

Scope of an Economic Evaluation

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TVEE
TEACHING VACCINE
ECONOMICS EVERYWHERE

Overview

- Defining the scope of an economic evaluation
- What is your target audience, target population
- Comparing vaccine programs to standard of care

Defining the Scope of an Economic Evaluation for a Vaccine Program

At the beginning, the scope of the Vaccine program evaluation needs to be clearly defined – who is impacted by the vaccine availability?

The scope of the Vaccine program evaluation would directly determine which costs and health benefits are considered relevant and therefore should be included in the analysis. This would in turn affect the final results with respect to vaccine value

The key factors to consider in setting the scope for the Vaccine program evaluation include:

- The target audience, key stakeholders in Vaccine program investment
- The target infectious disease patient population – who is at risk?
- The perspective of the analysis with respect to Vaccine program value
- The Vaccine intervention being evaluated
- The alternative vaccines or standards of care
- The analytical time horizon of vaccine or disease impact in short-/long-term

Target Audience

Key Stakeholders to Vaccine Program

The stakeholders determine what Vaccine program costs and benefits are considered.

- Examples of vaccine program stakeholders:
 - International financing agencies (World Bank, IMF)
 - Aid agencies (USAid)
 - International development agencies (GAVI)
 - Non-governmental organisations (NGOs)
 - Private healthcare providers
 - Government health ministries
 - Patient advocacy groups
 - Sponsors of vaccine programs and research (Gates Foundation)

Study Question and Objective

- These elements must be well-defined and outlined in a form that is answerable and relevant to the target audience
- Comparators: What are the alternatives to the vaccine program being considered?
 - Vaccine vs. Vaccine
 - Vaccine vs. do-nothing
 - Vaccine vs. standard of care
 - Vaccine vs. [public health intervention]
 - Vaccine vs. prevention
- What do you hypothesize?
 - Cost-effective?
 - Cost-neutral?

Study Question and Objective

- Examples of Questions that can be answered with some common vaccine program economic evaluations
 - For which new vaccine(s) should the GAVI alliance open a window of funding?
 - Should a new vaccine be introduced, e.g. Human papilloma virus or rotavirus vaccines?
 - Which strategy should be used to increase vaccination coverage, e.g. Fixed sites, mobile teams or health campaigns?
- **Can you think of how questions like these could be framed for an economic evaluation of COVID-19 Immunization Program?**

Target Population

To Whom Do the Results of the Vaccine Program Affect

- This is the population for which the Vaccine intervention or standard of care is intended
- The target population has implications for the magnitude of costs, benefits and budget impact
- For example:
 - Vaccinating only children against malaria could limit herd immunity (hence, result in less overall health benefits) since unvaccinated adults will continue to serve as reservoirs for the transmission of malaria parasites
 - Vaccinating adults as well as children is likely to result in higher herd immunity (and hence, higher overall health benefits) but is likely to result in higher costs

Example Target Populations

- Could vary by age, gender, ethnicity, socio-economic group, geographical areas or high-risk groups to certain infectious diseases
- If we have limited resources, who should we target for COVID-19 vaccination?

Age

Neonates
Infants
Children
Adolescents
Young people
Older people

Gender

Male
Females

High-risk groups

Pregnant women
Women of childbearing age
Men who have sex with men
Commercial sex workers
Drug users
Older population
Pre-existing conditions

Comparators

- Comparators are alternative Vaccine interventions, standards of care, etc against which the costs and effects of the new intervention are compared
- Comparators should accurately reflect the study question
- Decisions about which new vaccine programs or which new health care services to provide are often made in the context of what is currently provided to treat the infectious disease (e.g. standard of care)

Comparators

- The most relevant comparator for a new vaccine is the current form of treatment for an infectious disease where the vaccine does not exist.
- Current standards could either be
 - Standards of care for different patient groups with the infection
 - Doing nothing to treat the condition if treatment technologies do not exist, or are not financially viable to provide in low-income areas
- Other comparators include:
 - Best available alternatives, e.g. as represented by clinical guidelines or low-cost alternative
 - Alternative levels of scope and intensity for the new intervention
 - Other interventions competing for resources from same national budget
 - Vaccine vs. Education
 - Vaccine vs. Infrastructure
 - Vaccine vs. Transportation
 - Vaccine for disease A vs. Vaccine for disease B

Example Comparators

- Cost and benefits of COVID-19 vaccine can be compared against:

Do-Nothing

- Not vaccinating against COVID-19 **and not** treating cases
- Not vaccinating against HBV but treating cases

Alternative levels or scope for the new intervention

- Universal COVID-19 vaccination with/without treating remaining cases
- Vaccinating only health workers, older population, those with pre-existing conditions against COVID-19 with or without treating remaining cases

Non-COVID19 options competing for same resources

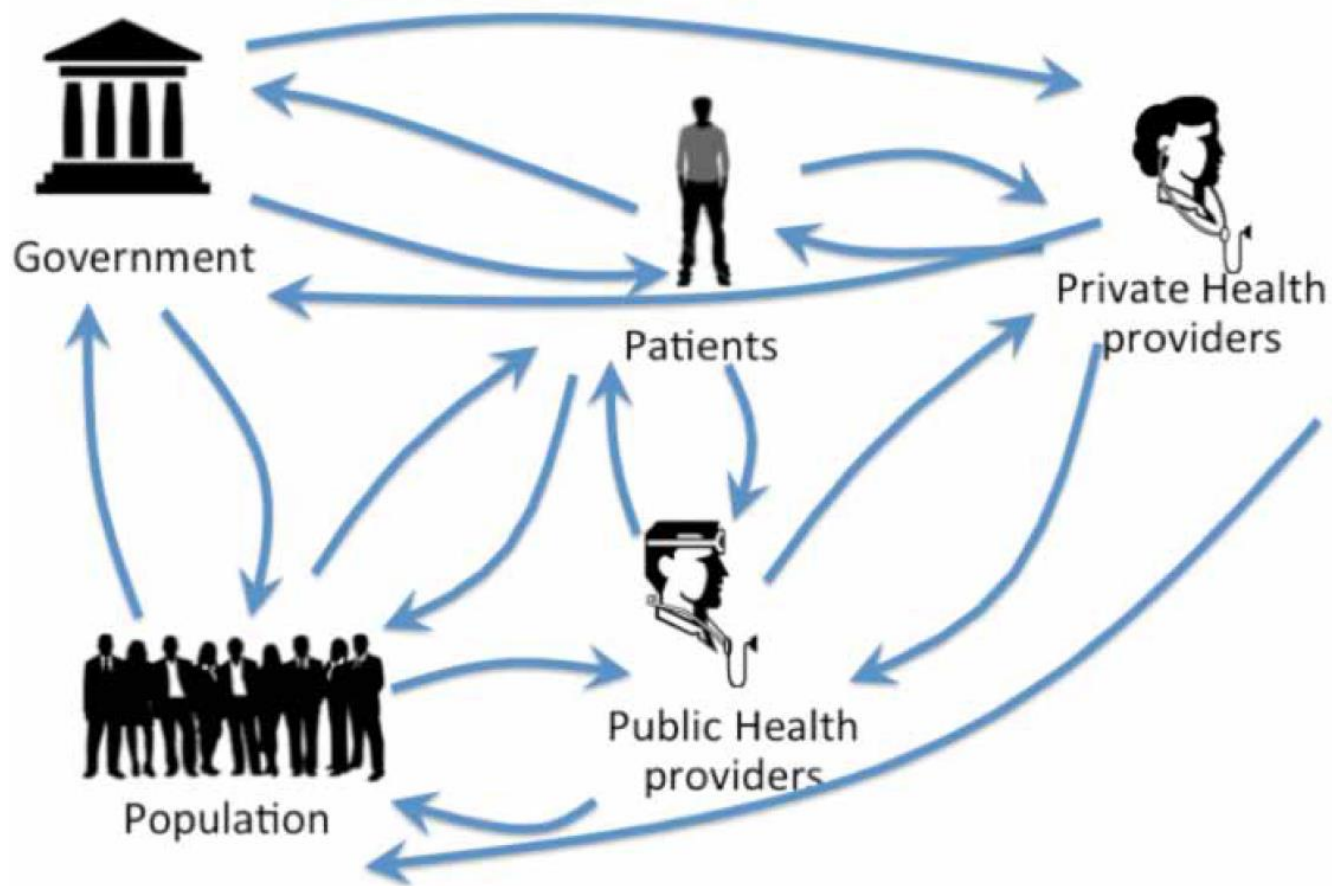
- Introducing another health technology to prevent viral transmission
- Extending coverage of an existing vaccine programme

Examples Describing the New Intervention and Comparators

Questions to answer	New intervention/strategy: COVID-19 vaccination	Comparator: Social-distancing
Who?	Community health workers & Nurses	Everyone
To whom?	HCW, Older population and those with pre-existing condition	Everyone
Where ?	At clinics	Everywhere
How often?	Once in a year	All the time

Perspectives and Time Horizons

Perspective



Study Perspective

- The choice of perspective or viewpoint determines the scope of the costs and benefits.
- Determined by the context of the study, persons or institutions affected by outcome of interest, and those that bear the costs of the intervention.
- Important to separate costs borne by different stakeholders such as providers, payors, patients, and others to allow analysis from different perspectives.
- Range of perspectives included in the analysis depends on availability of data, resources, and time to conduct the study
- However, analysts should be aware that a broader perspective that includes productivity losses or gains will improve cost-effectiveness. This could be used to justify higher vaccine prices
 - increases the break-even price per dose

Study Perspective

Can influence how outcomes are measured

Perspective	Benefit categories	Definition
Narrow	Health gains	Reduction in morbidity and mortality through vaccination
	Healthcare cost savings	Savings of medical expenditures because vaccination prevents illness episodes
	Care-related productivity gains	Savings of patient's and caretaker's productive time because vaccination avoids the need for care
Broad	Outcome-related productivity gains	Increased productivity because vaccination improves physical or mental health
	Behaviour-related productivity gains	Vaccination improves health and survival, and thereby changes individual behaviour, for example by lowering fertility or increasing investment in education
	Externalities	Improved outcomes in unvaccinated community members, e.g. through herd effects and reduction in the pace at which resistance to antibiotics develops

Types of Perspectives

- Generally, there are most comprehensive study perspectives in vaccine economics evaluations:
 - Healthcare sector (payer + patient + provider)
 - Societal (population-level, including government)
- However, studies can be conducted from other perspectives as well, e.g.
 - The Patient
 - Family caregiver (proximal to the patient)
 - The Provider
 - Payer, both public and private parties
 - Employer (e.g. employee-based health insurance)
 - Government (payer and investor of vaccines)
 - Manufacturers and Distributors of Vaccines

Recommendations on Perspective from U.S. Panel

- The U.S. Second Panel recommends that all CEA should be conducted using both healthcare sector and societal perspectives
 - The perspective you use is based on Target Audience
 - For example, a private insurer may only care about costs associated from payer perspective (not patient costs)
- Some examples of perspective-varying cost-benefit measures
 - Medical costs (current and future, related and unrelated) borne by third-party payers and paid out-of-pocket by patients,
 - Time costs of patients in seeking and receiving care,
 - Time costs of informal (unpaid) caregivers,
 - transportation costs,
 - effects on future productivity and consumption,
 - other costs and effects outside the health care sector

How Perspective Influences the Cost to be Considered in Cost Analysis

Cost	Societal	Government	Payer	Patient
Hospitalizations, physician consultation fees, medications, diagnostic tests etc.	Yes	Yes	Yes	Yes
Transportation, food, accommodation, etc.	Yes	No	No	Yes
Time loss from work, informal caregiving etc.	Yes	No	No	Yes
Pain and suffering	Yes	No	No	Yes
Others (welfare, education)	Yes	No	Yes	Yes

The Societal Perspective

- Medical costs (current and future, related and unrelated) borne by third-party payers and paid out-of-pocket by patients
- Time costs of patients in seeking and receiving care
- Time costs of informal (unpaid) caregivers
- Transportation costs
- Effects on future productivity and consumption
- Other costs and effects outside the health care sector

Healthcare Sector Perspective

- Include all costs and benefits impacting a system of providers, payers and patients.
- Do not consider impact outside of the health system (e.g. long-term value to patients)
- Based on Direct Medical Costs reimbursed by a third party
- Can include out-of-pocket costs to the patient
- Can include current and future costs as a result of a pathway of care

Study Perspective Examples

- Healthcare Sector perspective: Healthcare costs (drug, hospital costs, analytic procedures) including costs arising from the consequences of treatment to patients, providers and payers
- Government perspective: Healthcare costs & other publicly provided services (community services, social services) where taxpayer funds are financed
- Societal perspective: Healthcare and other public sector costs incurred for the management of disease from all perspectives involved in care (e.g. patient, provider, public/private payers, government, family caregivers, etc.)

Examples of Societal Perspective

CEA of Hib Vaccine

The studies considered costs incurred by the health care provider, the government, the GAVI alliance, and households

Cost items include:

- Government cost for treating meningitis and pneumonia (outpatient and inpatient)
- Household expenditure for each type of disease including medicines, user fees, lodging, transport etc. in public and private sector.
- Opportunity cost in terms of time spent while looking after a sick child
- GAVI supported vaccine price
- Vaccine delivery cost including price of syringes, safety boxes, wastage factor, handling charges

Example of Healthcare Sector Perspective

CEA of Rotavirus and Varicella Vaccines

Studies estimated CEA of rotavirus vaccine and varicella vaccine from health care provider perspective included the following cost components

- Cost per dose of vaccine
- Cost of administering the full vaccine schedule (excluding vaccine cost)
- Daily cost of pediatric intensive care unit care
- Daily cost of general pediatric ward care
- Daily cost per outpatient visit

Examples of Cost/Benefit from Patient perspective

Cost components under patient perspective include

- Fees for consultation in clinics, traditional healers, hospitals,
- Bed day charges at the health facility (private and/or public) etc.
- Expenses on medicines, diagnostic tests,
- Travelling expenses to the health facility for the patient and accompanied persons for treatment,
- Special food consumed for coping with the disease,
- Amount spent on meal / food taken while waiting for treatment,
- Expenses for overnight accommodation for seeking care etc.
- Time loss of the patient and the accompanied persons for seeking treatment,
- Informal caregiving,
- Work days lost by the patient for being sick etc., Including losses in productivity
- Pain and suffering from a particular disease.

Example of Government Perspective

Ho et al. conducted a study on cost-effectiveness of rotavirus vaccine in Hong Kong in 2008 using government perspective.

Why did they consider government perspective?

- Decision to include a new vaccine into a national immunization program is primarily a government decision
- Including the societal perspective would strengthen the overall case for vaccination but is unlikely to be an important consideration for the government.

Example from government perspective

In the CEA of rotavirus vaccine in Hong Kong, only those costs incurred by the government health care system were used.

Cost components:

- Cost to Hong Kong per hospitalization due to rotavirus
- Cost to Hong Kong per outpatient clinic visit due to rotavirus
- Cost of vaccinating each child (cost of vaccine plus administration cost)

Example from Payer Perspective

The purchaser or payer perspective includes the costs that would be incurred or saved by a purchaser or payer (e.G. Insurance company).

Inclusion

- Hospitalizations, physician consultation fees, medications, diagnostic tests etc.

Exclusion

- Transportation or child care expenses incurred because of an illness,
- Time loss from work or informal caregiving.

Analytical time horizon

- Should be of sufficient length to capture all costs and effects relevant to the decision problem
 - Life Cycle of Disease
 - Vaccine delivery protocol (e.g. number of provider visits)
 - Frequency of follow-up for disease management/advancement
- It should be selected to:
 - Cover all the main costs and benefits that are incurred
 - Allow for any seasonal or cyclical variations
 - Cover costs and benefits occurring in different time periods
- The time horizon used for modelling vaccine programs often depends on the type of vaccine evaluated, the intervention and target population, and thus the type of model developed.
- For costs and benefits accruing beyond one year, an appropriate discount rate should be applied to discount cost and benefits to present value.

Time Horizon

- The analytic horizon may often be short (i.e. one year or less), e.g. vaccination campaigns, particularly if herd immunity can be ignored and only one (birth) cohort is modelled.
- When using a dynamic model, and if the indirect effects change non-linearly with the number of (birth) cohorts vaccinated, the analytic horizon should be long enough for the modelled infection to attain a new endemic equilibrium, as the current epidemiology is altered after the start or change in the vaccination programme.

Time Horizon Examples

Study	Analytical horizon
CEA of HIV/AIDS	Lifetime
CEA of Hib vaccine in India	20 years
CEA of 7vPCV in Hong Kong	10 years
CEA of rotavirus vaccine in Hong Kong	5 years
CEA of rotavirus vaccine in Mexico	5 years
CEA of COVID-19 vaccine in USA	1-2 years
CEA of seasonal influenza vaccine (many countries)	1 year

Time Horizon Example: Influenza Vaccination

- Assume only seasonal influenza concerns
 - Influenza vaccination manufactured some time in the spring/summer with strains of influenza predicted to be prevalent in the coming season
 - Most individuals to be vaccinated some time between early fall and early winter
 - Trying to prevent influenza incidence in the fall, winter, and early spring
- All of the events described above occur within one year
 - Is that the relevant time horizon?

Time Horizon Example Influenza Vaccination

- If a person gets influenza, what happens?
 - Most patients will be symptomatic, recover, and go on with their lives
 - If this were the only set of events possible, then the time horizon would not need to be more than one year
- What are possible complications?
 - Pneumonia
 - Mortality
- What do these complications imply about the time horizon?

Vaccination Time Horizon

Mortality and Influenza

- If immediate mortality were the only complication then it is still the case that all events and effects would be within one-year
- The outcome could be influenza cases prevented or influenza mortality prevented
- The outcome could also be DALYs with a simple average DALY averted figure used as the loss associated with premature mortality

Pneumonia and Influenza

- Pneumonia can last much longer than influenza and can have long- term negative impacts on quality of life
 - This suggests that the time horizon may be longer than one year
 - and approaching a lifetime
 - Could use the CHEC-list suggestion to follow until the situation
 - stabilizes
 - ✓ In other words, until all effects of ever having had influenza are gone

Other Thoughts on Influenza Vaccination

Time Horizon

- The time horizon that is most appropriate may vary for different clinical populations
 - Healthy adults under the age of 65 have low probability of complications
 - Risks are different for older adults, school-age children, and preschoolers
- Strains of influenza like H1N1 may have much different risk profiles, including different times of year at which incidence is high