

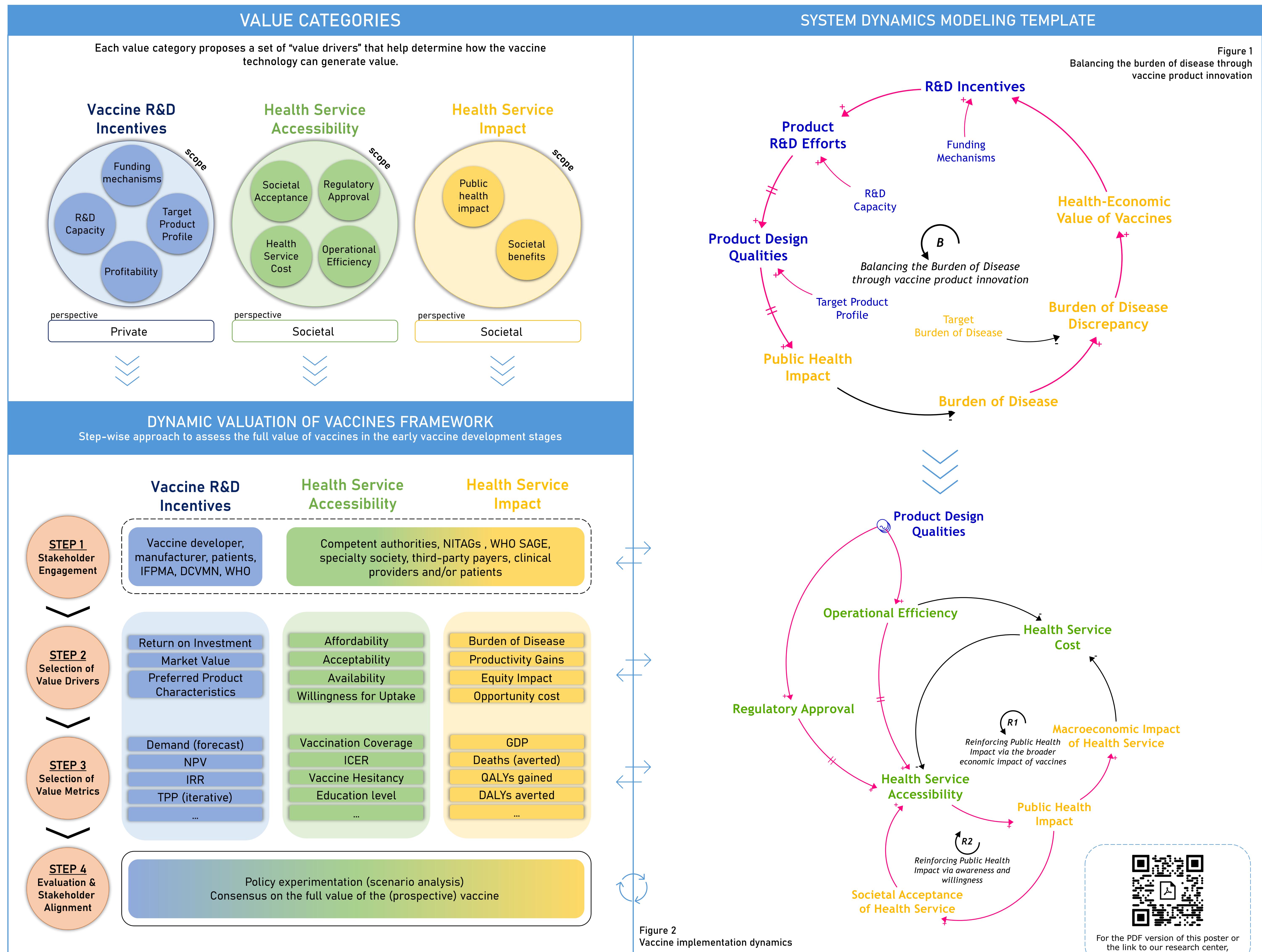
# Dynamic Valuation of Vaccines: a Method Framework for Early Health Technology Assessment

Driving Innovation and Implementation Strategies using System Dynamics Modeling

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## BACKGROUND

### Developing Vaccines: A High-Risk, High-Cost Challenge

- **High Risk and High Cost:** Most vaccine candidates fail before reaching the market, with successful candidates often costing over \$1 billion to develop [1, 2]
- **Traditional HTA Limitations Discourages Innovation:** Health Technology Assessments (HTAs) typically focus on only direct health impacts through static, linear models, which often overlook the broader, societal benefits of vaccines [3-5]. This narrow and incomplete approach can result in undervaluing vaccines by neglecting crucial externalities [6-10]

### Methodological Gaps in Current Evaluations

- **Static vs. Dynamic Assessment:** HTAs traditionally rely on static models that do not account for feedback loops, interdependencies, or real-world complexities involved in vaccine development and implementation [11]
- **Recognizing Broader Societal Value:** Recent frameworks, such as the Full Value of Vaccines Assessment (FVVA), have aimed to capture these broader values – such as societal and economic impacts – but face challenges in practical application due to methodological constraints [5]

## OBJECTIVES

### Primary Objective:

To introduce the Dynamic Vaccine Valuation (DVV) framework for Early HTAs, aiming to create a more realistic and adaptable model that reflects the complexities of vaccine R&D and implementation. This framework broadens the scope of evaluation to include societal, economic, and public health impacts, ensuring alignment with the needs of end-users and supporting more dynamic, multi-stakeholder decision-making early in the product lifecycle.

### Secondary Objective:

To illustrate the use of System Dynamics modeling in early vaccine evaluation, addressing the limitations of traditional HTAs by incorporating non-linear relationships and real-world uncertainties, thereby providing a more robust and timely approach to stakeholder-driven vaccine assessment and development.

## METHODS

### Framework Development and Design

This study developed the Dynamic Vaccine Valuation (DVV) framework through an iterative approach, combining qualitative system dynamics modeling with primary and secondary data analysis (Jan 2023 – Oct 2024). A systems diagram was created to map key variables and stakeholder influences. Methodological triangulation ensured relevance and applicability, with inputs drawn from literature reviews and expert interviews.

### Data Collection, Analysis, and Integration

- **Literature Review:** An integrative review identified key issues in vaccine R&D, valuation, and implementation. Targeted searches across multiple databases (Web of Science, Scopus, PubMed) supplemented by snowball sampling provided a foundation for the systems diagram.
- **Expert Interviews:** Nineteen semi-structured interviews with stakeholders across sectors validated the framework's structure, informing model variables and capturing real-world challenges.

### System Dynamics (SD) Modeling

SD modeling principles were applied to build a systems diagram, capturing dynamic relationships and feedback loops in vaccine development and implementation. This dynamic systems approach provides a foundation for exploring complex, non-linear interactions in vaccine development and valuation.

## CONCLUSIONS

1. **Holistic and Aligned with FVVA Principles:** Building on the FVVA framework, DVV emphasizes stakeholder perspectives, adaptability to evolving evidence, and transparent evaluation – fostering cross-sectoral collaboration to streamline the continuum from development to public uptake
2. **Support for Policy Decisions:** The DVV method framework proposes to evaluate vaccines according to the identified value categories via a step-wise procedure and SD simulation modeling for which it puts forward an aggregated vaccine-agnostic modeling structure to guide modelers in the field of Health Economics and Outcomes Research.

Or invite me for coffee :)

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[1] Exler JL, Saville M, Privor-Dumm L, Gilbert S, Hotez PJ, Thompson D, et al. Factors, enablers and challenges for COVID-19 vaccine development. Vol. 8, *BMJ Global Health*. 2023.

[2] Kaslow DC, Black S, Bloom DE, Dalla M, Salisbury D, Rappoport R. Vaccine candidates for poor nations are going to waste. *Nature*. 2018 Dec 20;564(7736):337-9.

[3] Archer RA, Kapoor R, Isaranuwatchai W, Teerawattananon Y, Giersing B, Botwright S, et al. It takes two to tango: Bridging the battle country need and vaccine product innovation. *PLoS One*. 2020 Jun 1;15(6).

[4] Botwright S, Kahn AL, Hutubessy R, Lydon P, Biey J, Karim Sidibe A, et al. How can we evaluate the potential of innovative vaccine products and technologies in resource constrained settings? A total systems effectiveness (TSE) approach to decision-making. *Vaccine*. 2020 Dec 11;6.

[5] Hutubessy R, Lauer JA, Giersing B, Sim SY, Jit M, Kaslow D, et al. The Full Value of Vaccines Assessments (FVVA): a framework for assessing and communicating the value of vaccines for investment and introduction decision-making. Vol. 21, *BMC Medicine*. 2023.

[6] Giersing B, Shah N, Kristensen D, Amorji JP, Kahn AL, Gandraup-Marino K, et al. Strategies for vaccine-product innovation: creating an enabling environment for product development to uptake in low- and middle-income countries. *Vaccine*. 2021;30:7208-19.

[7] Brassel S, Neri M, O'Neill P, Steuter S. Realising the broader value of vaccines in the UK. *Vaccine*. 2021 Aug 1;8:100096.

[8] Newall AT, Beutels P, Tufaha HW, Hall PS, Jit M. How can early-stage economic evaluation help guide research for future vaccines? Vol. 40, *Vaccine*. 2022; p. 175-7.

[9] Torrejón E, Mazzucato M, Li HL. Delivering the People's Vaccine: Challenges and Proposals for the Biopharmaceutical Innovation System. UCL Institute for Innovation and Public Purpose, *Policy Brief series* (IIPP PB 12); 2021.

[10] Bell E, Neri M, Steuten L. Towards a Broader Assessment of Value in Vaccines: The BRAVE Way Forward. *Apppl Health Econ Health Policy*. 2022 Jan 1;20(1):105-17.

[11] World Health Organization. *WHO guide for standardization of economic evaluations of immunization programmes*, 2nd ed. 2019.