a comparison of no vaccine (*status quo*) versus the introduction of the new vaccine. In such an analysis, the cost-effectiveness of a vaccine is expressed as the cost per unit gain in health [4]. The most commonly used outcome measure for such an analysis is the QALY or quality adjusted life year. This measure takes into account the cost of the intervention, the impact on quality of life or prevention of death and the incidence of the disease. Thus a vaccine for a common disease with low impact on quality of life can have the same cost effectiveness as an uncommon disease with high morbidity and mortality. This can lead to some counter intuitive decisions, as we will see later.

A cost benefit analysis is similar to a cost effectiveness analysis, but in this type of analysis, both the cost and the benefits are expressed in a monetary unit such as dollars or euros. This approach requires assigning a monetary value to outcomes such as years of life lost due to death, partial disabilities such a deafness, blindness or retardation, and disfigurement. An adjustment for the time value of money is usually made with the frame of reference is usually net present value. Because of inflation, this approach requires discounting the value of dollars saved in the future. This is important in consideration of vaccines because while costs usually are incurred “up front”, the benefits may not accrue for months or years [5]. However, for very effective vaccines, freedom from disease will be worth more to the health care system than the individual case analysis would indicate. This is because public health resources dedicated to monitoring and development of control strategies can be allocated to other areas. However, it must be recognized that the need for such estimates can limit the generalizability of the conclusions of a given cost-benefit model to the time and place where it was conducted.

A cost-utility analysis is similar to a cost effectiveness analysis in that outcomes are expressed in the cost of an intervention to provide an improvement in quality of life. While the measure here is similar to that of a cost-effectiveness analysis, the product of the analysis is a number that then can be used to compare the cost-utility of other unrelated health expenditures. That is, the cost-utility of a vaccine can be compared to a clean water intervention or mammography screening [6]. This has been used in some settings, such as the UK, to introduce a cost-utility “threshold” for the evaluation of new interventions above which the event is less likely to be funded [7].

## 3. Potential impact of the use of vaccine health economic analyses upon public health

Common to all health economic evaluations is the assumption that the higher the cost-effectiveness of a vaccine, the higher priority it should be given for development and then generalized use. As can be seen in Table 1, this can lead to a situation where very common diseases such as the common cold or rotavirus infection

in developed countries can be prioritized for introduction into a national immunization program because of their economic benefit rather than their impact upon mortality and morbidity. That is, a little inconvenience or minor malaise in a large number of individuals can outweigh significant morbidity or mortality in a smaller number of people. A good example of this conundrum is the common cold. Here we have an entity which is very common with most people experiencing at least one episode per year and which results in discomfort as well as a considerable expenditure for medications or other over the counter remedies. However, there are no deaths or long-term disabilities due to the common cold. If we compare this to an uncommon infection such as meningococcal disease which has a 10% mortality and leaves approximately 50% of individuals with long term disabilities, the development of a vaccine against the common cold and its routine use would likely be more cost effective than the use of a meningococcal vaccine. Perhaps a more relevant example is that of rotavirus infection in developed countries such as countries in Europe or the US and Canada. Rotavirus infection is almost universal by two years of age. However, death is virtually unknown as is long-term disability in the developed country setting. However, since most parents seek medical attention for their child's gastroenteritis and since hospitalizations for dehydration can occur, the economic cost of the disease is high. Again, if one evaluates the cost-effectiveness of rotavirus vaccine in the UK or the US as compared to meningococcal vaccination, there is no contest and rotavirus vaccination is more cost effective. However, in terms of prevention of deaths and morbidity vaccination against meningococcal disease is clearly preferable. One way of approaching the issue of the use of cost-effectiveness analyses in vaccine decision-making is to ask, “What are we trying to accomplish?” If the goal is to maximize cost saving in health care, then vaccines become a tool to achieve this outcome. If the goal is to minimize human suffering and to prevent loss of life, then the use of a cost-effectiveness threshold for public health interventions such as vaccines is problematic.

In Fig. 1, we can see a schematic representation of five diseases and the vaccines that have been developed to prevent them. The disease outcome information is presented in the form of a pyramid while the supporting data is shown below the diagram. The tip of the pyramid includes less common but more severe events such as mortality and long-term disability. More common manifestations of the disease are represented in the wide portion of the pyramid. In looking at the rotavirus example discussed above, we can see that there are an estimated 20 deaths per year in the US, but that there are 600,000 outpatient medical visits and a moderate amount of time lost from work by parents. For pneumococcal disease, we see an interesting hybrid. The number of deaths due to pneumococcal disease (before vaccine introduction) was essentially equivalent to that for meningococcal disease with sequelae being less common than with meningococcal disease. However, the pneumococcus also causes a common disease syndrome – otitis media—that drove the cost effectiveness of pneumococcal conjugate vaccine programs in pre-implementation models. Similarly for varicella, death and sequelae of infection were relatively uncommon but the vaccine was considered to be cost-effective because the disease was common and while the disease was mild, it almost always resulted in some medical utilization. If we look again at the meningococcus, we can see that although it results in about the same number of deaths as pneumococcal infection in childhood and more sequelae, because it is not associated with a common mild disease syndrome as well, it will not fare well in a cost-effectiveness analysis.

One can view this as an “iceberg effect” in which a common disease syndrome, largely below the surface in terms of mortality or morbidity, floats the vaccine program.

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