



Foundation Merieux

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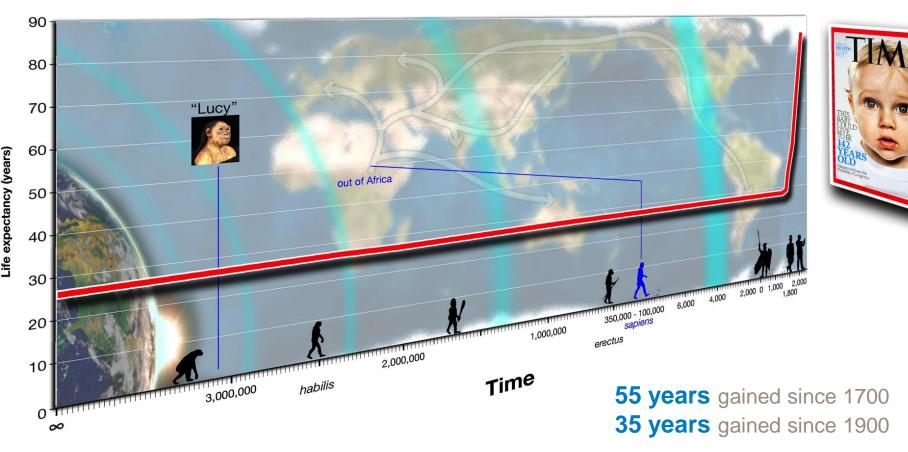
Siena January 11th 2016



Some history of human evolution

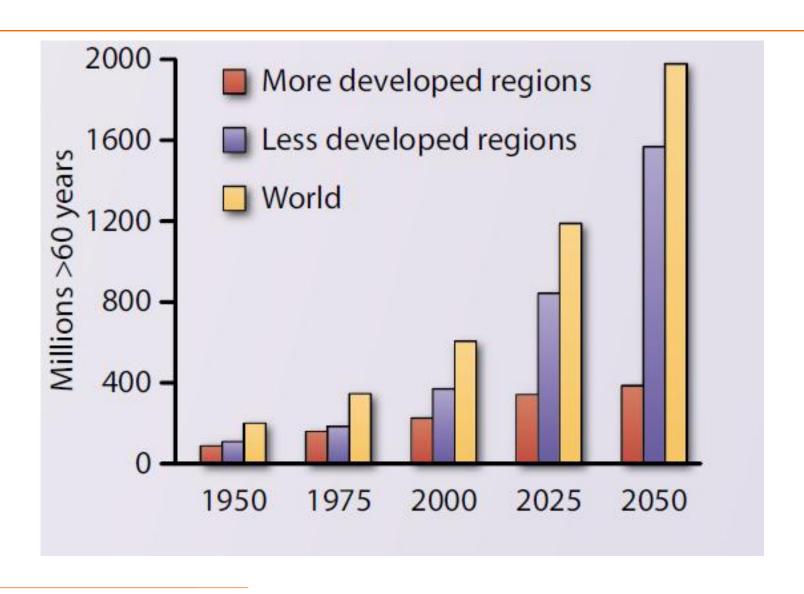


For 99.99 % of the history of mankind, life-expectancy has been < 30 years



Aging population





Vaccines for every age **Elderly Adolescents Adults** Infants **Pregnancy** Next target! Children Flu GBS Men Diphtheria Pneumo Flù **RSV** Diphtheria CMV GAS Zoster dTAP boost Flù HAV **EBV HBV** Candida **HBV** Flu Men C. difficile Hib **Pertussis** HSV E. coli **IPV HPV RSV** Klebsiella Men Men Tetanus P. aeruginosa **Pertussis** Pneumo Staph Rotavirus **Breast Cancer RSV** Colorectal Cancer Tetanus **Prostate Cancer** 'Great job!



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MONTHS! YEARS

CMV

GBS

HBV

Men

RSV

Pertussis

Tetanus

Flu

55

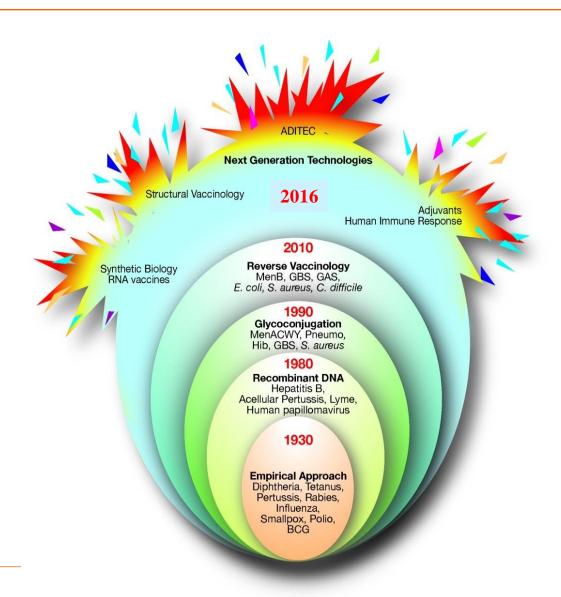
90

18

8

We have an explosion of new technologies to target new diseases





Three breakthrough vaccines in 2015



Vaccines continue to serve our society

First Malaria vaccine licensed

Efficacy and safety of RTS,S/AS01 malaria vaccine with or without a booster dose in infants and children in Africa: final results of a phase 3, individually randomised, controlled trial

RTS,S Clinical Trials Partnership*

www.thelancet.com Vol 386 July 4, 2015

Zoster vaccine 97% efficacy in the elderly

Efficacy of an Adjuvanted Herpes Zoster Subunit Vaccine in Older Adults

N ENGL J MED 372;22 NEJM.ORG MAY 28, 2015

Ebola vaccine 100% efficacy

Efficacy and effectiveness of an rVSV-vectored vaccine expressing Ebola surface glycoprotein: interim results from the Guinea ring vaccination cluster-randomised trial

Vaccines are ready to play a major role in healthy aging





Developing vaccines is not enough

It is important that vaccines become part of the public health intervention

Define the needs: epidemiology, impact of the disease, etc Antigen Vaccine Vaccination Adjuvant Vector **Publich Academy Industry** Health

The importance to give the right value to vaccines

How do we make decisions?



Cost effectiveness is a largely used for vaccine decisions



Cost/QALY

- Costs are easy to calculate
- Do QALY capture the real value of vaccines?

Institute of Medicine (IOM) initiative SMART Vaccines



http://www.nap.edu/smartvaccines

To Cost/QALY + 27 attributes

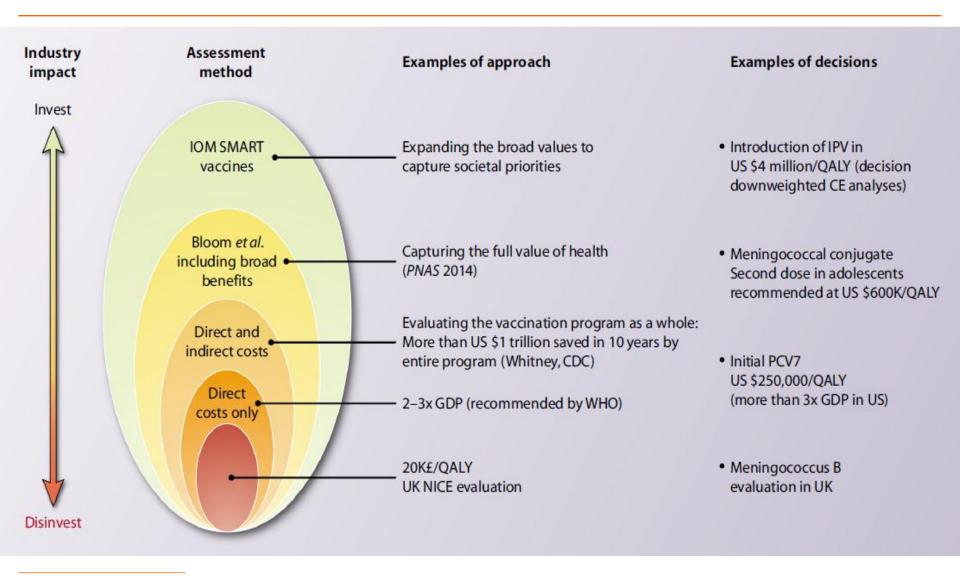
28 attributes 8 categories

Health Considerations	Premature Deaths Averted per YearIncident Cases Prevented per YearQALYs Gained or DALYs Averted
Economic Considerations	 Net Direct Costs (Savings) of Vaccine Use per Year Workforce Productivity Gained per Year One-Time Costs Cost-Effectiveness (\$/QALY or \$/DALY)
Demographic Considerations	 Benefits Infants and Children Benefits Women Benefits Socioeconomically Disadvantaged Benefits Military Personnel Benefits Other Priority Population
Public Concerns	 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	 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	 Potential to Improve Delivery Methods Fits into Existing Immunization Schedules Reduces Challenges Relating to Cold-Chain Requirements
Intangible Values	Eradication or Elimination of the Disease Vaccine Raises Public Health Awareness
Policy Considerations	 Interest for National Security, Preparedness, and Response Advances Nation's Foreign Policy Goals
User-Defined Attributes	Up to Seven Attributes

Strategic Multi-Attribute Ranking-Toll (SMART) Vaccines

Methods for evaluating the value of vaccines







Consensus from the Grand Convergence Meeting

Siena July 2015



Additional attributes to be considered for

DEVELOPED COUNTRIES

- Severe and frequent diseases
- Rare severe diseases
- Frequent non severe illness
- Targets a disease primarily occurring in the elderly
- Interest for national security and response

Additional attributes to be considered for

LOW & MEDIUM INCOME COUNTRIES

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



- Vaccine safety considerations
- Economic evaluation capturing the full benefits of vaccination

Additional attributes to be considered for

MANUFACTURERS

- Feasibility (technical & regulatory)
- Likelihood of licensure < 10 years</p>
- Likelihood of profitability
- Likelihood of a recommendation
- Demonstrates new product platform
- One time cost of development

Additional attributes to be considered for

EMERGING INFECTIONS

- Epidemic and Pandemic potential
- Potential to eradicate the disease
- Targets rare but severe disease with potential for outbreaks/pandemics