Estimating the full public health value of vaccines

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Les pensieres  Dec 6 2016
A tale from my grandmother
A tale from my grandmother
Some history of human evolution

For 99.99% of the history of mankind, life-expectancy has been < 30 years

55 years gained since 1700
35 years gained since 1900
Vaccines generated more health gains than pharmaceuticals, however their economic value is quite different.
Cost effectiveness is a largely used for vaccine decisions

Cost/QALY

- Costs are easy to calculate
- Do QALY capture the real value of vaccines?
Why QALY and cost-effectiveness?

Cities will result in a small number of potentially avoidable hospitalizations and deaths. A value cannot be placed on a human life, but resources are finite, and an ethical imperative mandates selection of those interventions that will provide the greatest good to the greatest number of people. Use of a non-cost-effective in-

**JAMA** Published online February 8, 2016

But combining cost and QALYs into cost-effectiveness ratios has a number of limitations ([http://bit.ly/29T7bJ1](http://bit.ly/29T7bJ1)). One of them is that they give rise to the ordering of treatments that is inconsistent with value as people would normally judge it.

In other words, cost per QALY may be how policy makers or managers of a public program would assign value but not how the populations it serves or that pay for it would do so.
Health economists are ideologically opposed to frivolity. It has come to our attention that an annual, quasi-religious festival has been held for some years without having been subjected to the rigours of a cost effectiveness analysis. In these sombre days of economic rationalism, such an oversight is unconscionable. The money spent on gifts and wrapping paper, tinsel and turkey is a significant opportunity cost, which might be better spent on improving the health care of the nation. We present a cost effectiveness analysis of Christmas.

Results
Christmas is not cost effective.

Discussion
There is no discussion. We will, however, recommend to the government that considerable cost savings could be made by the immediate abolition of Christmas. Next Christmas could be the last Noel.

We will next be applying for a grant to examine the cost effectiveness of Easter.
The value of vaccines according to CDC

USA 1994-2013

Vaccine prevented
- 322 million illnesses
- 21 million hospitalizations
- 732,000 deaths

Vaccines generated net savings of
- 295 Billion direct costs
- 1.38 Trillion in total societal costs
Methods for evaluating the value of vaccines

<table>
<thead>
<tr>
<th>Industry impact</th>
<th>Assessment method</th>
<th>Examples of approach</th>
<th>Examples of decisions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Invest</td>
<td>IOM SMART vaccines**</td>
<td>Expanding the broad values to capture societal priorities</td>
<td>• Introduction of IPV in US $4 million/QALY (decision downweighted CE analyses)</td>
</tr>
<tr>
<td>Invest</td>
<td>Bloom et al. including broad benefits</td>
<td>Capturing the full value of health (PNAS 2014)</td>
<td>• Meningococcal conjugate Second dose in adolescents recommended at US $600K/QALY</td>
</tr>
<tr>
<td>Disinvest</td>
<td>Direct and indirect costs</td>
<td>Evaluating the vaccination program as a whole: More than US $1 trillion saved in 10 years by entire program (Whitney, CDC)</td>
<td>• Initial PCV7 US $250,000/QALY (more than 3x GDP in US)</td>
</tr>
<tr>
<td>Disinvest</td>
<td>Direct costs only</td>
<td>2–3x GDP (recommended by WHO)</td>
<td>• Meningococcus B evaluation in UK</td>
</tr>
<tr>
<td>Disinvest</td>
<td>Direct costs only</td>
<td>20K€/QALY UK NICE evaluation</td>
<td></td>
</tr>
</tbody>
</table>

**IOM SMART vaccines**
the initiative of the Institute of Medicine to assign the right value to vaccines
Institute of Medicine (IOM) initiative SMART Vaccines
http://www.nap.edu/smartvaccines

multi-criteria decision making
28 attributes 8 categories

From Cost/QALY To Cost/QALY + 27 attributes

<table>
<thead>
<tr>
<th>Health Considerations</th>
<th>• Premature Deaths Averted per Year</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Incident Cases Prevented per Year</td>
</tr>
<tr>
<td></td>
<td>• QALYs Gained or DALYs Averted</td>
</tr>
<tr>
<td>Economic Considerations</td>
<td>• Net Direct Costs (Savings) of Vaccine Use per Year</td>
</tr>
<tr>
<td></td>
<td>• Workforce Productivity Gained per Year</td>
</tr>
<tr>
<td></td>
<td>• One-Time Costs</td>
</tr>
<tr>
<td></td>
<td>• Cost-Effectiveness ($/QALY or $/DALY)</td>
</tr>
<tr>
<td>Demographic Considerations</td>
<td>• Benefits Infants and Children</td>
</tr>
<tr>
<td></td>
<td>• Benefits Women</td>
</tr>
<tr>
<td></td>
<td>• Benefits Socioeconomically Disadvantaged</td>
</tr>
<tr>
<td></td>
<td>• Benefits Military Personnel</td>
</tr>
<tr>
<td></td>
<td>• Benefits Other Priority Population</td>
</tr>
<tr>
<td>Public Concerns</td>
<td>• Availability of Alternative Public Health Measures</td>
</tr>
<tr>
<td></td>
<td>• Potential Complications Due to Vaccines</td>
</tr>
<tr>
<td></td>
<td>• Disease Raises Fear and Stigma in the Public</td>
</tr>
<tr>
<td></td>
<td>• Serious Pandemic Potential</td>
</tr>
<tr>
<td>Scientific and Business Considerations</td>
<td>• Likelihood of Financial Profitability for the Manufacturer</td>
</tr>
<tr>
<td></td>
<td>• Demonstrates New Production Platforms</td>
</tr>
<tr>
<td></td>
<td>• Existing or Adaptable Manufacturing Techniques</td>
</tr>
<tr>
<td></td>
<td>• Potential Litigation Barriers Beyond Usual</td>
</tr>
<tr>
<td></td>
<td>• Interests from NGOs and Philanthropic Organizations</td>
</tr>
<tr>
<td>Programmatic Considerations</td>
<td>• Potential to Improve Delivery Methods</td>
</tr>
<tr>
<td></td>
<td>• Fits into Existing Immunization Schedules</td>
</tr>
<tr>
<td></td>
<td>• Reduces Challenges Relating to Cold-Chain Requirements</td>
</tr>
<tr>
<td>Intangible Values</td>
<td>• Eradication or Elimination of the Disease</td>
</tr>
<tr>
<td></td>
<td>• Vaccine Raises Public Health Awareness</td>
</tr>
<tr>
<td>Policy Considerations</td>
<td>• Interest for National Security, Preparedness, and Response</td>
</tr>
<tr>
<td></td>
<td>• Advances Nation’s Foreign Policy Goals</td>
</tr>
<tr>
<td>User-Defined Attributes</td>
<td>• Up to Seven Attributes</td>
</tr>
</tbody>
</table>
A meeting to discuss SMART vaccines

PUBLIC HEALTH

Multicriteria decision analysis and core values for enhancing vaccine-related decision-making

Michèle A. Barocchi,1 Steve Black,2 Rino Rappuoli1*

Vaccines have the potential to transform the health of all individuals and to reduce the health inequality between rich and poor countries. However, to achieve these goals, it is no longer sufficient to prioritize vaccine development using cost-effectiveness as the sole indicator. During a symposium entitled “Mission Grand Convergence—The Role of Vaccines,” held in Siena, Italy, in July 2015, key stakeholders agreed that the prioritization of vaccine development and deployment must use multicriteria decision-making based on the following core concepts: (i) mortality and severity of the disease, (ii) vaccine safety considerations, and (iii) economic evaluation that captures the full benefits of vaccination.
3 Universal (core) values common to all evaluations

Core values

- Mortality and severity of the disease
- Vaccine safety considerations
- Economic evaluation that captures the full benefits of vaccination
Criteria for prioritization in addition to the core values

**Developed countries**
- Severe and frequent diseases
- Rare severe diseases
- Frequent nonsevere illness
- Diseases primarily occurring in the elderly
- Interest for national security and response

**Low-and medium-income countries**
- Interest from NGOs
- Lack of availability of alternative measures
- Targets a disease occurring primarily in disadvantaged populations
- Premature deaths averted per year

**Emerging infections**
- Epidemic and pandemic potential
- Potential to eradicate the disease
- Rare but severe disease with potential for outbreaks or pandemics

**Manufacturers**
- Feasibility (technical and regulatory)
- Likelihood of licensure in < 10 years
- Likelihood of profitability
- Likelihood of a recommendation
- Demonstrates new product platform
- Onetime cost of development

Core values

Mortality and severity of the disease

Vaccine safety considerations

Economic evaluation that captures the full benefits of vaccination
Vaccines can do more for our society

-3 0 8 18 55 90
MONTHS+YEARS

Pregnancy
- CMV
- Flu
- GBS
- HBV
- Men
- Pertussis
- RSV
- Tetanus

Infants & Children
- Diphtheria
- Flu
- GAS
- HAV
- HBV
- Hib
- IPV
- Men
- Pertussis
- Pneumo
- Rotavirus
- RSV
- Tetanus

Adolescents
- CMV
- dTAP boost
- EBV
- Flu
- HSV
- HPV
- Men

Adults
- Diphtheria
- Flu
- HBV
- Men
- Pertussis
- RSV
- Tetanus

Elderly
- Flu
- GBS
- Men
- Pneumo
- RSV
- Zoster
- Candida
- C. difficile
- E. coli
- Klebsiella
- P. aeruginosa
- Staph
- Breast Cancer
- Colorectal Cancer
- Prostate Cancer

Great job!
Next target!

R.Rappuoli, C. Mandl, S: Black , E. De Gregorio
Nature Reviews Immunology | November 2011; doi:10.1038/nri3085
Vaccines for today’s society

Poverty
- Cholera
- Dengue
- ETEC
- HAV
- HBV
- HEV
- Flu
- JEV
- Malaria
- Men B
- Parasitic infections
- Paratyphoid
- Rabies
- Rotavirus
- Salmonella
- S. enterica
- S. typhimurium
- Shigella
- TB
- Typhoid fever

Emerging infections
- AIDS
- Anthrax
- Asian influenza
- Cholera
- Diphtheria
- Dengue
- Ebola
- EV71
- Malaria
- SARS
- SRS
- Smallpox
- West Nile
-yersinia

Travelers
- Cholera
- Dengue
- ETEC
- Flu
- HAV
- HBV
- JEV
- Malaria
- Men
- Paratyphoid
- Rabies
- Shigella
- TB
- Typhoid fever
- Yellow Fever

Patients with Chronic diseases
- CMV
- Flu
- Fungal infections
- P. aeruginosa
- Parainfluenza
- RSV
- Staph
- TB

Immunotherapy/therapeutic vaccines?
- Cancer
- Autoimmune diseases
- Alzheimer
- Chronic infections (HCV, HBV, HPV, HIV, ...)
- Metabolic diseases
- Allergy
- Drug addiction
No sustainable mechanism is in place to develop vaccines needed only in developing countries

Vaccines against poverty
An Institute to address the gaps in vaccine development

Novartis Vaccines Institute for Global Health (NVGH)

New name: GSK Vaccine Institute for Global Health (GVGH)

A new non-profit initiative
to develop effective and affordable vaccines for neglected infectious diseases of developing countries

- Located in Siena, Italy
- Legal entity started in Feb 2007
- Allan Saul hired as CEO Sept 2007
  - Inauguration
    - Feb 22, 2008
- Typhoid vaccine licensed to BioE post phase II, June 2013
- Shighella vaccine Phase I 2014
Vaccines for today’s society

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- Smallpox
- West Nile
- Yersinia

**Travelers**
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Response to Emerging Infectious Diseases
Response to Emerging Infectious Diseases

- **Reactive** we start once the outbreak is out

- **Not effective** solutions arrive when the emergency is over

- **No lesson learned so far** we start all over again, no regulatory solutions, No sustainable solutions,

- **No sustainable** Industry diverts best assets and people to face the emergency, huge opportunity costs, nothing in return

![Graph showing the response to emerging infectious diseases]
proactive strategy for Emerging Infectious Diseases
Who is right?
the largest petition ever in the UK is for MenB vaccination

– More than 820,000 people have backed a campaign for all children up to the age of 11 years to receive GlaxoSmithKline’s Bexsero, which is currently used as part of routine vaccination for babies born since May 1, 2015, with doses at 2 months, 4 months, and a booster at 12 months.

– The Lancet Infectious Diseases 16, pg 385, April 2016

Faye’s story