Global Vaccine and Immunization Research Forum Incheon, 28-30 March 2023

The Full Value of Vaccines Assessment (FVVA) concept

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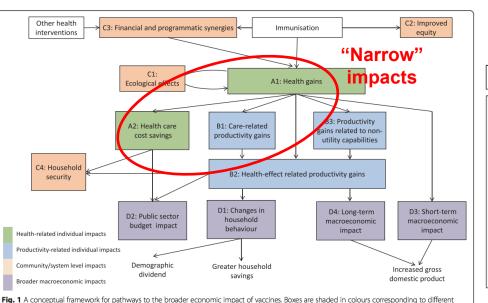
I have no conflicts of interest to declare



Paradigm shifts in assessing the value of vaccines



From "narrow" to "broad" impacts Jit et al. 2015



major categories in Table 1

From "the brick wall" to "the other side" Gessner et al. 2017

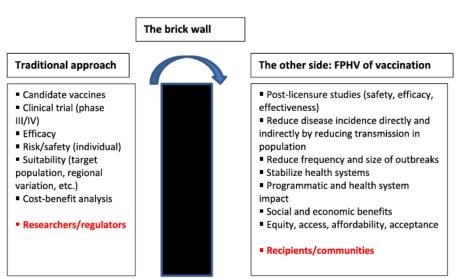
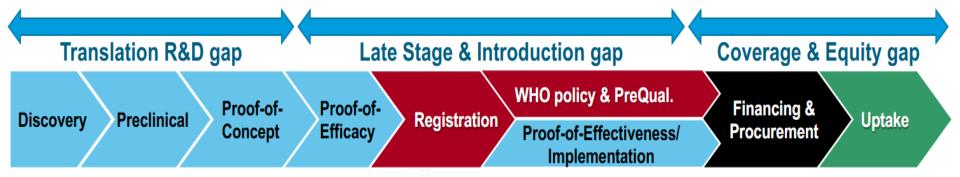


Fig. 2. The brick wall: Moving from vaccines to vaccination.

Jit M et al. The broader economic impact of vaccination: reviewing and appraising the strength of evidence. BMC Medicine 2015; 13:209. Gessner B et al. Estimating the full public health value of vaccination. Vaccine 2017; 35:6255.

The "full value of vaccines" continuum^{1,2}





"Should we invest in developing a new vaccine?"

"Should we recommend/fund a new vaccine?"

"Should we introduce a new vaccine?"

¹As discussed at Fondation Mérieux consultation, 5-7 December 2016; WHO Product Development for Vaccines Advisory Committee (PDVAC) Consultation, 26-28 June 2019, Wilder-Smith et al. BMC Medicine 2017; 15:138 etc.

²Adapted from presentations by David Kaslow (PATH), Kaslow Nature 564(7736):337; O'Brien Lancet 2016; 387(10031):1887; Hutubessy et al. 2021 SSRN.

Addressing multiple stakeholders



Translation gap



Bench research

Clinical studies

Introduction gap



Clinical studies

and market access

Implementation gap



Licensed vaccine

High uptake

Audience: research funders, manufacturers, academia







Audience: donors, regulators





Audience: WHO, UNICEF, Gavi, NITAGS, ministries





Key requirements:

- Value of information
- Financial (manufacturers) or societal (funders) return on investment
- Economic surplus and market analysis

Key requirements:

- Cost-effectiveness
- Broader benefits (equity, development, security etc.)

Key requirements:

- Cost-effectiveness
- Fiscal/budget impact
- Equity (extended CEA)
- Broader benefits

Feedback loop: ensure products meet country needs

Antecedent: Investment cases*



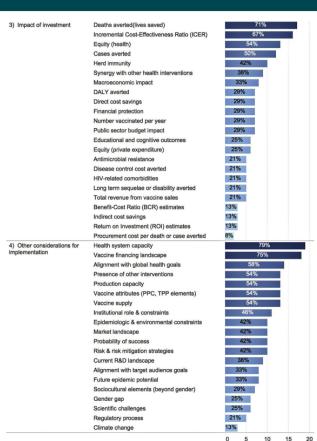
Frequency

A Scoping Review of Investment Cases for Vaccines and Immunization Programs

So Yoon Sim, MA, MSPH, Mark Jit, PhD, 2.3 Dagna Constenla, PhD, David H. Peters, MD, DrPH, Raymond C.W. Hutubessy, PhD 4.8

Category	Outcomes	
1) Burden of disease	Deaths	83%
	Cases	75%
	Total cost	63%
	Direct cost of treatment	54%
	Indirect cost of treatment	50%
	Long-term sequelae/Disability	50%
	Cases- Outbreaks	33%
	Deaths- Outbreak	29%
	Number of outbreaks	29%
	DALY	25%
2) Cost of investment	Vaccine price	71%
	Quantity demanded	54%
	Total procurement cost	46%
	Total delivery cost	42%
	Country introduction scenario (adoption forecast)	21%
	Clinical trials (Phase 1 - 3)	17%
	Discovery	17%
	Total development cost	17%
	Cost of capital	13%
	Manufacturing	13%
	Post-marketing activities	13%
	Process development	13%
	Marketing	8%
	Regulatory	8%

^{*&}quot;investment case", "value proposition", "business case" etc.



Multiple analyses: a dashboard approach

• Maternal GBS vaccination costs \$100 per DALY averted and \$200 per case avoided.

Threshold cost • Maternal GBS vaccination is cost-effective at \$2/dose.

Return on investment • Maternal GBS vaccination brings \$2 in economic returns per \$1 invested.

• Maternal GBS vaccination will cost \$10m in the year of introduction, and \$5m a year thereafter.

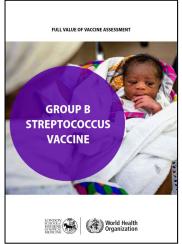
• Maternal GBS vaccination prevents twice as many deaths and thrice as many cases of catastrophic expenditure in Q1 compared to Q5.

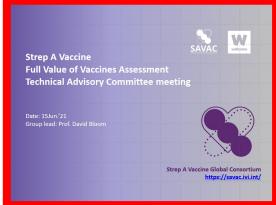
• Development of a GBS vaccine is worth \$20bn to manufacturers, \$100b to HICs and \$75bn to LMICs.

Antibiotic resistance • Maternal GBS vaccination reduces prescribing by 25%, the proportion of resistant carriers by 15% and the cost of resistance by 10%.

Current and pipeline FVVAs











Work in progress:







Key messages about the FVVA concept



- 1. Understanding the value of a vaccine is important to inform investment decisions by manufacturers, donors and countries.
- 2. The FVVA concept brings three key considerations to vaccine evaluations in an integrated framework.
 - Global value to producers and consumers (especially LMICs)
 - Decision-making across the vaccine development to uptake continuum
 - Broader socioeconomic and public health effects.
- 3. Work is ongoing to further flesh out this framework and apply it to potential vaccine candidates.