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# Towards a Global System of Innovation: the Role of Donors in Immunisation for International Development

Submitted for the degree of Doctor of Philosophy (PhD)

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## **ABSTRACT**

This research examines what role donors play with respect to innovation in immunisation for international development. It uses as its conceptual framework the global innovation system (GIS) model to examine the principal donors within the sector. Because the empirical data is in-depth, contextualised, and qualitative, the research design adopted is that of a multiple case-study of donor organisations, using triangulated, mixed-methods qualitative data collection. The examined cases are UNICEF, the Bill and Melinda Gates Foundation, and Gavi, the Vaccine Alliance.

Knowledge gaps in the existing literature related to how these donors engage actors and institutions across different spatial levels for innovation; to how donors' manifold power relations affect this; and to how donor structure and capabilities determine their particular roles in innovation.

The research finds strong evidence of an emerging GIS in immunisation for international development. This consists of a global sub-system and a set of sub-systems at the national level, each representing a country receiving development assistance in immunisation. Donors perform four principal roles within this GIS. Firstly, they provide, maintain and extend structural elements of the GIS, especially its networks and linkages between sub-systems. Secondly, donors generate and utilise resources of financial investment, market access and innovation legitimacy for the valuation of innovation. Thirdly, donors coordinate to ensure complementarity in the activities they and other actors provide, which enables effective distributed agency across the GIS. Fourthly, donors navigate the rules, norms and presumptions of the GIS on behalf of partnerships of actors, variously complying, co-opting or contesting them.

The relationship is shown between each of these principal roles and the system's spatial levels, inter-actor power relations and donors' structure and capabilities. This offers new, detailed understanding to close significantly the previously-identified knowledge gaps.

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## Table of acronyms

ADS	auto-disable syringe
AMC	advance market commitment
BMGF	Bill and Melinda Gates Foundation
CCE	cold chain equipment
CCEOP	Cold Chain Equipment Optimisation Platform
CDC	United States Centers for Disease Control and Prevention
CO	UNICEF Country Office
DAC	Development Assistance Committee (of the OECD)
DCVMN	Developing Countries Vaccine Manufacturers Network
DTP3	Diphtheria, tetanus and pertussis vaccine, third dose
DUI	Doing, using and interacting (form of knowledge)
EPI	Expanded Programme on Immunization
GFATM	Global Fund for HIV/AIDS, Tuberculosis and Malaria
GIS	global innovation system
GVAP	Global Vaccine Action Plan
HIC	high income country
HMIS	Health management information system
HSS	health system strengthening grant
IA2030	Immunization Agenda 2030
IAVI	International AIDS Vaccine Initiative
IDIA	International Development Innovation Alliance
IFFIm	International Financing Facility for Immunisation
IHP	International Health Partnership
IMF	International Monetary Fund
IPR	intellectual property rights
IRC	Independent Review Committee

IVI	International Vaccine Institute
JHSPH	Johns Hopkins Bloomberg School of Public Health
JSI	John Snow Incorporated
LEDC	less economically developed country
LMIS	logistics management information system
MEDC	more economically developed country
NIAID	United States National Institute of Allergy and Infectious Diseases
NIH	United States National Institutes of Health
NSI	national system of innovation
OECD	Organisation for Economic Co-operation and Development
ODA	official development assistance
OoI	UNICEF Office of Innovation
PDP	product development partnership
SCM	senior country manager (in Gavi)
SDG	Sustainable Development Goal
SIDA	Swedish International Development Agency
SSI	sectoral system of innovation
STI	Science, technology and innovation (form of knowledge)
SVI	Sabin Vaccine Institute
TPP	target product profile
UNDP	United Nations Development Programme
UNICEF	United Nations Children's Fund
USAID	United States International Development Agency
VIPS	Vaccine Innovation Prioritisation Strategy
VIS	Vaccine Investment Strategy
VVM	vaccine vial monitor

# **1 INTRODUCTION TO DONOR INNOVATION AND IMMUNISATION**

## **1.1 Innovation in international development**

‘Innovation fever’ is how the Financial Times chooses to describe the recent tendency within international development for donors to aim explicitly for innovation within their programmes (Murray, 2014). A survey by the OECD Development Assistance Committee (DAC), whose reportees provide over 95% of total global development assistance (OECD, 2022a), found that innovation featured explicitly or implicitly in the stated aims of more than three-quarters of its members in 2020 (OECD, 2020, p. 27).

Two factors have been identified as driving this trend. The Financial Times suggests that it is a response by traditional bilateral and multilateral donors to the emergence of new global actors such as the Bill and Melinda Gates Foundation (BMGF) and public-private partnerships such as Gavi, the Vaccine Alliance. These new actors have demonstrated to this historically public sector industry the possibility and value of bringing approaches, skills and tools from the private sector (Murray, 2014).

In parallel, the populations of many bilateral donor countries have felt increased financial pressures since the global financial crisis of 2007-08. These have resulted in increased questioning by those tax-paying constituents of the worthwhileness of the aid which their taxes fund. Donors have perceived innovation as a means to enable them to achieve and demonstrate greater impact, and thereby respond to public scepticism (Chang, 2018; Kumar, 2019; Ingram and Lord, 2019).

The public relations impetus of this dynamic, however, has raised questions about how donors have understood and applied the concept of innovation. As Richard Horton, editor-in-chief of The Lancet dramatically expresses it:

If anyone else uses the word ‘innovation’ I will scream: the most overused and meaningless word in global health (Horton, 2015).

This research aims to distinguish the public relations aspects from the substantive role which donors play with respect to innovation, and to examine that role in depth.

### **1.1.1 What is a donor?**

International development is a broad concept including a range of different emphasises and approaches, but at its core involves the provision of assistance for

social and economic development in less economically developing countries (LEDCs). Official development assistance (ODA), financed from public sources, is provided by donor governments, or by multilateral organisations such as development banks, UN agencies or development funds. Non-official development assistance is that provided from private sources such as philanthropic foundations (Devinit, 2013). These sources of development assistance represent the categories which for the purposes of this research we consider as donors. They are summarised by the International Monetary Fund (IMF) in Schieber *et al.* (2006):

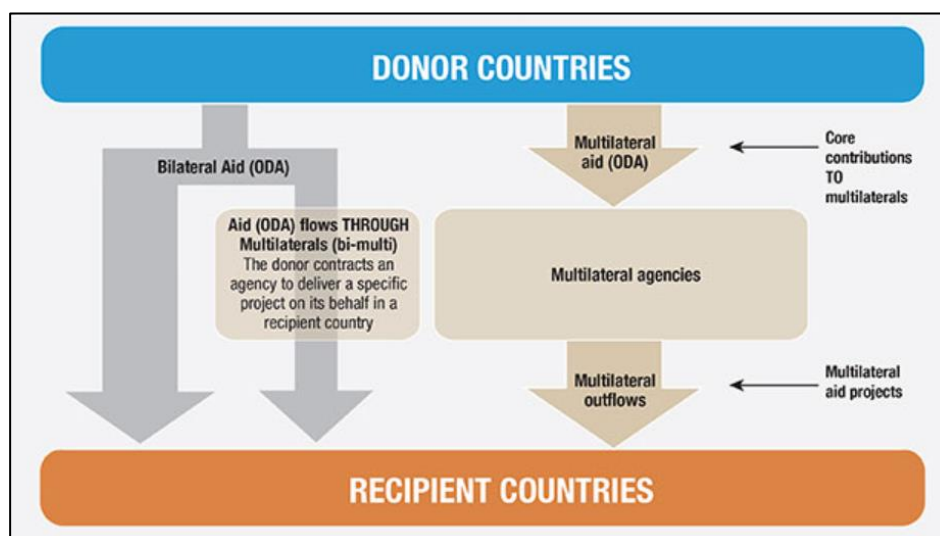
- i. Bilateral agencies
- ii. Private foundations
- iii. Development banks
- iv. UN agencies
- v. Other multilaterals (including the European Union, Global Fund to Fight AIDS, Tuberculosis and Malaria and Gavi, the Vaccine Alliance)

(Schieber *et al.*, 2006, Chart 2)

The set of donors in each of these categories can be identified through reference to the OECD's Development Assistance Committee (DAC), which is the global body for bilateral ODA. Membership requires assurance of certain standards, relating to targets, strategies, policies and performance monitoring and evaluation (OECD, 2022b). There are currently 30 DAC member countries and 25 associate countries. In addition to these bilateral donors, 65 multilateral donors and 39 private foundations also report their development assistance to DAC (OECD, 2022c). Together, these 150-odd donor organisations provide more than 95% of total global development assistance (OECD, 2022a). For the purposes of this research, we regard the set of organisations reporting on development assistance to DAC as representing a comprehensive list of donors in international development.

Measurement of the total amount of development assistance, however, is complicated by the fact that bilateral donors or foundations often themselves provide funding to multilateral donors. In fact, multilateral organisations are dependent upon such sources of funding. This relationship is shown in the following figure.

Figure 1: Bilateral and multilateral ODA flows (OECD, 2022d)



(OECD, 2022d, #2.4)

The figure illustrates two situations in which bilateral ODA flows through multilateral organisations. The minority case is that of *bi-multi aid*, in which the multilateral organisation delivers a specific project on part of a bilateral donor, and is not thus considered as a donor of those funds, which essentially just pass through it. In contrast, donor countries provide significant ODA to multilateral agencies in the form of *multilateral aid*. DAC explains that this funding:

... is pooled and used to meet an agency's running and programme costs, in a way that means that it loses its identity and becomes an integral part of the recipient institution's financial assets (OECD, 2022d, #2.5).

When the multilateral agency uses these financial assets to provide development assistance, the multilateral agency is thus considered also as a donor, despite itself having originally received those funds from another donor. UN agencies and vertical development funds<sup>1</sup> such as Gavi represent examples of this. In calculating total

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<sup>1</sup> Vertical development funds are global financing mechanisms for allocating development assistance which focus on a specific issue or theme.

development assistance, DAC has established methods to avoid double-counting of aid passed in this way from one donor to another.

### 1.1.2 Donor definitions of innovation

The breadth of donor types is reflected in the wide variety of donors' own definitions of innovation, as shown in the following table. The definitions are marked-up to highlight references to the following two aspects: **innovation for impact** (highlighted in the table in bold), and degree of innovation (underlined in the table).

Table 1: Donor definitions of innovation (Author)

Agency	Definition of innovation	Reference
Asian Development Bank (ADB)	Innovation means change that <b>adds value</b> for clients... Innovation happens along <u>a continuum, from incremental or disruptive ideas to transformative ones</u> that change our whole way of thinking... to solve <b>a concrete problem</b> .	ADB (2020, p. 5)
Australian Department of Foreign Affairs and Trade (DFAT)	We define innovation as the application of a new approach that creates a <b>positive impact</b> that is <u>significantly greater</u> than can be realised through current practice.	DFAT (2018, p. 3)
Development Assistance Committee (DAC)	Innovation for development <b>impact</b> [is] creative new approaches brought to bear <b>on long-standing problems</b> .	OECD (2020, p. 5).
Government of Canada	The aim of innovation in international assistance is to find and adopt concrete solutions that address problems more <b>effectively and efficiently</b> than existing approaches... Innovation in international assistance can be <u>either transformational (i.e., an entirely new solution to a problem) or incremental (i.e. an improvement to an existing solution to make it more effective and/or efficient)</u> .	Global Affairs Canada (2019, p. 7)
Global Fund for HIV/AIDS, tuberculosis and malaria (GFATM),	Innovation is a new perspective on an <b>old problem</b> . Innovation comes in many forms, from brilliant technology breakthroughs in Silicon Valley to less flashy advances like a simpler way to deliver essential products. In many cases, even a low-tech innovation can <b>improve</b> health care <u>in a life-changing way</u> .	GFATM (2016, p. 1)



Global Innovation Fund	Innovation is any solution that has potential to address an <b>important development problem more effectively</b> than existing approaches.	Global Innovation Fund (2020, p. 1)
International Development Innovation Alliance (IDIA)	An innovation is a new solution with the <u>transformative</u> ability <b>to accelerate impact</b> .	IDIA (2019, p. 4)
Rockefeller Foundation	An innovation is a <u>disruptive</u> solution that will allow us <b>to leapfrog</b> current approaches.	Rockefeller Foundation (2020)
Swedish International Development Agency (SIDA)	Innovation is defined as the use of knowledge – ideas, technologies and processes – into procedures, products and services that <b>bring added value</b> and are new in a specific context.	SIDA (2019, p. 5)
United Nations Children's Fund (UNICEF)	UNICEF defines innovation as a new or <b><u>significantly improved</u></b> solution that contributes to progress for children and accelerates results for children or young people. It is about doing new things <b>to solve problems and improve the lives</b> of children around the world. It is about matching today's challenges with tomorrow's solutions.	UNICEF (2020a, p. 7)
United Nations Development Programme (UNDP)	Innovation is a new entry point to <b>address the most stubborn development challenges</b> . It is a new and more effective solution that adds value for the people affected by development challenges	UNDP (2017, p. 5)
United States International Development Agency (USAID)	USAID defines innovation as the pursuit of novel approaches that lead to <b>substantial improvements in addressing development challenges</b> . Innovation involves an iterative and dynamic process that can result in new or improved business or organisational models, operational or production processes, or products and services. <u>Innovation is neither synonymous with invention nor limited to new gadgets, technology, or radical change.</u>	USAID (2019, p. 8)
World Bank	Innovation is the implementation of a new or <b><u>significantly improved</u></b> product, good or service; a new marketing method; or a new organisational method in business practices, workplace organisation or external relations.	World Bank (2013, p. 1)

In each of the donors' definitions, innovation is presented as a means of bringing greater impact to their mission. Different donors express that impact using different terms to highlight particular aspects, with reference either to impact itself (e.g.,

DFAT, 2018; IDIA, 2019), to effectiveness (e.g. Global Innovation Fund, 2020), to efficiency (e.g. Global Affairs Canada, 2019), or even simply to 'improvement' (e.g. UNICEF, 2020; USAID, 2019; World Bank, 2013).

We can also see an indication that donors approach innovation from a broad perspective: their definitions consistently emphasise that innovation is possible in areas other than products, with goods and services often being explicitly also included and sometimes also organisational structure, methods and processes (e.g., USAID, 2019; World Bank 2013). Accordingly, this research adopts a definition of innovation which is sufficiently broad as to embrace these. We allow that innovation need not necessarily be new to the world as a whole, but may be new only in a particular market, where it creates value. We follow Geels (2014) in referring broadly to innovations as *artefacts*, which may be material or immaterial in substance, to reflect the range of possible types of innovations. We don't presume that innovation is necessarily radical, or that it necessarily utilises digital technology.

An emphasis included in a significant number of the donor definitions is of the importance of innovation in addressing particularly long-standing or stubborn problems (e.g., GFATM, 2016; OECD, 2020; UNDP, 2017). Though examples of such problems are not specified in the donor definitions, this emphasis serves to illustrate the relatively greater power which donors see innovation as providing them with, compared to the tools they previously had available. UNICEF explains this by arguing that development challenges are more complex and inter-connected than ever before:

The world is changing faster than ever before, and so too are the challenges facing its most vulnerable. [These] are growing increasingly complex and inter-related, demanding new strategies and approaches (UNICEF, 2019a, p. 1).

UNICEF, elsewhere, gives the examples of climate change, disease outbreaks, conflict and displacement and urbanisation (UNICEF, 2016a, p. 104). Papaioannou (2014) makes a similar point, arguing that 'addressing twenty-first century developmental challenges requires innovative processes and products' (p. 187). The reasoning behind these arguments lies in the characteristics of these *wicked problems*, so termed by Rittel and Webber (1973). These are challenges which are particularly complex, with many exogenous linkages and factors, many of which are unknowable at any point, and which change over time (Rittel and Webber, 1973).

The reason for donors' focus on impact is related to their bi-directional accountability. Donors are accountable to the LEDCs to which they provide their development assistance. This accountability is directly to the intended community and individual beneficiaries of the donor's projects, but in practice often manifests as accountability to the LEDC government. Donors are also accountable to the original source of their funding. For bilateral government donor agencies, being publicly funded, this is their domestic taxpayers. United Nations agencies are funded through contributions by member states, to whom the agencies are accountable. Foundations, because they are resourced by privately donated funds, are accountable to those individuals or corporations which provide those funds. Those constituencies in both recipient and donor countries have become more questioning of development assistance in recent years, with DAC writing that:

In many developing countries, citizens and civil society organisations are increasingly pressing their leaders to demonstrate the effects of public spending and policies on everyday life. In donor countries, taxpayers are also demanding that their governments demonstrate the positive development changes resulting from aid expenditure. In a climate of rapid change and fiscal retrenchment, these factors have put pressure on development co-operation agencies to demonstrate that aid is actually working to combat poverty (OCED, 2014, p. 14).

Thus, DAC describes a logical flow in which constituent pressure drives greater measurement of impact, which results in greater achievement of impact. The same logic is reflected in the accounts of individual donors, who suggest, for example, that 'the need to measure development and demonstrate results has never been more urgent within donor agencies than it is today' (SIDA, 2019, p. 9), and that 'we need to work harder than ever to implement solutions that get the biggest bang for our development bucks' (USAID, 2017). The exacerbated pressures to which these donors refer are those resulting from the global financial crisis of 2007-08. The director of UNICEF's Innovation Centre in Nairobi, for example, explains the increased importance of innovation as due to 'a shift from programme delivery to programme results and a large part of that has evolved out of the financial crisis and looking for value for money' (Murray, 2014). Also explicitly making the linkage to innovation, DAC highlights the value of innovation to donors in 'providing the means to demonstrate the transformative effects of their investments, domestically and internationally' (OECD, 2020, p. 5).

As we examine donor roles in greater depth, we will find ourselves limited by the fact that individual donors are not particularly self-reflective concerning their innovation. Rather, the bulk of literature by donors about innovation tends to be produced by multi-donor organisations or alliances, reflecting the views of the member donors. Such multi-donor organisations include DAC, and the International Development Innovation Alliance (IDIA), which has as members 16 donors. We will also refer to the Whistler Principles to Accelerate Innovation for Development Impact, agreed in 2018 across the G7 group of countries; and the Principles for Digital Development, initially developed by seven leading donors and since endorsed by 54 international organisations.

### 1.1.3 Donor model of innovation

The Sustainable Development Goals (SDGs) include, within Goal #9, the aim to 'foster innovation'. The only associated target, however, is to

Enhance scientific research... increase the number of research and development workers... and public and private research and development spending' (United Nations, 2015, p. 25).

This association of innovation with scientific research and development (R&D) is reflected widely across donor literature. It represents an assumption on the part of the donor community of a linear model in which innovation stems from basic scientific research, subsequently commercialised within a market. The steps of this sequence are represented in the following figure:

Figure 2: The linear model of innovation (Author)



In its purest form, the linear model is a deterministic process, in which new knowledge produced through basic research leads to applied research, artefact development, production, and then diffusion. Well-informed, rational agents direct R&D to generate and use explicit knowledge to meet user-demand and gain market share (Freeman, 1996; Lundvall, 2007).

The model describes a clear set of typical roles for specific actors at each stage. It presents scientific research as essentially the only source of technical innovation

and there are no feedback loops from later to earlier stages in the process (Stokes, 1997; Cohen, 2002).

The linear model involves conceiving of scientific knowledge as a resource external, or independent, of the actor using it (Sampath and Roffe, 2012). The primary donor response to this understanding of innovation has been the policy of technology transfer. This has existed in various forms during the post-World War II period which equated development with industrialisation and saw technology transfer from more economically developed countries (MEDCs) to less economically developed countries (LEDCs) as a way to enable them to 'catch-up'. This donor policy was influenced by the very low proportion of R&D focused on the needs of LEDCs, and was made explicit by the Sussex Manifesto, commissioned in 1969 as an advisory note for the UN Commission on The Second Development Decade (1971-1980). It found that 98% of R&D took place in MEDCs, and proposed increases in the proportion of R&D carried out in LEDCs and in the proportion of MEDC-based R&D into the needs of LEDCs. It also proposed an increase in, and mechanisms for, technology transfer (Singer *et al.*, 1970)<sup>2</sup>.

In practice, however, LEDCs found it difficult to apply the transferred technologies. This was initially attributed to low levels of human resource capacity in those countries. The solution attempted by donors was to increase the supply of scientists or engineers into public research institutes in LEDCs, to which donors facilitated the transfer of technology from donor-funded international research centres (Clark, 2002).

Fundamental weaknesses, however, remained in the technology transfer model, resulting in insufficient connection between the needs and perspectives of the intended beneficiaries, and the interests of the international donors. The weakest link in the chain was that of the national research centres, which were focused on academic, scientific questions; isolated from the practical economic questions of the poor; non-interdisciplinary (in contrast to the complex problems faced by the poor);

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<sup>2</sup> Similarly, the more recently conceived '90/10 gap' refers to an estimate that 90% of global medical R&D is into problems affecting only 10% of the world's population (Doyle, 2004).

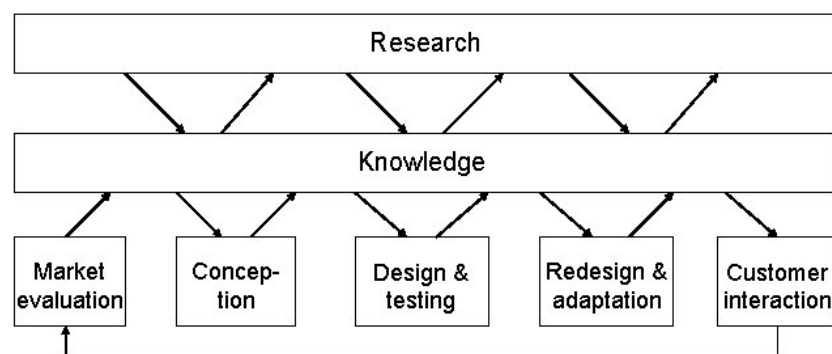
and with their funding also based on scientific rather than development-based success criteria (Sampath and Roffe, 2012).

These failures in technology transfer and in the linear model more broadly can be understood on the basis of deep epistemological misunderstandings (Balconi *et al.*, 2010). In this argument, even codified scientific knowledge entails parallel tacit knowledge. Such tacit knowledge is not easily transferred, however, as it is embedded in economic, historical and cultural contexts. Thus, its transfer along the linear process, or between actors, cannot be simply a transactional process, but one which is heuristic. It entails additional, more closely interactive engagement, and much greater taking into account of context, in the process of the transfer of the scientific knowledge (Sampath and Roffe, 2012). As a result:

The definition of transfer of technology has gradually expanded to include tacit knowledge as a clear and important component, thus moving away from the older, arcane discussion on technology in the form of machinery, equipment and blueprints (Sampath and Roffe, 2012, p. 47).

This understanding is reflected in an evolution of the linear model to incorporate less assumed sequentiality, multiple feedback loops, and greater interactivity between actors. This *chain-linked model* of Kline and Rosenberg (1986) moves away from the conception of innovation as a series of steps, rather presenting it as a set of related required tasks, as shown in the following figure:

Figure 3: The chain-linked model of innovation (Kline and Rosenberg, 1986)



(Kline and Rosenberg, 1986, p. 290)

Other authors have highlighted that innovations do not necessarily originate in basic research, with innovations being produced without a full understanding of why they work (Mansfield, 1991; Klevorick *et al.*, 1995). Balconi *et al.* (2010) give the example

of vaccines, pointing out that their discovery still involves a large element of trial and error, and experimentation, rather than being derived from first principles.

The essence of these refinements to the linear model involves recognising that there is not one single route to innovation. Rather, it differs between industries, and even within an industry may differ over time. Balconi *et al.* (2010) describe this as ‘the linear model in a weak form’ (p. 7), in which scientific advances can be an important source of innovation, but are neither sufficient to ensure innovation, nor necessary for it. This more sophisticated understanding of the limitations of scientific research has been increasingly adopted by donors, who highlight the importance of iterative connections between upstream R&D and their programmatic work with beneficiaries in the field. The Development Assistance Committee (DAC), for example, suggests that ‘there is often a need to strengthen the feedback loop between the production of research and its use to inform innovation efforts of DAC donors and their partners’ (OECD, 2020, p. 46).

Relatedly, donors have recently consistently emphasised the importance of interaction in driving innovation. The International Development Innovation Alliance (IDIA), for example, describes broad partnerships as ‘an essential tool for the world to generate new solutions’ (IDIA, 2019, p. 24), and highlights the importance of such partnerships being across the public, private and civil society sectors. The G7’s Whistler Principles state that broad interaction allows those actors ‘to leverage intellectual, financial and social resources from all, and share data, standards, results and learning widely’ (G7, 2018, p.2). DAC states that donors allocate a high importance to the ‘vital’ collaboration on innovation. It suggests, further, that this is because of collaboration’s value in ‘enhancing perspectives, strengthening capacities, co-creating solutions, sharing implementation of innovation processes, and pooling and sharing risks’ (OECD, 2020, p. 45).

The concept of wicked problems introduced earlier is also relevant to this understanding of innovation as iterative and collaborative. As a consequence of wicked problems’ imperfect information and fundamental uncertainty, there is often conflict between actors both about possible solutions, and about the nature of the problem itself (Rittel and Webber, 1973). The resolution of such problems is not possible simply through intellectual design, because the uncertainties fundamental to wicked problems are not just endogenous uncertainties, but also strategic and institutional uncertainties (Koppenjan and Klijn, 2004). Consequently, such resolution necessitates new interactions, as no individual actor is sufficiently fully

equipped to manage it alone, in terms of access to knowledge or other resources, meaning that actors must instead cooperate in order to innovate. Koppenjan and Klijn propose especially joint working across the public and private sectors. In the following two sections we examine the key interactions relating to this joint working.

#### **1.1.4 Donor inclusion of intended beneficiaries**

Intended beneficiaries should be included in innovation planning, design and implementation, according to donor-wide documents. The G7's Whistler Principles, for example, suggests that beneficiaries should 'play a decisive role in the design, testing, learning and adoption of innovative solutions' (G7. 2018, p. 1), and the Principles for Digital Development refer to 'partnering with users throughout the project lifecycle, co-creating solutions, and continuously gathering and incorporating users' feedback' (Digital Impact Alliance, 2022a). The first and third of the Busan Partnership Agreement principles for cooperation for effective development reflect this too, though in terms of governments rather than individual beneficiaries, specifying the importance of 'ownership of development priorities' by those receiving development assistance; and for 'inclusive development partnerships' between them and donors (OECD, 2011, p. 3).

Two principal arguments exist for the importance of beneficiary inclusion. The sociological argument for participation is that it contributes towards participants' empowerment, which is the ability for them to influence decisions which affect them (SIDA, 2010). The underlying theory is that greater participation in a system increases individuals' awareness of their relative place within it, and of any socio-political inequalities (Friere, 1972). This awareness may drive individual or collective action to address those inequalities, leading to contestation for power or the sharing of it (Kreisberg, 1992). This *entitlement argument* for beneficiary participation within the innovation process argues thus that it is important by virtue of democratic principle (Chataway and Smith, 2007).

The economic, or *productivity argument* for participation is built upon the premise that the intended beneficiaries of development projects have unique insights into their own needs, and into the likely success of possible solutions. Their participation in project planning, design and implementation should therefore result in better incorporation of these insights and hence in improved project outcomes, in terms of efficacy, equity and sustainability (Chataway and Smith, 2007).



These two arguments can be characterised as participation as an end in itself versus participation as a means to an end (Parfitt, 2004). Chataway, Hanlin and Kaplinsky (2014) refer to both arguments when they suggest that innovation brings a greater imperative for participation than other forms of development assistance as a result of:

[Innovation's] capital-intensive nature, its scale intensity, its dependence on high-quality networked infrastructure, its reliance on skilled labour and its product portfolio (producing products which meet the needs of the rich) [which] all have the effect of disadvantaging the poor, both as consumers and producers (Chataway, Hanlin and Kaplinsky, 2014, p. 34).

In practice donors tend strongly towards the productivity view. The International Development Innovation Alliance (IDIA), for example, states that 'investing locally and ceding control over innovation decision-making helps ensure that solutions fully respond to contextual challenges, which in turn helps position them to maximize impact' (IDIA, 2019, p. 8). Similarly, the Principles for Digital Development state that 'by designing with the users, and not for them, you can build digital tools to better address the specific context, culture, behaviours and expectations of the people who will directly interact with the technology' (Digital Impact Alliance (2022a).

This preference on the part of donors is likely related to their dependence on the consent of the government to work in a country. Donors struggle to challenge the political factors perpetuating inequality or injustice (Papaioannou, 2014).

Participation as an end involves political challenge and potential conflict, whereas participation as a means doesn't explicitly address power relations, and can at least appear politically neutral (Parfitt, 2004; Chataway and Smith, 2007). The risk is therefore that donors treat participation in a reductionist manner, managing it as a purely technocratic process, rather than more fundamentally about the relations of power and political influence (Hickey and Mohan, 2005).

There are also ways in which participation may be carried out sub-optimally (but sometimes necessarily) through the use of proxy participants such as governments or civil society organisations instead of the actual beneficiary communities themselves (OECD, 2020; Cooke and Kothari, 2001). Participation may also be misused, by being managed and manipulated towards certain outcomes (Cooke and Kothari, 2001), or used to legitimise outcomes to a degree unjustified by the level of participation itself (Chataway and Smith, 2007).

There are, furthermore, different degrees of inclusive innovation. At its most basic, it consists just of the inclusion of marginalised groups within the process of innovation (Foster and Heeks, 2013). However, as Papaioannou (2014) observes, this level of participation retains power with the donor rather than the beneficiary. In contrast, innovation may be seen as inclusive only if it delivers equitable outcomes for basic needs (Papaioannou, 2014). Heeks *et al.* (2014) propose a 6-point scale of degrees of inclusive innovation, culminating in actualised positive impact for the intended beneficiaries, resulting from a process they own and is based around their framework of knowledge. Although Heeks *et al.* suggest that there is no right or wrong level, Chataway and Smith (2007) speak for the consensus when suggesting that inclusion in the form of an isolated event is much less impactful than when inclusion is handled as an integral and ongoing aspect of the innovation process, in an intentional effort to address power relations (Chataway and Smith, 2007).

Donors themselves recognise that they have a particular challenge in achieving beneficiary inclusion in the process of innovation, with the Development Assistance Committee (DAC) stating that:

A critical blind spot in current innovation efforts is ignoring national and local actors or not thinking about them until it is too late. Despite widespread ideas about working with end users in context-specific ways and being participatory and open, in practice DAC members' work has placed much more emphasis on innovation work by mainstream development and humanitarian actors themselves (OECD, 2020, p. 48).

DAC suggest that a consequence of this is that innovation tends towards top-down processes such as technology transfer rather than 'innovation collaboration' (OECD, 2020, p. 54). This results in incremental innovations, rather than the more radical innovation that is dependent upon the full participation of beneficiaries.

### **1.1.5 Donor engagement with the private sector**

'The private sector is widely seen as the partner of choice for innovation', according to the Development Assistance Committee (DAC), based on a survey of its members, and case-studies into particular donors (OECD, 2020, p. 46). DAC suggests that this is because donors believe that the private sector, defined as for-profit enterprises, has greater expertise in innovating than the public and non-profit sectors, nationally and globally (p. 59). The International Development Innovation

Alliance (IDIA) relates this perceived comparative advantage particularly to start-up companies, on the basis that these 'are inherently innovative, agile and adaptive... [with] the ability to pioneer new solutions that others perhaps may overlook or disregard, bringing continuous creativity and healthy competition' (IDIA, 2022a).

Interpreted literally, this presumption is too simplistic, as private sector actors do not innovate in isolation, but require significant facilitation which often only the public sector can provide (Mazzucato, 2011). It seems likely that donors, rather, are emphasising the principal transformation required, i.e., greater private sector inclusion, rather than presenting all of its dependencies. According to the linear model of innovation assumed by donors, consumer demand steers firms in the direction of their unmet needs. This prompts firms to combine their productive resources in new ways in order to achieve competitive advantage in this growth market. They do so by producing a more effective artefact, or greater productivity enabling an increase in sales volume, or greater efficiency leading to a decrease in unit cost. Any of these contribute to the firm increasing its market share and hence financial profit (Schumpeter, 1934). As a result of this incentive, the private sector has a comparative advantage in matching market demand to available knowledge, as long as they invest sufficiently in processes of learning from the needs of the intended users (Wamae, 2009). This latter caveat, though, is a significant one, as in a resource-constrained environment, corporations will tend to focus on their core market, whether consciously or unconsciously, and consequently, face greater challenges in engaging with new customers (Christenson, 1997).

Within the linear model, two principal causes of impetus are identified. In a *technology push* dynamic, innovation is driven by the strength of potential of a research discovery or early-stage invention, imbuing sufficient momentum to take the innovation through all the subsequent stages. In a *demand pull* dynamic, the demand of users pulls innovations through the chain by prompting a focus at each stage on meeting the explicit, specific needs identified. In both cases, however, private sector innovation depends on any market in which they are involved being well-functioning. This means that it enables effective information exchanges between actors, and hence allows innovators to profit from their investments in these innovations. Without an effective market, as for innovations in less economically developed countries (LEDCs), firms receive limited feedback or intelligence, and this serves to bound the decisions which they make. In this context firms will tend to prioritise the criteria they use, or to use subjectivity, either of which

may result in decisions which are not necessarily absolutely rational. In making decisions in the context of uncertainty about the technology, the market or the institutional context, the high level of potential risks may result in a firm only 'satisficing' rather than optimising (Nelson and Winter, 1982). This tends towards establishing a path dependency around existing approaches, as a result of which, innovation tends towards the incremental (Arthur, 1994). This dynamic is exacerbated by the firms' investment in the structure, resources and capabilities needed to produce their existing artefacts. This creates a mutual dependence between the firm and its artefacts, which discourages radical innovation (Dosi, 1982; Geels, 2004).

In order to avoid these sub-optimal dynamics within an imperfectly-functioning market, other actors must facilitate interactions and knowledge flow within an innovation system. Kaplinsky *et al.* (2009) point to this role being played in LEDCs by new donors including Gavi, and the Bill and Melinda Gates Foundation (BMGF). Historically, however, donors have focused too much on the technological rather than the sociological or institutional aspects of innovation. They have over-assumed the extent to which technical results could be replicated in different contexts of social and political dynamics (Zelinka and Pearce, 2011; Bound and Ramalingam, 2016). This has not been sufficiently moderated by beneficiary participation because in practice, power still sits overwhelmingly with the donor rather than the beneficiary (Papaioannou, 2014). It is the donor who decides whom to consult, what technology is appropriate and whether the project goes ahead (Perez, 2012).

#### **1.1.6 Donor ecosystem facilitation**

Donors increasingly recognise the existence of innovation systems, with the International Development Innovation Alliance (IDIA), for example, referring to the collective nature of actors' actions, stating that:

Achieving and sustaining any development outcome depends on the ability of multiple and interconnected actors – governments, civil society, the private sector, universities, individual entrepreneurs and others – to work together effectively (IDIA, 2022b).

Furthermore, IDIA also alludes to innovation ecosystems being dynamic, to the effectiveness of each actor being dependent upon other parts of the system, and with changes in one part of the innovation ecosystem leading to changes in other

parts. IDIA refer to actors' actions and their resources being coordinated, and to ecosystems having boundaries (IDIA, 2022b). Summarising all of these, IDIA suggests:

An innovation ecosystem is made up of enabling policies and regulations, accessibility of finance, informed human capital, supportive markets, energy, transport and communications infrastructure, a culture supportive of innovation and entrepreneurship, and networking assets, which together support productive relationships between different actors and other parts of the ecosystem (IDIA, 2022b)

The Development Assistance Committee (DAC), in addition, recognises the existence of 'innovation ecosystems at different levels' (OECD, 2020, p. 58), referring to national and sub-national regional innovation ecosystems, as well as to global ecosystems, although the sole example they provide of the latter is of the now moribund Global Alliance for Humanitarian Innovation.

Donors necessarily operate at both global and national levels. Their national level engagement is in those countries to which they provide development assistance. It includes the donor's relations with the host government, their contribution to national strategy and planning discussions, and their participation in development partner coordination and monitoring processes in those countries. At the same time, donors are also necessarily involved in global level mechanisms for the agreement of strategy, of the principles underlying donor approaches, and for coordination.

Donors are increasingly 'exploring the role they can play in strengthening innovation ecosystems as a whole, building connectivity and capacity of ecosystem actors' (IDIA, 2022a). Intervention of this sort in an innovation system is particularly important in international development, because of the limitations to the markets and actors in less economically developed countries (LEDCs), particularly relating to the provision of public goods. DAC refers to 'ideas about the entrepreneurial state starting to filter into the development discourse (OECD, 2020, p. 47). This reference is to the argument of Mazzucato and others that governments' role in connection with the private sector should be facilitational, correcting failures in existing markets and creating new markets, through strategic investments in new technologies. It might be seen initially as relating to governments' roles, but the principles are being more widely applied by a wider range of donors, who position themselves, for

example as to 'fund to facilitate, not to execute' (IDIA, 2019, p. 8), and to support beneficiaries 'with tools and resources as innovators' (G7, 2018).

This facilitation on the part of donors requires them to be willing to take a less prescriptive approach to programming. Bound and Ramalingam (2016) conceive this as donors needing to move away from being 'answer delivery mechanisms, with a tendency to provide a known solution whatever the context, to increasingly becoming 'answer generating systems' (p. 68).

Donors also increasingly recognise that their role in innovation is affected by their organisational characteristics and in particular their own management of knowledge, and their learning. DAC proposes a series of four phases through which donors pass, of increasing sophistication and capacity in the management of innovation processes. At its most basic, donors design, fund and implement projects to foster innovation 'in narrow areas and in a more or less ad hoc fashion' (p. 40). More refined phases incorporate organisational learning, greater coordination and investment in wider system-strengthening. DAC's ideal model involves organisations adopting a decentralised, cross-organisational approach to innovation strategy, processes and learning (OECD, 2020). It is significant firstly, at the meta-level, that donors appreciate that their organisational structure has an effect on their ability to foster innovation. Organisational characteristics have been shown to represent a more significant distinguishing feature between firms' abilities to innovate even than those firms' access to particular technologies (Nelson, 1991). This is because organisational characteristics are both more complex and difficult and slow to adapt, but yet can transform the organisation's innovation capabilities over time (Teece, Pisano and Shuen, 1997).

Secondly, from DAC's descriptions against these phases can be identified a specific focus within the organisational characteristics around internal coordination, knowledge management and in particular, of learning. This reflects the characterisation within the academic literature of innovating firms as 'organisations that represent social knowledge of coordination and learning' (Kogut and Zander, 1996, p. 502).

Donors sometimes explicitly highlight the importance for innovation of an increased ability to learn, and optimal systematisation of their learning. DAC describes donors as having realised that they need to have 'a greater emphasis on ensuring that projects and programmes build on what is known, and seek to build on that knowledge

through active learning' (OCED, 2020, p.39). IDIA, similarly, states that the group of donors needs 'a paradigm shift in how it views failure, learning and iteration', emphasising that innovation necessarily involves failures as well as successes, and suggesting that donors need to establish structures and systems which allow them to fail 'in small, controlled ways' and to learn from those (IDIA, 2019, p. 20). Donors also acknowledge, however, that 'there is not yet a culture of evidence-based innovation', with evidence and evaluation often not meeting aspirations, with particular gaps in ex-post assessment of impact, costs and benefits to prove concept (IDIA, 2019, p. 56).

This first introductory section has introduced various concepts key to this research. We have established parameters including the definition of a donor, and of innovation which aligns to the breadth of donor engagement with the concept. We have identified that donors' motivation for innovation is because of their perception that it will enable them to achieve greater impact in international development. We have highlighted that donors are influenced in their innovation by the principle of intended beneficiary inclusion, and their aim for engagement with the private sector. We have seen that donors are starting to recognise the concept of innovation systems, and to consider how they might facilitate these.

We have, however, seen very limited empirically-based analysis of these donor roles. This research aims to contribute to filling that gap. As the following section explains, we will do so by looking specifically at innovation in immunisation for international development, which we will argue is particularly relevant and revealing.

## **1.2 Immunisation for international development**

Chataway *et al.* (2007) suggest that 'vaccine production is now at the heart of the debate on development'. In this section we explain why the case of immunisation enables us to better understand the role which donors play with respect to innovation in immunisation for international development.

Immunisation for international development is only a part – albeit a significant one – of the wider immunisation field. Our broad focus on international development entails a scope which includes immunisation in less economically developed countries (LEDCs), especially those countries classified by the World Bank as low-income; but excludes those in more economically developed countries (MEDCs), especially those which are high- or high-middle income countries. Our focus on donors means examining their interactions with other actors and excludes primary consideration of interactions which do not involve donors.

### 1.2.1 Donor interest in immunisation

Immunisation is the process by which a person becomes protected against a disease through vaccination. It has caused a 45% decline in deaths in less economically developed countries (LEDs) from vaccine preventable diseases and thus averted 37 million deaths over the period 2000-2019 (Li *et al.*, 2021).

Vaccination currently saves between 2 and 3 million lives globally, every year (WHO, 2022a). Estimated averted future deaths from the major vaccine preventable diseases for children vaccinated between 2000 and 2030 total 120 million. When you factor in the full range of diseases prevented by vaccination of infants or adults, the total number of lives saved is significantly greater (Cohen, Patel and Cherian, 2021).

Vaccination has also enabled the eradication of smallpox, verified by WHO in 1980. The international community now aims also for the eradication of polio, and has succeeded in reducing the number of cases worldwide by 99.95%, and eradicating two of the three types of wild poliovirus, since 1988 (Greene *et al.*, 2019; Gerberding and Haynes, 2021).

Immunisation's high level of impact, combined with the low unit costs of vaccines, often only a few pennies per dose, mean that it is widely regarded as being one of the most effective forms of development assistance. Margaret Chan, then WHO Director General, said at the World Health Assembly in 2011, 'We know for a fact that vaccine is the most cost-effective intervention and the best buy in terms of return on investment in saving lives of children, women and men' (Nebehay, 2011). Direct benefits to individuals include a reduction in the costs of their healthcare and in lost productivity when a parent or other caretaker has to look after a sick child. In the longer term, by reducing illness, immunisation improves a child's cognitive skill and physical strength, both of which lead ultimately to increased productivity (Bärnighausen *et al.*, 2014).

This return on investment has been quantified using econometric methods to estimate the cost of illness and value of a statistical life. These show that an investment in immunisation in LEDs, including of the required supply chain and service delivery infrastructure, results in a net return 16 to 26 times greater than the investment. This takes into account the calculated costs of medical treatment and associated productivity losses which would have been incurred but were averted by vaccination. Furthermore, when broader economic and social benefits, such as the



value people place on living healthier and longer lives, are taken into account and quantified, the net return on investment rises to 44 to 51 times the costs of vaccination (Ozawa *et al.*, 2016; Sim *et al.*, 2020).

At the societal level, immunisation drives the reduction in illness and long-term disability in children and adults, reducing the burden of disease on health systems and societies. Through the herd immunity effect, once immunisation reaches a level of approximately 85% in a community, diseases are unable to propagate widely, resulting in the increased protection even of unvaccinated individuals (Bärnighausen *et al.*, 2014; Jit *et al.*, 2015).

The number of diseases which vaccines can prevent continues to grow, and includes more than 20 life-threatening diseases, including cervical cancer, cholera, Ebola, hepatitis B, Japanese encephalitis, measles, meningitis, pneumococcal pneumonia, polio, rotavirus, typhoid and yellow fever (WHO 2022b). The number of children vaccinated each year also continues to grow, reaching 86% of all infants born in 2020, or more than 116 million children (WHO, 2022a). So too does the number of countries to have introduced vaccines they did not previously use (WHO, 2020a). As a result, vaccines will keep an estimated 24 million people from falling into poverty by 2030 (Chang *et al.*, 2018). Thus, immunisation contributes not only to the third Sustainable Development Goal (SDG), which aims to 'ensure healthy lives and promote well-being for all at all ages', but also contributes to a further 13 of the 17 SDGs (WHO, 2020a). Nonetheless, WHO also estimates that vaccine preventable diseases are still responsible for 1.5 million deaths each year, because 18.2 million infants worldwide still do not receive any vaccines, and a further 6.8 million are only partially vaccinated (WHO, 2022a).

As a consequence of all these factors: effectiveness, value-for-money, demonstrated progress, but enduring challenges, immunisation represents a priority amongst many donors for their investment. Bill Gates describes vaccines as 'the most effective and cost-effective health tool ever invented' (BMGF, 2011), and the Bill and Melinda Gates Foundation (BMGF)'s investment in Gavi, the international public-private partnership dedicated to immunisation, as 'the most important thing that we've done' (Gavi, 2015a). This sense is shared by other donors. Donor contributions to Gavi totalled US\$ 4.2 billion for 2000-2010; US\$ 5.2 billion for 2011-2015; US\$ 7.1 billion for 2016-2020; and US\$ 8.9 billion for 2021-2025 (Gavi, 2022a).

### 1.2.2 Innovation in immunisation

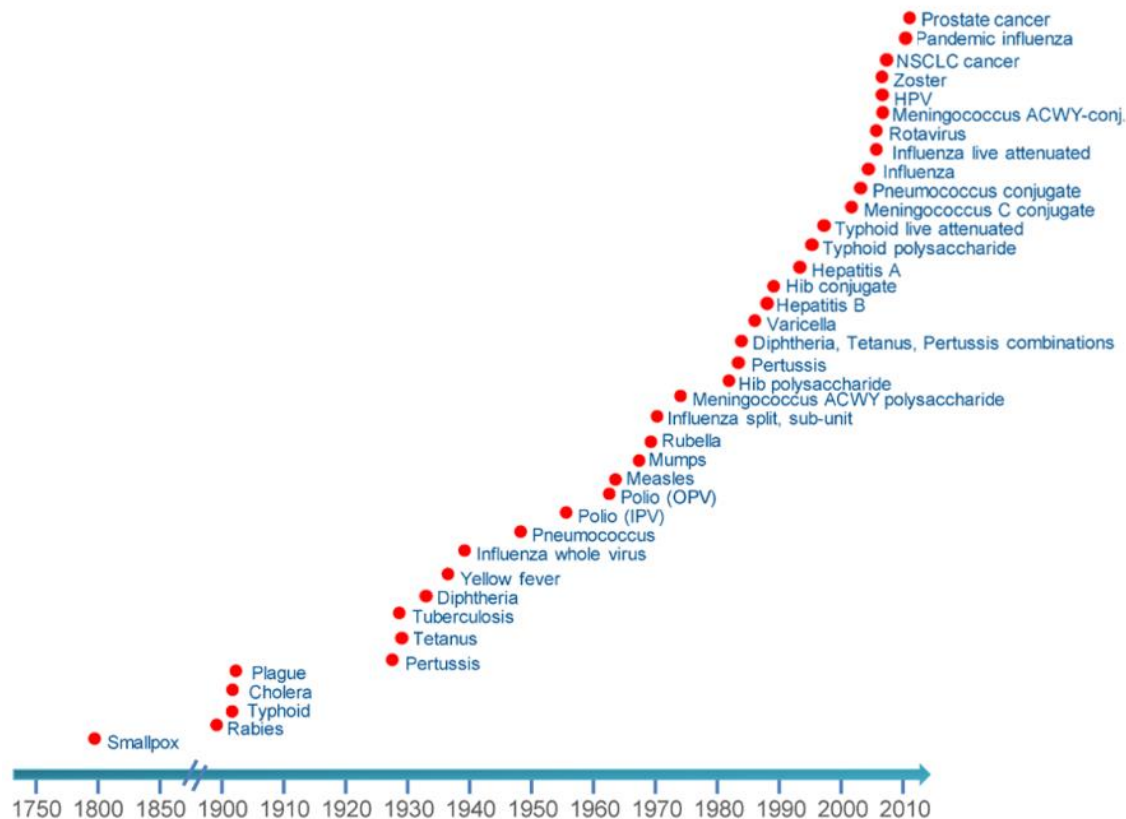
Innovation has been highly significant in immunisation since the late 18<sup>th</sup> century. It was then that Edward Jenner observed that milkmaids managed to avoid contracting smallpox disease, and he hypothesised that the cowpox to which they were exposed was protecting them against smallpox. He conceived the practice of inoculating people deliberately, tested it successfully on his gardener's eight-year-old son, and named the process after the Latin word for cow, *vacca* (Baxby, 2011). Nearly a century later, Louis Pasteur and others developed the first laboratory techniques for the development of vaccines, by attenuating or fully inactivating a bacterium. This enabled their safe use as antigens, which are substances capable of stimulating an immune response (Bazin, 2011). Using this method, vaccines against typhoid, cholera and plague had all been developed by the early 20<sup>th</sup> century (Plotkin and Plotkin, 2011).

Throughout the first half of the 20<sup>th</sup> century, scientific discoveries continued to be used to derive techniques for the development of vaccines. Chemical conversion of toxins into toxoids, which are immunogenic but non-toxic, enabled vaccines against diphtheria (Relyveld, 2011). The discovery that bacteria and viruses may be genetically selected for avirulent, but immunogenic, strains enabled vaccines against yellow fever and tuberculosis (Plotkin and Plotkin, 2011).

Techniques for the growth of viruses in cell culture enabled an acceleration in vaccine innovation during the second half of the 20<sup>th</sup> century. This facilitated the use of selective mutation and virus attenuation or inactivation to develop vaccines against polio, measles and Japanese encephalitis (Katz, 2011). Contemporaneously, conjugation of proteins with bacterial material to increase its immunogenicity enabled a further set of vaccines, including against meningococcal and pneumococcal diseases (Bobbins *et al.*, 2011). Genetic engineering began to be used to insert the genes for immunogenic proteins into harmless substrate cells to use as vaccines (Plotkin and Plotkin, 2011).

The timeline below illustrates the number and pace of this innovation in vaccines.

Figure 4: A history of vaccine development (adapted from Cravioto, 2018)



(Adapted from Cravioto, 2018, slide 6)

From this timeline can be seen the highly significant nature of innovation in immunisation especially over the past century. Since 2010, when this timeline ends, further new vaccines, including against dengue, Ebola virus disease, malaria and Covid-19 have been developed.

This is not the whole picture, however. Despite this high rate of innovation in terms of vaccines new to the world, these tended overwhelmingly to be developed in more economically developed countries (MEDCs), and to be introduced only to those markets. They were not diffusing into less economically developed countries (LEDs), thereby creating significant inequity in protection from vaccine preventable diseases (Lindstrand *et al.*, 2021). Global vaccine coverage, usually measured as a proportion of annual surviving infants receiving the third dose of vaccine against diphtheria, tetanus and pertussis ('DTP3'), plateaued around 70% of infants by 1990 (Sridhar & Tamashiro, 2009; Gomez and Atun, 2013).

During 1998 and 1999, international organisations, donors, non-governmental organisations and vaccine manufacturers met in an attempt to overcome these problems. They were incentivised by the willingness of Bill and Melinda Gates to provide substantial financial support for a new approach in immunisation. They proposed an alliance along the lines of the existing, but small-scale, International AIDS Vaccine Initiative (IAVI), and Medicines for Malaria Venture (MMV), which were successfully bringing together recipient governments, manufacturers and civil society alongside donors and UN agencies. Whereas these health funds managed budgets of a few tens of millions of dollars, the Gates' offer of US\$ 750 million over five years promised to be transformational (Nossal, 2003; Lidén, 2013).

In January 2000 Gavi, the Vaccine Alliance, was launched at the World Economic Forum annual meeting in Davos. Its aims included, for the first time in global health, the combination of increasing demand for the introduction of innovative vaccines in developing countries, alongside a shaping of the market so that vaccine manufacturers would increase the production of these innovative vaccines suitable for LEDCs, and make them available at a significantly lower price (Gavi, 2017a).

As a result of the support provided since then by Gavi and its partners, LEDCs have introduced these and other innovative vaccines to a large degree, and the historic time lag between their introduction in MEDC and LEDC markets has reduced significantly (Lindstrand *et al.*, 2021). At the same time, the global strategy for immunisation, *Immunization Agenda 2030 (IA2030)*<sup>3</sup>, describes there having been significant innovation also in vaccine secondary attributes. These are distinct from the fundamental immunogenicity of vaccines, but complement it. Examples of such innovations include preservative-free vaccine presentations, improved thermostability and filling or packaging innovations (WHO, 2020, p. 6). Such innovations often challenge the norm of vaccines presented in multi-dose glass vials, delivered through a cold chain, reconstituted with diluent, and administered using a syringe and needle (Giersing *et al.*, 2021).

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<sup>3</sup> This thesis is written in British English, with the exception of proper nouns, titles and quotations, all of which retain their original spelling.

These innovations in vaccine secondary attributes are important to enabling an effective response to the wicked problems related to immunisation, with WHO (2019) suggesting that the period from 2010 has seen increased and more complex challenges in immunisation. WHO gives as examples increased migration and urbanisation, political instability and conflict, vaccine supply problems, and increasing vaccine hesitancy. Recognising this, *IA2030* thus aims to:

Accelerate the development of new vaccines, technologies and improved products, services and practices, while ensuring continued progress in the development of vaccines for priority targets (WHO, 2020a, p.44).

Immunisation, then, represents a field of highly significant innovation new to the world, with donors playing important roles in extending the diffusion of these innovations to new LEDC markets and influencing innovation in associated vaccine secondary attributes.

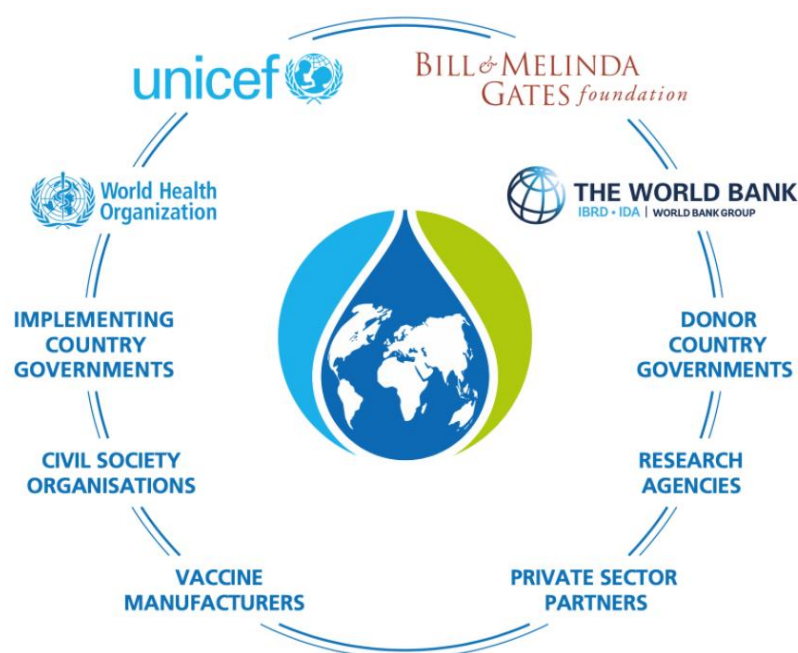
### **1.2.3 Actors and spatial levels in immunisation**

The set of principal actors involved in immunisation for international development is identified in *Immunization Agenda 2030* as involving:

National governments, regional bodies, global agencies, development partners, health care professionals, academic and research institutions, vaccine developers and manufacturers, the private sector and civil society (WHO, 2020a, p. 8).

This breadth of actors is consistent with that recognised by Gavi and represented on the Gavi Board, as shown in the following figure:

Figure 5: Principal actors in immunisation (Gavi, 2022b)



We can observe several features of this set of actors. It is broad in its inclusivity. Beneficiaries are reflected, in the form both of implementing country governments, and civil society organisations. Donors to Gavi are represented, both generally, as a group of bilateral country governments, but also specifically the Bill and Melinda Gates Foundation (BMGF). Gavi's core partners of WHO, UNICEF and the World Bank are included. The private sector is represented, in the form of vaccine manufacturers and other 'private sector partners'. The inclusion of research agencies means upstream public sector actors are also considered.

Note that at this point, other than implementing country governments, the actors represented here are not categorised in terms of any particular geography or spatiality. This includes vaccine manufacturers, which are not limited to those in high impact countries, but may also include those in emerging economies such as India and Indonesia.

The existence of multiple spatial levels is, though, referred to in *Immunization Agenda 2030*. It identifies 'community, national, regional and global' levels (WHO, 2020a, p. 8). The national level, it suggests, involves governments in setting targets and timelines for achievement of their immunisation programmes, with donor support 'tailored to each national context'. The regional level includes collaboration by donors with actors from different sectors, 'to take advantage of synergies and promote integration'. The global level focuses 'on those components that are best

coordinated globally' (p. 56). *Immunization Agenda 2030* doesn't provide any further detail about the actors, roles, interactions or institutions involved at each of these levels. It does, though, acknowledge that historically there have been weaknesses in coordination within and across these different spatial levels. It highlights weaknesses in partnerships at the national level with in particular, civil society organisations and the private sector; and at the global level in responding to emerging challenges, including migration and urbanisation, conflict and climate change (WHO, 2020a).

Included as core principles in *Immunization Agenda 2030* are several elements highly consistent with a focus on beneficiaries, including an aim across the board to be 'people-centred, country-owned [and] partnership-based' (WHO, 2020a, p. 5). It also has a specific aim to:

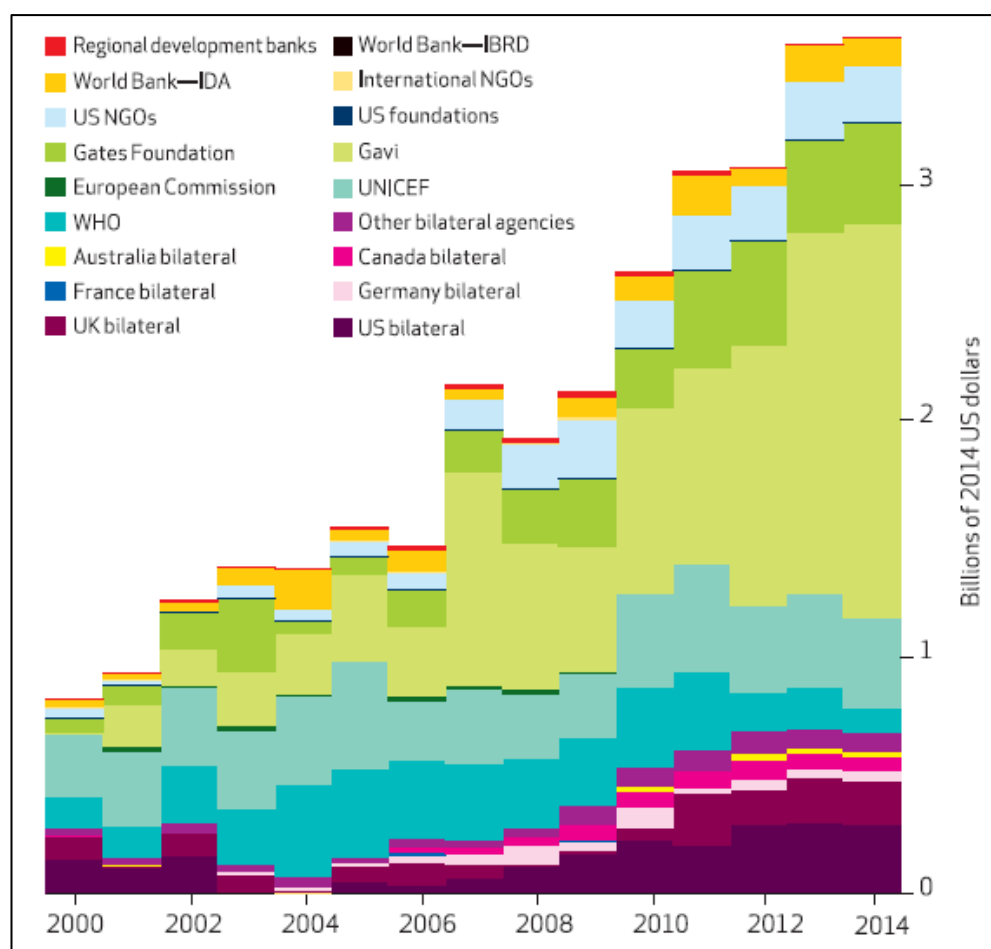
Strengthen mechanisms to identify vaccine-related research and priorities for innovation according to community needs, particularly for underserved populations, and ensure that the priorities inform innovations in immunization products, services and practices (WHO, 2020, p.44).

*Immunization Agenda 2030* also makes reference to the linking of beneficiary and manufacturer knowledge, alluding to 'implementation and operational research and through evidence-informed decisions' (WHO, 2020, p.44), as well as to the need for 'a more nimble, robust research agenda' (p. 26). This is reinforced by the narrative under the strategy's priority relating to research and innovation, which includes that 'innovations in products, services and practices will be client-focused and address community and provider needs and preferences... drawing on the complementary expertise of national and global stakeholders' (p. 44). Again, though, details about the mechanism by which actors at these different spatial levels would interact are not specified.

#### **1.2.4 Principal donors to immunisation**

The donor interest in immunisation we have identified has translated into a significant consistent increase in the amount of development assistance provided by donors to immunisation, from US\$822 million in 2000 to US\$3.6 billion in 2014 (Haakenstad *et al.*, 2016), as we see in the following figure:

Figure 6: Development assistance to immunisation, 2000-2014 (Haakenstad *et al.*, 2016)



(Haakenstad *et al.*, 2016, p. 244)

Within the set of donors contributing to this significant increase in development assistance to immunisation, three donors in particular stand out: Gavi, UNICEF and the Bill and Melinda Gates Foundation (BMGF). They represent the three largest donors in recent years in the figure above, but they are also particularly significant for other reasons.

Gavi, the Vaccine Alliance, alone provides 50% of the total development assistance to immunisation, representing US\$1.7 billion in 2014 (Haakenstad *et al.*, 2016). As an organisation, it is dedicated to the mission to increase equitable use of vaccines in less economically developed countries (LEDCs) (Gavi, 2022b). Equitable use, for Gavi, means that no infants in those LEDCs are excluded from access to those vaccines. Coordination of the alliance is by a 400-strong Secretariat based in Geneva, Switzerland. Across the breadth of its strategic goals in immunisation, Gavi



describes a particular comparative advantage in enabling ‘implementation at scale’, examples of which are the number of children it has enabled countries to immunise (700 million by the end of 2018) and the number of new vaccine introductions it has supported in countries (400 to end-2018) (Gavi, 2018a, p. 2). The basis upon which Gavi claims this advantage is related to its market reach, in purchasing vaccines for 60% of the world’s birth cohort (Boran, 2018).

BMGF, as well as being the founding funder and largest contributor to Gavi, has donated significant funding to a wide range of other actors in immunisation for international development over the last 20 years. Moreover, BMGF has brought to the sector new approaches based upon a ‘single-mindedness and hard-boiled business habits’ which are radical within global public health (Nature, 2003, p. 435). BMGF’s narrower accountability and higher risk-appetite than traditional actors in global public health provides it with perhaps unique capabilities to engage with longer-term, earlier-stage vaccine research and development.

UNICEF is also an important donor in immunisation, both because of the scale of its support, and because of its reach. UNICEF works in 190 countries and 85% of its 13,000 staff are based in its seven regional and 124 country offices. UNICEF regards immunisation as a right guaranteed by the Convention on the Rights of the Child and supports immunisation across almost all its country programmes, with about 650 staff dedicating most of their time to immunisation (UNICEF, 2018a, p. 16). In addition, UNICEF works with these predominantly LEDCs to identify and procure for them 2.5 billion vaccine doses, often Gavi-financed, for almost half the world’s children (UNICEF, 2018a, p. 16). UNICEF also claims a strong culture of innovation, suggesting that its ‘ability to evolve and innovate [is] one of its major strengths’ (United Nations, 2017a, p. 28).

These three donors are not the only donors within immunisation, but due to their respective capabilities, they are particularly instrumental for innovation in immunisation. Accordingly, it is these three donors, Gavi, UNICEF and BMGF which, as we will argue in our methodology, are selected as the cases for this research.

### **1.3 Research question and thesis structure**

This chapter has introduced the topic of innovation in international development, with a focus on the role of donors with respect to that innovation. We have proposed

definitions of a donor, of international development and of innovation. Donors' aims for innovation arise from their perception that it will enable them to achieve greater impact in international development. In delivering such innovation, donors tend to presume that the private sector has a comparative advantage, but also that intended beneficiaries should be included in innovation planning, design and implementation.

There is, however, very limited understanding about how donors engage with these presumptions and with other more formal institutions relating to innovation. Similarly limited is an understanding of how donors interact with other actors to innovate; and of how donors' organisational characteristics affect their relevant capabilities. By examining all those aspects, this research aims to contribute significant new knowledge about the roles donors play with respect to innovation. It will do so by looking specifically at innovation in immunisation for international development.

Donors are very invested in immunisation, attracted in particular by the very high return on investment which results from vaccines' very high levels of effectiveness and value-for-money. Immunisation's demonstrated progress, but enduring challenges, makes it a top priority amongst donors. Immunisation represents a field of highly significant innovation new to the world, with donors playing roles in at least extending the diffusion of these innovations to new less economically developed country (LEDC) markets and influencing innovation in associated vaccine secondary attributes.

Immunisation for international development involves a broad set of actors, including implementing country governments, and civil society organisations, research agencies, vaccine manufacturers and other private sector partners. Donors include bilateral donors, foundations, WHO, UNICEF and the World Bank. There is some reference to the existence of multiple spatial levels in the field: involving LEDC governments at the national level, collaboration by donors with actors from different sectors at the regional level, and global level coordination.

On the basis of these characteristics, immunisation represents a relevant and revealing area for research to better understand the role which donors play in innovation in international development. Our research question accordingly is 'what role do donors play with respect to innovation in immunisation for international development?'

We will answer this question empirically by investigating the cases of principal donors in the field. Gavi, the Vaccine Alliance, which alone provides 50% of

development assistance to immunisation, and describes a particular comparative advantage in enabling implementation at scale, based on being the only international organisation dedicated to immunisation for international development. The Bill and Melinda Gates Foundation (BMGF) has donated significant funding to a wide range of actors in immunisation for international development over the last 20 years. BMGF has brought to the sector new approaches which are radical within global public health, and its narrow accountability and high risk-appetite provide BMGF with perhaps unique capabilities to engage with longer-term, earlier-stage vaccine research and development. UNICEF works in 190 countries, with seven regional and 124 country offices. It works with these primarily LEDCs to identify and procure for them 2.5 billion vaccine doses, often Gavi-financed, for almost half the world's children and has invested significantly in structures and strategies to increase its innovation in immunisation and more broadly.

This thesis is structured as follows. Chapter 2 critically reviews the literature on this topic. It finds that donors play an important role in setting the global strategy for immunisation, and in ensuring that innovation is a priority within that. They accompany their driving of this strategy with increased levels of financing for the sector, resulting in an increase in the level and pace of vaccine development. Other key areas of donor roles relate directly to the market. Upstream, this involves *push* catalysing product development, by establishing and/or funding partnerships conducting research into LEDC-oriented innovative vaccines. Downstream, this involves *pull* incentivising vaccine manufacturers by decreasing the risk to those manufacturers of investing in development and distribution to LEDC markets, either by increasing the financial reward, guaranteeing demand, or providing reliable market intelligence. Finally, donors draw lessons from their experience in vaccine innovation to take a holistic approach to innovation in vaccine secondary attributes. These innovations often necessitate adoption by the vaccine industry, but there are significant counter-incentives for the vaccine industry to do so, related especially to incorporation into the manufacturing processes of the vaccine, and the associated changes, testing, licencing and regulatory compliance. It is this 'innovation conundrum' which donors are playing a role in trying to overcome. Their role involves, firstly, understanding country needs; then articulating a clear public-health need and use, before aligning stakeholders and coordinating engagement through the cycle.

Within the literature, however, we discern some important gaps in knowledge. These relate to innovation i) spatial levels, ii) power relations, and ii) organisational capabilities. Firstly, we see multiple reference to the existence of two distinct important spatial levels: the national and the global, but the literature doesn't explain how donors engage actors and institutions across these two spatial levels for innovation in immunisation. Secondly, we see reference in various forms to the power relations which exist around donors, because of the power integral to authority over the provision of financial investment. Power relations are particularly acute with respect to innovation, because of the diverse set of knowledge and capacities which tend to be required for innovation. The literature, however, does not provide a good understanding of how donors engage with these power relations with respect to innovation in immunisation. Thirdly, we identify that different actors have different capabilities, which contribute to determining the roles which they play with respect to innovation, and how successfully they perform those roles. The examination of donor capabilities, however, within the literature, is piecemeal, such that we do not have a good understanding of what determines a donor's comparative advantage for one particular set of roles for innovation as opposed to another.

Chapter 3 explains the principal conceptual framework and additional analytical tools utilised. It is within this conceptual framework that the research will be carried out. The conceptual framework is based on the global innovation system (GIS) model of Binz and Truffer (2017). This responds to the dynamics of globalisation in which the movements of knowledge, capital and people have become increasingly globally interconnected. The GIS model introduces significant new conceptual tools, including of specific system resources beyond those of knowledge, of typographies of GIS depending on the distribution of these resources, of sub-systems at different spatial levels, and of agency understood as the creation or maintenance of structural couplings between different sub-systems. At the country level, elements of the national system of innovation (NSI) explain the dynamics at play within countries which are recipients of innovation by donors. At the same time, the institutions and other characteristics of the sector as a whole are understood by the sectoral system of innovation (SSI) model, which attempts to explain innovation across a sector, independent of territorial limits, on the basis that the degree of innovation varies significantly between sectors, as do the routes towards that innovation. Neither, however, is sufficient alone to explain how the increasingly globally interconnected movements of knowledge, capital and people affect innovation in immunisation. The

GIS model incorporates the concept of the NSI heavily, as well as some aspects of the SSI. Though the GIS model is nascent, it offers good potential for our research.

Chapter 4 explains the research methodology. Recognising the fundamental importance within the research topic of both scientific knowledge, and of actors' interaction and interpretation of reality, this research adopts a critical realist philosophy, within which it uses abductive explanatory logic. Because the empirical data is in-depth, contextualised, and qualitative, the research design adopted is that of a multiple case-study of donor organisations, using triangulated, mixed-methods data collection. The resulting data set is analysed using thematic analysis and is assessed for research validity and reliability.

Chapter 5 examines the role of UNICEF with respect to innovation in immunisation for international development. It argues that UNICEF engages actively at both global and national levels, each of which relates to particular key organisational capabilities. At the national level these are UNICEF's in-depth understanding of national contexts and actors; and at the global level, UNICEF's strong reputation, authority and convening power. UNICEF links these two spatial levels in a *divisionalised* structure, providing value to innovation through generating and utilising market access, by sharing authoritative information between potential inventors and LEDC governments. UNICEF also provides value through innovation legitimisation, on the basis of pilots it has carried out in countries and endorsed globally once proven. However, there is internal confusion within UNICEF regarding its policy and priorities for innovation, and conflict between internal actors located at national and global levels. This is most acutely seen in the degree of support, or scepticism, relating to a *techno-fix* perspective on the balance between knowledge generated primarily from *science, technology and innovation* (STI) and knowledge generated primarily through *doing, using and interacting* (DUI). In its formal global procurement, UNICEF has managed to combine both forms of knowledge effectively, so that innovations both draw upon new STI knowledge, and meet the needs and context of LEDCs. Outside this focused area, however, the balance remains unresolved in UNICEF. This necessitates a high level of customisation of innovation valuation resources, which constrains its broader impact through innovation in immunisation.

Chapter 6 examines the role of BMGF with respect to innovation in immunisation for international development. It argues that this is fundamentally oriented around power. BMGF uses its financial transfers to other donors and agencies to influence

their agendas towards BMGF's aims, including increasing emphasis on both immunisation and innovation. This influencing is important for BMGF because it engages actively with innovation in immunisation essentially only at the global level. BMGF's financial investment also provides it with power of agency, in permitting a high risk appetite, which enables BMGF to fund higher risk innovations, especially those at an earlier stage of development. This combines with Gates' particular focus on entrepreneurialism to draw into immunisation a wide range of new private sector actors. BMGF also invests particular efforts at the global level to strengthening complementarity, coordination and learning between actors. The combined effect of these dynamics is both to strengthen linkages within the global innovation sub-system, and to expand its boundaries through the proactive inclusion of new and diverse actors. BMGF's financially-derived power relations thus both drive incremental structural change in the innovation system, and facilitate other actors to sustain it. BMGF's *simple structure* form of organisation is key to achieving the high levels of coordination required for the effective deployment of its various forms of power.

Chapter 7 examines the role of Gavi with respect to innovation in immunisation for international development. It argues that Gavi provides extensive linkages between diverse actors and between spatial levels, with power playing an important part in enabling Gavi to influence or leverage particular behaviour by other actors. This power derives from Gavi's generation and utilisation of innovation valuation resources of market access and financial investment. The primary example of this is Gavi's vaccine market shaping, in which it effectively links recipient countries on one side and private sector manufacturers on the other to align supply and demand for innovative vaccines. This engagement is highly standardised, as is Gavi's engagement in cold chain equipment and in vaccine secondary attribute innovations. Gavi's engagement in other private sector partnerships is much more customised, and much less widely scaled. These innovations also bring a risk of a techno-fix approach and consequently are a source of inter-organisational tension. In providing linkages, Gavi does so in a dynamic way, enabled by its *adhocratic* organisational type. This highly flexible project-based form is able to coordinate and combine (or relinquish or acquire) its resources. Gavi's resulting dynamic capabilities enable it to respond quickly to new opportunities for innovation in immunisation.

Chapter 8 discusses the empirical findings of the case studies of UNICEF, BMGF and Gavi. It argues that there is significant evidence for an emerging global innovation system (GIS) in immunisation for international development. This system is multi-spatial, with a sub-system at the global level, and multiple national sub-systems. These national sub-systems are largely independent of each other but are individually connected to the global level through related rules and norms. The global and national sub-systems are directly linked through structural couplings provided by donors, who use these to generate and provide knowledge and other innovation resources. These factors all serve to dynamically determine the boundaries of the global sub-system. In terms of resources, the GIS overwhelmingly utilises knowledge generated primarily from *science, technology and innovation* (STI). Other innovation valuation resources, of market access, financial investment and innovation legitimacy, vary in degrees of customisation or standardisation depending primarily on the stage of development of an innovation from invention, through application to diffusion.

## **2 DONOR INTEGRATION IN IMMUNISATION**

This chapter reviews the existing literature relating to our research question, ‘what role do donors play with respect to innovation in immunisation for international development?’ The chapter builds upon the early studies by Joanna Chataway with various co-authors into the public-private partnership the International AIDS Vaccine Initiative (IAVI). These reinforce that a particular feature of immunisation for international development is vaccine market failure, in which social return exceeds private return, as a result of which many vaccines which would save lives in less economically developed countries (LEDCs) are not prioritised by manufacturers (Kremer and Glennerster, 2004; Archibuigi and Biazziari, 2005).

Mitigation of this market failure has been limited, Chataway *et al.* (2007) suggest, because integration of the various actors and phases of vaccine innovation has been weak. Historically, vaccine research was usually carried out by public sector, and vaccine manufacture by the private sector, with neither bearing responsibility for coordination between them (Milstien and Candries, 2000; Blume, 2005). In addition, vaccine research and development (R&D) has not taken enough account of institutional dynamics, and ‘the evolution over time of the specific nature of the research space and of the research process’ (Chataway *et al.*, 2007, p. 103).

Rather, innovation depends, Chataway and Smith (2006) emphasise, upon the interactions between actors, institutions and the combination of explicit and implicit knowledge. They suggest that this is the particular strength of public-private partnerships in international development. IAVI was established in order to address this very disconnect between basic R&D of vaccines for LEDCs. Consistent with the then predominant framing for vaccine innovation, IAVI embraced research through a network of research partners, but was the first such organisation also to include within its remit innovation development, scale-up and distribution (Chataway and Smith, 2006).

The role of donors such as IAVI includes elements which are identified by several authors as intermediation. The collation and communication of knowledge, for example, is common to the intermediary roles identified by Seaton and Cordey-Hayes (1993), Bessant and Rush (1995) and Hargadon and Sutton, (1997). Also consistently identified by authors as an important intermediary role is the drawing-in of other actors into a system, in order to encourage new combinations of knowledge (Stankiewicz, 1995; Lynn *et al.*, 1996).



Intermediation, conventionally understood, is a triadic 'one-to-one-to-one' relationship between supplier, intermediary and user, but Howells (2006) challenges this assumption. Instead, he suggests, in distributed innovation systems, these collaborations tend to be more complicated, to the extent of being 'many-to-one-to-many', or even 'many-to-many-to-many'. This complexity serves to increase the dependence of actors upon intermediaries, and hence the relative power of intermediaries in relation to other actors. Relatedly, the impetus behind intermediation, previously perhaps assumed to be supplier-led, is increasingly driven from the user or beneficiary perspective (Howells, 2006). Consistent with this, an intermediation role may be played by a variety of public or private sector actors (Watkins *et al.*, 2015), although a position of authority is advantageous in intermediation (Scharpf, 1993; Lynn *et al.*, 1996; Kuhlmann, 2001).

Watkins *et al.* (2015) summarise three principal functions of intermediaries within an innovation system. Firstly, an intermediary may establish or develop networks within the system, including selecting actors and establishing ways of working and other expectations (Kogut & Zander, 1992; Rosenfeld, 1996). Secondly, an intermediary may identify information relevant to an innovation system, such as that relating to new technology, actors or institutions, and share it with networks within the system (Hargadon and Sutton, 1997). Thirdly, an intermediary may actively facilitate collaboration between actors, by convening those actors (Davenport *et al.*, 1999; Luukkonen, 2005). Building upon the work of Pavitt (2000) and Brusoni *et al.* (2001), Chataway and Smith (2006) and Chataway *et al.* (2007) characterise such activities into two broad intermediary roles. '*Integration*' involves the bringing-in of knowledge, its transformation, and use to coordinate and shape other actors' activities. Building upon Hargadon and Sutton (1997), '*Brokerage*' involves gaining knowledge through networks, by collating and disseminating knowledge by bringing actors together, refining information and facilitating cooperation.

IAVI is both broker and integrator, suggest Chataway *et al.* (2007). As an example of IAVI's brokerage, they identify IAVI's advocacy nationally and internationally, describing IAVI's role in this as a facilitational one between other actors. As an example of IAVI's integration, Chataway *et al.* (2007) identify IAVI's Neutralising Antibody Consortium (NAC). This initially brokered, in consolidating research around this particular vaccine technology and creating new linkages between evidence and research. Seeing the limitation to this in prompting other actors to invest in this technology, however, IAVI began to drive the research, funding it and actively

coordinating it across a wide variety of actors – i.e., integrating knowledge – using an interlinking of contracts to formalise this integration (Chataway *et al.*, 2007).

In integration in particular, Chataway *et al.* (2007) emphasise the importance of working with beneficiaries, writing that ‘the ability to deliver an effective vaccine rests on gaining the collaboration of developing countries’ (p. 108). They see this as being the key to avoiding a *techno-fix* approach to development. This is an approach in which technological innovation is seen as virtually a golden bullet for the solving of problems, and consequently pushed upon other actors with little consideration of contextual limitations.

We suggest, however, that Chataway and Smith (2006) and Chataway *et al.* (2007)’s distinction between brokerage and integration is better conceived as a continuum, rather than there being a fundamental difference between the two concepts. Distinguishing active from passive coordination, or facilitation from consensus-building is, we suggest, too subtle and at risk of being subjective. Chataway *et al.* (2007) attempt to clarify the distinction by characterising the integrative role of IAVI as akin to that of a vaccine manufacturer, and the brokerage as that of a development agency; or by relating it to tension between the ‘private’ and ‘public’ ethos; or between ‘scientific efficiency and development sustainability’. These, though, only serve to highlight the limitation of the distinction: as we will examine in this chapter, the roles of each of these types of actors have become more flexible over time, diverging from traditional types and blurring previous distinctions.

Performing activities widely along the brokerage-integration continuum creates management challenges within IAVI. Chataway *et al.* (2007) suggest that it necessitates an organisational type which is less hierarchical or centrally controlled, but which encourages reflection and learning. We can accept that for IAVI to find a right balance on the continuum, and maintain that dynamically, will indeed be a source of tension between competing interests and cultures. In this chapter we examine the extent to which these findings in IAVI reflect those within the broader immunisation sector.

The chapter is divided into four sections: the first examines the role donors play in setting the global strategy for immunisation, and in ensuring that innovation is a priority within that. The second and third sections examine key areas in which donor roles relate directly to the market. Upstream, this involves *push* catalysing product

development, by establishing and/or funding partnerships conducting research into LEDC-oriented innovative vaccines. Downstream, this involves *pull* incentivising vaccine manufacturers by decreasing the risk to those manufacturers of investing in development and distribution to LEDC markets, either by increasing the financial reward, guaranteeing demand, or providing reliable market intelligence. The fourth section examines how donors draw from lessons from their experience in vaccine innovation to take a holistic approach to innovation in vaccine secondary attributes.

## **2.1 Strategising and financing**

Infectious diseases do not respect national borders, making global cooperation end-to-end along the value chain and across government, academic, private sector and public sector actors crucial (Veugelers, 2021). Donors are centrally involved in this global level strategic direction for immunisation. The launch of the *Decade of Vaccines* from 2010 to 2020 was led by WHO, UNICEF, Gavi, the Bill and Melinda Gates Foundation (BMGF) and the US National Institute of Allergy and Infectious Diseases (WHO, 2019). It introduced six guiding principles of which one related explicitly to the necessity for innovation throughout immunisation. Other guiding principles were also relevant to innovation, in their emphasis on shared responsibility and partnership, on integration into broader health systems, and on sustainability of investment and management. Innovation is also reflected in the six strategic objectives of the accompanying Global Vaccine Action Plan (GVAP), with one referring to the importance of research and development (R&D) for innovation, and another of countries being able to access the resulting innovation (WHO, 2019).

This was the first global vaccine strategy to have included a focus on R&D. WHO's Strategic Advisory Group of Experts (SAGE) on immunisation concludes that this inclusion served to focus increased attention on the pipeline of innovations and the importance of considering the critical paths and potential bottlenecks across that pathway (WHO, 2019). SAGE also suggests that as a result of the doubling of donor funding for immunisation between 2010 and 2018, there was a better stock of innovations in those pipelines than previously. In terms of the impact of the GVAP goal to introduce new vaccines, between 2010 and 2017, 116 low- or middle-income countries introduced at least one such vaccine. A total of 470 new vaccine introductions occurred in these countries. Countries introduced new vaccines in this period more rapidly than ever before (WHO, 2019).

Although such strategic impetus top-down from the global level is important in driving change, it cannot be sustained without substantive engagement and support at the local level. Muraskin (2004) points to the benefit of the big picture at global level, and the benefit of the local level familiarity with the details on the ground. He suggests that this gap is not always bridged, however, with local actors not having been sufficiently involved in, for example, the creation of Gavi. Rather, in that case, Muraskin suggests, global level actors interacted primarily with their peers. He attributes this to conscious choice, that the determination to drive transformation on the part of these global actors meant a conscious minimisation of the obstacles or objections. As Gavi's then Executive Secretary, Tore Godal, is reported as saying, transformation entailed establishing 'simple global principles' focused on cross-country commonalities, rather than differences or country specificities, in order to accelerate impact (Muraskin, 2004, p. 1923). There remain challenges in this balance, with WHO writing that the inclusion of country-level actors within the GVAP was in-general, weak (WHO, 2019). We will explore this tension further in our discussion of the empirical data.

## **2.2 Push catalysing product development**

The 10% of the world's population living in sub-Saharan Africa suffers 25% of the global disease burden, measured in disease-adjusted life-years (DALYS) (Kettler, 2005). Yet only 10% of the US\$ 70 billion spent on health research annually worldwide is devoted to those health issues which affect the 90% of the world's population living in less economically developed countries (LEDCs) (Global Forum for Health Research, 2000; Hale, 2005). Vaccine manufacturers are disincentivised by an adverse evaluation of the costs and risks of investing in research and development, as against expected return on sales (Batson, 2005). In particular, a low expected return from investments for these markets is linked to a concern that the patients or their governments are unable to afford to purchase even existing treatments against these 'diseases of poverty' (Kettler, 2005; Kettler and Marjanovic, 2004). Average total health expenditure per capita in low-income countries in 2019 was US\$ 35 (World Bank, 2022), well below the price of most vaccines in more economically developed country (MEDC) markets. Donor support to LEDC governments is often inadequate to fill the gap, insufficiently long-term and unpredictable (Batson, 2005; Batson *et al.*, 2006)

This constitutes risk for potential innovators in terms of the level of likely demand. Vaccines are particularly exposed to marketing risks and associated uncertain

demand (Milstein *et al.*, 2006). The impact of this risk is exacerbated by the fact that the process of vaccine development and certification can take up to 20 years, and cost up to US\$1.5 billion (Grace, 2010). Keith *et al.* (2013) estimate the duration range at 8 to 19 years and the cost of development at \$200 million to \$900 million.

The nature of working with biological factors, and the associated highly regulated approval process makes the process a highly risky, capital-intensive one (Grace, 2010). Consequently, vaccine manufacturers are loath to develop products for which there is not a good prospect of sufficient market potential to recoup these costs.

In response, donors aim to shape the market to improve the expected profitability of investment in innovations against these neglected diseases (Kettler, 2005; Kettler and Marjanovic, 2004). This *push* facilitation of product development involves donors providing funding to reduce the costs of product development and thereby attract new suppliers, increase overall supply and reduce price (Ford *et al.*, 2018). *Push* interventions typically include cost-sharing of vaccine trials and regulatory harmonisation.

A good example of *push* intervention was the development of a vaccine against meningococcal group A meningitis. Meningitis is a severe infection of the lining around the brain and the spinal cord, affecting in particular children. Meningococcal group A meningitis is a bacterial form of the disease and the most likely to occur in epidemic form (Center for Global Development, 2015). A meningitis A outbreak in 2016 affected 250,000 people, killing 25,000 (WHO, 2019). The fact that meningitis A is overwhelmingly found within the ‘meningitis belt’ across central Africa makes it a prime example of a disease of particular – almost exclusive – interest to LEDC markets rather than higher-income country markets.

The disease was the focus of the Meningitis Vaccine Project (MVP), a collaboration between PATH<sup>4</sup>, WHO, and vaccine manufacturer the Serum Institute of India. Funding was provided by the Bill and Melinda Gates Foundation (BMGF). The project enabled the development of a new conjugate vaccine, called MenAfriVac, and its introduction into countries in 2010 at a price of less than US\$ 0.50 per dose

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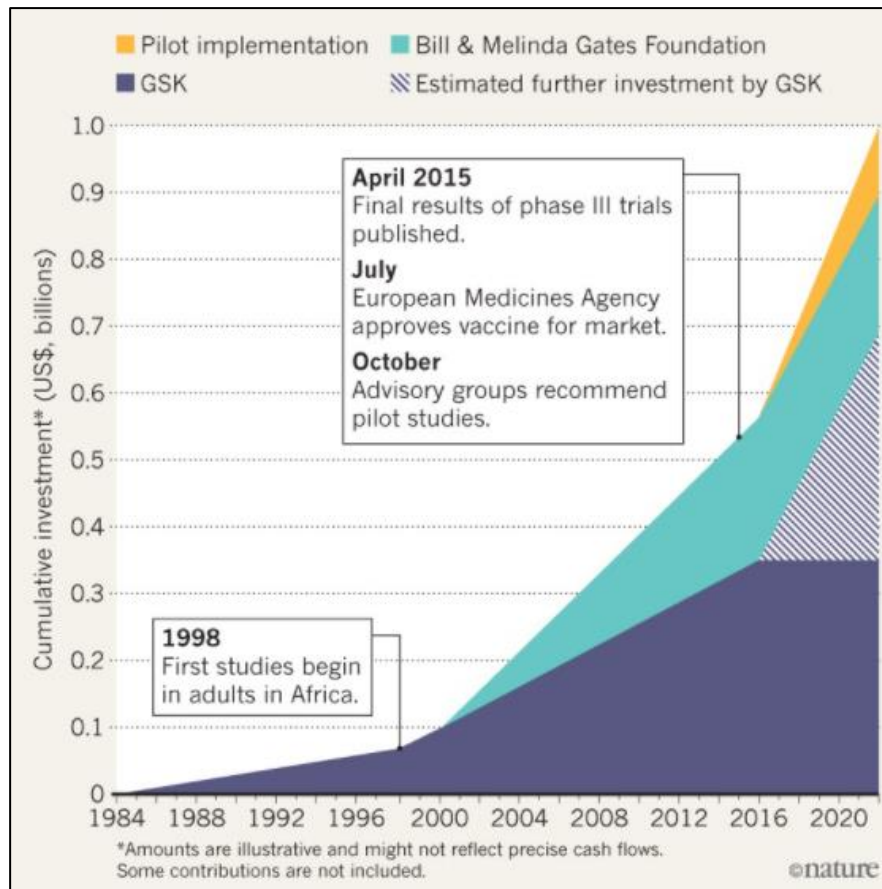
<sup>4</sup> US not for-profit organisation, see [www.path.org](http://www.path.org).

(Okeibunor *et al.*, 2013). Gavi provided funding of \$367 million for campaigns and vaccine stockpiles, and over the following years, more than 230 million children were immunised. This had an immediate and dramatic effect in breaking the cycle of these epidemics and as a result, has virtually eliminated the disease across the belt (Center for Global Development, 2015).

This MenAfriVac example also illustrates the range of positions which different donors take on their potential role. Gavi's Board decided early on that Gavi should not pursue a research agenda, but rather would focus on the scale-up of vaccines to LEDCs (Clemens *et al.*, 2010). Gavi funds vaccines for LEDCs only once they have been quality-assured by WHO (Kaslow *et al.*, 2018), and WHO's technical role in such partnerships is therefore a vital element. In contrast, and as we will see further below, BMGF has been a major funder of research and development in vaccination, often through PATH, for whom BMGF is by far their largest funder (PATH, 2022). The funding for vaccine development for diseases that primarily affect LEDCs has come overwhelmingly from donors, of which Kaslow *et al.* (2018) highlight BMGF, Wellcome Trust, European Union and US Government. They suggest that it is as a result that a large number of candidate vaccines are moving through the pipeline (Kaslow *et al.*, 2018).

This is consistent with the position of Veugelers (2021), who argues that public resources should support the early stage, riskiest but highest potential vaccine candidates. She suggests that public-private partnerships allow the capturing of the comparative advantage of each sector, with the public sector coordinating and funding, and the private sector focusing on the technical skills to develop vaccines. A second example illustrates these trends: development of the RTS,S vaccine for malaria, as shown in the following figure:

Figure 7: Cumulative investment in malaria vaccine development (Kaslow *et al.*, 2018)



(Kaslow *et al.*, 2018, p. 339)

To 2022, the RTS,S programme had cost more than US\$ 1 billion. This figure illustrates co-investment by donors with vaccine manufacturer. BMGF co-funded vaccine development, and the US\$ 49 million cost of the pilot implementation is being jointly met by Gavi, GFATM, and UNITAID, and carried out by WHO (Gavi, 2016a). Manufacturer GlaxoSmithKline has committed to a final price which will cover vaccine manufacture costs plus about 5% profit, which it has committed to invest in R&D for second generation malaria vaccines or other neglected tropical diseases (IFPMA, 2016).

In fact, 40% of the R&D into vaccines for neglected diseases is carried out through formalised product development partnerships (PDPs) (Keith *et al.*, 2013). These are non-profit entities which bring together private sector manufacturers with donor funding to aim to accelerate the design and development of new vaccines. Formal agreements set out responsibilities on issues such as intellectual property,

regulatory process, manufacture, marketing and price. The single largest donor of PDPs is BMGF (Mahoney, 2011).

On the manufacturer side, GlaxoSmithKline (GSK) refers to the fact that more than 90% of the vaccines they are developing are in partnership with others. They explain this with reference to their belief that 'partnerships with academic institutions, foundations, and research organisations will help us to better tackle some of the toughest challenges facing immunisation' (GSK, 2014, p. 8). Veugelers (2021) agrees, arguing that this enables access to complementary competencies amongst actors. PDPs may also include an established multinational vaccine manufacturer in partnership with a new entrant based in an LEDC. This enables the transfer of technology from MEDCs to LEDCs, including in clinical trial expertise, to production capacity. Their success, however, is dependent upon factors including political stability, quality of regulation, and respect for intellectual property rights (Keith *et al.*, 2013).

Breakthroughs in vaccines are often the result of such PDPs between biotechnology companies, established manufacturers, academia and the public sector (Keith *et al.*, 2013). Grace (2010) suggests this is because PDPs are able to increase cost-efficiency and reduce time to market by bringing together all the required skills, knowledge and resources to navigate effectively the global health architecture, including regulative requirements and financing. She highlights the inclusion of donors such as Gavi as being crucial (Grace, 2010). Mahoney (2011) concurs, finding that the public and private components each bring distinct complementary value. The public sector brings an understanding of LEDC markets and their public procurement and health systems, knowledge of the global public goods policies and regulations, and access to scientific research facilities; and the private sector brings skills in product development, manufacture, reaching markets and dealing with regulation.

Mahoney describes the emergence of PDPs as representing an 'era of partnerships' (p. 2). He suggests that this follows earlier eras. The 'era of the public sector' from about 1850 to 1915, during which health innovation was epitomised by the vaccine research in the Pasteur Institute and other public sector bodies. This, he suggests, was followed by an 'era of the private sector', from about 1915 to 1970, in which especially European chemicals companies realised the potential of pharmaceutical industry and invested in vaccine and drug R&D and manufacture. An increasing realisation that the benefits of these were not being seen in LEDCs led to the 'era of



public sector reawakening' from about 1970 to 2000 and involved a focus on transferring these technologies also to LEDCs, though closer working between the public and private sectors. Initially, Mahoney suggests, these two held cynical positions with respect to the other, with the public sector seeing the private as unconcerned about those in LEDCs, and the private sector seeing the public as not having the skills to develop health technologies. He suggests that the 'era of partnerships' has been largely funded by BMGF, and is characterised by an understanding that the public and private sectors each have important contributions to this shared agenda (Mahoney, 2011).

Chataway et al. (2007), however, see PDPs as doing more than simply combining private sector business acumen and skills with public sector mission. They suggest that rather, they have brought new structure and strategy to the responsibilities for vaccine innovation coordination. Ford *et al.* (2018) similarly, advances a perspective which is more strategic, characterising PDPs as taking 'broad systems perspectives in conceptualizing, developing, prioritizing and implementing vaccine innovations' (p. 918). They describe how initially, donors aimed simply to make available to LEDCs those vaccines already developed for MEDC markets, before the understanding that these were sometimes insufficient for the range of infectious diseases in especially tropical regions. PDPs were created in order to address that gap both epidemiologically, but also to allow delivery in resource-constrained environments (Ford *et al.*, 2018). The essence of these perspectives is of PDPs contributing more than the sum of their constituent parts.

## **2.3 Pull incentivising vaccine manufacturers**

It has historically taken perhaps 20 years for vaccines to diffuse from more economically developed countries (MEDCs) to less economically developed countries (LEDCs) (Clemens *et al.*, 2010). Kaslow *et al.* (2018) suggest that this delay is 'largely because of the absence of a global agency able to purchase vaccines for the countries that couldn't afford them, and because suppliers were reluctant to invest in the manufacturing capacity needed for uncertain returns' (p. 339). They point to the role of donor governments, the Bill and Melinda Gates Foundation (BMGF) and Gavi as being able to help address this market failure (Kaslow *et al.*, 2018).

These *pull* interventions reduce the risk of demand uncertainty and include activities such as demand forecasts and purchase commitments. They also include early

recommendations for product introduction from international organisations (Widdus, 2001; Kettler and Marjanovic, 2004). Donors aim to credibly demonstrate to vaccine manufacturers that they can provide accurate and realistic demand forecasts based upon good quality national plans, and that LEDC governments and donors are willing to pay for the vaccines those plans specify (Batson *et al.*, 2006).

One such tool was the Advance Market Commitment (AMC) which Gavi launched in 2007 to accelerate the development, availability, and introduction of pneumococcal conjugate vaccine (PCV). It aimed to do this by guaranteeing a particular purchase price for a specific quantity of vaccine – which incentivised manufacturers to scale up their production to take advantage of this, and reduced their risks. An independent evaluation found that the PCV AMC had indeed accelerated vaccine coverage. It found that the key mechanism by which the AMC achieved this was by stimulating demand, and advancing supply. It did not directly accelerate R&D, and did not cause additional manufacturers to enter the market. Indirectly, however, it did demonstrate the LEDC market demand. Clemens *et al.* (2010) found that an increase in global coverage in PCV vaccines was the result.

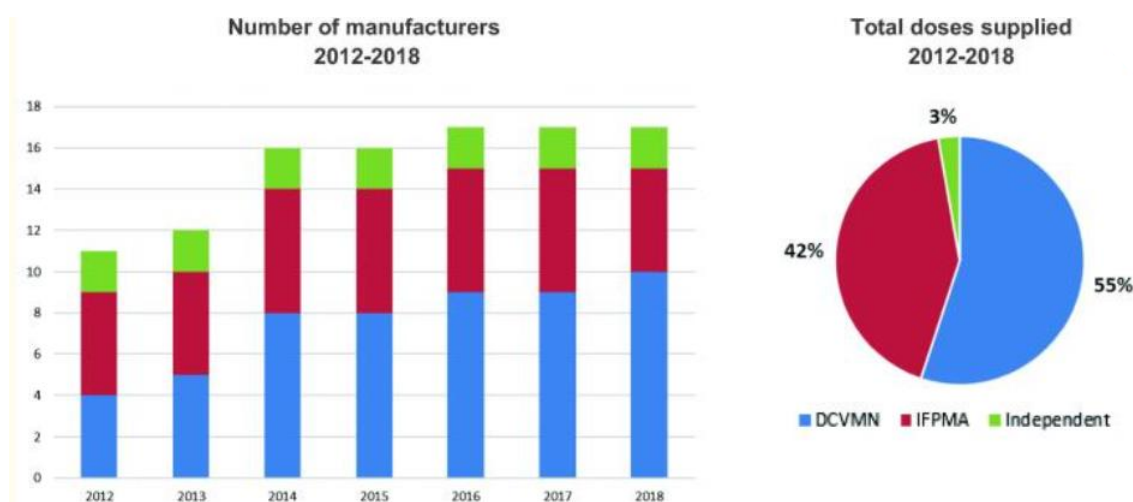
Ford *et al.* (2018) describe Gavi as ‘a major driver in shaping current and future vaccine markets’ (p. 916). They point to the importance of Gavi’s Vaccine Investment Strategy, which is an evidence-based, multi-stakeholder process performed every five years to review new vaccines and their potential impact on LEDC disease burden, and thereby to assess their relative value towards Gavi’s mission. The process also serves to highlight evidence gaps and thus represents a feedback or learning process within the overall vaccine innovation cycle. Ford *et al.* (2018) characterise this as a virtuous circle, in which reliable forecasts of demand leads to manufacturers scaling-up production, which increases supply and lowers cost. This stimulates further demand, which prompts further investment in capacity.

Advance purchase commitments and forecast-based tools are pull mechanisms intended to lower risks for manufacturers to innovate for a new market (Ford *et al.*, 2018). WHO assesses these as having successfully incentivised new manufacturers into the market, thereby both increasing availability and reducing price. The cost of

pentavalent vaccine<sup>5</sup>, for example, fell from US\$ 2.98 in 2010 to US\$ 0.79 in 2019. WHO attributes this to especially the market-shaping of UNICEF and Gavi, and in particular to their market demand forecasting and communication, on which basis manufacturers are able to make informed decisions about investment in new vaccines (WHO, 2019; Lindstrand *et al.*, 2021).

The role of developing country vaccine manufacturers is an important dynamic. The Developing Countries Vaccine Manufacturers Network (DCVMN) is a network of manufacturers established and majority-owned in developing countries. It doesn't include multinational companies with manufacturing facilities in developing countries, or their subsidiaries. The network's 37 members are distributed across 14 countries, including Bangladesh, Brazil, China, Egypt, Indonesia, South Africa, Thailand, and Vietnam (Pagliusi *et al.*, 2013). UNICEF and Gavi have been increasing the proportion of Gavi-funded vaccines procured from these manufacturers, as shown in the following figure:

Figure 8: Vaccine manufacturers' share of Gavi market (Pagliusi *et al.*, 2020)



(Pagliusi *et al.*, 2020, p. 5854)

The IFPMA is the International Federation of Pharmaceutical Manufacturers and Associations, which reflects those manufacturers in high-income countries. The

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<sup>5</sup> A combined vaccine against diphtheria, tetanus, pertussis, hepatitis B, and Haemophilus influenzae type b

number of these manufacturers and their share of the total doses supplied has been steadily overtaken by those of DCVMN. From 2012-18, 55% of the total doses purchased by Gavi were procured from DCVMN manufacturers (WHO, 2019).

## **2.4 Vaccine secondary attribute innovation**

Donors have attempted to bring the same *modus operandi* of *push* catalysis and *pull* incentivisation to innovations in vaccine secondary attributes. These are distinct from the fundamental immunogenicity of vaccines, but complement it. Examples include preservative-free vaccine presentations, improved thermostability and filling or packaging innovations. Such innovations often challenge the norm of vaccines presented in multi-dose glass vials, delivered through a cold chain, reconstituted with diluent, and administered using a syringe and needle (Giersing et al., 2021).

Vaccine secondary attribute innovations can significantly improve vaccine safety, acceptability and effectiveness of vaccines (Kristensen and Chen, 2013).

Innovations such as nasal-sprays, inhalers, jet injectors and microneedle patches, for example, represent alternatives to syringes as the mode of administration of a vaccine into the body. Such needle-free modes offer the potential to address some patient fears, as well as reducing risks of cross-contamination and the extent of sharps waste.

Such innovations are able to increase the impact of vaccination programmes by extending vaccination to as many people as possible by making vaccines better suited to local needs, and improve service delivery (Lindstrand *et al.*, 2021; Gavi, 2022c). For example, increased vaccine thermostability enables vaccines to remain viable even after extended periods outside the cold chain, thus facilitating their transport to more remote areas (IFPMA, 2015).

A broad set of donors and other actors have important roles in vaccine secondary attributes innovation development, production, marketing and diffusion. This is illustrated by auto-disable syringes (ADS), which are single-use syringes which automatically disable after use, thereby removing the risk of transmission of disease through the improper sterilisation and reuse of needles. The first commercial ADS was available in 1992, following which market competition reduced the price per syringe from US\$ 0.13 to US\$ 0.06 (Kristensen and Chen, 2013). In 1999 WHO, UNICEF and UNFPA issued a requirement for their exclusive use in vaccination. From 2002 Gavi began to provide ADS free to its recipient countries, alongside

training for health workers. This guaranteed demand and incentivised investment by syringe manufacturers. Levin *et al.* (2010) describe Gavi's provision of funding for ADS as being instrumental in accelerating their introduction, alongside the importance of the global advocacy by WHO and UNICEF, which achieved alignment across the public and private sectors (Giersing *et al.*, 2021).

A second example of successful vaccine attribute innovation is the vaccine vial monitor (VVM). This is a sticker, heat-sensitive to indicate exposure to heat outside a certain range, attached to a vaccine vial. The problem this innovation solves is that exposure to heat reduces the potency of a vaccine, resulting in an ineffective vaccination, if administered, or wastage of vaccine, if recognised before being injected. WHO proposed the concept in 1979. The first was produced in 1996, by manufacturer Temptime, in partnership with PATH, and purchased by UNICEF for oral polio vaccine. From 1999 WHO and UNICEF advocated their use for all vaccines, and UNICEF specified them as required in order for vaccines to be eligible for procurement. Many manufacturers did not initially comply, however, due to the additional costs and complexity. In 2002 Gavi introduced a requirement for VVMs on all vaccines it purchased from the start of 2004, and in 2014 VVMs were required for WHO quality-assurance of a vaccine. Giersing *et al.* (2021) identify the various regulative or facilitational steps performed by UN donors and Gavi as being crucial in the introduction of the VVM innovation.

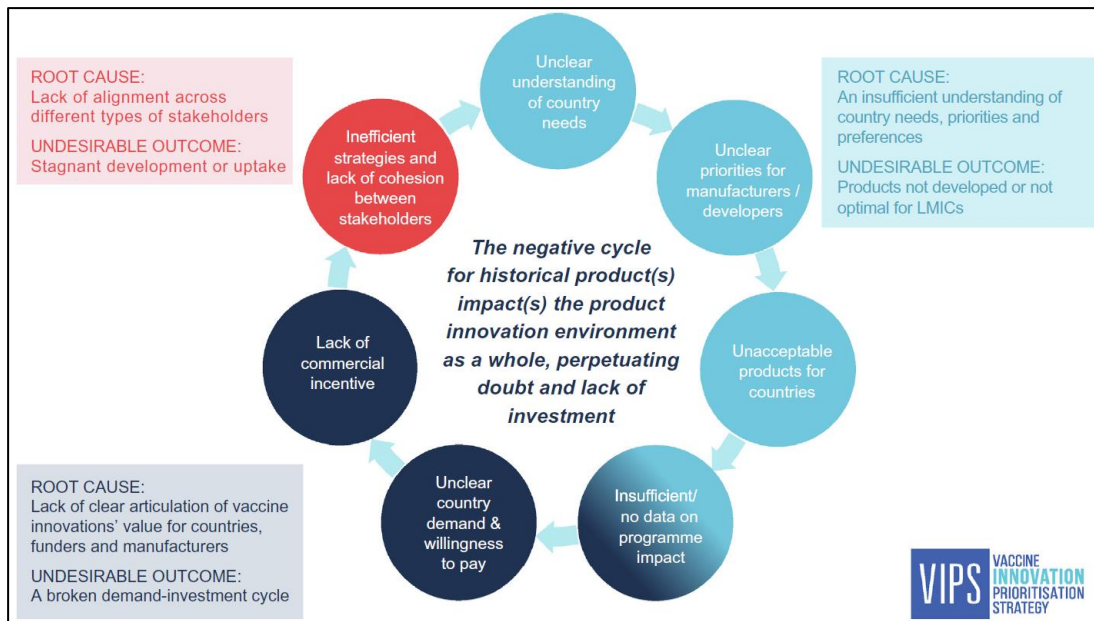
Overall, Kristensen and Chen (2013) suggest that there is a larger number than ever before of various actors (manufacturers, academics, non-governmental organisations and other inventors) working on these innovations for LEDCs, which they attribute to 'global advocacy'. WHO (2019), certainly, has quality-assured various innovative delivery technologies developed during the Decade of Vaccines, including needle-free administration, blow-fill-seal primary containers, and improved vaccine vial monitors. WHO acknowledges, however, that take-up has been slow, suggesting that this is largely because of additional costs involved in transitioning to these (WHO, 2019).

Kristensen and Chen (2013) attribute the slow take-up primarily to existence of counter-incentives for manufacturers. Developers of vaccine secondary attribute innovations need to work closely with vaccine manufacturers to ensure no adverse effect on the safety or potency of the vaccine itself. Even using a new container for a vaccine (let alone a new adjuvant or administration mode such as microneedle matches) would require extensive and expensive testing and access by those

innovators to the tools and the expertise to do so. Many vaccine secondary attribute innovations would require incorporation into the manufacturing processes of the vaccine, and the associated changes, testing, licencing and regulatory compliance. The vaccine industry, though, has a low risk appetite. Changes in the late-stage of manufacture are the most expensive, and there is continual pressure to reduce vaccine prices. Moreover, it is often hard to quantify the value of a secondary attribute innovation. This value, much more than that of a vaccine itself, differs depending on the perspectives of different actors. This is exacerbated by the fact that the primary users, health workers in LEDCs, tend to be little consulted in those processes (Kristensen and Chen, 2013).

Giersing *et al.* (2021) point out that, though highly impactful, the ADS and VVM innovations took decades to develop, and suggest that such long timelines serve to hamper commitment by private and public sector actors alike. They term this an 'innovation conundrum', as shown in the following figure:

Figure 9: Innovation conundrum for vaccine-product innovation (Giersing *et al.*, 2021)



(Giersing *et al.*, 2021, p. 7215)

Giersing *et al.* (2021) highlight three particular critical process segments in achieving successful country adoption of vaccine secondary attribute innovations. The first (in blue in the figure) is sufficient understanding of country needs, priorities and preferences. It is informed by country context and intended use case. Without this, potentially impactful innovations will not be developed, and those which are developed will not be adopted in the intended markets. A second segment (in grey in the figure) is clear articulation of value, including reference to a clear public-health need and use. Without this, investment by stakeholders is limited, and a lack of confidence in the cycle perpetuated, making it harder to access facilitational resources such as policy recommendations and financial support. A third segment (in red in the figure) is alignment across stakeholders. Without this, investment and effort aren't balanced appropriately for the critical path at any point in the development cycle. It necessitates comprehensive strategies from the beginning, and iterative feedback loops and (though Giersing *et al.* don't specify this) regular proactive coordination.

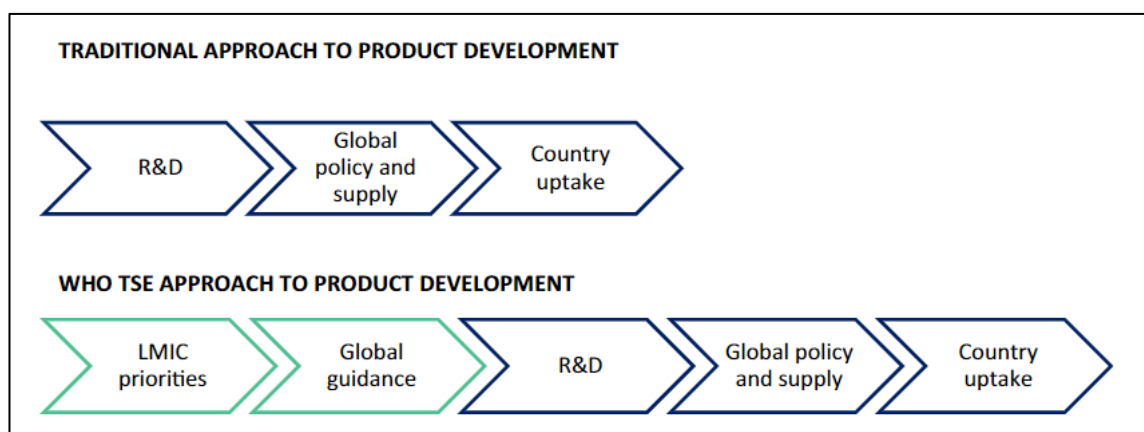
Giersing *et al.* (2021) suggest that achieving these critical segments requires 'substantial engagement' and 'focused and significant investment' (p. 7209) by

donors from early in the development cycle and constantly throughout it. As Kristensen and Chen (2013) put it:

When the required attributes are defined by a compelling evidence base through a standard and objective process and consistently enforced through policy and purchase specifications, then manufacturers' risks are minimized, and success is likely to be greater' (p.160).

Botwright *et al.* (2020), in a similar emphasis, propose what they term a Total System Effectiveness model. This aims to highlight the importance of donor-led steps of priority-setting and issuing related global guidance before R&D is performed. These steps relate to two of the three segments identified by Giersing *et al.* (2021) and are intended to change the risk-benefit calculation which as we have seen otherwise limits manufacturer investment in these innovations.

Figure 10: Total System Effectiveness model (Botwright *et al.*, 2020)



(Botwright *et al.*, 2020, p. 4)

There are signs that donors are responding to this understanding. Some steps are modest, with WHO increasing the rigour of its assessment of programmatic suitability for LEDCs as part of its quality-assurance process for vaccines. Other steps are more ambitious, with Gavi, WHO, UNICEF, the Bill and Melinda Gates Foundation (BMGF) and PATH establishing in 2018 a major initiative, the Vaccine Innovation Prioritisation Strategy. This aims systematically to evaluate emerging vaccine product innovations against country needs. This is intended to be used to communicate a prioritisation of these to manufacturers such as to inform their, and donors', investment decisions. The Vaccine Innovation Prioritisation Strategy includes significant consultation with intended users through both surveys as well as



in-depth interviews, as well as the development of a methodology to comprehensively evaluate different innovations at different stages of development (Gavi, 2022c).

The initial process concluded in mid-2020 by recommending three innovations. Firstly, microarray patches; secondly heat-stable and controlled temperature chain liquid vaccine formulations; and thirdly, barcodes on primary packaging. The Vaccine Innovation Prioritisation Strategy is subsequently developing strategies to accelerate the introduction of each of these innovations (Gavi, 2022c).

## 2.5 Conclusion

The existing literature increases our understanding of the role donors play with respect to innovation in immunisation. Firstly, we have seen that donors contribute to setting the global strategy for immunisation, including ensuring that innovation is a priority within that. We have seen that they have accompanied their driving of this strategy with increased levels of financing for the sector. Resulting from these efforts has been an increase in the level and pace of vaccine development.

Other key donor roles relate directly to the market. We have seen donors' playing a role upstream, in *push* catalysing product development, by establishing and/or funding informal or formal product development partnerships (PDPs) conducting research into innovative vaccines designed for less economically developed countries (LEDCs). The vaccines developed against meningitis A and malaria illustrate the potential impact of this type of intervention. We have also seen donors' role downstream, in *pull* incentivising vaccine manufacturers. Donors do this in a set of approaches which involve decreasing the risk to those manufacturers of investing in development and distribution to LEDC markets, either by increasing the financial reward, guaranteeing demand, or providing reliable market intelligence. The accelerated coverage of pneumococcal conjugate vaccine achieved through Gavi's advance market commitment illustrates the potential impact of this type of intervention.

We have also seen donors involved in innovation in vaccine secondary attributes, drawing from lessons from their experience in vaccine innovation itself. They use essentially the same approaches: a combination of *push* funding and *pull* incentivisation. This has produced important innovations, particularly the auto-disable syringe and the vaccine vial monitor. Yet these innovations took decades to

diffuse across markets, and such long timelines disincentivise commitment by the private and public sector alike. The primary challenge is that these secondary attribute innovations usually necessitate adoption by the vaccine industry, but there are significant counter-incentives for vaccine manufacturers to do so. These relate particularly to incorporation into the manufacturing processes of the vaccine, and the associated risks and costs of changes, testing, licencing and regulatory compliance. It is this 'innovation conundrum' which donors are playing a role in trying to overcome. Their role involves, firstly, understanding country needs; then articulating a clear public-health need and use, before aligning stakeholders and coordinating engagement through the cycle.

Within the literature, we discern some important gaps in knowledge. These relate to innovation i) spatial levels, ii) power relations, and ii) organisational capabilities.

Firstly, we have seen multiple reference to the existence of two distinct important spatial levels: the national and the global. The national level consists of countries and the needs of beneficiaries in them, which we have seen contrasted with the limited understanding of context and use-case held by manufacturers and other actors at the global level. We saw in our introductory chapter how donors have in the past tried to bridge the global and national levels, through the use of technology transfer and similar policies, and how those have not succeeded. In this chapter, we have identified more recent attempts by donors in immunisation to shape global markets to reflect national disease burdens or other contextual considerations around innovation characteristics. The examination of this, however, within the literature, is yet very limited, such that we do not have a good understanding of how donors engage actors and institutions across these two spatial levels for innovation in immunisation.

Secondly, we have seen reference in various forms to the power relations which exist around donors, because of the power integral to authority over the provision of financial investment. This is most applicable to donors' interactions with the intended beneficiaries of their programmes. Consequently, consideration around the inclusion of intended beneficiaries in planning, design and implementation is highly relevant. Power also derives from knowledge, and donors are often in a more knowledgeable position than other actors, because they bridge knowledge domains. Donor understanding of LEDC markets and contexts, in particular, provides donors with a degree of power in their relationship with private sector actors who would like to move into LEDC markets but are not familiar with these countries. The philanthropic

mission of donors also provides them with power, in the form of moral authority and reputation. This provides donors with control of access, being often in a position to choose between which actors to invite to participate in partnership. Power relations are particularly acute with respect to innovation, because of the diverse set of knowledge and capacities which tend to be required for innovation. For LEDC contexts in particular this requires actors proactively to bring these resources together, as they would not otherwise all be present. The examination of these power relations, however, within the literature, is yet very limited, such that we do not have a good understanding of how donors engage with these power relations with respect to innovation in immunisation.

Thirdly, we have identified that different actors have different capabilities, which contribute to determining the roles which they play with respect to innovation, and how successfully they perform those roles. Gavi, for example, because it purchases vaccines for 60% of the world's birth cohort, is able to exert a high level of influence over the vaccine market which it uses in particular to *pull* innovation into LEDCs. The entrepreneurial approach of the Bill and Melinda Gates Foundation (BMGF) combine with a narrow accountability and high risk-appetite to provide it with perhaps unique capabilities to engage with longer-term, earlier-stage vaccine research and development. UNICEF's global reach, through its 124 country offices, its role as procurer for many LEDCs, and its strong culture of innovation position it ideally to work directly with those countries to help them to adopt innovations. The examination of donor capabilities, however, within the literature, is piecemeal, such that we do not have a good understanding of what determines a donor's comparative advantage for one particular set of roles for innovation as opposed to another.

These three knowledge gaps represent the principal areas for further investigation during our research. As we look to close these gaps empirically, we take as our starting point the argument of Chataway *et al.* (2007) that in shaping vaccine markets for LEDC countries, donors need to consider not only the economic levers at their disposal, but also the institutional and organisational context. We will progress from there to the systems approach to innovation which we present as our conceptual framework in the following chapter.

### **3 THE INNOVATION SYSTEMS CONCEPT**

This chapter establishes the conceptual framework within which this empirical research is carried out. It argues that the evolution of the systems of innovation approach provides important explanatory concepts for this research. Elements of the national system of innovation (NSI) model help explain innovation-related dynamics within countries which are beneficiaries of immunisation for international development. At the same time, institutions and other characteristics of the sector as a whole are given insight by the sectoral system of innovation (SSI) model, which encompasses innovation across a sector, including multiple spatial levels. These approaches, however, are insufficient to explain how the increasingly globally interconnected movements of knowledge, capital and people relate to innovation in immunisation for international development. For that, the global innovation system (GIS) model proposed by Binz and Truffer (2017) adapts and extends the innovation systems approach. It incorporates the concept of the NSI heavily, as well as some aspects of the SSI. It also introduces significant new tools, including the concepts of specific system resources beyond those of knowledge, of typographies of GIS depending on the distribution of these resources, of sub-systems at different spatial levels, and of intermediation understood as connection between different sub-systems.

The chapter is divided into six sections: the first and second expound the principles consistent across approaches of systems of innovation, and their relevance for this research, before the third and fourth sections review the relative merits and constraints for this research of the national and sectoral variant approaches. The fifth section introduces the GIS approach and examines in detail its explanatory power with respect to particular characteristics of innovation in immunisation for international development. The sixth section examines the relationship between the innovation systems approach and organisational capabilities.

#### **3.1 Integrating innovation with production**

In Chapter 1 we identified a default on the part of donors to assume the linear model of innovation, in which research and development (R&D) is the driving factor for scientific discovery. Kaplinsky *et al.* (2009), building upon the framework for classification of knowledge proposed by Gibbons *et al.* (1994), term this *Mode 1* innovation. In contrast, they point to an increasing understanding of the importance of more collective and interdisciplinary approaches to innovation which are demand-

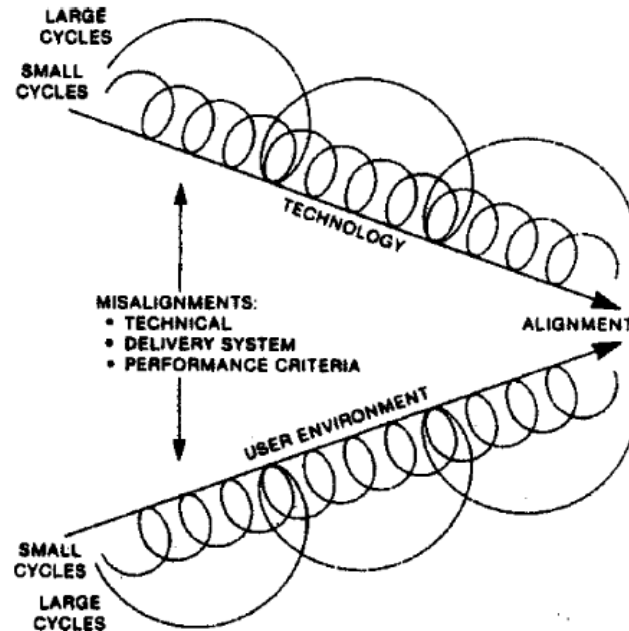
driven, focused on application, and reflexive and iterative. Kaplinsky *et al.* term this *Mode 2* innovation.

In Chapter 2 we identified donors' increasing realisation of this importance of iterative connections between upstream R&D and their programmatic work with beneficiaries in the field. This approach explains innovation as arising from the combination of knowledge generated primarily from *science, technology and innovation* (STI) and knowledge generated primarily through *doing, using and interacting* (DUI). This can result from the utilisation by actors of resources in interaction with other actors and with the wider institutional environment (Greenacre *et al.*, 2012; Di Stefano *et al.*, 2012). Kaplinsky *et al.* (2009) describe it as the integration of innovation with production, concluding that 'it is in the *doing of it* that knowledge is expanded' (p. 183).

This concept of the combination of diverse knowledge helps explain the importance to donors of the interactions with the two sets of actors they identify particularly: the private sector, and the intended beneficiaries of the innovation. The private sector, Kaplinsky *et al.* (2009) highlight as having a particular expertise in learning-by-doing; and beneficiaries, or users, von Hippel (1988) identifies as having an unparalleled knowledge of an artefact and its use. Kaplinsky *et al.* (2009) suggest that innovation is directly related to the quality of the linkages between these two sets of actors, and of the knowledge which flows between them.

The 'primacy of practice' reflected in *Mode 2* innovation emphasises the importance of the specific context for each innovation, making it less likely that innovations which are successful in one context will work as well in other times or places (Mulgan, 2016). The importance to the functional use of innovations in the context of sociological considerations alongside technological ones is illustrated by the following figure.

Figure 11: Co-evolution of technology and user environment (Leonard-Barton, 1988)



(Leonard-Barton, 1988, p. 251)

As Geels (2004) says of this relationship, 'adoption is no passive act, but requires adaptations and innovations in the user context' (p. 902). He describes the importance of the co-evolution of technology and society, of form and function, via continual feedback and mutual adaptation. Perceptions of user preferences are important because if actors believe these are being met well, they will not seek to innovate radically (Christensen, 1997). Similarly, if innovators expect that a problem is solvable within the prevailing set of activities and interactions, they will not seek, or invest, to move away from those existing paths (Dosi, 1982).

### 3.2 Systems of innovation approach

The innovation systems approach expands the scope of analysis from innovations themselves to systems around them. It explains innovation as an ongoing dynamic process of collective learning and knowledge-development through the relationships and interactions of a range of actors, highly influenced by the institutional environment surrounding them. Even though innovation may finally emerge as an output of a specific actor, it is fundamentally a collective process. Actors do not innovate in isolation, but rather, innovations arise through the interactions between actors, and the learning that occurs as a result. Thus, the interactions between actors are as important for innovation as the actors themselves. Actors interact in a

wide range of ways, including cooperation and competition, communication and exchange, and in so doing, they combine elements of existing knowledge and form new knowledge. In general, the more disparate the combined knowledge, the more radical the innovation. Importantly, the innovation systems approach embraces the potential for non-market actors and interactions to a greater extent than previous models of innovation (Freeman, 1987; Edquist, 1997; Lundvall, 2007; Malerba and Adams, 2014).

Use of the term 'system' is intended to convey the sense of inter-connected elements, separated from its environment by a boundary (of varying possible degrees of permeability) and operating such as to represent a whole more than the sum of its parts. Rather than a mechanical system, the sense is of an organic one, with the component actors connected in an organised way and affected by their interactions, but not constructed, governed or manipulated. Rather it self-organises, behaves and evolves (Clark, 2002).

A system's ability to innovate is related to the quality, extent and level of dynamicism of linkages and flow of knowledge between actors. In an increasingly technologically sophisticated society, increasing amounts of information are produced. Hence managing this, understanding it, organising it and using it becomes increasingly difficult and increasingly important. This requires collective skills, system-wide, rather than being manifested in a single actor (Clark, 2002).

The innovation systems approach conceives innovation as fundamentally complex and evolutionary process, influenced by actors' historic paths, inter-actor dynamics and wider contemporary institutions. Actors possess only incomplete and imperfect information, and hence are bounded in their rationality (Simon, 1982).

Consequently, innovation is an uncertain and unpredictable process (Nelson, 1993; Smits and Kuhlman, 2004).

In an innovation system, successful innovation is dependent upon diverse actors purposely, recursively and regularly interacting to share knowledge, activities, feedback and learning (Hall, 2005; Watkins *et al.*, 2015). Innovation results from these 'positive sum' interactions (Lundvall, 2007).

Institutions are fundamentally important to innovation systems approaches because of their influence over the processes of innovation. Such influence both constrains and enables actors' activities. Yet, actors consciously and actively interpret and implement institutions, at the same time, transforming or reforming them. Geels

(2004) extends North's (1992) analogy of institutions as the 'rules of the game', by highlighting that within any game there is scope for interpretation and boundary-stretching. In this way, the rules change gradually whilst the game is being played (Geels, 2004).

Various categorisations for institutions have been proposed, to reflect their wide range of degrees of formality (Nelson and Winter, 1982; Edquist and Johnson, 2000; Soete *et al.*, 2010). The taxonomy of Scott (1995) is particularly useful in distinguishing regulative, normative and cognitive institutions. The regulative category refers to explicit, formal rules which act in a regulatory and constraining manner. Normative expectations confer responsibilities, duties, rights and norms, which are internalised in actors through socialisation. Cognitive institutions provide the framework through which actors process information to attribute meaning, including beliefs, but also the means of communication, including words, symbols and concepts. Scott's categories are shown in the following table:

Table 2: Three categories of institutions (adapted from Scott, 1995)

	<b>REGULATIVE</b>	<b>NORMATIVE</b>	<b>COGNITIVE</b>
<b>Legitimacy basis</b>	Legally sanctioned	Morally governed	Culturally supported
<b>Logical basis</b>	Instrumentality ('rules')	Appropriateness ('how we do things')	Orthodoxy (shared concepts)
<b>Compliance basis</b>	Expedience	Social obligation	Taken for granted
<b>Compliance mechanisms</b>	Coercion (force, punishment)	Normative pressure (social sanctions)	Mimetic, learning, initiation
<b>Examples</b>	Formal rules, laws, protocols, standards, governance systems	Norms, values, duty, codes of conduct, hierarchies	Presumptions, beliefs, paradigms, categories, language

Scott's categorisation is significantly broader than Northian definitions of institutions, which would not include cognitive aspects as institutions. Yet, we anticipate that this breadth is useful in this research. It embraces, for example, the presumption of private sector advantage in innovation which we identified in our introductory chapter as being widely shared across donors. Such shared presumptions, we anticipate, will be important factors in determining donors' decisions about the roles they plan within innovation.



The set of actors, interactions and institutions is conceived of as a system, in that it consists of components (i.e., actors) within a boundary, interacting coherently to generate as a whole properties different from the component parts, to deliver a function. The approach emphasises that the relationships and interactions between actors are as important in achieving innovation outcomes as are the actors themselves. This is critical to the ability of the system to be more than the sum of its parts, self-organising and evolving (Lundvall, 2007).

Whilst it is possible to argue that an innovation system need only be concerned with production, the function of innovation systems, according to Lundvall (1992) is to both produce and diffuse innovations. This broader view is consistent with the breadth of goals which donors see for innovation, which include the scaling-up across multiple countries of successfully-piloted innovations.

Early versions of the approach conceived systems in which actors were largely independent and loosely coupled, but within clearly-defined boundaries. Later understanding portrayed innovation systems as tending to involve actors which are strongly interlinked, but around which the boundary is less clear or fixed (Smits and Kuhlman, 2004).

The innovation systems approach is distinct from other models in focusing explicitly on innovation, rather than seeing it as an exogenous outcome of other processes (Edquist, 2006). Its holistic explanation of innovation, incorporating the wide range of likely determining factors, brings the implication that innovation will tend to be incremental and cumulative. It follows too that the process of innovation is more continuous than Schumpeter's distinction between invention, innovation and diffusion (Lundvall, 1992; Soete *et al.*, 2010).

The holistic, evolutionary nature of the innovation systems approach, whilst granting it significant explanatory power, also results in various weaknesses. These essentially arise from the innate diffuseness of the approach, or as Hall puts it 'a theory of every body working with everybody on everything' (Hall, 2005, p. 626). Establishing the boundaries to an innovation system is the principal problem to result from this, but it also risks minimisation of the role of agency. If actors' activities are influenced by historic paths and contemporary slow-evolving institutions, and if these activities are not themselves sufficient for innovation, then individual actors' abilities to effect innovation are severely limited. Various authors have proposed conceptualisations to resolve this *structure-agency dilemma*. These characterise the

impact of the overarching environment as being to influence but not determine agency; and also emphasise that actors' actions at the same time also affect structures, in a two-way dynamic relationship. The conceptualisations recognise, too, that as well as constraining action, structure serves to enable it (Giddens, 1984; Bourdieu, 1977; Burns and Flam, 1987).

An additional criticism of the innovation system approach is in its inability to generate specific propositions of cause and effect between variables. This limitation results from the complexity and inter-relation of factors. The notion of optimality is difficult for similar reasons: if innovation processes develop over time, are path dependent and multi-factorial, an optimal system of innovation, whilst it could in theory be described, would be so remote from real systems as to be of no use (Edquist, 2006; Hall, 2005). Lundvall (2007), however, doesn't see this as necessarily a problem, suggesting the approach be used primarily as a 'focusing device', or qualitative explanatory tool.

A further criticism is more de facto than fundamental: that most innovation systems-based studies focus primarily on the production of innovation, rather than on its diffusion or use (Carlsson, 2006). This does, though, vary depending on author. Nelson and Rosenberg (1993) for example, emphasise particularly the actors and processes involved in creating knowledge, whereas Lundvall (1992) and Freeman (2002) describe a broader lens on actors and their influences throughout the innovation process. In fact, one of the key influences towards the development of the innovation systems approach was an understanding of the importance of user-producer interaction (von Hippel, 1976), and this particular set of relationships remains fundamental to the success of innovation (Lundvall, 2007).

These weaknesses, however, do not hinder the use of the innovation system approach as a conceptual framework, because the approach involves sufficient flexibility as to embrace a range of different applications. These are considered in the following sections.

### **3.3 National systems**

The original scope of analysis for research into systems of innovation was the national level, with case-studies in Japan and the rapidly emerging economies of East Asia confirming the important role for innovation of actors and institutions at that level (Freeman, 1987; Lundvall, 1992; Nelson, 1993; Freeman and Soete, 1997,

2007). The interactive learning identified as important for innovation was found to be facilitated by the shared institutions and especially linguistic and cultural commonality linking these national actors, and the geographical proximity facilitating their interactions (Edquist, 2006; Carlsson, 2006). The same reasoning around geographic proximity has been extended, particularly within large nation states, to the clustering of innovation within sub-national regional innovation systems (Cooke and Kothari, 2001; Carlsson, 2006).

The national system of innovation (NSI) model initially conceived firms as being the pivotal actor within the innovation system. With further empirical research, this subsequently evolved to reflect the *triple helix* which included government and universities playing important roles for innovation in complementarity to firms. Governments roles relate particularly to the regulatory and policy environment; and universities, in skills-raising and specific new research (Watkins *et al.*, 2015)

The weakest aspect of the NSI model in its applicability to this particular research is that the empirical basis of the approach is in industrialised countries, rather than in less economically developed countries (LEDCs) which are the recipients of international development assistance. This brings with it several challenges. Most fundamentally, it's not clear a-priori that the approach explains innovation when one or more of these triple helix dimensions are so weak as to make the system not sufficiently self-sustaining. For example, the influence of firms is weaker when lower per-capita incomes mean that domestic markets are much narrower and less responsive; or the financial system less able to support more risky entrepreneurial effort; or when other factors of production are also significantly more constrained. Similarly, the education system in LEDCs is less capable of delivering wider skills across the workforce, or cutting edge research within its universities. LEDC national governments are less capable of facilitating the policy, regulation and intellectual property rights important to the facilitation of innovation, and more prone in general to risks and instability (Hall, 2005; Lall and Pietrobelli, 2005). Each of the triple helix actors is much more constrained in their ability to reach potential beneficiaries of innovation than they would be in an industrialised economy.

These capacity and institutional weaknesses at the national level drive actors in LEDCs to engage to source innovation from outside the national boundaries. 'Innovation is costly, risky, and path dependent' (Fu, Pietrobelli and Soete, 2011, p. 1204) and because of the capacity constraints for NSIs in LEDCs, innovation in these countries requires instead access to significant capabilities and knowledge

located beyond national borders. Hence the need for them to develop international networks for knowledge sharing and capacity building. This is political, and potentially sensitive, touching on questions of influence and independence, and the risk of external actors taking captive much of the NSI in a LEDC to their interests (Watkins *et al*, 2015).

The NSI model focus on the national level of actors and institutions remains an important component of any more globalised systemic models of innovation because it represents a necessary level through which to engage with beneficiaries of innovation. The user-producer linkages at this level are important to collective learning, for example through user-feedback through initial marketing and product testing to inform further product development (Carlsson, 2006; Lundvall, 1992; Nelson and Winter, 1982). The national level authorities and institutions retain a key influence over the ability for intended beneficiaries of innovation actually to benefit from the adoption and adaption of international innovation. The government, in particular, at national and local levels, provides consent to international development programmes, and is important in ensuring technical engagement by regulatory bodies and policy ministries. Alternative models which mitigate the weaknesses of the NSI model are examined in the following sections.

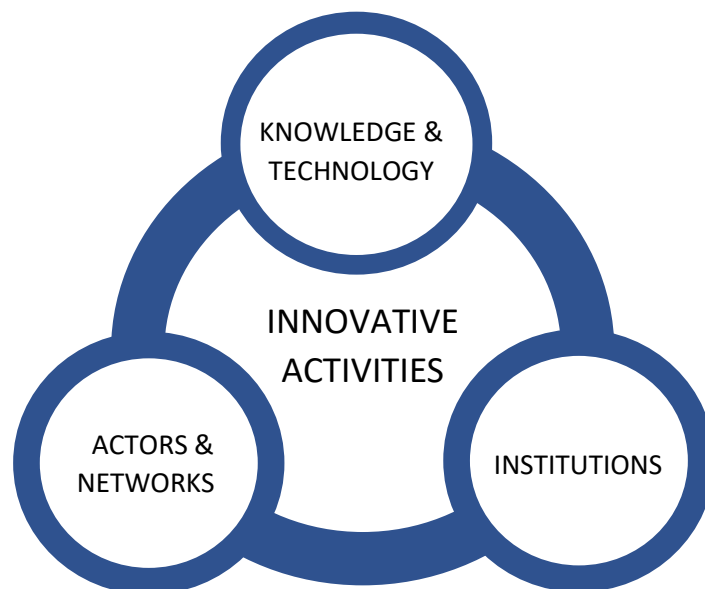
### **3.4 Sectoral systems**

In response to criticism of the system of innovation approach as being too broad and all-inclusive, the sectoral system of innovation (SSI) model developed by Breschi and Malerba (1997) focused on a more specific set of knowledge, artefacts and actors. Breschi and Malerba defined a sector as 'a set of activities which are unified by some related product groups for a given or emerging demand and which share some basic knowledge' (Malerba, 2005, p. 65). They argued that the primary weaknesses of the national system of innovation (NSI) model were overcome by framing an innovation system around a sector because its shared fundamental knowledge and related artefacts and actors are more specifiable and focused (Malerba, 2005). In the SSI model, the spatial distribution of an innovation system will vary across industries, because it is determined by the unique combination of actors, institutions and resources (Malerba, 2005; Castellacci, 2008). Accordingly, the power of the SSI model compared to the earlier national or regional versions of the innovation systems approach is in its ability to accommodate multiple spatial levels within a system of innovation. This also allows for different variables to play a greater relative role at each level of this hierarchy. Malerba (2005) gives the

example of knowledge interaction predominating at the global level, institutions at the national level, and labour resources at the local level. Malerba also suggests the concept of sub-sectors as applicable for even more narrowly defined systems within a sector, although he doesn't set out a mechanism for how these sub-systems might inter-relate.

The SSI model reflects broadly the same sets of variables as does the NSI model, but in a more structured way, as shown in the following figure, in which Malerba and Adams (2014) emphasise the building blocks of innovation as being knowledge and technologies, actors and networks, and institutions.

Figure 12: The framework of sectoral systems of Innovation (Malerba and Adams, 2014)



(Malerba and Adams, 2014, p. 7)

Whereas the NSI model explained innovation as an ongoing dynamic process of collective learning and knowledge-development, the SSI model replaces that with a vaguer concept of 'innovative activities'. The loss of explicit reference to learning, especially, leaves the SSI model weaker than the NSI model in its explanation of the intersection between variables within the system. At the same time, though, the SSI model designates knowledge as a discrete variable in its own right: being affected by other variables, but also affecting them, in the same bi-directional way in which actors and institutions engage in the system. This is helpful in emphasising that knowledge, like actors and institutions, can have both positive and negative impacts

and needs to be treated critically. In addition, this SSI conception of knowledge enables it to contribute to determining the boundaries of the sector and to the inclusion or emergence of new actors or new institutions (Malerba and Adams, 2014).

This framework brings significant advantages for the analysis of innovation at an international level. It has not managed, however, to overcome all of the weaknesses of the NSI model, in particular the accusation of vagueness. In the NSI model this manifested as over-inclusivity of variables (actors and institutions). In an SSI, the breadth of variables is indeed smaller, but the boundaries to an SSI are not always self-evident and are less easy to define than they were for an NSI. With a definition of SSI boundaries itself being an exercise which is arguably theoretical, there is a risk that the setting of these reflects only the boundaries of the research itself (Edquist, 2006).

Like the NSI, the SSI model also places particular emphasis on the production of innovation rather than its diffusion and use. In contrast, as we have seen, these latter stages are also important to donors, in their objectives to scale-up the use of innovations across less economically developed countries (LEDCs). The SSI model also emphasises the role of firms within the group of actors. In its original definition, an SSI was defined as 'that system (group) of firms active in developing and making a sector's products and in generating and utilising a sector's technologies' (Breschi and Malerba, 1997, p. 131). Later descriptions by Malerba broadened this out definitionally, but nonetheless still the SSI model 'places firms and the related capabilities and learning processes as the major drivers of innovation and production' (Malerba and Mani, 2009, p.3). The primary concern at this focus on firms is that it minimises consideration of the important role of beneficiaries. Even though SSI proponents acknowledge that the quantity, quality and diversity of interactions between actors significantly affects the performance of an SSI (Malerba and Adams, 2014), the model doesn't provide specific tools to facilitate consideration of the potential role of other actors in the LEDC contexts in which markets are weaker and firms accordingly less functional.

This sense is reinforced by the fact that the SSI model conflates knowledge and technology. This suggests that the knowledge primarily envisioned in the model is that generated primarily from *science, technology and innovation* (STI) rather than that generated primarily through *doing, using and interacting* (DUI). This feels like a limitation of the SSI model as Malerba and his co-authors have used it. True,

nothing precludes utilising the SSI model in a way which explicitly and fully incorporates beneficiaries and the institutions around them, alongside other actors and institutions. The SSI model, however, doesn't aid such analysis. Its major strength is in enabling one to consider innovation systems beyond the national, but its weaknesses mean it is of limited general applicability in this research.

In fact, the increasing internationalisation of systems of innovation which initially contributed to the succession of the NSI model with that of the SSI has since been understood to be much more nuanced. Essentially, it has become more apparent that a NSI remains a highly important influence over even internationally active actors. Freeman (1995) argues that even with innovation systems becoming more internationalised, the actors and institutions which influence their interactions are often country-specific. These include, for example, national educational systems, culture, and other institutions. Similarly, Pavitt (2001) found that for firms operating internationally, their original national system retained a high level of influence over the nature of their international activities and interactions. Pavitt also found that many of the key skills and resources which confer comparative advantage upon firms within an international innovation system are less internationalised than many other aspects of those firms' activity. The upshot is that recent understanding of internationalisation of innovation systems doesn't replace the NSI model, but augments it, bringing complementary skills, or extending existing skills into new fields.

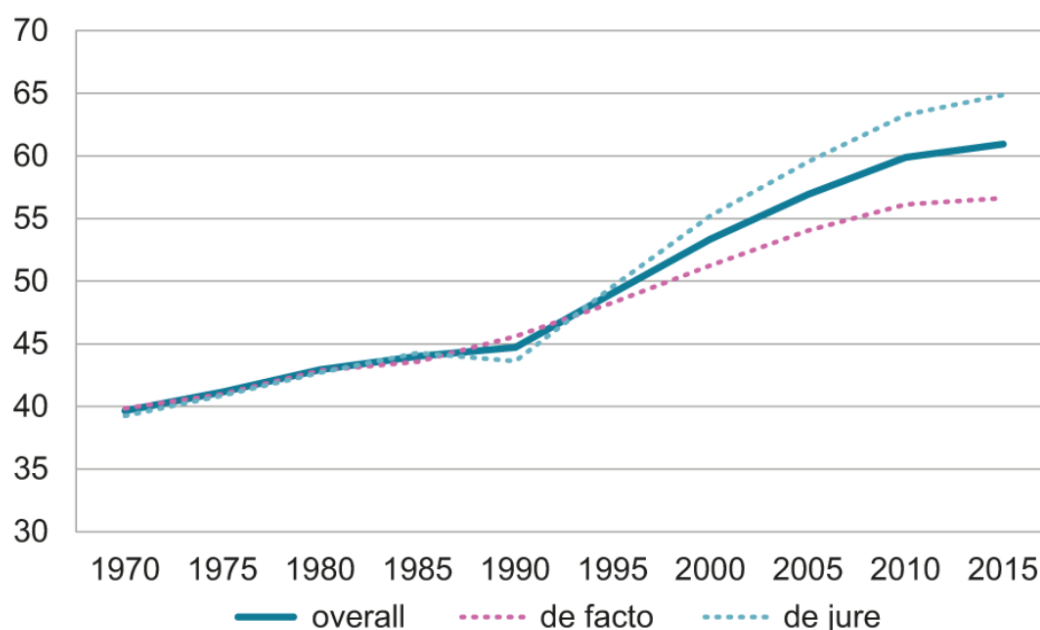
Carlsson (2006) suggests that in the past the process of internationalisation of an innovation system might have consisted simply of the attempted replication of a national innovation system in another country by actors common to both, seeking a new market. Carlsson suggests, however, that innovation systems are now 'globalised' in the sense that there are new global structures for knowledge creation. This is explored in the following section.

### **3.5 Global systems**

The world's populations, cultures and economies are increasingly interdependent, as flows of information, investment and people between countries have grown and become more important (PIIE, 2018). This process of globalisation has grown at a faster rate over the past 30 years, as demonstrated, for example, by the KOF Globalisation Index, which measures economic, social and political dimensions of globalisation. These include the extent of financial flows, trade in goods and

services, migration, international patent applications, internet access, numbers of embassies and non-governmental organisations, and membership of international bodies (KOF Swiss Economic Institute, 2018). In the following figure, the de jure line shows the policies and activities affecting globalisation, and de facto line shows actual flows:

Figure 13: KOF Globalisation Index, World Average (KOF Economic Institute, 2018)



This acceleration in the pace of globalisation has rendered increasingly insufficient national innovation system components, as national level actors have found it increasingly important to engage in these globalised networks themselves (Watkins *et al.*, 2015; Carlsson, 2006; Soete *et al.*, 2010).

Recognising both the enduring importance of national level institutions, language and relationships, but the emergence of new, globalised knowledge creation systems, the global innovation system (GIS) model (Binz and Truffer, 2017) attempts to embrace both those. This is a nascent field and the literature remains limited. Nonetheless the model has begun to be tested empirically in areas including solar photovoltaics (Hipp and Binz, 2020), solar water heaters and membrane



bioreactors<sup>6</sup> (Binz *et al.* 2020) and offshore wind farms (Tsouri, Hanson and Normann, 2021). These studies have served to reinforce the value of a conceptualisation of an innovation system operating at global and other spatial levels; and the usefulness of the specific tools enabled by the GIS model for analysis and explanation.

### **3.5.1 Knowledge and valuation resources**

The preceding sections have shown different treatments of knowledge within the various different approaches of systems of innovation. The national system of innovation (NSI) model treats knowledge primarily as an output of the interactions between actors. The sectoral system of innovation (SSI) model goes further, in designating knowledge as a discrete variable and therefore being affected by other variables, but also affecting them. However, in its application, the SSI model has tended to assume knowledge as generated primarily from *science, technology and innovation* (STI); giving less weight to knowledge generated primarily through *doing, using and interacting* (DUI).

The global innovation system (GIS) model conceives of knowledge in a different way, designating it a resource. This is neat, as a resource can act as an input to innovation, and can also be generated, as an output. A resource also has the qualities of being affected and affective, as a discrete variable, thereby capturing the advantages of both the NSI and SSI treatment of knowledge. Moreover, the GIS sets out an explicit continuum for knowledge, or innovation mode, from STI at one extreme to DUI at the other. Binz and Truffer (2017) also recognise the inter-play of these types of knowledge, emphasising the 'co-evolution of a technology and its institutional embedding' (p.1288).

In addition, the GIS model introduces three further system resources, which it groups and terms *valuation resources*. These are market access, financial

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<sup>6</sup> Solar water heaters absorb the sun's radiation and convert it to heat water. Membrane bioreaction is an advanced filtration process for wastewater treatment and reuse.

investment and technology legitimacy<sup>7</sup>. They provide value by enabling the connection between user demand and relevant innovation supply (Binz and Truffer, 2020). This implies a focus also on innovation application and diffusion, to which other innovation system models have devoted less attention, because both of these phases are as critical to innovation valuation as is production.

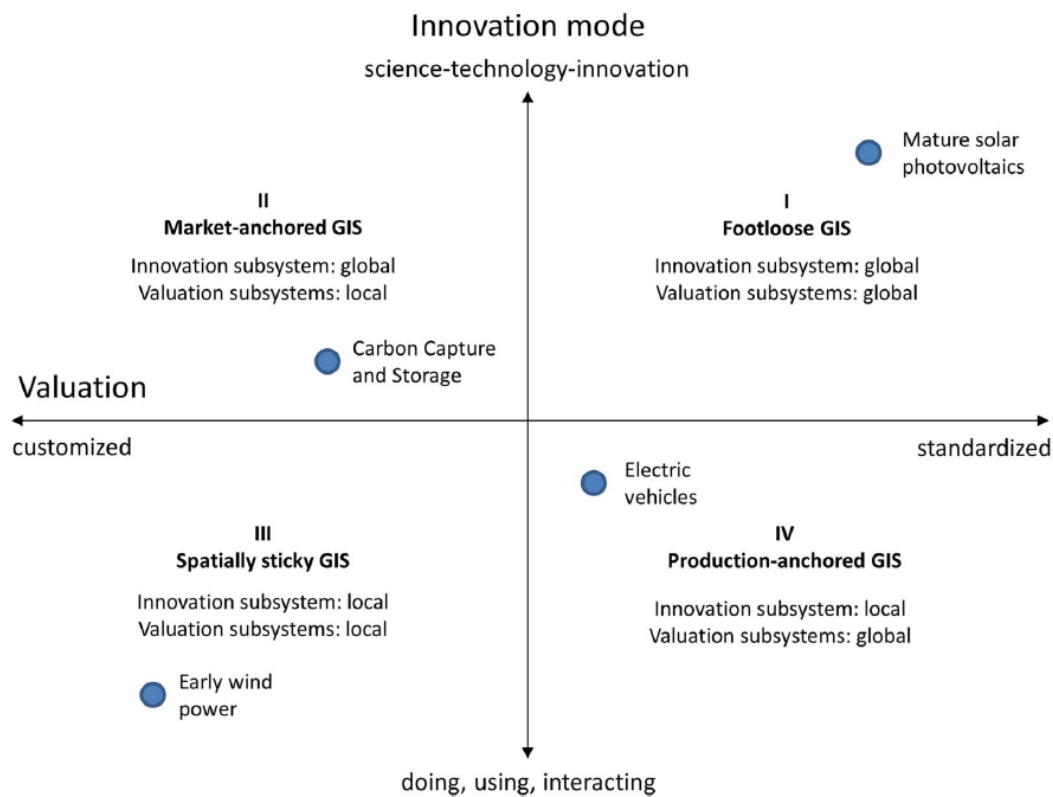
With reference to the specific context of our research we can see that these valuation resources align well with the critical aspects of an innovation's successful use in less economically developed countries (LEDCs). Financial investment is important given that, particularly in LEDCs, the risks and uncertainties around innovation are greater, and commercial investment lower, hence the need for donors often to catalyse innovation to these contexts. Market access relates to the ability for an innovation to reach its intended users or beneficiaries, which we have seen to be significantly harder in the weaker markets of LEDCs. Innovation legitimacy relates to the relevance and feasibility of an innovation to solve the actual needs of the intended beneficiaries, and again, arises as a significant challenge in a weaker market context.

Binz and Truffer place knowledge and valuation resources as two axes on a single matrix as shown in the following figure.

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<sup>7</sup> We replace Binz and Truffer's term from this point onwards with *innovation legitimacy*, in order to emphasise both that innovation is broader than just technology, and that legitimisation has the potential to add value to any innovation.

Figure 14: Ideal-type global innovation system configurations (Binz and Truffer, 2017)



(Binz and Truffer, 2017, p. 1290)

The y-axis reflects the nature of the predominant knowledge mode along the continuum explained above from STI to DUI. The x-axis takes into account the three non-knowledge resource types in the GIS: market access, financial investment and innovation legitimacy. Based on these, the x-axis indicates whether the valuation so derived is primarily standardised across those resources, or whether it is more customised. Innovations whose value is generated on the basis of more standardised resources involve more clearly identified products or services, tending to be uniform across users, who have relatively undifferentiated preferences.

Binz and Truffer argue that each of the axes have implications for the nature of a GIS. The balance of combination of types of knowledge, for example, determines the extent to which an innovation system is localised, with a primarily DUI-based GIS being more dependent upon co-location and frequent face-to-face interaction for innovation.

Similarly, Binz and Truffer argue that the balance of the degree of valuation standardisation also has implications for the nature of a GIS. For example, quality standards for more standardised innovations are either set globally, by WHO in health, for example, or are highly consistent across countries. Such innovations require little adaptation from one market to another. In contrast, innovations whose value is generated on the basis of customised resources need to be tailored to the needs of specific markets or user groups. This entails highly localised knowledge, and as a result financial mobilisation is likely also to be localised.

On that basis, Binz and Truffer propose a taxonomy of different types of GIS, as seen in the four quadrants of the above figure. According to this typology, a *footloose GIS* involves an innovation knowledge mode which is primarily scientific and located in international networks or communities. It also involves valuation which is primarily standardised across markets, relying on international standards and coherent user preferences for international legitimation; on mass-markets with economies of scale for market access; and on investor-driven financial investment. These characteristics are consistent with both such resource sets (knowledge and valuation) being concentrated at a global level. Binz and Truffer illustrate this segment with mature solar photovoltaics, but also suggest as examples consumer electronics, investment banking, and the pharmaceutical industry.

A *market-anchored GIS* also involves an innovation knowledge mode which is primarily scientific. Valuation resources are of a mixed nature, but tend overall to be customised across markets: market access, for example, involves high levels of adaptation to local user preferences; innovation legitimation, similarly, requires adaptation to local institutional contexts in order to achieve proof of concept; although financial investment can be less sticky, through transnational corporations or international investors. These characteristics are consistent with knowledge resources being concentrated at a global level, but valuation resources primarily at the local level. Binz and Truffer illustrate this segment with carbon capture and storage, but also suggest as examples hospitals, water treatment and insurance services.

A *spatially sticky GIS* involves an innovation knowledge mode which is generated primarily through *doing, using and interacting* (DUI) between users and producers. Its innovation valuation is highly customised, with markets initially forming around niches based on local conditions; legitimation results from innovations' consistency with local institutions; and financial investment is highly targeted and/or is from local

sources. These characteristics are consistent with both such resource sets (knowledge and valuation) being concentrated at a local level. Binz and Truffer illustrate this segment with early wind power, but also suggest as examples construction, personal services (including health) and education.

A *production-anchored* GIS also involves an innovation knowledge mode which is generated primarily through *doing, using and interacting* (DUI) in localised manufacturing clusters. The valuation of its innovation is primarily standardised across a global market which serves to homogenise user tastes and legitimisation, though drawing from regional cultural motifs; conversely, financial investment tends to originate more locally. These characteristics are consistent with knowledge resources being concentrated at a local level, but valuation resources primarily at the global level. Binz and Truffer illustrate this segment with electric vehicles, but also suggest as examples mass tourism, automobiles and clothing.

Based on Binz and Truffer's examples of each type of GIS, it is possible to identify several possible areas of direct read-across to immunisation for international development. Indeed, health-oriented global public goods feature in the examples in three of the four quadrants in this typology, with medicines (and by extension, vaccines) classified as footloose, hospitals as market-anchored and health services as spatially sticky.

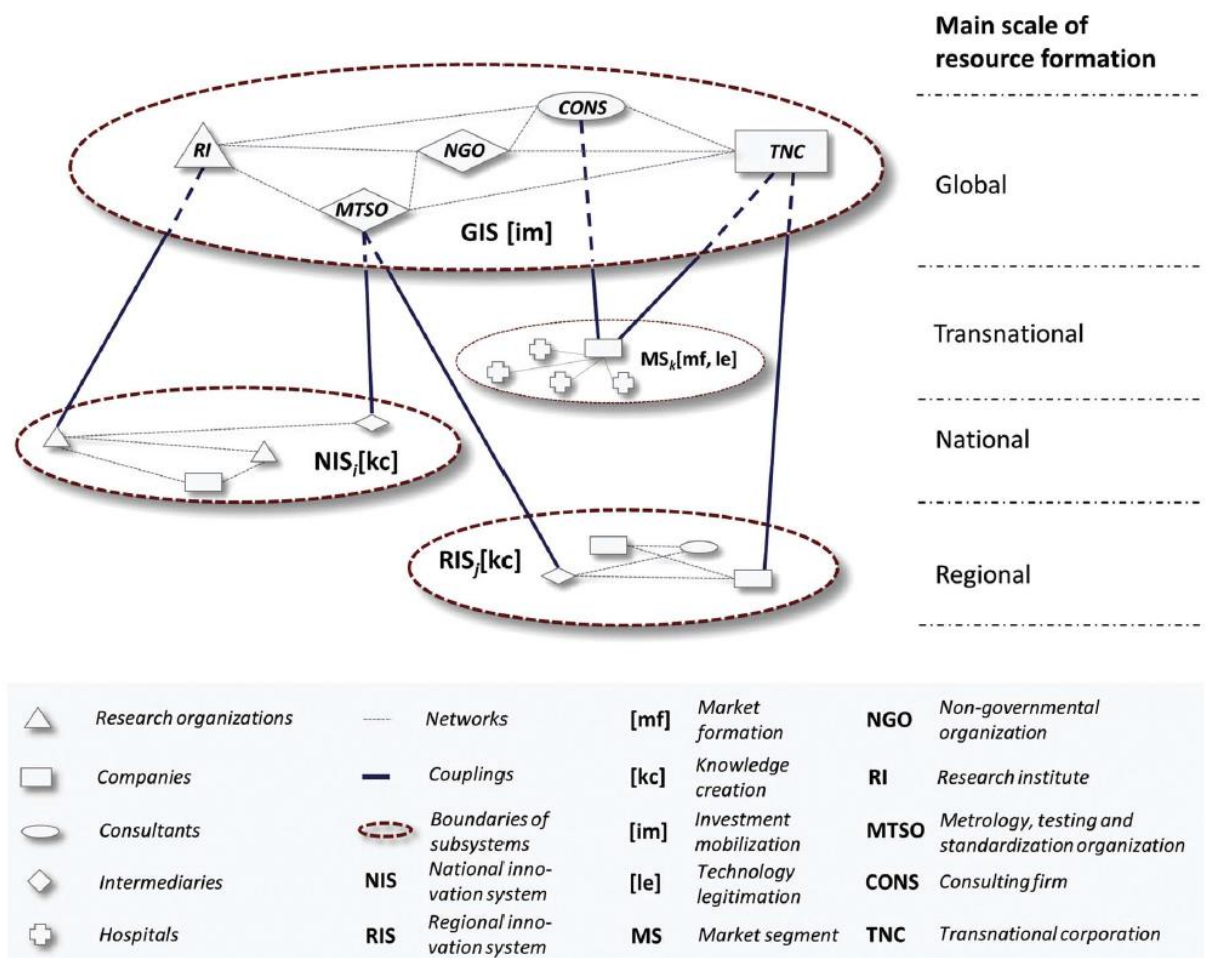
This role and use of resources within the GIS approach is significantly more nuanced than that in the NSI or SSI approaches, and anticipated to be highly relevant and useful for this research.

### **3.5.2 Sub-systems and structural couplings**

The global innovation system (GIS) model is also able to incorporate the concept of different spatial levels, each of which it conceives as operating as a sub-system within the overarching system. The institutions, actors and interactions within each sub-system vary, and provide each with a distinct comparative advantage, such that different resources are created through distributed agency at the different spatial levels. Because these resources are created through distributed agency, individual actors are not usually able alone to appropriate a dominant share of these. Therefore, they need to create and use alliances with other actors to enable access to a greater share of resources (Boschma, 2005; Binz and Truffer, 2020).

Within each sub-system the actors interact in networks, and the sub-systems themselves are connected by structural couplings. These arise when there is an overlap between sub-systems of actors, networks, or institutions. The performance of the overarching system is determined by the extent of the structural couplings connecting sub-systems. Binz and Truffer (2017) provide a mapping of an illustrative innovation system in global public health, replicated in the following figure.

Figure 15: Illustrative global innovation system (Binz and Truffer, 2017)



(Binz and Truffer, 2017, p. 1288)

In this figure, the global sub-system<sup>8</sup> primarily serves to mobilise financial investment. In this space are involved actors with a global reach, including transnational corporations, non-governmental organisations, research institutes and standard-setting bodies. Knowledge is formed within two sub-systems: in a national sub-system in which research institutes are particularly important, and in a regional sub-system in which firms play a major role. In each case, these main actors at national or regional level are structurally coupled to counterparts at the global level.

Sub-systems may also exist at the transnational level, representing activities which take place simultaneously in multiple countries. In the illustration a transnational sub-system contributes the resources of innovation legitimisation and market-formation, with these resources being generated as innovations reach markets and users provide feedback. In this case structural coupling to the global level is again through the transnational firm, but also through a consultancy based at the global level.

In this way, the GIS model overcomes the limitations of the sectoral system of innovation (SSI) model in explaining the enduring importance of national systems of innovation. Yet the GIS model also manages to capture the advantages of the SSI, in its narrower focus on a specific set of knowledge, artefacts and actors.

The model has good promise for application to immunisation for international development. Donors would sit as intermediaries in a global sub-system focused on knowledge provision. Innovations developed at that global level would then be tested in less economically developed country (LEDC) national sub-systems using financial investment from donors. Positive feedback on those innovations from beneficiaries in national sub-systems would then result in market access and innovation legitimisation at the transnational level. Structural couplings between these levels would be provided in particular by global public-private partnerships.

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<sup>8</sup> Binz and Truffer use the term *GIS* to refer both to the overall, multi-level system and to the global level sub-system, which risks confusion. Hence in this paper, we use the term *GIS* to refer only to the overall system, with reference within that to a global sub-system, as needed.

The role of global public-private partnerships and other donor actors in providing structural couplings between sub-systems is examined further in the following section.

### **3.5.3 Accommodating weak markets**

We have seen that the national system of innovation (NSI) and sectoral system of innovation (SSI) models are formulated primarily around the role of the firm, operating within the assumption of a functioning market. Within the SSI model in particular, consumer demand has been seen as a major dynamic, with Malerba (2005) defining a sector by reference to 'a given or emerging demand' (p. 65) and later emphasising the importance of demand as a stimulus for innovation and as a factor in the organisation of activities for innovation (Malerba, 2005). The SSI model does acknowledge actors of both firm and non-firm types, and expects that networks of actors will be complex, and that the nature of relationships and networks will differ from sector to sector. However, the experience of applying the SSI model to various case study sectors has demonstrated a tendency to focus on macro-level dynamics, larger players and more formal institutions (Malerba, 2005). This emphasis on firms as the principal actors within a market represents a significant weakness in the applicability of the NSI or SSI models to settings in which there is not a well-functioning market.

The Global Innovation System (GIS) model is very different, in not assuming a well-functioning market. Rather, this model treats market access as one of the four types of system resources, alongside knowledge, financial investment and innovation legitimacy. At the same time as allowing for variation in the role of the market in this way, the GIS approach also provides for alternative means of generating value other than through market access, i.e., through the model's other valuation resources, which are financial investment and innovation legitimacy. In these alternative valuation paths, the GIS approach offers greater potential than do other models to explain the dynamics of an innovation system which are derived primarily from philanthropy than from classical economics. Financial investment, for example, in the form of donor funding for innovation, can drive supply. Donors provide financial investment for the innovations they think the intended beneficiaries would make if a market enabled them to convey that demand. And firms respond accordingly, to manufacture and supply innovations in order to benefit from the donor financing available. Similarly, donors are able to drive supply by communicating to manufacturers the needs which intended beneficiaries would communicate if they



could. This gives particular innovations a legitimacy on which basis manufacturers are willing to invest to manufacture and supply them. This explanation aligns well with the *push* catalysis and *pull* incentivisation which we identified in Chapter 2 as being performed by donors in their shaping of the markets for vaccines and for vaccine secondary attributes.

Also in Chapter 2 we examined the concept of intermediation. In light of the innovation systems approach, we identify a limitation in the concept of intermediation because of its implication of externality to the process of innovation. As we have seen, the systems of innovation model, rather, explains innovation as resulting from the activities of a breadth of actors, each of which plays a role, however small, contributing to the resulting innovation. The GIS model describes this, in which single actors in a GIS will not be able to appropriate a dominant share of these resources alone. Instead, they will have to create alliances with other actors to collate sufficient, and diverse, resources to innovate (Binz and Truffer, 2017).

Rather than intermediation, we consider instead the concept of innovation system governance. Binz and Truffer (2020) describe this as:

[T]he self-organising networks, negotiated inter-organisational coordination, and de-centred, context-mediated inter-systemic steering that influences the creation, diffusion and application of novel technologies, products and services (Binz and Truffer, 2020, p. 398).

This definition responds to the risk of externality in intermediation, by conceiving this governance as being indistinguishable from the systems of innovation themselves. In contrast to Chataway *et al.*'s (2007) concepts of brokerage and integration, the GIS model relates this governance role to the structure of the innovation system, through the concept of structural couplings, as explained in the preceding section. As an example, Binz and Truffer suggest a multinational company which is able to connect knowledge from one region to a distant market; or the networking amongst professional peers which takes place at international conferences. The exchange and recombination of knowledge which takes place through these couplings is fluid and multi-directional. Although Binz and Truffer's examples do not include donors or public-private partnerships, the framework provides a good basis for the overall conceptualisation of the roles of those types of organisations within international development.

### 3.6 Organisational capabilities for innovation

Knowledge is understood as the fundamental resource of an innovation system, and learning as its fundamental process (Lundvall, 1992, 2007). Such learning requires actors to be able to integrate both codified and tacit knowledge and apply it productively (Dosi, Nelson and Winter, 2000). Effective learning in turn affects actors' capabilities to combine knowledge and to facilitate institutional and market embedding through the creation and use of valuation resources (Binz and Truffer, 2020). This learning needs to be both individual and organisational (Soete *et al.*, 2010; Watkins *et al.*, 2015).

It is firms' internal resources which provide them with their competence for learning and other capabilities, according to the resource-based view of firms (Prahalad and Hamel, 1990; Nelson, 1991; Barney, 1991; Teece, Pisano and Shuen, 1997). The internal resources which provide these capacities include human resources, intellectual resources, financial investment, equipment and other physical resources (Barney, 1986; Wernerfelt, 1984, 1995). In addition, Teece (1998) suggests that firms' innovation rate and strategy is impacted by their formal structures, cultures and values, and external relations.

The typology proposed by Mintzberg (1979) synthesised much of the existing work on the relationship between organisational structure and capabilities, including Burns and Stalker (1961) and Lawrence and Lorsch (1967). As Hodgson (2006) emphasises, however, organisations are not homogenous, but consist of individual actors. These actors' different perceptions, interests and skills are likely to lead to various degrees of conflict. This is not to say that organisations cannot be treated as single actors, especially with respect to their ability to reach and act on decisions (Hindess, 1989). We need, though, to understand that this potentially conceals conflicts (Hodgson, 2006), as we will explore in detail in Chapter 8. Nonetheless, with that caveat, Mintzberg's typology provides a useful framework for understanding organisational types. For each of Mintzberg's archetypes, Lam (2005) sets out their innovation potential. These are shown in the following table:

Table 3: Mintzberg's structural archetypes and their innovative potential (Lam, 2005)

Archetype	Key features	Innovative potential
Simple structure	An organic type centrally controlled by one person but can respond quickly to changes in the environment, e.g., small start-ups in high-technology.	Entrepreneurial and often highly innovative, continually searching for high-risk environments. Weaknesses are the vulnerability to individual misjudgement and resource limits on growth.
Machine bureaucracy	A mechanistic organisation characterised by high level of specialisation, standardisation, and centralised control. A continuous effort to routinise tasks through formalisation of worker skills and experiences, e.g., mass production firms.	Designed for efficiency and stability. Good at dealing with routine problems, but highly rigid and unable to cope with novelty and change.
Professional bureaucracy	A decentralised mechanistic form which accords a high degree of autonomy to individual professionals. Characterized by individual and functional specialisation, with a concentration of power and status in the 'authorised experts'. Universities, hospitals, law, and accounting firms are typical examples.	The individual experts may be highly innovative within a specialist domain, but the difficulties of coordination across functions and disciplines impose severe limits on the innovative capability of the organisation as a whole.
Divisionalised form	A decentralised organic form in which quasi-autonomous entities are loosely coupled together by a central administrative structure. Typically associated with larger organisations designed to meet local environmental challenges.	An ability to concentrate on developing competency in specific niches. Weaknesses include the 'centrifugal pull' away from central R&D towards local efforts, and competition between divisions which inhibit knowledge sharing.
Adhocracy	A highly flexible project-based organisation designed to deal with instability and complexity. Problem-solving teams can be rapidly reconfigured in response to external changes and market demands. Typical examples are software engineering firms and professional partnerships.	Capable of fast learning and unlearning; highly adaptive and innovative. However, the unstable structure is prone to short life, and may be driven over time toward the bureaucracy.

(Lam, 2005, p. 9)

Mintzberg and Lam focus on firms, but we suggest that, as the system of innovation approach has recognised the importance of a much more diverse set of actors for

innovation, so too may be Mintzberg's archetypes applicable to any organisation which manages resources for innovation, including donors.

The resource-based view has been criticised for not explaining the mechanism by which organisational resources translate into comparative advantage (Williamson, 1999; Priem and Butler, 2001). Providing that explanation is the dynamic capabilities framework, which posits that the ownership of resources is not sufficient for superior performance in the long run. Rather, an actor's comparative advantage derives from its ability to coordinate and combine (or relinquish or acquire) its resources, to respond quickly to new opportunities. This implies that an organisation's ability to bring capabilities to innovation relies on the effectiveness of the internal management of its resources (Pisano, 1994; Grant, 1996; Teece, Pisano and Shuen, 1997; Eisenhardt and Martin, 2000).

Such management entails continuously reviewing and evolving an organisation's resource base to ensure it is optimally configured and able to respond to further changing user needs and technological opportunities. Importantly, this includes the ability to identify emerging opportunities or threats, and to understand the resource implications of these in order to respond to them. Management then needs to ensure effective processes to move resources accordingly, all within a context of uncertainties. As Fueglistaller and Schrettle (2010) write in their review of Teece (2009), 'it is the management that makes knowledge useful and skilled workers productive' (p. 523), and therefore plays a key role in innovation. Dynamic capabilities are idiosyncratic to an organisation but are themselves path dependent (Teece, Pisano and Shuen, 1997; Eisenhardt and Martin, 2000).

The dynamic capabilities framework arose from empirical observation that some firms, despite having accrued a large resource-base, do not gain a comparative advantage in the market. Rather, the most successful firms are those with the management capability to quickly and effectively coordinate and redeploy internal resources to ensure quick and flexible product innovation. Dynamicism is particularly important for firms when the external environment is changing rapidly, and the nature of the future market is unknown (Teece, Pisano and Shuen, 1997).

The dynamic nature of capabilities makes particular sense within a system, in which decisions about actors' strategies and activities need to take into account those of other actors. For this interdependency to function effectively, within the distributed coordination of an innovation system, requires a continual adjustment on each

actor's part in order to ensure that it continues to play a complementary role with respect to others, and that any path-critical gaps are being filled. This is consistent too with the emphasis on learning fundamental to the innovation system approaches. With the innovation systems approach explaining innovation as involving a broad set of actors, there is no reason why the dynamic capabilities concept could not be applicable to this broader set of actors beyond firms.

### **3.7 Conclusion**

The chapter has argued that the systems of innovation approach provides several important explanatory elements for this research, but that neither the national system of innovation (NSI) model nor sectoral system of innovation (SSI) model is sufficient alone to explain the global level dynamics at play within international development. The nascent global innovation system (GIS) model incorporates the concept of the NSI, which has the advantage of capturing the NSI focus on the national level of actors and institutions which represents a necessary level through which to engage with beneficiaries of innovation, with the user-producer linkages at this level as being important to collective learning.

The GIS model also introduces significant new concepts which are promising in explaining some of the specific innovation within international development. The first such GIS concept is that of system resources: of knowledge being a resource, and of three *valuation resources* of market access, financial investment and innovation legitimacy. In these alternative valuation paths, the GIS model offers greater potential than do other models to explain the dynamics of an innovation system in which there is not a well-functioning market. In particular, the resources provide for alternative means of generating value other than through market access, with donors, for example, driving supply through the provision of financial investment, or by legitimising innovations based on their donor-assessed relevance.

Secondly, the GIS concept of sub-systems enables explanation of the relative roles and relationships between different spatial levels. Essentially, these different spaces exist to create resources, and each operates as a sub-system within the overarching system. The institutions, actors and interactions within each sub-system vary, and provide each with a distinct comparative advantage, such that different resources are created at the different spatial levels. This model incorporates the national level sub-system as an important sub-system.

Thirdly, the GIS concept of structural couplings between sub-systems enables explanation of donor roles as a means of combining resources within the overarching system. The organisational typology of Mintzberg (1979), and Lam's (2005) assessment of each archetype's innovation potential provide a useful framework for understanding actors' different capabilities in resource management. This is complemented by the concept of dynamic capabilities of Teece, Pisano and Shuen (1997). We argue that their concept is applicable to systems of innovations, because it explains how the distributed coordination fundamental to an innovation system is obtained and maintained. Furthermore, the multiple resource flows described within the GIS model and the associated requirement upon actors for active management of these make the concept of dynamic capabilities particularly relevant.

## **4 RESEARCH METHODOLOGY**

Recognising the fundamental importance within the research topic of both scientific knowledge, and of actors' interaction and interpretation of that which they perceive, this research adopts a critical realist philosophy, within which it uses abductive explanatory logic. Because the empirical data is in-depth, contextualised, and qualitative, the research design adopted is that of a multiple case-study of donor organisations, using triangulated, mixed-methods data collection. The resulting data set is interrogated using thematic analysis and is assessed for research validity and reliability. The research methodology also considers the position and perspective of the researcher, as being inseparable from their research (Saunders *et al.*, 2009). It is particularly important in our research, given the employment of the researcher within the field.

The chapter is divided into four sections. The first addresses the research philosophy, including its critical realist ontological and epistemological positioning, and abductive explanatory logic, as these align closely to the fundamental concepts of the nature of the world manifested in international development. A multiple case-study approach is proposed in line with this philosophy. The second section explains the reasons behind our selection of cases. Data collection methods are explained in the third section as being semi-structured interviews, and document review, along with the strengths and weaknesses of these, and the ability to triangulate between them. Ethical considerations are also examined at this point, including the role of the researcher as working within the sector. Section four explains the data analysis techniques utilised in this research and assesses the quality of the research against established criteria.

### **4.1 Research philosophy**

This first section addresses the philosophy underpinning the main methodological choices for this research, including its ontological and epistemological positioning, which provide the basis to explain any link between observed data and emergent theory (Easterby-Smith *et al.*, 2008; Potter, 2013). Our research philosophy is driven by the nature of the world manifested in the broad area of international development, within which donors innovate, and the topic sits. In drawing elements from both realism and interpretivism, critical realism aligns most closely with the fundamental concepts of this domain, which emphasise both scientific truth and the importance of interaction in interpretation. Data is identified as being in-depth,

contextualised, and qualitative, and necessitating the use of abductive explanatory logic. The research design, of a case-study approach, follows both from the research philosophy and the nature of the topic as contemporary and complex.

#### **4.1.1 Ontological and epistemological background**

Our underlying philosophy is driven by the nature of the world manifested in immunisation development, within which donors innovate, and the research topic sits. A first fundamental characteristic of this work is the importance of scientific knowledge, seen in the common identification of innovation with research and development. Donors have over time reflected this consistently in their conceptualisation of scientific knowledge as a resource external, or independent, of the actor using it, and thus as representing a source of innovation transferable across contexts (Sampath and Roffe, 2012). This indicates a realist ontology, in which the world is regarded as governed by laws, independently of its observation or interpretation (Laws, Harper and Marcus, 2003; Potter, 2013). In contrast, in an idealist ontology, rather than universal laws or external causes, the 'social life-world' can only be understood through an observer's own frame of reference based on cultural and historical context (Gray, 2014). Research conducted based upon this philosophy primarily aims for understanding of individual perspectives but would limit the ability of this research to develop conclusions relating to cause and effect (Sayer, 1997; Laws, Harper and Marcus, 2003; Bryman, 2004; Gorski, 2013).

In its strongest form, realism combines with a positivist epistemology, which classifies knowledge as significant only if based upon observation of an independent external reality (Easterby-Smith *et al.*, 2008). This assumes that social phenomena are independent of human behaviour (Hussey and Hussey, 1997; Potter, 2013), which would limit the ability of this research to explore and understand the social dynamics around innovation systems.

However, the innovation systems approach explains that innovation is determined through interaction between actors, and that social structures, networks and institutions play an important, complex, role in innovation (Freeman, 1987; Edquist, 1997; Lundvall, 2007; Malerba and Adams, 2014). This highlights the importance of actors' perceptions, interpretations and even values and principles. It suggests the appropriateness of an epistemology which is interpretivist, in which social reality varies depending on the social interactions and dynamics at play at any time and in

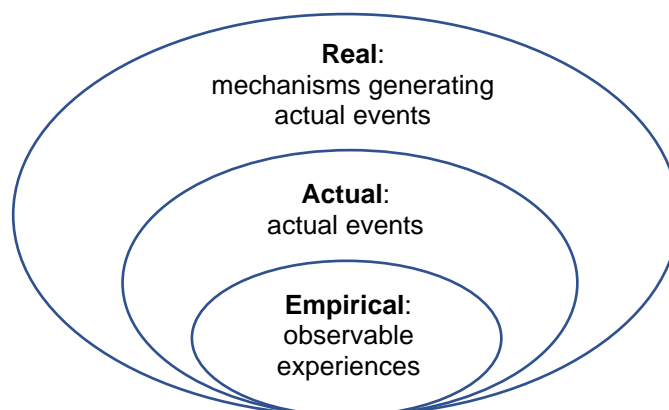


which knowledge, therefore, depends on the perspective of the observer (Laws, Harper and Marcus, 2003; Bryman, 2004; Jupp, 2006).

This combination of a realist ontology and interpretivist epistemology is the position of the critical realism conceived by Bhaskar (1975). This philosophy attempts to capture the explanatory power of the concepts of laws, and cause and effect, integral to scientific positivism. Ontological realism which asserts a reality independent of our knowledge of it, is at the heart of critical realism. Yet, this ontology is approached critically, in the sense of a recognition that empiricism is imperfect. Rather, the social world affects, in a highly complex way, our ability to perceive this reality accurately, if at all. Knowledge is dependent upon social, cultural and historical context and concept, and consequently is fallible. Being able to form explanations, therefore, necessitates a deep and broad understanding of the activities, structures and relationships of the relevant, complex, social world. This enables the critical realist to apply a judgmental rationality, to assess the relative value of alternative explanations about the world (Archer *et al.*, 2016):

Bhaskar (1975) reflects these principles in positing an objective reality consisting of three domains: the real, actual, and empirical, as illustrated in the figure below. These nested domains allow the application of the philosophy to social science as well as to natural science, by preserving the advantages of realism, and of interpretivism, whilst avoiding the *epistemic fallacy* of determining what is real based on what we can know.

Figure 16: Schematic representation of three domains of critical realism (Bhaskar, 1975)



The real domain consists of the entities and structures which independently exist, and the rules or mechanisms which determine how they interact, and which may

generate actual events. The actual domain is a sub-set of the real domain consisting of those events which result when generated by the interaction of entities and structures. The empirical domain is a sub-set of the actual domain, consisting of those events we are able to experience. Our cognition and interpretation of the world is ontologically real, but distinct from the actual events themselves, and it is fallible with respect to the actual events. This sense of a hierarchy of levels of reality is termed a doctrine of emergence (Bhaskar, 1975; Sayer, 1992; Wynn and Williams, 2012).

Critical realism, at the same time as recognising the existence of objective structures which constrain or enable actors, also recognises the reality of power relations within social structures, and that actors make subjective interpretations and responses (Wynn and Williams, 2012). This enables an understanding of the mechanisms of agency, with Easton (2010) proposing that critical realism enables research questions of the form 'what caused the events associated with the phenomenon to occur?' (p. 123). Thus, in critical realism, causal explanation of an event involves inferring how underlying structures, contextual conditions, and actors' interpretations have interacted to generate an event. Accordingly, research utilising critical realism is capable of explanation of the mechanisms causing an event, rather than predicting future events. Prediction would require determination of the breadth of specific precedents, which is not fully knowable within the critical realism philosophy (Ackroyd, 2010; Easton, 2010; Wynn and Williams, 2012). Critical realism recognises that it is possible to describe a range of empirical views of actual events, and even to conclude on a pre-eminent explanation, but not ultimately to know that this is the single, correct one (Roberts, 2001; Cox, 2013).

Of particular relevance in this research, given the centrality of the role of agency on the part of donors in seeking to innovate, critical realism holds that mental attributes, even though they are not directly observable, are part of the real world (Maxwell, 2012). Because critical realism separates the causal properties of an event from its surroundings, this allows for objective analysis of the role of social structures (Gorski, 2013).

#### **4.1.2 Explanatory logic**

Within the identified research philosophy, an explanatory logic connects empirical data with theory, whether pre-existing or emergent. This may be one of three logics: deductive, inductive or abductive.

Deduction is the application of a rule to a given set of circumstances, as a result of which a particular effect must result. The simplest form of deduction, that of modus ponens, is of the form 'if A then B; given A, therefore B'. The use of deductive logic in research involves testing new data against an existing theory, in order to strengthen the theory or refute it in line with Popper's principle of falsification.

Induction is the proposition of a generalised conclusion about events in the world based on a pattern identified in specific observation. For example: 'of a sample, proportion P has attribute A; therefore, of the population, proportion P has attribute A'. Induction doesn't involve theorising about the cause of the observed pattern, or about the existence of patterns not represented in the empirical data.

Abduction is the proposition of a theory, the simplest or most likely theory, to explain a generalised conclusion about events in the world based on a pattern identified in specific observation (Ritchie, Spencer and O'Connor, 2003)

The fundamental characteristics of the critical realism philosophy have implications for the choice of explanatory logic adopted in research based upon it. Of particular relevance is the ontology based on an independent reality with cause and effect between real (but not necessarily actual) events; and the epistemology of many possible explanations, some of which may not be empirically observable. In this case, the appropriate choice of explanatory logic is that of abduction (though within the critical realism literature this tends to be referred to as *retroduction*) in which an existing theoretical mechanism is adapted or new theoretical mechanism<sup>9</sup> proposed which, 'if it were to exist and act in the postulated way would account for the phenomenon in question' (Bhaskar 1975, p. 12). This tends to involve considering a range of possible mechanisms which might explain the empirical data. The choice of the best of these involves establishing a mechanism which is sufficient to cause the observed effect, does so most exactly and simply, and is reasonably believed to have been actually present (Sayer, 1992; Wynn and Williams, 2012). In this process

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<sup>9</sup> Strictly, explanation based on the application of a previously-identified mechanism is *retrodiction*, and the identification of a new mechanism is *retroduction*. But in practice the subsequent term is often used for both, and is the equivalent of abduction (Wynn and Williams, 2012)

of *empirical corroboration* we also refine the understanding of the contextual conditions in which a mechanism operates, thereby simultaneously strengthening the theoretical mechanism itself. Importantly, given the wide range of relevant variables identified in our literature review, such corroboration involves using the full spectrum of data, including that relating to social dynamics, actor agency and cognitive institutions, all of which are legitimate factors within a proposed mechanism. The different properties of these variables, and the subjectivity implicit in interpreting them means that the use of multiple data collection methods and triangulation in data analysis is important (Wynn and Williams, 2012).

Such an explanatory logic necessitates a qualitative approach, allowing a richness of information such as to generate a particular explanatory power (Holland and Campbell, 2005). This enables well-founded and nuanced observations and interpretations, taking into account the socio-cultural characteristics (Ritchie, Spencer and O'Connor, 2003; Jupp, 2006; Denzin, 2010). In the context in which linkages are not known (nor is the extent to which they are not known, known) a qualitative approach facilitates the revealing of these (Hussey and Hussey, 1997).

A research question consistent with this research philosophy would be of the form 'What caused the events associated with the phenomenon to occur?' (Easton 2010, p. 123). A retrospective causal question of this form establishes a focus on the identification of mechanism in a specific context. This is indeed the case in our research, in which the central question is 'what role do donors play with respect to innovation in immunisation for international development?'

The conceptual framework highlights the important determining role of non-quantifiable factors including the institutional environment, nature of actor interactions, and role of knowledge. Methodologically, these argue for a primarily qualitative empirical method, given the ability of this method to draw from descriptive data to nuance ambiguities, and provide contextual detail. The resulting research design is discussed in the following section.

## **4.2 Research design**

### **4.2.1 Case-study approach**

In general, the choice of research design depends primarily on the nature of the research question (Yin, 2009). We have already seen that our research necessitates a qualitative approach, capable of identifying both structural elements and subjective

interpretations of actors. The literature and context examined in Chapter 2 further emphasises that the research topic involves a complex, contemporary, real-world setting, rather than, for example, one conducive to a laboratory or other controlled environment. The boundaries between the phenomenon of donor-driven innovation and this context are not known in advance of the research. These characteristics suggest the use of a case-study approach. Such an approach is more than just a means of empirical data collection, being rather an overall research design (Stoecker, 1991).

A case-study is:

An empirical enquiry that investigates a contemporary phenomenon in depth and within its real-life context, especially when the boundaries between phenomenon and context are not clearly evident (Yin, 2009, p. 18).

The strength of a case-study approach is in explanation of a complex contemporary real-life phenomenon within important contextual conditions (Yin, 2003; Lewis, 2003). This is more than just the data-management exercise Langrish (1993) implies when he refers to 'unravelling causation'. Rather, the relationships between cause and effect may themselves be iterative and indirect. This is certainly the expectation based on the literature relating to innovation in international development. A case-study is particularly useful in this context because it allows the use of multiple sources of evidence, enabling triangulation between data, and iteration against the research question and theoretical propositions to refine data collection and analysis (Keddie, 2006; Yin, 2009, 2013).

Moreover, a case-study approach also allows for comparison between a number of cases or of analytical units for the examination of similarities and differences. This strengthens the validity and generalisability of results, based on a literal replication (similar results given similar factors), or a theoretical replication (contrasting results for predictable reasons) (Yin, 2003).

Criticism of a case-study approach revolves around research validity and reliability, related to the high level of discretion and judgement residing in the researcher, compared to other research methods. Validity concerns are based on an elevated risk of bias (Dooley, 2002; Yin, 2003; Jupp, 2006). Such bias may be direct, in terms of the researcher's objectivity with respect to the case itself; or indirect, in terms of the researcher's possible over-reliance on particular pieces of evidence, at the expense of other evidence (Schwandt, 1997; Ritchie, Spencer and O'Connor, 2003;

Yin, 2003; Silverman, 2013). The fact that interviews represent a common means of data collection in case-studies introduces a further challenge to the validity of the research method, through the dynamic between the researcher and the informant. Reliability concerns are based on challenges in replication of the research: that another researcher's use of the same data collection methods for the same cases would result in the same findings and conclusions (Yin, 2003).

Mitigation of each of these risks includes a high level of detail in the establishment of protocols in advance of empirical data gathering, of record-keeping of the processes followed and of the data obtained (Schwandt, 1997; Dooley, 2002; Yin, 2003; Silverman, 2013). In addition, mitigation is provided through the triangulation of data obtained both from the assimilation of data from multiple sources, and the use of several types of data, as is enabled within a case-study approach (Olsen, 2004; Gray, 2014). Yet Flyvbjerg suggests persuasively that as a result, in fact, the typical researcher adopting a case-study approach finds that they have to revise their understandings, rather than being expecting to be simply confirmatory. The level of depth involved in a case-study approach is so much that it is essentially impossible to boil down to a simple answer which lends itself to a confirmatory bias (Flyvbjerg, 2006).

A more fundamental weakness to a case-study methodology, generally, is in the extent to which conclusions are generalisable, especially when the number of cases is small. In general, the strategic selection of cases can significantly increase the power of a case-study approach, through the selection of cases which allow for theoretical generalisation (Flyvbjerg, 2006). However, a single case-study may be justified if a case is particularly unique within a domain, or if critical to the testing of an existing, well-formulated theory. This is a consideration not, therefore, about statistical representation but about theoretical generalisation. Within a critical realist philosophy, research is often on a limited number of cases within a specific context, in order to focus on identifying an explanatory mechanism which explains empirical data as closely as possible (Sayer, 1992; Wynn and Williams, 2012).

This can be mitigated instead by the integration into the research design of an established conceptual framework (Yin, 2003), especially when combined with a multiple-case approach which demonstrates conceptual or theoretical alignment across multiple contexts (Miles and Huberman, 1994), as long as these cases are 'systematically contrasted yet contextually grounded' (Miles, Huberman and Saldana, 2014, p. 67).

The choice of cases is explained in the following section.

#### **4.2.2 Case selection**

Within a case study approach, the selection of cases is a vital subsequent step (Gerring, 2004). This research uses theoretical sampling in the selection of cases, which are chosen to best illuminate the research questions, either by replicating other cases, or by extending emergent theory. This approach follows Eisenhardt (1989), who explains the random selection of cases fundamental to statistical sampling as ‘neither necessary, nor even preferable’ (p. 537).

Cases should be selected based on the research topic and question, and with reference to the conceptual framework (Yin, 2009). The primary question in this research is framed in terms of the role of donors, suggesting that each case be a donor organisation. That is not to say that all innovation in immunisation involves donors, nor that every donor is involved in innovation. Our literature review, however, has shown that donors play various roles in innovation in immunisation, with priorities and approaches variable between donors. Donor organisations represent the coherent cases required for case study, and are selected based on expectations as to their value in providing understanding pertinent to the research question (Flyvbjerg, 2006).

In this research, the selection criteria for the cases are based on the research question, ‘what role do donors play with respect to innovation in immunisation for international development?’. Thus, to be selected as a case, an organisation must be i) a donor; ii) contributing significantly to immunisation; and iii) involved in innovation.

Concerning the criterion of being a donor in international development, the indicator adopted is that of being a reportee to the OECD Development Assistance Committee (DAC). As we saw in Chapter 1, there are currently 30 DAC member countries and 25 associate countries. In addition to these bilateral donors, 65 multilateral donors and 39 private foundations also report their development assistance to DAC (OECD, 2022c). Together, these 150-odd donor organisations provide more than 95% of total development assistance (OECD, 2022a). For the purposes of this research, we regard the set of organisations reporting on development assistance to DAC as representing a comprehensive list of donors in international development.

For the second criterion, that of contributing significantly to immunisation, we identified in Chapter 1 the three largest donors in recent years as being Gavi, UNICEF and the Bill and Melinda Gates Foundation (BMGF). Furthermore, we identified these as being significant also for other reasons.

Gavi, the Vaccine Alliance, alone provides 50% of the total development assistance to immunisation, representing US\$1.7 billion in 2014 (Haakenstad *et al.*, 2016). As an organisation, it is dedicated to the mission to increase equitable use of vaccines in less economically developed countries (LEDCs) (Gavi, 2022b). Equitable use, for Gavi, means that no infants in those LEDCs are excluded from access to those vaccines. Coordination of the alliance is by a 400-strong Secretariat based in Geneva, Switzerland. Across the breadth of its strategic goals in immunisation, Gavi describes a particular comparative advantage in enabling 'implementation at scale', examples of which are the number of children it has enabled countries to immunise (700 million by the end of 2018) and the number of new vaccine introductions it has supported in countries (400 to end-2018) (Gavi, 2018a, p. 2). The basis upon which Gavi claims this advantage is related to its market reach, in purchasing vaccines for 60% of the world's birth cohort (Boran, 2018).

BMGF, as well as being the founding funder and largest contributor to Gavi, has donated significant funding to a wide range of other actors in immunisation for international development over the last 20 years. Moreover, BMGF has brought to the sector new approaches based upon a 'single-mindedness and hard-boiled business habits' which are radical within global public health (Nature, 2003, p. 435). BMGF's narrower accountability and higher risk-appetite than traditional actors in global public health provides it with perhaps unique capabilities to engage with longer-term, earlier-stage vaccine research and development.

UNICEF is also an important donor in immunisation, both because of the scale of its support, and because of its reach. UNICEF works in 190 countries and 85% of its 13,000 staff are based in its seven regional and 124 country offices. UNICEF regards immunisation as a right guaranteed by the Convention on the Rights of the Child and supports immunisation across almost all its country programmes, with about 650 staff dedicating most of their time to immunisation (UNICEF, 2018a, p. 16). In addition, UNICEF works with these predominantly LEDCs to identify and procure for them 2.5 billion vaccine doses, often Gavi-financed, for almost half the world's children (UNICEF, 2018a, p. 16). UNICEF also claims a strong culture of



innovation, suggesting that its 'ability to evolve and innovate [is] one of its major strengths' (United Nations, 2017a, p. 28).

For the third criterion, that of involvement in innovation, grey literature of the three primary candidates were further examined for reference to key terms 'immunisation' or 'immunization' and 'innovation'. Concerning timeframe, the innovations were considered as contemporary if still relevant under the organisations' current strategy. The findings are shown in Appendices A to C. These indicate a broad and diverse set of innovation initiatives, including both one-off events (e.g., the creation of Gavi) and broad types (e.g., private sector engagement) as well as individual initiatives. In so doing they represent a preliminary assessment of the set of initiatives that form the focus of study of each case.

Analysing the application of the criteria for case selection leads to the conclusion that three organisations meet all three criteria: Gavi, BMGF and UNICEF. These three donors are not the only donors within immunisation. Due, however, to respectively, their reach, scale and leverage, they are particularly instrumental for innovation in immunisation. Accordingly, it is these three donors which were selected as the cases for this research.

### **4.3 Data collection**

The case-study approach allows a wide range of types of data collection methods (Dooley, 2002), with the choice, again, to be determined by the research philosophy, question and context (Yin, 2009). Our adoption of critical realism as research philosophy brings particular implications because it describes an independent reality with the possibility of multiple mechanisms, which can only be partially and fallibly observed. Moreover, the structures involved in these mechanisms may be of a wide variety of type, physical, social, normative, cognitive, for example, with very different properties. The use of multiple viewpoints in critical realist research is for two-fold facilitation: firstly, to overcome the epistemological limitations implicit in the emergent, stratified form of reality; and secondly, to provide tools capable of examining the widest range of structure properties in any one strata (Wynn and Williams, 2012).

To these reasons must be added a third, associated with the use of semi-structured interviews within a case-study methodology: which is to try to control for the existence of bias on the parts of the individuals, both key informants and researcher.

Informants may hold personal prejudices, may suffer poor or inaccurate recollection, or may struggle to articulate issues. Consequently, methodological triangulation is adopted, in which a second data source type is used to collect different but complementary data, concurrently but separately, before both feeding into data analysis (Morse, 1991).

The explanatory research question ('how...') necessitates a data collection approach capable of examining the topic in detail, as well as to explore unexpected angles or paths as and when these might arise. Triangulation is enabled through the use of a document analysis as a second data source type.

Two other data collection methods were considered and subsequently discarded. Focus groups enable a wide range of ideas on a discussion topic, with participants able to respond to others' points. They are, however, limited for in-depth investigation into particular aspects illustrated by experiences not shared across the whole group. It can also be harder for individuals to express contentious or sensitive views. With a large number of different manifestations of donor-fostered innovation having been apparent from the cases and criticism emerging of some donors' approaches, it was felt that individual interviews were more likely to provide more useful data.

A questionnaire was also briefly considered, to enable the gathering of a much larger set of views, in complementarity to more specific qualitative data. Again, however, with innovation apparently both manifesting in detailed exemplars and sensitive considerations, it was decided that a survey would not be appropriate.

This section discusses each of the selected data collection techniques in detail. Ethical considerations are also examined in this section, including in particular the role of the researcher as an employee within the sector.

#### **4.3.1 Semi-structured interviews**

Semi-structured interviews involve a pre-determination of topics and guiding questions, with the researcher modifying the use, extent and order of these, or introducing additional questions, based on the emergent direction of the guided conversation (Rabionet, 2011). This allows for the collection of rich data based on individual perspectives. It has the advantage of accessing high-quality data from expert informants in an efficient manner, allowing the clarification or follow-up of particular responses (Gray, 2014). Their usual face-to-face setting allows the

building of rapport and confidence between researcher and informant and also enables the taking into account of non-verbal communication or reaction (Yin, 2003). The semi-structured nature balances researcher control of the general content and pace of the interview with the ability for the interviewees to express their views on particular aspects, in an order and emphasis natural to the flow of the conversation and in their own words (Woodhouse, 1998). It provides sufficient space for respondents to identify concepts or views which had not been anticipated by the researcher. It also enables a systematisation of the data collected through these interviews, enabling a consistency and perhaps comparison across multiple cases and facilitating data analysis.

This is in contrast to more extreme forms of interviews, with too highly-structured and formal interviews leading informants to respond narrowly, limiting nuance and eliminating exploration of new avenues (Piore, 2006). Conversely, entirely open-ended interviews are much more dependent upon real-time facilitation by the researcher and consequently risk challenges in generating relevant and comparable material (Piore, 2006).

To facilitate this semi-structured format, an interview guide was developed (provided as Appendix D) based upon the research question and conceptual framework, following the approach of Eisenhardt and Graebner (2007). Accordingly, the questions explored donor strategy and role in immunisation for international development, as well as dynamics around knowledge and valuation resources, donor interactions with other actors, the influence of institutions, and the impact of donor organisational characteristics. Wherever possible, specific examples were asked of the informant to illustrate points they were making, and these examples further interrogated as necessary.

An initial set of informants was selected in advance, on the basis that by virtue of their post or role, these individuals would have insights into the research sub-questions as they relate to one of the donor cases. These included those responsible within the donor organisations for driving innovation, such as top managers and those leading on strategy-development. Also included were donors' staff involved in implementing innovation initiatives, including front-line field officers, and monitoring and evaluation officers. In addition, several interviews were conducted with key informants who work closely with the donor cases but are not their staff members. This included members of partner organisations and immunisation officials from recipient governments. In this way, the selection of

informants was intended to meet the suggestion of Shadish, Cook and Campbell (2002) to 'include instances chosen deliberately to reflect diversity on presumptively important dimensions, even though the sample is not formally random' (p. 23).

Following this purposive selection process, during the course of the research, further participants were identified through a snowball method, in which respondents were asked at the end of their own interview whether they could recommend other key informants for the research. In following these up, the guidelines proposed by Dexter (2006) were adopted: to request introduction by an intermediary, but averting provision of their own explanation of the research, to avoid bias.

As a result of these approaches, a total of 42 key informant interviews were conducted. The total number of such interviews was not determined in advance of the process. Rather, they continued until the point at which marginal new data gains were being achieved from further interviews. The following table shows the breakdown of interviews conducted across each organisation

Table 4: Breakdown of interviews conducted across organisations (Author)

<b>Organisation</b>	<b>Count</b>
UNICEF	11
BMGF	10
Gavi	14
Other global partner	3
Recipient government	4
	42

The order in which the interviews was conducted followed in general a pattern of interviewing first those informants in each donor organisation primarily involved in innovation strategy, before proceeding to those responsible for implementation. The majority, 34, of the interviews took place face-to-face; with 8 being conducted by videoconference. In each case, the participants were in a familiar setting: their own workplace, or a meeting room in a conference facility. This was purposeful, in order to minimise logistical barriers to their participation, and to enable them to be more relaxed and hence engaged. The duration of interviews was determined by the

participant's extent of knowledge and willingness to discuss issues, and varied between 30 and 90 minutes, with the average duration being 55 minutes. The interviews were all recorded, with each participant having given their informed written consent to this.

Each interview was subsequently transcribed, adopting standard protocols, with the use of brackets to indicate any words added to clarify meaning; and dots to indicate a break in flow. No substantive words were cut out, but the transcripts were edited to add punctuation and remove filler words ('um', 'uh', 'you know', etc). Transcription was performed by the researcher themselves, consistent with Braun and Clarke's (2006) assertion that this is the first step in familiarity with the data. The transcripts are separately available, as Yin (2004) suggests, independent of the researcher's interpretations and analysis. This chain of evidence is be maintained to increase reliability, by allowing a putative reader to follow the derivation of evidence from research question to conclusion, or indeed, to work backwards.

#### **4.3.2 Document review**

Complementing the academic literature review and the semi-structured interviews, data was collected through a review of grey literature relating to the research topic (Yin, 2003; Wharton, 2006;). Such data is able to provide context which allows for more informed exploration during conversations with key informants. It may also be evidential, which allows for triangulation against the emergent theory from those interviews (O'Laughlin, 1998; Jentoft and Olsen, 2019).

In this research, grey literature was identified initially through searches on the websites of the case study donors. From these webpages or documents, further relevant grey literature was identified on linked websites or related organisations, akin to the snowball method adopted to identify key informants. A total of 212 documents were analysed. These were primarily from two types of sources. Donors themselves produce a wide range of material such as annual reports, board papers, policy documents and press releases. Complementing this is non-academic material written about donor-fostered innovation by others, such as independent evaluation, media articles or industry commentary represents the second source of empirical data.

Documents were analysed through the perspective of the research question and conceptual framework. Themes examined included donor strategy and role in

immunisation for international development; as well as dynamics around knowledge and valuation resources, donor interaction with other actors, the influence of institutions, and the impact of donor organisational characteristics. Wherever possible, specific examples of innovations were noted and further researched where necessary.

Grey literature, though, must be critically appraised too, in terms, for example, of its intended audience, purpose, politics, authors and remit (O’Laughlin, 1998). Donor documentation, though very relevant, is open to bias, given that documents are written for a specific purpose, and often a specific audience, for example the taxpayers who ultimately provide the funding for bilateral donors.

This is exacerbated by the modern world’s context to research, in which information is more readily accessible than ever before, but in which the manipulation of information to suit particular agendas is also more prevalent (Ruane, 2016, in Croxton).

This research in consequence tends to rely on them not as a literal recording of events, but rather to corroborate and build-upon evidence from other sources; to suggest avenues for further investigation; and occasionally for inference based on meta-data. The types of donor documentation utilised include publicly available strategy documents, project implementation documentation (both public and private), public communications material (including for example, press releases, articles, interviews), and reviews or evaluations.

### **4.3.3 Reflexivity and ethics**

The selection of Gavi as a case gave rise to various ethical considerations by virtue of the researcher’s position as a staff-member of Gavi. Understanding and addressing these starts with the process of reflexivity, which is the recognition on the part of the researcher of the effect they themselves inevitably have on the research (Thomas, 1998). It was important therefore for the researcher to have reflected on ‘how does who I am, who I have been, who I think I am, and how I feel affect data collection and analysis’ (Pillow, 2003, p. 176).

The researcher’s proximity to the research topic can help to produce findings which are more informed and more valid (Altheide and Johnson, 1998), but it also brings risks which need to be managed. These advantages and risks can be understood in terms of informational and relational aspects.

Firstly, familiarity with the concepts, terminology, strategies and actors enables the researcher quickly to understand and contextualise key informants' points, and then to explore them further in discussion with the key informants. Moreover, such familiarity can equip the researcher to understand informants' unspoken implications or omissions which can add further insight on what may be more sensitive points. The associated risk is that the researcher comes to the topic with pre-conceived ideas or assumptions which may influence their direction of questioning or even their conclusions. Mitigating this involved the researcher firstly recognising and acknowledging it as a risk, so that the researcher could consciously try to avoid being so swayed, though complete objectivity is unlikely to be achievable in such situations (Thomas, 1998; Snape and Spencer, 2003). In addition, the use of multiple data source types and the triangulation which this enabled, reduced the risk of unconscious bias on the part of the researcher affecting the research findings.

Secondly and relationally, the shared professional context between a researcher and key informant can enable higher levels of empathy between them, which Lewis (2003) suggests can result in richer data. The associated risk is that the cultural proximity between researcher and informant leads to shared assumptions being unexplored (Lewis, 2003). Mitigating this, the interview guide served to provide a semi-structured format which facilitated systematic consideration of each discussion topic. As a potentially greater risk, informants may feel constrained in their ability to be critical of Gavi or other actors because the researcher is a staff-member of Gavi. Mitigation of this was through the protection provided by the confidentiality of informants, and their informed consent to take part on that basis. All participants were required to read an information sheet before completing the consent form (provided as Appendices E and F). Interviewees were given the option on the consent form that the data they provided be identified in the research either to them by name; anonymised to organisation and generic area of expertise (e.g., 'a senior country manager in Gavi'); anonymised to organisation only; or fully anonymised. Interviews were recorded with participants' explicit permission and the tape transcribed in full, before being anonymised through use of a coding system, in accordance with participants' confidentiality preferences. During the course of the research, softcopy data was stored in a password-protected secure electronic folder, and hardcopy in a locked cabinet. Raw data, including interview recordings, researcher notes and the coding linking participant names to anonymised transcripts, will be retained until one year after the conclusion of the research. Transcribed data, anonymised per participant instructions, will be deposited in a

specialist data centre, so it can be used for future research and learning, for a period of ten years after the conclusion of the research.

The researcher themselves faced a similar challenge to the informants, in potentially being constrained in their ability to be critical of Gavi. In the researcher's case, non-attribution of views was not a feasible mitigation. Rather, mitigating this involved the researcher obtaining the approval of the relevant Gavi managing director to carry out this research, and proactively sharing with them emerging research themes, including any potentially critical findings. Further mitigation was provided through Gavi's organisational culture as a critical-thinking and learning organisation, which makes criticism acceptable and indeed, welcomed.

This research follows the Open University Code of Practice for Research and Ethics Principles for Research Involving Human Participants and the ESRC Framework for Research Ethics (FRE). The research proposal was reviewed by, and has received a favourable opinion from, the Open University Human Research Ethics Committee, reference number: 2896.

## **4.4 Data analysis**

Once the data collected from the semi-structured interviews had been transcribed and the documents reviewed had been marked-up to indicate relevant topic sections, this data was analysed, understood as the 'process of taking things apart and putting them together again...[and] linking the material from respondents with the original questions' (Laws, Harper and Marcus, 2003, p. 381). This is an iterative process involving repeated review of the data, categorisation, and theorisation (Yin, 2003), as a result of which concepts not initially apparent with the data, especially qualitative data, become clearer as themes (Laws, Harper and Marcus, 2003). Particularly with multiple-case studies, the volume of data can be challenging, entailing a close focus on the research question (Eisenhardt, 1989), as well as a focus on the themes identifiable across the cases. This also increases the applicability of any resulting theory (Miles, Huberman and Saldana, 2014).

### **4.4.1 Thematic analysis**

The data analytic approach is that of thematic analysis, which involves the search for patterns within the data through an iterative process of reading of the interview transcripts and documents, annotating on the basis of themes and comparing these across the data set for coherence and consistency. At the same time, though, the



analysis must remain open to exceptions, new themes, or gaps in the data (Laws, Harper and Marcus, 2003; Braun and Clarke, 2006). Proactively checking assumptions and retaining reflexivity are important in being able to do this (Dooley, 2002; Spencer, Ritchie and O'Connor, 2003).

The analytic approach taken in this research was that of thematic network analysis. This hermeneutic approach involves coding the transcript for common themes, which, with any emergent sub- or overarching themes, are used to generate a thematic map to explain the empirical findings, under three categories: global themes, organising themes, and basic themes (Attride-Stirling, 2001). The thematic analysis uses the six-stage process of Braun and Clarke (2006); supplemented with Patton's (1990) dual criteria for judging themes: internal homogeneity and external homogeneity.

Various possible approaches to data analysis were considered. Approaches which involved a successive review of cases, such as interpretative-phenomenological analysis or constructivist grounded theory were disregarded on the basis that the conceptual framework places focus on actor interactions, necessitating a view across those (Rapley, 2011)

Framework analysis and thematic analysis were both considered, and the final method adopted utilised elements of each. Framework analysis involves doing an initial framing of anticipated themes and sub-themes, based on the research questions and conceptual framework. These are then used to annotate the transcript of document. The results of this are then included in a grid and sorted, to allow for the development of categorisations of findings (Rapley, 2011). For example, impact was frequently mentioned as a reason for a donor to foster innovation. Some data was relevant to two categories, in which case, it was presented against each.

In thematic analysis, a system of codes, themes and categories is also used to identify, interpret and describe patterns (Boyatzis, 1998; Braun and Clarke, 2006; Gray, 2014). Although it is ideal to identify a theme in multiple instances in the data set, the finding of more instances does not necessarily make the theme more important than others (Braun and Clark, 2006). Rather, their relevance to the research question is what determines importance.

Thematic analysis may be conducted in one of two primary approaches. An inductive approach is 'bottom-up' from the data, whereas a theoretical analysis is 'top down', from an initial theory. In this research, the more exploratory, bottom-up approach is adopted, in iteration with the overall guiding conceptual framework. The

process of collating themes necessarily involves some loss of complexity, but in the cause of greater explanatory power, and can be mitigated through descriptive richness across the cases, which is valuable especially in a relatively under-researched area like this one (Braun and Clark, 2006).

Using Braun and Clark's six-stage approach, codes were applied to a word, phrase or longer section of text (Belk, Fischer and Kozinets, 2013) when these identified a fact of possible relevance. From this themes and sub-themes, or 'patterns of meaning' were identified, then challenged, checked again against the data and the research question, and defined or modified as needed. This interpretive process followed the inductive logic identified as appropriate in this research (Braun and Clarke, 2017). At the conclusion of this process, the themes were again checked as being clear, with the selection of examples or quotations which illustrated each theme, embedded within the overall analytical narrative.

#### **4.4.2 Validity and reliability**

The process of analysis of the data has an important bearing upon the research validity and reliability. Validity of research is the degree to which it represents what is happening in the actual events (to use the critical realist term) being researched. Reliability of research relates to the replication of its findings if the research were repeated (Hussey and Hussey, 1997). These concepts have been raised already in discussion of the adoption of a case-study approach, because it places higher levels of discretion and judgement upon the researcher, compared to other research methods (Schwandt, 1997; Ritchie, Spencer and O'Connor, 2003; Yin, 2003; Silverman, 2013). The use of interviews as a data collection method within case-studies exacerbates this risk further, in introducing a dynamic between the researcher and informant (Yin, 2003). Various mitigations have been discussed, in terms of the use of multiple-cases, in mixed methods of data collection, and in multiple sources of each data type.

In addition, data analysis involves exploring overall replication logic, and whether the cases provide convergent evidence, following Yin (2014), with respect to four aspects:

- Construct validity: choosing suitable measures for the concepts under research, including ideally, multiple sources of evidence, and the establishment of a chain of evidence.

- Internal validity: establishment of causal relationships, using various tools including pattern matching, explanation building, and addressing of rival explanations.
- External validity: defining the domain to which a study's findings can be generalised, through use of replication logic in the multiple-case studies.
- Reliability: repeatable methods, including through use of a case study protocol and database.

Further explicit consideration of the research validity and reliability can also aid data analysis and conclusion in informing decisions about the extent to which research findings are generalisable (Gray, 2014). Golden-Biddle and Locke (1993) propose a framework for this, based on three elements: authenticity, plausibility and criticality. They developed it initially for ethnographic research, but it may be applied more broadly in qualitative, inductive research (Golden-Biddle and Locke, 1993; Hogg and Maclaran, 2008).

Authenticity is the basing of the research analysis and conclusion upon the empirical data (Hogg and Maclaran, 2008). In more ethnographic research, establishing authenticity relates to the researcher's presence in the field, sharing their informants' experiences, including in their own words. In terms of methodology, the transparent account of the process of data collection also increases authenticity (Golden-Biddle and Locke, 1993). In this research, the use of quotations from key informants is used to convey the same authenticity, within the context of the explained careful iterative data analysis process to identify meaningful patterns whilst remaining true to the informants' experiences. The fact of the researcher's role as an employee within the sector, the ethical aspects of which are discussed above is an advantage in respect of increasing the authenticity of the research.

Plausibility relates to the establishment that a reasonable knowledge gap exists, which the research satisfactorily bridges. The gap in knowledge must be sufficiently significant not to be trivial, but the bridging capable of connecting new and existing knowledge (Golden-Biddle and Locke, 1993). As identified during the literature review innovation is a significant dynamic within international development, but one in which research and explanation is light. We saw in our introductory chapter the particular relevance of innovation in immunisation for international development. Here too, the data analysis stage is key, in ensuring the categorisation and taking-into-account of the breadth of empirical data. The use of Braun and Clark's six-stage approach aids the rigour of this data analysis.

Criticality is the challenging of existing ideas or underlying assumptions (Golden-Biddle and Locke, 1993; Hogg and Maclaran, 2008). This is aided in this research by the use of a conceptual framework which brings ideas and tools which have not been applied before in international development. The concepts of valuation resources and of sub-system structural couplings are particularly promising, though still nascent. A critical perspective will be applied to both existing literature and empirical evidence.

#### **4.5 Conclusion**

We have designed the research methodology presented here to be consistent with the research question and conceptual framework, and cohesive and robust across philosophy, design, data collection and data analysis. The adoption of a critical realist philosophical perspective responds to both the strong scientific principles underlying immunisation, as well as the interactionism fundamental to the global innovation system (GIS) and other systems of innovation approaches. The use of a case-study approach is consistent with the abductive explanatory logic within critical realism. It is also highly appropriate for the nature of our research topic, which is complex, contextualised and contemporary. The selection of cases is robust and has resulted in a set of cases which are central to the field, but also diverse in organisational type and mission. The use of triangulated, mixed-methods data collection will serve both to strengthen the research findings, and to mitigate for the fact that the researcher is also employed within the field. The resulting data set will be analysed using thematic analysis and is assessed for research validity and reliability.

The following three empirical chapters present this research's findings with respect to each of the donor cases.

## 5 THE CASE OF UNICEF

This chapter examines the role of UNICEF with respect to innovation in immunisation for international development. It argues that UNICEF engages actively at both global and national levels, each of which relates to particular key organisational capabilities. At the national level these are UNICEF's in-depth understanding of national contexts and actors; and at the global level, UNICEF's strong reputation, authority and convening power. UNICEF links these two spatial levels in a *divisionalised* structure, providing value to innovation through generating and utilising market access, by sharing authoritative information between potential inventors and less economically-developed country (LEDC) governments. UNICEF also provides value through innovation legitimisation, on the basis of pilots it has carried out in countries and endorsed globally once proven.

However, there is internal confusion within UNICEF regarding its policy and priorities for innovation, and conflict between internal actors located at national and global levels. This is most acutely seen in the degree of support, or scepticism, relating to a *techno-fix* perspective on the balance between knowledge generated primarily from *science, technology and innovation* (STI) and knowledge generated primarily through *doing, using and interacting* (DUI). In its formal global procurement, UNICEF has managed to combine both forms of knowledge effectively, so that innovations both draw upon new STI knowledge, and meet the needs and context of LEDCs. Outside this focused area, however, the balance remains unresolved in UNICEF. This necessitates a high level of customisation of innovation valuation resources, which constrains its broader impact through innovation in immunisation.

The United Nations International Children's Emergency Fund (UNICEF) was created in 1946 to help children affected by the Second World War. In 1953 it became a permanent UN agency, dropping 'international' and 'emergency' from its name (though retaining the acronym) and pivoting towards international development, retaining its focus on children. UNICEF's mission is 'to save children's lives, to defend their rights, and to help them fulfil their potential, from early childhood through adolescence' (UNICEF, 2022a). UNICEF regards immunisation as a right guaranteed by the Convention on the Rights of the Child and supports immunisation across almost all its country programmes, with about 650 staff dedicating most of their time to immunisation (UNICEF, 2018a, p. 16).

The chapter is divided into three sections. The first section examines UNICEF's engagement with institutions relating to innovation in immunisation. Three cognitive institutions are identified as being particularly relevant. These are the presumptions that innovation is necessary for impact; that innovations utilising digital technology are the most impactful type of innovation; and that innovations should be rooted in the local context, through the participation of intended beneficiaries. Staff in different roles in UNICEF engage with these presumptions in different ways: sometimes aligning with them, sometimes engaging selectively, and sometimes contesting them.

The second section examines how UNICEF's organisational characteristics affect its innovation in immunisation. It argues that three such characteristics in particular do so. These are UNICEF's extensive network of offices, in 124 countries; the existence of a high-profile Office of Innovation responsible for leading UNICEF's innovation work; and UNICEF's capacity to procure innovations at scale.

The third section examines how UNICEF interacts with other actors for innovation in immunisation. It argues that there are three important sets of interactions between UNICEF and other actors. A first is that involved in connecting local and global level actors, in a role which UNICEF terms 'being glocal', and which constitutes a key strategic value-addition by UNICEF. A second set is that between UNICEF country offices and their host government, in which UNICEF attempts to balance a tendency to push 'solutions seeking problems' upon countries, as opposed to playing the 'honest broker'. A third set of interactions relate to what UNICEF terms 'ecosystem mobilisation', which is facilitation of a wider actor network for innovation diffusion.

## 5.1 UNICEF's institutional engagement

This section examines UNICEF's engagement with institutions relating to innovation in immunisation. Three cognitive institutions<sup>10</sup> are identified as being particularly relevant. These include the presumption that innovation is necessary for impact, especially against those problems which have proven stubbornly resilient to previous development programming. A second presumption is that innovations utilising digital technology are the most impactful type of innovation. There is also a third presumption that innovations should be rooted in the local context, through the participation of intended beneficiaries. In some cases, UNICEF is aligned with these presumptions. In other cases, UNICEF emphasises only certain aspects or interpretations of them. In others, UNICEF's response to a presumption is contested within the organisation.

### 5.1.1 Innovation 'to improve performance'

A first cognitive institution influencing UNICEF's innovation in immunisation is the presumption that innovation is critical to enabling donors to increase the impact of their work. In UNICEF's case, it describes this as to 'better deliver programmes' (United Nations, 2018, p. 51) by going 'beyond business as usual' (UNICEF, 2018b, p. 2). Indicating the scale of this ambition, UNICEF claims this represents an opportunity for 'a significant step change' in their work (UNICEF, 2018c, p. 6).

The logic behind this is understood at the operational level within UNICEF as being linked to the potential for innovation to disrupt current ways of doing things and hence to deliver either greater impact or greater efficiency, according to a UNICEF regional immunization officer:

If you are for a number of years reaching the same number of people, then you've got to think of what it is that you need to do differently to improve

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<sup>10</sup> As we saw in Chapter 3, Scott's (1995) taxonomy distinguishes regulative, normative and cognitive institutions. Cognitive institutions provide the framework through which actors process information to attribute meaning, including presumptions, as well as words, symbols and concepts.

performance, or at least maximise outputs of inputs that you already have (Interviewee 30, p. 2).

UNICEF is one of a small group of donors which specifically links innovation, broadly defined, to the ability to overcome the wicked problems of Rittel and Webber (1973) we identified in our introductory chapter. UNICEF language in this respect is that of innovation being 'a new approach to solving difficult problems' (UNICEF, 2016a, p. 104). Moreover, UNICEF assesses that these challenges are evolving, giving the examples of climate change, disease outbreaks, conflict and displacement and urbanisation (UNICEF, 2016a). UNICEF asserts that the evolution of these challenges necessitates innovative solutions, suggesting that:

As we consider the many challenges ahead, we know that we cannot keep up without a relentless focus on finding new and better ways to design, deliver and finance our programmes and services with our partners (UNICEF, 2018c, p. 5).

This argument is also recognised by UNICEF operational staff, according to a UNICEF regional immunization officer:

I think there are emerging issues and challenges... that will also imply that governments and donors and agencies, development partners think differently to cope with these new challenges (Interviewee 30, p. 2).

UNICEF subsequently strengthens this argument to suggest not only that challenges are evolving, but that they are evolving at an ever faster rate, and are increasingly inter-connected:

The world is changing faster than ever before, and so too are the challenges facing its most vulnerable. [These] are growing increasingly complex and inter-related, demanding new strategies and approaches (UNICEF, 2019a, p. 1).

UNICEF makes the same argument specifically about innovation in immunisation, writing in its strategic *Immunization Roadmap*:

A 'one-size-fits-all' approach is no longer appropriate in this changing world. Diverse contexts are increasingly apparent, not only among countries but also within countries... UNICEF and its partners must therefore continue to



adapt their approaches to stay relevant to current needs (UNICEF, 2018a, p. 10).

This presumption is based on the underlying intent that such a focus on results would increase the prospect that development assistance would achieve ‘a lasting impact on eradicating poverty and reducing inequality’ (OECD, 2011, p. 3). As we examined in our introductory chapter, the logic behind it is explained by OECD as enabling donors better to communicate their achievements and future plans, which contributes towards their accountability, particularly in light of constituencies in both recipient and donor countries having become more questioning of development assistance in recent years.

This public-facing imperative is reflected in the brand which UNICEF presents publicly of itself, of its ‘ability to evolve and innovate’ being one of its major strengths (United Nations, 2017a, p. 28). UNICEF even uses the concept as one of the primary adjectives for itself, as ‘a results-based, innovative organization’ (United Nations, 2017a, p. 51). In so presenting itself, UNICEF does not pitch innovation as a new organisational strategy, but rather as a continuation of an existing fundamental approach, suggesting that innovation ‘has always been an important part of UNICEF’s story’ (UNICEF, 2018c, p. 5); that it has ‘always fostered innovation (UNICEF, 2018b, p. 29) and that it is ‘what generations of UNICEF staff members have always done: apply new thinking to old problems’ (UNICEF, 2018c, p. 6). The consequence of these imperatives in UNICEF is an increase in the levels of investment, expectation and focus within the organisation on innovation.

### **5.1.2 Innovation, ‘more than technology’?**

A second cognitive institution influencing upon UNICEF’s innovation in immunisation is the presumption that innovations utilising digital technology are the most impactful type of innovation. Conceptually, UNICEF has adopted an expansive definition for innovation, defining it as ‘a new approach to solving difficult problems’ (UNICEF, 2016a, p. 104), as ‘new thinking to old problems’ (UNICEF, 2018c, p. 6) or as ‘exploring new ways of delivering programmes, with new partners and new technologies’ (UNICEF, 2019a, p. 1). Yet in practice when describing specific examples of intended or actual innovations, UNICEF displays a marked preference for innovations utilising digital technology. Its most common formulation is to make a general statement about innovation, but specifying as the prime example digital technology (or ‘technology’ used as a synonym). For example, UNICEF’s strategic

plan identifies as one of eight change strategies, the general 'fostering [of] innovation for children', then highlighting:

This will include enhancing the use of technologies to better engage communities and enhance social accountability... this change strategy will also involve identifying the most promising programme innovations for different contexts (United Nations, 2017b, p. 18).

Thus, UNICEF first highlights the value of technological innovations, before only then moving on, almost as an after-thought, to other types of innovation. The same relative formulation is used again by UNICEF in 2018 to describe its intention to scale-up work to 'pursue and apply innovations in every aspect of UNICEF work, and include technologies...' (United Nations, 2018, p. 29). And again, when claiming in its 2018 annual report to have achieved results through innovation: 'UNICEF accelerated results for children and young people through innovation, including the use of real-time and digital technologies' (United Nations, 2019, p. 21).

Moreover, UNICEF's Venture Fund, established in 2016 and eventually a US\$ 17.9 million fund which provides seed funding to help early-stage innovations generate evidence of impact, is eligible only for 'frontier technologies' (UNICEF, 2022b). As examples it suggests:

Blockchain, UAVs, virtual and augmented reality, 3D printing, machine learning, quantum computing, genetic engineering, Internet of Things, artificial intelligence, nano-satellites and human dynamics (UNICEF, 2020b, p. 1)

In their Statements to the Executive Board, successive UNICEF executive directors when speaking about innovation list examples which exclusively utilise digital technology. In September 2017 this consisted of drones, wearable technology, use of 'big data', and social media for critical information (UNICEF, 2017a, p. 12).

In the June 2018 Statement the examples still overwhelmingly utilised digital technology, including a social messaging tool, an SMS-based monitoring system, drones, children tracking software and geographic information technology to predict disease outbreaks. The sole non-digital example was a rapid diagnostic tool for Zika (UNICEF, 2018d, p. 6). Subsequently, however, UNICEF's tone evolved. By September 2018, though technological innovations still pre-dominated, the

Statement to the Executive Board by the then executive director Henrietta Fore emphasised explicitly that innovation was broader than this:

Innovation holds incredible, nearly limitless promise to reach more children in new ways. Not just through technology, but through new partnerships, new ways of working, new sources of financing, and new ways to identify and scale-up promising platforms, services and programmes that will reach more children and young people in need (UNICEF, 2018c, p. 5).

This point Executive Director Fore reiterated, saying later 'innovation is about more than technology' (UNICEF, 2018c, p. 7). It seems likely that this change is not due solely to the new executive director, but reflects a broader weakening of the underlying presumption. By February 2019, the Executive Director's Statement reflected a focus on innovation which was for the first time evenly balanced across innovations utilising digital technology and other innovations including new vaccines (UNICEF, 2019b, p. 12).

This breadth of innovation is seen in UNICEF's *Immunization Roadmap*:

UNICEF's approach to using innovations will go beyond applying technological innovations to employing innovative approaches or ways of doing business to reach children who are missing out on immunization (UNICEF, 2018a, p. 30).

The roadmap gives examples of areas within immunisation in which the organisation has already fostered innovation. These represent a range of innovations including in supply chain technologies, health worker incentivisation, electronic immunisation registries, data visualisation, population communication and community engagement' (UNICEF, 2018a, p. 45).

The reason for this bias for innovation utilising digital technology is proposed by a UNICEF innovation officer as relating to a perceived greater attractiveness to the public of digital technology solutions, and hence to greater media coverage for UNICEF:

But is [an innovation which doesn't utilise digital technology] a great story versus 'we're using a drone' or 'we think that block-chain might be interesting'? You can get no end of coverage. We joke about saying we just need to throw '...and block-chain' at everything. I think that's why.

Technology, just naturally people gravitate to it. They just love new things (Interviewee 36, p. 9).

UNICEF frontline staff variously described these media-friendly innovations utilising digital technology dismissively as 'shiny bright objects' (Interviewee 28, p. 1), 'fancy' solutions (Interviewee 35, p. 2), and as creating a media 'buzz' (Interviewee 31, p. 1). They acknowledge that this does have positive impact, in contributing to improving UNICEF's brand and consequently attracting additional donor resources to UNICEF:

But I think that [UNICEF] recognise that the media is hungry for new things. So that drives a lot of it. That's really helpful for positioning UNICEF constantly as an organisation that is engaged with new things, with cutting edge things and therefore innovative by that definition and typically technology... But I think donors themselves are complicit in this because much of the money is still flowing into 'let's do something new' (Interviewee 36, p. 10).

Other UNICEF staff, though, point out more serious implications of a bias towards digital technology, as impacting negatively on UNICEF's ability to foster other types of innovations, as reflected in the 2018 evaluation of Innovation in UNICEF:

Many respondents felt that UNICEF had come to focus too greatly on technologies, particularly digital technologies, as representing innovation, to the detriment of other potential approaches like [non-technology] product innovation and programming approaches (UNICEF, 2019a, p. 5).

Furthermore, other UNICEF officers suggest that innovations utilising digital technology suffer particularly from challenges in moving from pilot to scale, saying 'there're fewer examples of where a technological innovation has been applied rapidly at scale' (Interviewee 31, p. 1). Rather, these types of innovation tend to 'remain in the pilot stage and never get scaled up' (Interviewee 28, p. 1). The reason for this, it is suggested, is because innovations utilising digital technology fail more

than other types of innovation to be sufficiently adapted to the use-context. We examine this further in the following chapter.

### **5.1.3 Innovations ‘rooted in local circumstances’**

A third cognitive institution influencing UNICEF’s innovation in immunisation is the presumption that innovations should be rooted in the local context, through the participation of intended beneficiaries - in order ‘to ensure that they are responding to priority needs’ (UNICEF, 2016b, p. 4). The 2018 evaluation of innovation in UNICEF found that this presumption was well-embedded within UNICEF:

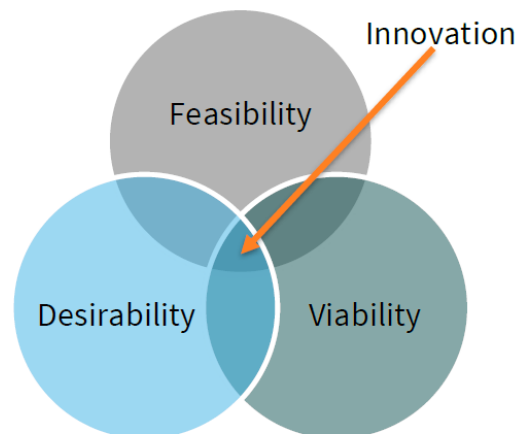
The need for contextual adaptation and local ownership is reflected throughout UNICEF’s work. It is well recognized that failing to ensure this could jeopardize any handover of innovations and potential scale-up (UNICEF, 2019c, p. 63).

To aid this, UNICEF’s innovation work at country level should be guided by the overarching three- to five-year country programme document setting out programmatic priorities agreed upon with the government based on an analysis of needs (UNICEF, 2019c, p. 63). However, a 2018 survey of UNICEF staff found that only 50% of respondents from a country or regional office agreed or strongly agreed that innovation activity in their office was well aligned with the priorities and needs of the country/region. 29% disagreed or strongly disagreed (UNICEF, 2019c, p. 63). This is reinforced in the views of immunisation-focused UNICEF staff. They suggest that innovation demands a lot of engagement from people in the country, on the ground, to balance out headquarters ‘lack [of] the understanding of countries’ realities’ (Interviewee 30, p. 9), with a UNICEF senior adviser explaining:

It’s trying to explain to people who are less connected with the field why this is a field need and then to explain to people working in innovation why it is that we should be helping to scale something that is a more of a need than another piece of technology (Interviewee 36, p. 8).

This people-centric approach to innovation is related in a UNICEF lessons-learning paper on scaling innovation to the IDEO model of design thinking as shown in the following figure:

Figure 17: IDEO model of design thinking (UNICEF, 2019d)



(UNICEF, 2019d, p. 9)

In this model, desirability relates to users' perception of an innovation's ability to meet current needs; feasibility to the innovator's capability to deliver the innovation; and viability to long-term consistency with the ecosystem (IDEO U, 2020). UNICEF states the counter-factual, that 'innovation in isolation has limited impact' (UNICEF, 2018e, p. 7). Rather, UNICEF's position is that an innovation will achieve its intended outputs only if all the critical factors around it and affecting it are acting in the same direction as the innovation, rather than opposing it. This is also referred to in UNICEF as the 'enabling environment' (UNICEF, 2019d, p. 4), by which UNICEF means ensuring that innovations are 'rooted in local social, cultural, economic, institutional and political circumstances' (UNICEF, 2014a, p. 12). UNICEF also warns that taking into account context may be constraining (rather than enabling), especially when it comes to adapting innovations which utilise digital technology (UNICEF, 2017b, p. 20).

UNICEF also recognises the importance of inclusion in order to avoid 'innovation from widening gaps' (UNICEF, 2014a, p. 5). It focuses on this dynamic at the community level, proposing mitigation by involving all members of communities in creating solutions, and by addressing 'the specific needs of marginalized and vulnerable children and families' (UNICEF, 2014a, p. 12).

A UNICEF country immunization officer suggests that:

Innovation doesn't automatically equal gadget... Even if you have the gadget, you still need to think about the relations between people, organisational relations, incentives, psychology to make things work (Interviewee 31, p. 4).

This quote emphasises the importance of intended use context in innovation, and illustrates some important dimensions to this, such as user psychology and incentives. It also demonstrates a particular mindset, which is the taking into account of use context as a post-hoc exercise, i.e., once ‘you have the gadget’. This is in contrast to a more inclusive innovation process, in which use-context drives gadget design in the first place.

This illustrates how UNICEF’s engagement with this presumption is conflicted. UNICEF has started to try to reconcile it with other presumptions, such as that of the greater impact of innovations utilising digital technology. The conflict we have identified is the result. It is clear, though, that the direction is consistently increasing rooting of innovation in the local context, through the participation of intended beneficiaries. The following section examines how this conflict relates too to UNICEF’s organisational characteristics.

## **5.2 UNICEF’s organisational characteristics**

This section examines how UNICEF’s organisational characteristics affect its innovation in immunisation. It argues that three organisational characteristics in particular do so, by affecting UNICEF’s capability to provide knowledge and valuation resources<sup>11</sup> for innovation. A first characteristic is UNICEF’s extensively distributed and decentralised structure. A second is the existence of a high-profile Office of Innovation responsible for leading UNICEF’s innovation work. A third characteristic is UNICEF’s ability to procure innovations at scale. These three characteristics have both positive and negative impacts on UNICEF’s capabilities, consistent with the innovation potential of a *divisionalised* form of organisation (Mintzberg, 1979; Lam, 2005).

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<sup>11</sup> As we saw in Chapter 3, in the GIS model, the three non-knowledge resource types, market access, financial investment and innovation legitimacy, collectively constitute the valuation of an innovation.

### 5.2.1 A 'deep field presence' in countries

A first organisational characteristic affecting UNICEF's innovation in immunisation is its extensively distributed and decentralised structure. UNICEF works in 190 countries and 85% of its 13,000 staff are based in its seven regional and 124 country offices. This is fundamental to its ability to understand the country needs and context important for innovation. UNICEF's then executive director herself makes an explicit claim of the advantage that this brings UNICEF for its innovation:

Innovation also means finding new and better ways to directly deliver primary health care to the most disadvantaged, under-served populations - including in conflict areas or regions vulnerable to outbreaks... UNICEF is well-suited to this, with our deep field presence and expertise at the local level - in both rural and urban communities alike (UNICEF, 2018d, p. 7)

The executive director's claims are supported by the 2018 evaluation of Innovation in UNICEF, which described UNICEF's decentralised structure as 'perhaps the most significant feature of the institutional architecture for innovation' (UNICEF, 2019a, p. 6), and found that:

Important benefits of the decentralized structure include strong partnerships with country actors, knowledge of in-country situations, and understanding of stakeholder needs (UNICEF, 2019a, p. 6).

This description closely aligns with that of a national system or sub-system of innovation. UNICEF's field-level staff emphasise the importance of interactions at this level, with one commenting that 'UNICEF's strength is especially in being present globally in countries with links to governments' (Interviewee 25, p. 1), and another emphasising the historic path of these links, saying 'when I look at comparative advantages obviously our footprint across all these countries and the fact that that is a consistent thing... we've been everywhere for decades' (Interviewee 36, p. 4).

Importantly, UNICEF's engagement on innovation at the national level is not just that of a passive understanding of context. UNICEF's country immunization officers describe taking part in dialogue with governments about innovation in immunisation, including being prepared to speak candidly to decision-makers about the potential and performance of innovations:



We see ourselves as in-country 'critical friends' of the government, working closely with the government but also able to challenge them and so on and so forth. Our role would be help them think through the innovations, refine them and scale them up as the case may be (Interviewee 28, p. 3).

In so doing, a UNICEF country immunization officer suggests that donors and other international organisations have a particular advantage in speaking truth in a way that civil servants or domestic organisations may not be able to:

I think that the fact that we're not beholden to the Ministry of Health gives us a little bit more flexibility (Interviewee 16, p. 3).

A government immunisation manager confirms the usefulness of the dialogue with UNICEF, whilst implying that it is not as critical as UNICEF suggests. They illustrate this with examples of ways in which UNICEF engages with them on innovation, in three categories: proactively bringing ideas; bringing ideas when asked for solutions; and responding to ideas proposed by government:

Sometimes we have them suggest [an innovation] to us based on their understanding of what we are going through... Another way is where we ask [for an innovative solution] and then they say 'well, at the country level, our understanding is that this is what WHO could support, this is what UNICEF would suggest, but let me reach out to regional level, the global level'... Most of the time it's us asking them if what we have thought about could work (Interviewee 33, p. 5).

The nature of this thought-partner role by UNICEF varies by country. The proactive bringing of ideas is particularly important for those less economically developed countries (LEDCs) with lower capacity to develop their own solutions, and with less capability to critically assess the value of externally-developed innovations. In contrast, more economically developed countries (MEDCs), for example, in the words of a UNICEF regional immunization officer 'they demand, they propose, sometimes they do their own thing' (Interviewee 30, p. 3).

Other UNICEF frontline staff highlight the importance that UNICEF's relationships in-country are not just with government, but also directly with communities. These trust-based relationships enable deeper UNICEF understanding of beneficiary needs and collation of feedback:

A huge advantage is also that community level engagement that's been persistent. Having trust, being connected with all these frontline workers and being able to have these platforms that allow for dialoguing, that allow for multi-way feedback and discussions on what those needs are and what the potential is, I think is a huge area of advantage (Interviewee 36, p. 4).

UNICEF's in-country community level engagement can be understood in terms of two resources it provides for innovation. Firstly, UNICEF provides knowledge, and in particular knowledge generated primarily through *doing, using and interacting* (DUI). This enables 'taking the local context into consideration, to align with country priorities and to integrate into country-level plans and systems' (UNICEF, 2019a, p. 6). The second resource which UNICEF's in-country community level engagement provides for innovation is that of innovation legitimacy. UNICEF alludes to that when claiming 'UNICEF has the global authority to influence decision-makers' (UNICEF, 2014b, p. 3). Similarly, a UNICEF immunization officer alludes to the power of the combination of UNICEF's country presence and authority:

Having that global presence and being able to utilise UNICEF with the convening legitimacy we have, I think we can, and I'm always being told that, really play a pivotal role (Interviewee 25, p. 1).

UNICEF's provision of these resources of knowledge and innovation legitimacy is examined in further detail later in this chapter.

### **5.2.2 Centralised innovation: 'something others do'**

A second organisational characteristic affecting UNICEF's innovation in immunisation is the centralisation of its formal innovation function. Rather than contributing positively, though, this centralisation has served to contain and constrain UNICEF's internal flows of knowledge and innovation valuation resources of market access, financial investment and innovation legitimacy. This limits UNICEF's ability to provide these resources within a wider innovation system.

In 2016 UNICEF established a dedicated Office of Innovation, consolidating various separate innovation-oriented units which had evolved in different parts of UNICEF headquarters, and with a comprehensive mission:

UNICEF Innovation is an interdisciplinary team of individuals around the world tasked with identifying, prototyping, and scaling technologies and practices that strengthen UNICEF's work (UNICEF, 2014b, p.3).

That team consists of 15 full-time staff and up to 50 consultants, structured in four teams. The Futures team explores technologies which are emerging, and are up to five years from implementation, and it forecasts trends in discussion with larger technology corporations. The Ventures team reviews innovations which are sufficiently far advanced as to be perhaps two years from implementation, focusing on 'frontier technology' likely to be relevant to UNICEF's work, and making targeted investments to guide their development and shape the market. The Scale team is responsible for taking to scale innovations which have been demonstrated to work on a smaller scale and have the potential to bring significant impact to UNICEF's mission. The Product team, in UNICEF's Supply Division, focuses specifically on global procurement of product innovations (UNICEF, 2019c, p. 67; Interviewee 36, p. 1).

The Office of Innovation describes an apparently coherent, structured flow between these teams, in a 'three-stage approach', involving a progression from technological forecasting (Futures), prototyping or testing solutions (Ventures) and then scaling effective innovations (Scale) (UNICEF, 2017c, p. 2). Indeed, when the Office of Innovation was established, it was intended to 'develop a common, coordinated strategic plan' (UNICEF, 2019c, p. 67). Yet, according to one UNICEF senior adviser, this has not been achieved:

It's very fractured at the moment... we have these Future, Ventures, Scale, Product, but you also have innovation roles sitting varyingly at country level. They might be technology-focused specifically, they might be broadly innovation officers, but we don't have a coherent strategy, or related to that strategy, a coherence to the structure of it (Interviewee 36, p. 1).

Another UNICEF senior officer confirms this characterisation, but regards the fracturing as both to-a-degree inevitable, and also as having a positive effect:

Throughout UNICEF, there's quite a bit of confusion about what innovation is and how it's structured. I guess part of that will maybe never be solved, as we are such a decentralised organisation and people use innovation as a framework to play around. It's a space of freedom (Interviewee 25, p. 6).

However, the 2018 evaluation of innovation in UNICEF found that the centralisation of UNICEF's innovation work in the Office of Innovation has meant that the responsibility for innovation has largely been seen as abrogated for other staff:

The weight of the evidence suggests that for UNICEF, having a single, central unit sent a signal that the function was being centralized, which therefore meant innovation was 'something others do' (UNICEF, 2019c, p. 69).

This conclusion is shared by a UNICEF immunization officer:

I think part of the trouble in UNICEF is we've actually got an innovation unit, whereas innovation should be something that's integral to every workstream. And so, by doing that, it in some ways disempowers staff members from thinking they can do innovation as well because that's another person's job (Interviewee 34, p. 5).

In this fragmented structure, the Office of Innovation (OoI) is widely perceived as suffering in particular from a lack of coordination with UNICEF's country offices and their in-country understanding:

Most frequently, respondents felt that the OoI was disconnected from the priorities of COs and inadequately attuned to the needs of contextualizing innovations to the setting (UNICEF, 2019c, p. 69).

In that way, a UNICEF senior adviser likened UNICEF's approach to innovation to lacrosse: elitist and cliquey; suggesting that instead, UNICEF should aspire to a football-like approach: accessible, inclusive and easy to try (Interviewee 36, p. 6).

UNICEF staff observe this disconnect as a difference in focus and approach between the Office of Innovation and the front-line programme teams, with one country officer saying of the Office of Innovation that 'their focus has been pretty squarely on technological solutions. We promote a lot more of the programmatic innovation' (Interviewee 28, p. 3); and another that:

The Office of Innovation in New York focuses primarily on mobile and tech. You also have innovation taking place in country offices that do a limited but a little bit of everything... In terms of tools and approaches, there are very different routes (Interviewee 25, p. 5).

Indeed, the 2018 evaluation of innovation in UNICEF found that the Office of Innovation (Ool) was over-focused on presenting a good-news picture relating to innovation in order to strengthen UNICEF (and, they suggest, perhaps the Office of Innovation's own) brand:

It was also noted that the Ool devotes considerable time and attention to 'branding' its products and 'selling' its ideas to others (sometimes expressed as 'self-promotion'). Respondents felt that materials produced were 'good news stories' with little meaningful insight about pitfalls or struggles encountered. Some innovations were seen as 'oversold' at the expense of other technologies that may better fit the need (UNICEF, 2019b, p. 69).

Supporting this view, a UNICEF country immunization officer said of the Office of Innovation that 'there's some discussion around to what degree they do cool stuff versus to what degree they do useful stuff' (Interviewee 16, p. 2). Other UNICEF immunization officers suggest that this extends to the wider organisation, and that 'some innovations we do are not that innovative, and we try to repackage old products to be an innovation success' (Interviewee 34, p. 5), and:

I think that sometimes we're also trying to sound innovative when we're not, and use examples of things that have been done elsewhere and kind of repackaging things and calling it innovative (Interviewee 14, p. 1).

The existing of 'repackaging' doesn't mean that real innovation doesn't also occur in UNICEF. In fact, there is evidence that innovation is frequently taking place within UNICEF's programmes, without being well reflected in the organisation's innovation planning or reporting, as a result of the freedom which UNICEF's decentralised model provides country offices. The 2018 evaluation of Innovation in UNICEF found that 57% of staff responded that they were involved in innovation (UNICEF, 2019c, p. 69). This tallies with UNICEF's reporting against their 2017 key performance indicators, in which 55% of country offices reported that they use innovation in programmatic implementation (UNICEF, 2019a, p. 5)

As early as 2016, UNICEF had identified the need for its innovation work to be better integrated into UNICEF country programming, in order to enable evidence-based decisions on when to scale-up or replicate innovations, and the incorporation of effective innovations into UNICEF's programmatic mainstream (UNICEF, 2016b, p. 4). Hampering this integration, however, is a dislocation between the human resources and financial investment for innovation. The Office of Innovation benefits

from staff dedicated to innovation, but ‘must rely on project-based, small-scale funding, which can hinder progress’ (UNICEF, 2017c, p. 11). In contrast, the long-term, large-scale funding for UNICEF’s programme work is held by its country offices. Yet human resources in those country offices are so stretched as to be unable to allocate even a moderate proportion of staff time for strategic innovation. Country immunization officers recognise that ‘innovation in the next few years is going really to be a full-time job for someone if you want really good results’ (Interviewee 30, p. 6), especially because ‘it involves a lot of consultation and different stakeholders’ (Interviewee 35, p. 5).

A further limitation relates to country officers’ risk appetite around innovation, with one UNICEF senior adviser suggesting they see themselves as subject to rules to which the Office of Innovation is exempt (Interviewee 36, p. 6). The role of risk-appetite in limiting UNICEF’s innovation is recognised in the 2018 evaluation of innovation in UNICEF, which found that its culture and management practices generally discourage risk-taking and that there is little discussion and learning from failure (UNICEF, 2019a, p. 5).

The result of these limitations is a non-strategic, piecemeal approach to innovation in UNICEF’s country offices ‘with small sums of money, short funding cycles, [and] high staff turnover’ (UNICEF, 2019a, p. 6). This perspective is reflected by a UNICEF immunization officer:

I think what we do in innovation is not very deliberate. In our team I would say we don't have a very deliberate approach. Every team does a bit on innovation... each team does that on their own, in an organic manner, but not in a very specific manner (Interviewee 10, p. 1).

Moreover, this situation significantly hinders systematic sharing of knowledge relating to innovation, with ‘competing demand from core work continually crowding-out the time needed for ‘reflection, documentation and dissemination of lessons-learned’ (UNICEF, 2019c, p. 92).

Consequently, innovation in UNICEF is largely dependent on the enthusiasm, initiative and drive of individuals, according to a UNICEF regional immunization officer:

You'll see people who are very good and enthusiastic, and they love to try innovation. They love to try something new. They push for it; they do a lot of

marketing for it; they find research and data and evidence to sell those innovations... if you like it, you understand more about it, you will drive it. If not, then maybe you'd be a little bit lazy in pushing for it (Interviewee 30, p. 9).

They suggest that this dependence on individuals arises from the lack of a shared innovation vision and strategy across the organisation:

I think perhaps we need to have a common understanding. At least a minimum level of understanding of what kind of support we need to put into this agenda... I don't think everyone has the same understanding, and then it becomes a personal thing (Interviewee 30, p. 9).

Other interlocutors suggest that even more fundamentally, in UNICEF 'there has not been a common language of describing what we're doing in innovation' (Interviewee 36, p. 5), with many staff aware that 'we use the term innovation fairly broadly' (Interviewee 28, p. 1) and confused as to whether in UNICEF, 'is it about introduction of new technologies and using technology to deliver a service or is it about trying to find innovative ways to manage resources or resolve issues?' (Interviewee 30, p. 1). Or indeed, is it about focusing primarily on testing early-stage innovations or taking them to scale, as examined in the following section.

### **5.2.3 Operating at scale: 'put a zero on that'**

A third organisational characteristic affecting UNICEF's innovation in immunisation is its ability to procure innovations at scale. In particular, this relates to UNICEF's global procurement of vaccines and other health commodities on behalf of developing countries of over 5000 different products which help meet the needs of children. UNICEF's Supply Division manages this process, worth a total of US\$ 3.5 billion annually. This includes procurement each year of 2.5 billion vaccine doses, for almost half the world's children (UNICEF, 2018a, p. 16).

One senior UNICEF officer suggests that this is unconnected from any role which UNICEF plays in innovation:

We are a procurer, not an innovator. Some NGOs are innovators, but in general where many of the innovators in our space get it wrong is that they compare themselves to the innovator or the venture capitalist. The strength of an institution like UNICEF or all of the UN agencies, frankly, is our role in

procuring and driving uptake of these products. We're not a little nimble creative institution (Interviewee 25, p. 4).

This quote adopts a narrow interpretation of innovation as relating essentially to invention, in order to emphasise the point that UNICEF's comparative advantage does not lie in that area. Reference to 'all of the UN agencies' indicates that this is more fundamental a point than just reference to the dysfunctionality we have identified earlier between UNICEF's centralised innovation function and its country offices. Yet at the same time, the senior UNICEF officer recognises that there is a role in 'driving uptake' of innovations, and also emphasises the importance of this in enabling the adoption of innovations which 'aren't commercially available or are commercially available but not sufficiently used, relative to their potential impact' (Interviewee 25, p. 1). This approach is set out also in UNICEF's *Immunization Roadmap 2018–2030*:

UNICEF will continue to work with industry to incentivize the development of innovative new products and steer research and development investment toward vaccines and technologies that meet the needs of national immunization programmes (UNICEF, 2018a, p. 12).

Indeed, public procurement for innovation is recognised as an important policy instrument in driving innovation (Edquist and Zabala-Iturriagagoitia, 2012; Edquist *et al.*, 2015). UNICEF uses the global leverage its procurement provides to shape the market to achieve this. Since 2009 this has been the responsibility of the Supply Division Innovation Unit (SDIU), which was absorbed into the wider Office of Innovation structure when that was established in 2016. SDIU manages about 20 such projects at any one time (UNICEF, 2016b, p. 20). UNICEF, we can agree, isn't an inventor, but as the systems of innovation approach explains, an inventor isn't capable of innovation on their own. UNICEF, as a procurer, plays crucial role in driving innovation for immunisation of children.

UNICEF does this by developing a Target Product Profile (TPP), with external expertise as required, to guide industry on a desired innovation's ideal attributes. This TPP includes information on the intended role and usage of the innovation and its ideal, and minimum, performance criteria (UNICEF, 2019c, p. 81). The TPP is shared, 'transparently, non-exclusively with everyone on a market' (Interviewee 25, p. 1). The 2018 evaluation of innovation in UNICEF found that the TPP was an



effective tool in focusing manufacturers' product development on UNICEF's needs (UNICEF, 2019c, p. 81).

In parallel, UNICEF assesses the risk for global manufacturers associated with developing that product, based on factors including the maturity of existing research and development, the regulatory risk, and the extent of possible market demand. These essentially determine whether the market is likely to function alone to deliver the product, in which case 'it's just about waiting, or do we need to go in and play an active role?' (Interviewee 25, p. 3). Such intervention, for products of higher-risk for manufacturers, involves UNICEF utilising market incentives, ranging from facilitating field-trials, to issuing formal market guarantees (Interviewee 25, p. 1).

Taking an innovation to scale has recently been an increasing focus of UNICEF, with the midterm review of UNICEF's 2014-17 Strategic Plan finding that UNICEF had increasingly focused on 'fostering, identifying and supporting' the scaling of innovations as an implementation strategy (UNICEF, 2016b, p. 16). UNICEF links this to its global mission, describing innovating at scale as needed to ensure positive impact for the largest possible number of children (UNICEF, 2019d, p. 2).

Executive Director Fore reinforced this greater emphasis on the pace and extent of scaling of innovations than did UNICEF previously, stating formally that:

[One] priority is to pursue and apply new innovations in every aspect of our work, and do so at-scale, more broadly than ever before (UNICEF, 2018d, p. 6).

Informally and interpersonally, the executive director was reportedly even more focused on scale, as the following account of a UNICEF officer indicates:

She really wants to scale at a massive scale. So, for example, when, whenever I'm meeting with her, we'll talk about having reached 5 million, she'll go 'that's good start. I really want 50, so put a zero on that'. She's very much saying our scaling ambition needs to be much bigger and she wants to see it happen much faster (Interviewee 36, p. 2).

Executive Director Fore delivered the same message to regional offices, telling them that 'she would like people to try things at large scale and even if you fail, that's still OK' (Interviewee 30, p. 3). It is UNICEF's Scale team which is responsible for providing 'support for the roll-out and scale-up of a select portfolio of proven,

innovative solutions' (UNICEF, 2019c, p. 67). In contrast to the Futures and Ventures teams, the Scale team is not so explicitly focused on innovations utilising digital technology. It is, however, noticeable that UNICEF's examples of innovations it has taken to scale all utilise digital technology: U-Report, a social messaging tool; RapidPro, an SMS-based monitoring system; and the Internet of Good Things, an online communications platform (UNICEF, 2017c, p. 2).

The Scale team has tried to adopt an approach more integrated into the internal UNICEF system than those approaches of the Futures and Ventures teams. They describe this as 'demand driven' (UNICEF, 2018e, p. 3), and as using systematic processes to help mainstream innovations 'as the new normal in programming'. The team has evolved 'from product-focused roles into a team of eight scaling practitioners' some of whom are embedded into UNICEF's regional offices in order to ensure closer linkages to the frontline (UNICEF, 2018e, p. 11).

As a strategy in the scaling-up of innovations, UNICEF claims to focus on trying to unblock the 'innovation pile up at proof of concept' (UNICEF, 2018e, p. 39) by which it means those innovations which have demonstrated their effectiveness, but which have not managed to secure the resources needed for scale. Other organisations have identified this need, with the International Development Innovation Alliance (IDIA) referring to a 'missing middle' in the innovation life cycle' (IDIA, 2019) and BMGF to an 'innovation pile up' to describe the lack of a 'systematic path for the subset of innovations that should move forward to be able to access the attention and resources needed to achieve scale' (Buchsbaum and Singer, 2014).

This strategy of focusing on the set of products already-identified which could make a significant contribution to UNICEF's impact if scaled-up is in contrast to the 'continual pursuit for magic bullets' (Interviewee 31, p. 5). Arguing not to let the best be the enemy of the good, a UNICEF officer said:

[W]hy do we as a community always focus on driving the R&D of this next silver bullet, when anybody who's ever worked in innovation will know that there is no such thing. So rather than naively chasing ghosts, well, some of them may not be ghosts, but let's focus in on driving scale of all these products out there (Interviewee 25, p. 1).

UNICEF has alluded to this also in its publications relating to scale:

The resource gap between innovation pilots and scale is a key area of focus. Ten years ago, there was a lack of innovation in the development sector. Today, there is much innovation activity and there are numerous sources of funding for early-stage innovation... The challenge now is to ensure that promising, early-stage innovations are supported to scale their impact for millions of beneficiaries (UNICEF, 2018e, p. 39).

This implies that UNICEF's strategy is linked to the positioning of other donors within the innovation cycle and based upon the proactive sharing of information between them. Executive Director Fore reportedly did not want to compete with other United Nations organisations which have chosen to focus on early-stage innovations (prompted by UNDP announcing a US\$ 120 million, 180-person, 60 country focus on early stage innovation (Interviewee 36)):

She feels that we need to really take a much closer and different look at the ecosystem and stop doing things that we can find other partners doing better, more closely to their unique advantages (Interviewee 36, p. 2).

UNICEF suggests that in scaling innovations, its focus is on adaptation, rather than, for example, consistent replication or repeated reinvention:

Adaptation is our most frequently applied scaling approach as it allows us to leverage the economies of a consistent core offering, as well as the local context-sensitive changes that are essential for successful adoption at scale (UNICEF, 2019d, p. 8).

This is consistent with the principle fundamental to UNICEF's comparative advantage, of country contextualisation through UNICEF's 'deep field presence'. These principles are reflected in UNICEF's 2018 'Immunization Roadmap, which suggests as innovation principles:

the importance of designing with the end-user in mind, understanding local ecosystems, designing for scale and using open source technology and open data sources (UNICEF, 2018a, p. 25).

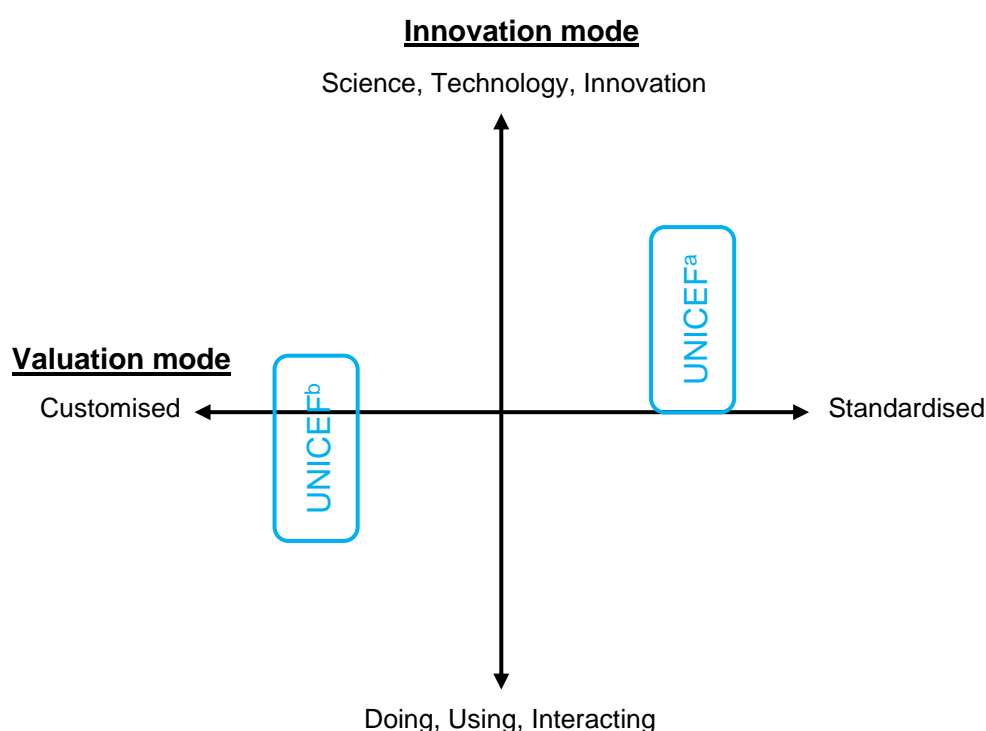
UNICEF's organisational characteristics are consistent with it being an organisation of the archetype designated by Mintzberg as *divisionalised* (see Table 3). This he described as having highly decentralised, quasi-autonomous units 'designed to meet

local environmental challenges’ – which describes well UNICEF’s country office-based structure and values.

For each of Mintzberg’s archetypes, Lam (2005) sets out their innovation potential. A *divisionalised* form of organisation, she describes as having competence in specific areas, as indeed, we see in country-engagement and in supply. As weaknesses, she identifies a ‘centrifugal pull away from central R&D towards local efforts’, and competition between divisions. This, too, closely matches the tensions we have observed between country-oriented innovation and UNICEF’s promotion of the centralised Office of Innovation.

These same tensions are reflected in terms of UNICEF’s innovation resource modes, mapped against the innovation resources matrix of Binz and Truffer (2017), adapted as the following figure:

Figure 18: Innovation resource modes of UNICEF (Author)



Source: Author

According to this representation, the distribution of resources provided by UNICEF for innovation in immunisation is polarised. The organisation has two innovation resource modes, distinct from each other.

Firstly, UNICEF has a function relating primarily to its global procurement role, marked as *UNICEF<sup>a</sup>* in the figure. This is highly standardised in terms of valuation resources, with its market access, financial investment and innovation legitimacy all utilised in a very highly consistent way across innovations and markets. Accordingly, this mode involves codified, explicit, knowledge generated primarily from *science, technology and innovation* (STI). Based on Binz and Truffer's typology, this aligns to that of a *footloose* global innovation system (GIS). In this type, knowledge is primarily scientific and located in international networks or communities; and innovation valuation is primarily standardised across markets, relying on international standards and coherent user preferences for international legitimisation and on mass-markets with economies of scale for market access.

Secondly, UNICEF has a function relating to its country partnerships, implemented through its highly decentralised country offices. It is marked as *UNICEF<sup>b</sup>* in the figure. Innovations deriving from UNICEF's global private sector partnerships often

manifest in countries as pilots. Based on Binz and Truffer's typology, this aligns to that of a spatially sticky global innovation system (GIS). In this type, knowledge is generated primarily through *doing, using and interacting* (DUI) between users and producers. Its innovation valuation is highly customised, with markets initially forming around niches based on local conditions; legitimisation results from innovations' consistency with local institutions; and financial investment is highly targeted. This aligns with our observations, in which financial investment is projectised towards specific pilots. Market access, when it has been achieved, has been through country-specific piloting, national ownership and government-private sector relationships convened by UNICEF. Innovation legitimacy has arisen through the successful implementation of an innovation at the national level, on the basis of evidence being produced through monitoring and evaluation there. UNICEF's innovation mode in this case is primarily based around DUI knowledge, though not fully, as the organisation retains a preference for STI based innovation. This innovation mode is an area of contestation between the centralised innovation function and the country-focused offices. In terms of market access, for example, the Office of Innovation's good access to global sources of innovation is not effectively linked to country offices' excellent understanding of demand, with the result that the organisation is not able to fulfil its potential to enable market access to either suppliers or beneficiaries. In terms of financial investment, structural disconnects also mean lost opportunities, as the donor resources attracted by the Office of Innovation for early-stage innovation are not making it down to country level and the human resources at country level not being strategically used towards UNICEF's innovation. In terms of innovation legitimacy, the technology being pushed by the Office of Innovation is not being allied with the legitimacy able to be conferred through UNICEF's deep country engagement, with the result that the potential beneficiaries are not attracted to these technologies.

The two models of innovation in UNICEF are recognised, with the 2018 evaluation of innovation in UNICEF finding that:

There are contrasting opinions within the agency as to the correct focus for UNICEF's innovation activities, notably between focusing on existing, tried-and-tested technologies that need scaling up vis-à-vis those that need developing from early stages (UNICEF, 2019a, p. 1).

This debate, however, is also influenced by UNICEF's interactions with other actors within the space. This is examined in the following section.

### **5.3 UNICEF's interactions with other actors**

This section examines how UNICEF interacts with other actors in its innovation in immunisation, and in particular its provision of vertical structural coupling between the global and country levels. It argues that there are three important sets of interactions by UNICEF with other actors. A first is that involved in connecting local and global level actors, in a role which UNICEF terms 'being glocal', and which constitutes a key strategic value-addition by UNICEF. A second set of interactions is that between UNICEF country offices and their host government, in which UNICEF attempts to balance a tendency to push 'solutions seeking problems' upon countries, as opposed to playing the 'honest broker'. A third set of interactions relate to what UNICEF terms 'ecosystem mobilisation', which is facilitation of a wider actor network for innovation diffusion.

#### **5.3.1 'Being glocal': linking country and global actors**

A first set of interactions in UNICEF's innovation in immunisation is that involved in connecting local and global level actors. UNICEF's premise is that partnerships are 'at the heart of innovation' and necessary in order to identify, implement and scale-up innovations (UNICEF, 2018c, p. 11). In fact, UNICEF suggests that 'the people component accounts for a notional 90% of successful scale' (UNICEF, 2019d, p. 11), and that its innovation activities 'almost invariably involve engagement with external stakeholders' (UNICEF, 2019c, p. 78).

Moreover, UNICEF emphasises the importance of diversity in the convened actors, suggesting that 'a diverse range of actors' is important in ensuring effective innovation (United Nations, 2016, p. 27). The organisation's logic for this is the bringing of new ideas from other domains, saying that 'diversity within a team brings in thinking from other fields of practice to build innovative, scalable ideas' (UNICEF, 2018f, p. 6). And consistent with its frontline focus, UNICEF also highlights not just domains, but more broadly, countries and cultures, saying that:

Recognizing that the world's biggest challenges will not be solved by one organization, group of people or country, UNICEF Innovation takes an interdisciplinary approach, working across industries, countries, and cultures (UNICEF, 2022c).

To that end, UNICEF suggests that it 'combines local understanding with global knowledge to innovate new, scalable solutions' (UNICEF, 2014b, p. 3). UNICEF also

phrases this in terms of actors, claiming a particular ability to 'link global and local problem solvers' (UNICEF, 2014a, p. 2), and to shape innovations via 'input from technical experts bringing experiences from countries and regions around the globe' (UNICEF, 2020b, p. 2). UNICEF terms this comparative advantage 'being glocal' (UNICEF, 2018e, p. 11), whilst a UNICEF senior adviser compares this to the market insights that are so valuable in the private sector:

Having trust, being connected with all these frontline workers and being able to have these platforms that allow for dialoguing, that allow for multi-way feedback and discussions on what those needs are and what the potential is, I think is a huge area of advantage that we're still not taking advantage of. Because if you took a private sector market research approach and how much they spend on trying to understand the local market and what products they could put into that market and what the need is, those are the insights that we have access to, but we just don't think about them in quite the same way (Interviewee 36, p. 4).

The reference to not taking advantage of UNICEF's access to beneficiaries is related to the criticism that UNICEF's innovation is primarily associated with the Office of Innovation, which is largely disconnected from country contextual understanding. This serves to limit the full potential of UNICEF's 'glocal' reach for innovation.

There are, however, some indications that UNICEF's 'glocal' dynamic potentially works multi-directionally. Firstly, in enabling UNICEF to translate and consolidate country needs upwards, from the local to the global level. UNICEF immunization officers describe this as being able 'to bring research and evidence to policy making'<sup>12</sup> (Interviewee 10, p. 2) and highlight the range of experience drawn-upon by UNICEF: across multiple sectors within international development; within different types of countries; and experience not just at the national level in countries but 'at the sub-national level as well' (Interviewee 28, p. 1).

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<sup>12</sup> Other interlocutors described this as implementation research.



Secondly, the 'glocal' dynamic potentially also functions, to a degree, in a downwards direction, enabling UNICEF to adapt global solutions to the local level. A UNICEF country immunization officer described UNICEF's country programmes as being part of a 'system' at the country level, based around the strategic multi-year plan 'and embedding innovation in that', drawing from guidance, frameworks and strategy from the global level (Interviewee 14, p. 6). The 2018 evaluation of innovation in UNICEF found that country officers wanted the Office of Innovation to act as a broker, discussing needs with country offices and matching to relevant global experts and innovations to support implementation (UNICEF, 2019c, p. 72).

UNICEF anticipates that those global level solutions will particularly originate through its partnership with the private sector, which UNICEF sees as bringing 'speed, agility and drive to reinvent', alongside donors' 'ability to convene partnerships, inform policies and implement solutions on the ground' (UNICEF, 2014a, p. 8). A UNICEF country immunization officer suggests that UNICEF sees the private sector as complementing the set of traditional health sector actors which 'doesn't anticipate the future well-enough, and that we are slow adopters of things that really could change the way we are doing' (Interviewee 31, p. 7). In contrast, UNICEF sees the private sector as having a culture, approach and tools which facilitate innovation; and as businesses being 'an important source of innovations, market reach, and research and development' (UNICEF, 2019b, p. 13). UNICEF sees this as based on the differential motivations and incentives of each sector:

Technology companies were driven by profit while actors in the public sector strived for social impact. The most successful partnerships were those which had a common metric that involved all stakeholders, and which harnessed the creativity of the private sector with the responsibility of the public sector (United Nations, 2018, p. 66).

Accordingly, UNICEF's approach has been to seek to create 'shared-value partnerships' with business (United Nations, 2019, p. 20), or 'co-creating new initiatives' with them (UNICEF, 2018d, p. 6). UNICEF's primary targets within the private sector are corporations from high-growth tech industries. For example, UNICEF's corporate partnership with Arm, a global semiconductor and software company, involves a financial contribution of US\$ 3.7 million over three years, to support areas including joint research into emerging market possibilities, and scaling of innovations; (UNICEF, 2017c, p. 11). These partnerships with the private sector are intended to use their 'expertise, networks, internal platforms and data' for

developmental impact, but also to allow those corporations to develop new 'viable business strategies' (UNICEF, 2022c, p. 1).

Indeed, businesses see high commercial value in such partnerships, in particular in terms of their image, which benefits from association with a well-regarded UN agency. It also raises awareness of the company internationally, including in new and emerging economies and markets. The UN is, further, able to make introductions to decision-makers within those environments. These benefits can be very good value for the businesses, often costing, for example, many times less than their annual advertising budgets (Seitz and Martens, 2017).

There is also potentially a third dimension to the 'glocal' dynamic, which is horizontal, in transferring knowledge between country contexts, as described by a UNICEF senior immunization officer:

We also serve as a knowledge disseminator. So, if there's an innovation in a district of the country, we can help to disseminate it. If the innovation is in a country, we can help to disseminate it outside the country, to similar contexts (Interviewee 28, p. 2).

Although UNICEF acknowledges that this is an underutilised dimension, such that even when lesson-learning has been undertaken, 'we did not effectively share these accomplishments through other channels, nor track these engagements as we ideally should have' (UNICEF, 2018e, p. 12).

The fact that UNICEF has innovation pilots ongoing in different countries is one means for lesson-learning, and ultimately innovation transfer, between countries, as identified by a UNICEF country immunization officer: 'the fact that we have different pilots ongoing in different countries gives a lot of South-South learning opportunities that are often facilitated by our global partners' (Interviewee 16, p. 3).

However, views differ within UNICEF about the value of pilots, with the organisation having a reputation for 'more pilots than American Airlines' (Interviewee 16, p. 4). Despite general recognition that piloting provides an opportunity to field-test innovations, some staff highlight the risk of pilots being conducted under artificial circumstances such as an unsustainable level of technical or financial investment used to support the pilot, or 'just tested in idealised circumstances' (Interviewee 31, p. 3). Ensuring high quality piloting of relevant innovations is dependent upon a

good relationship between the UNICEF country office and their host government, which is examined in the following section.

### **5.3.2 'Selling' innovations or 'honest broker'?**

A second set of interactions in UNICEF's innovation in immunisation is that between UNICEF country offices and their host government. A concern prevalent amongst UNICEF country immunization officers is that they are expected to push upon governments innovations which UNICEF headquarters has selected, but which, because of the disconnected nature of the Office of Innovation are not always appropriate:

We have centrally driven, technological, shiny bright innovations which we drive down through the system from higher levels, which is obviously not as attractive because that's almost like solutions looking for a problem rather than solutions addressing a problem (Interviewee 28, p. 2)

That view is reflected by a broad set of UNICEF staff, as found by the 2018 evaluation of innovation in UNICEF:

Feedback from [country office]- and [regional office]-level interviews indicated that innovation activity is (or should be) driven by country needs and national priorities. Others commented on HQ-led initiatives that were not well aligned with field priorities. Interviewees sometimes referred to such activities as 'solutions seeking problems' (i.e., driven by a top-down view of needs rather than the de facto situation on the ground) (UNICEF, 2019c, p. 64).

This top-down push of innovative solutions from headquarters results in a dynamic in which regional and country offices are expected to 'market' or 'sell' innovations to countries, as described by a regional immunization officer:

In the UNICEF Immunization Roadmap 2017-2030, innovation is an important topic. So, it is a big agenda. There is a push from headquarters, from the regional office as well, we talk about it to countries. We try to sell it and do marketing around doing innovation or innovative work (Interviewee 30, p. 1).

Furthermore, there is a concern that the countries to which an innovation is being 'sold' are pre-selected at the headquarters level, as expressed by a UNICEF

regional immunization officer saying 'if they get some funding, they come up with some ideas and they decide, sitting at headquarters, which are the countries which are the priority (Interviewee 35, p. 4). In some cases, a UNICEF immunization officer in a country is simply told 'this company would like to do a pilot' (Interviewee 30, p. 3).

Instead, regional and country immunization staff suggest that UNICEF's role should be to ensure that country counterparts understand what innovations are available and the potential benefits, and ideally, costs, relative to other innovations:

Our role as a regional office is to make sure that our counterparts, governments and country offices of UNICEF and other development partners, are aware of what is out there. That they know the details about it. That they know how much benefit it could bring. That they know how much efficiencies and cost-saving it would bring, if we introduce A, B, or C innovation or technology (Interviewee 30, p. 2).

However, the appearance that UNICEF backs a specific innovation can undermine its ability, or at least perceived ability, to provide advice to governments which is in their best interests. This is identified by the 2018 evaluation of innovation in UNICEF:

Respondents felt that materials produced [by the Office of Innovation] were 'good news stories' with little meaningful insight about pitfalls or struggles encountered. Some innovations were seen as 'oversold' at the expense of other technologies that may better fit the need. When it appears that UNICEF is backing a specific solution, it can hinder the agency's ability to serve as an honest broker with governments in the search for solutions (UNICEF, 2019c, p. 70).

A senior UNICEF adviser suggests that, for this reason, it was also important that UNICEF was not involved in the development of innovations. They emphasise UNICEF's role instead as that of procurer:

There's a big difference between developing an app and developing a diagnostic or whatever it might be, in terms of money needed and time etc, but also in terms of to what degree UNICEF wants to be associated with the development. Part of the reason we don't want to be that is because we want

to remain 100% impartial. We are the procurer and not the developer (Interviewee 25, p. 6).

A further mitigation by UNICEF is in the use of objective data 'as a priority in any discussion on innovation' (United Nations, 2018, p. 66), to monitor progress and results achieved, with evidence-based evaluation particularly important when deciding whether to scale-up innovations:

Specific attention must be paid to robust, independent assessment prior to making decisions on if or how to promote scale up or replication of innovations, and to facilitate the incorporation of effective innovations into the mainstream of UNICEF programming (UNICEF, 2016b, p. 17).

A UNICEF country immunization officer emphasised how, in fact, they see evidence-generation as the primary role of UNICEF in innovation in countries:

A major focus of our work is much less about service delivery and much more about evidence-generation, learning, technical advice to influence policy. So, you need a strong evidence base to be able to do that (Interviewee 16, p. 8).

However, country governments are generally reluctant to be the first in which a donor pilots an innovation, as described by a UNICEF regional immunization officer:

Some of them were a little bit suspicious that they are guinea pigs, asking why we were testing the innovation there. Some, without seeing a good evaluation report, or concrete outcomes from countries with similar context to their context, are reluctant to accept it (Interviewee 30, p. 3).

The solution, according to a UNICEF country immunization officer who gives the example of an innovative digital health management information system, is that pilots are embedded in country systems technical and political systems. The officer specifies that a successful pilot is based on existing government platforms for service delivery; is focused on producing relevant, reliable evidence; and that the conclusions are owned, championed and communicated by government. The implication of this for UNICEF staff, 'as outsiders', is that they are merely playing a facilitational role for government:

As long as you're doing [piloting] in a way where you're thoughtful about where you introduce it and skilful with how you're generating evidence and

lessons and ensuring that there are local spokespeople. That you as outsiders are not the people presenting the evidence, but just facilitating the process... So that's where partners like UNICEF can potentially play a huge role in getting things going, and demonstrating that it adds value to existing systems (Interviewee 16, p. 4).

In these ways, UNICEF-led piloting can be useful, in bringing additional financial and human resources which would not otherwise be available for innovation. The country immunization officer adds, furthermore, that however intrinsically well-designed an innovation, it is very important to plan and budget for an explicit transfer period of training and other change-management to ensure its institutionalisation (Interviewee 16).

Even with this, successful pilots may not subsequently be scaled-up, according to a UNICEF regional immunization officer:

The EPI Managers have experienced themselves that many, many new things we are piloting in their countries with very good results, people launching something, they have evaluated it, they have good reports, good outcomes or good outputs. But what's next? (Interviewee 30, p. 3).

This is consistent with the view of a government EPI Manager, who suggests that the solution is that planning for scale be fundamental to piloting:

The ministry was getting concerned that you had these pilots going on everywhere and it didn't appear that anyone had thought beyond the period of the pilots... So, from the outset we had adopted a principle that we've always called 'developing to scale'. So, I don't think, even when we write these innovations, we ever use the word piloting. Because the idea is that whatever we want to develop, we are developing each to scale. It may not be scaled as an initial idea, but it is meant to be that whatever we are starting with has to lead to something (Interviewee 33, p. 5).

Complementing this, UNICEF publishes various guidance documents to help equip governments to negotiate with private sector innovation providers, which includes 'strategic guidance and detailed documentation on mobile content development, negotiation of distribution deals, and implementation of both above the line and below the line promotional initiatives' (UNICEF, 2018e, p. 22).

Taking this further, a UNICEF senior advisor described a premise that less economically developed country (LEDC) governments don't always understand the potential commercial leverage that they have, with 'governments who are going into this for the first time, don't understand the leverage that they have when they issue these licences' (Interviewee 36, p. 12). As a result, UNICEF is exploring a role as a 'trusted independent broker of advisory services' to governments, to level up the playing field in their negotiations with private sector companies, to 'help you exploit this resource in a way that you're not going to get fleeced' (Interviewee 36, p. 12). This, and other roles played by UNICEF are examined in the following section.

### **5.3.3 Ecosystem mobilisation for diffusion**

A third set of interactions in UNICEF's innovation in immunisation is that of facilitating a wider actor network. UNICEF terms this 'ecosystem mobilisation'. It defines an innovation ecosystem as 'that set of different actors, relationships and resources that all play a role in taking an innovation from ideation to impact at scale' (UNICEF, 2019c, p. 59). UNICEF claims to have 'mobilized many parts of ecosystems to diffuse and adopt an innovation' (UNICEF, 2019d, p. 11) and suggests that it regularly analyses 'what kind of ecosystem of support is required to identify, apply and scale-up new innovations across our work' (UNICEF, 2018c, p. 7).

A UNICEF officer highlights that at the global level an ecosystem can be an important way to tackle the range of theoretical and regulatory issues which may affect innovations. Global experts are able to advise on these before an innovation is introduced to any country context; and can play an ongoing role in learning and transferring lessons between national contexts (Interviewee 37, p. 4). At the same time, UNICEF suggests that globalisation means the opportunities for collaboration for large-scale change now allow 'grassroots problem-solvers' to access a 'global collaborative workspace' for transformative innovations, including with groups usually excluded from this exchange of ideas:

In our hyper-connected, globalized world, people, technologies and ideas move more fluidly than ever before, generating unprecedented opportunities for collaboration to create large-scale change. Indeed, a global infrastructure of exploration is beginning to emerge, with innovators sharing ideas across borders and among groups of people previously excluded from the marketplace of knowledge and ideas (UNICEF, 2014a, p. 8).

At other times UNICEF hints at the integration of an innovation within the relevant existing system at the national level in order to change that system itself. This is more fundamental than the 'rooting in local circumstances' examined earlier in this chapter. The UNICEF strategic plan 2018-21, for example, highlights the importance of 'the use of new technologies to strengthen systems (UNICEF, 2018b, p. 29). This brings with it the concept of much deeper contextual engagement in order to achieve change in the broader country system. A lessons-learning paper on scaling innovation highlighted the need for innovation to be deeply embedded in national systems, 'given the magnitude of ecosystem change, stakeholder commitment and resources' needed to achieve real impact (UNICEF, 2019d, p. 3).

This transformative approach necessitates collaboration between those people who understand the service delivery system and its problems with those who are bringing the proposed innovation, as described by a UNICEF country immunization officer:

What we need to get is the people who understand the systems, who understand the service delivery problems, with the gadget people. Put them together to solve real problems. I think that's often done, but in a rather superficial way because they both come from these long traditions, different paradigms. So, you need go across those cultures (Interviewee 31, p. 4).

Another UNICEF country immunization officer emphasises the necessity of understanding the complex overarching set of interconnected actors and knowledge:

A lot of my job I guess is trying to understand what the existing space landscape looks like: who are the players, what are the gaps, where can you add value in ways that do not undermine the existing system and perhaps strengthen it, and then how do you communicate that to government (Interviewee 16, p. 3).

Similarly important, emphasises another UNICEF country immunization officer, is understanding the relevant institutions, which they describe as 'histories and cultures' and 'long traditions, different paradigms'. They suggest that because this is very hard to do, donors sometimes find it 'easier to focus on gadgets' (Interviewee 31, p. 5), but that 'gadgets might be a stimulus' to transforming systems (Interviewee 31, p. 4). UNICEF itself has at times described a similar argument, saying that

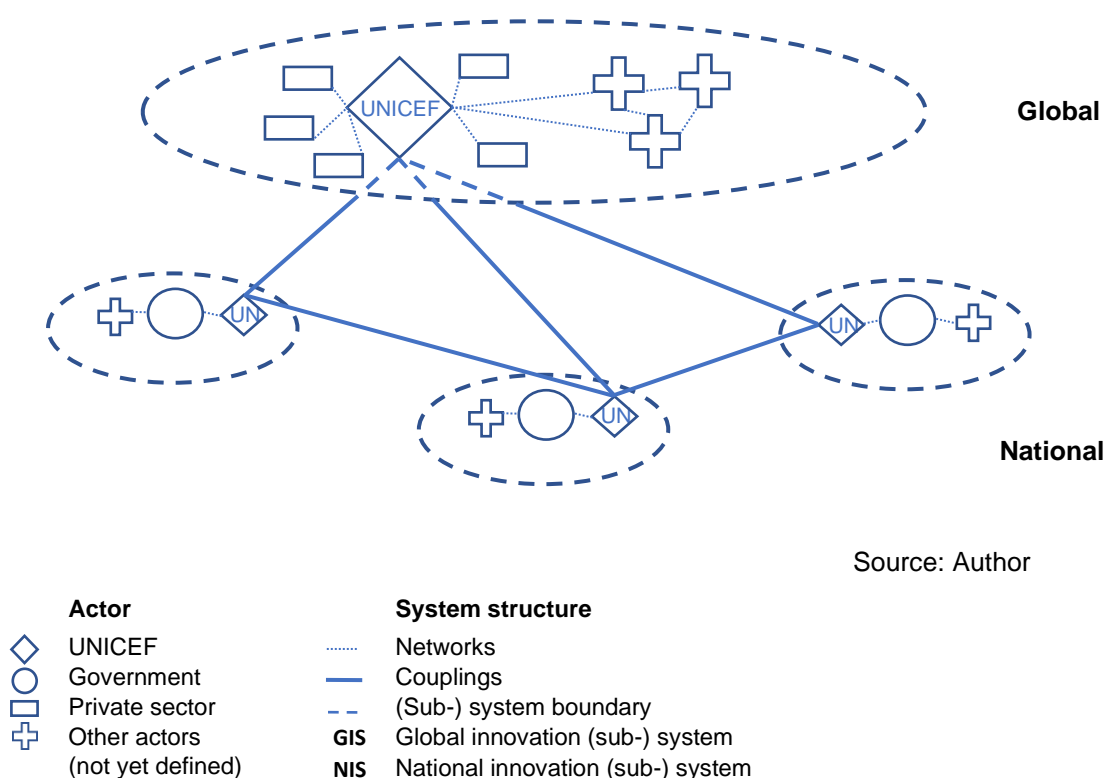


‘technology can support human behaviour as a key driver of success in solving complex, systemic problems’ (UNICEF, 2016a, p. 105).

Earlier in this chapter we identified a key role which UNICEF plays between sub-systems of innovation at the global level at which innovations primarily originate, and sub-systems at the country level in which immunisation service delivery, and hence innovation valuation, takes place. As we saw, UNICEF does this by directly connecting local and global level actors, in a role which it terms ‘being glocal’.

In the Global Innovation System (GIS) model such connections are represented by structural couplings, as shown in the following figure, adapted from the illustrative GIS of Binz and Truffer (2017):

**Figure 19: Structural couplings in immunisation GIS involving UNICEF (Author)**



The structural couplings provided by UNICEF are bi-directional: those linking global and country sub-systems vertically enable UNICEF to translate and consolidate country needs upwards, from the local to the global level; and also function in a downwards direction, enabling UNICEF to adapt global solutions to the local level. It is through these structural couplings that knowledge is created, and innovation

valuation resources generated. Similarly, the horizontal structural couplings between country sub-systems enable the sharing between them of knowledge.

## 5.4 Conclusion

UNICEF engages actively with innovation in immunisation at both global and national levels. Each of these correlates with strong organisational capabilities of UNICEF. At the national level these are UNICEF's in-depth understanding of national contexts and strong relations with less economically developed country (LEDC) governments and other actors, though its highly decentralised organisational structure. At the global level, the relevant organisational capabilities are UNICEF's reputation, authority and convening power in impact, innovation and immunisation. UNICEF claims to have a strong comparative advantage in a role linking these two spatial levels, and indeed, in principle, it does. There are instances of this manifesting, for example, in the use of UNICEF's SMS-based reporting system for the monitoring in real-time of vaccine campaigns in countries, and in the systematic collating by UNICEF's Supply Division of country needs in immunisation in order to issue target product profiles for the procurement of innovation. When this role works well, UNICEF provides value to innovation in two primary respects. It generates and utilises market access, by providing authoritative information to potential inventors, globally, about likely demand in LEDC markets, and by informing LEDC governments and other national level actors about the resulting innovations. UNICEF also provides value through innovation legitimisation, at the global level on the basis of pilots it has carried out in countries, and at the national level, on the basis of its organisational endorsement of innovations once proven. Perhaps counter-intuitively for a donor organisation, financial investment is not a means through which UNICEF adds significant value to innovation.

The relatively small number and limited nature of examples of effective valuation, however, illustrate how UNICEF is not fulfilling the potential of this linkage for innovation in immunisation. This manifests in internal confusion regarding UNICEF's policy and priorities for innovation, and in conflict between internal actors located at these different levels. The conflict is also apparent in the way in which UNICEF interacts with presumptions, with different internal actors supporting particular presumptions.

This is most acutely seen in the degree of support, or scepticism, relating to a *techno-fix* perspective on the balance between knowledge generated primarily from

*science, technology and innovation* (STI) and knowledge generated primarily through *doing, using and interacting* (DUI). This relates to the power relations between UNICEF and LEDC governments, and specifically to the balance between pushing innovations upon countries, or being instead overwhelmingly country-led and paced. UNICEF has found an effective equilibrium for this in its role in formal global procurement, but outside this focused area, the balance remains unresolved in UNICEF. This necessitates a high level of customisation of innovation valuation resources, which significantly constrains its broader impact through innovation in immunisation.

## 6 THE CASE OF THE BILL AND MELINDA GATES FOUNDATION

This chapter examines the role of the Bill and Melinda Gates Foundation (BMGF) with respect to innovation in immunisation for international development. It argues that this is fundamentally oriented around power. BMGF uses its financial transfers to other donors and agencies to influence their agendas towards BMGF's aims, including increasing emphasis on both immunisation and innovation. This influencing is important for BMGF because it engages actively with innovation in immunisation essentially only at the global level. BMGF's financial investment also provides it with power of agency, in permitting a high risk appetite, which enables BMGF to fund higher risk innovations, especially those at an earlier stage of development. This combines with Gates' particular focus on entrepreneurialism to draw into immunisation a wide range of new private sector actors. BMGF also invests particular efforts at the global level to strengthening complementarity, coordination and learning between actors. The combined effect of these dynamics is both to strengthen linkages within the global innovation sub-system, and to expand its boundaries through the proactive inclusion of new and diverse actors. BMGF's financially-derived power relations thus both drive incremental structural change in the innovation system, and facilitate other actors to sustain it. BMGF's *simple structure* form of organisation is key to achieving the high levels of coordination required for the effective deployment of its various forms of power.

The chapter is divided into three sections. The first examines how BMGF's organisational characteristics affect its innovation in immunisation. It argues that three such characteristics in particular do so. A first characteristic is the leadership of Bill and Melinda Gates and in particular their *charismatic authority*. A second characteristic is BMGF's strong scientific positivist philosophy. A third characteristic is the status of BMGF as a foundation, and its associated narrow accountability and high risk-appetite.

The second section examines BMGF's engagement with institutions relating to innovation in immunisation. It argues that BMGF aims strategically to align with several norms, in order to gain access and influence within the community of actors in the space, and to advance particular presumptions.

The third section examines how BMGF interacts with other actors for innovation in immunisation. It argues that there are three important dynamics to these interactions, and that these take place overwhelmingly at the global level. A first

dynamic is that of BMGF investing significantly in its influence over other actors, which it then utilises in pursuance of innovation in immunisation. A second interaction dynamic is that of BMGF playing a particular role convening or coordinating other actors in innovation. A third interaction dynamic is that of BMGF interacting with private sector actors in shaping the market for vaccines and other innovations.

## **6.1 BMGF's organisational characteristics**

This section examines how BMGF's organisational characteristics affect its innovation in immunisation. It argues that three such characteristics are particularly relevant. A first is the leadership of Bill and Melinda Gates, whose *charismatic authority* gives BMGF legitimacy to pursue its objectives, of which innovation and immunisation are both high priorities. The Gates' leadership also generates significant financial investment for innovation, through both direct provision from the Gates' fortune and their mobilisation of finances from other sources. A second characteristic is BMGF's scientific positivism which drives its focus on immunisation, innovations and the role of the market, which interplay constructively. A third characteristic is the status of BMGF as a foundation, which brings with it a narrow accountability and high risk-appetite unique amongst actors in global public health. These enable BMGF to invest in high-risk, high-reward, innovation. As a result of these three characteristics, BMGF brings to the systematic fostering of innovation resources<sup>13</sup> in the form of financial investment, standardised across its activities and located overwhelmingly at the global level.

### **6.1.1 Leadership and legitimacy**

A first relevant organisational characteristic relates to BMGF's eponymous high-profile founders and funders, Bill and Melinda Gates. The couple<sup>14</sup> established

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<sup>13</sup> As we saw in Chapter 3, in the GIS model, the three non-knowledge resource types, market access, financial investment and innovation legitimacy, collectively constitute the valuation of an innovation.

<sup>14</sup> Bill and Melinda Gates announced in May 2021 that they would divorce, though they would continue to lead the foundation together.

BMGF in 2000 in order to fulfil their aim to share their significant wealth, 'to help all people lead healthy, productive lives'. Bill Gates explains there being an underlying personal emotional drive for this:

It was sobering to realize that the innovation and health care that we took for granted were not available for everyone. When I began to understand how billions of people are deprived of these benefits, it made me angry. And that's when I decided to use not only my time but also all the wealth I'd acquired to confront that inequity (Gates, 2011a, p. 2).

This wealth, which forms the foundation's endowment, was earned through Bill Gates' founding and investment in Microsoft from 1975 to 2008. As a result of this, he was the world's richest person from 1995 to 2007; has regularly since been number one, and not yet since out of the top four (Dolan and Peterson-Withorn, 2022). BMGF was founded a year after the Gates' wealth first reached the US\$100 billion mark (Gibbs, 2005). Gates' fortune has generated criticism both on philosophical grounds which question the equity of individuals amassing such a fortune (Moran and Stevenson, 2013); and on specific ethical grounds relating to Microsoft's near-monopoly in the personal computer operating system market. This was the subject of a high profile 2001 US Government antitrust case against Microsoft, accusing it of illegally maintaining its monopoly position through legal and technical restrictions it put on PC manufacturers. The case was finally settled with moderate concessions by Microsoft, but significant reputational damage for the company, though not directly for BMGF.

Since its creation BMGF has been by far the largest foundation in the world, in terms both of assets and of expenditure, with assets of US\$52 billion and annual expenditure of US\$6bn (2017 figures) (Clarke, 2019). From inception to 2019, BMGF has made grants totalling US\$ 50 billion in three focus areas: global development, global health and the USA (especially educational programmes) (Partzsch and Fuchs, 2012). The Gates' generosity, however, also has its critics, who question whether this philanthropy is an attempt to divert attention from, or gain public favour following, the 2001 US antitrust case against Microsoft (Editorial, 2003). Arguing against such criticism is the disproportionate scale of the Gates' philanthropic contribution in comparison to their overall wealth: the Gates have pledged to give away half of their wealth to charity and have been lobbying other billionaires also to sign up to this 'Giving Pledge'.

As a consequence of the huge scale of its ambition and of its resources, BMGF has become ‘the current era's most influential global health (and education, development, and agriculture) agenda-setter’ (Birn, 2014) and ‘arguably the most important actor in global health... increasingly shaping global health priorities... and dominating the overall discourse of health and development’ (Mahajan, 2018). Yet BMGF is controlled by a very small group consisting of Bill and Melinda Gates and their friend Warren Buffett, who in 2006 announced that he intended to donate the majority of his fortune, then the second largest in the world (behind Gates’ own), to BMGF on the condition that Bill or Melinda Gates would remain active in the foundation’s administration (Loomis, 2006).

Eponymous philanthropic foundations are typically closely associated with a family or individual (Clarke, 2019), and indeed BMGF has remained constantly closely associated with in particular Bill Gates. Critical discourse analysis of Microsoft’s representation of Gates finds that it is essentially of ‘a geek computer nerd who built a corporate empire’, upon which narrative he has emerged as a particularly iconic entrepreneur (Boje and Smith, 2010, p. 315). The image of Gates, often represented in glasses and a jumper, suggests a narrative that Gates relies on evidence-based decision-making rather than intuition, and adaptation rather than creative destruction (Boje and Smith, 2010; McGoey, 2015). Although this narrative can be challenged as being reductionist, it does illustrate that Bill Gates in particular has a high-profile public persona with quite clear characteristics which tend to be positively regarded within society.

The Gates’ exceptional skills, philanthropic aims, and visionary approach meet the criteria for what Weber terms *charismatic authority* (Weber, 1958; Harman, 2016). This has three major effects on BMGF. Firstly, the Gates’ personal values are closely reflected in foundation policy. Vaccination, for example, has consistently been a high priority for BMGF’s investment, with grants to Gavi, the Vaccine Alliance alone totalling US\$ 5.9 billion since 2000 (Gavi, 2022d). Bill Gates regularly publicly extols the benefit of vaccination, describing vaccines, for example, as ‘the most effective and cost-effective health tool ever invented. I like to say vaccines are a miracle’ (BMGF, 2011a, p. 8). Similarly, Gates has consistently demonstrated a very high level of expectation also from innovation, writing that:

I believe innovation is the most powerful force for change in the world.

People who are pessimistic about the future tend to extrapolate from the

present in a straight line. But innovation fundamentally shifts the trajectory of development (Gates, 2011a, p. 4).

As well as illustrating the high value that the Gates place on innovation, this also indicates their underlying reasoning, that innovation is the means to achieve transformational impact improvements. This focus on impact, and of the critical role of innovation in achieving it is manifest in BMGF's approach to grant-making, being focused on 'collaboration, innovation, risk-taking, and, most importantly, results' (BMGF, 2022a). The conjunction of risk-taking and collaboration with innovation is purposeful, with the organisation seeing them as inseparable from innovation. Secondly, the Gates' *charismatic authority* confers legitimacy on BMGF. This mechanism occurs through normative societal acceptance of an individual's 'exemplary character' (Weber, 1958; Harman, 2016), which provides the basis upon which the foundation claims recognition and ultimately legitimacy in its external activities and interactions. Thirdly, the Gates' *charismatic authority* serves to increase the financial investment available in international development and immunisation, in several ways. Aside from the couple's own financial donations, contributions have also been made to BMGF from similarly wealthy friends of the Gates, like Warren Buffett, on the basis of their confidence in the Gates. In addition, the Gates' entrepreneurial approach to development assistance, sometimes termed *philanthrocapitalism* (Bishop and Green, 2008), is important in combating the fatigue and scepticism expressed by taxpayers concerning the use of their taxes for international development in light especially of the global financial crisis of the past decade or so, and the associated government austerity policies. BMGF's core narrative relating to a market-based approach to aid, and to the opportunities presented by innovation have indeed generated increased political will behind aid of this sort (Moran and Stevenson, 2013). Furthermore, the Gates see innovation as a means to increase efficiency of the available development resources, writing that:

Key innovations like new seeds and vaccines – and new ways to deliver them to the poorest – can multiply the impact of the resources we're already devoting to development. We've made a big difference, but we can improve the basic tools of development by making them cheaper, easier to use, and more efficient – or by inventing wholly new tools (Gates, 2011b, p. 2).

This financial investment generated by the Gates for international development is, however, criticised on the basis of its allocation being based on entrepreneurialism and scientific positivism, as examined in the following section.



### 6.1.2 Entrepreneurialism and scientific positivism

A second relevant organisational characteristic is BMGF's entrepreneurialism and scientific positivism. Gates' background in the private sector contributes to BMGF being seen as having an approach towards global public health which is 'entrepreneurial' (Youde, 2013) and with a 'single-mindedness and hard-boiled business habits' which are radical within global public health (Nature, 2003). The underlying factors behind that approach are well summarised as being BMGF's adherence to 'narrow, scientific, positivist and... market-oriented principles' (Moran and Stevenson, 2013). These scientific principles, and their link to innovation are explicit, with BMGF stating that it aims to achieve its mission 'by harnessing advances in science and technology to reduce health inequities and save lives in poor countries' (BMGF, 2011b, p. 1).

This scientific approach includes driving a strong focus on using data as the basis upon which to make decisions. BMGF's reasoning behind this is that it promotes innovation, 'by encouraging diversity of analysis and opinion, facilitating evaluation of alternative hypotheses, permitting meta-analysis, and facilitating synthesis of results' (BMGF, 2011b, p. 1), and also by facilitating improvements in collaboration, efficiency, accountability and capacity-building. This approach correlates with BMGF's commitment to results-based resource allocation, through the linking of BMGF grants to measurable outcomes (Brown, 2007). Partly as a consequence, public-private partnerships are seen as 'pragmatic, solution-oriented, flexible, efficient and un-bureaucratic' (Seitz and Martens, 2017, p. 47). This is in contrast to the common perception of traditional aid, and represents an important reassurance to a public increasingly cynical about aid.

The nature of BMGF's approach, however, is criticised from several perspectives. The most fundamental criticism is that BMGF's focus on targeted technical programmes based primarily around technological innovations is highly reductionist. At its most extreme this criticism claims that BMGF assumes a *techno-fix* approach, in which innovations can solve the persistent political, economic and social problems of inequitable distribution of power and resources within and between societies (Birn, 2005, Birn, 2014). Others phrase this in terms of BMGF addressing 'symptoms not solutions' (Faubion, Paige and Pearson, 2011), pointing out that tackling the larger, structural causes of poverty would require radical, political reform of country systems (Moran and Stevenson, 2013) and not just cutting-edge technologies. At the least, critics suggest BMGF's approach underestimates the

relevance of political and structural barriers to development (Brown, 2007; Seitz and Martens, 2017). They cite Sen's demonstration that starvation of the poor during famine is not because of a lack of availability of nutritional food. Sen found that political and economic factors mean that the poor are unable to afford nutritional food, as a result of inequitable domestic income distribution, and diversion of food to a more profitable export market (Sen, 1981). By extension, these critics suggest that rather than funding technological innovations such as vaccines, BMGF would better use its resources to raise political support for wider improvements in living and working conditions in less economically developed countries (LEDCs) (McCoy *et al.*, 2009). If not this, the critics suggest that BMGF should at least make less focused investments. Rather than investing in the development of vaccines that do not require a cold chain, for example, they suggest that BMGF should invest in increasing electricity coverage in LEDCs, because of its positive developmental impact on living standards and livelihoods (Birn, 2005; Brown, 2007; McNeil, 2008).

Bill Gates addresses these criticisms explicitly in his keynote speech at the 2005 World Health Assembly. He recognises the wider societal problem of poverty and 'tragic inequality' and although not describing a role for BMGF funding, Gates uses his access to high-profile political platforms to argue for the importance of political action and responsibility, challenging that 'many developing countries are not doing nearly enough to improve the health of their own people'. He also describes as part of this advocacy a role for technology, specifically in global communications, through its ability to increase awareness of these inequalities and to convey pressure for their resolution (Gates, 2005, p. 1).

In fact, within international development, other voices raise concerns that political engagement by donors represents a threat to the autonomy of the state, especially if involving the privatisation of public health. BMGF's more focused engagement in technical areas of health, accompanied by selective engagement with the government avoids these negative aspects (Mahajan, 2018). Rather, Gates sets out a theory of change in which instead of directly addressing political, economic or social drivers of inequality, BMGF mitigates them indirectly:

We do need to produce and deliver a vaccine – and the vaccine will save lives, improve health and reduce poverty. Improving health improves education; it expands productivity; it results in people having smaller families, so resources go further. When health improves, life improves by every measure (Gates, 2005, p. 5).

Central to this position is BMGF's understanding that vaccines are particularly impactful and cost-effective, as when Gates says at the 2011 World Health Assembly:

Vaccines are an extremely elegant technology. They can be inexpensive, they are easy to deliver, and they are proven to provide lifelong protection from disease. At Microsoft, we dreamed about powerful and simple technologies. Well, vaccines are such a technology, and now I dream about what the world will look like as we take full advantage of vaccines (Gates, 2011a, p.2).

This position is reflected in BMGF's funding distribution, of which it is estimated at least half (across research and development, healthcare delivery, advocacy or policy development) is related to vaccination (McCoy *et al.*, 2009). The distribution of these funds, however, gives rise to further criticism. The fact that vaccines and other innovations are more dependent than other interventions upon global expertise for their development and introduction (Bowman, 2012) contributes to a dynamic in which the majority of BMGF funding for global health is granted to organisations based in high-income countries. As of 2014, 90% of the 50 organisations receiving three quarters of these funds were based in the United States, United Kingdom and Switzerland (Birn, 2014). Geneva-based Gavi, BMGF's single largest grantee, is a prime example. This raises concerns that BMGF's scientific positivism perpetuates the geopolitical power dynamics which make it difficult to eliminate poverty and inequality, which, critics remind us, is never more evident than in the scale of the Gates' personal wealth (Arnove and Pinede, 2007; (Brown, 2007; McCoy *et al.* 2009).

Against these criticisms is the recognition that the heavily BMGF-supported vertical initiatives such as Gavi and the Global Fund do provide, alongside their vaccines and other health commodities, significant funding for the strengthening of the related health system, and in many cases, also of civil society accountability mechanisms. BMGF tends to justify this on the grounds of innovation-effectiveness, rather than on broader principles, with a BMGF senior advisor saying that:

You can keep introducing new innovative products, whether they're vaccines or all kinds of other global health interventions. But they only reach people through systems. And so those systems have to be strong... You've got also to simultaneously strengthen and improve the performance of the system (Interviewee 39, p. 1).

BMGF also provides complementary support. In addition to, for example, its support to Gavi for the vaccine against rotavirus (a diarrheal disease), BMGF also supports non-governmental organisations to deliver water and sanitation programmes to reduce the insanitary conditions in which rotavirus thrives, and agricultural programmes to address malnutrition.

Thus, BMGF's approach to global public health, prioritising as it does scientific research, pharmaceutical development and the integration of technological innovation, reflects both BMGF's philosophy and its assessment of where the foundation can best contribute (Youde, 2016). Bilateral donors, by contrast, tend to be better positioned by virtue of their extensive country-office network, to working with LEDC governments to achieve more comprehensive health system strengthening, leaving BMGF to focus on narrower or higher-risk programmes (Editorial, 2005). BMGF adopts a similar 'informal responsibility divide with national governments' (Youde, 2016, p. 210) such as to ensure, for example, that large-scale infrastructure projects are led by government, whom BMGF sees as best placed to do so (Youde, 2016).

The second aspect arising from Bill Gates' background working within the private sector is that of being free market-oriented, and particularly in seeing the market as representing a sustainable and scalable approach to providing innovations to meet the needs of the poor. This is the premise behind a philosophy which Gates describes as 'creative capitalism', defining it as:

an approach where governments, businesses, and non-profits work together to stretch the reach of market forces so that more people can make a profit, or gain recognition, doing work that eases the world's inequities (Gates, 2008, p. 3).

Gates describes how capitalism's profit incentive leads to significant innovation within businesses, and that large numbers of people benefit from those innovations, as long as they have the ability to pay for them. In contrast, Gates sees conventional aid as being of insufficient scale, and he implies, insufficiently transformative to meet the needs of the world's poor. To draw innovators into this mission in the absence of a functioning market, Gates proposes altruistic 'recognition' as an alternative motivation, which he suggests is sufficiently powerful as to incentivise innovation until the point at which the market is mature enough to enable profits to be made.

BMGF sets out scenarios in which such innovation might be brought to the benefit of the poor. Firstly, through mechanisms to distribute in LEDCs a suitable innovation which already exists in HICs; secondly, by adapting an existing innovation to the resource-constraints or other contextual factors in LEDCs; or thirdly, through innovation to meet challenges in LEDCs currently unmet anywhere (Flower, 2018). Bill Gates illustrates this, as often, with reference to vaccines, saying:

In the past, innovators were developed first for the rich countries, and it often took a decade or two before they were introduced to the poor countries that need them the most. But that is changing. These new pneumonia vaccines were available in developing countries only a few years after they were approved for use in developed countries (Gates, 2011a, p. 3).

Bill Gates, furthermore, identifies a major role for BMGF in driving this creative capitalism, writing that ‘the focus of Melinda’s and my foundation is to encourage innovation in the areas where there is less profit opportunity but where the impact for those in need is very high’ (BMGF, 2012, p. 2). In fact, he identifies a particular comparative advantage for such foundations in fulfilling this role, writing that:

Foundations provide something unique when they work on behalf of the poor, who have no market power, or when they work in areas like health and education, where the market doesn’t naturally work toward the right goals and where innovation requires long-term investments (BMGF, 2009, p. 14).

Furthermore, Bill Gates’ separately suggests that foundations endowed by business-generated wealth have a particular comparative advantage in liaison with the private sector because of a common mindset, people and relationships. These assertions are both examined further later in this chapter.

Important to BMGF’s market-orientation is the principle of intellectual property, which BMGF sees as fundamental to private sector-led innovation because of its ‘inherent potential to incentivize product research and development’ (Flower, 2018, p. 7). The protection intellectual property rights provide is argued by pharmaceutical companies as being essential for them to invest in research and development. This is based upon the costs of research and development being very high, at an average of US\$ 800 million per new product, including the costs of failures and opportunity costs (DeMasi, 2001). This amounts to more than 30% of the total cost of bringing a vaccine to market (Kettler and Marjanovic, 2004). Manufacturers argue that patent protection is necessary to allow them to set prices sufficient to recoup

those costs, without price competition on generic products from competitors (Batson, Meheus and Brooke, 2006). In response to advocacy by some LEDCs for a loosening of intellectual property around vaccines, BMGF argues that intellectual property is particularly relevant to the development of low-cost vaccines, to enable, for example, the licencing of vaccines for different viral strains from different manufacturers (Flower, 2018). Instead, BMGF points to the need to increase technology transfer:

To maximize global supply, we need to have innovative ways to ease and encourage tech transfer... A tech transfer requires time, it requires resources and sharing of know-how, not just intellectual property (Hoecklin, 2021, p. 4).

To illustrate this Gates refers to a Dutch vaccine manufacturer which holds the intellectual property rights for a cholera vaccine, which it has retained in more economically developed countries (MEDCs), but has shared with manufacturers in LEDCs (Gates, 2008). This is an example of *dual market technology*, which involves the out-licencing of an innovation to different national markets, or on the basis of different applications serving different income-based market segments.

In addition, Bill Gates claims that BMGF exerts 'control' over its investments to ensure that 'when our medicines go into the poor countries, they are always going in without any intellectual property fee, at very lowest cost pricing' (New and Saez, 2011). BMGF attempts to leverage both the incentivisation provided by IP rights, as well as the flexibility of price tiering through its 'Global Access' conditions, in which recipients of BMGF grants agree that:

(a) the knowledge gained during the project to be promptly and broadly disseminated, and (b) the intended product(s) to be made available and accessible at reasonable cost to people most in need within developing countries (Flower, 2018, p. 8).

BMGF asserts that these conditions allow the philanthropic aim of its grants to remain paramount, whilst not precluding commercial benefit in MEDCs. Indeed, this differential pricing is used successfully extensively in the vaccine market, enabling manufacturers to recoup their research and development costs and earn a profit in MEDCs, whilst also enabling LEDCs to access the vaccines (Trouiller *et al.*, 2002; Batson, 2005).

Critics of BMGF acknowledge that BMGF supported vaccine manufacturers do operate a tiered pricing mechanism. They argue, however, that the manufacturers 'are subject to almost no transparency requirements and to toothless contractual nods to equitable access that have never been enforced' (Zaitchik, 2021, p. 6). This, indeed, is consistent with the approach of BMGF described by Flower (2018) above in which BMGF's expectations of their private sector partners are based essentially ultimately on trust.

### **6.1.3 Accountability and risk-appetite**

A third relevant organisational characteristic is BMGF's status as a foundation, which brings with it a narrower accountability and higher risk-appetite than traditional actors in global public health.

Bilateral government donor agencies, being publicly-funded, are accountable to their nation's taxpayers, who are obliged to pay taxes and have very limited direct ability to influence government expenditure. UN agencies are funded through a combination of states' assessed contributions, over which, like individuals' taxes, states have no choice or control; and voluntary contributions which states may make additionally. This puts UN agencies in a position of accountability towards multiple governments, and hence indirectly, their constituents. In contrast, foundations, because they are resourced by privately donated funds, are accountable for those funds only to those individuals or corporations which provide those funds, which manifestly is of a scale many orders smaller than that of the taxpayer base in a country.

The impact of this very narrow accountability is two-fold. Firstly, it makes it much quicker and simpler to gain buy-in from stakeholders on the foundation's strategy and approach, including to changes in these, by virtue simply of the much smaller numbers of stakeholders involved. Moreover, those who contribute to a foundation do so voluntarily, as opposed to those paying tax. Those providing voluntary funding will tend to be more homogenous in their world views, because they are attracted by the same foundational offer. This functions such as also to make it easier to reach sufficient consensus on a foundation's strategy and approach. The result of this twin advantage is for such organisations to be more focused in their strategy, and nimbler to adapt to changes in context, needs or opportunity (Rushton and Williams, 2011).

The second impact of the focused accountability seen in foundations is that they are able to adopt a risk appetite which is more radical than in other organisations. As Bill Gates sets this out:

Melinda and I see our foundation's key role as investing in innovations that would not otherwise be funded. This draws not only on our backgrounds in technology but also on the foundation's size and ability to take a long-term view and take large risks on new approaches (BMGF, 2010, p. 3).

In comparison to publicly-funded agencies, foundations' greater risk appetite allows them to invest in projects which have a higher degree of risk, whether because they are less-proven, or because the timelines until expected impact are longer. Both of these aspects are particularly relevant to innovation, involving as it does solutions which are exploratory and for which developing proof of impact takes time. As Bill Gates describes, innovation is both 'high-risk and high-reward' (BMGF, 2009, p.14).

The relative nature of this appetite in respect of other organisations within the field is important, as set out by a BMGF immunization program officer:

In general, our value-add or comparative advantage is on those riskier or longer-term bets. At least in the Vaccine Delivery Team, that's where we've seen that. I mean, Gavi potentially can't sink US\$ 50m into something and have a potentially 50% chance of failure even though failure is important, and those risks are necessary (Interviewee 8, p. 2).

Other actors recognise this advantage, with a senior UNICEF immunisation officer saying that 'we think the Gates Foundation has a better advantage in investing into more moon-shot stuff' (Interviewee 10, p. 3). This conscious, strategic setting of risk appetites based not just on internal factors but also on interrelations with other actors is an important feature of the sectoral dynamics around innovation.

This narrow accountability on the part of foundations can be a matter of concern if accompanied by significant influence over broader public policy and spending, which has the effect of giving disproportionate weight in these forums to the view of individual foundational donors, the skewing of the focus of international effort, and the exclusion of other, arguably more objectively legitimate, perspectives (Youde, 2013). This is examined in detail later in this chapter.



Critics accuse BMGF of not engaging enough directly with beneficiaries, suggesting that as a result ‘they make the communities where they work subjects rather than agents’ (Rothkopf, 2008; Harman, 2016; Youde, 2016). BMGF’s profile and scale makes them a particular target for this criticism. BMGF has mitigated this criticism to a degree, by establishing in recent years country offices in India, China, Ethiopia, Nigeria and South Africa (BMGF, 2020b), and the fact that BMGF tends to operate at the country level through the auspices of its grantees which do have country offices.

BMGF’s greater risk appetite does, though, bring with it increased expectations around learning and knowledge-sharing, as explained by a BMGF immunization program officer:

If we want to solve big problems, we need to find new solutions to them in certain areas, which means we need to take the risk of failure. And then we just need to fail well, fail fast and intelligently (Interviewee 22, p.2).

In order to help enable this learning, around innovation, BMGF organised its Vaccine Delivery Team around the sequential development phases of innovation, with three sub-teams: Strategy and Innovation; Development and Scale; and Global Implementation. This structure is intended to enable greater knowledge-sharing and creation, and hence greater progress towards scaled innovation. Innovations are first sourced by the Strategy and Innovation team. Once innovations have been shown to work in concept, they move on to the Development Scale Team, to test their replicability across a breadth of contexts. Finally, if an innovation is assessed as being useful across a wide range of countries, then it moves to the Global Implementation Team, which in particular sees its primary route to scale as being through Gavi (Interviewee 40).

This process is facilitated by an assessment framework used by the Vaccine Delivery Team to determine when innovations are sufficiently proven or proceed. The framework involves criteria including acceptance, viability, effectiveness, sustainability and adaptability. It provides a consistent lens and language across the organisation’s review of innovations, and provides the basis for BMGF ultimately to answer the question, as put by an immunization program officer, ‘what is the feasibility to scale and what does it take and then are we confident that we can do those things, or we can get the suite of partners within the [Gavi] Alliance to be able to do that?’ (Interviewee 8, p. 7). The allusion in this quote to the potential to

influence Gavi to implement an innovation is an important element in BMGF's approach to innovation and is explored in detail later in this chapter. The upshot of the structural and analytical systems in BMGF means that they are able effectively and efficiently to review opportunities and move resources accordingly.

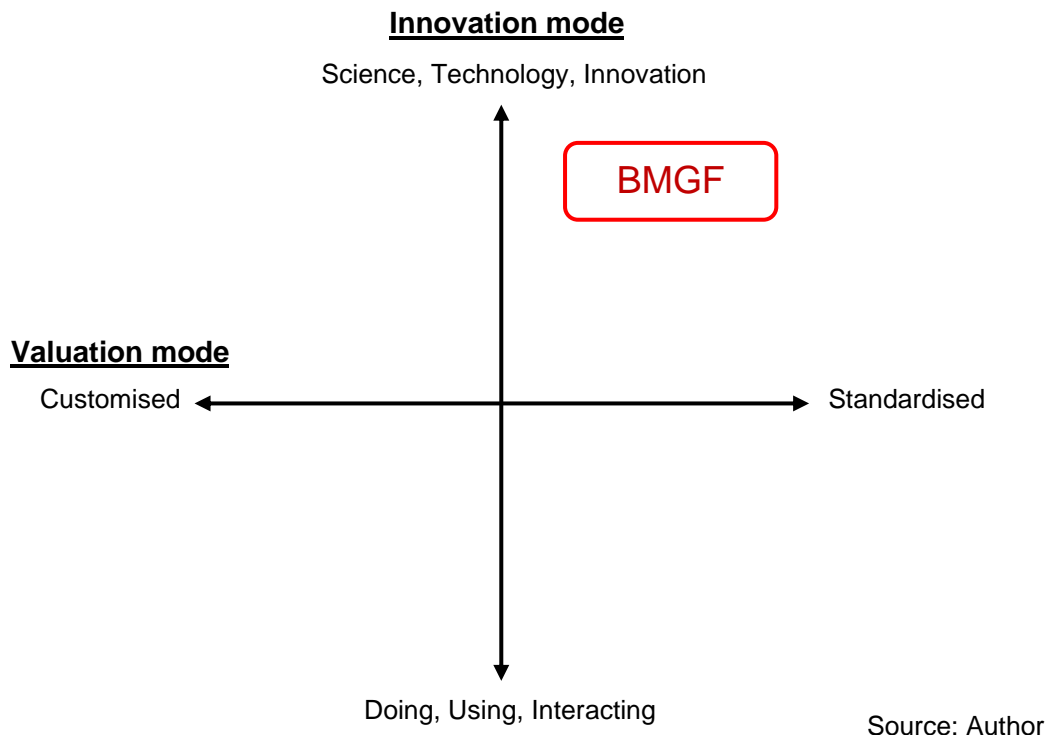
BMGF's organisational characteristics are consistent with it being an organisation of the archetype designated by Mintzberg as a *simple structure* form (see Table 3). This he described as being centrally controlled by one person, and highly reactive and responsive to environmental changes – which describes well BMGF's orientation around in particular Bill Gates, and its dynamic engagement in the sector.

For each of Mintzberg's archetypes, Lam (2005) sets out their innovation potential. A *simple structure* form of organisation, she describes as being entrepreneurial and as 'continually searching for high-risk environments', as indeed we have seen BMGF does. As weaknesses, she identifies vulnerability to individual misjudgement and resource limits – again, we see this reflected in BMGF's sometimes contentious attempts to influence the wider set of actors to its own agenda, in order to leverage these wider resources.

In terms of the innovation valuation resource which BMGF provides for systematic fostering of innovation, it is overwhelmingly that of financial investment. BMGF provides direct financing from the Gates' fortune, as well as the fortunes of others attracted by the Gates' *charismatic authority*, and these are complemented by indirect financing BMGF brings by achieving efficiencies through innovation, and by increasing public support for development assistance. BMGF utilises the resource and especially its risk-tolerance and flexibility, specifically to foster high-risk, high-reward, innovation, consistently.

Combining this standardised valuation resource with BMGF's basis in a mode of innovation which is overwhelmingly scientific, this distribution of resources is mapped against the innovation resources matrix of Binz and Truffer (2017) adapted as the following figure:

Figure 20: Innovation resource modes of BMGF (Author)



Source: Author

According to this representation, the distribution of resources for BMGF's innovation sits in the top right-hand quadrant. Based on Binz and Truffer's typology, this aligns to that of a footloose global innovation system (GIS). In this type, knowledge is primarily scientific and located in international networks or communities; and innovation valuation is primarily standardised across markets, relying on international standards and coherent user preferences for international legitimization and on mass-markets with economies of scale for market access.

The weaknesses are largely mitigated in BMGF through its strategic alignment with the prevailing norms in the sector in order to multiply up its impact beyond its own (significant) resources. It also serves to bring BMGF into policy and strategy discussion forums, thereby benefitting themselves from the views of others. This is examined in the following section.

## 6.2 BMGF's institutional engagement

This section examines BMGF's engagement with institutions for innovation in immunisation. It argues that the defining characteristic of this is BMGF's strategic aim to align with the prevailing norms in the sector. It does so in order to gain access and influence within the community of actors in the space (Harman, 2016) which it uses to increase the systematic strength of particular theories.

A first norm to which BMGF strategically aligns is that donors must participate in international governance mechanisms. At this highest level, this is reflected in the international consensus around global targets for development, in the form first of the Millennium Development Goals (MDGs) and then the Sustainable Development Goals (SDGs). BMGF has positioned itself as a high-profile advocate for the SDGs, with Bill Gates often addressing UN high-level fora relating to them, usually as the only non-Head of State or Government. BMGF complements this political engagement with alignment with the technical and normative lead of UN agencies in their respective technical areas. In the case of global public health, this is primarily the World Health Organisation (WHO). Its normative role is grounded in international law, in the form of the International Health Regulations, which it is WHO's role to uphold, adjudicate on, and to issue relevant technical guidelines. Specifically with respect to innovation in immunisation WHO manages various committees responsible for analysing innovations in different technical areas and advising WHO as to the policy to take with respect to them. The formal quality assurance role played by WHO at the conclusion of these processes is that of pre-qualification. This is a system of assessing and validating new medicines, vaccines, associated products and tools against pre-defined standards<sup>15</sup>. BMGF works in alignment with these technical processes, with design of innovation programmes in which BMGF is a major contributor and steering member, such as the Gavi Cold Chain Equipment Optimisation Platform, explicitly utilising the WHO processes for validation and endorsement of specific refrigerator models. The advantage of BMGF alignment to this norm, as well as supporting its influencing agenda examined later in this chapter is that such bodies provide an independent standard-setting mechanism for innovations, providing them with an established pathway representing part of the route towards introduction at scale, and increased legitimacy through it.

BMGF also aligns strategically with the norm that donors endorse the global immunisation strategy. BMGF was an active participant in design, use and monitoring of the Global Vaccine Action Plan (GVAP) for immunisation, 2011-20. The advantage of BMGF alignment to this norm, as well as supporting its influencing agenda, is that the plan includes a setting out of the importance of innovation in

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<sup>15</sup> See [www.who.int/topics/prequalification/en/](http://www.who.int/topics/prequalification/en/)

immunisation, and in so doing legitimises the focus which BMGF puts on innovation. In illustration of this, in the drafting of GVAP's successor, *Immunization Agenda 2030 (IA2030)*, BMGF led the drafting of the innovation section. It also represents a means for BMGF to reinforce the mutuality between donors in the innovation space for immunisation, and through that to put pressure on the other actors also to allocate their own resources to it. Further to that end, BMGF established and has continued to fund the Global Vaccine and Immunization Research Forum (GVIRF), first held in 2014 and every two years since. Its aim is to track progress on GVAP's R&D agenda, identify opportunities and challenges to GVAP goals, promote partnerships for vaccine research, and facilitate the inclusion of all stakeholders. This forum includes regular discussion of the potential benefits of specific innovations, as well as of broader considerations relating to innovations in general, such as work to develop metrics to better quantify innovations' potential benefits (Ford et al., 2015, 2018).

A third norm to which BMGF strategically aligns is donors upholding of aid effectiveness principles. These are enshrined in the principles agreed at periodic high level forums, the culmination of which was the Busan Partnership Agreement, which proposed four principles for cooperation for effective development:

- 1) Ownership of development priorities by developing countries
- 2) Focus on results
- 3) Inclusive development partnerships
- 4) Transparency and accountability to each other

(OECD, 2011, p. 1)

Bill Gates has been vociferous in exhorting other donors 'to get serious about maximizing aid's effectiveness' and highlighted the importance of data in assessing and improving the performance of aid (Gates, 2011b). The advantage of BMGF alignment to this norm, as well as supporting its influencing agenda, is that these aid effectiveness principles tend to align closely with the principles underlying BMGF's own approach, including for more rigorous, transparent and efficient aid (Fejerskov, 2015), and of the high impact of the new development models manifested in organisations such as Gavi and the Global Fund. This serves as a virtuous circle, as BMGF supports innovations, and other donors subsequently come-on board, the role of BMGF as a pioneer, leader and authority is strengthened (Harman, 2016).

In a similar dynamic, BMGF uses the access and influence it gains from normative alignment to strengthen certain sectoral presumptions which are important to it. One is that of the opportunity of digital technology to enable transformative innovation. BMGF's strong natural alignment with this presumption derives both from Gates' own background in computing and his scientific positivism, but also from his entrepreneurial approach to invest particularly in those interventions with the greatest return on investment. BMGF similarly aligns naturally with the presumption that there is a comparative advantage of the private sector in innovation. As we identified in our introductory chapter, donors see the private sector as being more innovative than the public sector as a result of the profit motivation driving its search for greater impact or efficiency through innovation. Donors see the private sector as having greater capacity to gather and use for decision-making data, to analyse costs and benefits, to move at pace, and to make decisions to move resources, including especially, away from failing projects.

Clarke (2019) describes BMGF as a rule-maker rather than a rule-taker, in terms of their setting of the global health agenda. As we have seen, BMGF's engagement with rules is more nuanced than this implies. We have seen how its taking of norms is a strategic approach in order to enable rule-making around presumptions. In the following section we examine how this is achieved.

### **6.3 BMGF's interactions with other actors**

This section examines how BMGF interacts with other actors for innovation in immunisation. It argues that there are three important such dynamics. A first is that of BMGF investing significantly in its influence over other actors, which it then utilises in pursuance of innovation in immunisation. A second dynamic is of BMGF convening or coordinating other actors in their innovation. This serves to increase the efficacy and efficiency of the process of innovation itself, through the identification of complementarities and elimination of duplications, as well as the inclusion of additional expertise and knowledge-sharing across actors. It also reinforces the position and influence of BMGF amongst those actors. A third interaction dynamic is BMGF shaping of the market for vaccines and other innovations, which it perceives as a critically important mechanism towards sustainable global poverty reduction. It does so by operating upstream, with a 10 to 15 year time horizon, and in complementarity with other actors.

BMGF's interactions with other actors play a key role in firstly, strengthening complementarity, coordination and learning between actors, and secondly, in bringing-in new actors. The combined effect of these dynamics is both to strengthen linkages within the innovation system, and to expand its boundaries. In this way, we will argue, BMGF both drives incremental structural change in the innovation system, and facilitates other actors to sustain it (Moran and Stevenson, 2013).

### **6.3.1 Influencing, not just 'a source of money'**

A first interaction dynamic in BMGF's innovation in immunisation is that related to its influencing of other actors in immunisation. During the first years after it was founded, BMGF took a deliberately independent position amongst the set of other actors. This strategy of isolation, Fejerskov (2015) attributes to a belief on the part of BMGF that this would provide it greater freedom of action. From about 2002-03 onwards, BMGF apparently realised that this strategy was not sufficient to enable it to achieve the scale of impact it desired, and that this, rather, entailed a wider breadth of global health assistance adopting BMGF's approach for increased effectiveness. It would also necessitate a complementary set of actors, on the basis that while foundations can be well positioned to catalyse innovation in governance, they tend not to be well-placed to sustain it (Moran and Stevenson, 2013). BMGF appreciated, accordingly, the need to build coalitions and influence those actors to use their resources and strategies to contribute to the achievement of BMGF's aims (Bishop and Green 2008, Partzsch and Fuchs, 2012; Fejerskov, 2015; Clarke, 2019). BMGF's Vaccine Delivery Director emphasises this principle with the example of the Gavi Alliance:

By working within a coordinated Gavi effort, our voice gains impact and legitimacy as compared to working alone (Gavi, 2015b, p. 53).

Primarily, BMGF has attempted to gain influence through funding, by making large multi-year commitments to international organisations. The potential for BMGF to do this at scale is illustrated by the fact that BMGF's annual budget exceeds that of every UN specialised agency except the World Food Programme (Clarke, 2019). BMGF's annual spending on global health alone is comparable to the annual budget of WHO (McGoey, 2015). Between 2014 and 2017, BMGF granted more than US\$ 1 billion to WHO (Seitz and Martens, 2017). Since then, BMGF has granted a further US\$1 billion to WHO (WHO, 2022c). In WHO's 2018-2019 biennium, BMGF's US\$ 530 million grant made it the second-largest funder to WHO after the US

Government (WHO, 2020b). The grant was provided in the form of *specified voluntary contributions* which allowed BMGF to designate amounts to specific areas of WHO work, which ability BMGF utilised significantly, directing it to 33 different areas (WHO, 2020b). This approach takes advantage of the situation in which earmarked projects were already undermining multilateral organisations' abilities to implement coherent, coordinated actions (Seitz and Martens, 2017) thus increasing the opportunity for influence by a more coherent, well-resourced external party like BMGF.

BMGF has been an even more significant funder of vertical health funds. In Gavi's five-year strategic period 2016-20, for example, BMGF provided US\$ 1553 million, making it the second-largest funder to Gavi, after the UK Government (Gavi, 2022a). Such a level of funding to a public-private partnership is usually accompanied by BMGF representation on its Board, as is the case in Gavi. This allows BMGF formal leverage into the organisation's decision-making (McCoy *et al.*, 2009; Harman, 2016; Seitz and Martens, 2017). The governance structure of the UN agencies tends to be too fixed to allow formal BMGF involvement, and in these cases, BMGF often makes use of strategic secondments of staff into the agencies, or the funding of specific posts, which represents an opportunity for soft influence (Seitz and Martens, 2017). This approach is characterised by a UNICEF official as resulting in BMGF being 'always present at the table, even if it is not in the room' (Mahajan, 2018, p. 1365).

BMGF is also involved significantly at a technical level in agencies' agenda- and policy-setting processes (McCoy *et al.*, 2009). To do this, however, BMGF recognised that buying influence was not likely to be sufficiently effective. Rather, it needed to influence from a position of having a recognised legitimacy and respect, as described by a senior advisor in BMGF in interview with Fejerskov (2015):

Material power is a strong force, but to truly capitalize on normative forms of power you naturally need legitimacy, and such legitimacy can so to speak not be taken, it can only be given, you need the respect, the deference, from other organizations around you (Fejerskov, 2015, p. 1110).

A director in Gavi illustrates the thoroughness of BMGF's approach to gaining this respect and deference, saying:

They've developed remarkable technical sophistication actually. They're a case-study in going from just a source of money to a source of money that



has significant technical expertise and can actually drive thinking. I have a lot of respect for them. I deal with them all the time on some of these technical issues, and they do their homework (Interviewee 19, p.4).

Thus, BMGF's investment in their technical competence is seen as important to their legitimacy and hence ability to influence. The increased demand this places on human resources is evident in BMGF's staffing. During its early years, BMGF specifically adopted a lean bureaucracy, with only 130 employees in 2000, and administrative costs of US\$ 45 million in 2002. Over the following decade these grew 10-fold, to a workforce of more than 1200 in 2013, and administrative costs of US\$ 450 million in 2012 (Strouse, 2000; Fejerskov, 2015). By 2019, BMGF had 1500 staff based primarily at its headquarters in Seattle, government-liaison offices in Washington, DC, London and Berlin, and country offices in India, China, Ethiopia, Nigeria and South Africa (Youde, 2013; KPMG, 2020, BMGF, 2022b).

A complementary approach to soft influencing on the part of BMGF is its use of Bill Gates' access to international platforms, including the G7/8, G20, various UN-organised international development forums, and BMGF's membership of informal groupings such as the 'Health 8', which is a group of the most important organisations in global health<sup>16</sup> (Partzsch and Fuchs, 2012), all which have served significantly to increase the focus on global public health in the international political agenda (Editorial, 2015). Specifically, a ripple-effect can be observed, caused by BMGF's high profile support for specific under-funded areas of global public health raising public pressure on donor governments to increase their allocations of aid to those areas (Cohen, 2002; Youde, 2013).

With bilateral donors collectively contributing ten times more resources to global health each year than does the BMGF (McCoy and McGoey, 2011), BMGF specifically aims also to influence their development assistance allocations. The ability of BMGF to identify potential high yield projects, and to fund the initial, high-risk phases, represents a form of seed-funding to catalyse other donors to pick up on and fund follow-up phases. This can be seen in immunisation at the macro, meso

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<sup>16</sup> Other members are the World Bank, WHO, UNICEF, UNAIDS, UNFPA, Gavi, and GFATM.

and micro levels (Partzsch and Fuchs, 2012; Editorial, 2015). For example, BMGF as well as being Gavi's founding donor, has continued to be its principal funder, with increasingly large contributions. From 2000-2010 BMGF provided Gavi with US\$ 1.23 billion; US\$ 1.31 billion in 2011-15, US\$ 1.55 billion in 2016-20, and US\$ 1.81 billion for 2021-25 (Gavi, 2022d). At the meso level, the same can be seen between, for example, BMGF and Gavi funding, with Gavi highlighting how several of the private sector innovations funded through its INFUSE private sector innovation competition were previously funded under the BMGF Grand Challenges, which Gavi claims illustrates the hand-off between BMGF's upstream focus and INFUSE's focus on scale (Gavi, 2018b, p. 5). The same dynamic can be observed at the micro-level, with one Gavi senior country manager explaining that BMGF's 'initial additional money serves as a catalytic power to encourage Gavi to follow them, or to drive Gavi' (Interviewee 5, p. 8). BMGF uses the tool of matching funds, in which it commits to double the contributions of other donors, to increase the attractiveness of funding to specific areas, including innovation within immunisation (Seitz and Martens, 2017). The influencing of Gavi is important to BMGF's approach to taking innovations to scale, with a BMGF immunization program officer saying that 'it's clear that our investments in innovation have to link to Gavi. So, if that doesn't happen then we've done something, but it doesn't really amplify' (Interviewee 8, p. 3), and a senior immunization program officer that 'Gavi is the ultimate engine to drive scale' (Interviewee 21, p. 4).

BMGF's influencing of the wider global health agenda is criticised on several grounds. Firstly, that this influence, when combined with its very narrow accountability means that public policy is disproportionately skewed by the views of a small number of people (even perhaps just those of Bill and Melinda Gates), to the exclusion of other more broadly accountable and hence arguably more objectively legitimate perspectives (Youde, 2013; Callahan, 2018). This exclusive *philanthrolateralism* is contrasted unfavourably with inclusive UN-led multilateral decision-making (Seitz and Martens, 2017). It is also suggested to be at the expense of state power (Sending and Neumann, 2006; McCoy and McGoey, 2011). BMGF's greater willingness to challenge the status quo can lead to it being characterised as a 'veto player' (Cohen, 2002). This sense of BMGF not operating on a level playing field is exacerbated by its provision of large amounts of funding to international agencies which creates widespread dependence upon BMGF for funding and a consequent concern that this limits their willing to criticise BMGF and its aims or approaches (Nanz and Steffek, 2004; Harman, 2016).

This criticism also emerges at the country level, with one Gavi senior country manager explaining:

Gates can be seen as very arrogant as well. So, I think where they have to be careful is that they can really push their ideas or views on a country. And when Bill Gates comes to visit your country, it's hard for the President to say no. He has a real force. I think they need to be very aware how to use that force: that they really use it for good and not to dominate (Interviewee 3, p.9).

In response to these criticisms, BMGF's supporters highlight the importance of the disruption which BMGF brings to the sector, both in terms of addressing policy areas which may not traditionally have been prioritised; and in the application of successful models from the private sector to an overly bureaucratic and ineffective international system around global health (Moran and Stevenson, 2013; Youde, 2013). Arguably, BMGF's role in global public health is not at the expense of bilateral and multilateral actors, because BMGF focuses on those technical areas it perceives as important only if these are relatively neglected by other actors (Birn, 2014), or on those types of engagement for which it perceives traditional actors are ill-equipped (Youde 2016). It is possible, even, that other actors are complicit in this new dynamic because of the potential for increased impact on the wicked problems of global public health (Schwab, 2008), and in its alleviation of pressure on their own aid budgets (Bishop and Green, 2008; Clarke, 2019). Supporting this interpretation, Partzsch and Fuchs (2012) suggest that BMGF relies largely not on a mechanism of 'power over' others, but rather that of 'power with' them. 'Power with' is essentially that of cooperation and learning, to build collective strength; and 'power over', coercion and manipulation, with one party's advantage being at the expense of another's (Partzsch and Fuchs, 2012). Central to BMGF's power with other actors is its ability to convene them, which is examined in the following section.

### **6.3.2 Convening, so 'greater than the sum of its members'**

A second interaction dynamic in BMGF's innovation in immunisation is that of their convening of actors at the global level. Koch *et al.* (2019) quote BMGF as wanting to convene 'like and unlike minds' to identify innovations (p. 279). Explaining the reasoning underling this, Bill Gates writes that 'innovation proceeds more rapidly when different parties can build on each other's work and avoid going down the same dead end that others have gone down' (BMGF, 2010, p.5). The aim, as

described here is for non-duplication, and efficiency. Specifically, with respect to immunisation, BMGF's vaccine delivery director expands on these principles in interview with Gavi:

We dedicate more of our own internal resources (time and people) to novel, innovative projects because Gavi takes care of important inputs for market shaping, like roadmaps and SDFs [strategic demand forecasts]. Our partnership with Gavi is based on sharing information, which enables all partners to access critical information we might not otherwise have (Gavi, 2015b, p.53).

Thus, BMGF explains convening on the basis of the value of sharing complementary knowledge. At other times BMGF describes a more ambitious agenda for convening, suggesting that 'by fostering collaboration and the sharing of lessons learned, this network becomes greater than the sum of its individual members' (Grand Challenges, 2022, p.3). Conveyed in this is the premise that knowledge itself is advanced through collaboration. To that end, BMGF aims to convene a wide diversity of actors, with a BMGF officer describing these as being 'everything from a government department to a local NGO, to a global NGO, to an academic department, to a private company, to a social enterprise, to a tech start-up' (Interviewee 21, p. 5). This diversity of actors means that the sector is more resilient to a negative impact of exogenous shocks (Moran and Stevenson, 2013), but comes at a cost of greater challenge and cost of coordination and hence risk of missed opportunities, fragmentation or duplication (Birn, 2005; Szlezák *et al.* 2010). The consensus is that BMGF is capable of mitigating this risk, having 'a remarkable capacity to bring together the necessary collection of states, development banks, international organisations, firms and civil society organisations' (Moran and Stevenson, 2013, p. 118).

BMGF also extends its convening beyond global health, on the premise that knowledge-sharing across different domains is particularly impactful; and that the foundation has a comparative advantage in enabling this, as made explicit by a BMGF senior immunization program officer:

That's another comparative advantage: that we can reach out to organisations who may not work in this sector, whether it's immunisation or global development and lower income countries and have discussions about

either what they're doing that could be interesting in our space or trying to bring them in (Interviewee 40, p.3).

The suggestion that foundations have a comparative advantage in bringing together diverse sectors is supported by Moran and Stevenson (2013), who attribute this to foundations' 'sectoral ambiguity' (p. 136). Moreover, they suggest that foundations have a particular ability to draw in the private sector, because they retain particularly strong linkages to it, due to it often being the source of their endowments, and because of common exchange of staff between the business and the foundation, which also contributes to a shared culture. Because BMGF believes that 'when it comes to innovation, the real expertise lies with the private sector' (Gates, 2011b, p. 10), the foundation has several initiatives specifically intended to draw the private sector into global public health, as described by a BMGF immunization program officer:

We're trying to find ways to lower the entry for new partners because there's a recognition that we have lots of ideas, but can sometimes be an echo chamber and so... our role is to find the best ideas and to bring in new partners that haven't been part of this space (Interviewee 8, p.5).

A specific tool which BMGF has used since 2003 to attract innovative ideas to respond to global development problems, focusing on a particular problem at a time, are its Grand Challenges. The first decade of Challenges focused on global health specifically and through 14 rounds, awarded 44 grants worth over US\$ 450m to winning proposals for research projects. After that period, BMGF expanded the initiative, removing the focus on global health. Application is on the basis of a simple form, and is open to any individual or organisation, with initial grants of US\$ 100,000 awarded, and further funding of up to US\$ 1m for successful projects (Grand Challenges, 2022). In addition to seeking to reap the ideas of the private sector, through its Grand Challenges, BMGF also aims to draw them more strategically into international development, as a market. This particular market-shaping aspect of BMGF's interactions with the private sector is explored further shortly.

However, BMGF is criticised on the basis that the solutions it identifies through the Grand Challenges and other mechanisms are not sufficiently well informed by the specific social, economic or capacity context into which the innovations are intended. This is linked to BMGF's scientific positivism examined earlier in this chapter. Our discussion there concerned the underlying theory of change behind

BMGF's investments in tackling poverty. Here, the issue is narrower: around the extent to which the innovations BMGF funds may themselves fail because of insufficient integration into the surrounding system. The problem manifests particularly in innovations not scaling, as a BMGF senior advisor explains:

When we looked at our experience to-date and even the experience that Gavi and others have had, we have created a whole bunch of roads to nowhere; meaning we pick a spot, we create a pilot, we might do it in two or three countries, but they don't scale. Why is that? What's not working? What do we have to think differently about? (Interviewee 39, p. 6).

BMGF now recognises that the problem may be that innovations may not be sufficiently contextualised. This quote from Chris Elias, BMGF's President of Global Development in July 2018, for example:

Initially [BMGF was] very focused in our investments on new tools and technologies. We had a strong pipeline of new technological innovation for people living in very poor countries. But that technological innovation was then facing health systems that were ill-prepared to adopt it or to scale it. One of the things I think we've learned is that you have to go beyond just creating new technologies. You have to think about the systems into which those technologies will have to be delivered in order for you to have the impact that you want to have (Airbel Impact Lab, 2018, p. 3).

In this quote, Elias refers to the context as being the systems, in-country. Within Vaccine Delivery, the same understanding is apparent, as described by an immunization program officer:

We started very much thinking that innovation and solutions will solve the world's problems, and we've started to see that those innovations sit in an ecosystem and a health system. And so there's a recognition that those less sexy or more complicated system dynamics also need to be understood... it depends on funding being available and the right data and people empowered to use that (Interviewee 8, p. 2).

Bill Gates himself acknowledges the importance of use-case context, in highlighting that innovations need to be 'not only effective, but also inexpensive to produce, easy to distribute, and simple to administer' (Gates, 2005, p. 5). As a BMGF senior advisor puts it, considerations 'aren't just about there being a great new innovation

on the science side or technology side... You also have to understand the system it's going to move through, and the people in the system (Interviewee 39, p. 1). This understanding, BMGF attempts to convey to those private sector innovators it draws into immunisation, which is examined in the following section.

### **6.3.3 Market-shaping: 'incentivise and de-risk'**

A third interaction dynamic in BMGF's innovation in immunisation is that of the shaping of the market for innovations. As we saw earlier in this chapter, BMGF sees the market as ultimately representing a sustainable approach to providing innovations to meet the needs of the poor, and it perceives a focus for the foundation 'to encourage innovation in the areas where there is less profit opportunity but where the impact for those in need is very high' (BMGF, 2012, p.2). BMGF's approach to this begins upstream, in order to provide a 'bridge between the laboratory and development' (Volansky, DuPont and Hughes, 2010) which is a particular interest of the foundation (Nature, 2003), and with more than a third of BMGF's funding dedicated to this (McCoy *et al.*, 2009).

The strategy is explained by a member of BMGF's Vaccine Development Team:

[A]s much as we talk about making markets work for the poor, fundamentally the value proposition cannot compete with high income country markets, so what we try to do is incentivise and de-risk to the extent that you change the NPV [net present value] calculation of working in global health (Interviewee 20, p.3).

To this end, as a first step BMGF aims to de-risk private sector investments through the provision of market intelligence, as set out by a BMGF senior adviser:

[Companies] want to make sure they're solving a problem that's a real problem or a real challenge that ultimately can result in, in their case, countries wanting to procure their product or their service or whatever... And in particular when entrepreneurs are coming in from other sectors or haven't worked in the countries we work in, there is a ton about the environment that they don't understand that actually affects the design of the product (Interviewee 39, p.2).

This is the approach of the Vaccine Innovation Prioritisation Strategy, launched in 2017 and involving the Gavi Secretariat, WHO, UNICEF, BMGF and PATH. The

Vaccine Innovation Prioritisation Strategy (VIPS) aims to accelerate vaccine product attribute innovations that best suit country needs, by aligning the Gavi Alliance partners around shared definitions and principles around the value proposition of innovative products; developing tools to allow for quantification of these; consulting wide-ranging countries on their innovation needs; and convening global experts to assess and rank collated possible innovations against those country needs. These innovation priorities are then communicated to manufacturers to help inform their investment decisions (Gavi, 2022c). The impact on the private sector is one of a de-risking, as described by a member of BMGF's Vaccine Development Team:

VIPS is hoping to create that articulation of that trade-off [between risk and reward] and also, from our perspective, helping us when we work with manufacturers to say 'look, we'll de-risk this technology for you. Yes, you still need to make an investment in order to take it all the way through to commercialisation, but that investment's going to be worth it because there's this market for it.' Because right now we work with manufacturers and say 'take this on faith, that there's a market out there.' And no company wants to do that (Interviewee 20, p. 6).

To achieve this, the Vaccine Innovation Prioritisation Strategy recognises the need for extensive country engagement both upstream, to well understand their needs, preferences and contextual constraints; and downstream, to communicate innovations' potential benefits and total cost of ownership (upfront and operating costs (Gavi, 2015c; Gavi, 2022c).

Secondly, and more actively than just provision of market intelligence, BMGF aims to manipulate reward levels such that companies perceive a profit opportunity in the global health market, through the use of price or volume guarantees (Bishop, 2013; BMGF, 2022c). The vaccine market is a major space in which BMGF attempts this, pointing to the example of the BMGF-influenced, Gavi-managed, advance market commitment (AMC) for a pneumonia vaccine, which set a price which Gavi would pay for a target quantity for pneumococcal vaccines. Manufacturers who signed a legally-binding commitment to meet the required quantity and price levels received both payment for the vaccines and in addition a share of a US\$ 1.5 billion fund which donors provided to Gavi to incentivise manufacturers to invest in the research and development and to expand their manufacturing capacity (Gavi, 2020a). Gates attributes to the advance market commitment the result that the vaccine was



available much earlier than it would have been, allowing its global roll-out (Gates, 2011b, p.11).

A member of BMGF's Vaccine Development Team sets out some of the complexities and strategic considerations encountered by the foundation in market shaping for innovation in vaccine-development:

You want to increase competition, but at the same time you want to manage quality control. So, what are the trade-offs you're making? Do you want ten suppliers, or do you want five? How do you think about driving innovation? (Interviewee 20, p.2).

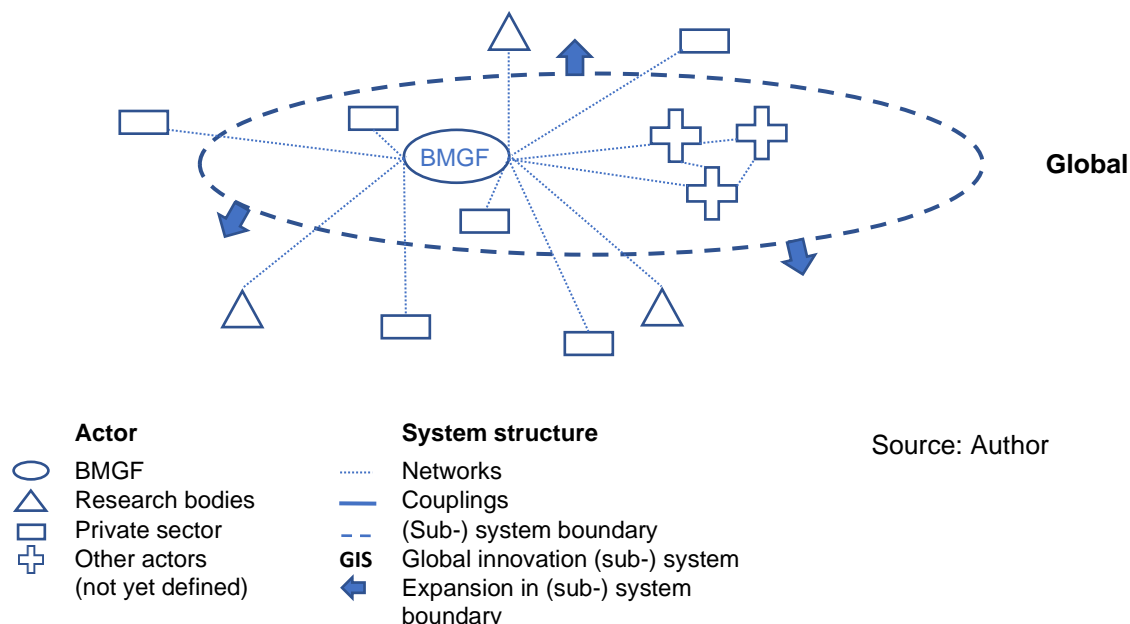
This illustrates the high level of intentionality which goes into the market shaping approach of BMGF over what the team member later describes as being a 10- to 15-year timeline. A prime example is the search for a malaria vaccine, which we examined in Chapter 2, for which BMGF provided periodic grants since 1999 (Sorensen, 2007), with Christian Loucq, Director of the PATH Malaria Vaccine Initiative saying that 'development of the product would not have been possible without the Gates Foundation' (Volansky, DuPont and Hughes, 2010, p.2).

BMGF's third market-shaping approach is a form of impact investment through its Strategic Investment Fund (SIF) which aims to support entrepreneurial small- and medium-sized companies, whether profit or non-profit, which have a high potential for social impact but which 'need additional funding to get off the ground' (BMGF, 2021). The SIF utilises various tools for that purpose, including grants, direct equity investments, investments through investment fund intermediaries, low-interest loans or credit enhancements, or a combination of these, ideally matched by other investors. In return, the companies commit to use the proceeds in support of specific BMGF strategies (BMGF, 2022c). According to a BMGF senior advisor, BMGF is wary of the risk of an uneven market and is candid on not having exclusive relationships, and also on not behaving like a conventional investor: they will push regulators for more competition for the companies they fund. BMGF tends to take a Board observer seat in companies, but without fiduciary responsibility (private exchange with author).

It can be seen, thus, that BMGF plays a key role in enabling important interactions with a range of other actors which are fundamental to innovation in immunisation. Knowledge creation through these interactions is an important resource for the systematic fostering of innovation, alongside that of financial investment examined

earlier. These couplings are shown in the following figure, adapted from the original illustrative Global Innovation System (GIS) of Binz and Truffer (2017).

Figure 21: Networks in immunisation GIS involving BMGF (Author)



Binz and Truffer’s original figure is modified in several respects to better reflect an immunisation GIS involving BMGF. Significantly, actors have been shown outside the boundaries of the GIS, and the GIS boundaries themselves are shown as being capable of expansion. BMGF’s role in any GIS is, in contrast to that of other key actors such as UNICEF or Gavi, essentially only at the global level, rather than also in-country. At that global level, BMGF’s interactions with other actors play a key role in firstly, strengthening coordination and learning between actors, and secondly, in bringing-in new actors. The combined effect of these dynamics is to expand the boundaries of the GIS itself. In this way, BMGF not only ‘benefit[s] from, and accelerate[s], growing movement towards a distinct polycentric ‘system’ for the coordination of international society’ (Clarke, 2019, p. 209) but moreover is a ‘facilitator of incremental structural change’ of that system (Moran and Stevenson, 2013, p. 132).

## 6.4 Conclusion

BMGF’s role with respect to innovation in immunisation is oriented around power. This originates in the financial investment accrued and then donated by Bill Gates, but it manifests in various respects. Firstly, BMGF uses its financial transfers to

other donors and agencies as a powerful tool to influence their agendas towards BMGF's aims, including increasing emphasis on both immunisation and innovation. This influencing is important for BMGF because in contrast to other donors such as UNICEF, BMGF engages actively with innovation in immunisation essentially only at the global level. In terms of the innovation valuation resource which BMGF provides for innovation in immunisation, it is essentially only financial investment. Market access and innovation legitimacy are not means through which BMGF directly adds significant value to innovation. Hence its reliance for these on other donors such as UNICEF and Gavi, and its strategy to influence their provision of those resources. BMGF's co-dependence with other donors makes the relationship more one of 'power with' than 'power over' those actors.

BMGF's financial investment also provide it with power of agency, in the way in which they permit a significantly higher risk appetite than other actors, which enables BMGF to fund higher risk innovations, especially those at an earlier stage of development. This combines with Gates' particular focus on entrepreneurialism to draw into immunisation a wide range of new private sector actors. BMGF also invests particular efforts at the global level to strengthening complementarity, coordination and learning between actors. The combined effect of these dynamics is both to strengthen linkages within the global innovation sub-system, and to expand its boundaries through the proactive inclusion of new and diverse actors.

BMGF's financially-derived power relations thus both drive incremental structural change in the innovation system, and facilitate other actors to sustain it. BMGF's *simple structure* form of organisation is key to achieving the high levels of coordination required for the effective deployment of both of these forms of power.

## 7 THE CASE OF GAVI, THE VACCINE ALLIANCE

This chapter examines the role of Gavi with respect to innovation in immunisation for international development. It argues that Gavi provides extensive linkages between diverse actors and between spatial levels, with power playing an important part in enabling Gavi to influence or leverage particular behaviour by other actors. This power derives from Gavi's generation and utilisation of innovation valuation resources of market access and financial investment. The primary example of this is Gavi's vaccine market shaping, in which it effectively links recipient countries on one side and private sector manufacturers on the other to align supply and demand for innovative vaccines. This engagement is highly standardised, as is Gavi's engagement in cold chain equipment and in vaccine secondary attribute innovations<sup>17</sup>. Gavi's engagement in other private sector partnerships is much more customised, and much less widely scaled. These innovations also bring a risk of a *techno-fix* approach and consequently are a source of inter-organisational tension. In providing linkages, Gavi does so in a dynamic way, enabled by its *adhocratic* organisational type. This highly flexible project-based form is able to coordinate and combine (or relinquish or acquire) its resources. Gavi's resulting dynamic capabilities enable it to respond quickly to new opportunities for innovation in immunisation.

The chapter is divided into three sections. The first examines how Gavi's organisational characteristics affect its innovation in immunisation. It argues that three such characteristics in particular do so. A first is that of Gavi being an alliance of organisations from the public and private sectors. A second characteristic is Gavi's ability to exert levers over other actors to drive the scaling-up of innovation. A third is the duality of Gavi's aim to mobilise from the private sector both financial investment and innovation expertise.

The second section examines Gavi's engagement with institutions relating to innovation in immunisation. These include the presumptions that innovation is

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<sup>17</sup> As we saw in Chapter 2, these are distinct from the fundamental immunogenicity of vaccines, but complement it. Examples of such innovations include preservative-free vaccine presentations, improved thermostability and filling or packaging innovations.

necessary for impact; and that intended beneficiaries should be included in innovation planning, design and implementation. We argue that the defining characteristic of Gavi's engagement with these is overwhelming one of co-optation, in terms of how it interprets, responds to, and challenges those presumptions.

The third section examines how Gavi interacts with other actors for innovation in immunisation. It argues that there are three important sets of interactions between Gavi and other actors. A first is that with the private sector, which Gavi aims to attract into immunisation. The other key party to this dynamic is the recipient national government, which represents a second key set of interactions. A third set of interactions is that of facilitation and knowledge brokerage between other actors.

## **7.1 Gavi's organisational characteristics**

This section examines how Gavi's organisational characteristics affect its innovation in immunisation. It argues that three organisational characteristics in particular do so, by affecting Gavi's capability to provide knowledge and valuation resources<sup>18</sup> for innovation. A first characteristic is that of Gavi being an alliance of organisations from the public and private sectors, and the advantage that provides Gavi in convening diverse actors for innovation. A second characteristic is Gavi's ability to exert levers over both manufacturers and recipient national governments to drive the scaling-up of innovation, deriving from the use by Gavi of its market access, financial investment and, to a lesser degree, innovation legitimacy. A third characteristic is the duality of Gavi's aim to mobilise from the private sector both financial investment and innovation expertise.

The degree of standardisation of the resources which Gavi brings to innovation depend on the type of innovation. Those innovations which Gavi has taken to scale are reliant on standardised resources, without further tailoring at the country level. In contrast, Gavi's other private sector innovations are reliant on customised

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<sup>18</sup> As we saw in Chapter 3, in the GIS model, the three non-knowledge resource types, market access, financial investment and innovation legitimacy, collectively constitute the valuation of an innovation.

resources, require significant tailoring to the country context, and consequently struggle to achieve scale.

### **7.1.1 'A unique public-private partnership'**

A first relevant organisational characteristic is that of being an alliance of organisations from both public and private sectors within immunisation, and the advantage that provides Gavi in convening diverse actors for innovation.

Gavi is an alliance which aims to increase equitable use of vaccines in lower-income countries (Gavi, 2022b). The 'core partners' of WHO, UNICEF, World Bank and the US Centers for Disease Control (CDC) are responsible for the majority implementation of its programmes, alongside recipient countries, vaccine manufacturers and Gavi's own bilateral donors. Coordination is by a 400-strong Secretariat based in Geneva, Switzerland.

Gavi suggests that this structure equips Gavi with 'tremendous convening power' (Interviewee 24, p. 6) and makes it particularly well-equipped to innovate because 'drawing on the particular strengths of each sector makes for a fertile environment for innovation' (Gavi, 2012, p. 3). This is based on a premise that innovation results from the combination of knowledge, which itself follows from the convening of actors, as explained by a Gavi officer:

It's about connecting things, connecting people, and so in that sense, any innovation, wherever it resides requires the presence of connectors and a connecting mind-set and a connecting culture. And then magic happens. Innovation is about connecting things, with new things emerged from that connection (Interviewee 1, p. 2).

Examples of the convening provided by Gavi are that of the Vaccine Innovation Prioritisation Strategy, examined in the preceding chapter; and the Cold Chain Equipment Optimisation Platform, examined later in this chapter. In each case, Gavi officers describe partner organisations as having specific roles aligned to their comparative advantage, including:

Supply Division is the procurement agent, and UNICEF Program Division provides the TA to help countries develop their proposals (Interviewee 41, p. 6).

WHO obviously has the normative role and they bring a lot of insights in terms of the regulatory pathway approach, TPPs<sup>19</sup>... Gates obviously supporting development of innovations, their contracts with manufacturers... And I would say Gavi plays a lot of the project manager role (Interviewee 13, p. 3).

Common to both initiatives are WHO's focus on standards-setting, UNICEF's on procurement, and Gavi's on funding and overall coordination. BMGF's role, in both cases, is primarily that of driving from behind, which is consistent with their *modus operandi* to influence other organisations, as we saw in the preceding chapter. The Gavi Secretariat role within the Alliance is seen, according to a Gavi senior country manager (SCM)<sup>20</sup>, as being:

[T]o try to animate the process and lead a process together with colleagues in Gavi, the country partner, technical partners, other funding agencies as well, to get all the conditions in place to achieve those results (Interviewee 5, p. 1).

The implication above, that this coordinating role by the Gavi Secretariat is complementary to other actors' technical roles, is reinforced by a Gavi officer saying 'Gavi weren't meant to be technical. So, I had to always do almost *facipulation*<sup>21</sup>: I had to lead it but not be seen to lead. But obviously leadership was needed to get things going' (Interviewee 42, p. 1). As this suggests, despite some complementarity of roles, coordination across the alliance can be challenging. This is acknowledged by a senior Gavi officer, with reference to a weak basis of trust between the alliance

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<sup>19</sup> TPP: target product profile, a description of the desired attributes of a new product; used to communicate to potential suppliers within a procurement process. See [www.who.int/research-observatory/analyses/tpp/en/](http://www.who.int/research-observatory/analyses/tpp/en/)

<sup>20</sup> senior country managers (SCMs) lead the engagement of the Gavi Secretariat in Gavi-eligible countries: managing grants and relations; influencing government and development partners and feeding their perspectives back into policy and other decision-making.

<sup>21</sup> A portmanteau word combining facilitation and manipulation, thus implying surreptitious manipulation of the agenda through a facilitating role.

partners, 'I think there was a lot of concern that Gavi would drive it and lead it and take all the credit and ignore some of the other partners' contributions' (Interviewee 13, p. 3). Other Gavi key informants describe similar issues of trust, with a Gavi director suggesting that this is exacerbated by innovations' high-profile:

With regard to who do we partner with and sit down with to generate innovation, there's a bit of having their name associated to the innovation piece that we would be able to fund. And that has been a source of tension (Interviewee 11, p. 2).

The other perspective on this tension is raised by a senior UNICEF officer, who suggests that Gavi's approach is both non-collegiate, and as a result, ineffective:

So much money was spent in the past; some announced innovations and nothing has happened. I don't think Gavi actually has the right approach necessarily, to do it by themselves (Interviewee 10, p. 3).

The reason why the Gavi Secretariat might 'do it by themselves' is explained by a senior Gavi officer in terms of its particular comparative advantage:

Where we have scored, and we have been able to because of Gavi's unique nature, is that we are global and we're country and our SCMs are I think much more deeply engaged in country know-how... Our counterparts at global are sitting at global, but because of Gavi I've engaged with [SCMs] in [countries] (Interviewee 42, p. 4).

This argument is that the Gavi Secretariat is able to bridge the global and country levels, because of 'Gavi's unique nature', by which they mean the concentrated engagement, influence and resources which the small Gavi Secretariat brings at both these levels. This is illustrated by an example given by a Gavi senior country manager (SCM):

Where I think Gavi's role has been just, if you will allow me this [when talking about a drone innovation], to make this fly. Obviously through the funding but also the convening power in organising the discussion with the ministry and



with EPI<sup>22</sup>. So, our role was more about creating an opportunity and then bringing the resources (Interviewee 5, p. 10).

This language of opportunity-creation and resource-provision reinforces the argument that it is these which relate to Gavi's comparative advantage. The impression also given, of a tactical convening of actors by Gavi at the country level, is shared by its private sector partners, with one reflecting that:

Gavi worked with the company to build in-country relationships and find entry points to working with governments (Gavi, 2017b, p. 1).

In counterpart, at the global level, Gavi claims a 'convening power to help vet new solutions and connect disruptive innovators directly with countries' (Gavi, 2016b, p. 5). Gavi never refers to its in-country relationships and actors as being part of an 'ecosystem', but does periodically use the term when describing the set of actors at the global level (Gavi, 2018c, p. 39; Gavi, 2017c, p. 2; Interviewee 9, p. 3). In the closest to a definition of an ecosystem it offers, Gavi suggests that:

An ecosystem that embraces innovation in immunisation relies on a community that not only works together to create collaborative solutions, but also uses its combined influence to jointly effect a change in the global health environment (Gavi, 2016b, p. 9).

In this way, Gavi conveys the sense of an ecosystem involving intentionality and coordination to be more than the sum of its constituent parts. Gavi also describes varying roles within that: sometimes passive, being 'plugged into the ecosystems that can help us source these late stage or proven interventions' (Interviewee 9, p. 2), whilst at other times actively moulding an ecosystem, 'creating a space for innovators to network with potential partners and investigate ways to improve, align and integrate their solutions' (Gavi, 2016b, p. 9). Gavi's characterisation of these roles, and its use of the term ecosystem only at global level reflects the focus of

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<sup>22</sup> The *Expanded Programme for Immunization*: the initiative launched in 1974 by WHO to support countries' vaccination programmes. The initiative and associated term have now become institutionalised within the community of international and national officials working in immunisation.

Gavi's role in innovation, primarily at the global rather than the country level. This is linked to Gavi's comparative advantage examined in the following section.

### **7.1.2 An 'engine to drive scale'**

A second relevant organisational characteristic is Gavi's ability to exert levers over other actors to drive the scaling-up of innovation. Gavi uses in particular its financial investment and market access to apply conditionality and incentivisation differentially.

Across the breadth of its strategic goals in immunisation, Gavi describes a particular comparative advantage in enabling 'implementation at scale', examples of which are the number of children it has enabled countries to immunise (700 million at the end of 2018) and the number of new vaccine introductions it has supported in countries (400 to end-2018) (Gavi, 2018a, p. 2). The basis upon which Gavi claims this advantage is structural, with a Gavi director saying, 'we have a natural advantage in that there is scale in our model itself' (Interviewee 24, p. 6). What Gavi means by this is related to its market reach, writing:

Our superpower within the vaccine ecosystem is scale. We now work across 68 countries, and we purchase vaccines for 60 per cent of the world's birth cohort (Boran, 2018, p. 3).

Other actors recognise Gavi's comparative advantage in this, with a member of BMGF's Vaccine Delivery Team describing Gavi as 'the ultimate engine to drive scale' (Interviewee 21, p. 4), and a senior staff member of UNICEF saying that:

Gavi, I think is useful once we have innovations that are able to be scaled up. I really see Gavi more as a financing mechanism to scale up certain things and support the market shaping of this (Interviewee 10, p. 3).

Implicit in this comment is also a criticism of involvement by Gavi in the early stage development of innovations, rather than just in their scaling. In principle, Gavi too sees itself as not involved in the developing of innovation, but rather in funding and facilitating, as described by a Gavi director:

We consider innovation in our world as funding an intervention at scale or something that might have been developed by others... and then as part of our innovation agenda, we're going to fund these things (Interviewee 11, p. 3).

This view, however, is not consistently held across Gavi, with the organisation also introducing initiatives aimed at engaging with earlier stage innovations, as we will see later in this chapter.

As examples of Gavi's scaling of innovations, Gavi points to having catalysed the now universal use of innovations auto-disable (AD) syringes and vaccine vial monitors (Gavi, 2018a, p. 3) we examined in Chapter 2. This claim is endorsed by a member of UNICEF's Immunization Team, saying:

We've gone from basically no countries using AD syringes at the start of the 2000s when I first started in EPI to, in the space of three or four years, all Gavi-supported countries using AD syringes for the administration of all the antigens they provided, both Gavi and non-Gavi. I think, Gavi was successful there partly through their weight to procure globally and actually change markets and drive innovation at the manufacturing level, but also too, actually the way they provide their support, to make it a requirement that countries then do this for all vaccines (Interviewee 34, p. 2).

This perspective specifies Gavi's use of its market weight to leverage the scaling of innovation, bidirectionally: with manufacturers, and with recipient countries. With respect to manufacturers, Gavi makes innovation a requirement for its purchase of certain products from manufacturers, such that, for example, Gavi would only purchase vaccine vials which included on them a VVM and syringes which would auto-disable. This is complemented by a second lever, which is less coercive, and which involves Gavi catalysing innovation in manufacturers through the flagging of a viable market opportunity. A third lever acts with respect to recipient countries, and is the incentivising of countries to select innovations for inclusion in their immunisation programmes in order to access Gavi funding. These levers are evident in several major initiatives which Gavi has introduced for scale, examined below.

The most fundamental area in which Gavi fosters innovation at scale is that of innovation in vaccines' fundamental effect, whether the creation of new vaccines against previously non-vaccine preventable diseases; or improvements to the fundamental effectiveness of existing vaccines, such as protection against additional strains of a disease (Gavi, 2015c, p. 14). The mechanism which Gavi has established to scale this innovation is its four-yearly Vaccine Investment Strategy, which assesses the potential global impact of new or improved vaccines and their supply and demand dynamics, making conclusions about Gavi's ability to shape the

market in order to foster the Introduction of the most impactful such innovations. Approved innovative vaccines are then procured at scale and offered by Gavi to less economically developed countries (LEDCs), who are incentivised to introduce them through the provision of Gavi financing (Gavi, 2022e; Gavi, 2022f).

Gavi has extended the same approach to scaling innovation in secondary vaccine product characteristics, as we saw in Chapter 2. These include non-fundamental characteristics of existing vaccines, such as improved thermostability; and new means of vaccine delivery, such as microneedle patches or jet injectors. The mechanism established by Gavi to scale these innovations is the Vaccine Innovation Prioritisation Strategy, as we examined in Chapter 6. This mechanism currently focuses only on catalysing manufacturer innovation through the provision of market intelligence. Other levers, including requirements of manufacturers, or funding to incentivise countries, may subsequently be introduced (Interviewee 13, p. 5).

Gavi has replicated a similar model for the fostering of innovation in areas other than vaccines themselves. The most extensive is in cold chain equipment. Development timelines for such equipment are significantly shorter than for new vaccines, which enables the market to respond more quickly to donor market-shaping. Gavi developed in 2015 the Cold Chain Equipment Optimisation Platform as a pooled procurement mechanism to increase take-up of the most modern cold chain equipment technologies. Solar direct drive refrigerators, for example, do not require mains electricity, but use an ice-lined compartment to keep vaccines cold for 24 hours on only four hours of sunlight, and only require periodic cleaning of their solar panels (Gavi, 2015d, p. 63).

In the Cold Chain Equipment Optimisation Platform, Gavi leveraged demand by making available additional funding to countries to mitigate the additional upfront costs associated with this cutting-edge technology, whilst also proactively communicating to countries the benefits of the new technologies (Gavi, 2015d). To leverage cold chain equipment supply, Gavi utilised both market-intelligence provision, and conditionality. Rather than a formal guarantee of demand or an advance market commitment to manufacturers, Gavi produced strategic demand forecasts for cold chain equipment:

[strategic demand forecasts] say 'here's the information about the market. We estimate we'll be buying about 120,000 units in five years. If you divide that up, it's between 20 and 25,000 units per year. But we cannot tell you

you're going to get this. But we guarantee you, it is a forecast backed-up with funding. So, you want to get market share? Develop products that meet these eligibility criteria' (Interviewee 41, p. 3).

This informal market-shaping is impactful upon the manufacturers because of the credibility which Gavi has established with them on the basis of its parallel and previous commitments relating to vaccines. Alongside the strategic demand forecasts, Gavi generated target product profiles (TPPs) to describe the required attributes of the cold chain equipment it would procure (Gavi, 2015c; Gavi, 2015d; Gavi, 2016a). A Gavi senior manager described how:

Once Gavi has made that decision that these are new features we want, manufacturers adopted them immediately. Because otherwise they'd not get any share. So, they've adopted them. And it has shown that if you are able to back TPPs with funding then manufacturers are generally very keen on making the necessary changes (Interviewee 41, p. 2).

This serves to incentivise innovation by reducing the risk to manufacturers of investing in innovation for this immature market. It provides well-founded information about demand, and indicates in addition the likelihood of future Gavi funding for these innovations. That these requirements are published as transparent and open-access also meant that the Cold Chain Equipment Optimisation Platform avoided the risk of seeming to prefer certain manufacturers, which would have curtailed competition. Moreover, Gavi positively encouraged a broader market, by requiring that 25% of the cold chain equipment chosen by each country would be from a non-dominant market brand, as described by a Gavi senior manager:

For a country decision-maker, it's very simple: 'I don't want to risk my investment in vaccines. I don't know this new equipment. I know this one. It is expensive, but we've had the same brand for 10 or 15 years and its working, so why change?'... Our theory of change is that if countries see this new brand, test them, they will likely change (Interviewee 41, p. 4).

In a less interventionist approach, Gavi also fostered introduction of logistics management information systems, which are used to manage vaccine stocks in countries. Gavi established and communicated to manufacturers 'target software standards, TSS' (Interviewee 41, p. 10), then assessed and published a list of manufacturers' systems meeting the TSS, intending that:

Countries will have to talk to [a manufacturer], and say 'we've seen that you meet the Gavi TSS, and we want you to give us an offer' (Interviewee 41, p. 10)

Gavi does not provide a logistics management information systems funding window, but would consider coordinating a pooled procurement exercise on countries' behalf, to secure them economies of scale (Interviewee 41, p. 10).

In a still less interventionist way, Gavi is collating information about drones, such as:

... a list of drone suppliers, what is the business model? Are you paying for the drone? Are you paying for each flight? Does the drone land or like [one company], does it just drop it? Can you do numerous health facilities? (Interviewee 41, p. 12)

In this case, however, Gavi has not gone further, to develop standards or list complying manufacturers. Nor is Gavi providing dedicated funding to incentivise countries, as it did in the Cold Chain Equipment Optimisation Platform, despite some actors suggesting doing similarly for drones, on the basis of logic described by a Gavi senior manager:

The challenge is, unless you're able to back up such innovation with earmarked funding, it may be difficult, because countries have so many needs... Why pay for a drone if you can buy a motorbike or even a bicycle for the nurse to go, and the nurse can use that for something else [too]? (Interviewee 41, p. 12).

Gavi has not systematised its fostering of drone innovation to the degree of other innovations probably because their relationship with a single, preferred, drone provider is important for Gavi's resource mobilisation objectives, which can act counter to Gavi's ability to derive impact from innovation, as examined in the following section.

### **7.1.3 Innovation 'strongly influenced by resource mobilisation'**

A third relevant organisational characteristic is the duality of Gavi's aim to mobilise from the private sector both financial investment and innovation expertise. In its 2016-20 Strategy, Gavi aims through its private sector partnerships to achieve the following three objectives:

1. Raise significant financial contributions: multi-year partners, each with financial contributions of at least US\$ 3-5 m/year;
2. Create operational partnerships: develop individual partnerships aimed at improving operational challenges and creating value for countries, Alliance members and the Secretariat;
3. Foster innovation and new models: catalyse partnerships and cooperation models with countries, Alliance partners and new players

(Gavi, 2014a, p.6)

There are several respects in which the first objective to raise money and the third to foster innovation are in tension. The bottom-line, as expressed by one Gavi senior country manager, is that Gavi prioritises innovations 'in terms of resource mobilisation for Gavi, rather than a context-driven innovation project' (Interviewee 2, p. 4). Similarly, another senior country manager suggests that 'we want to be innovative, but we don't think the whole process through – of all the processes; of all the resources; of all the steps that are needed to actually achieve that' (Interviewee 3, p. 4). The same sense is conveyed by a WHO immunization officer saying:

In the end, Gavi is trying to report things on short-term deadlines and needs to link it to fundraising and that is not always so compatible with a more sophisticated understanding or a systems understanding (Interviewee 31, p. 5).

The premise shared by these key informants, that innovation should be 'context-driven', well thought-through or have a 'systems understanding' is consistent with the Mode 2 and innovation systems literature examined in Chapter 3. The implication is that Gavi's focus on innovation in the context of the aim to mobilise resources from the private sector may be inconsistent with the literature. One specific area of tension is identified by the key informant above in terms of a difference in acceptable timeline. Another Gavi senior country manager suggests a second specific area of tension, in terms of mass appeal:

I see us talking so much about innovation, but chasing it a way that seems to be just about the announcement, without thinking through the implications, how best to work together, or lessons learned on previous experiences (Interviewee 6, p. 2).

This same tension is picked up by an external interlocutor who describes the INFUSE workshop (see later in this chapter), as being ‘more focused on the cool and not on the practical’ (Interviewee 16, p. 6). Similarly, a member of BMGF’s Vaccine Delivery Team says of Gavi that ‘there is a tendency to go chasing after something which looks good from afar, but when you peel it back, how much is really going on?’ (Interviewee 21, p. 5).

The third area of tension is in the extent to which provider selection is informed by a comprehensive assessment of potential providers. Gavi’s resource mobilisation objective incentivises selection of a specific provider without a comprehensive review of potential alternatives. The counterfactual is reflected by a Gavi senior country manager:

Let’s keep it open, let’s not align ourselves with one company, let’s look at multiple drone agencies, gather lessons learned from multiple and then decide. Because there could be different operation models, different costing models, different ways of working (Interviewee 3, p. 2).

A Gavi senior manager highlights the importance of provider-agnosticism also from a market-shaping perspective:

We know, given the scale, that we probably can’t find just one technology; we need to find a whole range of them. It defuses the risk, but it also defuses a potential market monopoly that we might be inadvertently creating (Boran, 2018, p. 2)

Government EPI managers’ perspective on this issue is driven by the premise that access to a range innovation providers would allow countries greater ability to choose one most suited to the specific context, as described by a Gavi senior country manager:

The EPI Manager<sup>23</sup> was interested in a new registration system and we told them to go with a certain system whereas he said, ‘let me shop around for us

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<sup>23</sup> A government’s EPI Manager is the Ministry of Health official responsible for that country’s immunisation programme, or *Expanded Programme of Immunization (EPI)*



a little bit because I want to know what's out there, what's best for me'  
(Interviewee 3, p. 4).

Underlying this is the unequal power dynamic between a donor and a recipient government, explicitly recognised by a Gavi senior country manager:

What I felt uncomfortable with is that we write to the countries saying we're partnering with [a company] and because we're a large donor the country may interpret this as saying they need to work with [that company]  
(Interviewee 3, p. 2).

This is acknowledged by a government EPI manager themselves, highlighting the power a donor has in general through their ability to engage at political levels:

We've been able to say no until now because what we didn't want was to develop another tool that's doing exactly what we are already... but once in a while we have institutions go directly to the senior management within the Ministry of Health. And when instructions are coming down, it's a bit difficult  
(Interviewee 33, p. 6).

The government EPI Manager from one Gavi-supported country described the contrasting approach, with Gavi partners supporting strong government leadership in innovation:

Sometimes we have [Gavi partners] suggest [an innovation] to us based on their understanding of what we are going through, which we would have indicated before... Another way is where we ask [for a solution] and then they say 'well, at the country level, our understanding is that this is what WHO could support, this is what UNICEF would suggest... Most of the time it's us asking them if what we have thought about could work. That's another way I didn't mention: there's them suggesting, us asking, but there's also us putting something on the table (Interviewee 33, p. 5).

This role of partners, especially UNICEF and WHO, at the national level is also addressed by Gavi's Independent Review Committee<sup>24</sup> (IRC) which emphasised the importance that they support countries to evaluate piloted innovations and scale them up when justified (Gavi, 2016f). A Gavi senior country manager, further, illustrates the complementary financial support provided by the Bill and Melinda Gates Foundation (BMGF) and Gavi, alongside partners' technical advice at the country level:

Gates funds into this electronic immunisation system. They invested a grant of about US\$ 10m to design a new system, allowing for failure. So, it was not saying 'this is the system you need', but really allowing partners to design a thing through the system, so a lot of lessons learned and going back to the drawing board, but they had this long timeframe. It was driven by an EPI manager who had a vision, who said 'this is what I want', and now Gates' grant is ending and they're stepping back and we're rolling it out, and then Gavi can step in to support the further rollout (Interviewee 3, p. 2).

These in-country partnerships receive less focus within Gavi than the private sector partnerships. Nonetheless, Gavi does occasionally highlight country-driven innovation, such as Nigeria's development of a SMS-based system to track vaccinations in real-time (Gavi, 2018c). The IRC has periodically highlighted innovations, often non-technological, they have observed in countries' grant proposals. These include, in Côte d'Ivoire an initiative to sponsor children to be immunised; civil society-led random checks on vaccine stocks at health facilities in Burkina Faso; and the availability of emergency medical staff during the introduction of human papilloma virus (HPV) vaccine in Sri Lanka (Gavi, 2016c). Gavi, though, tends to characterise non-technological innovations like these as know-how, not as innovation, distinguishing in their 2021-25 strategy, for example, 'supporting

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<sup>24</sup> The Independent Review Committee is an independent group of experts convened by Gavi to review new grant proposals received from countries. See [www.gavi.org/our-support/irc](http://www.gavi.org/our-support/irc)

immunisation delivery system innovations and technologies' from 'sharing immunisation know-how' (Gavi, 2018a, p. 10).

Gavi's organisational characteristics are consistent with it being an organisation of the archetype designated by Mintzberg as an *adhocracy* (see Table 3). This he described as being a highly flexible organisation, designed to operate in complex environments, with project-based teams able to be rapidly reconfigured as needed – which describes well Gavi's dynamicism and solution-orientation.

For each of Mintzberg's archetypes, Lam (2005) sets out their innovation potential. An *adhocracy*, she describes as being highly adaptive and capable of fast learning. As weaknesses, she identifies a tendency towards bureaucracy. Indeed, each of these traits we recognise in Gavi's experience in translating its success in innovation in vaccine and secondary vaccine attributes into other areas.

The levers which Gavi exerts over other actors to foster innovation may be seen in terms of innovation valuation resources. It is its global market access which gives Gavi the weight of influence over manufacturers which enables it to make innovation a condition of Gavi's purchase of their products, or simply to catalyse innovation by providing manufacturers with market-intelligence indicating a viable market opportunity. It is financial investment which Gavi provides at the national level which enables Gavi to incentivise recipient countries to introduce innovations into their programmes. Innovation legitimacy is not a means through which Gavi adds significant value to innovation.

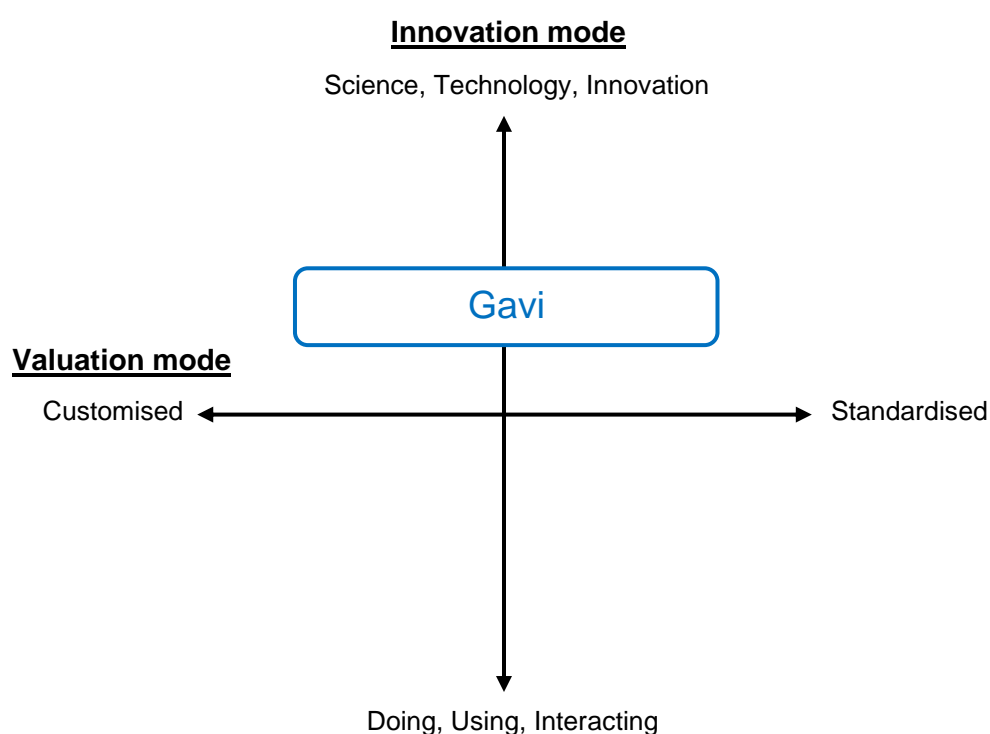
These resources are interlinked and mutually dependent, with Gavi's market access into recipient countries enabled through its offer to them of financial investment; and the financial investment into Gavi by global donors perpetuated by the attraction to them of Gavi's market access.

There is a difference, however, in the extent of these resources' standardisation or customisation depending on the area of innovation. Those innovations which have gone to scale, in vaccines, in particular, but also for example in cold chain equipment through the Cold Chain Equipment Optimisation Platform, are able to rely on standardised resources. The innovations themselves require no tailoring at the country level, but simply selection by the recipient government. In contrast, Gavi's private sector innovations benefit from the same set of resources, but are given value in a more customised way, in the individual countries in which Gavi operates.

These innovations require a lot of specific tailoring to the country context and have been seen to have struggled to achieve scale.

This distribution of resources is mapped against the innovation resources matrix of Binz and Truffer (2017) adapted as the following figure:

Figure 22: Innovation resource modes of Gavi (Author)



Source: Author

Gavi's innovation mode, i.e., the primary locus of development of innovations themselves, is overwhelmingly scientific, related in particular to the scientific basis to vaccinology which is Gavi's *raison d'être*.

According to this representation, the distribution of resources for Gavi's scaled vaccine and cold chain equipment innovations sits in the top right-hand quadrant. Based on Binz and Truffer's typology, this aligns to that of a *footloose* global innovation system (GIS). In this type, knowledge is primarily scientific and located in international networks or communities; and innovation valuation is primarily standardised across markets, relying on international standards and coherent user preferences for international legitimization and on mass-markets with economies of scale for market access. Accordingly, the resources of market access and of innovation legitimacy which Gavi brings to the global level based on feedback from

its engagement with countries, undergo a process of standardisation and feed into the scaling-up of innovation in this *footloose* GIS.

Conversely, the distribution of resources for Gavi's private sector partnership innovations sits in the top left-hand quadrant. Based on Binz and Truffer's typology, this aligns to that of a *market-anchored* GIS type, with its innovation mode also being primarily technological and concentrated at a global level, but its innovation valuation resources primarily customised and located at the national level.

Gavi's organisational characteristics also affect how it engages with institutions, as examined in the following section.

## **7.2 Gavi's institutional engagement**

This section examines Gavi's engagement with institutions relating to innovation in immunisation. It argues that the defining characteristic of Gavi's engagement with these is overwhelming one of co-optation, in terms of how it interprets, responds to, and challenges those institutions. Two cognitive institutions<sup>25</sup> are identified as being particularly relevant.

A first cognitive institution is the presumption that innovation is necessary for impact. Gavi sees innovation as 'essential for achieving Gavi's strategic goals' and 'critical to unlocking progress' (Gavi, 2019a, p. 19). This position is reinforced by a Gavi director:

In immunisation, but maybe even broader global health, we have been doing things in the same way for decades and things haven't moved as fast as we wanted. So, the recognition that we need to bring new ways of thinking... That's one driver (Interviewee 12, p. 1).

The director, however, goes on to describe a second driver:

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<sup>25</sup> As we saw in Chapter 3, Scott's (1995) taxonomy distinguishes regulative, normative and cognitive institutions. Cognitive institutions provide the framework through which actors process information to attribute meaning, including presumptions, as well as words, symbols and concepts.

The second one... is that we push for innovation because that's what's going to sell the Gavi model for our donors... to be able to say that Gavi is at the forefront of new ways of doing things (Interviewee 12, p. 1).

Other Gavi staff also identify these twin goals. A Gavi senior country manager explains the donor attraction to innovation in the context of greater public questioning of aid:

I definitely think that in the global donor climate of the past 10 years, where there's more and more scepticism from the taxpayer about what they are funding... It's this drive to show impact. This drive to be at the forefront. This drive to do new things. And that's a strength of Gavi. It really keeps us on our toes and sets us apart from other organisations (Interviewee 3, p. 4).

The senior country manager suggests a particular comparative advantage of Gavi for innovation. Members of other organisations share this assessment, with a UNICEF immunization officer saying:

Gavi was designed to bring innovation to immunisation programmes. That's its whole purpose... innovation was part of Gavi's DNA at the start. Like Gavi's always trying to work out 'what can we do next? How can we improve this, this and this'  
(Interviewee 34, p. 7)

It is indeed an important part of Gavi's narrative that Gavi itself was an innovative model when it was created in 2000, in the way in which it created between the public and private sectors a 'shared-value partnership' (Gavi, 2017c, p. 1), or even 'a new model for development' (Gavi, 2018a, p. 2). In evidence for this, Gavi offers policies such as the requirement for countries to co-finance vaccine costs; of the transition of countries from Gavi support once they reach middle-income country status; and vaccine market-shaping. Gavi claims that its 'innovative public-private partnership has transformed global progress in immunisation, health and development' (Gavi, 2019b, p. 2). In this way, Gavi co-opts this presumption for its own interest, in arguing that Gavi is already highly impactful, as a result of being itself an innovative model, and because immunisation is itself highly impactful.

Gavi's engagement is also robust with respect to a second presumption, that intended beneficiaries should be included in innovation planning, design and implementation. Gavi interprets this as meaning that innovations must be owned by

the recipient government. This principle is generally recognised within Gavi's governance and programmatic application and design principles, with Gavi claiming:

Our business model is built on the principle of empowering developing countries to take the lead in applying for support, managing development grants and, ultimately, financing their own immunisation programmes (Gavi, 2022g)

With respect to innovation, however, adherence to this principle varies significantly between different initiatives. At one end of the scale Gavi's market-shaping of vaccines includes extensive consultations with countries, in order to increase the level of understanding of their needs, on the basis that, as well as the manufacturers taking on a risk in investing in product development, so too do countries. According to a Gavi senior manager:

It's also a risk from a country perspective to maybe introduce a product that is going to be more expensive and in theory could improve coverage and equity, but until proven it doesn't (Interviewee 13, p. 6).

A Gavi managing director complements this with a more detailed description of the commitments needed on the part of the country government:

It requires a huge investment from the country. It's not something that I can sign with an entity. It's something that I have to negotiate. It has to be translated into budget. It has to be translated into a commitment, political and resources. It has to be maintained beyond, otherwise everything would fall (Interviewee 7, p. 3).

As we saw earlier, however, Gavi's aim to mobilise financial investment from the private sector alongside its innovation expertise can result in a compromising of government ownership of the innovation. Gavi's response to these presumptions is manifest in its interactions with other actors, which we examine in the following section.

### **7.3 Gavi's interactions with other actors**

This section examines how Gavi interacts with other actors for innovation in immunisation. It argues that there are three important sets of interactions by Gavi with other actors. The first is that with the private sector, which Gavi privileges as the source of 'the latest innovation and expertise' (Gavi, 2017c, p. 1) and which it

aims to attract into immunisation for international development. In Gavi's engagement with manufacturers of vaccines, of cold chain equipment or other immunisation-specific technical areas this is advanced and systematic. In other markets, however, Gavi's global-level private sector partners' low level of understanding of the less economically developed country (LEDC) in-country context limits the impact of their innovation. The other key party to this dynamic is the recipient government, which represents the second key set of interactions. This country government engagement is important to ensuring that an innovation is appropriate, comprehensive, fit for purpose and consequently impactful. The third set of interactions is that of facilitation between actors in general. Consistently, interlocutors identify Gavi's primary value addition as being around brokering knowledge, to which several aspects are identified, including setting standards, presenting pros and cons, evaluating impact or transferring lessons.

In these respects, Gavi provides structural coupling between sub-systems of innovation at the national and global levels. This thereby overcomes a spatial separation between the locus of the generation of the resources Gavi brings for innovation and their valuation, with market access and innovation legitimacy bringing value at a global level but based on feedback from Gavi's engagement with countries; and Gavi's financial investment bringing value at national level but generated from donors at a global level.

### **7.3.1 Targeted company facilitation through 'the smallest keyhole'**

A first set of interactions is that with the private sector, which Gavi privileges as the source of 'the latest innovation and expertise' (Gavi, 2017c, p. 1), and 'cutting-edge technology' (Gavi, 2018d, p. 9); even describing it as 'the world's biggest engine of innovation' (Gavi, 2017a, p. 39). The logic underlying this is described by a Gavi senior manager:

This idea of constantly looking at the same problem and trying to innovate is inherent within the private sector because of the competitive nature in which they operate and their need to improve visibility and to maintain market share (Interviewee 9, p. 1).

Gavi's nature as a public-private partnership is inextricably linked to this assumption of the comparative advantage of the private sector in innovation, and the role of the market in unlocking this. As we examined in Chapter 2, however, the ability of the



private sector to innovate is limited by the effectiveness of the prevailing market. Limited feedback or market intelligence serves to bound the decisions which firms can make, as a consequence of which it tends to a path dependency around existing markets or products (Arthur, 1994). Recognising this, Gavi describes aiming to 'leverage' (Gavi, 2018b, p. 5; Gavi, 2018d, p. 9) or 'harness' (Gavi, 2014b, p. 14) the private sector to bring greater 'resources, expertise and innovation' to areas of intersection between Gavi's strategic goals and private sector expertise (Gavi, 2022b, p. 2). Specifically, Gavi aims to align the incentives of the private sector and the needs of countries, to enable companies to 'successfully enter new markets and improve care for local populations' (Gavi, 2017b, p. 1).

In some areas, this aim is well advanced, through Gavi's engagement with manufacturers of vaccines, and of cold chain equipment, as we saw earlier. Gavi also aims, however, at 'directing its disruptive influence to new markets' (Gavi, 2017a, p. 44), by establishing 'private sector partnerships'. These target specific industry-leading organisations to try to encourage them to bring the solutions which those companies are implementing successfully in a high-resource market and adapt them to the low-resource countries in which Gavi works, or, as phrased by a Gavi senior manager, to say to those companies:

'We know that you can do x, y, and z. You can go through this big keyhole. We know you can do that. Now your challenge is to go through the smallest keyhole possible' (Interviewee 9, p. 4).

Gavi calls this 'the Shared Value proposition' (Gavi, 2017d, p. 1), suggesting that it will 'redefine existing business models' (Gavi, 2017e, p. 5). Resulting from this approach have been partnerships with organisations like UPS, DHL and Unilever (Gavi, 2017c). The usual form of this arrangement is that the company provides a several-million dollar donation, accompanied by an in-kind donation of technical expertise, deployed in a set of countries agreed with Gavi. UPS and DHL, for example have provided supply chain advice and the use of their logistics network in Uganda, and Kenya respectively, and Unilever has combined demand promotion for vaccines along with that for its Lifebuoy soap in India.

Complementing their private sector partnerships with market leaders, Gavi established in 2016 a mechanism targeting innovation from less-established companies, through a competitive model. The INFUSE (Innovation for Uptake, Scale and Equity) initiative aims to identify innovations of proven effectiveness and the

potential for significant impact in immunisation (Gavi, 2018d, p. 9; Gavi, 2022h). Gavi has described this as an 'innovation accelerator' (Gavi, 2017c, p. 1) and also compared it to venture capitalist-type engagement with these start-ups, 'providing them with mentoring, exposure and the right connections', though without taking equity in return (Boran, 2018, p. 1). Shortlisted applicants are invited to a collaborative workshop at which their innovations are discussed and reviewed, before a panel selects the most promising, designating them 'Pacesetters' (Gavi, 2016b, p. 3). The opportunity offered by Gavi is to connect Pacesetters with technical specialists, investors and other partners to help take their innovation to scale (Gavi, 2018d, p. 9). Gavi describes these actors as constituting 'an innovation ecosystem' (Gavi, 2018c, p. 39; Gavi, 2017c, p. 2). In-country actors, however, are not consistently included in the list, despite Gavi describing INFUSE as an initiative that 'addresses market failures that hinder scale up of potentially transformative innovations in developing countries' (Gavi, 2017c, p. 1; Gavi, 2017e, p. 5).

Interlocutors, however, question whether the INFUSE innovations really are 'thoroughly vetted' as proven (Gavi, 2017c, p. 1). Rather, several Gavi senior country managers suggest that the proposals are often earlier stage:

I think it's almost like just doing that first stage. 'That's a good idea. Let's see if you can actually make it happen with funding. Go and do it in a few countries and see if you have any success'. It's a bit 'Dragon's Den-ish' (Interviewee 2, p. 4)

A staff member of UNICEF shares this concern, and adds a second criticism, that the INFUSE selection process is not comprehensive across the market:

The fact that it has the INFUSE stamp doesn't mean that we believe it's ready for procurement. It's just that it's a good entrepreneur (Interviewee 25, p. 5).

Related to this, Gavi's programmatic staff describe challenges around the top-down nature of INFUSE-identified innovations, as described by the head of a Gavi team:

INFUSE is slightly flawed... they come up with these solutions but not necessarily directly tied to a problem. They come up with a generic solution, like 'we think this would be great'. And then we cast around going, 'well where are we going to fit it?' (Interviewee 42, p. 5).

The result is that the private sector partnerships identified at the global level are not always capable of adding value at the country level because of their lack of contextual understanding, as described by a Gavi senior country manager:

[A corporation], with no presence in the country, decided they were going to come in with... a very big, expensive design phase and pilot, without any cognisance of this massive landscape of data projects and other failed attempts in that space. And over a year showed no real interest in learning about that and just wanted to do the project as a kind of parachute-in, parachute-out exercise (Interviewee 2, p. 3).

A Gavi managing director described this with a metaphor, that 'when you have global corporate agreements, then as we say in my own culture 'you take the hat and try to fit it to the heads' Not that you have a head and you go buy a hat' (Interviewee 7, p. 4). A Gavi senior manager illustrated this problem with reference to a counter-factual: that the need be identified first, then the actors, and then the innovation:

The challenge we've had so far is that we have decided on partnerships on innovation and looked for countries to come... I think it should be the other way round. SCMs should be the one saying 'I have this issue and we don't know how to solve it. Perhaps CHAI<sup>26</sup> or JSI<sup>27</sup>, or WHO or maybe the private sector can help'. And that's where they should come in. It shouldn't be the other way around (Interviewee 41, p. 8).

Gavi also describes working with the private sector on 'known problems to which there are poorly defined solutions' (Interviewee 9, p. 1). In those cases, Gavi looks for partnership with organisations which could bring a mindset which might lend itself to finding solutions. Gavi's starting point for that has been through outreach to innovation hubs, especially Silicon Valley (Interviewee 9, p. 1), whose desire for this dialogue is also apparent:

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<sup>26</sup> International non-governmental organisation, the Clinton Health Access Initiative

<sup>27</sup> Consulting company in global public health, John Snow Incorporated

[Entrepreneurs] identified Gavi as a critical source of information that can tell companies to build their markets overseas where there is a bigger impact... [They] emphasised the importance of building a strong and visible case to Silicon Valley investors who may not know the opportunities even exist (Gavi, 2017b, p. 1).

Through this dialogue with the private sector Gavi aims to improve communication between companies and governments so that potential benefits are defined 'in terms that matter the most to countries' (Gavi, 2016b, p. 9), and so that, in the other direction, countries' needs are clearly understood by the private sector, as described by a Gavi senior manager:

A lot of our work as well is brokering, advising, guiding and translation. We are a translator. Certainly, the work that I've been doing has been translating the needs of countries through what we've sourced through our existing structures and translating that to the private sector (Interviewee 9, p. 4).

This is consistent with the experience described by Nexleaf Analytics, which is a US-based start-up company manufacturing a wireless temperature monitoring system for vaccine fridges, which has expanded from an initial engagement in India to Kenya, Mozambique, Senegal and Tanzania (Gavi, 2018d, p. 9):

Nexleaf has plans to scale across several countries, an achievement co-founder Nithya Ramanathan attributed to Gavi's assistance in identifying market demand and trends that the company can use to make decisions. Ramanathan said that the private sector and the public health space are often 'misaligned' and Gavi's ability to ensure companies meet the needs of local markets has been an important factor in Nexleaf's success (Gavi, 2017b, p. 1).

This description is supported by Gavi senior country managers, although they emphasise the complexity and challenge in this role, saying of companies:

They've not been aware of any of the subtle politics and the difficulties of actually getting acceptance, so that's been a big learning curve for them. Our job has been a broker: to bring everybody together, to gain acceptance from it, to design it properly and then let them get on with it (Interviewee 2, p. 2).

The other key party to the brokerage to which Gavi refers is the recipient government, which is examined in the following section.

### **7.3.2 Government buy-in, ‘otherwise everything would fall’**

A second set of interactions is that with recipient governments, with whom Gavi staff invest significant effort to try to implement innovations at the national level, aligning interests, information and investment, as described by a Gavi senior country manager:

My role is to make sure that innovation can be appreciated, selected, understood by the country and after that, that they could make a decision either to go for a pilot and after that eventually to go for scale-up... We appreciate because our understanding of the country perspective, the country agenda, the country capacity of implementation and human resources and in many systems (Interviewee 11, p. 1).

This goes to the heart of why Gavi senior country managers see national engagement as crucial: to ensure consideration of the dependencies related to an innovation, and that these are also addressed so as not to limit the impact of the innovation. A Bill and Melinda Gates (BMGF) vaccine officer suggests evocatively, of Gavi: ‘the struggle is to distinguish the shiny from what it takes to use the shiny’ (Interviewee 8, p. 13).

A Gavi senior manager describes one approach towards resolving this problem:

New technologies such as drones or smart fridges can meet these challenges, but they cannot be power-hungry, rely on expensive-to-replace parts, or require overly specialist technicians to regularly maintain them because – although they may be developed at cutting-edge start-ups – they must be robust enough to operate in low-income countries (Boran, 2018, p. 1).

The Gavi senior manager suggests the answer to the question of how to ‘use the shiny’ is to make the shiny easier to use, overcoming dependencies at point of development, rather than in the field. This is the approach of the Cold Chain Equipment Optimisation Platform in incentivising development and introduction of higher-technology refrigerators which require less user intervention and maintenance.

Other interlocutors, though, describe the solution as lying not just within the inherent nature of the innovation, with Gavi increasingly ‘focused on innovation for what we think are the critical issues or use cases but not as much on how does this actually absorb into a system’ (Interviewee 8, p. 13). A Gavi manager provides a specific example, saying ‘if you think of the drone, we don’t want to see it as an isolated project. It needs to fit into the system. And that is what is complicated: to make it fit into the system’ (Interviewee 41, p. 13). A WHO immunization officer characterises it as ‘a systems approach to innovation’ (Interviewee 31, p. 5), and a Gavi senior country manager proposes an analogy:

If you introduce a little bit of one of these technical innovations quite often the inertia of the way that everybody does things for so long, the systems and stuff that everyone’s so familiar with, it just gets lost in that and it’s very hard to actually make more than a little ripple (Interviewee 2, p. 2).

Here, the innovation was an outsourcing of vaccine delivery from the national cold-store direct to peripheral health facilities. Unforeseen dependences included staff at the district stores not allowing deliveries direct to health facilities, because they were concerned that district stores would not have enough stock. This was addressed by adding deliveries to the districts. Another unforeseen dependency was some health facilities not having enough gas to operate their propane-powered refrigerators to store these additional vaccines. This was addressed by ‘bolt[ing] in a component where we’re actually delivering gas as well as vaccines’ (Interviewee 2, p. 2).

A WHO immunization officer describes Gavi’s tendency to think of innovations as stand-alone solutions, saying:

Unfortunately, in global health, there’s still this continual pursuit for magic bullets... I don’t think there’s a very sophisticated understanding or a real understanding even of the limitations of HMIS<sup>28</sup> systems or the limitations of the way health workers use data and how difficult it is to get them to

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<sup>28</sup> HMIS: health management information system

change... Changing that and changing people's practices is actually very difficult (Interviewee 31, p. 5).

Indeed, Gavi publications and interlocutors rarely acknowledge such constraints explicitly. The Independent Review Committee is one exceptional and important such interlocutor. In this case, they both imply the limitation to Gavi's current approach to innovation, and also propose a system-oriented solution:

For the most part, technological innovation seems to be restricted to bits and pieces of activities instead of anchoring it to national systems (e.g., national eHealth plans) and inclusion of key stakeholders (Gavi, 2015d, p. 26).

The Independent Review Committee also highlighted the role of Gavi's other grants to help achieve this integration, writing that '[technical assistance] should encourage innovations and systems-wide thinking at country level to address key challenges' (Gavi, 2016d, p. 21), and 'HSS applications should foster innovation and build on the specifics of local contexts for strengthening health systems' (Gavi, 2016d, p. 12).

Nonetheless, 'anchoring [innovation] in national systems' is a complex and sensitive role, as illustrated by another Gavi senior country manager:

We have had to be careful not to push it too hard with government. They've had to own it and want it to happen. That's been a major challenge because it's very hard for you to come in with your idea (Interviewee 2, p. 2).

The Gavi senior country manager is alluding the fine balance, for an impact-focused donor like Gavi, between supply of a potentially-transformative innovation and country-owned demand for innovation. Another Gavi senior country manager gives a specific example of utilising a powerful government champion to conceal the full extent to which Gavi is driving the agenda:

In a way, my role or my tactic is to try to appear [to national actors] as little interventionist as possible and that most of this is driven by the minister himself, which is largely true. So, it's not a lie when I say to them during the discussion 'this comes from the minister'. Obviously, they know we agree. They may sometimes think that it comes from us actually. But the idea is to protect Gavi as much as possible in terms of being an independent broker and not to be too pushy (Interviewee 5, p. 5).

Aside from this sensitivity relating to Gavi-government relations, the Gavi senior country managers are also aware of the risk that innovation, entailing change, can upset individual interests, further complicating the dynamic. One senior country manager describes how in response to an innovative approach to apply a performance-based funding model to health worker payments during a nationwide vaccine campaign, government officials opposed the innovative model, 'because it's a source of money directly for them and also for all the health workers' (Interviewee 5, p. 5). On another occasion, government officials opposed the innovative outsourcing of vaccine supply chains, 'because they will lose so much power' (Interviewee 5, p. 2).

These dynamics are, though, variable across countries and counterparts. Another senior country manager describes how their in-country interlocutors are informed and proactive about innovation, and that the limitations are different:

I had a manager tell me 'EPI Managers in general are not interested in innovation, so it's your role to convince them'. At least in my countries that is not the case. These guys are advanced. They study abroad, they meet with others through regional meetings, they're collecting information, but they sometimes lack the resources (Interviewee 3, p. 4).

The fact that Gavi brings funding with its innovations can help to overcome the inertia created by a lack of funding for innovation within the country government. At the tactical level, the offer of funding can open doors in-country, as counterparts are keener to meet donor officials when funding is a possibility - with one Gavi senior country manager saying that 'the fact that we come with significant funding gives us a very strong, influential role' (Interviewee 5, p. 1).

At the strategic level, funding also serves as a crucial facilitator for innovation. Firstly, it can provide the funding needed to prove the concept, as described by a senior country manager:

There's no money for innovation in the government, and there's not really very much appetite for innovation. So, I think that our money created the interest; it created the possibility of doing something. It's paying for it all. Then if we prove the concept... then the idea is to make a case to the government to say, 'look, this is the cost benefit argument. Do you want to go wider?' (Interviewee 2, p. 3).



Secondly, funding can provide the start-up costs for implementation of a proven innovation at scale, as described by another senior country manager:

We have the funding to provide incentives to government to look at initiatives that are at a first level more expensive. They don't have the start-up cost to initiate these kinds of investment, but with the help from donors, it then can be sustained by the government. So sometimes that first injection is where donors can really be beneficial... And we hope that once the system is fully rolled out, the operational costs can be sustained by the government... [and] reduce those costs much lower (Interviewee 3, p. 2).

The reference to the importance of objective assessment of impact as a means of appealing to decision-makers is consistently emphasised (Interviewee 5, p. 2), with Gavi often specifically funding evaluation of innovation alongside implementation (Interviewee 2, p. 3). This knowledge-brokering aspect of the role played by Gavi is examined in the following section.

### **7.3.3 Knowledge-brokering innovations, 'not re-inventing the wheel'**

A third set of interactions relates to Gavi's role facilitating joint working by actors. Gavi aims through this to achieve the knowledge brokerage necessary for a market to function for innovation:

In well-functioning markets... is a clear flow of information between stakeholders that conveys reasonable certainty around demand, supply, and cost to all parties involved (Gavi, 2015c, p. 2).

We have seen reference in the preceding sections to 'brokering' (Interviewee 2, p. 2; Interviewee 5, p. 5; Interviewee 9, p. 4), and INFUSE participants also identify 'the role Gavi could play as a knowledge broker' (Gavi, 2016b, p. 8). However, the sense of these references is specifically that of connecting specific innovations from the global level with governments at the national level, as described by a Gavi senior country manager:

Our role is to look at those products and services and innovations [and] enable countries to make an informed decision as to whether they want to take this thing or not (Interviewee 9, p. 4).

This implies that a much more targeted brokering, driven from the global level. This is consistent with Gavi's belief, a senior manager suggests, that 'we also have a

mandate, if we think there's a good technology we think can help, to bring the innovation to the countries' (Interviewee 41, p. 8).

Even within that push, though, there is variation in the nature of the dynamic. At one extreme, 'it is very private sector driven and it's really very driven by what is coming to us instead of us searching for a solution' (Interviewee 3, p. 1). At the other, Gavi describes 'ensuring robust learning, evidence generation and implementation experience are disseminated to inform scale-up within and across countries' (Gavi, 2018c, p. 1). The norm sits between these extremes, with a Gavi senior manager describes 'guiding' countries, saying 'it's a question of matchmaking, informing and advising and guiding the other party as to how they would adapt' a proposed innovation (Interviewee 9, p. 4). This necessitates the senior country managers 'to try to animate the process and lead a process together with colleagues in Gavi, the country partner, technical partners, other funding agencies as well, to get all the conditions in place to achieve those results' (Interviewee 5, p. 1).

Further, Gavi recognises the 'unique opportunity' it has around standard-setting for innovation:

To help achieve [Gavi's] objective of accelerating deployment of high-performing technologies that meet user requirements across health facility types, the Secretariat must specify a minimum standard of quality for technology purchased with its support (Gavi, 2015d, p. 41).

Private sector partners see standard-setting as useful also from their point of view 'to facilitate the alignment between various solutions and to make expansion to different markets possible' (Gavi, 2016b, p. 9). Indeed, for Gavi's Cold Chain Equipment Optimisation Platform, Vaccine Innovation Prioritisation Strategy and Logistics Management Information System, standard-setting was a central element. All three initiatives also went further to produce a listing of innovations which met the standard. A Gavi team head highlights the utility of this:

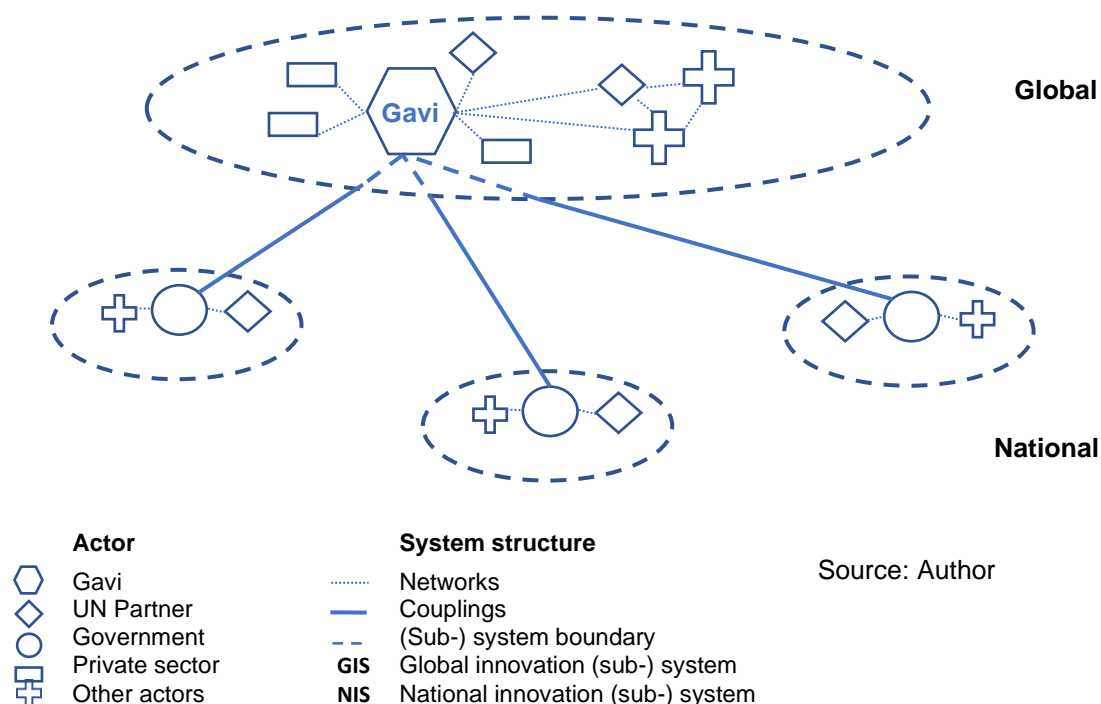
There's development of standards, for example, that gives a lot of people a common language and a platform to say, 'you're bringing these ten technologies, but actually two of them meet 80% of the standards' and there's a credibility that comes to those technologies (Interviewee 1, p. 5)

There is occasional reference to other facilitational roles by Gavi, including a convening ‘project manager role’ (Interviewee 13, p. 3) within in particular those multi-partner initiatives aiming to take innovations to scale.

The output of the roles which Gavi provides is that of structural coupling between sub-systems of innovation at the national and global levels. This serves to overcome the spatial separation we have identified between the locus of the generation of the resources Gavi provides for innovation and their locus of valuation. Market access and innovation legitimacy bring value at a global level but are based on feedback from Gavi’s engagement with countries; and Gavi’s financial investment brings value at a national level, but is generated from donors at a global level.

These structural couplings are shown in the following figure, adapted from the original illustrative Global Innovation System (GIS) of Binz and Truffer (2017).

Figure 23: Structural couplings in immunisation GIS involving Gavi (Author)



The figure shows the two levels of sub-systems involved in Gavi’s role in innovation in immunisation. Gavi’s structural couplings link primarily to governments at the national level, but at the global level involve wider multi-actor networks. Knowledge creation, which as we argued is generated primarily from *science, technology and innovation* (STI), is generated overwhelmingly at the global level, through

interactions with the private sector and other actors. The financial investment resources are shown against the country level, because although they are generated, or ‘formed’ (to use Binz and Truffer’s term) at the global level, their valuation is primarily at the national level, through the funding of innovation there. Similarly, the market access resource is shown against the global level, because although this is generated at the country level, its valuation is at the global level, through the market shaping which this access enables. Innovation legitimacy, likewise, is based on feedback from countries but provides value at the global level through the selection of innovations to take to scale.

With this spatial separation of the generation and innovation valuation of these resources, the linkages between the sub-systems which Gavi provides represents a vital role in the systematisation of innovation within immunisation.

## **7.4 Conclusion**

Gavi’s role with respect to innovation in immunisation is characterised by its extensive provision of linkages between diverse actors and between spatial levels. The primary example of this is Gavi’s vaccine market shaping, in which it effectively links recipient countries on one side and private sector manufacturers on the other to align supply and demand for innovation in vaccines. This engagement is highly standardised, as is Gavi’s engagement in cold chain equipment and in vaccine secondary attribute innovations. Gavi’s engagement in other private sector partnerships is much more customised, and hence less widely scaled. These innovations also bring a risk of a *techno-fix* approach and consequently, though to a lesser degree than in UNICEF, are a source of inter-organisational tension.

In forming and maintaining linkages between actors, power plays an important part in enabling Gavi to influence or leverage particular behaviour by other actors. This power derives from Gavi’s generation and utilisation of innovation valuation resources of market access and financial investment. Gavi’s global market access gives it the weight of influence over manufacturers of vaccines and associated products which enables it to make innovation a condition of Gavi’s purchase of those products, or to catalyse innovation through authoritative market-intelligence. Gavi’s financial investment at the national level enables Gavi to incentivise recipient countries to introduce innovations into their programmes.

In providing these linkages, Gavi does so in a dynamic way, enabled by its adhocratic organisational type. This highly flexible project-based form is able to coordinate and combine (or relinquish or acquire) its resources. Gavi's resulting dynamic capabilities enable it to respond quickly to new opportunities for innovation in immunisation.

## **8 TOWARDS A GLOBAL INNOVATION SYSTEM IN IMMUNISATION**

This chapter discusses the empirical findings of our case studies of UNICEF, the Bill and Melinda Gates Foundation (BMGF) and Gavi. It argues that there is significant evidence of an emerging global innovation system (GIS) in immunisation for international development. This system is multi-spatial, with a sub-system at the global level, and multiple national sub-systems. The global and national sub-systems are directly linked through structural couplings provided by donors, who use these to generate and provide knowledge and other innovation resources. These factors all serve to dynamically determine the boundaries of the global sub-system.

The chapter is divided into three sections. The first section identifies the existence of relevant regulative, normative and cognitive institutions, with one set of these at the national level, and another at the global level. Moreover, we discern a close relationship between national and global rules and norms, and argue that this suggests the two spatial levels are connected within a single system which is coherent and consistent. The chapter also highlights tensions between presumptions predominant at the global level and those predominant at the national level, and examines how donors respond to this tension.

The second section examines how innovation valuation resources are generated and utilised through the interplay of donors' activities across the two spatial levels. It proposes that the balance between innovation knowledge modes, and between the customisation or standardisation of valuation resources varies depending on whether the innovations are the stage of invention, application or diffusion. This represents an evolution of the GIS model proposed by Binz and Truffer (2017), who envisaged a consistency of distribution of knowledge and innovation valuation resources within a GIS.

The third section relates donor generation and utilisation of valuation resources to their provision of structural linkages between sub-systems. It also introduces the idea that it is the existence of different actor capabilities which necessitates such networks. To examine this further, the section relates donor generation and utilisation of valuation resources to the concept of system building, and highlights that this requires concentrated agency. It relates this to organisational capabilities and hence to organisation type.

## 8.1 System institutions

This section reviews the empirical evidence to identify those regulative, normative and cognitive institutions relevant to innovation in immunisation. It identifies six at each of the national and global levels. Moreover, we identify a close relationship between national and global rules and norms. This supports the argument that these different scale levels are part of a single innovation system which is coherent and consistent. It is also bounded: the rules serve to provide a hard boundary, excluding those actors or innovations who do not align; and the norms serve to provide a soft boundary, facilitating the participation of those donors who align with them, and hampering those who do not. The section also highlights tensions between presumptions predominant at the global level and those predominant at the national. The empirical evidence is that donors do not engage with these presumptions in a homogeneous way. Rather, they do so in a way which is influenced by their organisational structure, culture and objectives.

### 8.1.1 National level rules, norms and presumptions

The national level is an important locus for innovation within immunisation because it is in less economically developed countries (LEDCs) that innovations are designed to have impact in international development. In the empirical data, six national level rules, norms and presumptions are identified as relevant to innovation in immunisation, as shown in the following table:

Table 5: National level rules, norms and presumptions (Author)

Rules	Norms	Presumptions
National laws and standards	National development strategy	Viability in use-context
Accountability to host government	Donor coordination	Inclusion of beneficiaries

Firstly, donors must follow national laws and standards. National laws affect innovation by setting legal frameworks and boundaries on relevant assets and rights. These are often widely applicable, such as protecting intellectual property rights, or determining ownership and use of data, such as the vaccine record data which is increasingly being digitised and placed in innovative information management systems. National laws also cover more specific issues, such as

authority for the use of air-space to deliver vaccines by drones. National standards do not have the same level of legal weight as laws, but are often closely related. They set out formal requirements for artefact quality, and are assessed and enforced by the national regulatory authority. Formal standards are particularly relevant to innovations in vaccines themselves by virtue of these being medical products but also pertain to other types of innovations such as electronic equipment.

Secondly, donors must be accountable to their host-government. This relates to the fact that donors follow certain rules of accountability. For example, their presence and programming in a country is by consent of the host sovereign government<sup>29</sup>. In practice the Government representative in whom this manifests most often is the Minister of Health, who has 'to own [an innovation] and want it to happen' (Interviewee 2, p. 2). We saw this explained repeatedly by both UNICEF country immunisation officers and Gavi senior country managers. This rule affects innovation primarily in positioning government as a gatekeeper for access to beneficiaries, and often as their representative within participative processes of innovation design and implementation. This may be enabling of innovation, because beneficiary participation is important in the design of innovations which are most impactful. It may, however, also be constraining of wider impact, as the need to preserve consent can limit donors' ability to challenge social norms which may inhibit the participation of marginalised communities, for example. UNICEF is particularly focused on this, highlighting the need to avoid 'innovation from widening gaps' (UNICEF, 2014a, p. 5) by addressing 'the specific needs of marginalized and vulnerable children and families' (UNICEF, 2014a, p. 12).

Thirdly, it is the norm that donors align to national development strategies. These set out the theory of change in an LEDC's economic and social development. It also specifies the priority sectors in which the LEDC government would like donors' support. This facilitates the engagement of actors and resources for innovation

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<sup>29</sup> There are some very rare exceptions to this, in situations in which a government does not have control over a part of its territory. For example, in Kareni and other ethnic minority areas in Myanmar bordering Thailand; or Saudi-controlled areas of Yemen. Nonetheless, in these cases, there still exists a de facto regulative institution which determines that donors operate in those areas by consent of the alternative controlling authority.



within priority sectors but constrains it in non-priority areas. It also serves to concentrate donors, pushing them to work in a coordinated or complementary way within those priority areas, including on the innovation they foster. UNICEF and Gavi both talk about the importance of ‘anchoring [innovation] to national systems (e.g., national eHealth plans)’ (Gavi, 2015d, p. 26) and strategies. More broadly, this norm is also set out in the 2005 Paris Declaration on Aid Effectiveness, 2008 Accra Agenda for Action and 2011 Busan Partnership for Effective Development Cooperation.

Fourthly, it is the norm that donors coordinate amongst themselves. This is in order to make more effective and efficient the assistance they provide, by reducing duplication in an area, or collective neglect of another. This norm is often championed by host governments, and by those donors for whom aid-effectiveness is a particular agenda. It serves to push donors to actively coordinate on innovation, as in their broader programming (Interviewee 33, p. 5). Beyond this coordination, we have seen examples of complementary support by donors to innovation in-country. For example, WHO and UNICEF provided technical advice to a new electronic immunisation system in one sub-Saharan African country, funded by BMGF, with Gavi ‘step[ing] in to support the further rollout’ (Interviewee 3, p. 2).

Fifthly, donors share the presumption that innovations should be viable in their intended context. This is the understanding that to be impactful, innovations must be well integrated into the ‘local social, cultural, economic, institutional and political circumstances’ (UNICEF, 2014a, p. 12). We saw this explained repeatedly by both UNICEF country immunization officers and Gavi senior country managers. Donor emphasis on this presumption is so that the innovations’ dependencies, such as those relating to infrastructure or minimum user skills, are identified and mitigated. Without this, the presumption states, however intrinsically well-designed an innovation may be, its impact will be significantly limited.

Finally, donors share the presumption that intended beneficiaries should be included in innovation planning, design and implementation. Donor support for this presumption is driven primarily by a productivity view of participation as important in helping to derive the best possible outcome; rather than an empowerment view which would explain participation as being important by democratic principle. Specifically, donors see the inclusion of beneficiaries as being the primary source of information about the intended context for the innovations they foster. A UNICEF officer described this as ‘being connected with all these frontline workers and being

able to have these platforms that allow for dialoguing, that allow for multi-way feedback and discussions on what those needs are and what the potential is' (Interviewee 36, p. 4).

### 8.1.2 Global level rules, norms and presumptions

The global level is an important locus for innovation within immunisation because it is here that actors manage response to intercontinental outbreaks of disease; develop new international policies; and harmonise standards across countries (Milstein *et al.*, 2006). Globalisation has contributed to the cross-border nature of global public bads and the increasing requirement for international cooperation to address them, and to provide global public goods (Kaul and Faust, 2001). It is at the global level that actors make cross-country comparisons and aggregations of need, opportunity and capacity, and it is here that donors combine knowledge from diverse sources, create other important resources such as financial investment, and draw in new actors (Chataway and Smith, 2006).

In the empirical data, six global level rules, norms and presumptions can be identified as being relevant to innovation in immunisation, as shown in the following table:

Table 6: Global level rules, norms and presumptions (Author)

Rules	Norms	Presumptions
International health regulations	Global immunisation strategy	Opportunity of digital technology
Accountability to constituents	Aid effectiveness principles	Private sector comparative advantage

Firstly, donors must follow the *International Health Regulations*<sup>30</sup>. These are set of global rules which specify the safety and efficacy of medical products including vaccines, but also set out required standards for products such as cold-chain

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<sup>30</sup> [www.who.int/health-topics/international-health-regulations](http://www.who.int/health-topics/international-health-regulations)

equipment and other technologies used in immunisation. It is the role of the World Health Organisation (WHO) to uphold, adjudicate on, and to issue relevant technical guidelines. Moreover, WHO's Expert Committee on Biological Standardization, the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, and other such global bodies are contributing to greater harmonisation of standards across countries (Milstein *et al.*, 2006). Donors in immunisation work in alignment with these regulations and guidelines, explicitly utilising the WHO-established processes for validation and endorsement of specific innovations, including for example vaccines and cold-chain equipment.

Secondly, donors must be accountable to their constituents by following certain rules of accountability. For bilateral donors this accountability is to their parliament; for multilateral donors it is to those member states who provide funding contributions; and for foundations to their funders, board and often also to their governments to justify a charitable or favourable tax status. The accountability entails impact monitoring and reporting. Recent global financial pressures have increased pressure on donors to demonstrate significant impact through their investments, which has increased their drive for innovation, which is seen as being particularly impactful. UNICEF, for example, explain the increased importance of innovation as due to 'a shift from programme delivery to programme results... and looking for value for money' (Murray, 2014). The same argument was set out by Gavi, relating this 'drive to show impact... [because of] more and more scepticism from the taxpayer about what they are funding' (Interviewee 3, p. 4).

Thirdly, it is the norm that donors should align to the global immunisation strategy. This, *Immunization Agenda 2030 (IA2030)*, sets out the mission and objectives for the community of actors in immunisation. It is jointly developed and owned and serves to reflect and maintain the consensus of priorities, which include 'research and innovation'. As a UNICEF regional immunisation officer put it, 'innovation is an important topic... it is a big agenda' (Interviewee 30, p.1). IA2030 also sets out principles relating to innovation, including that they be 'people-centred' and 'country-owned' (WHO, 2020a, p. 44) which influence donor approaches to innovation in immunisation.

Fourthly, it is the norm that donors should uphold aid effectiveness principles. These principles are set out in particular in the 2005 Paris Declaration on Aid Effectiveness, 2008 Accra Agenda for Action and 2011 Busan Partnership for

Effective Development Cooperation. BMGF has positioned itself as a particular champion of aid effectiveness, with Bill Gates exhorting other donors ‘to get serious about maximizing aid’s effectiveness’ (BMGF, 2011b). Aid effectiveness principles serve to push donors to actively coordinate on innovation, as in their broader programming.

Fifthly, donors share the presumption that digital technology presents particular opportunities for radical innovation. The empirical data suggests that donors tend to follow this presumption and also as a result often associate innovation with digital technology. We saw this with respect to BMGF, resulting, interlocutors suggested, from Bill Gates’ history within the information technology industry. In fact, the same tendency is apparent with other donors. For example, we saw UNICEF tending to default towards examples of innovations utilising digital technology in any reference to innovation, and its Venture Fund eligible only for ‘frontier technologies’ (UNICEF, 2017c, p. 1; UNICEF, 2022b). The same dynamic is evident in Gavi, whose INFUSE initiative, for example, is also focused on technological innovation. Gavi tends to characterise non-technological innovations as know-how, not as innovation, distinguishing in their 2021-25 strategy, for example, ‘supporting immunisation delivery system innovations and technologies’ from ‘sharing immunisation know-how’ (Gavi, 2018a, p. 10).

Finally, donors share the presumption that the private sector has a comparative advantage in innovation. By the private sector, donors mean in general terms any for-profit actor. Donors conceive this profit motivation as providing a much stronger drive for the private sector towards innovation than does the public service drive of the public sector. Moreover, donors understand that the private sector has greater capacity than the public sector to gather and use data for decision-making, to analyse costs and benefits, and to make critical decisions. Gavi is explicit in its privileging of the private sector as ‘the world’s biggest engine of innovation’ (Gavi, 2017a, p. 39), due to ‘the competitive nature in which [firms] operate and their need to improve visibility and to maintain market share’ (Interviewee 9, p. 1). UNICEF sees the private sector as ‘an important source of innovations, market reach, and research and development’ (UNICEF, 2019b, p. 13) because ‘technology companies were driven by profit’ (United Nations, 2018, p. 66). BMGF also shares the assumption that capitalism’s profit incentive leads to significant innovation within businesses (Gates, 2008).

The global rules, norms and presumptions identified in this section and those at the national level identified in the preceding section are closely related, and provide a boundary function. Others, in contrast, appear at odds, and are contested by and within donors. These aspects are examined in the following section.

### 8.1.3 Institutional relatedness and tension

The rules, norms and presumptions affecting innovation in immunisation across the national and global levels are compared as shown in the following table:

Table 7: National and global rules, norms and presumptions compared (Author)

	<b>National</b>	<b>Global</b>
<b>Rules</b>	National laws and standards	International health regulations
	Accountability to host government	Accountability to constituents
<b>Norms</b>	National development strategy	Global immunisation strategy
	Donor coordination	Aid effectiveness principles
<b>Presumptions</b>	Viability in use-context	Opportunity of digital technology
	Inclusion of beneficiaries	Private sector comparative advantage

A close relationship between national rules or norms and global ones can be identified. For example, the international health regulations determine or influence national standards relating to health. Those global international health standards are themselves legislated at the World Health Assembly, which is a WHO member-state based body. In terms of the rules of donor accountability to their constituents, at the global level, and to host governments at the national level, these are related though the principle and means of accountability. In particular, this is the use of data to monitor the performance and impact of donor programmes, and to communicate this to both their constituents and host government. Each instance of donors being accountable to these groups perpetuates and reinforces both these rules.

Similarly, the priorities and policies set out in the global immunisation strategy contribute to those reflected in the national development strategies. There is also influence in the other direction, again through the mechanism of global governance bodies, at which UN member states are able to contribute their views of the development of global strategies for immunisation or other areas of global health. There is a close relationship between the norm of the global aid effectiveness principles and donor coordination at the national level. Those global principles include the specification that donors should coordinate amongst themselves, as well as that donors should align to the national development strategy. Again, feedback from these national norms influences the global principles through member states' contributions to discussions and decisions within global governance forums.

That these rules and norms are closely related across different spatial levels supports an argument that they are part of a single system which is coherent and consistent. It is also bounded. The rules serve to provide a hard boundary, excluding those actors or innovations who do not align. The norms serve to provide a soft boundary, facilitating the participation of those donors who align with them, and hampering those who do not, in terms, for example, of other actors willingness to work with them, or of their constituents willingness to tolerate activities without such alignment. These norms, though, are themselves modifiable by actors over the medium- to long-term, by virtue of their participatory nature.

The situation, however, is different with respect to presumptions. Here, rather than a close relationship, we see a tension between the global and national. The presumption that digital technology presents particular opportunities for radical innovation is maintained by donors at the global level because of the nature of their focus at that level. That focus is on achieving impact across multiple countries, and in parallel, on demonstrating that impact to their constituents. Against those aims, digital innovation is attractive because of its potential, when successful, to achieve change which is radical and transformative. The private sector actors which donors identify as being those they need to engage with to develop such innovations are also readily accessible: overwhelmingly in the USA or Europe, or even if in developing countries, easy to work with as being highly connected and speaking a common technical language. In contrast, at the national level, donors and other actors emphasise the importance of ensuring that any innovation is well integrated into the existing system and capabilities. Without this, they highlight that an

innovation is not viable, and there is a particular concern that digital innovations suffer this risk more than other innovations.

We observed this within UNICEF, in which despite the organisation defaulting corporately towards an assumption of innovations being technological, UNICEF programme staff variously described these media-friendly innovations utilising digital technology dismissively as 'shiny bright objects' (Interviewee 28, p. 1), 'fancy' solutions (Interviewee 35, p. 2), and as creating a media 'buzz' (Interviewee 31, p. 1). Many respondents to the 2018 evaluation of Innovation in UNICEF pointed to UNICEF's bias towards technology as impacting negatively on UNICEF's ability to foster other types of innovations (UNICEF, 2019a, p. 5).

Rather, UNICEF staff suggest that innovation in immunisation demands an 'understanding of countries' realities' (Interviewee 30, p. 9) with innovations 'rooted in local social, cultural, economic, institutional and political circumstances' (UNICEF, 2014a, p. 12) so that UNICEF would be 'helping to scale something that is a more of a need than another piece of technology' (Interviewee 36, p. 8).

We observed similar tensions in Gavi, with interlocutors suggesting that Gavi's focus on innovations utilising digital technology is linked to the fundraising potential of these. This, they suggest, results in innovations which are not 'context-driven' (Interviewee 2, p. 4) or have a 'systems understanding' (Interviewee 31, p. 5). Interlocutors highlighted specific tensions around time-frames, with the global level desire for short-term deliverables challenged by the longer durations needed to build deeper country understanding (Interviewee 31, p. 5). These tensions are also seen in terms of the degree of mass appeal, with innovations utilising digital technology tending to capture that more than other sorts of innovations which may be more country context-oriented (Interviewee 6, p. 2). Also, related to this tension is the extent to which provider selection is informed by a comprehensive assessment of potential providers. Gavi's resource mobilisation perspective on technology incentivises selection of a specific provider without a comprehensive review of potential alternatives (Interviewee 3, p. 4), which can be directly at odds with the ability for host-governments to choose a provider and innovation most suited to their context (Interviewee 2, p. 4; Interviewee 4, p. 3; Interviewee 33, p. 6).

The same tensions are seen concerning presumptions relating to the key actor groups. At the global level, the private sector is seen by donors as an especially important actor, because donors perceive its profit motivation as making it

particularly innovative, as well as being highly performing in general. This aligns well to both the multi-country impact, and constituent management aims of donors at the global level explained above. Yet at the national level, the actor of primary importance for reasons of both productivity and empowerment, is the beneficiary. We saw in UNICEF this tension manifesting as UNICEF country offices feeling as though they were expected to 'sell' or push upon government innovations which UNICEF headquarters has selected, rather than acting as honest brokers (Interviewee 30, p. 1; Interviewee 35, p. 4). The 2018 evaluation of innovation in UNICEF reported a broad set of UNICEF staff suggesting that 'HQ-led initiatives that were not well aligned with field priorities... [but were] solutions seeking problems' (UNICEF, 2019c, p. 64).

Relatedly, country governments are generally reluctant to be the first in which a donor pilots an innovation (Interviewee 30, p. 3). The solution, according to a UNICEF country officer is that pilots are embedded in country systems technical and political systems: that the pilot is based on existing government platforms for service delivery; is focused on producing relevant, reliable evidence; and that the conclusions are owned, championed and communicated by government (Interviewee 16, p. 4). These principles are consistent with those for wider aid-effectiveness and innovation.

#### **8.1.4 Compliance, co-optation and contestation**

The empirical evidence gathered throughout this research suggests that actors do not engage with these rules, norms and presumptions in a homogeneous way. Rather, actors do so in specific ways which are influenced by their organisational structure, culture and objectives.

The Bill and Melinda Gates Foundation (BMGF)'s normative engagement is overwhelmingly one of compliance and reinforcement. It does so to gain access and influence within the community of actors in the space (Harman, 2016) which it uses to increase the systematic leverage of particular presumption. The norm of donors' upholding of aid effectiveness principles, is a typical example. Bill Gates has been exhorting other donors 'to get serious about maximizing aid's effectiveness' and highlighted the importance of data in assessing and improving the performance of aid (BMGF, 2011b). The advantage of BMGF alignment to this norm is also that these aid-effectiveness principles tend to align closely with the principles underlying BMGF's own approach, for example for more rigorous, transparent and efficient aid



(Fejerskov, 2015), and BMGF's support to the new development models manifested in organisations such as Gavi and the Global Fund. This serves as a virtuous circle, as BMGF supports innovations, and other donors subsequently come-on board, the role of BMGF as a pioneer, leader and authority is strengthened (Harman, 2016). Similarly, BMGF's adherence to the norm that donors should align with the global immunisation strategy, which includes a setting out of the importance of innovation in immunisation, thereby legitimises the focus which BMGF puts on innovation. It also represents a means for BMGF to reinforce the mutuality between donors in the innovation space, and through that to put pressure on the other actors also to allocate their own resources to it.

In contrast, Gavi's engagement with presumptions in immunisation is overwhelmingly one of co-optation. The rule of donor accountability to their constituents, at the global level, and to host governments at the national level, both emphasise the importance of demonstrable performance and impact of donor programmes. Gavi co-opts this to advance the narrative that Gavi is already highly impactful, as a result of being itself an innovative model, and because immunisation is itself highly impactful. The presumption that intended beneficiaries should be included in innovation planning, design and implementation, Gavi also co-opts, applying it as the principle that innovations must be owned by the recipient government. This principle is generally recognised within Gavi's governance and programmatic application and design principles. With respect to innovation, however, Gavi's resource mobilisation objectives can act as more of a primary driving factor.

UNICEF, in contrast to both BMGF and Gavi, in its engagement with the norms and presumptions in immunisation is overwhelmingly one of internal contestation. This is in particular with respect to those areas of tension between the global and national levels. Within UNICEF, the global Office of Innovation champions particularly those global norms, and UNICEF country staff, equally strongly, the national ones. This results in the internal contestation which we observed around, for example, whether UNICEF is 'selling' or pushing upon governments innovations which UNICEF headquarters has selected, rather than acting as honest brokers (Interviewee 30, p. 1; Interviewee 35, p. 4). Chataway and Smith (2006) observed a similar tension within the International AIDS Vaccine Initiative (IAVI), and described how it was considered and resolved through a decision that IAVI would focus on being

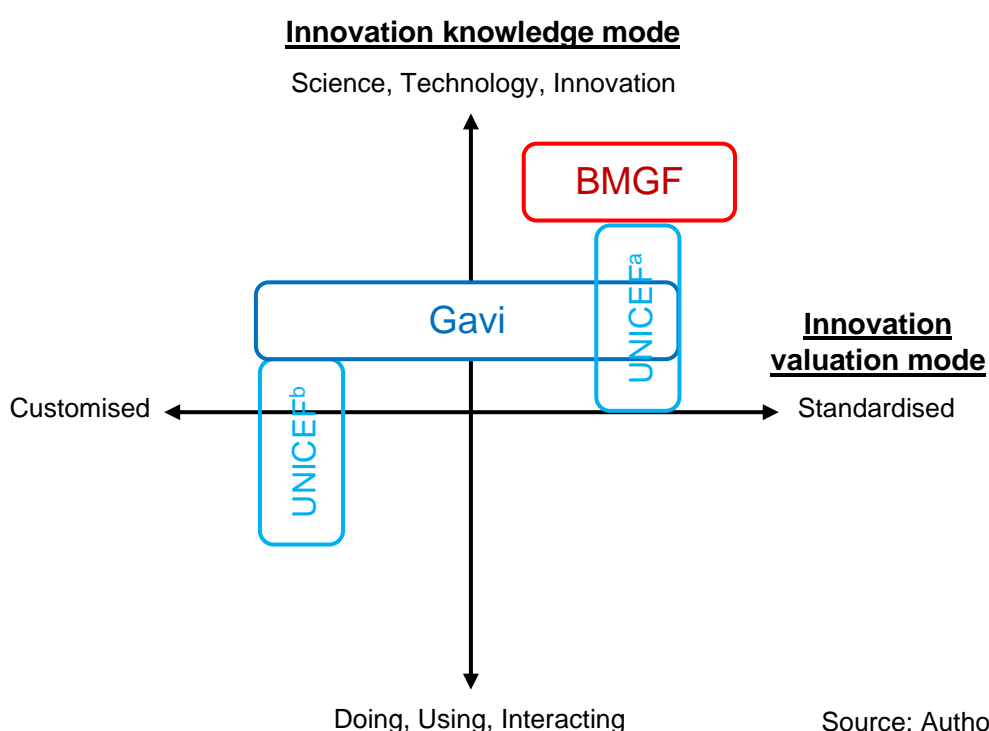
recognised for its in-country relationships ‘rather than as an organisation intent on imposing likely to fail *techno-fix* solutions’ (Chataway *et al.*, 2007).

## 8.2 System innovation resources

This section examines donors’ provision of resources for innovation in immunisation. System resources are ‘tangible and intangible assets of strategic value’ to which actors have access’ (Musiolik *et al.*, 2020). They may result intentionally and strategically (Musiolik and Markard, 2011) or may be emergent in individual actors, or through distributed agency (Garud and Karnøe, 2003).

In the empirical evidence, the three donor organisations’ resources are distributed differently on the adapted innovation resources matrix of Binz and Truffer (2017). In the empirical chapters each of the donors was individually mapped against the matrix, and are now shown consolidated in the following figure:

Figure 24: Innovation resource modes of donor cases (Author)



Firstly, we examine the vertical innovation mode axis. We see that donors tend to be positioned within the *science, technology and innovation* (STI) knowledge mode. There is, however, significant variation in this between donors. BMGF shows a very strong preference for STI innovation, followed by Gavi. UNICEF’s global procurement role, marked as UNICEF<sup>a</sup> in the figure, is similarly clearly STI-oriented.

In contrast, UNICEF's country partnerships mode, marked as UNICEF<sup>b</sup> in the figure, is positioned within the *doing, using and interacting* (DUI) knowledge mode. The innovation mode in immunisation is examined further in the following section.

Secondly, we examine the horizontal innovation valuation mode axis. In this case we note that no overall preference is discernible, with the donors spread across the full extent of the axis. Again, however, we note significant variation in the positioning of individual donors. BMGF engages innovation valuation resources which are overwhelmingly standardised. So too is UNICEF's global procurement function, UNICEF<sup>a</sup>. At the other extreme, UNICEF's country partnerships function, UNICEF<sup>b</sup>, engages innovation valuation resources which are overwhelmingly customised. Gavi engages the resources over a broad range which encompasses both customised and standardised. We identify how the interplay of some donors' activities across the two levels enables them to generate and utilise innovation valuation resources

In the final section, we advance an explanation for this observed distribution of the set of donors across the matrix. We propose that the balance between STI and DUI modes of innovation, and the degree of customisation or standardisation of valuation resources varies depending on whether the innovations are the stage of invention, application or diffusion<sup>31</sup>. This represents an evolution of the GIS model proposed by Binz and Truffer, who envisaged a consistency of distribution of knowledge and innovation valuation resources within a GIS.

### **8.2.1 Knowledge resource**

Vaccine development and production is a complex, non-linear process overwhelmingly carried out by for-profit private pharmaceutical companies.

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<sup>31</sup> We use this categorisation of Schumpeter (1947) as a simplified model of innovation in this case. Simplification of a sophisticated model like the innovation systems into a basic linear model for the purposes of analysis is recognised as legitimate (Balconi *et al.*, 2010).

Sometimes building upon basic<sup>32</sup> research by public research institutions (Kettler, 2005), these pharmaceutical companies invest significantly in research and development programmes which usually require more than 10 years to take a vaccine to licensure (Milstein *et al.*, 2006) and average more than US\$ 800 million per new product, amounting to more than 30% of the total cost of bringing a vaccine to market (Kettler, 2005).

The industry fulfils the three criteria proposed by Jensen *et al.* (2007) as meeting a mode of knowledge generated primarily from *science, technology and innovation* (STI). These are i) investment in research and development; ii) employment of staff with advanced science degrees; and iii) collaboration with university-based scientists (Kettler, 2005). This STI innovation mode relies primarily on deductive approaches and quantitative techniques in formalised settings. The resulting knowledge tends to be codified and explicit, and of the nature of *know-what* and *know-why* (Lundvall and Johnson, 1994; Jensen *et al.*, 2007; Fitjar and Rodríguez-Pose, 2013).

The same STI mode is observed more broadly in our empirical evidence. This preference is particularly emphasised in the case of the Bill and Melinda Gates Foundation (BMGF), driven by the foundation's principle of 'narrow scientific positivism' which is itself grounded in the information technology and global business mindset of Bill Gates. Vaccines represent this particularly, in the scientific consensus around their strong efficacy, and understanding as to how they achieve this. Aside from vaccines, BMGF also manifests this innovation mode in its focus on the particular opportunity represented by technology, including for example, technological innovations in cold-chain equipment and in nasal-sprays, jet injectors, microneedle patches or other alternatives to the needle and syringe, and on the importance of linking research and programme delivery. BMGF's STI knowledge

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<sup>32</sup> The term is misleading, as this research is anything but basic. We use it to align with the phases of innovation development reflected in the linear model of innovation and its successors. The sense, though, is more one of research of discovery.

focus also manifests in the high importance it places upon data obtained through assessment, monitoring and evaluation, and used for decision-making.

Many of these aspects are shared by Gavi, most obviously in terms of the value it places upon vaccines, which are its *raison d'être*, but Gavi too puts significant weight on the value of technology and aims to increase innovations utilising digital technology within the sector. In doing so, like BMGF, it engages particularly with technical private sector providers, in which interactions STI knowledge is the primary language and commodity. However, Gavi also engages with governments and other country-specific actors in its attempts to facilitate the introduction in countries of the innovations it identifies through its private sector engagement. The greater need for contextualisation of the innovations at that point is a consistent criticism from a large proportion of Gavi country-facing staff, and degree to which the organisation places value upon that represents an ongoing area of tension. Nonetheless, this internal debate within Gavi serves to illustrate the degree of greater importance of knowledge generated primarily through *doing, using and interacting* (DUI) within Gavi than in BMGF, within the context of Gavi's overall knowledge mode being STI.

The same dynamics are emphasised in UNICEF's global procurement function. There too is a recognition of the importance of immunisation, of data and of technological innovation. UNICEF, however, much more than Gavi, separately puts a high degree of value on country context in the innovations it fosters through its country partnerships. This is fundamentally linked to its extensive network of country offices and its strong principles around beneficiary engagement.

DUI knowledge relies primarily on inductive approaches and qualitative techniques through repeated interpersonal learning between users and other actors. The resulting knowledge tends to be of the nature of *know-how* and *know-who* and is tacit and highly localised (Lundvall and Johnson, 1994; Fitjar and Rodríguez-Pose, 2013; Tsouri, Hanson and Normann, 2021). Jensen *et al.* (2007) use as the key criterion for a DUI mode the existence of a close innovator-user relationship. As we will examine later in this section, UNICEF has particular capabilities for the leverage of these recipient country-based relationships. These capabilities are based both on UNICEF staff skills and its structure. Indeed, STI and DUI modes may have very different spatial characteristics. DUI knowledge development fundamentally requires both geographical and cultural proximity, to enable the close, repeated interaction on which it is based. Moreover, actors need to share similar experiences and frames

of reference (Fitjar and Rodríguez-Pose, 2013). It is this which UNICEF's extensive network of country offices enables.

Conversely, STI knowledge development, because it relies on more formal relations and codified, standardised knowledge, is much less dependent on geographical and cultural proximity (Tracey and Clark, 2003). It also, however, requires a greater investment of time and financial costs, which causes actors to be relatively highly selective about their partners, on the basis of their capability. As a result, as particular relationships are proven to be effective these are regularly reinforced and develop a preferred use (Fitjar and Rodríguez-Pose, 2013). This is what we observe especially with BMGF, which operates essentially only the global level, investing in relationships of both technical engagement and financial support with research institutions and manufacturers. This serves to reinforce the influencing agenda which we identified of BMGF.

For the immunisation global innovation system (GIS) as a whole, then, rather than individual actors, it is the combination of STI and DUI modes of knowledge is important for innovation. This conclusion is consistent with an important body of wider empirical work, with the actual balance between these two modes varying from context to context (von Hippel, 1976; Rothwell, 1977; Rosenberg, 1982; Pavitt, 1984; Jensen *et al.*, 2007). As Nelson (2004) puts it, innovations should be:

‘understood as involving both a body of practice, manifest in the artefacts and techniques that are produced and used, and a body of understanding, which supports, surrounds and rationalises the former’

(Nelson, 2004, p. 457)

### **8.2.2 Valuation resources**

We now turn to valuation resources. Valuation enables an artefact to become valued by its users, and hence to fulfil the requirement of an innovation to be both new and impactful (Rohe, 2020). In the GIS model, there are three resource types which are important in valuing an innovation: market access, financial investment, and innovation legitimisation. This legitimisation involves activities that embed an innovation within institutional structures or environments (Binz *et al.*, 2016).

We have seen how donors aim to shape the less economically developed country (LEDC) market to make it viable for innovations in immunisation. This market-

shaping consists of a combination of *push* and *pull* interventions to improve the expected profitability of investment in innovations (Kettler, 2004; 2005). *Push* interventions reduce the costs of product development, with examples such as cost-sharing of vaccine trials and regulatory harmonisation. *Pull* interventions reduce the risk of demand uncertainty, with examples such as demand forecasts and purchase commitments. They also include recommendations for product introduction from international organisations (Kettler, 2005; Widdus, 2001). Donors also aim to credibly demonstrate to vaccine manufacturers that they can provide accurate and realistic demand forecasts based upon good quality national plans, and that LEDC governments and donors are willing to pay for the vaccines those plans specify (Batson, Meheus and Brooke, 2006).

In our empirical research, we have observed donors shaping the market in a range of different ways, as summarised in the following table. We are now able to explain these with respect to the innovation valuation resource to which they relate, in the first column.

Table 8: Standardised innovation market-shaping in immunisation (Author)

	<b>Nature of market shaping</b>	<b>Target</b>	<b>Example</b>
Market access	Advance formal commitment to purchase specified quantity, if quality	Manufacturers	Pneumococcal conjugate vaccine
	Provision of forecast or intelligence detailing unmet demand in a market	Manufacturers	Vaccines, microneedle patches, jet injectors
Technology legitimacy	Specification of target technical standards for innovations, by area	Manufacturers	All vaccines, cold chain equipment,
	Listing of innovations meeting specified technical standards	Recipient governments	Logistics management information systems
	Analysis and communication of costs and benefits of specific innovations	Recipient governments	Vaccine delivery by drone
Financial investment	Requirement for innovation in an artefact to be eligible for subsidy	Manufacturers	Vaccine vial monitors, auto-disable syringes
	Subsidy to recipient governments to purchase specific innovations	Recipient governments	All vaccines, cold chain equipment
	Requirement that proportion of subsidy is used for new providers	Recipient governments	Cold chain equipment

The table shows how donors use the market access they have through their provision of vaccines to 300 million children each year to make either calculated formal commitments, or well-founded forecasts, to manufacturers of demand for further innovative vaccines or other artefacts. Each of these is a form of *pull* intervention designed to change manufacturers' cost-benefit analysis.

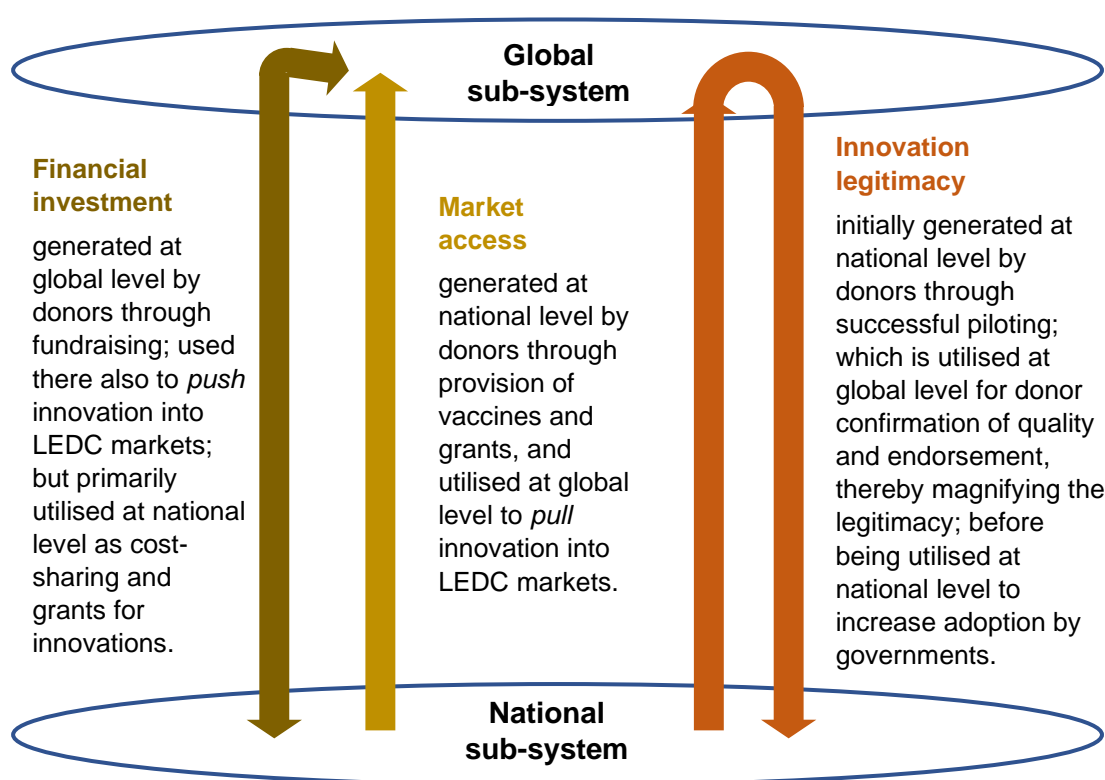
In parallel, donors confer innovation legitimacy upon the innovations in a bi-directional manner. With respect to manufacturers, donors may specify global standards which increase the likelihood that innovations are accepted by the intended beneficiaries and are viable within those contexts. This is based upon donors' engagement in the LEDCs which are the intended market for these innovations. With respect to the intended beneficiaries, donors are able to confirm that innovations meet these minimum global standards, thus increasing their acceptance by the intended beneficiaries. If standards have not been set, then donors are able at least to provide a less rigorous but more comprehensive listing of the costs and benefits of the innovations within a certain area.

Finally, donors also use their financial investment to require manufactures or incentivise recipient governments to increase the take up of innovations. Manufacturers may be required to incorporate an innovation within an artefact in order for donors to subsidise that artefact for the benefit of recipient governments. The provision of this subsidy to those recipients acts to reduce the cost of an innovation which can be greater than for non-innovative equivalent artefacts. At the same time, donors may require that the recipient governments use the subsidy partly for the innovations of non-dominant manufacturers, which serves to increase the number of competitive providers in the market.

These valuation resources are generated and utilised by donors through their interactions across the global and national sub-systems, as shown in the following figure:



Figure 25: Inter sub-system dynamics of innovation valuation resources (Author)



Source: Author

The valuation resources generated and utilised by donors are also interrelated, with donors' market access resulting from their financial investments in recipient countries, and being used to catalyse or incentivise manufacturers to innovate for that market, to certain standards. Donors then legitimise the resulting innovations as meeting those standards, and use their financial investments to incentivise recipient governments both to adopt the innovations, and to do so in a way which strengthens the sustainability of the manufacturer base. This dynamic has been observed in other studies, in which 'positive returns from one resource type can be transferred to generate positive returns from another' (Bathelt and Glückler, 2005; Rohe, 2020).

Importantly, the means of generating and utilising innovation valuation resources shown in the above figure are standardised. They are therefore essentially only applicable to innovations which have reached the required level of maturity at each stage. Valuation is standardised for relatively homogenous artefacts within an effective market of relatively uniform user preferences and coherent across institutional contexts (Huenteler *et al.*, 2016; Binz *et al.*, 2017; Rohe, 2020). In contrast, donors will not be able to reliably assess the likely demand for innovations which have not yet been piloted and assessed in a LEDC setting, or may not even

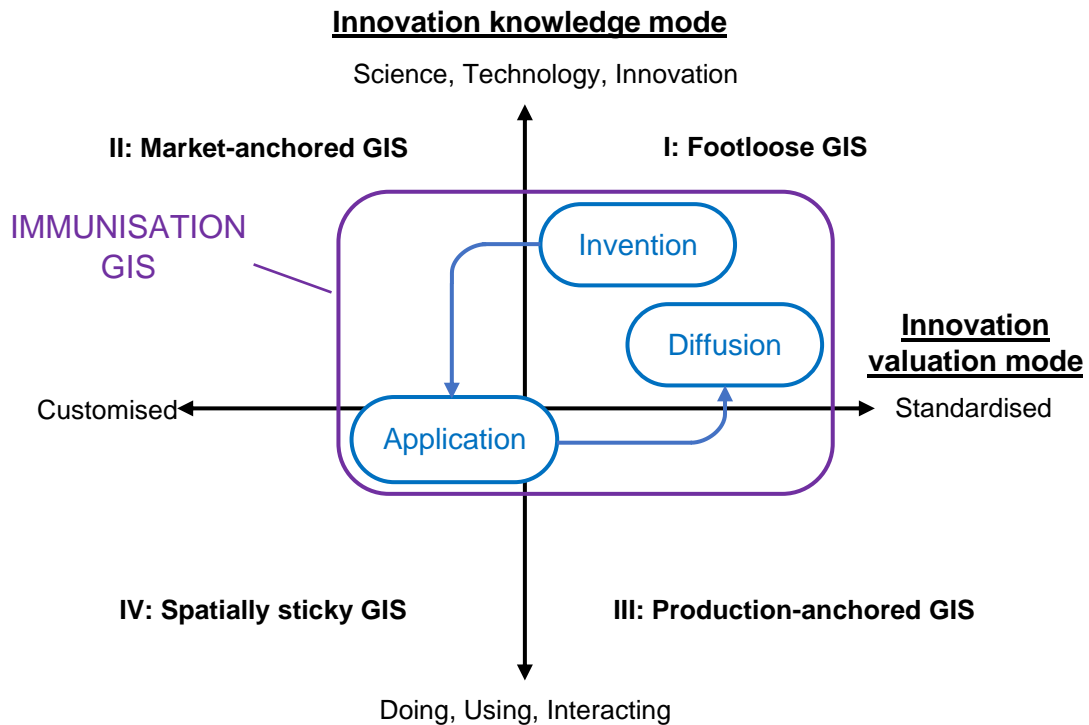
yet have a clear use-case. Consequently, donors are not able to catalyse or incentivise manufacturers to produce at scale, given the risks of doing so will be too great. If the use-case and potential support are still not well understood, donors are not able to define the standards to require of manufacturers, and upon which to legitimise innovations. Without that, few recipient countries are willing to invest, even with a subsidy, into purchasing those innovations. Innovation legitimacy, rather than being conferred through the meeting of international standards, is dependent upon demonstrable success of an innovation in a pilot project, which necessitates customised engagement by donors in those pilots in which they embark. The financial investment in such pilots is also significantly greater per unit-cost, because economies of scale are not obtainable.

Consequently, donors are not able to utilise standardised valuation resources to foster early-stage innovations. Instead, they must customise those resources through significantly higher levels of financial and human resource inputs. Valuation is customised for often-complex products needing to be tailored to specific customer demands or institutional contexts (Huenteler *et al.*, 2016; Binz *et al.*, 2017; Rohe, 2020). We examine these dynamics in the following section.

### **8.2.3 Resources by innovation stage**

The insights above allow us to advance an explanation for this observed relationship between knowledge mode and valuation resources in immunisation. We propose that the balance between innovation knowledge modes, and between the customisation or standardisation of valuation resources varies depending on the maturity of the innovation. To illustrate that, we use Schumpeter's conception of the stages of invention, application or diffusion (Schumpeter, 1947), as shown in the following figure:

Figure 26: Innovation modes within immunisation by innovation stage (Author)



Source: Author

The standardised use of valuation resources we examined in the preceding section we identified as relating to the scale-up of proven innovations, i.e., their diffusion, in Schumpeter's terms. This accordingly sits at the far righthand side of the innovation valuation mode axis. This stage also sits solidly within the innovation mode based on knowledge generated primarily from *science, technology and innovation* (STI), as this stage of innovation requires knowledge which is largely explicit and communicable over a distance. Against the global innovation system (GIS) types proposed by Binz and Truffer (2017), this stage reflects the characteristics of a *footloose* GIS: scientific and international, with a reliance on global standards and financing, and coherent user preferences in mass-markets. Such a GIS tends to be internationally dispersed, perhaps with centres of excellence managing particular elements of knowledge or other innovation valuation resources, but with national governments not playing a major role (Binz and Truffer, 2020).

Working backwards, the stage of application aligns to the customised use of valuation resources identified secondly in the preceding section. The application phase, in which innovations are piloted in the contexts in which their impact is intended, plays an important role in innovation development. It involves leveraging knowledge generated primarily through *doing, using and interacting* (DUI) to refine

the innovations further. If this demonstrates impact, it contributes to significantly increasing the prospect of market adoption, thus reducing the risks to the private sector around diffusion of the innovation (Frishammar *et al.*, 2015; Hellsmark *et al.*, 2016; Tsouri, Hanson and Normann, 2021). In this stage, innovation valuation resources are dependent upon embedding in specific local contexts, which operate as lead markets. Successful demonstration in those contexts may then be built-upon for subsequent diffusion (Beise and Rennings, 2005). This requires a high level of tailored resources in order to achieve impact. That necessitates actors developing targeted deployment policies (Edquist and Zabala-Iturriagagoitia, 2012) and engaging directly and in depth with users to establish new user-patterns and create reputational capital (Porter, 1990; Dewald and Truffer, 2011). Consequently, whilst an innovation in immunisation tends to be based upon STI knowledge, at this stage, DUI knowledge is most relevant, as the innovation is adapted to the intended use-case and context. It is only after this stage that the learning from that adaptation can be made explicit and utilised for diffusion. The application stage, sitting very near the centre of Binz and Truffer's axes, reflects a mixture of characteristics, rather than fitting neatly into one of their GIS types.

The initial stage, of invention, is the most highly STI focused, it is this which links particularly to basic research and development. Its placement on the valuation resources axis, however, bears no relation to that of the stage of diffusion, despite sitting in the same quadrant. The typical donor role in this case is that of BMGF in catalysing upstream innovation by the global private sector, through for example, its Strategic Investment Fund (SIF). The SIF uses standardised valuation resources: its financial investment is transacted through a standardised process and format. Through it, BMGF acts like a venture capitalist, in investing hundreds of millions of dollars in innovations which, although having potential for impact, the private sector would not otherwise take the risk to progress (Batson, 2005). A similar approach for AIDS vaccine candidates was observed by IAVI (Chataway *et al.*, 2007). In this stage, market access is not specific to a country, but provides a generalised impetus for invention based on the global market access of donors. In terms of innovation legitimacy, this stage necessarily uses generalisations about the set of intended beneficiary countries in order to be sufficiently abstract not to stymie conceptualisation in particularities. Let us, perhaps, refer to standardisation here rather as conceptualisation.

This idea of a differentiated distribution of knowledge and innovation valuation resources within a GIS represents an extension of the GIS model proposed by Binz and Truffer (2017). Another contemporaneous study has made similar empirical conclusions. Sebastian Rohe, (2020) examined the onshore wind energy GIS and found different resource distributions between the technological development phase of wind turbines and the phase in which this innovation is diffused. He found that the technological development phase aligns to Binz and Truffer's *production-anchored* GIS type, with a knowledge mode which is primarily DUI and valuation resources which are primarily standardised. In the diffusion phase, however, he found that valuation resources were primarily customised, with service firms creating market access and legitimacy in spatially sticky approaches, and with a knowledge mode which combined DUI and STI.

Whilst Rohe's study and ours both found that resource distributions differed between phases, the two studies did not find the same distribution for comparable phases. In immunisation for international development, diffusion is marked by standardised valuation resources and STI knowledge, whereas in onshore wind energy, diffusion uses customised valuation resources, and a mixture of DUI and STI knowledge.

Rohe hypothesises that the different resource distributions in his study are explained by the fact that onshore wind energy requires a diffusion phase which consists of complex installation and use of technology. He suggests that this represents a second occasion, after initial invention or development, when significant distinct resources are drawn upon. He distinguishes this from photovoltaic energy, for which installation and use is very simple, as a result of which the mode of a photovoltaic energy GIS is determined overwhelmingly by the single production phase.

Rohe's reasoning is similar to our own. The (in our case) three innovation phases are significantly different in focus of activities and actors, and spatial locations, from each other, with each necessitating substantive investments of knowledge and valuation resources. Consequently, it is not accurate to describe the whole GIS with reference to one single phase.

The level and distribution of resources we have examined here determine actors' different roles and capabilities in system-building (Musiolik *et al.*, 2020). We examine this in the following section.

### 8.3 System building by donors

The section builds upon the preceding section, to relate donor generation and utilisation of valuation resources to their provision of structural linkages between sub-systems. It also introduces the idea that it is the existence of different actor capabilities which necessitates such networks. To examine this further, the section relates donor generation and utilisation of valuation resources to the concept of system building, and highlights that this requires concentrated agency. It relates this to organisational capabilities and hence to organisation type.

#### 8.3.1 Structural linkage of sub-systems

Our empirical data shows the existence of two distinct important spatial levels: the national and the global. The global level is a fundamentally important locus for innovation within immunisation because it is here that donors primarily generate knowledge from *science, technology and innovation* (STI). This creates innovation resources of particular financial investment and innovation legitimacy, and draws in new actors. At the national level, each country represents a sub-system, largely independent of each other, but individually related to the global level. The primary function of the national level involves the generation of knowledge primarily through *doing, using and interacting* (DUI), via the application of innovations, and of the valuation resource of market access.

The importance of interaction between these two sub-systems is well summarised by Gardner, Acharya and Yach (2007) when they write that, to maximise the potential of innovation, for global health:

donors need to link two disparate schools of thought: 1) a search for technological solutions exemplified by global public-private product development partnerships and 2) a focus on systemic solutions exemplified by health policy and systems research.

(Gardner, Acharya and Yach, 2007, p. 1052)

Whilst Gardner, Acharya and Yach (2007) specify the importance of donors creating these linkages, Binz and Truffer highlight why that it, on the basis of those characteristics which are important in building linkages within the GIS:

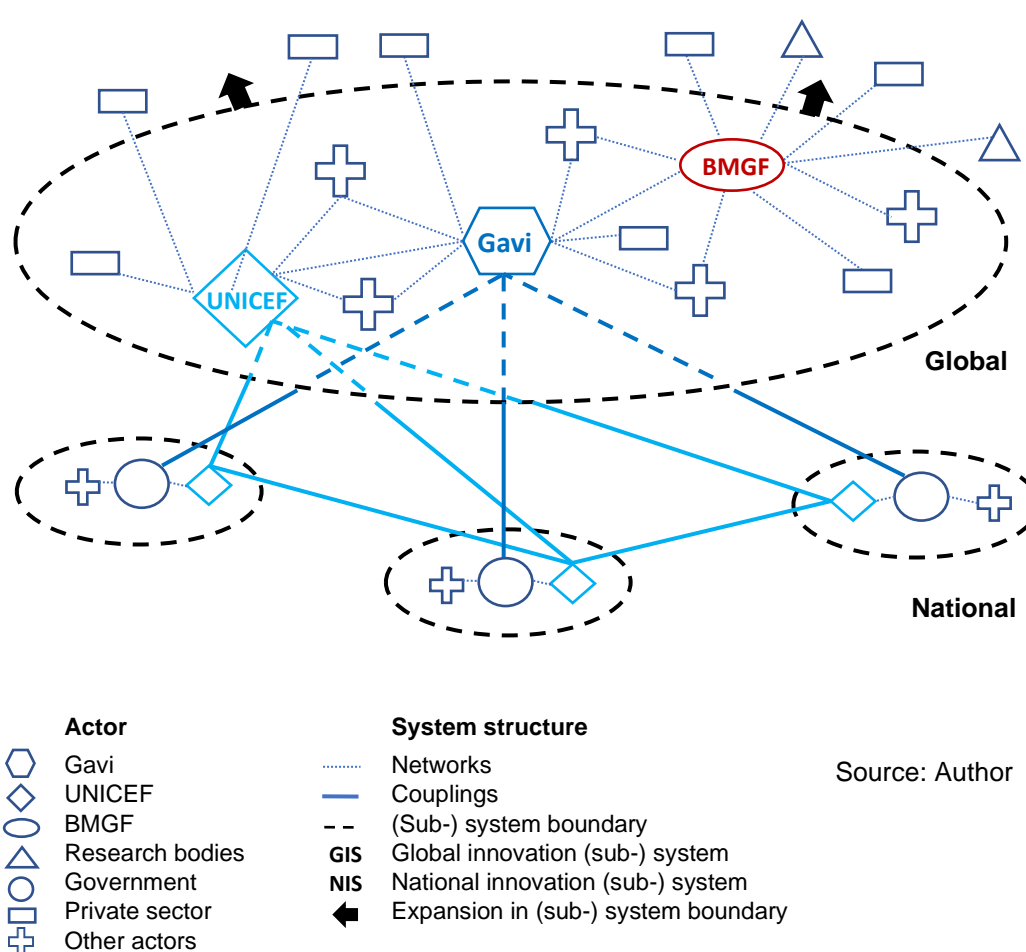
Resourceful actors with a global reach (such as transnational companies, global donor organizations or professional associations) are in a superior position to facilitate effective integration of spatially spread sub-systems.

(Binz and Truffer, 2020)

In the global innovation system (GIS), these linkages are represented as structural couplings between sub-system. This is illustrated in the following figure:

Figure 27: Actors and networks in immunisation for international development

(Author)



The figure shows these structural couplings provided by UNICEF and Gavi between the national sub-systems and the global sub-system. These donors' structural couplings, however, are distinct from each other in various respects. Gavi's primary interlocutor at the national level is the recipient government. This is implemented through the Gavi senior country managers who lead Gavi's country-facing function. We observed in the empirical chapters these senior country managers' direct

working with recipient governments to facilitate the taking-up of the opportunities offered to them by Gavi to scale up innovation via, for example, the Cold Chain Equipment Optimisation Platform. We also saw the senior country managers influencing governments to pilot early-stage innovations identified through Gavi's global level partnerships with the private sector and pushed downwards. Other actors such as pharmaceutical associations are represented on Gavi's Board. They play, however, only a limited intermediary role in the system, not, for example, being involved in UNICEF's contracting, which is bilaterally with individual vaccine manufacturers.

The emphasis is different in the structural coupling role of UNICEF. In this case, the counterpart to UNICEF's global headquarters at the national level is the UNICEF country office. That this is based in-country provides it with particular advantages over the Gavi senior country managers with respect to various roles. The primary such role is that of understanding the country context in which innovations need to function, and then communicating these to the global level. There they are aggregated and analysed for dissemination to global actors. UNICEF also provides couplings between national sub-systems. This represents a mechanism by which UNICEF is able to facilitate lesson-learning and best-practice exchange between national sub-systems. In practice, however, this represents a less important coupling for innovation than that between national and global levels, because it is between these levels that valuation resources are generated and utilised. The same is not the case for the national to national couplings.

We have seen how both Gavi and UNICEF provide linkages between the national and global sub-systems. There are two aspects of complementarity to this. Firstly, Gavi's linkage is directly with the recipient government, whereas UNICEF's linkage is conducted through the medium of its country office. This allows for a triangulation at global level by the two organisations, comparing the feedback received through the two routes but pertaining to the same context. UNICEF's feedback is potentially more nuanced, in the way in which its country staff are themselves able to develop deep relations and understanding at country level, and to formulate their feedback based on these, and on specific conversations with other actors at the national level. In contrast, Gavi's feedback, from government, is less rich, and risks being more influenced by the donor-government power dynamic which may affect the government's willingness to be candid. This linkage, however, does benefit from the fact that the same interlocutor, the Gavi senior country manager, is involved in both



the global and the national sub-system, so is able to make the linkages directly themselves (Interviewee 42, p. 4).

The Bill and Melinda Gates Foundation (BMGF), in contrast, positions itself earlier in the innovation development phasing, by virtue of its perceived comparative advantage especially on risk. BMGF's greater risk appetite allows them to invest in projects which have a higher degree of financial risk, whether because they are less-proven, or because the timelines until expected impact are longer. Both of these aspects are particularly important to innovation, involving as it does solutions which are exploratory, for which developing proof of impact takes time. Bill Gates describes BMGF's investments as 'high-risk and high-reward' (BMGF, 2009, p.14), and also acknowledges that this is an advantage relative to other actors: 'Melinda and I see our foundation's key role as investing in innovations that would not otherwise be funded' (BMGF, 2010, p.3). BMGF staff make the comparison specifically with Gavi, saying that 'our value-add or comparative advantage is on those riskier or longer-term bets... I mean, Gavi potentially can't sink US\$ 50m into something and have a potentially 50% chance of failure even though failure is important, and those risks are necessary' (Interviewee 8, p. 2). Conversely, BMGF is able to focus on these earlier stage innovations because it need not be involved at the later stages in which Gavi is in the lead (Gavi, 2015b, p. 53).

Malerba (2014) suggests that levels of knowledge vary significantly from one firm to another and that knowledge 'does not diffuse automatically and freely among firms' (Foray, 2004). Acquiring this knowledge, and then integrating it requires capabilities which also vary between actors, and Malerba suggests that it is because of this differential capability that networks emerge. We examine this further in the following section.

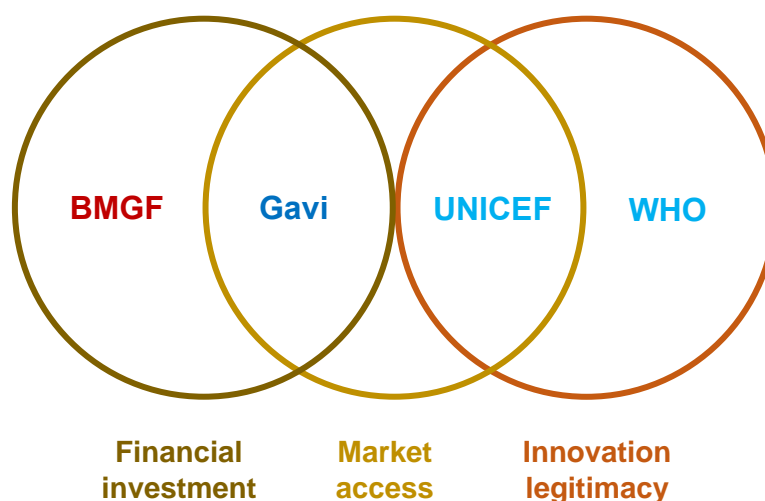
### **8.3.2 Concentrated agency and comparative advantage**

Earlier in this chapter we identified the valuation resources provided collectively by donors for innovation invention, application or diffusion. This collective behaviour is a form of *distributed agency*, in which the activities of different actors, often with different motivations and interests, combine to create a shared desired outcome.

Lam (2005) suggests that 'organisations with different structural forms vary in their patterns of learning and knowledge creation, engendering different types of innovative capabilities'. Teece (1998), similarly, suggests that different

organisational types are more suited to different contexts and types of innovation. It is possible to specify the differential generation and utilisation of each type of innovation valuation resources by individual donors, as shown in the figure below:

Figure 28: Distributed agency of innovation valuation resource provision (Author)



Source: Author

We identified that the Bill and Melinda Gates Foundation (BMGF) generates and utilises for innovation in immunisation essentially only financial investment for innovation valuation. Gavi provides both financial investment and market access, and UNICEF provides both market access and innovation legitimacy. Although not a case studied in this research, sufficient empirical data has emerged to indicate also the contribution of WHO, which is essentially only innovation legitimacy, and we have included that in the figure. The complementarity between individual donors' contribution of these resources can be seen from their separate placement across the valuation resources. The generation and utilisation of these innovation valuation resources serves to steer the evolution of interconnected elements within the innovation system, such as the *push* catalysis or *pull* incentivisation that we have observed in donors' market-shaping. This definition is that of *system building* (Musiolik *et al.*, 2020, p. 2).

System builders typically work to reduce ambiguity, establish common ground for collaboration, and create new organisational or institutional solutions to overcome challenges or constraints (Musiolik *et al.*, 2020). This description of system building aligns with the roles of donors we observed, in for example, the Vaccine Investment Strategy process which assesses the potential global impact of new vaccines

against previously non-vaccine preventable diseases; and of improvements to the fundamental effectiveness of existing vaccines (e.g., protecting against additional strains of a disease).

To be able to system build effectively, an actor must have *concentrated agency*, which necessitate them being technically, financially and/or politically powerful (Jacobsson and Johnson, 2000, p. 630). This is relatable to the valuation resources of innovation legitimacy (which can be understood as technical), financial investment (obviously, financial), and market access (which certainly has political elements). Moreover, it emphasises the importance of the role of the individual actors, alongside the distributed agency which is central to the innovation systems approach (Garud and Karnøe, 2003; 2005).

Different organisational characteristics of actors influence the mode of their system building. Hughes (1987) and Hellsmark and Jacobsson (2009) identify an *individual system builder* as being of any organisational type of an entrepreneur, aiming to influence the broader system around them. Jacobsson and Bergek (2004) and Maguire *et al.* (2004) describe an *organisational system builder*, which represents the form of a more established organisation which deploys its resources in a manner to create or change system structures. Musioik *et al.* (2011, 2012) and Sarasvathy and Dew (2005) identify the *system building network* or organised community of actors which co-creates system structures and is often itself forged by an individual system builder.

BMGF is typically an individual system builder, with Bill and Melinda Gates' eponymous foundation, as we have seen, closely linked to especially Bill Gates' vision, principles and approach. UNICEF aligns well to the model of an organisational system builder, using its own structure and resources, especially its country office network and 'glocal' capabilities, to build the system. Gavi is an example of a system building community of actors, or alliance. It also aligns with the pattern of other communities of actors in having been created by an individual system builder, BMGF.

These donors' different roles relate to the capabilities conferred on them by their organisational characteristics, including their formal structures, cultures and values, and external relations (Teece, 1998). Against the typology proposed by Mintzberg (1979) we have seen how UNICEF, with its extensive network of country offices delivering development assistance on a global scale to meet local challenges,

organised into regional divisions with significant autonomy, closely matches the archetype of a *divisionalised form* of organisation. Gavi, with its various, largely-discrete innovation initiatives which deploy Gavi's levers in different combinations and degrees; also, the convening of different actors within the alliance in various different configurations within these initiatives; and the nimbleness which Gavi has needed to deploy in order to try to reconcile the duality of its aim to mobilise from the private sector both financial investment and innovation expertise. In all these respects, Gavi closely matches the archetype of an *adhocracy* form of organisation. We have observed the existence in BMGF of centralisation of the foundation around Bill Gates, its entrepreneurial approach, and its high-risk appetite. In each of these respects, BMGF closely matches the archetype of a *simple structure* form of organisation.

System building may be emergent (Garud and Karnøe, 2003), or it may result intentionally and strategically (Musiolik and Markard, 2011). We saw empirical evidence of such a strategy in cases such as the Vaccine Innovation Prioritisation Strategy and the Cold Chain Equipment Optimisation Platform. Both of these mechanisms are highly collaborative, coordinated in both cases by Gavi and incorporating BMGF, UNICEF and WHO in both the steering and working groups, as well as several other actors at the global level, each with a specific area of expertise on which they focus (Interviewee 13, p. 3). Moreover, both mechanisms also periodically engage actors at the country level through the use of surveys which are sent to a wide range of country actors, as well as through the inclusion of selected representatives on the mechanisms' steering committees (Gavi, 2022c).

It is also apparent from the evidence of government EPI Managers and in-country donor officials that donors coordinate bilaterally on innovations in-country (Interviewee 33, p. 8; Interviewee 5, p. 8). Illustrating this, several innovations piloted in-country by BMGF are subsequently funded at national scale through Gavi funding. A good example of this is an electronic vaccine logistics management information system, eVIN. As described by a Gavi senior country manager, 'eVIN was started by a Gates grant. That was really the catalytic grant in I think two

districts in [country] before we stepped in and then the government asked us for HSS<sup>33</sup> money to scale up... to the rest of the country' (Interviewee 6, p. 3).

Wider coordination amongst donors on innovation in-country is often based around the country health or immunisation plan, at which 'everybody comes onboard and says "I'm supporting the country. Maybe my resources can do this". And if they need resources from Gavi too, they say' (Interviewee 38, p. 5). In this coordination, donors recognise that they have different comparative advantages with respect to roles they play in innovation in countries. BMGF is seen as 'having 'the funds available to really inject in certain initiatives and allow for testing' (Interviewee 3, p. 10). UNICEF is seen as sitting in the middle between these: 'in terms of bringing ideas, voluntarily, I think PATH and UNICEF are that kind. Gavi comes in more when you have an idea, then you say 'can this work? How can you support this?' (Interviewee 33, p. 5).

Similarly, the donors also demonstrate complementarity in the way in which they engage at the global level with the broader private sector. They describe broadly two mechanisms for this. The first is a competitive process by which relatively early-stage innovations can be identified, these aren't limited to the private sector, but in practice, it is the source of the majority of such innovations. BMGF's Grand Challenges is focused on those innovations which are often just at the ideas stage. UNICEF's Venture Fund is positioned further along the development pathway, looking to source innovations which are ready for prototyping and piloting. Gavi's INFUSE purports to seek innovations which have been proven as a pilot and are ready for scale-up (though, various informants question whether the INFUSE Pacesetters always are proven). In this way, the donors have ensured some complementarity. They also cooperate, with, for example, BMGF and UNICEF both sitting on the selection panel for INFUSE; and sometimes highlighting innovations that have successfully passed through an earlier-stage competition and could be considered for support by another agency through the next stage.

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<sup>33</sup> Health System Strengthening

UNICEF and Gavi also engage in dialogue with established firms in order to develop 'shared-value partnerships' which aim to catalyse the expansion of those corporations into the new markets in which the donors work. For both agencies, these partnerships fulfil a secondary (or, as some informants suggest, a primary) purpose in raising resources for the donors. Particularly with respect to private sector partnerships with established corporations, the drive for cooperation or complementarity is mixed by a competition for the resources, expertise and kudos which the private sector can bring; and for the media profile which success in this reaps. The donors are essentially competing for the attention and resources of these corporations. This limits the donors' willingness to coordinate in the development of these private sector partnership, and means they miss the opportunity to integrate those partners within the innovation system. This mixed nature of interactions between the donors reflects the concept of co-opetition. Conveying the sense of a mixture between cooperation and competition, the portmanteau term was coined by Gnyawali and Park (2011) to describe collaboration with competitors for technological innovation. Inverted, as competition between collaborators, the term also applies to the relationship between UNICEF and Gavi in this case.

#### **8.4 Conclusion**

This chapter has discussed the significant evidence for an emerging global innovation system (GIS) in immunisation for international development. Firstly, we have identified the existence of common rules, norms and presumptions, with one set of these discernible at the national level, and another at the global level. Moreover, we have suggested a close relationship between national and global rules and norms, and argued that this suggests the two spatial levels are connected within a single system which is coherent and consistent. It is also bounded: the rules serve to provide a hard boundary, excluding those actors or innovations who do not align; and the norms serve to provide a soft boundary, facilitating the participation of those donors who align with them, and hampering those who do not. In examining rules, norms and presumptions, we also identified trends we later see reflected in other aspects of the GIS. One of these is the heterogeneity of donors, who we observed to engage differently with these rules, norms and presumptions, varying between compliance, co-optation and contestation. We also identified the existence of tensions within donors around a *techno-fix* perspective on the balance between knowledge based generated primarily from *science, technology and innovation* (STI) and knowledge generated primarily through *doing, using and interacting* (DUI).

Secondly, we have explained how innovation valuation resources are generated and utilised through the interplay of donors' activities across the two spatial levels. Financial investment is generated at global level by donors through fundraising; used there also to *push* innovation into less economically developed country (LEDC) markets; but primarily utilised at national level as cost-sharing and grants for innovations. Market access is generated at national level by donors through provision of vaccines and grants, and utilised at global level to *pull* innovation into LEDC markets. Innovation legitimacy is initially generated at national level by donors through successful piloting; which is utilised at global level for donor confirmation of quality and endorsement, thereby magnifying the legitimacy; before being utilised at national level to increase adoption by governments.

Thirdly, we have advanced an explanation for the observed distribution across donors of these knowledge modes and innovation valuation resources, accommodating some individual heterogeneity again observed. We proposed that the balance between STI and DUI modes of innovation, and the degree of customisation or standardisation of valuation resources varies depending on whether the innovations are the stage of invention, application or diffusion. We suggested that invention within immunisation is particularly highly STI focused, and donors use valuation resources in a standardised way in order to foster this stage, in order that it be sufficiently abstract not to stymie conceptualisation in particularities. The balance is quite different in the application of these inventions, which requires a high level of customisation of valuation resources in order to achieve and prove impact. Consequently, at this stage, DUI knowledge becomes most relevant, as the innovation is adapted to the intended use-case and context. Finally, in diffusion of innovations, STI is again the predominant knowledge mode, as this stage of innovation requires knowledge which is largely explicit and communicable over a distance; and the use of valuation resources are standardised, in order to allow introduction of these innovations at scale across multiple markets. This represents an evolution of the GIS model proposed by Binz and Truffer, who envisaged a consistency of distribution of knowledge and innovation valuation resources within a GIS.

Fourthly, we have demonstrated a coherent model of a GIS which incorporates the observed donor interactions with other actors, and explains their generation and utilisation of valuation resources in terms of structural linkages between sub-systems. The global level is shown as a fundamentally important locus for

innovation within immunisation because it is here that donors primarily create new STI knowledge, creating innovation resources of in particular financial investment and innovation legitimacy, and draw-in new actors. At the national level, each country represents a sub-system, largely independent of each other, but individually related to the global level. The primary function of the national level involves the creation of new DUI knowledge via the application of innovations, and of valuation resources of in particular market access.

Fifthly, we have reconciled the distributed agency which is fundamental to the innovation system approach to the concentrated agency which is important in explaining differences in actor capabilities which underly the need for networks. This reconciliation is through use of the system-building concept. In so doing, we have identified heterogeneity in the organisational types of donors, alongside evidence that this heterogeneity is important for the strength of the overall GIS. We have illustrated examples of coordination between donors which suggests a degree of strategic planning behind this concentrated agency and individual comparative advantage, whilst also highlighting some tensions between individual donors.



## **9 CONCLUSION**

There has been very limited understanding of how, with respect to innovation, donors engage with institutions; of how they interact with other actors; and how donors' organisational characteristics affect their relevant capacities. By examining those aspects, this research aimed to contribute significant new knowledge about the roles donors play with respect to innovation. It has done so by looking specifically at what role donors play with respect to innovation in immunisation for international development.

We argue that, rather than a single role, donors perform several roles within an emerging global innovation system (GIS) in immunisation for international development. The GIS consists of a global sub-system and a set of sub-systems at the national level, each representing a less economically developed country (LEDC) receiving development assistance in immunisation.

We identify four principal roles which donors play within this GIS. Firstly, they provide, maintain and extend structural elements of the GIS, especially its networks and linkages between sub-systems. Secondly, donors generate and utilise resources of financial investment, market access and innovation legitimacy for the valuation of innovation. Thirdly, donors coordinate to ensure complementarity in the activities they and other actors provide, which enables effective distributed agency across the GIS. Fourthly, donors navigate the rules, norms and presumptions of the GIS on behalf of partnerships of actors, variously complying, co-opting or contesting them.

Moreover, we observe each donor fulfilling each of these four principal roles, but in heterogeneous ways. Different donors, for example, focus on the maintenance of different structural elements of the GIS; or generate and utilise different combinations of innovation valuation resources within the GIS. It is the organisational characteristics of each donor which equip it with different capabilities for innovation, and which influence its response to the relevant rules, norms and presumptions.

The identified principal donor roles, and their heterogeneous application by donors, represent a much richer understanding of the role of donors in innovation in international development than that provided by earlier authors. It contrasts in particular to the role of the public sector characterised in the linear model of

innovation, in which this was essentially limited to the funding of upstream basic research.

## 9.1 Four principal donor roles

Our research has enabled us to identify four principal roles which donors play within the emerging global innovation system (GIS). Firstly, they play a structural role. That involves providing, maintaining and extending elements of the structure of the GIS. This is especially the structural linkages between sub-systems, but also networks within sub-systems, and boundaries around them. This arises because donors are 'resourceful actors with a global reach... in a superior position to facilitate effective integration of spatially spread sub-systems' (Binz and Truffer, 2020). That is, donors are influential actors within both global and national subsystems and are able to use their leverage in each to form connections across them for innovation. When sufficiently influential in a single sub-system, donors are also able to build or reinforce linkages within that level. Further, some donors are in a position to make effective new linkages to actors outside the GIS and hence to expand its boundary.

Secondly, donors play a role in resource provision for innovation. That involves generating and utilising innovation valuation resources. The ability to perform that role is directly linked to the structural linkages which donors provide. These enable donors to transfer resources from one sub-system to another, and in so-doing, to produce a new input for innovation. Financial investment is generated at global level by donors through fundraising, and to a minor degree is used there to *push* innovation into less economically developed country (LEDC) markets. Primarily, though, donors utilise it at national level as cost-sharing and grants to incentivise the adoption of innovations. Market access is generated at national level by donors through provision of vaccines and grants, and then utilised at global level to *pull* innovation into LEDC markets. Innovation legitimacy is initially generated at national level by donors through successful piloting of innovations. It is then utilised at global level for donor confirmation of quality and endorsement, thereby magnifying the legitimacy, before being utilised at national level to increase adoption by governments.

Thirdly, donors play a coordinating role. That involves intentional discussion with other donors with the aim of ensuring complementarity in the structural linkages they provide, and the valuation resources they generate and utilise. This enables effective distributed agency across the GIS. The coordination occurs at both spatial

levels within the GIS, but is primarily strategic at the global level, and more tactical at the national level. This is often manifest in multi-donor innovation initiatives, to which various donors bring widely-recognised different comparative advantages. It also manifests in bilateral relations between donors, in which donors will ensure a hand-off of an innovation from one to another, as its maturity takes it into a new phase of development more suited to another donor's comparative advantage. This role is primarily with respect to other donors, but also involves taking account of other actors who are able also to provide linkages or resources, such as multinational companies. Decisions over activities in relation to other actors involves consideration of individual comparative advantages, which can be a source of tension.

Fourthly, donors play an institutional role. That involves navigating the rules, norms and presumptions of the GIS, to ensure that the donor's activities, and those of their partnerships, are consistent with them. As overwhelmingly publicly-funded and accountable organisations, donors are particularly sensitive to existing rules, norms and presumptions. They are thus better positioned than other actors in the GIS to engage with those, and to ensure the successful navigation of them. This is particularly the case with respect to the product development partnerships (PDPs) between vaccine manufacturers and donors which are a significant element within the GIS. Donors' philanthropic mission provides them with authority over other actors in this navigation.

These, then, represent the roles which donors play with respect to innovation in immunisation for international development. The fulfilling of these principal roles enables the ongoing dynamic process of collective learning and knowledge-development across diverse actors which is directly related to the ability of an innovation system to overcome the challenges of fundamental complexity and dynamicism to innovate (Lundvall, 2007).

## **9.2 Donor role heterogeneity**

Within the set of four principal roles performed by each donor in the global innovation system (GIS), our empirical evidence is of each donor fulfilling these in heterogeneous ways. These derive from the distinct organisational characteristics of each donor which equip it with different capabilities for innovation, and which influence its response to the relevant rules, norms and presumptions.

UNICEF's structural role is particularly in the provision of couplings between the national sub-systems and the global sub-system through its extensive network of offices. This provides it with particular advantages in understanding the country context in which innovations in immunisation need to function, and then communicating these to the global level to be aggregated and analysed for use by global actors. With respect to its role in innovation valuation resourcing, UNICEF generates and utilises market access by providing authoritative information to potential inventors, globally, about likely demand in less economically developed country (LEDC) markets, and by informing LEDC governments and other national level actors about the resulting innovations. UNICEF also provides value through innovation legitimisation, at the global level on the basis of pilots it has carried out in countries, and at the national level, on the basis of its organisational endorsement of innovations once proven. UNICEF's reputation, authority and convening power in impact, innovation and immunisation are important organisational characteristics enabling these innovation valuations. UNICEF's coordination role is primarily at national level, where its influential relationship with LEDC governments enables it to advise them on the selection of innovations likely to add value in that context. It can also be seen at the global level, in the way in which UNICEF coordinates global procurement exercises for innovation in order to shape the market for innovation in immunisation. Finally, UNICEF's institutional navigational role relates particularly to the norms and presumptions affecting national level, such as the presumption that intended beneficiaries should be included in innovation planning, design and implementation. UNICEF provides guidance to private sector partners at global level about how to engage with these. This, though, can cause internal contestation within UNICEF when global and national presumptions are in tension.

The Bill and Melinda Gates Foundation (BMGF)'s structural role is essentially only at the global level, in expanding the boundaries of the global sub-system and hence of the GIS itself. BMGF does this by actively bringing-in new actors to the GIS, utilising its particularly high risk-appetite, and its shared culture and approaches with the private sector. This also represents one of the directions in which BMGF plays its coordination role, through the convening power provided by its Strategic Investment Fund and Grand Challenge mechanisms. More significantly, BMGF also leverages its bilateral investment in other public health actors such as Gavi and WHO to influence their agendas and to play a coordination role behind the scenes of the innovation initiatives established by these actors. With respect to its role in innovation valuation resourcing, BMGF generates and utilises financial investment

for innovation. This includes direct financing from the Gates' fortune, as well as the fortunes of others attracted by the Gates' charismatic authority, and these are complemented by indirect financing BMGF brings by achieving efficiencies through innovation, and by increasing public support for development assistance. Finally, BMGF's institutional navigational role involves advocating for particular norms within the GIS. Those norms are those which align closely with BMGF's own approach, such as donor coordination and aid effectiveness.

Gavi's structural role is, like UNICEF, in the provision of couplings between the national sub-systems and the global sub-system. But in Gavi's case, its primary interlocutor at the national level is the recipient government. This brings greater risk of being negatively influenced by the donor-government power dynamic which can affect a government's willingness to be candid. This linkage, however, does benefit from the fact that the same interlocutor, the Gavi senior country manager, is involved in both the global and the national sub-system, so is able to make the linkages directly themselves. With respect to its role in innovation valuation resourcing, Gavi provides both financial investment and market access. These are linked, with Gavi's global market access giving it the weight of influence over manufacturers. This enables Gavi to make innovation a condition of its purchase of their products, or simply to catalyse innovation by providing manufacturers with market-intelligence indicating a viable market opportunity. It is financial investment which Gavi provides at the national level which enables Gavi to incentivise recipient countries to introduce innovations into their programmes. Gavi's coordination role is solely at the global level, in which it convenes and drives global multi-actor innovation initiatives such as the Vaccine Investment Strategy, Vaccine Innovation Prioritisation Strategy and Cold Chain Equipment Optimisation Platform. Finally, Gavi's institutional navigational role is overwhelmingly one of co-optation, on behalf of the Gavi-coordinated alliance of actors or of its specific innovation initiatives. This serves to mitigate the potentially constraining impact of relevant norms and presumptions upon those initiatives.

In fulfilling these four principal roles in heterogeneous ways the donors are being complementary to each other. In an increasingly globalised and technologically sophisticated society, increasing amounts of information are produced. Managing this, understanding it, organising it and using it becomes increasingly difficult and increasingly important. This requires collective skills, system-wide, rather than being manifested in a single actor (Clark, 2002). That donors fulfil their principal roles in

heterogeneous and complementary ways is consistent with the sense of a system which is dynamic and evolving to best enable these collective skills,

### **9.3 Closing of previous knowledge gaps**

The identified principal donor roles, and their heterogeneous application by donors, represent a richer understanding of the role of donors in innovation in international development than that provided by earlier authors. It contrasts in particular to the role of the public sector characterised in the linear model of innovation, in which this was essentially limited to the funding of upstream basic research. In the emerging GIS in immunisation for international development, we have seen that the roles played by donors are important across invention, application and diffusion. Donors are so important in such a system of innovation because they are highly influential actors in both global and national subsystems. They are able to use their leverage in each to form structural linkages between the sub-systems. These linkages enable donors to generate and utilise a diverse set of knowledge and valuation resources for innovation.

Within the literature, we previously identified several particular gaps in knowledge. Firstly, the literature, despite multiple reference to the existence of two distinct important spatial levels, didn't explain how donors engage actors and institutions across these two spatial levels for innovation in immunisation. Secondly, the literature, despite reference in various forms to the power relations which exist around donors, did not provide a good understanding of how donors engage with these power relations with respect to innovation in immunisation. Thirdly, the literature, despite some indication that donors are differentially involved in different categories of innovation, did not provide a good understanding of how donor structure and capabilities determine its comparative advantage for particular activities for innovation in immunisation.

The following table shows how we are now able to start to fill these three previously-identified knowledge gaps with reference to the four principal donor roles.

Table 9: Donor roles with respect to innovation in immunisation (Author)

Role type	Detail of role	Previously-identified knowledge gaps		
		Spatial levels	Power	Capabilities
<b>Structural</b>	Provision, maintenance and extension of structural linkages and networks	Structural linkages connect global and national sub-systems	Structural linkages and networks reinforce donor power of access	Donor structure affects its ability to modify system structure
<b>Resourceful</b>	Generation and utilisation of innovation valuation resources	Spatial transfer of resources is usually directly related to their generation and utilisation	Resource-provision reinforces donor financial power over other actors	Donor structure and capabilities determine its ability to generate and utilise resources
<b>Coordinating</b>	Coordination with other donors to ensure complementarity	Coordination is in different, but connected forms and fora at each spatial level	Power relations exist between donors, whether 'power with' or 'power over'	Coordination takes account of capability-derived comparative advantages
<b>Institutional</b>	Navigation of rules, norms and presumptions on behalf of partnerships	Different spatial sets, but with related rules and norms, whilst presumptions in tension	Presumptions relate to power relations, especially those concerning beneficiaries	Organisational characteristics influence donors institutional engagement

Consideration of the four principal donor roles allows us to use each of them as an aspect against which to consider each of the three previously-identified knowledge gaps.

With respect to the gap in explanation of how donors engage actors and institutions across these the national and global spatial levels for innovation in immunisation, we are able now to specify that donors connect these two levels through structural linkages, and that they use their interactions across the global and national sub-systems to generate and utilise innovation valuation resources. Financial investment is generated at global level by donors through fundraising, and to a minor degree is used there to *push* innovation into less economically developed country (LEDC) markets. Primarily, though, donors utilise it at national level as cost-sharing and

grants to incentivise the adoption of innovations. Market access is generated at national level by donors through provision of vaccines and grants, and then utilised at global level to *pull* innovation into LEDC markets. Innovation legitimacy is initially generated at national level by donors through successful piloting of innovations. It is then utilised at global level for donor confirmation of quality and endorsement, thereby magnifying the legitimacy, before being utilised at national level to increase adoption by governments. The two spatial levels also represent spaces in which common characteristics of the GIS are displayed differentially, but relatedly. Actor coordination, for example, takes place in different, but connected forms and fora at each spatial level. Rules and norms at the national and global level are of different sets, but are related; whilst presumptions at each spatial level are in tension.

With respect to the gap in explanation of how donors engage with the manifold power relations around them with respect to innovation in immunisation, we are able now to specify that in some respects, innovation reinforces those power relations. The fact that donors provide structural linkages and networks reinforces their power of access, and donors' provision of valuation resources for innovation reinforces their financial power over other actors. In inter-donors relations, though, we are able to distinguish the use of 'power over' from 'power with', for which there is evidence that this is in fact the norm in these relations. Several of the institutions within the GIS serve to reinforce or to challenge particular power relations. Some have the potential to transform power relations in a way which is more enabling of innovation, such as the norm that donors align to national development strategies, the norm that donors should uphold aid effectiveness principles, and the presumption that intended beneficiaries should be included in innovation planning, design and implementation. Conversely, some institutions serve to perpetuate the unequal power relationship which underlies a *techno-fix* approach to innovation, in which donors advance innovations based around digital technology with insufficient regard for the context or perspectives of the intended users.

With respect to the gap in explanation of how donor structure and capabilities determine its comparative advantage for particular activities for innovation in immunisation, we are able now to specify that a donor's organisational structure affects its ability to modify system structure, and to generate and utilise resources. Particularly important is a donor's ability to continuously review and evolve their resource base to ensure it is optimally configured and able to respond to further changing user needs and technological opportunities. In the distributed coordination



of an innovation system, such dynamic adjustment on each actor's part enables it to continue to play a complementary role with respect to others, and ensure that any path-critical gaps are being filled. Coordination and institutional navigation represent specific example of such path-critical gaps being filled in this way.

Our research findings are likely to be of use to practitioners in donor organisations looking to innovate in international development. In particular, our elucidation of principal donor roles is likely to provide a framework on which to base a strategy for innovation. Also likely to be useful is our explanation of the constraints to innovation which arise from an approach which doesn't sufficiently take account of the range of relevant institutions, and especially of a tendency towards a techno-fix perspective. In addition, our examination of the interaction between donor global headquarters and country offices offers a guide to internal donor working practices.

#### **9.4 Areas for further research**

Our research also indicates areas for further research. The most significant of these is how the structure and capabilities of a donor determine its comparative advantage for particular activities for innovation in immunisation. This relates also to the reconciliation between the distributed agency which is fundamental to the innovation system approach and the concentrated agency which is important in explaining differences in actor capabilities. We anticipate that the dynamic capabilities concept plays a role in that, because within a system, decisions about actors' strategies and activities need to take into account those of other actors. For this interdependency to function effectively, within the distributed coordination of an innovation system, this requires a continual adjustment on each actor's part in order to ensure that it continues to play a complementary role with respect to others, and that any path critical gaps are being filled. Examining this in much greater depth represents an area for further investigation.

Associatedly, there is an area for further research into whether the diversity of donor organisational types and competences affects the functioning of the GIS. We identified the existence of this diversity, with each of our donor cases resembling a different one of Mintzberg's (1979) organisational archetypes (see Table 3). Similarly, each also adopted a different mode of Musiolik *et al.*'s (2020) system building. We were also able to show that individual donors generated and utilised a different set of innovation valuation resources. Teece (1998) suggests that different organisational types are more suited to different contexts and types of innovation.

Examining how necessary this is in a GIS represents an area for further investigation.

A second area for further research relates to the *techno-fix* perspective on the balance between knowledge generated primarily from *science, technology and innovation* (STI) and knowledge generated primarily through *doing, using and interacting* (DUI). We observed this to be the principal source of tension between the presumptions and between the actors of the global and national levels. It translates into a balance between innovations developed at the global level which are largely technological, potentially radical, but usually highly dependent upon suitable infrastructure and training of users; and those probably more incremental innovations developed in a more inclusive, but slower way at the national level. Gardner, Acharya and Yach (2007) emphasise the importance that donors find a balance between those, in order to maximise the potential of innovation, for global health:

[D]onors need to link two disparate schools of thought: 1) a search for technological solutions exemplified by global public-private product development partnerships and 2) a focus on systemic solutions exemplified by health policy and systems research.

(Gardner, Acharya and Yach, 2007, p. 1052)

This represents an evolving balance, with donors increasingly recognising those tensions, and we anticipate, increasingly trying to resolve them. Observing this taking place also represents an area for further investigation.

Finally, in this research we have advanced an explanation for the observed distribution of knowledge modes and innovation valuation resources. We proposed that the balance between STI and DUI modes of innovation, and the degree of customisation or standardisation of valuation resources varies depending on whether the innovations are the stage of invention, application or diffusion. We suggested that invention within immunisation is particularly highly STI focused, and donors use valuation resources in a standardised way in order to foster this stage, in order that it be sufficiently abstract not to stymie conceptualisation in particularities. The balance is quite different in the application of these inventions, which requires a high level of customisation of valuation resources in order to achieve and prove impact. Consequently, at this stage, DUI knowledge becomes most relevant, as the innovation is adapted to the intended use-case and context. Finally, in diffusion of

innovations, STI is again the predominant knowledge mode, as this stage of innovation requires knowledge which is largely explicit and communicable over a distance; and the use of valuation resources are standardised, in order to allow introduction of these innovations at scale across multiple markets. This represents an evolution of the GIS model proposed by Binz and Truffer, who envisaged a consistency of distribution of knowledge and innovation valuation resources within a GIS. Further research into other instances in which in fact these are not consistent across a GIS would strengthen the argument to evolve Binz and Truffer's model further in this direction.

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## APPENDICES

### Appendix A: Initial analysis of UNICEF innovation initiatives

Innovation initiatives which focus on immunisation or include it as a major element:

	<b>Initiative nature</b>	<b>Innovative element</b>	<b>Organisation's apparent role</b>
<b>Product Innovation Projects (PIPs)</b>	New product development	Work with commercial developers for new products to fill unmet product needs in international development (includes vaccines and their delivery)	Expert assessment of need, with direct access to users for testing and feedback; convening power with private sector; provision of moderate funds; broad technical expertise for assessment, monitoring and evaluation
<b>Technical Support for innovation</b>	Technical support on government-led innovation projects	Partnership with governments, with UNICEF providing technical assistance, on specific innovative projects (includes vaccine delivery)	Expert identification of needs; awareness-raising with the public; access / convening power between entrepreneurs and governments; broad technical expertise for assessment, monitoring and evaluation.
<b>Private Sector Partnerships</b>	Programmatic partnership between public and private sector	Partnership with multinational companies in non-health sector, to bring approaches successful elsewhere into health	Expert identification of needs; awareness-raising / convening power with multinationals; provision of an altruistic reputation-gain for multinationals; technical expertise for assessment, monitoring and evaluation.

<b>Academic Partnerships</b>	Partnership between academic and UN sector	Partnership with academic institutions for exchange of ideas, joint capacity building, and applied research	Expert identification of needs; awareness-raising / convening power with academic institutions; provision of an application reputation-gain for academic institutions
<b>UNICEF Innovation Fund</b>	Funding for nascent innovative ideas in developing countries	Investment nascent open source technologies from developing countries using venture capitalist methods	Expert identification of needs; awareness-raising with the public; access / convening power with entrepreneurs; provision of moderate financial assistance; technical expertise for assessment, monitoring and evaluation
<b>Global Innovation Centre</b>	Funding for scale-up of proven innovations	Identifying and then supporting the scale-up across multiple countries or regions of field-tested, proven innovations that benefit all children, particularly the most disadvantaged; fostering “south-south” collaboration	Expert identification of needs; awareness-raising with the public; access / convening power with entrepreneurs and governments; provision of moderate financial assistance; broad technical expertise for assessment, monitoring and evaluation

## Appendix B: Initial analysis of Gavi innovation initiatives

Innovation initiatives which focus on immunisation or include it as a major element:

	<b>Initiative nature</b>	<b>Innovative element</b>	<b>Organisation's apparent role</b>
<b>International Financing Facility for Immunisation</b>	Financing mechanism for immunisation	Publicly issued bonds – in this case 'vaccine bonds' – to raise front-loaded financing on the basis of long-term, legally binding pledges by sovereign governments	Establishment and management of the robust mechanism required; provision to potential purchasers of well-founded financial assurance and programmatic-confidence
<b>Pneumo-coccal Advance Market Commitment</b>	Market-shaping initiative	Financial reward to manufacturers for meeting specified price, quantity and timeliness targets for pneumococcal vaccine	Expert identification of requirements and terms; establishment and management of the mechanism required; provision to manufacturers and donors of well-founded financial assurance; awareness-raising / convening of manufacturers
<b>INFUSE</b>	Competition to identify, test and scale-up innovations	Annual competition to identify, test and scale-up small-scale technological innovations with potential for greater cost-effective impact, focused on a different topic each year	Expert identification of needs; awareness-raising with the public; access / convening power between entrepreneurs and governments; provision of moderate financial assistance; broad technical expertise for assessment, monitoring and evaluation
<b>Private Sector Partnerships</b>	Programmatic partnership between public and private sector	Partnership with multinational companies in non-health sector, to bring approaches successful	Expert identification of needs; awareness-raising / convening power with multinationals; provision of an altruistic reputation-

		elsewhere into immunisation	gain for multinationals; broad technical expertise for assessment, monitoring and evaluation
<b>Cold-Chain Equipment Optimisation Platform</b>	Scale-up of new technology	Scale-up of proven new cold-chain equipment technology, by facilitating increased demand and supply; with distribution, installation, commissioning, and end-user training	Expert identification of requirements; access for engagement with countries for application; awareness-raising / convening power with manufacturers; provision of substantial financial assistance



## Appendix C: Initial analysis of BMGF innovation initiatives

Innovation initiatives which focus on immunisation or include it as a major element:

	<b>Initiative nature</b>	<b>Innovative element</b>	<b>Organisation's apparent role</b>
<b>Establishment of Gavi</b>	Public-private partnership-based health initiative	Vaccine demand-consolidation combined with market-shaping, and donor support for sustainable vaccine introductions	Identification and highlighting of a need; motivated and facilitated solution-funding; provision of significant financial support for the new model, Gavi
<b>Grand Challenges</b>	Competition to identify, test and scale-up innovations	Annual competition to identify, test and scale-up small-scale technological innovations with potential for greater cost-effective impact, including 'creating new interventions for global health', which itself includes immunisation	Expert identification of needs; awareness-raising with the public; access / convening power between entrepreneurs and governments; provision of moderate financial assistance; broad technical expertise for assessment, monitoring and evaluation
<b>Vaccine Innovation Award</b>	International award for individuals	Award based on criteria of proven impact, innovation, creativity and scale (2012-14)	Awareness-raising with the public and health professionals in developed and less developed countries.
<b>MenAfriVac</b>	Focused new vaccine development	Strategic partnership between NGO, WHO, governments and manufacturer to develop and manufacture a new vaccine to prevent meningitis A	Expert identification of needs; convening power across diverse organisations; significant financial support
<b>Innovative Financing</b>	Market-based innovative financing	Establishment, with private industry of innovative, market-	Expert identification of needs; convening power with manufacturers

		based financing mechanisms	
<b>Research &amp; Development</b>	Broader research and development (R&D)	Donor-funding of private sector R&D, both into improvements of existing vaccines and vaccine delivery mechanisms	Expert identification of needs; access to manufacturers and to feedback from developing country stakeholders
<b>Bihar Evaluation</b>	Monitoring and evaluation of innovations	Geographical focus of monitoring and evaluation of the impact of several immunisation-focused innovations	Convening power with donor and implementing organisations; broad technical expertise for assessment, monitoring and evaluation; moderate financial support
<b>Broader Initiatives</b>	Catalytic interventions across development policy and practice	A wide range of catalytic interventions, including new types of analysis, targeted support for innovators and public awareness	Convening power with donor and implementing organisations; broad technical expertise for assessment, monitoring and evaluation; moderate financial support

## Appendix D: Semi-structured interview guide

Research question: **what role do donors play with respect to innovation in immunisation for international development?**

### Introduction

1. What is your role at DONOR, and how does it relate to innovation in immunisation for international development?

### Definitions

2. What does DONOR understand by innovation?
3. Can you give examples to illustrate this innovation in DONOR?

### Strategy for Innovation

4. Why does DONOR innovate in immunisation for international development?
5. How does DONOR innovate in immunisation for international development?

### Resources

6. What role does knowledge play in DONOR's innovation?
  - a. (e.g., knowledge generated primarily from *science, technology and innovation*? Knowledge generated primarily through *doing, using and interacting*? A combination?)
7. What role do financial resources, market access or technology legitimacy play in DONOR's innovation?

### Interactions

8. How does DONOR interact with other actors on innovation?
  - a. (e.g., peers? The private sector? Beneficiaries?)
9. Does DONOR play a particular role in those interactions?
  - a. (e.g., intermediary? Integrator? Broker? Standard-setter? Financier?)

### Institutions

10. How do any broader presumptions, norms or rules influence DONOR's innovation?
  - a. (e.g., austerity? Risk-appetite? Private Sector partnerships?)

### Organisational characteristics

11. How do DONOR's organisational characteristics influence its innovation?
  - a. (e.g., culture? Leadership? Resource-management?)
12. How does DONOR's learning affect its innovation?

## Appendix E: Participant information sheet



### Innovation in international development: the pioneering role of donors in immunisation

#### PARTICIPANT INFORMATION SHEET

9 August 2018

This is an invitation to take part in a doctoral research study. Please take time to read the following information carefully. It is important that you understand why the research is being done and what your participation will involve before you decide to take part.

#### General information about the research study

The research is the basis of a PhD in development policy and practice, by Charlie Whetham, and is conducted by him.

The research question is ***why and how donors innovate in immunisation.***

Researcher: Charlie Whetham

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The responsible institution is the Department of Development Policy and Practice, the Open University, Walton Hall, Milton Keynes, MK7 6AA, United Kingdom

This research has been reviewed by, and received a favourable opinion from, the Open University Human Research Ethics Committee, reference number: 2896.

<http://www.open.ac.uk/research/ethics/>

For the collection of data, the research relies upon interviews and focus groups, as well as document analysis and observation of donor innovation policy- or decision-making. Document analysis and observation will focus solely on corporate perspectives, rather than those of individual contributors. The remainder of this information sheet and the attached consent form pertains to data gathered through interviews or focus groups.

The research is expected to be completed by 30 June 2020.

#### What will I be asked to do if I agree to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason.

If you choose to take part you are requested to participate in an interview of approximately one hour at your place of work, or by telephone/video conference. They will be audio-recorded and subsequently transcribed. You may also be invited to take part in a focus group discussion of a particular aspect of the research with other research participants. This would be held under the same conditions as your interview.

You should be aware that the research may identify findings which question the policies or practices of the donor organisations for which you work.

### **How will the data I provide be used?**

You are given the option on the consent form that the data you provide be identified in the research either to you by name; or anonymised to organisation and generic area of expertise (e.g. 'a senior country manager in Gavi'); anonymised to organisation only; or fully anonymised.

During the course of the research, softcopy data will be stored in a password-protected secure electronic folder on Open University servers; and hardcopy in a locked cabinet.

Raw data, including interview recordings, researcher notes and the coding linking participant names to anonymised transcripts, will be retained until one year after the conclusion of the research. Transcribed data, anonymised per participant instructions above, will be deposited in a specialist data centre, so it can be used for future research and learning, for a period of ten years after the conclusion of the research.

The research findings will be proactively shared with all participants when they are published as a PhD thesis at the conclusion of the research.

### **Your right to withdraw from the study**

You have the right to refuse to answer questions; and you have the right to withdraw from the study at any time during your participation by ending the interview or leaving the focus group. Chairs of observed meetings have the right at any time during the meeting to ask that the observation cease.

You have the right to ask for your data to be removed after your participation in the study by contacting the researcher on the above details, until 30 June 2019, which is the point from which all data will be aggregated for analysis.

### **How do I agree to take part?**

You should opt in for the study by completing, signing and returning the consent form to the researcher.

Thank you for taking time to read this information sheet and considering your participation in this research.

## Appendix F: Participant consent form



### Innovation in international development: the pioneering role of donors in immunisation

#### PARTICIPANT CONSENT FORM

9 August 2018

The research is the basis of a PhD in development policy and practice, by Charlie Whetham, and is conducted by him. The research question is ***why and how donors innovate in immunisation.***

The responsible institution is the Department of Development Policy and Practice, the Open University, Walton Hall, Milton Keynes, MK7 6AA, United Kingdom

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Tel: +41 79 339 1400  
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Lead Supervisor: Prof. Theo Papaioannou  
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1. I have read and understood the information sheet dated 9 August 2018, or it has been read to me. I have been able to ask questions about the study and these have been answered to my satisfaction.

Yes ☐ No ☐

2. Consequently, I understand that:

#### ***Regarding taking part in the study***

- 2.1. My participation will be in an interview of approximately one hour *at my place of work, or by telephone/video conference.* They will be audio-recorded and subsequently transcribed. I may also be invited to take part in a focus group discussion of a particular aspect of the research with other research participants, under the same conditions as my interview.
- 2.2. I can refuse to answer questions; and can withdraw from the study at any time by ending the interview or leaving the focus group. I understand that I can ask for my data to be removed after my participation in the study by contacting the researcher on the above details, until 30 June 2019, which is the point from which all data will be aggregated for analysis.
- 2.3. The research may identify findings which question the policies or practices of the organisation for which I work.

#### ***Regarding use of the information in the study***

- 2.4. During the course of the research, softcopy data will be stored in a password-protected secure electronic folder on Open University servers;

and hardcopy in a locked cabinet. Raw data, including interview recordings, researcher notes and the coding linking participant names to anonymised transcripts, will be retained until one year after the conclusion of the research.

- 2.5. The research findings will be shared with all participants at the conclusion of the research. At that point it will also be published as a PhD thesis.

***Regarding future use and reuse of the information by others***

- 2.6. Transcribed data, anonymised per my instructions in section 3 below, will be deposited in a specialist data centre, so it can be used for future research and learning, for a period of ten years after the conclusion of the research.

**Yes to all the above** ☐ **No to any of the above** ☐

3. I consent voluntarily to be a participant in this study, on the basis of that the data I provide will be identified to me:

**By name** ☐ **By organisation & expertise area** ☐

**By organisation** ☐ **Anonymised** ☐

4. Signature

\_\_\_\_\_  
Name

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

This research has been reviewed by, and received a favourable opinion from, the Open University Human Research Ethics Committee, reference number: 2896  
<http://www.open.ac.uk/research/ethics/>