Policy and Economic Considerations for the Provision of EVANS SCHOOL OF PUBLIC POLICY & GOVERNANCE Global Public Goods: Biomedical Research and Development

Jack Knauer & Caitlin O'Brien-Carelli

INTRODUCTION

Scientific knowledge from biomedical research and development (R&D) can be considered a public good insofar as it can be used repeatedly (non-rival) and it is difficult or costly to exclude non-payers (non-excludable)³. Private financing is unlikely for R&D with limited excludability, which occurs in the absence of intellectual property rights that allow investors to fully capture the financial benefits from R&D⁶. Economic theory suggests that private sector investments are primarily determined by positive financial returns, while public and philanthropic investments are determined by the likelihood and magnitude of social returns. This research considers how factors theorized to impact investments in R&D are associated with investments by public, private, and philanthropic sources.

RESEARCH QUESTION

How are factors theorized to impact costs and revenues from global health R&D associated with investments in R&D for specific diseases? How do those investments differ across the public, private, and philanthropic sectors?

METHODOLOGY

- The study begins with a literature review exploring factors theoretically associated with investments in early-stage biomedical research, including basic research and Phase I – III clinical trials.
- We analyze evidence on factors that impact how public, private, and philanthropic investments in R&D are allocated for four diseases with high incidence rates in low- and middle-income countries¹: malaria, tuberculosis disease (Tb), hepatitis C (HCV) (genotypes 4,5, and 6), and soil-transmitted helminthiases (STH).
- We then explore whether these factors are associated with distinct levels of R&D funding by disease.

ABOUT EPAR

Established in 2008, the Evans School Policy Analysis and Research Group (EPAR) uses an innovative student-faculty team model to provide rigorous, applied research and analysis to international development stakeholders. EPAR has prepared more than 250 technical reports including: statistical data analysis and research, literature reviews and analysis, and portfolio analysis and strategy support. Our reports focus on agriculture, development policy, financial services, poverty reduction, gender, and measurement and evaluation. Learn more at <u>http://evans.uw.edu/policy-impact/epar</u>.

REFERENCES

2. Moran, Met.al.. Neglected Disease Research and Development: The Ebola Effect. 2015. 3. Nordhaus, W. The Problem of Global Public Goods. 2005.

research and development. Health Research Policy System, 11(10) 6. Williams, H.L. Intellectual Property Rights and Innovation: Evidence from Health Care *Markets*. 2016.

Multiple factors influence estimated returns to global health R&D investments and allocations of R&D funding by public, private, and philanthropic sources, including disease pathology and epidemiology, the cost effectiveness of existing interventions (which may affect market share and willingness-to-pay), regulatory environments, and market conditions (Table 1). Figure 1 compares global R&D investment to neglected disease R&D investments by sector. Figure 2 illustrates levels of R&D funding and Disability-Adjusted Life Years (DALYs) by disease and sector.

S

Ř

FINDINGS

able 1. Factors associated	with costs	and revenues	/benefits fro	m R&D inve

actor	Aspects
Costs	Fixed and variable costs, political and public budgeting
	time-to-market, stage of research of candidates for tre
	prevention, regulatory systems, disease pathology, par
	(risk-sharing)
evenues/Benefits	Market size, share, and growth, willingness-to-pay (W
financial & social)	existence of effective treatment, intellectual property
	likelihood of knowledge advancement, partnerships, d

Figure 1. Percent of R&D investment by sector for global health R&D⁴ and neglected disease R&D²





Figure 2. Investments in R&D² by disease and by sector, with DALYs¹

* Hepatitis C DALYs include DALYS attributed to hepatitis C, and hepatitis C-associated liver cancer and cirrhosis. Funding includes only investment in genotypes 4, 5, 6.

UNIVERSITY of WASHINGTON

estments

processes, eatment or rtnerships

ΓP), rights, discount rate

100%

MALARIA

- Market Size: The global burden of malaria is high, but the ability-to-pay of consumers and high-burden country governments is low, limiting market size and purchasing power. Funding mechanisms have been developed to increase the purchasing power of consumers and demand-side incentives for further R&D.
- Stage of Research/Time-to-Market: The majority of vaccine candidates in the clinical trial stage are in Phase I (22) and II (5). The high risk and long time-to-market of early-stage trials indicates limited incentives for private sector investment and are reflected in increasing private investment after Phase I.

TUBERCULOSIS DISEASE (Tb)

- **Existence of Current Treatment:** The current BCG vaccine has limited effectiveness and current treatments take over 6 months, providing opportunity for returns on new vaccines and drugs.
- Location of Returns: Investments by middle-income countries with high incidence can provide domestic returns when considering averted treatment costs⁵.

HEPATITIS C

- Market Size: Surveillance for HCV in low-income countries (LICs) is limited, indicating an unknown market size in these regions, as most diagnostic tools were developed for genotype 1.
- Willingness-to-pay: The majority of interventions are designed for genotype 1, the most common genotype in high-income countries (HICs), while genotypes 4, 5, and 6 are more prevalent in low-income countries and receive less funding.

SOIL-TRANSMITTED HELMINTHIASES (STH)

- Market Size: Because of the cost effectiveness of presumptive treatment and the non-specificity of signs and symptoms, estimates of the global burden vary, such that the market size is unknown.
- Prevalence of Cost Effective Treatment: There is little early-stage research being conducted on STH, likely due to the cost-effectiveness of treatment and the feasibility of eliminating STH with existing interventions.

KEY FINDINGS

- There is a limited association between global burden (in DALYs) and investments in R&D across all diseases.
- Accurate disease surveillance is key for identifying market size; diseases with poor diagnostics have more uncertain estimates of potential revenues/benefits.
- Diseases with incidence in HICs and LICs show some association with increased private sector investment; dual markets can increase the likelihood of financial returns.

Research Symposium/May 19, 2017















^{1.} Institute for Health Metrics and Evaluation. GBD Data Tool. 2015.

^{4.} Røttingen, J. A., Regmi, S., Eide, M., Young, A. J., Viergever, R. F., Årdal, C., ... & Terry, R. F. (2013). Mapping of available health research and development data: what's there, what's missing, and what role is there for a global observatory?. The Lancet, 382(9900), 1286-1307 5. Walwyn, D. R. (2013). Determining quantitative targets for public funding of tuberculosis