

Estimating the full public health value of vaccines

Rino Rappuoli

Les pensees Dec 6 2016

A tale from my grandmother



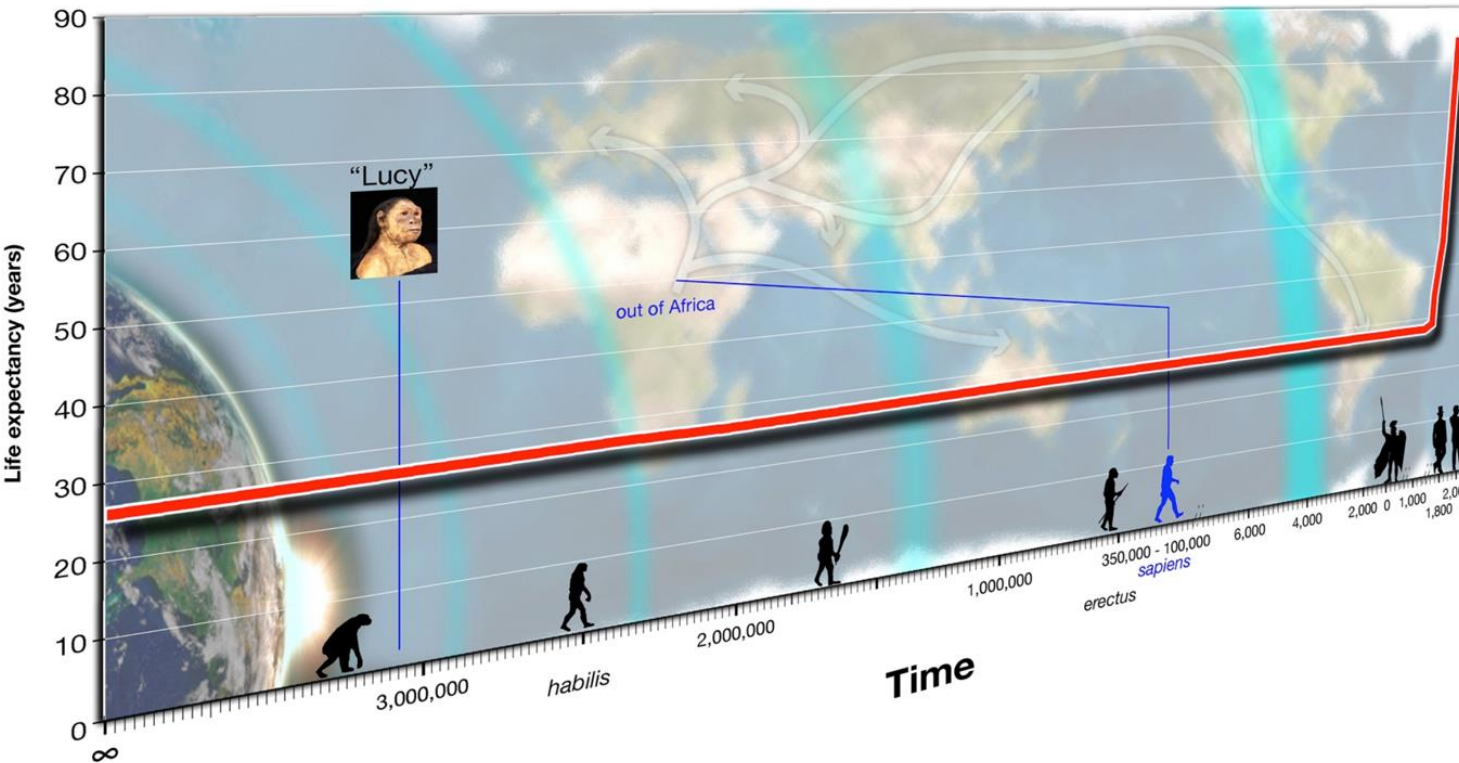
A tale from my grandmother



Some history of human evolution



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

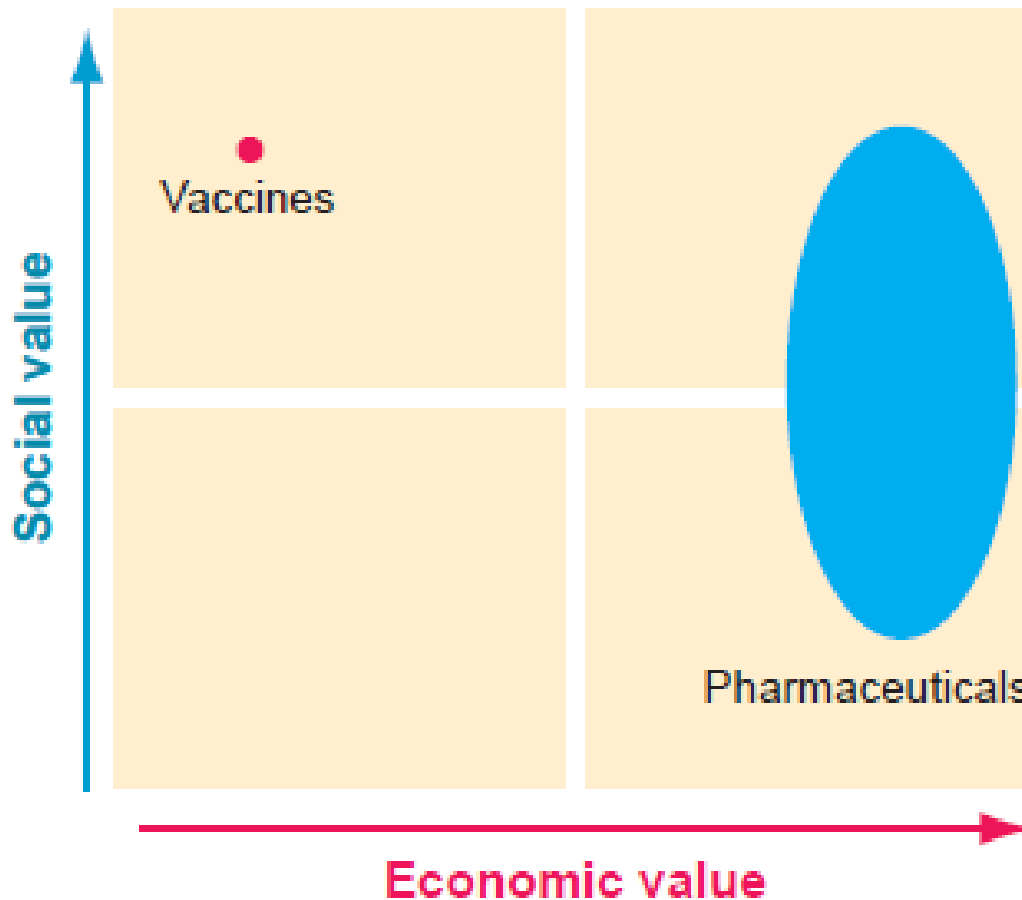


55 years gained since 1700
35 years gained since 1900

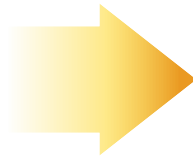
Vaccines generated more health gains than pharmaceuticals,



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?



...cies 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-

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But combining cost and QALYs into cost-effectiveness ratios has a number of limitations (<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.

A seasonal cost effectiveness analysis: the last Noel?

David Isaacs, Dominic Fitzgerald

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.

BMJ VOLUME 325 21-28 DECEMBER 2002 bmj.com

The value of vaccines according to CDC

MMWR / April 25, 2014 / Vol. 63 / No. 16

USA 1994-2013

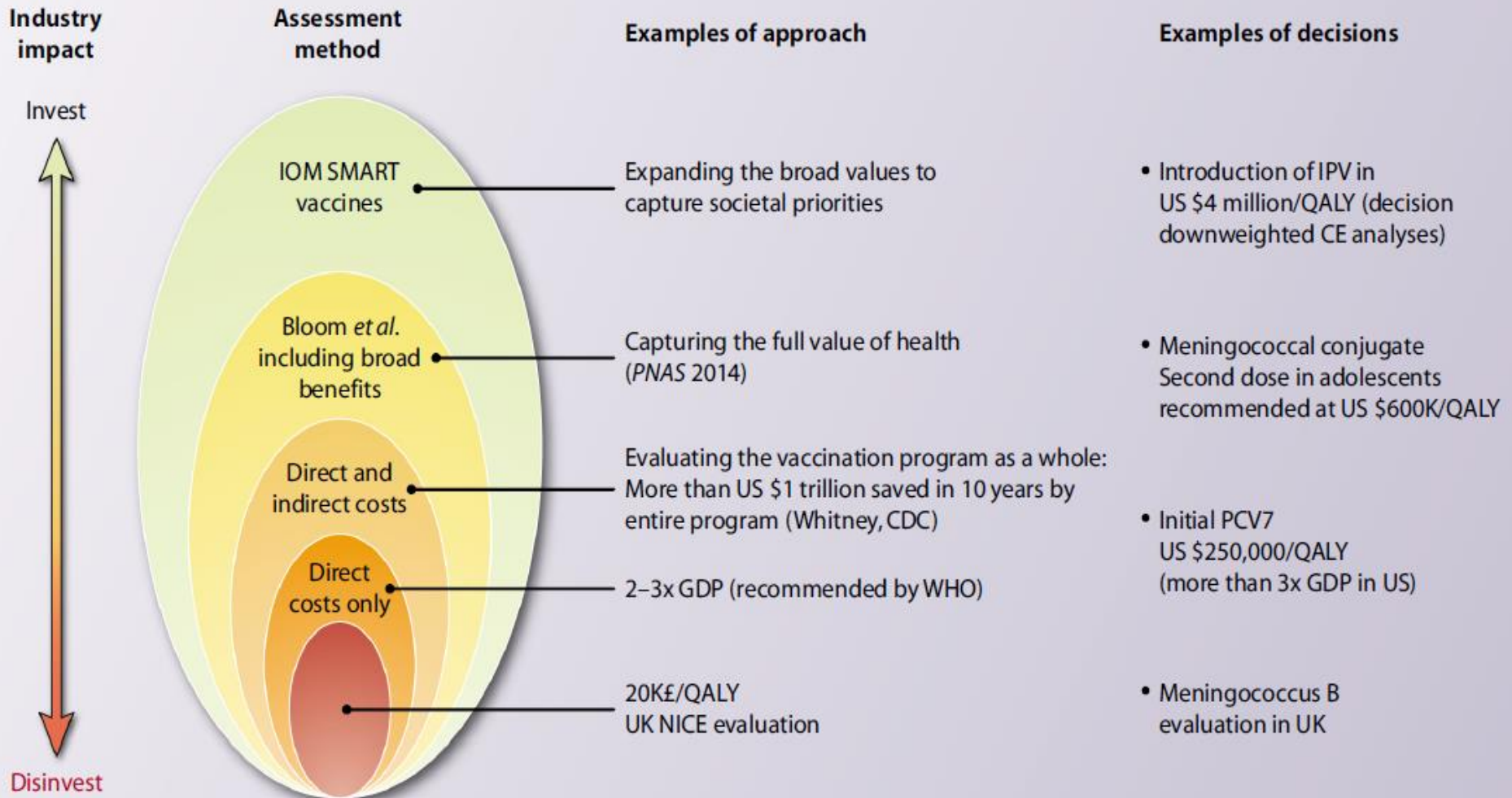
Vaccine prevented

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

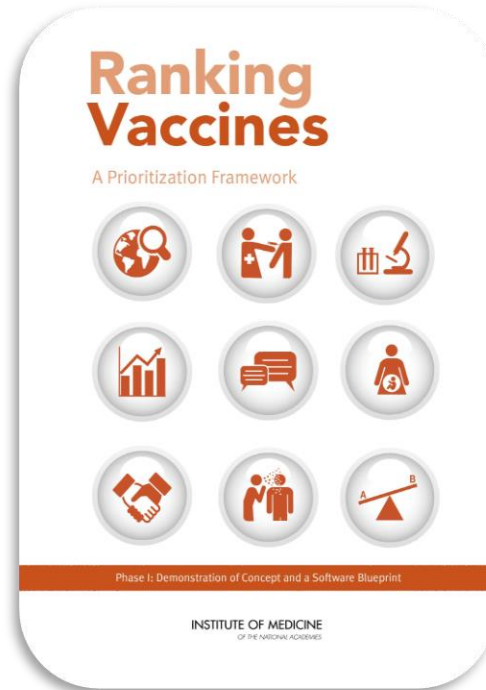
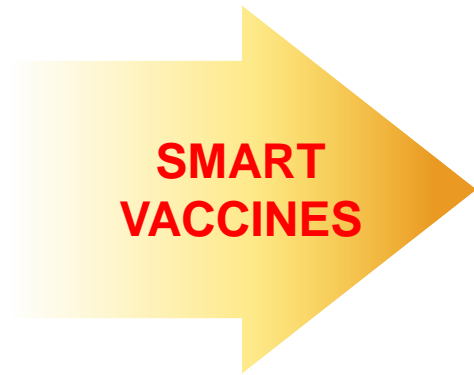
Vaccines generated net savings of

- 295 Billion direct costs
- 1.38 Trillion in total societal costs

Methods for evaluating the value of vaccines

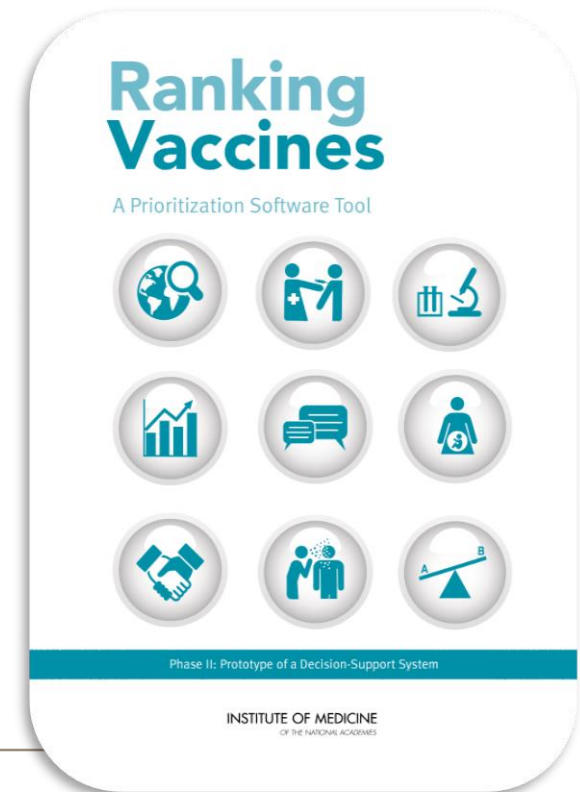


the initiative of the Institute of Medicine to assign the right value to vaccines



2012

2013

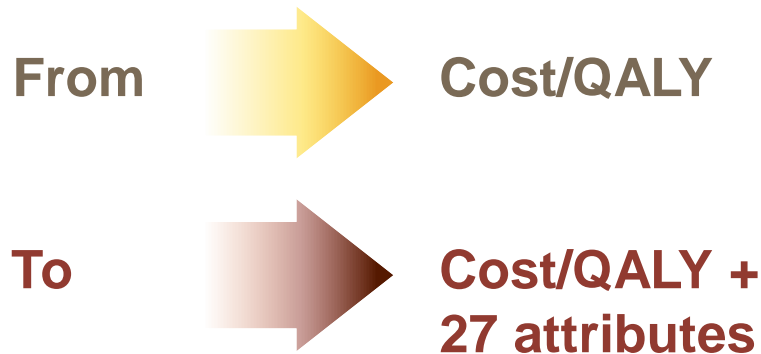


Institute of Medicine (IOM) initiative SMART Vaccines



<http://www.nap.edu/smartvaccines>

multi-criteria decision making 28 attributes 8 categories



Health Considerations	<ul style="list-style-type: none"> • Premature Deaths Averted per Year • Incident Cases Prevented per Year • QALYs Gained or DALYs Averted
Economic Considerations	<ul style="list-style-type: none"> • Net Direct Costs (Savings) of Vaccine Use per Year • Workforce Productivity Gained per Year • One-Time Costs • Cost-Effectiveness (\$/QALY or \$/DALY)
Demographic Considerations	<ul style="list-style-type: none"> • Benefits Infants and Children • Benefits Women • Benefits Socioeconomically Disadvantaged • Benefits Military Personnel • Benefits Other Priority Population
Public Concerns	<ul style="list-style-type: none"> • Availability of Alternative Public Health Measures • Potential Complications Due to Vaccines • Disease Raises Fear and Stigma in the Public • Serious Pandemic Potential
Scientific and Business Considerations	<ul style="list-style-type: none"> • Likelihood of Financial Profitability for the Manufacturer • Demonstrates New Production Platforms • Existing or Adaptable Manufacturing Techniques • Potential Litigation Barriers Beyond Usual • Interests from NGOs and Philanthropic Organizations
Programmatic Considerations	<ul style="list-style-type: none"> • Potential to Improve Delivery Methods • Fits into Existing Immunization Schedules • Reduces Challenges Relating to Cold-Chain Requirements
Intangible Values	<ul style="list-style-type: none"> • Eradication or Elimination of the Disease • Vaccine Raises Public Health Awareness
Policy Considerations	<ul style="list-style-type: none"> • Interest for National Security, Preparedness, and Response • Advances Nation's Foreign Policy Goals
User-Defined Attributes	<ul style="list-style-type: none"> • Up to Seven Attributes

Strategic Multi-Attribute Ranking- Toll (SMART) Vaccines

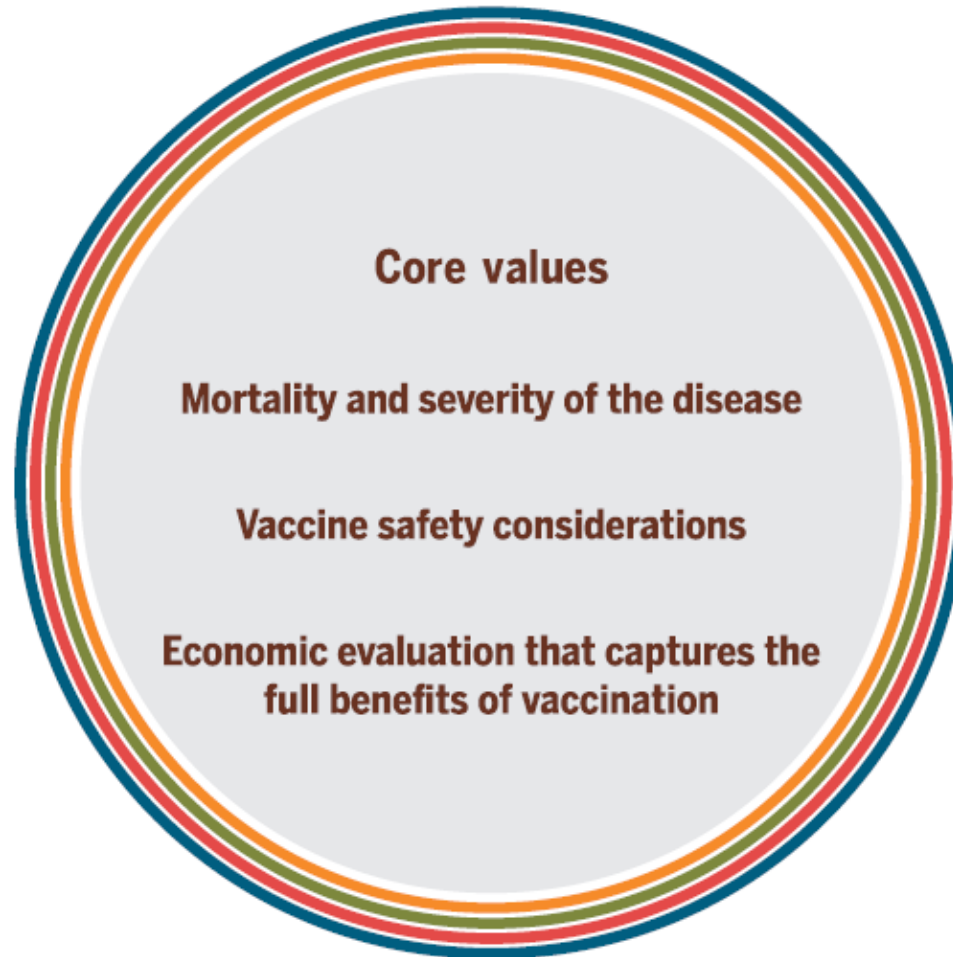
PUBLIC HEALTH

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

Michèle A. Barocchi,¹ Steve Black,² Rino Rappuoli^{1*}

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



Criteria for prioritization in addition to the core values

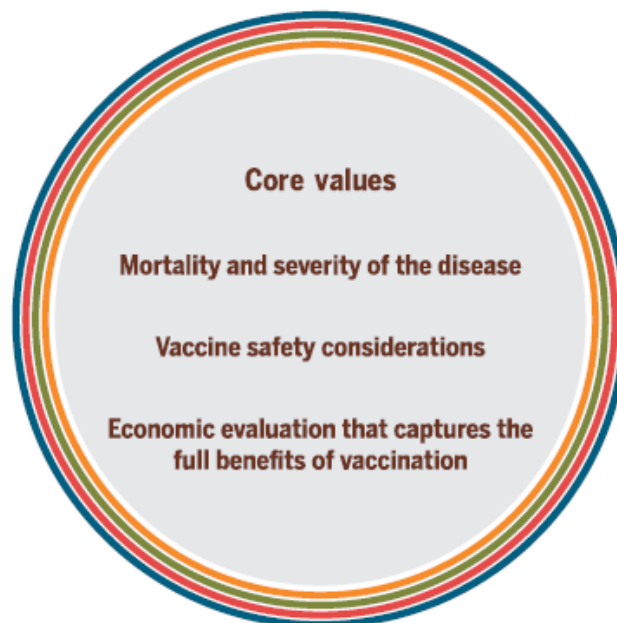


Developed countries

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

Emerging infections

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



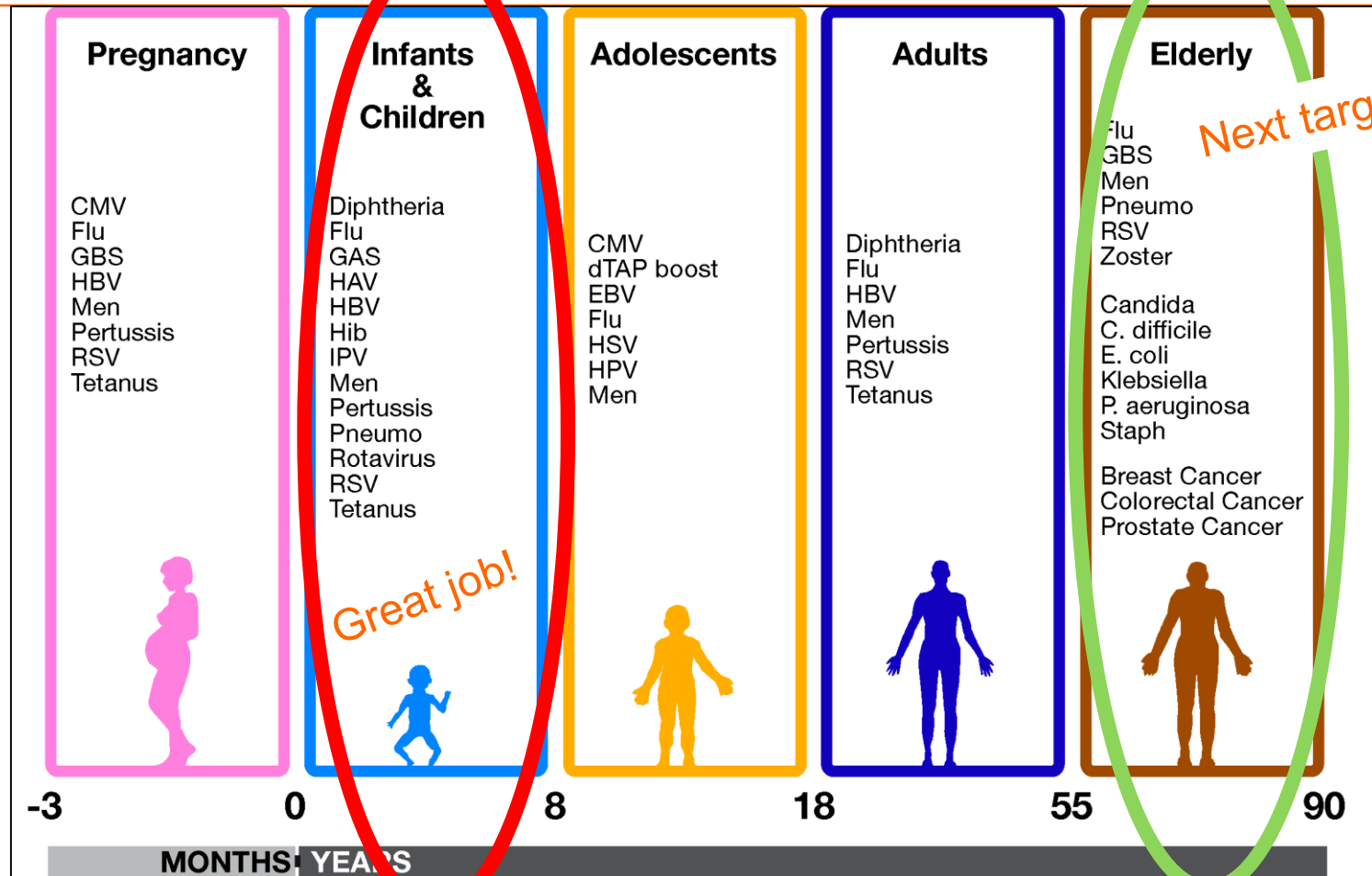
Low-and medium-income countries

- Interest from NGOs
- Lack of availability of alternative measures
- Targets a disease occurring primarily in disadvantaged populations
- Premature deaths averted per year

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

Vaccines can do more for our society



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
TB
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)**

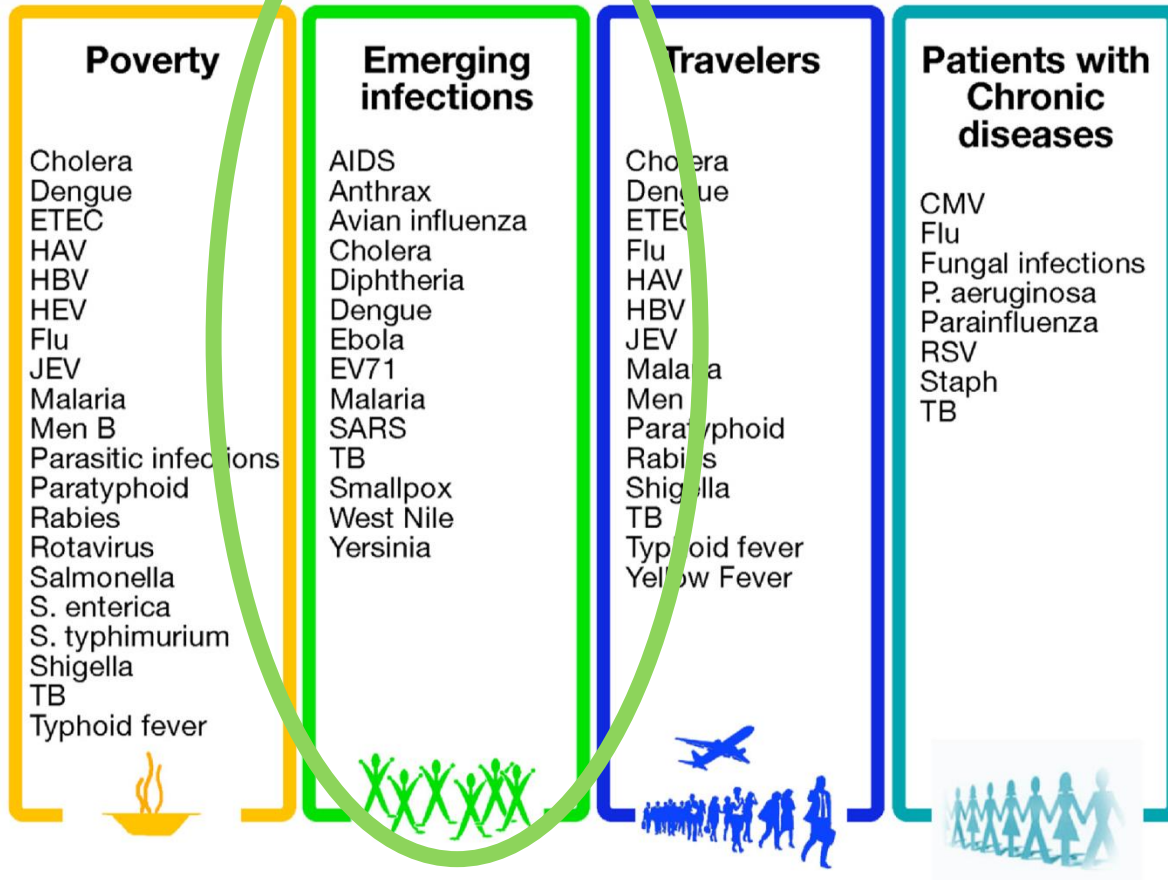
A new **non-profit initiative**

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

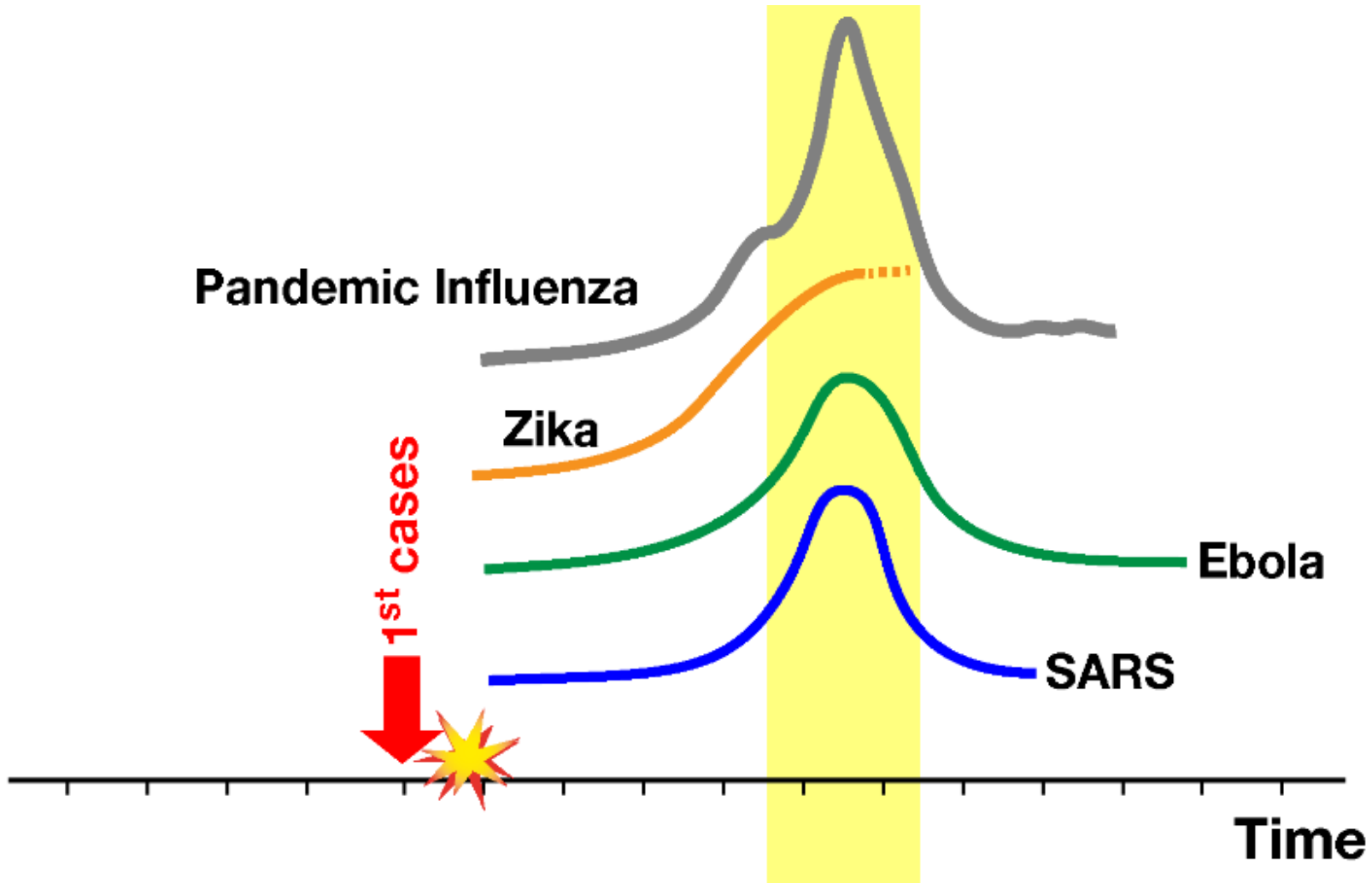


Immunotherapy/therapeutic vaccines?

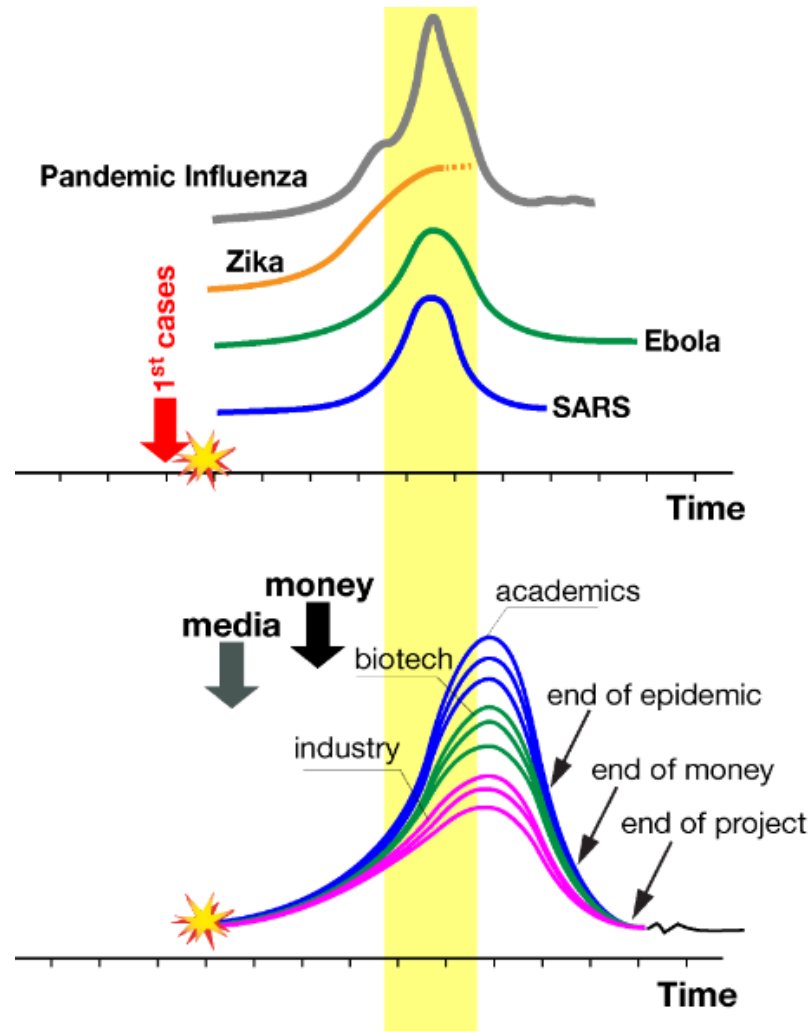
- Cancer**
- Autoimmune diseases**
- Alzheimer**
- Chronic infections**
(HCV, HBV, HPV, HIV, ...)
- Metabolic diseases**
- Allergy**
- Drug addiction**



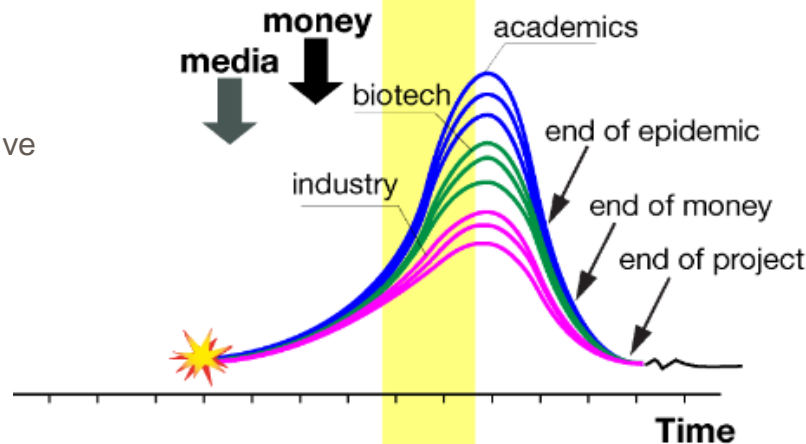
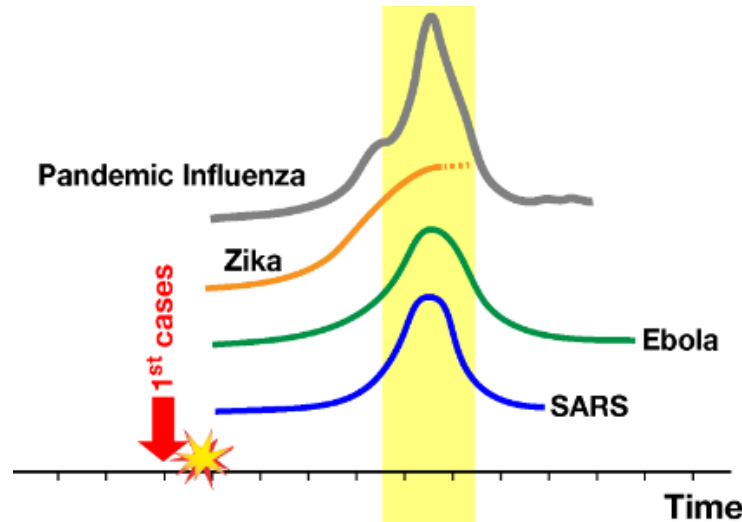
Emerging infectious diseases



Response to Emerging Infectious Diseases



Response to Emerging Infectious Diseases



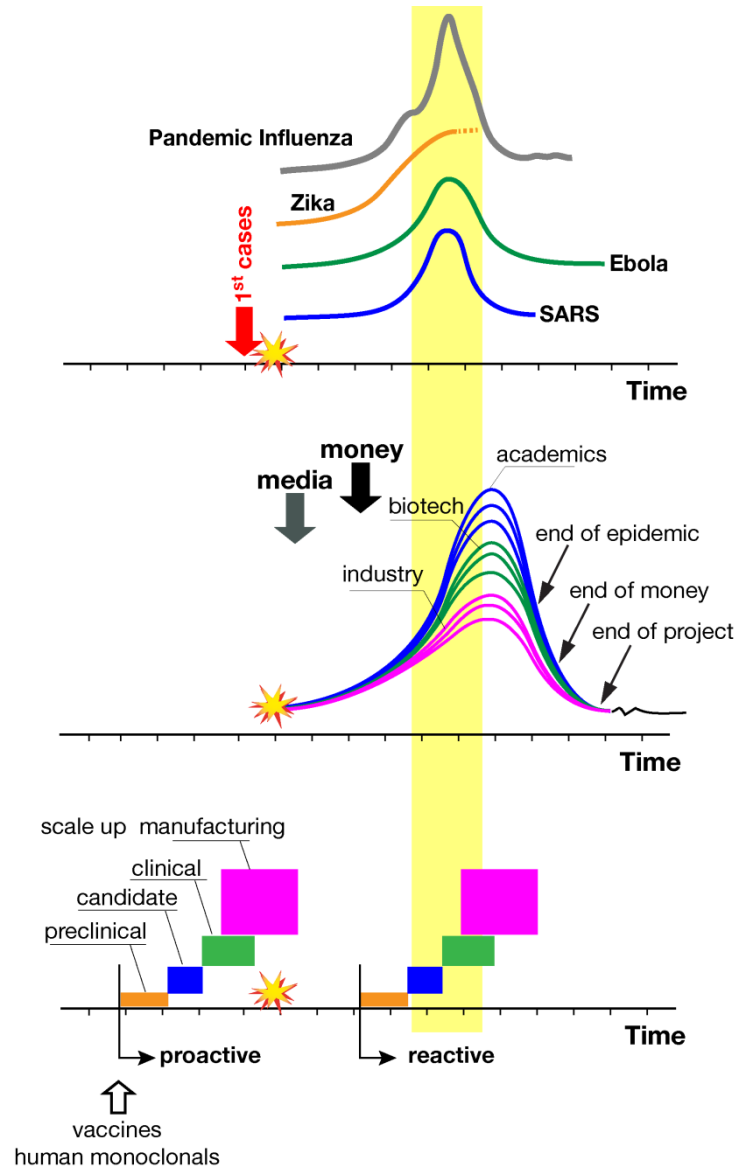
– No sustainable
Industry diverts best assets and people to face the emergency, huge opportunity costs, nothing in return

– No lesson learned so far
We start all over again, no regulatory solutions, No sustainable solutions,

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

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

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.

Meningitis B petition becomes UK's most signed

19 February 2016 | Kent

BBC

BBC iD



Faye's story

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.

1034 JAMA September 13, 2016 Volume 316, Number 10



Just Giving / Charlene Reed

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