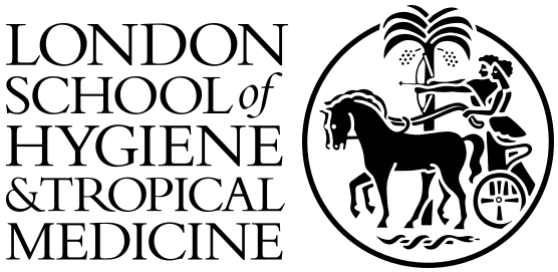

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The Role of Global Health Partnerships in Achieving Vaccine Equity: A case study of the COVAX Facility

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Thesis submitted in accordance with the requirements for the degree of

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I, Charnele Nunes, confirm that the work presented in this thesis is my own. Where information has been derived from other sources, I confirm that this has been indicated in the thesis.

Abstract

Background

The COVID-19 pandemic led to the creation of COVAX, a novel structure to support the discovery, development, and distribution of COVID-19 vaccines. It differed in an important aspect from the previous mechanisms, in that it was based on global solidarity. Ideally, one would have expected that the design of this innovative mechanism would draw on the lessons of the previous global health partnerships operating in the vaccine field. Consequently, this thesis asks two questions: (a) what lessons can we learn from previous experiences with vaccine global health partnerships?; (b) to what extent were those lessons learnt, or not learnt, when creating COVAX and what might explain this?.

Methods

This study uses an explorative single case study design, using qualitative methods, with a constructivist international relations framework by Rushton and Williams (2012). The research questions were answered using a combination of methods. The first involves a scoping review of the existing published literature. The second question is answered by means of an analysis of relevant documents and interviews with key informants involved in the creation and operation of COVAX. The documents reveal, primarily, the extent to which the lessons learnt, as identified in the answer to the first question, were addressed in the process of creating COVAX. The interviews confirm or refute the findings from the documents and seek explanations for why issues were addressed or were not. Data was analysed thematically, using inductive coding. Ethics approval was provided by the Research Ethics Committee at the London School of Hygiene and Tropical Medicine.

Findings

COVAX has largely replicated approaches adopted in existing global health partnerships (GHPs). Overall, this has been characterised by an exclusion of civil society organisations (CSOs) and low-middle income countries (LMIC) stakeholders in decision making processes, a subsidy-based approach to tackling innovation. This approach has largely ignored political determinants of vaccine equity, resulting in a mismanagement of political externalities which have led to vaccine nationalism and have benefitted a specific set of stakeholders, namely donors and high-income countries (HICs). COVAX endorses the assumption that market

friendly policies can be leveraged to achieve innovation which ultimately address donor concerns of cost effectiveness, however such measures have proven to be ineffective.

Summary of recommendations

The recommendations are as follows for GHPs:

- Ensure inclusivity in decision making processes: GHPs should champion the inclusion of LMICs and CSOs across all decision-making stages;
- Diversify regional manufacturing of vaccines: Expanding regional manufacturing will prevent manufacturing bottlenecks;
- Diversify solutions for different economies;
- GHPs should influence reform across the vaccine innovation process.

Acknowledgements

I would like to begin by thanking my supervisors, Professors Martin McKee, and Natasha Howard. Both have shown tremendous patience, kindness, accessibility, and enthusiasm during my entire DrPH journey. Whilst I was regularly pushed out of my comfort zone, particularly with setbacks during the pandemic, I never felt lost, and they supported me at every step of the way. I feel very privileged and honoured to have such wonderful mentors. I am grateful to Professor Simon Rushton for his guidance at the planning stage of this thesis and whose expertise was instrumental to my understanding of the international relations perspective.

I would like to express my gratitude to my fellow DrPH classmates, Hartley Dutczak and Ngozi Kalu, for their tremendous support and optimism during this entire journey. I have truly enjoyed witnessing our academic, professional, and personal growth over these years, and I hope to continue to do so for years to come beyond the DrPH.

My biggest thanks must of course go to my mother, father, and sister; for all they have done to keep me on track and who have inspired me in countless ways. With their unwavering support and belief in me, they allowed me to embark on this wonderful and challenging adventure, knowing full well it meant they would have to make sacrifices to financially support me as a self-funded student. I would simply not be here without them. Maman, Papa, et Rayelle, merci pour tout, du fond du cœur.

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List of abbreviations

ACT-A	Access to COVID-19 Tools Accelerator
AMC	Advanced Market Commitment
APC	Advanced purchase commitment
BCG	Bacille-Calmette-Guerin
BMGF	Bill and Melinda Gates Foundation
CEPI	Coalition for Epidemic Preparedness Innovations
COVAX	COVID-19 Vaccines Global Access
CSO	Civil society organisation
CVI	Children's Vaccine Initiative
DAH	development assistance for health
DCVMN	Developing Countries Vaccine Manufacturers Network
DFID	UK Department for International Development
DnDi	Drugs for Neglected Disease Initiative
DOTW	Doctors of the World UK
DrPH	Doctor of Public Health
DTaP	Diphtheria, Tetanus, Pertussis
EBPHP	Evidence Based Public Health Policy and Practice
EID	emerging infectious diseases
EUL	Emergency Use Listing
EPI	Expanded Programme on Immunisation
FAIR System	Fair Allocations of Innovations for Pandemic Relief
Gavi	Gavi, the Vaccine Alliance
GFATM	Global Fund to Fight AIDS, Tuberculosis and Malaria

GHP	global health partnership
GNI	Gross national income
GSK	GlaxoSmithKline
HIC	High-income country
IAVG	Independent Allocation Validation Group
IAVI	International AIDS Vaccine Initiative
IFPMA	International Federation of Pharmaceutical Manufacturers
IFRC	International Red Cross and Red Crescent Movement
IGBA	International Generic and Biosimilar Medicines Association
IGO	intergovernmental organisations
IHR	International Health Regulations
IMF	International Monetary Fund
IP	intellectual property rights
IRT	International relations theory
JAT	Joint Allocation Taskforce
LIC	low-income country
LMIC	low- and middle-income countries
LSHTM	London School of Hygiene and Tropical Medicine
MERS	Middle East Respiratory Syndrome
MIC	middle-income country
MMR	measles, mumps, and rubella
MoH	Ministry of Health
mRNA vaccine	messenger ribonucleic acid vaccine
MSF	Médecins Sans Frontières

MVI	Malaria Vaccine Initiative
NIH	National Institutes of Health
NCD	non communicable diseases
NGO	Non-governmental organisation
NTD	Neglected tropical diseases
ODA	Official Development Assistance
OPA	Organisational Policy Analysis
PAHO	Pan-American Health Organization
PCV AMC	pneumococcal vaccine Advance Market Commitment
PDP	Product development partnership
PHEIC	Public health emergency of international concern
PoC	proof of concept
PPP	public private partnership
PRISMA	Preferred Reporting Items for Systematic Literature Reviews and Meta-Analyses
R&D	research and development
RTA	reflexive thematic analysis
SAGE	Strategic Advisory Group of Experts
SARS-CoV-2	Severe Acute Respiratory Syndrome Coronavirus 2
SARS	Severe Acute Respiratory Syndrome
SDH	social determinants of health
SEYLL	standard expected years of lost life
SII	Serum Institute of India
TB	tuberculosis
TRIPS	Trade-Related Aspects of Intellectual Property Rights

UCI	Universal Childhood Immunisation
UK	United Kingdom
ULMO	Understanding Leadership, Management and Organisations
UN	United Nations
USA	United States of America
VAD	Vaccine Allocation Decision
VII	Vaccine Independence Initiative
VSV	Vesicular Stomatitis Virus
WHO	World Health Organization
WTO	World Trade Organization

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DrPH Integrating Statement

As is required under the regulations of the DrPH programme, in this integrating statement I outline my learning during the DrPH and how the three components of the degree, the taught component, Organisational Policy Analysis (OPA) and thesis, are linked. In this statement, I chronologically start with a brief summary of my interest in pursuing a DrPH, followed by my thoughts on and a review of the taught components, the OPA and the thesis.

My academic journey started with my undergraduate degree in French and English literature (BA), where I learned about the application of social science research methods, such as content, narrative, or thematic analysis, for literary studies. Following this, I pursued my post graduate degree in health policy (MSc), where I developed my interest in examining how policies affect different communities and populations. I worked with Doctors of the World UK (part of the Médecins du Monde network) as a Clinical Support Worker, and then later as a Project Lead for the Hackney pilot Clinic. In both roles, I was exposed to the effects of restrictive health policies and their effect on health seeking behaviours and health outcomes of migrant populations, both documented and undocumented. Following this, I decided I wanted to expand my research training and experience to gain furthermore formal policy and management instruction, whilst combining my interests in politics, discourse, and public health policy. I came to the DrPH programme with several years of work experience as a Research Assistant and four years' work experience in various organisations working in local health setting with migrant communities and working in different policy settings on activities related to research and advocacy in the UK and Europe.

The taught element of the DrPH programme allowed me to develop my analytical skills and ability to critically appraise research and evidence. This component comprised of two modules: Evidence Based Public Health Policy and Practice (EBPHP) and Understanding Leadership, Management and Organisations (ULMO). There are two aspects to the assignments for the taught components I would like to highlight here. The first, is the Knowledge Transfer and Influencing Strategy assignment I completed for the EBPHP course. The assignment was to develop an influencing strategy for a real or fictional public health organisation to help them advocate for a policy. This assignment was very useful to think about which strategies organisations may employ to achieve impactful outcomes.

The other notable element from the taught courses was the assignment for the ULMO course. The assignment was to complete a strategic analysis of an organisation and I used this as an opportunity to begin work for my OPA project that would follow. Unlike with the previously mentioned assignment, for this assignment I did use a real organisation. At this point, I had always worked at non-profit charities or non-governmental organisations and while there are many advantages to working at a small organisation, there are also many challenges and frustrations. For the assignment I used several management and organisational frameworks, including SWOT and PEST analyses, to outline the organisation's structure and mission, strengths, and weaknesses. This assignment highlighted the importance of analysis methods and consequently informed my approach to my OPA project.

For my OPA, I remained in London, UK for a work placement with Doctors of the World UK (DOTW), an organisation working to empower excluded populations and communities to access healthcare. DOTW run an advocacy programme and clinic, which supports destitute migrants, sex workers and people with no fixed address to access NHS care. Prior to my placement, DOTW were looking to expand their Policy and Advocacy team, who supports the advocacy programme, to include more research focused outputs to inform policymaking processes in the UK. The objectives of my OPA were to (1) assess whether DOTW's current knowledge engagement outputs and activities are compatible with knowledge transfer theories and practices; (2) assess whether DOTW evidence outputs meet stakeholder expectations; (3) provide recommendations on how DOTW might increase the influence of its research outputs on the UK national policy agenda.

My OPA provided me with useful experience going into the thesis process. The first, was further experience with and execution of qualitative data collection and analysis methods. I conducted a series of semi-structured interviews with the members of the Advocacy and Policy team and other relevant stakeholders. I analysed and synthesised interview findings into themes, which pointed to the importance of research framing, working on coalitions, the differences between research and evidence. Such findings accordingly informed a series of recommendations for DOTW in terms of how they can work with partners to produce high quality research outputs, work in partnerships with other organisation working in similar areas of migrant health or access to services and changes to make in the Policy and Advocacy team, such as recruitment of a Research Lead, which could be funded through a series of financial opportunities highlighted through the stakeholder interviews. This experience

taught me the value of strategic planning with relation to research framing and stakeholder engagement to increase the likelihood of evidence uptake to inform policy change. Upon completion of my OPA report, I prepared a short-abridged version of my report for the team. The OPA was also a very useful exercise in translating and presenting my findings to several different audiences and stakeholders; something I plan to do with my thesis results and throughout my career going forward.

The learning from the taught modules and the OPA informed the approach to my thesis, where the experience I gained in developing research protocols, conducting fieldwork, and analysing data were extremely valuable. Originally, I intended to expand on some of the findings from my OPA for my thesis and focus on a specific area of migrant access to health services, mainly undocumented women's access to sexual health services. However, my thesis study was heavily impacted by the COVID-19 pandemic. At the onset of the pandemic in 2020, various organisations, including DOTW, had to close their services due to ongoing lockdowns in the UK and a precarious funding situation. This would have made access to relevant stakeholders and undocumented migrant service users very difficult, particularly given the uncertainty surrounding how long lockdowns would be in place.

I decided to pursue a different area of study for my thesis, focusing on how global health governance processes influence COVID-19 vaccine research and development and delivery. This is inclusive of understanding how actors apply their own beliefs and values to interpret and respond to global health policies. Moreover, I am interested in how such an interpretation then affects various populations and communities, resulting in either barriers to access or health inequities. Producing the thesis has been the most rewarding stage of the programme, as it allowed me to step outside of my comfort zone by using social science theories from fields like international relations to understand ongoing policy debates from multiple perspectives and in real time. My chosen topic, "The Role of Global Health Partnerships in Achieving Vaccine Equity", uses the COVAX Facility Initiative as a case study.

My motivation for exploring this topic was my witness to the apparent gap in access between countries based on their economic power, where higher income countries were able to secure large doses of the COVID-19 vaccine by signing advanced purchase agreements, whereas low-middle-income countries were unable to do the same, despite the pandemic affecting the global community equally. Though COVAX was set up as an initiative to serve all countries, irrespective of their income, it has since been unable to achieve vaccine equity. My research

asks two questions: (a) what lessons can we learn from previous experiences with vaccine global health partnerships?; (b) to what extent were those lessons learnt, or not learnt, when creating COVAX and what might explain this?. I identified that COVAX's application of market-friendly solutions act as a barrier to achieving vaccine equity, where it did not sufficiently address the political elements of the pandemic. The application of international relations theory, through the selected framework, was useful in understanding why this was the case, by highlighting existing power dynamics between actors involved in determining policy outcomes. Though COVAX takes its design from existing global health partnership models such as Gavi and CEPI, it needs to adapt in order to better serve the global population, should it be used as a model during future pandemics. This thesis' recommendations have considered the various stakeholder priorities such as the need to support pharmaceutical innovation along with the expansion of manufacturing capacity in low-middle-income countries.

Chapter 1 Introduction

1.1 Overview

This chapter introduces core concepts relevant to this thesis, starting with a brief summary about, "what this thesis is about" (1.1) to situate COVAX in broader literature on global health partnerships and its usage during the pandemic. Following this, I provide background details (1.2) introducing vaccines and their usage in health (1.2.1), summarising what they are and how they work, why they are important, and how they come to be developed and manufactured. This section is followed by a summary of push (1.2.2) and pull (1.2.3) mechanisms used in the vaccine innovation system. The purpose of this is to illustrate the global actors' leveraging of economic tools used to create and innovate new vaccine technologies to address gaps in access in low and middle-income vaccine markets. In section 1.2.4 I provide details on how the innovation system changed during the pandemic, leading to the creation of the COVAX Facility Initiative (1.2.5). This section examines its design, governance structures and processes, and the main tools it employs to promote vaccine R&D, especially Advanced Market Commitments (AMCs), which seek to fix market failures that reduce access. I summarise some of the barriers COVAX has faced in its attempt to address gaps in access and what this means for achieving global vaccine equity (1.2.6). I then outline the gaps that exist in the literature (1.2.7). Finally, this chapter concludes with a thesis overview (1.3), presenting the thesis's aims and objectives (1.3.1) and a summary of the overall thesis structure (1.3.2) with a brief overview of the academic context and expectations of doctoral research for the award of a Doctor of Public Health (DrPH) at the London School of Hygiene and Tropical Medicine (LSHTM).

1.2 What is this thesis about?

This thesis is about how governments and other non-state actors, working individually and collectively within the global health architecture, ensure that people, wherever they live, have access to COVID-19 vaccines. Specifically, it looks at one initiative, the COVID-19 Vaccines Global Access, or COVAX, and asks what worked, what did not, and why.

COVAX started with the best of intentions. It was one of four pillars of the Access to COVID-19 Tools Accelerator (ACT-A), created early in the pandemic, in April 2020, by World Health Organization (WHO), the European Commission, and the government of France (Berkley, 2020, Berkley, 2021). Its goal was to coordinate the resources needed for all global economies to achieve equitable access to COVID-19 tests, therapies, and vaccines. It is led by Gavi, the Vaccine Alliance (Gavi), the Coalition for Epidemic Preparedness Innovations (CEPI), and WHO, with UNICEF as the primary delivery partner (Berkley, 2020). These organisations all have well-established track records in this field, and, in many respects, COVAX has been successful, in procuring and delivering enormous amounts of vaccines for low- and middle-income countries (LMICs) (Schwalbe, 2012, Saxenian et al., 2011, Kettler et al., 2020). But it had also fallen short of its goals, lagging behind schedule and facing substantial challenges in obtaining and distributing vaccines when there was intense competition for the limited quantities available. In the following chapters, I report what I have found from a detailed review of written material of different types and interviews with key informants that raises the question of what could have been done differently.

COVAX is not the first global health partnership (GHP). GHPs have been proliferating in recent decades, and we now know a great deal about their strengths and weaknesses (Buse and Walt, 2000a, Buse and Walt, 2000b). Like COVAX, they are created with the best of intentions. The world's governments have committed to improving the health of all people, perhaps most visibly in the health-related Sustainable Development Goals (Bali and Taaffe, 2017). And these governments, mostly, accept the importance of working together, albeit with one eye on their national interests. But the ambition often exceeds the reality.

The emergence of GHPs in the global health governance space has many implications for policies that affect the health of populations worldwide. The concept of global health governance, referring to, "any means or mechanisms used by various public and private actors, acting at a sub-national, national and international level" (Kay and Williams, 2009), is unpacked and discussed in further detail in Chapter 2. This thesis aims to understand the different policy processes that have resulted in a failure of global health governance (Rushton and Williams, 2012). That is, the failure of global health actors to meet the challenges posed by the COVID-19 pandemic and achieve global vaccine equity. In focusing on the political, I aim to understand how different actors, interests and power dynamics have influenced the

policy cycle, resulting in the creation of COVAX and its subsequent operationalisation. This approach acknowledges other approaches such as political economic ones which consider factors such international trade, investment, and finance are increasingly playing a role in population health outcomes (Lee et al., 2002, Kay and Williams, 2009). However, global health policy is a "catalyst" in an increasingly liberalised political economy of global health governance (Kay and Williams, 2009). As such, I aim to understand the sources of the strong market-oriented liberalising thrust, which has been influencing the vaccine innovation system and broader landscape of global health governance.

The key question I will ask as I seek to understand how COVAX came about and how it operated was the extent to which the many lessons from these earlier partnerships were taken on board in designing COVAX and, if not, why. Given the centrality of vaccines to this thesis, this chapter begins by examining the extent to which lessons from earlier partnerships were taken on board in designing COVAX, I draw on insights from constructivist international relations theory. This views structures and agencies as interrelated. The structure, in this case COVAX, is shaped by the distribution of power among the actors involved, which in this case include national governments, international agencies, and global philanthropies. Consequently, I will describe how each of these has different interests and ways in which they can exert influence, and I will ask to what extent this explains the structure that COVAX has taken. By doing this, I hope that my thesis could be useful next time, as undoubtedly will happen, a pandemic arises.

1.3 Background

1.3.1 Introduction to vaccines: What do they do, why do we need them

Unwanted foreign biological substances in our bodies are identified by markers on their surface that act as antigens, molecules that can stimulate an immune response. Vaccines work by priming the immune system by exposing it to the antigens found on a pathogen, typically disease-causing viruses, or bacteria (for completeness, it should be mentioned, but only in passing, that more recent vaccines are being developed against other antigens, such as those found on cancer cells). This controlled exposure leaves the body with a supply of "memory" T-lymphocytes and B-lymphocytes that will remember how to fight and respond

to future exposure to microorganisms bearing those antigens, which would otherwise cause disease. Vaccines have been developed that protect us from many once (or still) common infectious diseases. Some of the earliest examples protected against smallpox, cholera, typhoid, yellow fever, and polio. Vaccines take time to develop and evaluate for effectiveness and safety, but these processes are speeding up with scientific advances, so vaccines are increasingly looked to as a response to emerging novel infections, especially those with pandemic potential, a growing threat given growing international travel, including forced migration, itself often driven by accelerating climate change. It has been estimated that vaccines prevent 2-3 million deaths worldwide every year through immunisation against diphtheria, tetanus, whooping cough, and measles, but a further 1.5 million lives could be saved annually with increased global vaccine coverage (Vanderslott et al., 2013).

Vaccines take different forms (Box 1) (Gavi, 2020m, Pollard, 2021). They are sometimes administered in ways that mimic the invasion routes taken by the pathogen in question. For example, the oral polio vaccine is ingested to stimulate an immune response in the lining of the intestines, as the natural transmission of this virus is through ingestion of contaminated food and water. Similarly, the vaccine used to protect children against influenza is administered intra-nasally (Gavi, 2020m). Other vaccines, such as those for yellow fever and measles, mumps, and rubella (MMR), work best when released slowly into the body (subcutaneous injection). Consequently, such vaccines are injected into the layer of fat between the skin and muscle to prevent the vaccine from being distributed around the body too quickly.

Box 1 Typology of vaccines

Conjugate vaccines: Fights specific types of bacteria. These bacteria contain antigens coated in polysaccharides. This coating disguises the antigen, making it hard for a young child's immature immune system to recognise and respond to it. Conjugate vaccines therefore work to connect the polysaccharides to antigens that the immune system can respond to and accordingly create an immune response. The h*aemophilus influenzae* type B (Hib) vaccine is an example of a conjugate vaccine.

Inactivated vaccines: Fights viruses and bacteria. These vaccines are made by inactivating the germ during the production process. Numerous doses are needed to create or maintain immunity. The inactivated polio vaccine is an example of this type of vaccine.

Live attenuated vaccines: Fights viruses and bacteria. These vaccines contain a weakened version of the live virus or bacteria and does not cause severe disease in people with healthy immune systems. Examples of living, attenuated vaccines include MMR and varicella (chickenpox) vaccine.

mRNA vaccines: Uses messenger ribonucleic acid (mRNA) technology teaches cells how to make proteins that trigger an immune reaction, which produces antibodies that protect people from infection. The Pfizer-BioNTech and Moderna COVID-19 vaccines are the first RNA vaccines ever to be approved for use against any disease.

Subunit vaccines: Includes only parts of the virus or bacteria, or subunits, instead of the entire germ. These vaccines are less likely to cause side effects as they only contain essential antigens as opposed to all the other molecules that make up the germ. The pertussis (whooping cough) component of the Diphtheria, Tetanus, Pertussis (DTaP) vaccine is an example of a subunit vaccine.

Toxoid vaccines: Prevents diseases caused by bacteria that produce toxins (poisons) in the body. To make these vaccines, the toxins are weakened so they cannot cause illness. Weakened toxins are called toxoids. As a result of receiving a vaccine containing a toxoid, the immune system learns how to fight off the natural toxin. For example, the DTaP vaccine contains diphtheria and tetanus toxoids.

Viral vector vaccines: Use a modified version of a virus as a vector to deliver protection. Various viruses such as influenza, vesicular stomatitis virus (VSV), measles virus, and adenovirus, have been used as vectors. For example, the adenovirus is one of the viral vectors used in some COVID-19 vaccines. Broadly, there are two types of viral vector-based vaccines: non-replicating vector vaccines and replicating vector vaccines. Non replicating vaccines cannot make new viral particles and only produce the vaccine antigen. Comparatively, replicating vector vaccines produce new viral particles in infected cells, which then go on to infect new cells that will also make the vaccine antigen.

Vaccines are often highly effective in protecting individuals against the diseases they target, but few provide complete immunity, and effectiveness varies. For example, a three-dose course of inactivated polio vaccine (which, unlike the oral vaccine, is given by injection) is 99 per cent effective, whereas the main typhoid vaccine is approximately 70 per cent effective (Vetter et al., 2018, Pollard, 2021). However, individuals respond differently to vaccines; some immunosuppressed people may not mount an immune response (Lee et al., 2022). A further complication is that the benefits of some vaccines reduce over time, requiring a booster to "remind" the immune system how to identify such pathogens (Burckhardt et al., 2022). For example, two doses of the MMR vaccine typically provide protection for up to 20 years (Vetter et al., 2018).

Vaccines effectively stop the spread of some diseases at a population level by creating herd immunity. When most people in a population are vaccinated and become immune to an infection, this may be sufficient to interrupt transmission as there is little chance of an infected individual encountering someone who is susceptible. Thus, this protects people without immunity from infection too. However, the proportion of the population that needs to be vaccinated to achieve herd immunity varies as a function of the transmissibility of the infectious agent, the degree of mixing, and the protection offered by the vaccine. For example, measles, one of the most transmissible viruses, would require 95 per cent of the population to be immune to maintain herd protection (Vetter et al., 2018).

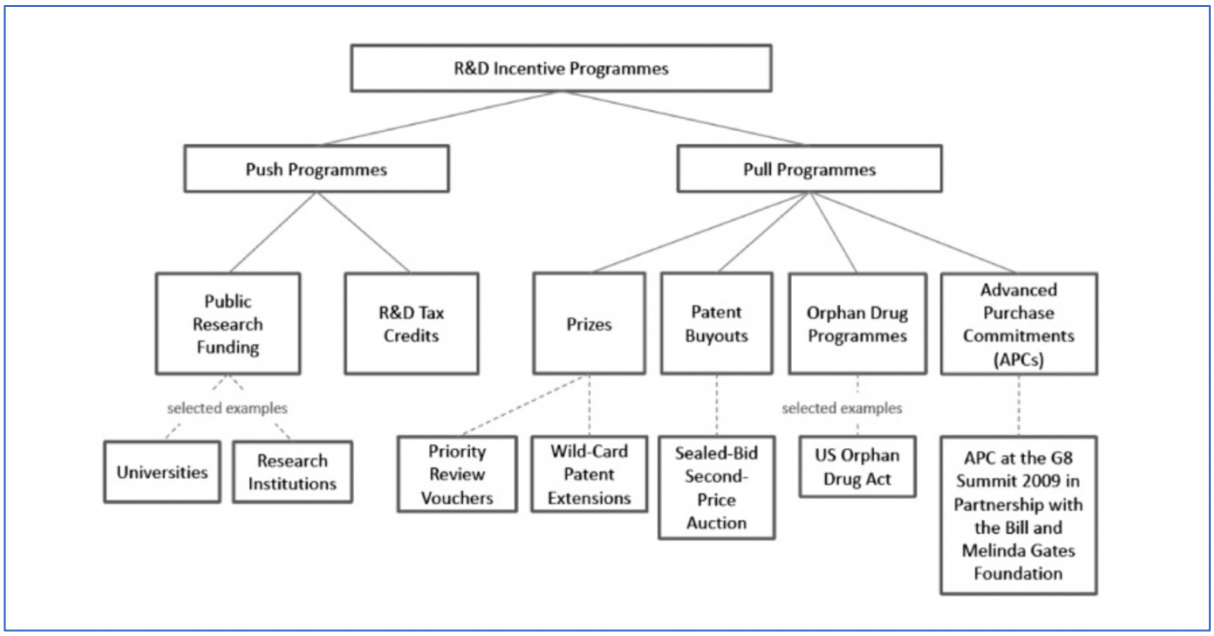
Vaccines are not available for every infectious disease. There are many reasons for this, such as but not limited to, characteristics of the microorganism, including the extent to which it presents antigens in ways that can be recognised by antibodies and its speed of mutation, where the virus' continuing evolution creates a constant stream of antigenically different variants, rendering any previous exposure useless. An example of this is the common cold. For other diseases, it may be a question relating to process: there may already be several promising vaccine candidates, but the rigorous safety and efficacy testing needed have not been prioritised, so an approved vaccine is still years away. In the past, vaccine development typically took over a decade, which is problematic when new microorganisms emerge. It is also problematic when viruses only become epidemic at long intervals, as it is only possible to assess protection when the virus is circulating. Finally, the absence of a vaccine may be due to commercial factors. Vaccine development is costly; however, many diseases

disproportionately affect populations in LMICs whose governments have limited vaccine manufacturing capacity or funds to purchase vaccines. Pharmaceutical companies, therefore, have little incentive to invest in treatments that are unlikely to return a profit. This has given us the term “neglected tropical diseases”, with several initiatives designed to address this problem.

All these potential factors result in a smaller demand for vaccines than what would have otherwise been expected for such an essential product (Abi Younes et al., 2020). Lower demand means that potential vaccine developers lack incentives to invest in research and development (R&D) and in large-scale manufacturing facilities. This results in “market failure”. This arises where those supplying a product fail to respond appropriately to demand so the outcome is inefficient in economic terms. In this case it results in lower qualities being placed on the market than is societally desirable (Mazzucato, 2016). The pharmaceutical industry is reluctant to invest in the development of vaccines needed to treat various diseases, because return on investment cannot be guaranteed (Trouiller et al., 2001, Mazzucato, 2016). Consequently, there are five major players on the vaccine market globally, namely GSK, Merck, Sanofi, Pfizer, and Novavax (Sampat, 2012).

The economic concept of ‘market failure’ tells us that the production of new knowledge through R&D (for instance a new vaccine) entails significant positive externalities that are difficult to capture by the innovator (Mazzucato, 2016, Abi Younes et al., 2020, Xue and Ouellette, 2020). In concrete terms, society benefits more from an innovation (social returns such as herd immunity) than the payoff that the innovator will get (private returns). Economists have shown that this gap, sometimes considerable, between social and private rates of return to inventions results in systematic underinvestment in R&D. Vaccine innovation therefore relies on the use of push and pull mechanisms to incentivise R&D inputs and successful development of technologies (Sampat and Shadlen, 2021). These mechanisms are used to address supply and demand problems and involve of series of actors working in partnership to address failure in the vaccine market in the vaccine market (Mazzucato, 2016).

Figure 1 Push and pull mechanisms



Source: Mueller-Lager (2013)

The vaccine innovation system is a complex network of public and private actors involved in developing and deploying vaccines, including those intended to combat emerging diseases that could lead to outbreaks or epidemics. Two mechanisms influence successful vaccine R&D: push and pull. Figure 1 illustrates the relationship between push and pull mechanisms and provides examples of programmes that seek to use them. Both sets of mechanisms aim to increase the incentives to allocate resources to vaccine R&D, but they differ in their approaches (Mueller-Langer, 2013).

1.3.2 Understanding the vaccine innovation system: Push mechanisms

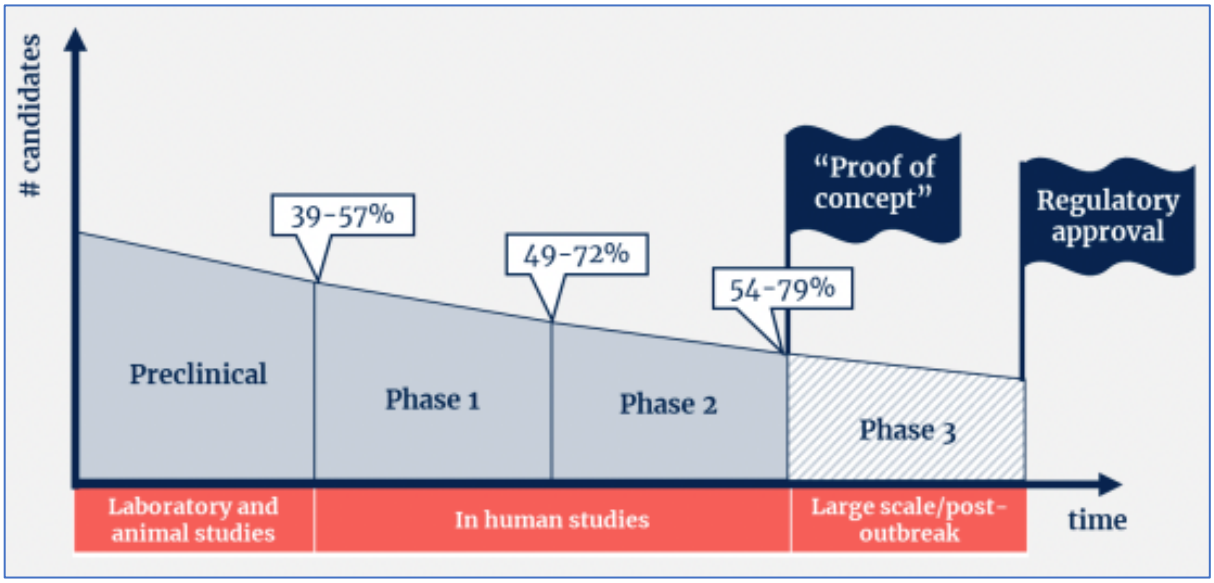
Push mechanisms address supply side issues by providing support for R&D. In contrast, pull mechanisms encourage demand for vaccines, which increases the likely return on investment by increasing the number of immunisations administered (Muzumdar and Cline, 2009, Sampat and Shadlen, 2021). Push mechanisms promote innovation through up-front funding for R&D, typically provided by the public sector, and pull mechanisms reward the successful development of products (Kremer and Williams, 2010, Mazzucato et al., 2020, Torreele et al., 2021). GHPs work across the vaccine innovation spectrum. Push mechanisms support preclinical research, such as understanding the structure of the virus and how it enters cells, and being able to filter, test, and generate the proof of concept (PoC) for new antigens and vaccine delivery platforms (Bernasconi et al., 2020a). Product development, including the financing of clinical trials, is supported by diverse actors, some in partnerships, though the private sector has mainly undertaken it. Globally, the most prominent single push actor has been the USA's National Institutes of Health (NIH), with a budget of approximately USD $40 billion in 2019 (Sampat and Shadlen, 2021).

Vaccine development consists of a preclinical phase and three clinical phases. The preclinical phase, undertaken in vitro (referring to research that is performed outside a living organism, such as a test tube or petri dish) and in vivo studies (referring to research that is conducted with or within a living organism) in animals (Bernasconi et al., 2020a, CEPI, 2019). This provides essential data to inform the design of the product, for example, which antigen to use. The clinical phases in humans ask whether the vaccine is safe (Phase 1), whether it works at a basic level, for example, by eliciting an antibody result (Phase 2), and whether it is better than an existing vaccine or a placebo (in practice, participants receiving controls are often given a vaccine known to be safe and effective in protecting against another disease). Figure 2 depicts these phases, with the average success rate at each point ranging from low to high (CEPI, 2019). It is generally held that one needs 3-5 candidates, on average, in preclinical studies for each successful phase II outcome. This is followed by a series of steps to ensure that a scalable, robust production process that complies with good manufacturing practice (GMP) can be created (Bernasconi et al., 2020a). There is also a 4th phase, post-marketing surveillance, in which systems are established to identify rare and unexpected adverse outcomes when the vaccine is rolled out.

The phase 3 clinical trial generates the primary data needed for regulatory approval. However, as noted earlier, emerging infectious diseases (EIDs) pose a particular problem. Put simply; you cannot demonstrate protection against a microorganism in the population if that microorganism is not circulating. This means that the trials can only be undertaken after the infection has emerged and before it has been controlled by other vaccines or non-pharmaceutical interventions (the exception is the challenge trial, where volunteers are inoculated with the microorganism in question, but for obvious reasons, this is only possible in limited circumstances).

This does not preclude having a portfolio of vaccines that have passed Phase 2 that can be evaluated rapidly when an outbreak occurs. There is also a "Phase IIb" trial, a small-scale efficacy trial that, for many EIDs, may be the most realistic option for generating data that could be used to gain an emergency use listing, short of full licencing (CEPI, 2019).

Figure 2 Different phases of vaccine development



Source: CEPI (2019)

The overall cost of development for vaccines varies and is dependent on vaccine type, innovation level, disease target and regulatory body (Plotkin et al., 2017). For example, authors indicate that the chemistry, manufacturing and controls development for a vaccine exceeds US$ 50 million (Plotkin et al., 2017), whereas the cost of developing a single EID vaccine from preclinical trials through to end of phase 2a is US$31–68 million, assuming no

risk of failure (Gouglas et al., 2018). Another report suggests that the total costs of vaccine development can range from US$ 200 to 500 million (Andre, 2002, Plotkin et al., 2017).

Beyond the issues of conducting trials set out above, the development of vaccines for EIDs is particularly challenging because the characteristics of the pathogen responsible for the disease may be poorly understood (although the ability to characterise pathogens and their behaviour is improving rapidly) and the time and location of future outbreaks are difficult to predict. In addition, extracting profits from what are, in effect, single purchase goods with long-term benefits rather than products purchased repeatedly that generate a predictable revenue stream can be challenging.

The benefits brought about by vaccine R&D, producing new vaccines and related technologies, are clear, both directly for individuals at risk of disease and via positive externalities, which are benefits accruing to others such as population immunity or disease eradication (Lefebvre et al., 2014). This latter category includes public goods, as the benefits cannot be limited to those who did not get vaccinated. Like all public goods, they often suffer from underinvestment as the interest in their creation is diffuse (Xue and Ouellette, 2020, Wouters et al., 2021). Here the problem is especially acute as the risks involved are high, with many putative products failing, while the development and production costs are often high. There is a double externality problem: vaccine manufacturers do not capture all the knowledge spill overs from their R&D efforts, and patients do not capture the social benefits like population immunity from their choice to vaccinate (Xue and Ouellette, 2020). Vaccine innovation policy attempts to address such market distortions.

Innovation policy is a “means to act on and improve the performance of innovation systems” (Edler and Georghiou, 2007) and can be classified as either demand side oriented or supply side oriented (Edquist and Hommen, 1999). Similarly, innovation theories can be classified as being linear or systems-oriented, the latter being dominant and emphasising the demand side and the significance of a large, differentiated group of public and private actors, research, or civic society organisations (Encaoua et al., 2006). Linear views of the innovation process support a supply-side orientation in innovation policies (Encaoua et al., 2006). This view applies a unidirectional flow from basic scientific research to commercial applications (Limoges et al., 1994). Innovation policy takes a systems perspective as it is concerned with optimising the interaction of actors and creating an “innovation friendly” framework. This

perspective primarily seeks to facilitate interaction between actors to achieve change rather than directing it from above (Mazzucato et al., 2020, Mazzucato, 2016). This approach namely seeks to function within the existing economic system, rather than challenging conditions which lead to system failures (Stevenson, 2017). This approach is problematic given the system failures resulting from the lack of linkages between science and industry and requiring the creation of new mechanisms to facilitate them (Mazzucato and Semieniuk, 2017). For example, in 2000, the Global Forum for Health Research and the WHO referred to the term, "10-90 gap", where less than 10% of global health research funding is devoted for diseases that primarily affect the poorest 90% of the world's population (Global Forum for Health and World Health, 2000). They argued that many of the diseases affecting communities in LMICs were "neglected", with limited investment from the pharmaceutical industry for these diseases (MSF, 2001).

CEPI, the Coalition for Epidemic Preparedness Innovations, is an example of a new mechanism to facilitate such linkages and promote innovation. It is a GHP launched in 2017 to coordinate international measures to deploy new vaccines and accelerate development and deployment of vaccines against EIDs (Bernasconi et al., 2020a). Appendix A illustrates CEPI's role in the vaccine R&D and delivery process and lists additional actors working across the different stages of the vaccine development and delivery pipeline (CEPI, 2022b). Since its launch, CEPI has announced various funding calls to develop vaccines against "priority pathogens" (Lassa, MERS, Rift Valley Fever, Nipah and Chikungunya) (CEPI, 2022a). To select the priority pathogens, numerous lists were proposed such as one list prepared by the Foundation for Vaccine Research (Plotkin, 2017). Despite this list being very comprehensive and complete, it was long, and it would not have been possible to develop vaccines for all these diseases. CEPI focuses on supporting vaccine candidates against the WHO R&D Blueprint priority pathogens, all of which are on the WHO watch list (Bernasconi et al., 2020b). Diseases are prioritised based on their epidemic potential or that they have no, or insufficient, countermeasures against them (Plotkin, 2017, Bloom and Cadarette, 2019). Included in this list is "disease x", which represents an unknown pathogen and with the potential to cause human disease and a serious international epidemic (Shrivastava and Shrivastava, 2018). Since its launch, CEPI has mobilised more than US $750 million of investments in 21 vaccine candidates, with a

portfolio that contains a wide variety of technologies such as recombinant viral vectors, nucleic acids, and recombinant proteins (Bernasconi et al., 2020b, CEPI, 2022a).

Whilst CEPI is considered a positive step in steering R&D towards public health goals (Gouglas et al., 2019), it has not overcome problems of vaccine accessibility, where private sector business concerns have been prioritised over public health goals. CEPI attracted criticism from Médecins Sans Frontières (MSF) in 2019 about its revised equal access policy. The original policy, published in 2017, outlined CEPI's expectations from grant recipients, which included stipulations on issues from price setting to intellectual property (IP). The original policy stated that "a summary of the provisions in agreements which CEPI enters into with awardees will be made publicly available unless there is an exceptional reason not to, which would require board approval. It is anticipated that the summary will focus on equitable access obligations, shared risks and shared benefits arrangements and management of IP" (CEPI, 2017).

Though many stakeholders embraced this policy, others, such as multinational vaccine companies, expressed concern and declared that they would not work with CEPI as currently designed (Huneycutt et al., 2020). They viewed the policy as inflexible and incompatible with their business models. For example, they were concerned about losing IP rights to processes (including trade secrets) that could be used for another commercial purpose (Gopinathan et al., 2020, Huneycutt et al., 2020) This was especially so with the mRNA vaccines, where the technology was seen to hold much broader potential and began with an idea to develop vaccines against cancerous cells (Fiedler et al., 2016, Miao et al., 2021). Additional concerns included CEPI's ability to manage a project and transfer it to a competitor or publish data they would prefer to keep private for commercial purposes (Huneycutt et al., 2020). In 2019, the policy's stipulations on price setting and IP were removed, with CEPI claiming that it "[was] confident that the implementation of CEPI's access policy will safeguard equitable access to the products developed through CEPI. This includes issues of affordability and data, and extends through development to licensure" (Ravelo, 2019). However, many advocates, including Médecins Sans Frontières (MSF), maintained that it is not possible to support such "commitments" without solid and transparent policies and processes.

1.3.3 Understanding the vaccine innovation system: Pull mechanisms

Some of these problems associated with vaccine R&D are addressed by means of safeguarding the intellectual property of the developer using patents, coupled with guaranteed returns on their investment using Advanced Purchase Commitments (APCs) or Advanced Market Commitments (AMCs), whereby governments and international agencies promise to purchase a certain quantity of the vaccine, thereby taking on much of the risk. APCs are producer-specific, rather than market-wide commitments adopted through the AMC model with the aim of spurring innovation.

The patent system is considered a crucial means to reward innovation (Encaoua et al., 2006, Drahos, 2002) and is an example of a pull mechanism. The patent system aims to protect the production of knowledge, such as the research and development involved in the production of various medical technologies like vaccines, preventing such knowledge from being copied and replicated after its invention (Williams, 2012).

Broadly, most international trade agreements in recent decades have enabled countries with manufacturing capabilities to secure patent protection for pharmaceutical and biological products, generally within the framework of the World Trade Organisation (WTO) agreement on Trade-Related Aspects of Intellectual Property (TRIPS). However, manufacturers may not seek regulatory approval or patent protection in countries with small markets or no manufacturing capabilities. The right to set aside patents for drugs in an emergency was established in 2001 in the Doha Ministerial Declaration on the TRIPS agreement and public health (2001). In this declaration, WTO agreed that the TRIPS Agreement does not and should not prevent WTO members from taking measures to protect public health. These may take the form of compulsory licenses, whereby a government can revoke patent protection for specific uses (Leoni, 2019, Matthews, 2004).

Patents or intellectual property rights (IP) allow innovators to avoid competition for a defined period (around 20 years) and thus earn a return on their investment (Williams, 2012). The absence of competition during this period allows innovators to make higher profits as they can charge higher prices than they would otherwise (Sampat and Shadlen, 2021). High prices have implications for access to their products, especially in LMICs, whose governments may not be able to afford them, leaving people unvaccinated (Pogge, 2012). However, there is

scant evidence that the patent system functions as a catalyst for R&D of drugs with small or temporary markets (such as with vaccines) (Williams, 2017). Additionally, patent-driven models challenge public health and global health imperatives of preparedness, which aim to develop response mechanisms to be deployed when an outbreak or health crisis occurs (Gostin, 2018). Preparedness frameworks such as the International Health Regulations (IHRs) (2005) outline the need to stockpile drugs and other pharmaceutical products to respond to an outbreak; however, the current frameworks are detached from the legal pharmaceutical ecosystem, which is meant to function as a catalyst for pharmaceutical R&D (Gostin, 2018, Santos Rutschman, 2021a, Santos Rutschman, 2021b).

The conflict between the IP regime and pandemic preparedness became apparent in 2007 when Indonesia, the country experiencing the most human cases of H5N1, refused to share virus samples of the avian influenza with the WHO (Fidler, 2010). Despite the international pandemic preparedness activity, Indonesia's decision exercised its "viral sovereignty", which contends that viruses circulating within the national borders, belong to that country and that it is national decision whether or not to share virus samples with the rest of the world (Halabi and Katz, 2020, Elbe, 2022). Indonesia adopted this stance due to its concern that it would not have equitable access to a vaccine, if and once developed, and that HICs would be given priority despite the samples coming from the most affected country (Supari, 2008, Elbe, 2022).

The next challenge is to ensure that vaccines are being delivered to the populations who need them. Historically, there was little R&D on vaccines for Neglected Tropical Diseases (NTDs) or diseases affecting mainly low-income countries (LICs). As such, pharmaceutical companies focused their R&D investments on diseases prevalent in high-income countries (HICs), for which the prospects of market returns are the greatest. Industry priorities are influenced by the expectation that products may be sold at prices that will cover risk-adjusted costs. As such, the expected return on investments in vaccines for LICs is low due to economic factors such as higher levels of poverty and market distortions for NTD vaccines (Cooper et al., 2005, Webber and Kremer, 2001). Consequently, towards the end of the 20th century, global immunisation rates began to plateau despite the availability of vaccines for diseases such as rubella, diphtheria, or tetanus, as countries could not afford vaccines at their current price. Gavi helped by developing AMCs, which are a legally binding contract and a pull-type financial

mechanism to ensure sufficient demand to incentivise a steady supply of vaccines to low-income countries (LICs).

Broadly, Gavi is a public-private partnership (PPP), with 80% of its finances paid by donor governments such as Canada, the United States of America (USA), the United Kingdom (UK) and the European Commission, and 20% of contributions from private sector donors such as the Bill and Melinda Gates Foundation (BMGF) (Gavi, 2020k). Gavi was created to increase access to vaccines in lower MICs and LICs. Countries become eligible for Gavi support if their Gross National Income (GNI) per capita is ≤ US$ 1,630 over the past three years. Once a country crosses the eligibility threshold, it enters the accelerated transition phase and starts to phase out Gavi's financial support (Gavi, 2018). In 2005 Gavi began to fund health systems strengthening (HSS), considering it to be amongst its strategic organisational objectives with the view that strong health systems lead to a scale-up in vaccination programmes to improve immunisation coverage and equity. However, interview findings by Storeng (2014) indicated that Gavi's form of HSS support was emblematic of a "Gates approach", which focused on targeted technical solutions and having measurable outcomes, such as the AMC approach, instead of encompassing social and political dimensions (Storeng, 2014, Tsai et al., 2016).

The goal of AMCs is to address market failure in LIC vaccine markets by increasing vaccine demand (Hargreaves et al., 2011, Gilchrist and Nanni, 2013). The contract involves donors committing, in advance of product development, to financing the purchase of vaccines for LICs at a fixed price specified in advance. This addresses the financial uncertainty for pharmaceutical companies and offers confidence about expected returns, thereby putting R&D for NTDs on par with diseases affecting HIC populations. AMCs aims to address the interests of all stakeholders involved in the vaccine ecosystem, such as the interests of the sponsoring donors (such as HICs and philanthropic organisations), potential vaccine developers and manufacturers (whose activities would be influenced by the AMC), and the LICs (who would benefit from the commitment and the co-payers of the vaccine (Berndt and Hurvitz, 2005). The AMC model is advantageous for donors as AMCs may be implemented alongside existing global health initiatives such as health programmes or interventions targeting disease-specific issues (Kettler et al., 2020, Chen et al., 2022). The AMC may be used as a complementary measure to increase the total amount of R&D for these diseases, thus accelerating the work and progress being done under existing global health arrangements

(Cernuschi et al., 2011, Kremer et al., 2020). Under this model, pharmaceutical companies are incentivised to engage in R&D projects as AMCs ensure return on investment and include a patent on the products developed, where the existing possibility of breaking legal patents during the commercialisation process became critical after the Doha Declaration on the TRIPS agreement and public health (2001) (Matthews, 2004, Snyder et al., 2011).

The pneumococcal vaccine Advance Market Commitment (PCV AMC) was a funding model that was announced in 2007 and launched in 2009 by the BMGF, Canada, Italy, Norway, Russian Federation and the UK and involved donors committing early funds to help speed up the development and availability of new vaccines against pneumococcal disease (Gavi, 2020a). Historically, it would take between 10-15 years after a new vaccine is introduced in HICs for it to be introduced in LICs (Gilchrist and Nanni, 2013, Zhou, 2022). More specifically, the PCV AMC sought to "reduce morbidity and mortality from pneumococcal diseases" by: (1) accelerating R&D of PCVs; (2) increasing availability of PCVs for LICs by guaranteeing the initial purchase price and incentivising manufacturers to invest in scaling up production capacity to meet LIC vaccine demand; (3) accelerating vaccine uptake by ensuring predictable vaccine pricing for countries and manufacturers; (4) testing the effectiveness of the AMC mechanism as an incentive for supplying needed vaccines and whether the model may be applied for other vaccines (Gavi, 2013, Gavi, 2015, MSF, 2020). The key design features of the PCV AMC are summarised in Box 2. In exchange, vaccine manufacturers are incentivised to provide the vaccine at a lower price for MICs and LICs by signing an AMC, which is legally binding (Berkley, 2019). Unlike the Gavi COVAX AMC, the PCV AMC did not use push mechanisms or include a risk-sharing agreement as it leveraged an already existing robust pipeline of effective vaccines (Berkley, 2021, Gavi, 2020a, Cernuschi et al., 2011, Berndt and Hurvitz, 2005). The first pneumococcal vaccine was licensed in the United States in 1977, and the first conjugate pneumococcal vaccine (Prevnar 7) was approved for use in the USA in 2000 (Gierke et al., 2021).

Box 2 Design features of the pneumococcal vaccines Advance Market Commitment (PCV AMC)

The pilot PCV AMC is a legally binding contract to support the market of pneumococcal vaccines with US$ 1.5 billion of funds for which vaccine manufacturers can bid. Interested manufacturers compete over successive tenders to supply a share of the annual forecasted demand for vaccines (expected to increase over time and reach around 200 million doses per year at peak) (Gavi, 2020a). In exchange, the AMC provides a fraction of the US$ 1.5 billion directly proportional to each manufacturer's supply share (Cernuschi et al., 2011).

AMC manufacturers are required to supply their annual share of doses for ten years at a maximum price of US$ 3.50 per dose (i.e., a "tail price cap", which was set at the time of the AMC design close to the estimated marginal cost of production), to be paid for by GAVI and GAVI-eligible countries. The manufacturer's share of AMC funds is disbursed as a subsidy per dose, making the cost of the first 20% of vaccine doses procured from each manufacturer US$ 7. By offering this "AMC price", companies can quickly recover incremental costs associated with serving the GAVI market.

In theory, AMCs differ from other "pull-funding" mechanisms, such as prizes which reward the first supplier, by creating a multi-manufacturer market. The terms are non-exclusive: any manufacturer with a qualifying product can bid on the annual forecasted demand for pneumococcal vaccines. Ultimately, companies compete based on both the price they offer and the quality of their products. The bids of competing suppliers are also considered to ensure sufficient supply and supply security in the future.

Many organisations and individuals, such as MSF have critiqued the AMC design as being an ineffective subsidy to Pfizer and GlaxoSmithKline (GSK), echoing findings of two Gavi AMC Secretariat-commissioned evaluations, one on the AMC's Process and Design (2013) and the other on its Outcomes and Impact (2015) (Gavi, 2013, Gavi, 2015, MSF, 2020). The evaluations indicated that none of the four objectives was achieved. R&D was not accelerated as the AMC model was flawed from the outset in its selection of the pneumococcal disease, which already had a conjugate vaccine on the market since 2000. The choice of a disease with an existing vaccine did not provide sufficient competition amongst vaccine manufacturers, where Pfizer and GlaxoSmithKline (GSK) were the only two manufacturers of PCV until 2019. Of the US$

1.5 billion, $1.238 billion (82%) was disbursed to Pfizer and GSK and only in 2020 was the Serum Institute of India (SII) finally awarded a portion of the funding at $75 million (5%) (MSF, 2020). Moreover, there has been an apparent lack of transparency on the costs and pricing decisions of vaccines. For example, the final subsidy of US$ 3.50 for the first 21% of supplied doses under each contract on top of the $3.50 tail price (total of $7.00 per dose) is still high; developing countries may not be able to afford this base price as they lose Gavi support.

During AMC implementation, demand sometimes exceeded supply despite the large subsidies given to the manufacturers to scale up production capacity. Pfizer and GSK were conservative in expanding their production capacity; this resulted in supply shortages of up to 29 million doses from 2012 to 2014, delaying 23 country introductions and leading to an estimated 26 million children without access to PCV (MSF, 2020). Lastly, there is no indication that the AMC model can encourage long-term, sustainable vaccine production, as there is no plan or incentive for technology transfer to vaccine manufacturers in LMICs (Chandrasekharan et al., 2015). Technology transfer would build capacity for LMIC manufacturers to produce and supply the PCV to their own populations. Though defenders of the PCV's subsidies claim that its US$ 1.5 billion have saved 700k lives by increasing access to the PCV, this remains unclear given the confidential agreements between GSK and Pfizer.

1.3.4 Understanding the context: the emergence of SARS-CoV-2 and how the innovation system has changed during the pandemic

The COVID-19 pandemic has prompted numerous shifts in the traditional vaccine innovation system, changing the dynamics between push and pull mechanisms. Though it is unclear whether these changes will persist during the post-pandemic period, it is important to note how various public and private actors within the innovation system have influenced the development and diffusion of vaccine technologies during the pandemic. Understanding the behaviour change will provide contextual details that continue to inform COVAX's development and continued use in achieving global vaccine equity.

Broadly, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (often referred to as "coronavirus") is the agent that causes coronavirus disease 2019 (COVID-19), the multisystem illness causing the pandemic that began in 2019 (Pascarella et al., 2020, Shereen et al., 2020). COVID-19 is a member of the coronavirus family, single-stranded RNA viruses found in many

different species, with the potential to jump from one to another, causing various illnesses of varying severity. Like earlier SARS viruses, but unlike most other coronaviruses, the spike proteins on SARS-CoV-2 bind to the angiotensin-converting enzyme-2 (ACE-2), which is widely distributed in the body. This, combined with the potential to elicit a hyperimmune response, often associated with increased thrombosis, means that infection can lead to a wide range of clinical manifestations affecting different body systems (Roberts et al., 2020).

SARS-CoV-2 differs in an important way from prior coronavirus epidemics, such as Middle East Respiratory Syndrome (MERS) and Severe Acute Respiratory Syndrome (SARS), where patients typically shed the virus only when symptomatic; COVID-19 patients can be contagious without or prior to displaying symptoms, accelerating its transmissibility and limiting the scope for controls that rely on detection of symptomatic cases, such as temperature screening (Skoll et al., 2020). COVID-19 started in Wuhan, capital of China's Hubei province. It was declared a Public Health Emergency of International Concern (PHEIC), as defined in the International Health Regulations, by the World Health Organization (WHO) in January 2020 (Georgalakis, 2020). The process for declaring a PHEIC is described in Appendix B (WHO, 2022b). On 11 March 2020, the WHO declared the COVID-19 outbreak a global pandemic (Cucinotta and Vanelli, 2020). The glossary includes definitions of outbreak, epidemic and pandemic. As of June 2022, there have been approximately 560 million COVID-19 cases and approximately 6.36 million deaths globally (Ritchie et al., 2020). Data scientists argue that the pandemic's true death toll is higher than official accounts, suggesting that the number is two to four times higher (Karlinsky and Kobak, 2021), placing the total death rate closer to 12-22 million deaths globally (Adam, 2022).

A comprehensive policy to contain the spread of the disease and subsequent illness has many elements, but, fundamentally, there are two main principles (van Seventer and Hochberg, 2017). The first is to reduce opportunities for transmission, for example, by limiting mixing in settings where the virus spreads, such as crowded indoor spaces. This is achieved through a portfolio of non-pharmaceutical measures, such as restrictions on the use of certain venues and face mask mandates and may need to be accompanied by measures such as financial support to mitigate unwanted consequences for those affected. The second, and ultimately most important, is to increase immunity through vaccination. The risk of future outbreaks and continued economic disruption will continue until vaccines that are effective against the

current variants and any newly emerging ones are developed and administered to a large portion of the global population (Wouters et al., 2021). On 24 June 2020, China approved the CanSino non-replicating viral vector vaccine and on 2nd December 2020, the UK gave temporary approval for the Pfizer-BioNTech mRNA vaccine, becoming the first country to approve the vaccine and the first country in the western world to approve the use of any COVID-19 vaccine (Mahase, 2020a, Mahase, 2020b). It then approved the Oxford AstraZeneca vaccine on 30th December (Mahase, 2020b). Box 1 provides a typology of different vaccine technologies, and Appendix C summarises the characteristics of approved COVID-19 vaccines as of June 2022 (Basta and Moodie, 2020, Craven, 2021).

During the onset of the COVID-19 pandemic, globally public sectors directed funds to the research and development of therapeutics and vaccines to combat COVID-19 through push funding, pull funding and a combination of the two (Sampat and Shadlen, 2021). A study by Cross et al. (2021) approximated that public and charitable financing accounted for 97%–99% of identifiable funding for the ChAdOx vaccine technology research underlying the Oxford–AstraZeneca vaccine until autumn 2020. Figure 3 maps the amount of funding identified for each funder type. Although contracts are often not publicly available, the public sector has also committed billions in funding for late-stage trials, manufacturing capacity and manufacturing at risk (Sampat and Shadlen, 2021).

Figure 3 Number of mentions and amount of funding identified for each funder type

Funder type	Mentions from the literature, n (%)	Percentage of mentions matched to a grant amount (%)	Total value of matched grants, £ (%)
Overseas government (including EU)	158 (27.4)	19.0	105 715 805 (46.3)
UK government	147 (25.5)	27.9	69 773 203 (30.5)
Charity	138 (23.9)	36.2	52 977 763 (23.2)
Research institution	113 (19.6)	0.0	0 (0.0)
PPP	15 (2.6)	0.0	0 (0.0)
Industry	6 (1.0)	0.0	0 (0.0)
Total	577	21% of all mentions matched	228 466 771

- EU, European Union; PPP, public–private partnership; UK, United Kingdom.

Source: Cross et al. (2021)

Such investments were considered at risk as they were made before assurance of R&D success or regulatory approval. For example, the American government's Operation Warp Speed, a partnership between the Department of Health and Human Services (which includes the NIH) and the Department of Defence, invested well over US$ 15 billion to develop treatments and a vaccine, alongside procuring 300 million doses for people in the US by January 2021 (Jit et al., 2021, Sampat and Shadlen, 2021). Most Operation Warp Speed funding has been routed through the Biomedical Advanced Research and Development Authority (BARDA). However, a Senate subcommittee questioned Operation Warp Speed/BARDA's decision-making processes, noting limited coordination with other global actors engaged in similar innovation funding activities, such as China and the Coalition for Epidemic Preparedness Innovations (CEPI) (Cohen, 2020).

Philanthropies, such as the BMGF, also one of the founders of CEPI, have also been heavily involved in vaccine innovation. CEPI committed approximately USD $1.2 billion to fund the development of vaccines with the expectation that recipients will provide doses to COVAX. Comparatively, CEPI's financial contributions are small compared to the resources provided by individual government initiatives, such as the USA, to the same recipients. Consequently, this limited CEPI's ability to steer global vaccine allocation and support of COVAX.

Scientists created multiple vaccines for COVID-19 within a year, despite most vaccines taking years to develop (Gilchrist and Nanni, 2013, Jaupart et al., 2019, Zhou, 2022). The rapid pace of technology development, particularly with vaccines, represents a scientific achievement and shift in vaccine innovation timelines for many (Shrotri et al., 2021, Kumari et al., 2022, Defendi et al., 2022). A study by Defendi et al. (2022) highlight regulatory and R&D factors as being the most relevant to factors leading to the successful development of COVID-19 vaccines. The authors note "fast track" procedures and regulatory flexibilities from the main regulatory agencies (Defendi et al., 2022). For example, the countries under the leadership of the European Medicines Agency (EMA) have been establishing greater flexibility in the regulatory pathways, as well as prioritising and improving R&D analysis processes and mobilising the workforce internally (Lumpkin and Lim, 2020, Defendi et al., 2022). Mainly, agencies monitored COVID-19 vaccine development closely, enabling clarification of issues during the R&D process and constant information exchange. Typically, this information exchange happened during the beginning of the clinical stages, whereas this started to

happen during preclinical development phases (Mahase, 2020b, Defendi et al., 2022, Tanveer et al., 2022). Technologically, manufacturers did not follow the linear sequence of vaccine development. Instead, they initiated phases in parallel, where sequential phases were initiated before the results of the previous phase (Defendi et al., 2022).

However, there remain relatively few factories around the world with the technological capacity to make generic versions of vaccines or can reach the high standards for sterility and quality that a vaccine requires (Plotkin et al., 2017, Aars et al., 2021). Exacerbating this, where factories do exist, there are ongoing shortages of supplies such as filters, tubes, bags, and glass vials (Forman et al., 2021). Additional measures needed for vaccine manufacturing include technology transfer (Van De Pas et al., 2022, Yamey et al., 2022). Logistical constraints were also present for countries with manufacturing capacity; however, it may have seemed logical for HICs to produce more vaccines and share them more widely globally, during the pandemic, such manufacturers were already producing at maximum capacity or were producing for their respective populations or to prepare for the potential future booster doses (Sparke and Levy, 2022).

With regards to patents, in October 2020, India and South Africa proposed a waiver from certain provisions of the TRIPS agreement (Sections 1, 4, 5 and 7 of Part II of the TRIPS Agreement) in relation to prevention containment or treatment of COVID-19, identifying a supply-demand gap and highlighted that IP rights acting as a potential barrier to the provision of affordable medical products (WTO, 2020). Both countries indicated that the rapid scale-up of manufacturing globally was crucial to address the timely availability and affordability of medical products to countries in need. Some critics note that intellectual property waivers are necessary and require a change in rules and legal commitments, further noting that vaccine manufacturers have government funded research into COVID-19 (Krishtel and Malpani, 2021). Indeed, a successful waiver would ensure that manufacturers cannot prevent access to raw materials or COVID-19 technologies globally, whilst also ensuring that manufacturers cannot charge higher prices without any competition (Legge and Kim, 2021, Thambisetty et al., 2021). For example, GlaxoSmithKline (GSK) and Merck dominated the patents held for the human papillomavirus vaccine and prevented competition (Chandrasekharan et al., 2015), resulting in LICs paying approximately 10 times the estimated cost for these vaccines (Clendinen et al., 2016).

However, HICs such as the UK, Switzerland, Germany, and Japan have opposed the proposal to suspend IP rights on COVID-19 vaccines. In May 2020, the USA signalled a shift in their position, where President Joe Biden announced support for vaccine patent waivers (Boseley, 2021). Though this announcement was welcomed by advocates pushing for IP protections to be waived to increase LMIC access to COVID-19 vaccines, other HICs and the pharmaceutical industry opposed it (Iacobucci, 2021). The European Union said it was "ready to discuss", despite Germany's unwillingness to waive IP rights that could open up competition from China and Russia (Feinmann, 2021). This is particularly relevant for mRNA vaccine platforms, such as the vaccines developed by BioNTech, which have proved successful and open to other potential non-COVID-19 applications. Reuters reported that the company's value is such that it could lift the German economy by 0.5% on its own in 2021 (Feinmann, 2021). Other critics also note that a waiver would not be sufficient in ensuring global access to COVID-19 vaccine technologies and note infrastructure limitations relating to supply chains and other production capabilities (Cabatbat, 2021, Althabhawi and Kashef Al-Ghetaa, 2022a). Furthermore, for a patent waiver to be successful, holders must agree to a technology transfer and sharing their knowhow (Santos Rutschman and Barnes-Weise, 2021, Althabhawi and Kashef Al-Ghetaa, 2022b).

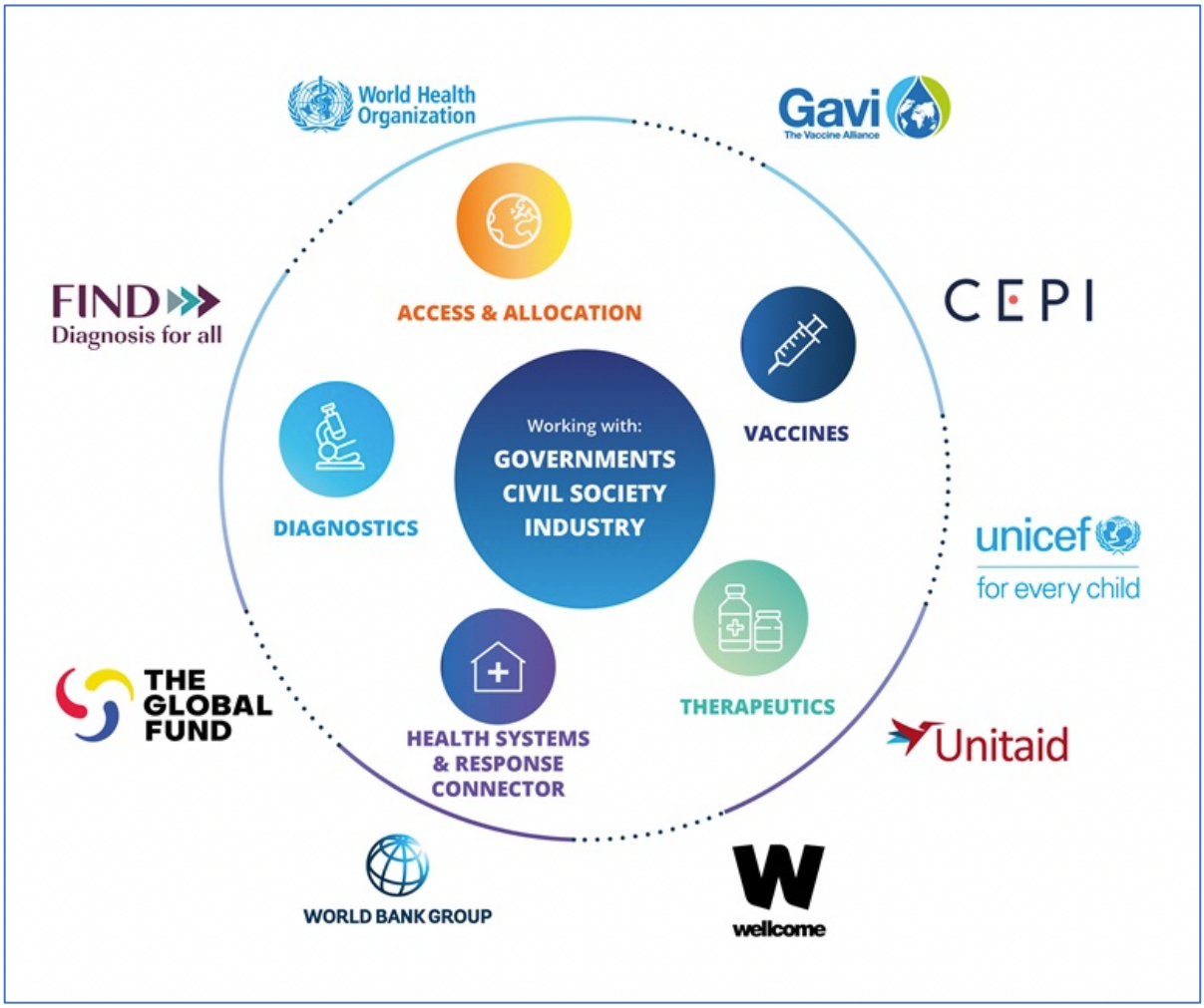
It is unclear whether patent protection offers a meaningful pull, where vaccine manufacturers may have diminished expectations about the enforceability of patents and the ability to use them to obtain high prices during the pandemic. However, as Sampat and Shadlen (2021) explain, "the pre-pandemic patent landscape may have a greater effect on pull incentives than future patent prospects do. Platforms based on messenger RNA (mRNA) and viral vector delivery systems are widely patented. Possibly, these patents provide firms with some exclusionary rights in the short run and shape incentives for follow-on innovation and development". Overall, governments and global health partnerships have supported the idea of using advance purchase agreements as innovation levers, given that innovation for COVID-19 vaccines has occurred irrespective of whether private sector companies were able to enforce patents. Many government-led vaccine R&D initiatives included procurement agreements in their funding contracts (Sampat and Shadlen, 2021).

1.3.5 What is the COVAX Facility Initiative?

Globally, the most significant pull arrangement has been brought forward by COVAX, a pooled procurement initiative. COVAX uses an AMC model to raise funding from donors and procure enough vaccines to vaccinate 20% of the global population through development assistance. COVAX's AMCs are contracts that go beyond standard APAs in two main ways. Firstly, they offer individual vaccine developers and manufacturers "volume guarantees" for vaccines before they are licensed. In this way, manufacturers know they will not be outcompeted if and when their final product is ready to be sold on the market. Secondly, they commit to market-wide demand guarantees available to any manufacturer, essentially committing to buying an overall quantity of vaccines if and when they are ready (Stein, 2021). However, COVAX has been unable to compete with individual country APAs, securing limited doses of successful vaccine candidates, resulting in unequal access to such technologies in HICs and LMICs.

The COVAX Facility Initiative, the vaccines pillar of ACT-A, is the primary manifestation of the international commitment to act collectively in the pursuit of global vaccine equity. Other pillars include access to therapeutics, diagnostics and health systems strengthening. Figure 4 summarises the four pillars of work and lists some of the main organisations involved in leading specific pillars. ACT-A was launched in April 2020, with the WHO playing a key role in all four pillars and leading the Access and Allocation, which cuts across all four pillars to ensure equitable allocation of all COVID-19 tools (WHO, 2022c). The diagnostics pillar is co-led by the Global Fund the FIND. Its overall objective is to increase access to COVID-19 diagnostic tests and sequencing. This pillar supports effective test, trace, isolate, and treat strategies (WHO, 2022c). The therapeutics pillar is co-led by UNITAID and the Wellcome Trust. Its overall objective is to support access to therapeutics, which can prevent infection, suppress symptoms or treat severe symptoms, and to speed up recovery (WHO, 2022c). The health systems and response connector pillar is co-led by the Global Fund, the World, UNICEF and the WHO. Its objective is to ensure that all countries have adequate health systems which are equipped with the necessary technical, operational, and financial resources, to incorporate new COVID-19 tools into their national responses (WHO, 2022c).

Figure 4 Pillars of the Access to COVID-19 Tools (ACT) Accelerator



Source: WHO (2022c)

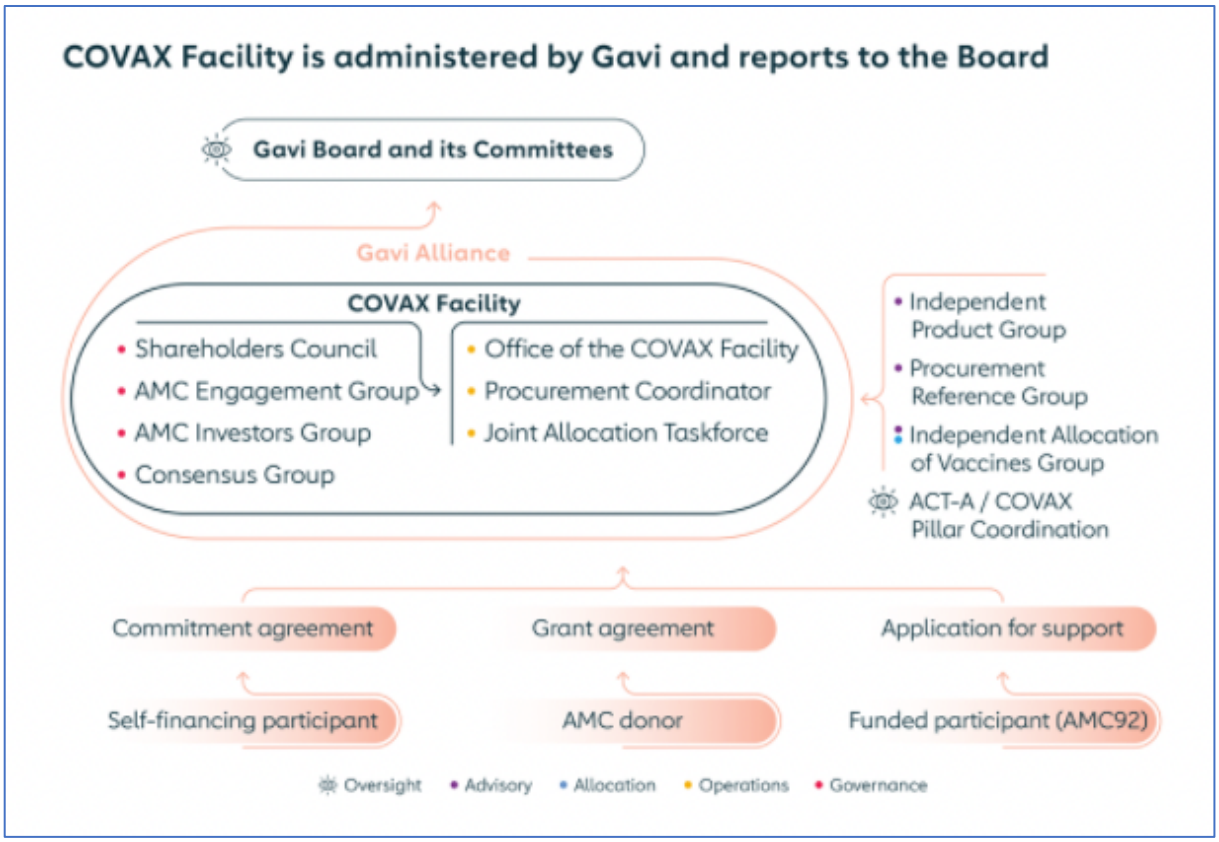
COVAX was founded in April 2020 and is sponsored by the BMGF, CEPI, Gavi, the Global Fund, UNITAID, the Wellcome Trust, WHO, the International Red Cross and Red Crescent Movement (IFRC), the International Federation of Pharmaceutical Manufacturers (IFPMA), the Developing Countries Vaccine Manufacturers Network (DCVMN) and the International Generic and Biosimilar Medicines Association (IGBA). Together, the three sets of technologies (diagnostics, therapeutics and vaccines) constituted 75% (US $28.6 billion) of ACT-A's initial target budget of US $ 38.1 billion (WHO, 2020a). Of this target budget, COVAX has made up 42% (US $16 billion) of ACT-A's initial target funding. As of mid-August 2021, it has received around 70% (US $12.5 billion) of all allocated funding pledges to ACT-A (US $18 billion) (WHO, 2022a). The funding arrangements of both ACT-A and COVAX illustrate the dominance of vertical approach to global health governance and financing, where interventions are mainly

“disease specific” and adopt market specific approaches to address public health issues (Storeng, 2014). Indeed, ACT-A does not consider weak health systems, as being a structural component or catalyst for the spread of COVID-19 (Leach et al., 2021, Stein, 2021, Lal et al., 2022).

COVAX is co-led by the CEPI, Gavi and the WHO, working with a critical delivery partner, UNICEF. Gavi acts as the Facility’s administrator and allocates human resources to support the Facility and is known as the Office of the COVAX Facility (Nguyen, 2020). COVAX was promoted as the, “only truly global solution to this pandemic because it is the only effort to ensure that people in all corners of the world will get access to COVID-19 vaccines once they are available, regardless of their wealth” (Berkley, 2020). COVAX’s lead espoused a rhetoric of equity and solidarity in the attempts of garnering international support and ensuring equitable allocation of vaccine products (de Bengy Puyvallée and Storeng, 2022).

Figure 5 illustrates COVAX’s governance structure and Appendix T summarises the roles and responsibilities of each group (Berkley, 2020). CEPI’s equitable access measures will be maintained under ACT-A/COVAX and strengthened by allocation schemes led by WHO and a global procurement mechanism led by Gavi. The Facility is considered distinct from Gavi resources, consisting of 30 staff positions recruited on temporary or consultancy contracts (Gavi, 2020j).

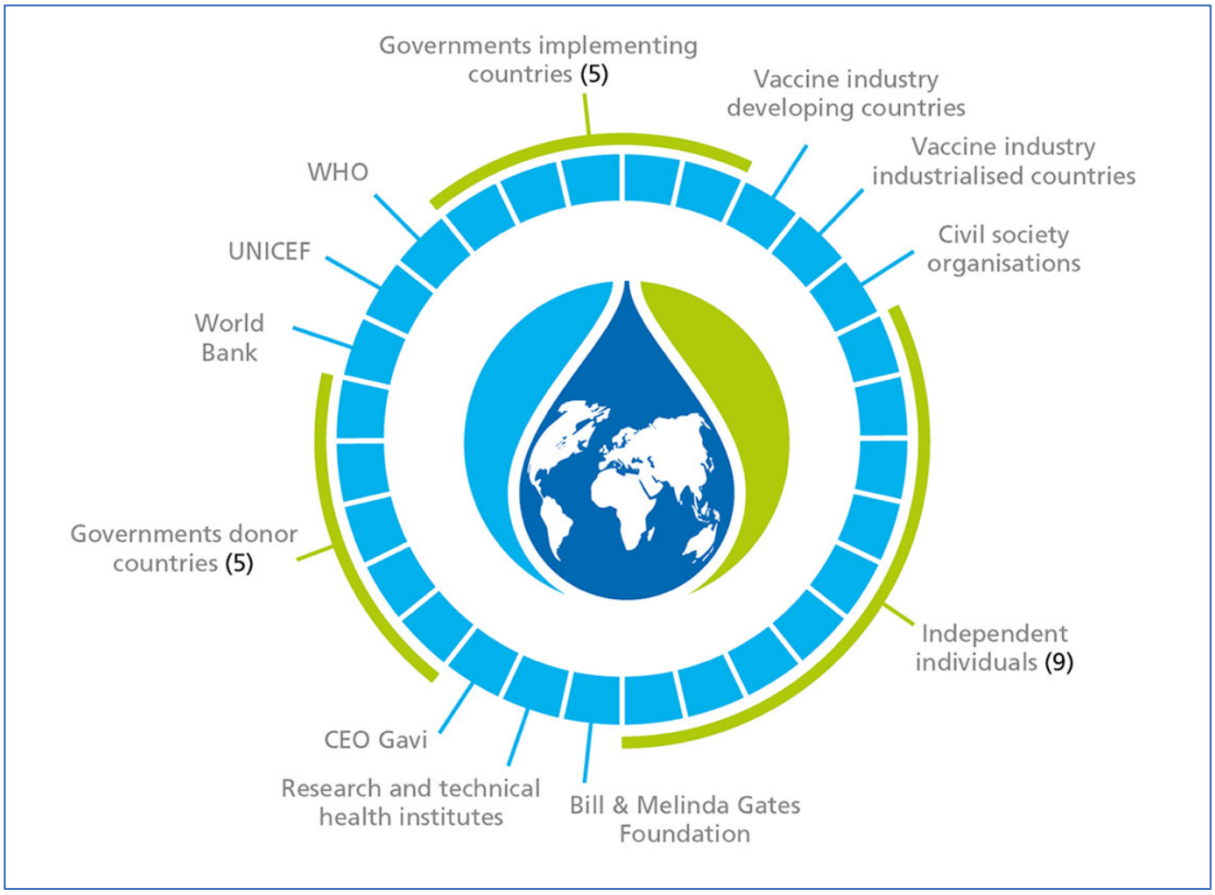
Figure 5 COVAX's governance structure



Source: Berkley (2020)

The Gavi Board is responsible for strategic direction and policymaking, oversees the operations of the Vaccine Alliance and monitors programme implementation (Gavi, 2020c). As shown in Figure 6, the Board is comprised of 18 "representative" seats, 9 seats for independent or "unaffiliated" individuals and one seat for Gavi's CEO. The Board's representative seats ensure that institutions and constituencies can provide formal input into the development of all Gavi's policies and the management of its operations. Independent Board members refer to private individuals with no professional connection to Gavi's work (Gavi, 2020c). They bring independent and balanced scrutiny to the Board's deliberations. These individuals also provide expertise in a number of critical areas such as investment, auditing and fundraising.

Figure 6 Gavi Board composition



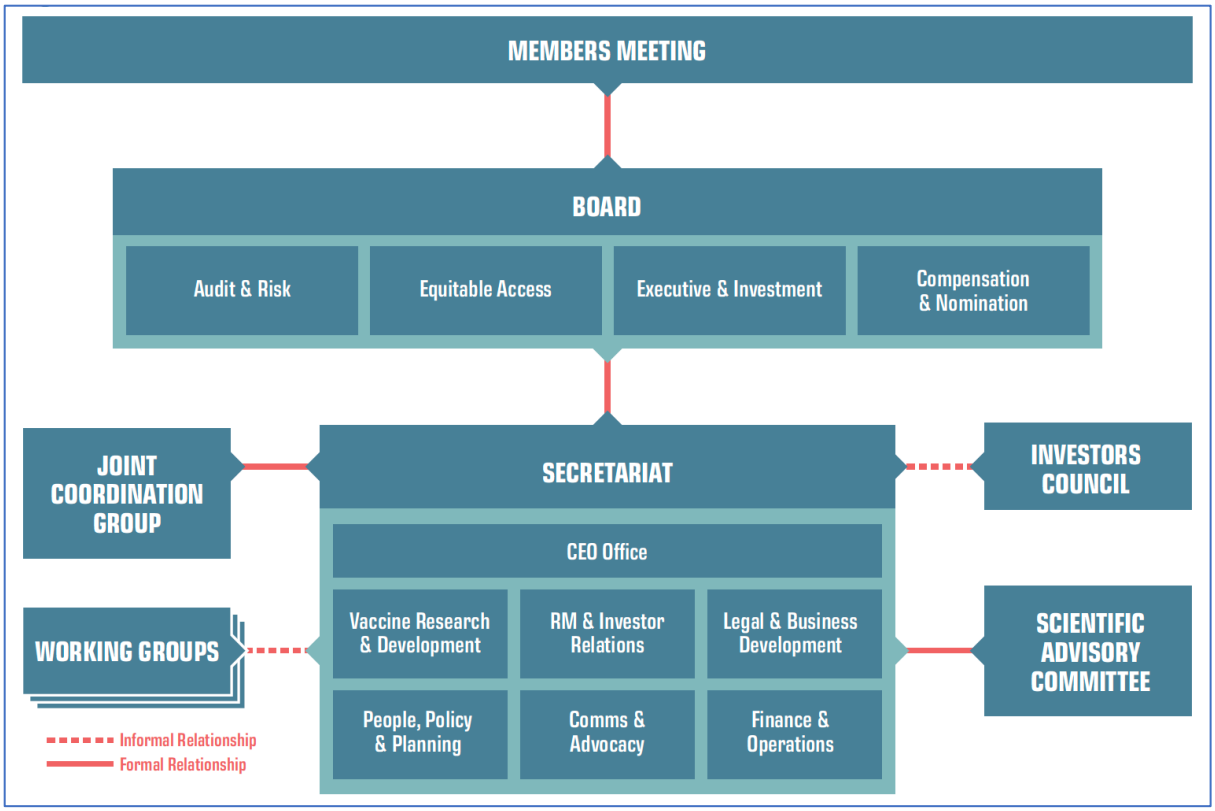
Source: Gavi (2020c)

The Board has five committees which assist with specific decision-making processes: the Audit and Finance Committee, the Evaluation Advisory Committee, the Governance Committee, the Investment Committee, and the Programme and Policy Committee (Gavi, 2020c). The role and function of each of these committees is outlined in Appendix T.

CEPI's primary governing body is the Board, which has 12 voting members (four investors and eight independent members representing competencies including industry, global health, science, resource mobilisation, finance) and five observers (Figure 7) (CEPI, 2021b). The CEPI Secretariat, from its three offices in Oslo (the Headquarter), London, and Washington, D.C, ensures the effective implementation of the strategy. Two additional bodies support and guide CEPI's work: the Scientific Advisory Committee is the principal scientific advisory group to the Board and Secretariat and the Joint Coordination Group works with critical external stakeholders to advance CEPI's portfolio of vaccines (CEPI, 2021b). In addition to this, there are four Board Committees: Executive and Investment, Nominations, Compensation,

Diversity and Inclusion, Audit and Risk, and Equitable Access. The role and function of the two advisory bodies and each of these committees is outlined in Appendix T.

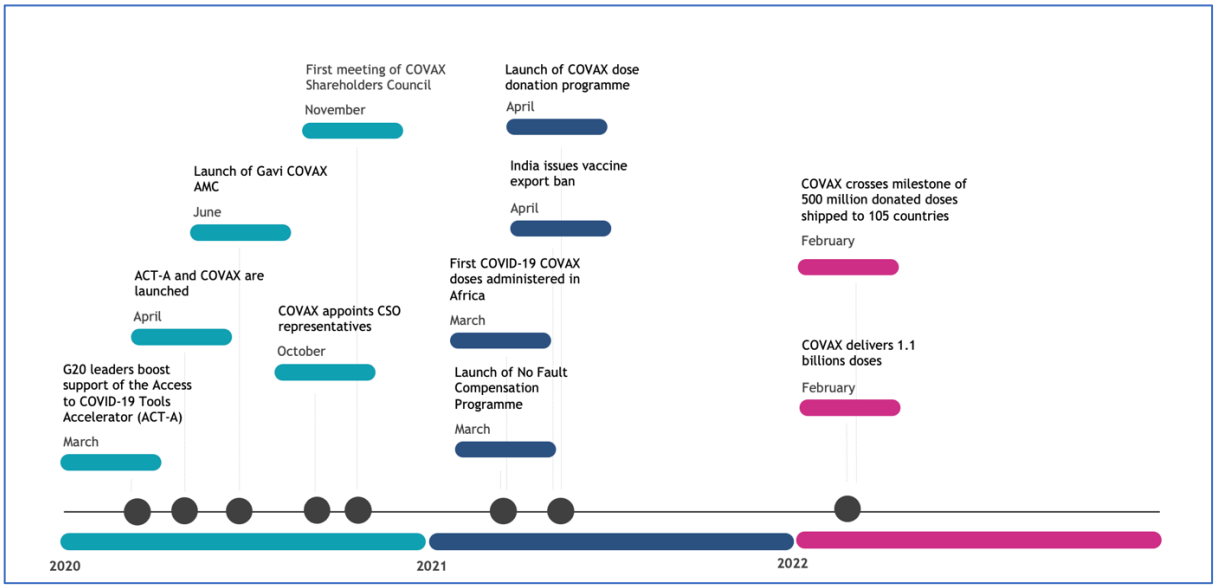
Figure 7 CEPI governance structure



Source: CEPI (2021b)

COVAX seeks to achieve its goals by acting as a risk-sharing mechanism, which ensures that all the most suitable candidate vaccines receive the required financing and manufacturing investments before the assurance of R&D success or regulatory approval. It does this by leveraging push and pull mechanisms (Berkley, 2020, Sampat and Shadlen, 2021, Legge and Kim, 2021). The initial aim is to have 2 billion doses available by the end of 2021, a figure it considers adequate to protect those at the highest risk and most vulnerable and frontline healthcare workers. As of February 2022, COVAX has fallen short of its initial goal and has delivered 1.1 billion doses. However, 80% of vaccines delivered to low-income countries have been via COVAX (Gavi, 2021d). Figure 8 provides a timeline of COVAX's conception, creation, and operationalisation.

Figure 8 Timeline of COVAX's conception, creation, and operationalisation



COVAX is widely considered to be the mainstay of contemporary efforts to achieve global vaccine equity (Mcadams et al., 2020, Sampat and Shadlen, 2021, Wouters et al., 2021). However, it has many limitations. It does not address the issue of IP. Nor does it address actions by governments, vaccine manufacturers, and others that have consequences for vaccine equity but lie outside the COVAX framework. Though its design and implementation are informed by the WHO Fair Allocation Framework (Appendix D) and the Values Framework for the Allocation and Prioritisation of COVID-19 vaccines (Appendix E), with overarching principles related to contractual transparency, vaccine affordability and pricing, COVAX's activities are threatened by national procurement strategies that undermine the global supply of vaccines (WHO, 2020b, Wouters et al., 2021). As more rich countries source vaccines directly from manufacturers, concerns increase about COVAX's ability to achieve its goal of vaccinating the world (Storeng et al., 2021, Wouters et al., 2021, de Bengy Puyvallée and Storeng, 2022).

COVAX builds on Gavi's procurement model and is a global mechanism that pools procurement and promotes equitable distribution of COVID-19 vaccines. It seeks to maximise the likelihood of developing successful vaccines, to manufacture them in the quantities needed to end the pandemic, and to ensure that the ability to pay for vaccines does not become a barrier to access. COVAX builds on CEPI's involvement in vaccine development and manufacturing and Gavi's participation in vaccine procurement and delivery in low-income country settings. COVAX aims to ensure "equitable access to COVID-19 vaccines". It intends

to achieve this by "acting as a platform that will support the research, development and manufacturing of a wide range of COVID-19 vaccine candidates, and negotiate their pricing" (Berkley, 2020). COVAX is therefore a departure from previous global health partnerships and initiatives as it leverages both push and pull mechanisms, by engaging in the entire vaccine innovation process from R&D into procurement and delivery.

Countries participating in COVAX fall into two categories, self-financing countries and funded. Self-financing countries are those HICs and upper-MICs that commit to procuring enough doses from the facility to vaccinate 10%–50% of their populations and make upfront payments to support vaccine development and manufacturing (Berkley, 2020, Gavi, 2020e). Examples of HICs and upper-MICs include Canada, the UK, and South Africa. Even though self-financing participants can request enough doses to vaccinate between 10-50% of their population, no country will receive enough doses to vaccinate more than 20% of its population until all countries in the financing group have been offered this amount (Berkley, 2020). Self-financing countries will be guaranteed sufficient doses to protect a certain proportion of their population, depending upon how much they pay into COVAX. Appendix C summarises the COVID-19 vaccines available through COVAX.

Self-financing countries can participate in the COVAX Facility in two ways: Committed Purchases Agreements or Optional Purchase Agreements. The definition of each Agreement is included in Box 3 (Berkley, 2020). As of May 2021, 85 countries signed commitment agreements to the COVAX Facility as a self-financing participant. Agreements are legally binding, and participants must make their upfront payments to the Facility by 09 October 2020 (Berkley, 2020). A list of participating countries is in Appendix F. Whether subscribing to the Committed Purchases Agreement or the Optional Purchase Agreement, the total cost that participants will incur has three main components: ex-factory costs (i.e., the purchase price of Approved Vaccines charged by manufacturers); access/speed premium; financing/risk mitigation and operating costs (Berkley, 2020). As stated in the COVAX Facility's Terms and Conditions for Self-Financing Participants: "The cost per dose for the Upfront Payment has been determined by the Office of the COVAX Facility based on proxy data and the latest available pricing information from manufacturer engagement for the portfolio of vaccines under consideration" (Gavi, 2020e).

Box 3 **Definitions of Committed Purchases Agreement and Optional Purchase Agreement**

A **Committed Purchase Agreement** requires countries to make committed guarantees to procure an agreed volume of doses through the Facility. Under this type of agreement, participants commit to purchasing a set number of doses, once available, which will be fairly and equitably allocated amongst participants. In exchange for this commitment, participants provide a down payment of US$ 1.60 per dose, or 15% of the total cost per dose, plus a Financial Guarantee of $ 8.95 per dose. This Financial Guarantee amount is equal to the All-Inclusive Weighted Average Estimated Cost per Dose ($10.55) net of the Down Payment per dose and is the estimated total financial exposure the Facility is taking on the participant's behalf. The Financial Guarantee will decrease over time as the financial exposure decreases through the purchase of Approved Vaccines through the Facility.

An **Optional Purchase Agreement** allows participants to maintain their bilateral agreements with vaccine manufacturers, through which they may have already secured sufficient doses. Participants choosing this Agreement can opt out of receiving any vaccine without jeopardising their ability to receive their full share of doses from other candidates. Participants will also be required to pay a higher proportion of the total cost per dose up front, making a down payment of US$ 3.10 per dose and a Financial Guarantee of $ 8.95 per dose. This payment will fully cover the Participant's pro rata share of the Facility's estimated pre-approval manufacturing costs, which includes the speed/access premium and a portion of the ex-factory costs, as well as a pro-rata contribution towards the Facility's operating costs.

Source: (Berkley, 2020)

Under the COVAX Facility, the Gavi COVAX AMC has been established to support vaccine purchases for countries with a gross national income per capita of less than 4000 USD. This mechanism was launched on 04 June 2020 (Berkley, 2021). Less wealthy countries fund these 92 countries and territories (lower MICs and LICs), with their financial commitments covered by Official Development Assistance (ODA) and contributions from the private sector and philanthropy (Berkley, 2021). Examples include Liberia, Malawi, and Yemen, while MICs include Nigeria, Pakistan, and Ukraine. Subject to the availability of funds and vaccines, funded countries will receive enough doses to vaccinate up to 20% of their population through the Gavi COVAX AMC. Since demand is initially likely to exceed supply, allocation will be based on the number of available doses. A list of country participants is included in

Appendix F. Funding for the Gavi COVAX AMC is entirely separate from that of the COVAX Facility, which means that the AMC is in no way cross-subsidised by the funds of self-financing participants. Instead, the AMC is funded mainly through ODA, as well as contributions from the private sector and philanthropy (Berkley, 2020). The average cost per dose for countries participating in the Gavi COVAX AMC is US$ 7.00 (Griffiths et al., 2021).

COVAX adopts the WHO's Allocation Framework definition of fair access and equitable allocation of vaccines which states that "vaccine equity means that vaccines should be allocated across all countries based on needs and regardless of their economic status. Access to and allocation of vaccines should be based on principles grounded in the right of every human to enjoy the highest attainable standard of health without distinction of race, religion, political belief, economic, or any other social condition" (WHO, 2020b). COVAX uses the WHO Allocation Framework as the basis for vaccine allocation decisions for all participants, whereby they will receive vaccine doses, "proportionally and gradually to immunise 20% of their population (unless they have chosen a lower percentage coverage of their population)" (WHO, 2020b). In 2020, the Allocation Framework was developed, focusing on identifying the priority population fraction (20%) that COVAX Facility participants would adopt and concentrated mainly on equitable allocation between countries (Emanuel et al., 2020, Sharma et al., 2021a). However, the premise of equitable vaccine distribution has been weakened by bilateral APAs, vaccine hoarding and underfunding of COVAX (Manriquez Roa et al., 2021, Wouters et al., 2021).

The Allocation Framework is operationalised through the Allocation Mechanism, which consists of the Joint Allocation Taskforce (JAT) and the Independent Allocation Validation Group (IAVG) (WHO, 2020b). The JAT comprises staff from the WHO and the Office of the COVAX Facility, who prepare a Vaccine Allocation Decision (VAD) proposal for review and approval by the IAVG. The VAD proposal is based on a data-driven allocation model, where the JAT will review all the data inputs needed for the allocation model and verify its output (WHO, 2020b, Jain et al., 2022). The IAVG is established as an independent body to validate the VAD proposal. It comprises technical experts jointly nominated by core COVAX partners, with observers from civil society organisations and representatives of economies participating in the COVAX Facility. Once the VAD has been approved, it is passed to the Office of the COVAX

facility for implementation with support from agencies like UNICEF and the Pan-American Health Organization (PAHO) Revolving Fund (WHO, 2020b).

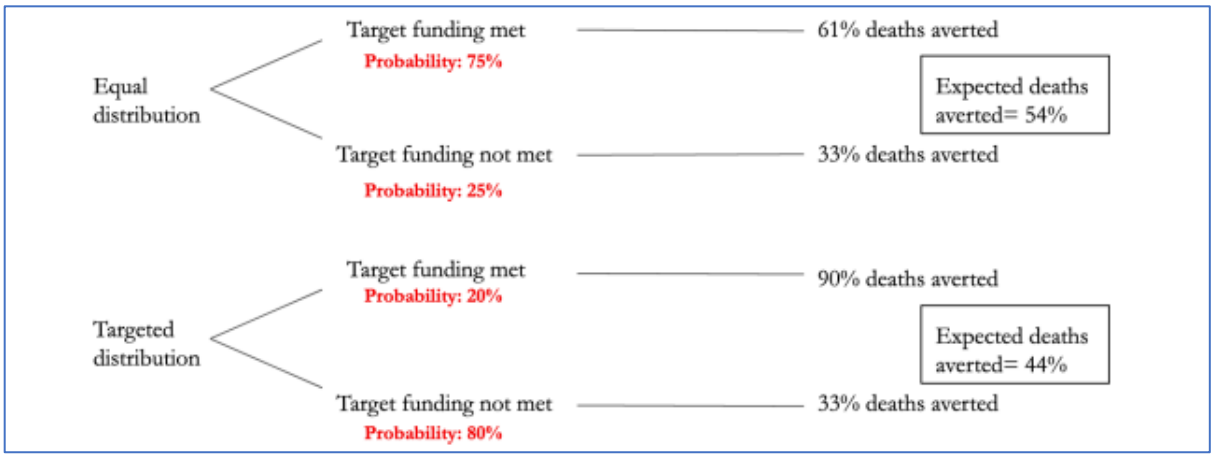
The fairness of the WHO Allocation Mechanism has been criticised, with ethicists arguing that health or well-being maximisation should be considered in resource allocation decisions (Emanuel et al., 2020, Sharma et al., 2021a). However, the WHO secretariat has not endorsed this approach and instead proposed an allocation of vaccines in two equal phases based on guidance from the Strategic Advisory Group of Experts (SAGE) (Sharma et al., 2021a). In phase 1, countries receive vaccine doses in equal proportions to cover up to 20% of their total population (Berkley, 2020). The COVAX Facility accepts this proposal and operationalises this definition (Berkley, 2020, Emanuel et al., 2020). Only in phase 2 (after all, countries have received enough vaccines to cover 20% of their population) does the secretariat suggest proposing a targeted distribution based on the burden of COVID-19 in the country and its health system capacity (Berkley, 2020).

However, those ethicists have argued that this approach does not recognise the significant differences in health outcomes and vaccine access between countries. They explain that a morally justifiable approach to vaccine allocation is to distribute vaccines based on need and propose alternative frameworks such as the Fair Priority Model (Emanuel et al., 2020). The Fair Priority Model has three phases: (1) using standard expected years of lost life (SEYLL) averted per dose of vaccine as the metric for reducing premature deaths; (2) reducing economic and social deprivation by retaining SEYLL as a mortality measure and a proxy for morbidity; (3) prioritising countries with higher transmission rates to facilitate countries' return to full function. Though Emanuel et al. (2020) justify their model based on the fundamentals of equity, Sharma et al. (2021a) point out that this model does not address the political realities of the COVID-19 pandemic. The authors argue "that taking into consideration the realities of a political economy, an equal distribution is justifiable from a wellbeing maximisation perspective as well, given the very real possibility of not attaining signatures to fund the COVAX facility. That is to say, a targeted distribution may lead to many more HICs refusing to sign up to the facility, which ultimately would reduce the number of vaccines that LMICs receive" (Sharma et al., 2021a).

Sharma et al. (2021a) crudely estimated that the current equal distribution model offered a 75% chance that COVAX would attain the required signatories and corresponding funding to

operate successfully. The authors' estimation of possible outcomes, measured by the percentage (%) of deaths averted, is presented in Figure 9. However, as of 2021, COVAX will need substantial additional funding to purchase vaccines. In February 2021, G7 countries, including the UK and US, and "Team Europe" (the European Union (EU) and neighbours including Norway) pledged to donate one billion doses to other countries by June 2022. However, as of February 2022, around 500 million vaccines have been shipped (Loft, 2022).

Figure 9 **Decision-tree estimating the expected deaths averted for proposing an equal or targeted distribution**



Source: Sharma et al. (2021b)

Some have indicated that COVAX has an identity crisis; while it was set up to provide access to COVID-19 vaccines globally, COVAX is viewed as an aid project benefiting LMICs (Lei Ravelo, 2021, de Bengy Puyvallée and Storeng, 2022). Additionally, COVAX's vaccine allocation policy, released in June 2020, puts no restrictions on the ability of self-funded countries to enter into parallel bilateral vaccine purchase agreements (Mcadams et al., 2020). By contrast, if a funded country enters into bilateral agreements to obtain additional doses, it will not receive access to its COVAX share until all other participating countries have taken their 20% shares (Berkley, 2020, Berkley, 2021, Gavi, 2021a). Many advocates have also criticised COVAX for not addressing the issue of free or compulsory licensing (Legge and Kim, 2021, Storeng et al., 2021, Stein, 2021). Waiving intellectual property rights and supporting technology transfers to manufacturers in LICs could help scale up global vaccine supply. Though COVAX doesn't involve itself in addressing the issue of IP rights, the WHO has expressed support for such changes (Lei Ravelo, 2021).

1.3.6 Vaccine nationalism and political barriers to achieving global vaccine equity

Developing and distributing vaccines against EIDs poses technical and financial challenges. Can a safe and effective vaccine even be developed? And will the financial rewards for doing so justify the investment? In a pandemic, additional considerations arise, including the need for speed, the desire by governments to secure adequate supplies for their own population, considerations of global equity (based on the principle that no one is safe until everyone is safe), the distribution of risks and rewards between the private and public sectors, and the technical and political challenges of maximising equitable uptake everywhere (Huzair and Sturdy, 2017).

As of June 2022, 31 COVID-19 vaccines have been approved for use by the WHO or at least one WHO-recognised regulatory authority. WHO has granted nine vaccines Emergency Use Listing (EUL). An additional 97 vaccine candidates are undergoing clinical trials (Basta and Moodie, 2020). Appendix C summarises the characteristics of the approved vaccines. However, as noted above, this is only a first step. Other aspects, in particular ensuring global equity of supply, have been more problematic. The uneven global distribution of COVID-19 vaccines is illustrated in the current divide in vaccine coverage, where HICs have received more than 87% of global vaccine supplies compared to low-income countries with just 0.2% (Peacocke et al., 2021, UN, 2021).

The next, arguably equally challenging task is to distribute them as quickly and efficiently as possible. This will require concerted international action to collect money to purchase them, production capacity to manufacture them, complex logistics to distribute them, and well-functioning health systems to administer them (Hotez et al., 2021, Wouters et al., 2021). All of these are in short supply. The international community has a strong interest in making this work (Bollyky et al., 2020). Despite such investments, the demand for safe, affordable and effective COVID-19 vaccines is expected to exceed supply for a considerable period (Berkley, 2020). The population-level immunity (as opposed to the immediate benefit conferred on the vaccinated individual) can be considered a global public good (Randolph and Barreiro, 2020). Everyone benefits from the reduced circulation of the virus with scope for reintroductions into places where it has been controlled and the risk of harmful mutations. It was estimated by the International Monetary Fund (IMF) that the world economy would shrink by 3.9% in 2020, primarily due to the COVID-19 pandemic (IMF, 2021). In a globalised and

interconnected world, COVID-19 has disrupted global supply chains, transborder flows of goods, services, money, and people-to-people connectivity (Arriola et al., 2020). Those early concerns are, of course, massively magnified by the impact of the war in Ukraine on global supply chains (Uwishema et al., 2022, Choudhary et al., 2022).

As noted previously, herd immunity is a "public good", while disease eradication or global immunity are "global public goods". A public good is non-rivalrous, which means that using it does not diminish its use for anyone else, and it must also be non-excludable, meaning that it should be freely available to all (Stiglitz, 1999, Smith and Mackellar, 2007). Disease eradication meets the criteria of being both non-rivalrous and non-excludable. The eradication of smallpox benefitted everyone. Thus, even though there were no examples of community spread of smallpox in high-income countries for over a decade before it was eradicated, those countries still had to spend considerable sums vaccinating their populations, given the risk of imported cases. However, the drugs and vaccines needed for disease eradication are often both rivalrous and excludable, where their provision is not automatically assured for global populations. For example, they may be subject to supply issues, or their prices may be set too high that low- and middle-income countries cannot afford to buy them.

In April 2020, at the United Nations (UN) General Assembly, countries debated whether there should be a reference to global public goods in the UN resolution "International cooperation to ensure global access to medicines, vaccines and medical equipment to face COVID-19", resulting in a resolution which considered, "the role of extensive immunisation against COVID-19 as a global public good for health in preventing, containing, and stopping transmission to bring the pandemic to an end, once safe, quality, efficacious, effective, accessible and affordable vaccines are available" (UN, 2020). The importance of something being a public good is that, in the absence of deliberate action by someone, a national government or an international coalition, it will be produced in insufficient quantities or not at all, as those who might benefit from it are unwilling or unable to translate their need into effective demand.

Effective demand creation requires that those with the necessary resources are able and willing to direct them to fund the global public good in question (Yamey et al., 2019, Forman et al., 2022). Money is not, however, enough. It is also necessary to ensure capacity to supply what is needed to achieve the global public good. This requires systems to enable high levels

of vaccine uptake to be put in place. These have several components, including those for discovery and development of vaccines, manufacture, and distribution, and those embedded in health systems for their administration (Hotez et al., 2021).

While all these pose challenges, the manufacture and distribution are, at least in theory, the least difficult to resolve technically. However, there are significant political and economic barriers. Countries that have vaccine manufacturing capacities, especially those in LMICs, would need to make full use of the agreed safeguards and flexibilities in the WTO Doha Declaration on the TRIPS and Public Health by temporarily waiving IP rights to share knowledge, data and technologies with poorer countries, so the capacity to produce vaccines is more widespread (Gavi, 2020b). Other routes of knowledge and technology transfer to facilitate access to vaccine technologies include voluntary or negotiated transfer (Eccleston-Turner and Upton, 2021, Peacocke et al., 2021). These can include formal transfer of intellectual property, such as non-exclusive licenses or obligations regarding affordability and accessibility of the final product (Nelsen, 2002, Guebert and Bubela, 2014), or informal transfer mechanisms such as collaborations and informal exchange of knowledge between private, academic and government actors (Etzkowitz and Leydesdorff, 2000, Perkmann et al., 2013, Jahn et al., 2020). Despite this, many European and other countries have maintained their support of IP rights during the pandemic, stating that a waiver would weaken incentives for future drug development (Jit et al., 2021).

In addition to their ongoing support for IP regimes that limit manufacture, many HICs have acted to restrict the equitable distribution of those existing supplies, signing APAs with vaccine manufacturers to ensure that their populations are covered. Vaccine nationalism describes the phenomenon by which individual countries purchase as many vaccine doses as possible by signing APAs with pharmaceutical manufacturers to supply their populations with vaccines before they become available to other countries (Santos Rutschman, 2021b).

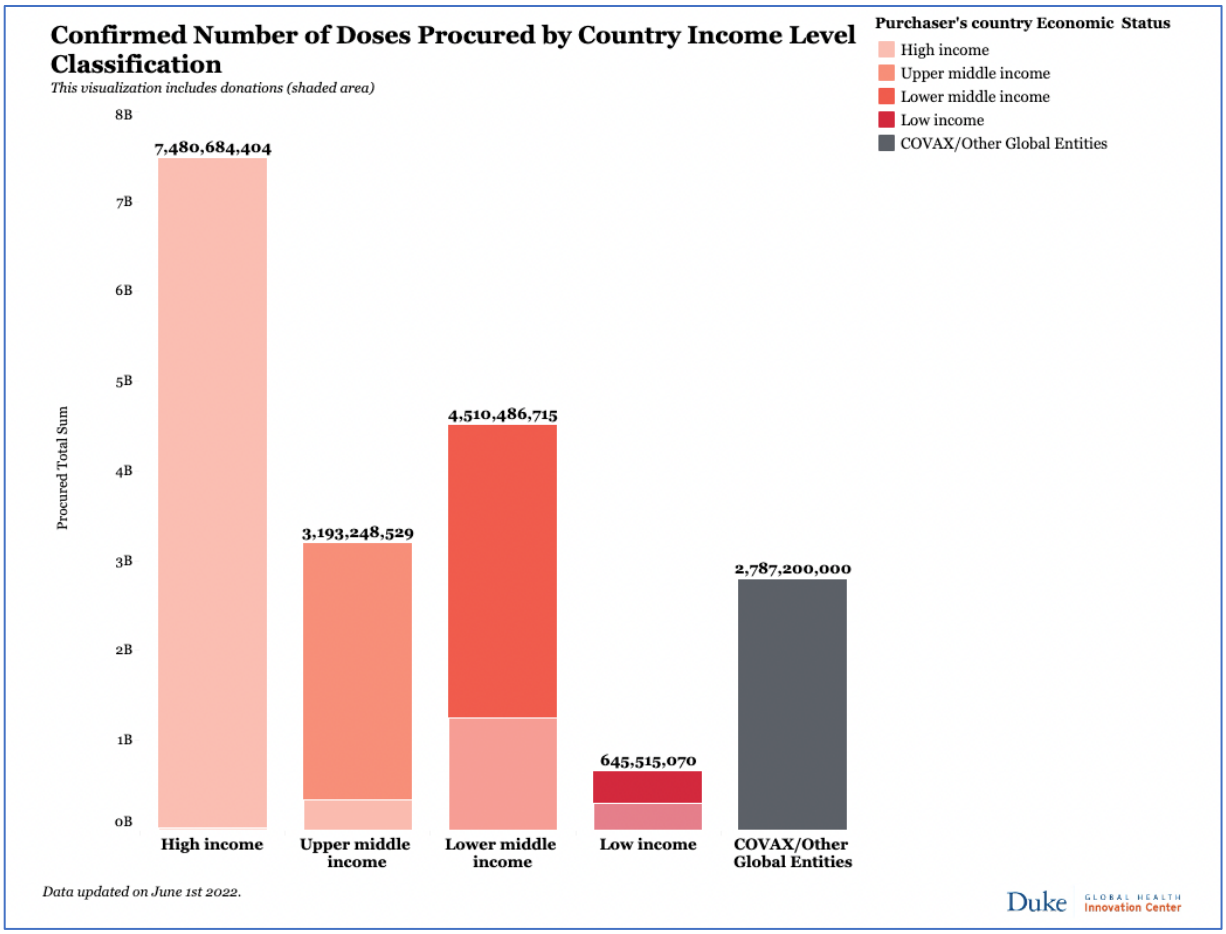
This was seen clearly in the H1N1 pandemic in 2009, where HICs prioritised their national interests as opposed to a more globally coordinated approach (Turner, 2016). The phenomenon of vaccine nationalism has been repeated during the COVID pandemic. As Figure 10 shows, most HICs have negotiated purchases linked to the investment of public research and development funds, leveraging their purchasing power to make deals across a

portfolio of vaccine candidates instead of engaging with global procurement mechanisms such as COVAX. As of November 2020, HICs' confirmed purchases covered 7.4 billion doses, with another 6.3 billion doses currently under negotiation or reserved as options (Kuehn, 2021, Wouters et al., 2021). While bilateral deals between wealthier countries and vaccine producers can positively affect vaccine research and development, they also hinder global cooperation on making the best vaccine candidates available globally (Balfour, 2020).

Such an approach embodies a "my nation first" approach, where each country protects its interest in vaccinating its population (although they may have other interests, for example, related to trade or foreign policy) and competes against others for the initially limited supply of vaccines (Bremmer, 2020). Ultimately vaccine nationalism is embedded in protectionist attitudes, which prioritises their own citizens when it comes to the supply and delivery or COVID-19 vaccines (Schuklenk, 2021). Certain HICs used their wealth to purchase vaccines to vaccinate their populations many times over. For example, Canada purchased approximately 10 vaccine doses per person (Forman et al., 2021). This approach has been portrayed by some as establishing a bias against populations in the Global South, resulting in barriers to access for LMICs and constraining their ability to negotiate favourable vaccine supply arrangements (Riaz et al., 2021, Vanderslott et al., 2021).

Vaccine nationalism has also manifested in countries threatening to issue export bans to safeguard supplies. For example, on 24 March 2021, the European Union reported exporting 10.9 million doses to the UK, but the UK had not reciprocated. The European Commission raised concerns that the UK had an unfair advantage in contracts it signed with vaccine manufacturers, some based in the EU (EC, 2021). As such, EU leaders considered but decided against introducing an export ban. Instead, they called for more transparency from the UK and other countries on the number of doses exported and urged AstraZeneca to deliver what it promised (BBC, 2021). Conversely, in April 2021, India imposed a vaccine export ban to prioritise domestic supplies and deal with a surge of infections domestically (Thakur, 2021). This ban was a setback for COVAX, given its reliance on the SII, where it had contracted SII for at least 200 million doses of AstraZeneca and Novavax vaccines to be delivered to mainly LICs. Accordingly, COVAX informed LIC recipients that orders would be delayed by several months due to delays at the SII.

Figure 10 Confirmed number of doses procured by country income level classification



An additional consideration is the unprecedented public and political scrutiny of these processes, which challenges the traditional secrecy in which many aspects are often shrouded. Some elements of this process are widely viewed as successful when developing vaccines against SARS-CoV-2. The speed of developing and approving several vaccines is seen as an example of successful public-private partnerships. Early in the pandemic, Oxford University set out its intention to donate the rights to the intellectual property related to its COVID-19 vaccine to any drug maker (Hancock, 2021). This would provide medicines preventing or treating COVID-19 at a low cost or free of charge. However, after having conferred with the BMGF, the University reversed its plan and signed an exclusive deal with AstraZeneca giving the pharmaceutical firm sole rights and insisting on no guarantees of low prices. Whether COVAX really receives not-for-profit prices for vaccines could only be assessed if manufacturing costs of COVID-19 vaccines were public knowledge. For example, the Transparency International Global Health report found an extremely low publication rate of COVID-19 vaccine contracts worldwide, with only 6% of contracts being published (Rhodes

et al., 2021). This has significant implications for governments with less negotiating power, contributing to global vaccine inequity, with wealthier countries achieving high vaccination rates and low-middle income countries struggling to vaccinate their populations.

Consequently, in 2021 COVAX pivoted from being a global procurement mechanism to promoting vaccine donation or "dose sharing" as a solution to the inequitable distribution of vaccines, thus positioning itself as a worldwide "vaccine sharing hub" (de Bengy Puyvallée and Storeng, 2022, Gavi, 2020l). This was considered a "win-win" situation, where COVAX would obtain additional doses through donations, HICs would be seen as donors rather than "vaccine hoarders", and the pharmaceutical industry would be able to maintain intellectual property rights and their commercial interests. Pharmaceutical companies protect commercial interests by prioritising deliveries to more profitable markets and by selling full price doses to wealthy countries, who then share or donate unused doses. Donated doses, mainly from HICs, consequently became an essential source of COVAX's vaccine supply in 2021, accounting for 60% of the doses the initiative delivered (543 million out of 910 million) (de Bengy Puyvallée and Storeng, 2022, Holzer et al., 2022). However, this still did not compensate for COVAX's ongoing procurement challenges. A complete list of dose donors and donated doses per manufacturer is included in Appendix G. By the end of 2021, it had delivered less than half of the 2 billion doses it had originally projected (de Bengy Puyvallée and Storeng, 2022). Critics have noted that this pivot has resulted in COVAX, initially, a buyer's club based on global solidarity, being reduced to a charity-based aid project (Stein, 2021, de Bengy Puyvallée and Storeng, 2022). Some critics extend this argument and suggest that COVAX is not only a form of charity but also serves as a smokescreen to mask vaccine nationalism (Hannah et al., 2021), thereby preserving the status quo on existing intellectual property regimes and protecting commercial interests (de Bengy Puyvallée and Storeng, 2022). This argument views donations of products manufactured by companies in the Global North as a means of avoiding any obligation to shift production, and with it transfer of knowledge and technology, to companies in the Global South. These critics point to concerns by the manufacturers that mRNA technology offers great potential beyond vaccines.

1.3.7 Gaps in the literature and study rationale

COVAX adopts a similar funding model as Gavi's pneumococcal vaccine AMC (PCV AMC); however, by contrast, it employs push funding mechanisms by providing financing in the form

of direct catalytic investment in production facilities and pull funding mechanisms by providing volume guarantees for specific COVID-19 vaccine candidates before they are licenced. As the Gavi website states, COVAX provides "volume guarantees for specific candidates before they are licenced, as well as market-wide guarantees, [it], will encourage manufacturers to make investments in production capacity". This, in turn, increases supply availability and reduces the time it takes for licenced vaccines to become available, particularly to the poorest countries around the world" (Berkley, 2020). However, as illustrated in Figure 10, COVAX has not procured sufficient doses of the available COVID-19 vaccines and has encountered funding shortfalls and other political barriers such as vaccine nationalism. Though the AMC model successfully delivered vaccines to specific LMIC populations, its design was flawed where it did not incentivise and support long-term and sustainable vaccine innovations (Chandrasekharan et al., 2015, MSF, 2020). The model crystallises existing limitations within the vaccine innovation system relating to IP, a heavy reliance on the private sector and limited manufacturing capacity in LMICs, all of which are barriers to achieving global COVID-19 vaccine equity (Stein, 2021, Storeng et al., 2021, Boro and Stoll, 2022, de Bengy Puyvallée and Storeng, 2022, Yamey et al., 2022).

Gavi primarily addressed issues affecting children in lower MICs and LICs, as many of the vaccines needed in these regions were already included in immunisation programmes in HICs (Gavi, 2020a). As a result, there was already capacity to produce the vaccines required and where this was not the case, there were mechanisms to allow production to be scaled up (Muraskin, 2002, Muraskin, 2004, Gilchrist and Nanni, 2013). There were challenges with logistics and with the capacity of health systems to deliver vaccines, but these were being addressed, to a greater or lesser extent, in other ways (Hardon and Blume, 2005). HICs' involvement with Gavi was primarily as funders, where financing was channelled towards the health sectors of MICs and LICs to meet the health needs of poorer populations (McCoy et al., 2009).

The situation with COVAX is different. While money is still a limiting factor, there are other constraints this time. Though the AMC model has been reappropriated and redesigned in the COVAX Facility to respond to the COVID-19 pandemic, it has not achieved its goals, and vast global disparities in access remain (MSF, 2020, Stein, 2021). HICs have resorted to prioritising the health of their citizens, given the limited global vaccine supply resulting from the

concentrated state of vaccine manufacturing capacity (Beaton et al., 2021, Wouters et al., 2021). Put simply; the world is not yet able to produce enough vaccines for everyone. This means that countries with the most power, however that is manifest, will compete for access and determine who can acquire the vaccines. They can do this in several ways. They can decide whether they will support global efforts to increase production and distribution, or they can place export bans on them or some combination of these approaches. Additionally, countries may also use the supply of vaccines for political influence.

Public-private collaborations are a mechanism for addressing global health challenges and have become the blueprint for international cooperation during the COVID-19 pandemic. To fully understand the role of GHP initiatives in addressing global health needs and access to vaccines, I undertook a scoping review of the literature described in the next chapter. The scoping review aimed to summarise the evidence on GHPs, the success of previous initiatives and how COVAX might learn from this evidence. It also describes the changing global health governance landscape and whether the current vaccine ecosystem, which prioritises private sector interests, is conducive to achieving global vaccine equity.

1.4 Thesis overview

1.4.1 Aim and objectives

This thesis aims to determine whether COVAX can reach its goal of achieving global COVID-19 vaccine equity by comparing the successes and failures of previous global health partnerships to attain global immunisation goals and investigating whether these lessons were incorporated into COVAX's initial design.

My objectives are to:

1. map previous global immunisation mandates and the role of global health partnerships in achieving these goals through a scoping review of the literature;
2. determine whether/how COVAX is a departure from previous partnership models through a case study of its governance structure;
3. discuss potential factors affecting COVAX's ability to achieve its intended goal of global vaccine equity using relevant theoretical concepts.

1.4.2 Thesis structure

This thesis is submitted for examination within the Doctor of Public Health (DrPH) programme at the London School of Hygiene and Tropical Medicine (LSHTM). Requirements for DrPH theses differ from those of the PhD programme at LSHTM, which mirror those of similar programmes widely offered at other United Kingdom (UK) universities. As with the PhD programme, an original contribution to knowledge is the critical requirement for the award of the DrPH. However, DrPH theses are around half the length of a PhD, meaning that their scope is more limited in terms of the breadth, if not the depth, of the analysis presented. The overarching structure of this thesis is a 'book style', whereby a single narrative is presented throughout all chapters, versus the 'publication' style thesis in which the results and discussion chapters are structured as a series of discrete articles written and formatted for direct submission to scholarly journals.

Chapter 2 describes the mixed methods employed to generate data: scoping literature review, document review and key informant interviews. Interviews were transcribed verbatim, and data were subjected to detailed thematic analysis. A document analysis of COVAX was conducted, where the document analysis followed the READ framework (Dalglish et al., 2020). This chapter also outlines the theoretical approaches and conceptual lens adopted. This chapter describes the epistemological position that informs the study and outlines this thesis's theoretical approach. It also describes the theoretical frameworks chosen to guide and analyse the data generated.

Chapter 3 presents the results of the scoping review of the literature.

Chapter 4 comprises the results of the case study of COVAX, using document review and key informant interviews.

Finally, Chapter 5 reflects on the findings and how they interact with existing literature. It describes the study's strengths and limitations, the originality of this research, and its contribution to knowledge. The conclusion reflects on the implications of this research for a policy concerning developing guidelines for achieving vaccine equity and improving the COVAX Facility.

1.5 Summary

This chapter has provided an outline of the thesis by introducing the context for this research and summarising the situation with the COVID-19 pandemic. I briefly described the use of vaccines in limiting the spread of infectious diseases, including details of different vaccine technologies and the core fundamentals of the vaccine ecosystem, which considers the vaccine innovation system by looking at the role of public-private partnerships and the use of push and pull mechanisms to address market failure. Describing these dynamics and how tensions are recognised and resolved, where possible, has been a reflective exercise to ground this thesis in the realities of the research milieu and the challenges encountered. This includes the launch of GHPs such as Gavi and initiatives such as COVAX.

Sections 1.2.2 and 1.2.3 of this chapter examines the use of GHPs and their preferred tools for incentivising private participation in global health decision-making and policy processes. It has explained the essential functions of vaccine R&D by describing the usage of push and pull mechanisms resulting from market failure, the usage of AMCs and reasons why they are used to address global health challenges of vaccinating LMIC populations with limited market return for vaccine manufacturers. This background information adds context to the thesis' aim, objectives, and primary research questions. Following this, I provided a thesis overview, consisting of the scope and structure of the thesis.

The following chapter discusses the methods used in this study, providing details on the tools used to conduct a scoping review of literature, document review and key informant interviews.

Chapter 2 Methodology

2.1 Overview

This chapter presents an overview of my theory and methods. I begin with an outline of the study design (2.2), which includes details of ontological and epistemological underpinnings, disciplinary approach, and bodies of literature I drew from (i.e., global health, international relations). Section 2.3 presents the thesis' main research questions, which considers the role of global health partnerships in achieving global immunisation mandates and whether lessons learnt were incorporated into COVAX's design. To answer these questions, I draw on constructivist international relations theoretical and methodological approaches and I present details of my theoretical stance in section 2.4.1 and framework by Rushton and Williams (2012) in section 2.4.2. Next, I describe in detail the methods (2.6) I use in each part of the thesis and how they will help me answer each of my research questions, including the collection (2.6.1-5), data analysis (2.7) and management (2.8). I then discuss reflexivity (2.9) and ethical considerations (2.10).

2.2 Study design

I chose an exploratory single case study design, using qualitative methods with a constructivist international relations lens. This combines rigour with the flexibility to allow me to explore how actors interpret reality while incorporating self-reflection about possible bias and any assumptions I may make, while enabling me to address potential limitations. I selected an exploratory case study design because it can capture the complexities of the policy process and effectively highlights the interdependencies among different groups and social processes. Yin (2013) defines a case as a "contemporary phenomenon within its real-life context" and a case study as an empirical research strategy to investigate the case or cases conforming to this definition by addressing the "how" and "why" questions concerning the phenomenon of interest. Unlike other research strategies such as surveys or experiments, case study research goes beyond the study of isolated variables, where case study data comes from multiple, and not singular, sources of evidence (Yin, 2013). This approach does not require applying a pre-specified theoretical framework before analysis.

I draw on a scoping review of relevant literature, document reviews, and semi-structured interviews with academics, policymakers and logistics experts who are key informants involved in COVAX planning and delivery. Given the limited word count of the thesis, I focus on the COVAX Facility, focusing on its governance structures and decision-making processes. I chose a single case study, focusing on COVAX Facility's governance structure and decision-making processes as my unit of analysis, as I sought to understand how identities, interests, and norms have shaped what COVAX has and has not done. By focusing on the COVAX Facility, I can gain insights related to the function of global health partnerships during health emergencies, their institutional design and how this influences engagement with issues related to vaccine nationalism, intellectual property waivers, risk-sharing agreements, and the role of donor countries in such initiatives during a pandemic. I examine the core issues of COVAX's governance and the relationship between global health actors during the pandemic.

This study is informed by a constructivist ontology and epistemology, which refers to knowledge being constructed through the interaction of the researcher and the research environment (Appleton and King, 2002). It draws on an interpretive (i.e., qualitative) approach to policymaking, which seeks to understand how policy is interpreted and put into practice and is therefore helpful in understanding the embodied practices of global health policy implementation (Smith-Merry and Gillespie, 2016). I wanted to understand phenomena throughout the social world, to achieve a sense of consensus of meaning based on various constructions through a continual process of interpersonal communication and of negotiation (Berger and Luckmann, 1967). No researcher can evaluate phenomena from a purely objective and neutral position, as they are embedded within their social context. This approach does not reject conflicting constructions of reality, where contextual elements, such as historical and positional factors, are essential considerations and does not mean that methodological standards do not apply. Thus, researchers should not "cherry-pick" findings to support their assumptions. Using reflexivity and triangulation or crystallisation, researchers become consciously aware of their own positionality and produce plausible accounts of social realities based on multiple data sources analysed. The accounts of social objects, and the supporting evidence produced by researchers, made open to scrutiny by the relevant community of scholars to evaluate, are in line with the established norms of peer review (Kelly et al., 2014, Horbach and Halffman, 2018).

I use qualitative (interpretivist) methods to allow exploration of complex interdependencies between the policy process and actors in global health partnerships. The combination of different qualitative methods contributes to a better understanding of a research problem, in contrast to research that uses only one methodological approach (Creswell, 2014, Mik-Meyer, 2020). My chosen qualitative methods all adopt the same epistemological perspective to strengthen the quality of the research, as different methods allow for different angles and nuances to be visible. Indeed, qualitative studies' research design is an iterative process and requires the researcher to refine methods and approaches in response to emerging data and other developments within the research process (Green and Thorogood, 2004). The data generated from other sources helped to either corroborate or identify divergences between what participants said and what organisational documents stated.

My use of constructivist international relations theory allowed me to explore the roles and influence of global actors in formulating norms and principles in international politics and what this means for global health partnerships such as COVAX to strengthen global vaccine governance and policy coordination. Specifically, this theory considers how ideas, agency, and structure have influenced the policy cycle. This approach allowed me to explore how norms shape international relations and, subsequently, global health policymaking and the creation of COVAX. This multi-perspective analysis highlights several issues related to global health, such as the dynamic relationship between public and private sector actors, including how they promulgate specific ideas to support their individual interests and policy positions. This leads me to ask whether it is possible for global health partnerships such as COVAX to achieve global vaccine equity and, accordingly, to propose specific policy reforms.

2.3 Research questions

My research questions are as follows:

1. What lessons can we learn from previous experiences with vaccine global health partnerships?
2. To what extent were those lessons learnt, or not learnt, when creating COVAX and what might explain this?

2.4 Theoretical stance and framework

2.4.1 Constructivist international relations theory

COVID-19, like any pandemic, is a clear example of a situation where it will be necessary for the countries of the world to work together to find a solution (Davies and Wenham, 2020). However, governments do not always act in what might be seen as their best interest (Kluge et al., 2018). To answer the question at the centre of this study, it is necessary to consider the large body of scholarship in international relations that examines how countries do or do not work together. Paradigms of international relations theory (IRT) help us understand why states fail to cooperate in the pursuit of common interests (Johnson, 2020). IRT's intellectual tools have important practical implications which could help explain states' policy responses to the COVID-19 pandemic, shape expectations about the degree of international cooperation that can be expected, and suggest ways to craft pragmatic policies to address such realities (Basrur and Kliem, 2021). Within IRT, Realism is a theory which asserts that states are inherently self-motivated and cannot rely on others to protect them (Paxton and Youde, 2018). As a result, states exercise constant vigilance and put their needs above others.

In the COVID-19 pandemic, many governments did not feel they could rely on other countries or intergovernmental organisations (IGOs), exemplified by the dispute between the UK and EU over vaccine supplies, or countries opting for APAs with vaccine manufacturers instead of procurement via COVAX. All countries working together should represent the best outcome; however, due to the allure of the self and short-term interests, most countries did not cooperate, thus leading to prolonged pandemic conditions. IRT scholars suggest delegation and socialisation as potential solutions to the prisoner's dilemma, where governments can either commit to collective goals (socialisation) or endure immediate pain to achieve future gain (delegation) (Mcadams et al., 2020). The classic game theory problem known as "the prisoner's dilemma", is where two rational individuals do not cooperate and, instead, resort to betraying the other as it appears to offer a greater reward (Mcadams et al., 2020). However, it may seem evident to a third party outside the game that working together would be in the best interest of the prisoners and could potentially result in a better outcome for both. However, both solutions have been inadequate for several reasons. Socialisation has not been successful due to political factors such as populist unrest, financial crises, Brexit, or

the securitisation of global health, which have undermined group identities and norms (Johnson, 2020). Such political factors manifest in many ways, such as nationalism, globalism or protectionism rather than economic liberalisation (Bearce and Jolliff Scott, 2019). Delegation has also not been possible given the lack of authority in global health governance and various power dynamics between different actors, where the WHO has not been given full authority to coordinate global responses to the virus. Despite the WHO declaring a PHEIC in January 2020, many countries prioritised their economies, while others entered lockdowns as advocated by public health experts.

IRT research helps us understand different ways governments behave, especially in relation to IGOs such as the WHO. For example, research on bureaucracy and institutional design examines the challenges in making IGOs accountable while insulated from inappropriate pressure from member states (Johnson, 2020). Research on delegation and socialisation reveals how governments prioritise short and long-term interests (Johnson, 2020).

IRT makes positivist and post-positivist assumptions. Positivists aim to emulate empiricism, whereas post-positivists recognise knowledge as socially conditioned and adopt qualitative research methods. Constructivist IRT emphasises the importance of norms, identities, and interests in international politics. Indeed, constructivism is an approach in international relations that brings together scholars with various ontological preferences such as realist or state-centric perspectives. The realist perspective explains states' protectionist responses to the COVID-19 pandemic, such as APAs, border closures or trade and travel restrictions, as rational and it positions international organisations, like the WHO, as lacking the power to compel states to take specific action. In comparison with the systems innovation perspective, realism stresses that states possess the most influence and dismisses the influence of non-state actors (such as private sector actors) as ephemeral or a result of states ceding power to them (and may also withdraw it) (Price-Smith, 2009).

I rejected the Realist perspective because it does not engage sufficiently with the influence of non-state actors, such as civil society organisations, charities, philanthropic foundations or corporate companies, and their roles in influencing global health policy. Omitting such actors from health policy analysis obscures important power dynamics and the reasons for the policy choices of some governments (Stoeva, 2016). For example, philanthropic organisations have been shown to influence national health systems and shift the direction of domestic politics

and policies by virtue of their support of specific health programmes (i.e., The Rockefeller Foundation and Ford Foundation's support of vertical disease programmes in the late 1970s) (Van Olmen et al., 2012). State and non-state actors will therefore exert power and influence to pursue strategies of norm generation, sometimes shaping them for "good" or "bad" (Sell and Prakash, 2004, Davies et al., 2015). This is particularly prominent when there are emergencies such as COVID-19, where actors with material resources may change their own definitions of national interests or alter their views on well-ingrained existing norms.

Norms serve the purpose of guiding behaviour by providing motivations for action, which can emanate and evolve overtime (Björkdahl, 2002). Norms are defined as, "the extent of collective expectations related to a principled idea" (Katzenstein, 1996), where norm strength is defined as, "the extent of collective expectations related to a principled idea" (Ben-Josef Hirsch and Dixon, 2021). Norms also have a prominent role in international politics, where different actors may employ them differently to achieve specific goals. For example, weak actors, with material deficiencies, can also employ norms as instruments of persuasion to make demands or claims (Keck and Sikkink, 1998).

Finnemore and Sikkink (1998) conceptualise the norm cycle and theorise change processes which consider how norm gains strength. Here, the authors argue that norms evolve in a three stage "life cycle" of emergence, followed by "norm cascades" and finally, "internalisation". Each stage is influenced by different motives, mechanisms and behavioural logics (Finnemore and Sikkink, 1998). The authors go on argue that the possibility for a norm cascade can be influenced by "institutionalisation" (Finnemore and Sikkink, 1998), which refers to the degree to which an idea is codified in international law and ratified by eligible states (Sandholtz, 2008). Institutionalisation likely reflects the strengthening of a norm, by explicitly stating what a norm is and what constitutes a violation (Bower, 2019, Brunnée and Toope, 2019). Given the absence of global government, multilateral networks and supranational arrangements between states have led to the institutionalisation of global governance arrangements (Nagel, 2005, Van de Pas et al., 2017). Some argue that the emerging global institutions prioritise donor interests (both state and non-state), thus distorting distributive justice (Stuckler et al., 2011).

For example, contrary to the norms embodied in the IHRs, many states did not heed WHO recommendations when COVID-19 was declared a PHEIC. As per the IHRs, the agency

recommended that borders remain open and advised that lockdowns should not be the primary containment mode. Instead, states should opt for coordinated national testing, contact tracing, and surveillance programs. Such recommendations rest on the fundamentals of international cooperation. Instead, states adopted “bad” norms such as vaccine nationalism to ensure vaccine access for their populations first. Instead, existing, or “good” norms of ensuring equitable global access to a vaccine were ignored until recent commitments made by G7 countries in June 2021. In June 2021, G7 countries (Canada, France, Germany, Italy, Japan, the UK, and USA) and the EU committed to the Carbis Bay Declaration (Wintour et al., 2021). In a joint statement, G7 countries pledged to secure approximately 1 billion doses by donating surplus supplies or providing further finance to COVAX. Within the G7 pledge, the UK committed to donating 100 million doses by June 2022, where 80% would be distributed through COVAX. As of December 2021, only 26.02 million doses of the Oxford-AstraZeneca vaccines had been delivered to COVAX by the UK (BBC, 2021).

In summary, understanding the social conditions and systems in which actors find themselves provides new ways of understanding how states and international organisations behave, what characterises their relations and the varied forms of power they wield (Rushton and Williams, 2012). Interpretive approaches to IRT studies emerged in contrast to rationalist and structuralist perspectives to IRT, where human and state behaviour were largely understood as driven by structurally defined material imperatives of the international system of states. In this study, the policy context in question is complex and influenced by various actors with varying levels of power. Vaccine research, development and delivery is a highly contested area, and the involvement of public and private actors has been the subject of much criticism from public health actors.

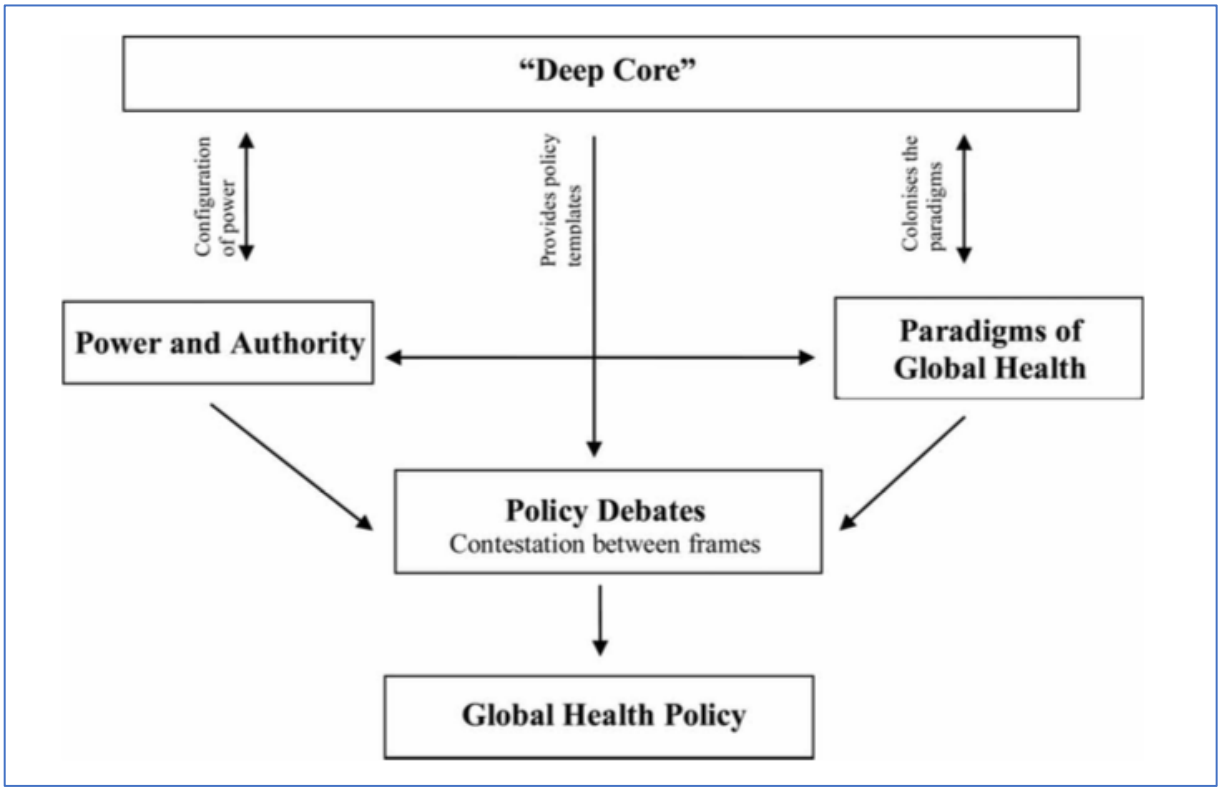
In selecting this theoretical stance, I also considered other political theories, such as cosmopolitanism or internationalism, which assert that all people, irrespective of their citizenship status, are entitled to equal respect and consideration (Wenham et al., 2022). More specifically, this view conceptualises the universal community in terms of political institutions to be shared and open to all in terms of cultural expressions and economic markets. Though this theory would be useful in terms of conceptualising vaccines as a global public good (Stiglitz, 1999, Gavi, 2020b), to be shared and accessed by all, this theory does not adequately explain the political realities witnessed during the COVID-19 pandemic,

relating to the role of non-state actors, the current vaccine innovation system, or states exhibiting protectionist attitudes (Jit et al., 2021). I consider this theory largely prescriptive and idealistic and do not see it as applicable to this study.

2.4.2 Theoretical framework

This study uses an IRT-inspired theoretical framework of the processes through which global health policy is made (Rushton and Williams, 2012). The framework's approach to global health governance is compatible with my constructivist international relations theoretical and methodological approaches to examining the COVAX Facility. This framework will be applied to understand the structural factors that may influence its ability to achieve specific goals. This framework recognises the role of various actors in policymaking, which applies to my examination of GHPs, and the numerous actors involved in the vaccine ecosystem. Much of the existing literature has identified a range of factors which explain the "failure" of global health governance. Still, it does not sufficiently engage with the global health policy processes perpetuating this failure. The proposed framework, shown in Figure 11, analyses the processes through which global health policy is made, highlighting the mixture of power and ideas, agency, and structure, which impact the policy cycle. This framework will be used to understand deeper structural determinants that may be preventing COVAX from achieving the goal of global vaccine equity or whether this goal is possible under core neoliberal influences and will structure study discussion and recommendations.

Figure 11 Framework for analysing global health policymaking



Source: (Rushton and Williams, 2012)

The framework recognises concepts relating to the emergence of global health governance over recent years, its link to globalisation, and how global policies, processes and institutions address health problems. For example, new institutions have been created, and bodies such as the G7 or the World Bank have added health to their agendas. GHPs have emerged, and non-state actors, such as the Gates Foundation or international NGOs, have increased influence on global health policymaking processes. This reshaping of the global health architecture has contributed increased resources for global health and the emergence of health as a matter of "high politics" (Fidler, 2009). Though these responses have been expected to improve responses to ongoing global health issues, such as access to health technologies or the health needs of the poor, it is widely accepted that the failure to generate adequate responses persists. This framework also acknowledges that global health policy is rooted in material and ideational drivers. Accordingly, the authors indicate that how proposed policies are "framed" is central to explaining how consensus is built around certain policy choices (Rushton and Williams, 2012). Consequently, certain "frames" remain persuasive, where an actor or policy entrepreneur connects with a deeper set of paradigms that form the

ideational underpinnings of global health governance. These paradigms influence how actors think or speak about global health problems. By framing a particular issue, actors draw on these deeper paradigms to identify a problem and propose a concrete policy solution. In response, actors are engaged in a policy debate, forwarding alternative framings, and a process of contestation ensues.

Yet the global health "arena" where these policy debates occur is not equally balanced. The power or authority of certain actors influences outcomes. As Rushton and Williams write, "as well as material power, policy debates in global health are also structured by deeply embedded ideas dominant in the contemporary global political environment, often referred to in the public policy literature as a 'deep core' (Rushton and Williams, 2012). As discussed in the scoping review, the rise of neoliberal approaches has influenced global health governance extensively, leading to the rise of GHPs and market approaches to solving global health problems.

Rushton and Williams (2012) define global health policy as "those policies, both formal and informal, adopted on either an international or domestic level that respond to or affect health". In this definition, they take a maximalist understanding of global health policy and recognise its various applications, whether "top-down", referring to the transmission of policies from international organisations to national health systems (Schiller et al., 2009), or "bottom-up", referring to "the ways in which globalisation may be impacting on health policy, and alternatively what health policies are needed to respond to the challenges raised by the globalising processes" (Lee et al., 2001).

Acknowledging policy as both top-down and bottom-up incorporates a wide range of actors and outputs, both formal and informal, involving both the influence of non-health and health policies on global health. Some outputs include formal national policies (i.e., PEPFAR – a national policy instrument addressing the global HIV/AIDS pandemic), formal international laws, rules, and standards which either directly (i.e., International Health Regulations) or indirectly address global health issues (i.e., structural adjustment). Informal outputs include national principles and norms; these are often culturally specific (i.e., the US culture of large-scale philanthropism) or international principles and norms (i.e., the expectation that wealthy countries will provide poorer countries with health development assistance). Given the wide range of actors with the capacity to produce policy at the global level, there have been few

attempts to build a framework to analyse its production, particularly given the fact that despite some individual institutions having clear policymaking mandates (i.e., the World Health Assembly), there is no overarching authority between institutions and actors.

Rushton and Williams' (2012) framework rests on four pillars: framing, paradigms, power and the "deep core". Frames refer to the linguistic, cognitive, and symbolic devices used to identify, label, describe and interpret problems. Global health governance actors strategically employ different frames to "fix meaning, organise experience, alert others that their interests and possibly their identities are at stake" and propose solutions to ongoing problems accordingly. When such actors succeed, the chosen frame resonates with public understandings, or deeper paradigms, and is adopted as new ways of discussing and understanding issues.

The likelihood of a frame successfully persuading an audience rest on several considerations, such as the identity of the policy entrepreneur, where powerful or authoritative actors are more likely to be successful in persuading an audience. Another is the degree to which the chosen frame resonates with shared commitments to the deeper paradigms and the applicability of that paradigm to the issue at hand. Many global health issues can be framed in more ways than one, and consensus between actors is not always achieved.

Paradigms lie in the cognitive background of policy processes and are the "underlying theoretical and ontological assumptions about how the world works". Actors' understanding of the world is influenced by paradigms. Other scholars, such as Sabatier, have coined the "policy core" to denote much the same thing (Sabatier, 1988, Jenkins-Smith et al., 2014). In contemporary global health, several powerful paradigms embody specific assumptions, norms, values, and understandings that are historically and structurally embedded and widely diffused. Some examples of paradigms include biomedicine, drawing from the western medical tradition and positivist scientific research, prevention, and intervention at the level of the individual patient, or human rights, referring to the normative stance recognising individual and community rights and the consequential obligation on others to protect those rights.

Ultimately framing, whether successfully or unsuccessfully, is affected by power. This does not mean that framing is a Habermasian "ideal speech" scenario, where the best argument wins; instead, outcomes in global health governance are determined by the persuasiveness

of a particular frame and by who is advancing this frame. Power is therefore exercised according to and in pursuit of particular ideas. There are different kinds of power to consider, such as material power, referring to economic resources for example. In extreme cases, material power (or coercion, which Barnett and Duvall refer to as “compulsory power”) is exercised either publicly or behind the scenes and can determine policy outcomes. For example, Rushton and Williams (2012) note that the American pharmaceutical industry and other knowledge-producing corporations developed the framework for the TRIPS agreement that was included in the Uruguay Round of the WTO between 1986 and 1994. It was imposed on LMICs by a combination of “trade weight” and carrot and stick measures, reflecting the exercise of “hard power”. However, it is rare for coercion alone to explain outcomes in global health governance as materially powerful actors frame their proposed governance responses in a way acceptable to others.

Other forms include authority that accrues to actors in certain influential positions. This authority results from expertise developed over time, where the bureaucracies of international organisations can use “discursive and institutional resources to induce others to defer to their judgement” (Barnett and Finnemore, 2004). Another example of influential actors includes epistemic communities, such as the global biomedical community, where they can advance specific framings within certain institutional settings. The biomedical community wields much “soft power” regarding its ability to persuade, argue for, and justify specific approaches and solutions to global health issues. The institutional culture of biomedicalism in various global international organisations and NGOs led to the framing health policies in biomedical terms, ultimately influencing such policies' implementation and outcomes.

Power also determines the institutional contexts within which policy cycles take place and the different combinations of policy actors involved. The extent to which an actor can engage in a policy process is a product of their position within the global health governance structure. Accordingly, this may result in “regime shifting”, whereby state and nonstate actors relocate rule-making processes to international venues whose mandates and priorities favour their ideas and interests. This is apparent in how American and European communities have shifted negotiations over the intellectual property regime from the World Intellectual Property Organization (WIPO) to the WTO and have continued to deploy this strategy regarding global intellectual property regimes.

Global policymaking processes are structured by the "deep core" of neoliberalism. This refers to the "highest level, the deep core of the shared belief system includes basic ontological and normative beliefs, which operate across virtually all policy domains" (Sabatier, 1988). Though the paradigms of global health identified above operate across global health governance, the deep core operates in many, if not all, areas of global governance. Within the context of global health governance, neoliberalism has its roots in a wider project at least three decades old, in which health and health policy have been subjected to the deployment and privileging of market-based policy responses, to the commodification, privatisation, liberalisation of health and healthcare, and the individualisation of risk and responsibility for health. Additionally, there has been a deliberate diffusion of authority away from states and multilateral organisations, not least to private and public-private actors such as health partnerships or foundations. Notwithstanding, neoliberalism is polymorphous as an ideology; it remains identifiable as a coherent project that continues to dominate social and political life.

Rushton and Williams (2012) contend that neoliberalism is considered to have shaped contemporary global health policy in three ways. First, it has changed the distribution of power and authority by rolling back state involvement in health whilst also diffusing authority across a broader range of public and private actors. The private sector has assumed a greater role in global health governance. This includes the appeal to markets as the most efficient mechanism for allocating health resources. Second, neoliberalism also structures global health governance by embodying a series of policy preferences. The most common is the promotion of liberalised and privatised health systems, a trend that is having significant global effects on the ability of people to access health services. Lastly, neoliberalism colonises many of the global health paradigms, for example, its relationship with biomedicine. Together, they emphasise individuals as autonomous and rational consumers who are ultimately responsible for their risk behaviours and wellbeing. Individuals and patients are considered to be rational economic actors.

Consequently, neoliberalism limits what is, "sayable, doable, and thinkable in global health governance" (Rushton and Williams, 2012). The range of arguments which can be legitimately advanced is limited. The structuring logic of neoliberalism exacerbates economic and health inequalities and limits the range of likely responses to global health problems. As such, many of the recent global health initiatives have not sought to challenge neoliberal global

governance. However, this does not mean there is no possibility of forwarding counter-hegemonic critical discourses; instead, there remains the possibility for change in global health governance.

To further understand the relationship between the pillars and operationalise the framework, (Rushton and Williams (2012) propose a series of questions provided in Appendix H. These questions informed my data collection for the document review and my interview guide. Finally, the framework also influenced analysis, with findings grouped by "global health policy", "policy debates", and "paradigms in of global health", and my discussion chapter, where I discuss the configuration of power and "power and authority" and the influence of the "deep core" in policy outcomes.

2.5 Study site

Documents and key informants who provided internal or external knowledge of COVAX and other key state and non-state actors were collected from wherever they could be found. Thus, my study site was the global health space, and my focus was on macro governance structures. Global governance refers to "the actions and means adopted by a society to promote collective action and deliver collective solutions in pursuit of common goals" (Dodgson et al., 2017). This differs from what takes place at the national level, where the "actions and means adopted" to deliver solutions in the pursuit of specific goals are identified and implemented by the state. To achieve this, the state has a formal system of rules within which governance takes place. These rules are also a means of reconciling the various interests of different groups. Conversely, at the global level, there is no formal authority to create and enforce a system within which policies are made. Global governance is therefore considered to have anarchic elements where the rules within which policies are made are much less clear and often contested (Basrur and Kliem, 2021, Johnson, 2020, Stoeva, 2016).

Since the 1990s, the private sector and GHPs have become increasingly involved in global health governance (Stevenson, 2017, Stevenson and Youde, 2021). This phenomenon has been observable in various policy fields, such as CEPI in vaccine R&D, the Global Reporting Initiative in global financial governance and the Forest Stewardship Council in global environmental governance. To describe this phenomenon, scholars from the disciplines of political science and international relations have coined the term "private governance", which

“emphasises the role of private actors, both profit and non-profit, in the establishment and maintenance of issue-specific transnational rule systems […] private governance could be understood as a functional equivalent to public forms of global governance involving states and intergovernmental institutions” (Pattberg, 2005).

The emergence of private governance in global health policymaking highlights a shift in thinking about governance, mainly occurring between individual states, in bilateral or multilateral settings. This meant that governance occurred primarily in international rather than national levels. International health governance emerged as a response to cross-border movements of infectious diseases such as cholera epidemics and was the dominant approach to health governance until the 19th century (Lee and Kamradt-Scott, 2014). However, globalisation challenged this assumption, as it increased population mobility and created a need for monitoring and control that state institutions, such as Ministries of Health (MoH), alone could not provide. Globalisation refers to the growth of ‘supraterritorial’ relations between people ... a far-reaching change in the nature of social space” (Scholte, 2017). During this time, advancing information technologies also equipped private organisations with the capacity to provide valuable assistance and support to states. The shift from international to global indicates that governance no longer occurs exclusively at an inter-state level but now increasingly at the trans-state level (McKee and Greer, 2021). Consequently, this means that organisations such as non-governmental organisations (NGOs), philanthropic foundations and corporations which operate in different countries are entering into partnerships with foreign states or organisations from other countries.

Globalisation's effects also contributed to disease outbreaks in the 1990s and 2000s, thus prompting the WHO to consider establishing governance arrangements for public health beyond the state level (Lee and Kamradt-Scott, 2014). Many LMICs had limited capacity to respond to outbreaks or were hesitant to report outbreaks for fear of disrupting international trade relations. The WHO formed the Global Outbreak Alert and Response Network to identify and respond to emerging epidemics. This network comprises technical and public health organisations, NGOs, governmental and inter-governmental organisations (Mackenzie et al., 2014). In this and other ways, governments have increased international collaboration, often involving private organisations in decision-making and implementation.

Globalisation is intimately linked to shifts in patterns of knowledge, production, governance, identity and how people relate to nature. It also affects the power and activities of the state, as well as the manifestations and strength of nationalism. The dominant form of globalisation is neoliberal globalisation. Neoliberal policy approaches adopt an economistic worldview, which regards globalisation as an economic process relating to the production, exchange, and consumption of resources (Scholte, 2005, Scholte, 2017). Consequently, cultural, ecological, geographical, political, and psychological aspects of globality are generally approached as functions of, and subordinate to, economics, if they are considered at all. Neoliberal policies have reinforced apolitical technocratic approaches to solving many global health issues, particularly with the involvement and support of private sector actors (McGregor, 2001, Ruckert and Labonté, 2014).

The COVID-19 pandemic has illustrated what happens when countries pursue neoliberal policies, such as the protectionist or nationalistic approaches seen when managing COVID-19 outbreaks or procuring vaccines. Governments have resorted to border closures, APAs with vaccine manufacturers, and implemented national lockdowns, contrary to WHO guidelines (Alwan et al., 2020). The governments of the UK and the USA worked closely with vaccine manufacturers to develop COVID-19 vaccine candidates. COVID-19 vaccine developers have received approximately US$10 billion in public and non-profit funding for their vaccine candidates. However, this number is probably underestimated, given the scarcity of data on some of these projects (Sampat and Shadlen, 2021, Wouters et al., 2021). For example, the USA's BARDA funded basic research and clinical trials, supported manufacturing capacity expansion, and scaled up production. This was a high risk as there was no guarantee that the candidates would prove effective and gain regulatory approval. Many of BARDA's vaccine contracts with individual vaccine candidates also included APAs, to secure advance access to successful vaccines. In COVID-19, procurement arrangements with governments replaced traditional pull incentives from patents for major private companies (Sampat and Shadlen, 2021). In doing so, HICs have been able to secure and administer many more doses to their populations than LMICs. GHP initiatives such as COVAX have been unable to compete with national arrangements, suffering underfunding and facing limited vaccine supplies. However, it is necessary to understand how such initiatives play a role in achieving global vaccine equity and what can be done to improve the fair allocation of COVID-19 vaccines.

2.6 Data collection

Data were collected from literature, document, and interview sources. Triangulation among data sources helped to either corroborate findings or identify cleavages between what interview participants said and what was stated in the literature review and documentary analysis. This was undertaken by means of a continuing process of comparison, seeking evidence of convergence, complementarity, and divergence.

2.6.1 Scoping review of literature

The scoping review involved a review of existing published literature on global health partnerships, primarily Gavi and CEPI, but also drew on insights related to global health partnerships in the vaccine field in general. The scoping review seeks to answer the first research question of this thesis: What lessons can we learn from the previous experience with global health partnerships?

A scoping review offers an understanding of key concepts, theories, and sources of evidence to guide innovations, empirical research or systematic reviews and informs policymakers. Scoping reviews typically do not involve critical appraisal of study methodology or detailed extraction of outcomes data since they are chiefly concerned with mapping the evidence landscape rather than establishing the effectiveness of particular interventions (Levac et al., 2010, Munn et al., 2018). By contrast, a systematic review seeks to answer a specific question, such as whether a policy or other intervention works and in what circumstances. It employs a set of methods and instruments designed to minimise bias. Table 1 outlines the key differences between scoping and systematic literature reviews.

Table 1 Characteristics of scoping reviews and systematic reviews

Defining characteristic	**Scoping review**	**Systematic review**
A priori review protocol	Yes	Yes
PROSPERO registration of the review protocol	No	Yes
Explicit, transparent, peer-reviewed search strategy	Yes	Yes
Standardised data extraction forms	Yes	Yes
Mandatory Critical Appraisal (Risk of Bias Assessment)	No	Yes
Synthesis of findings from individual studies and the generation of 'summary' findings'	No	Yes

Source: Munn et al. (2018)

The scoping review will inform the case study by illustrating which traits make a global health vaccine GHP likely to succeed and achieve its mandate, how COVAX can learn from past initiatives, and identify whether previous studies employed any relevant frameworks to assess GHPs' success or mechanisms for vaccine deliver and allocation. I will then assess whether COVAX crystallises existing norms and traits and develop recommendations to inform how COVAX could potentially contribute to global vaccine equity.

This scoping review was conducted using Arksey and O'Malley's five-stage framework (Arksey and O'Malley, 2005). Scoping reviews are 'particularly useful when a body of literature has not yet been comprehensively reviewed or exhibits a complex or heterogeneous nature not amenable to a more precise systematic review' (Khalil et al., 2016). Scoping reviews typically do not involve critical appraisal of study methodology or detailed extraction of outcomes data since they are chiefly concerned with mapping the evidence landscape rather than establishing the effectiveness of interventions (Levac et al., 2010, Munn et al., 2018). By contrast, a systematic review seeks to answer a particular question, such as whether a policy or other intervention works and in what circumstances. It employs a set of methods and instruments designed to minimise bias. The activities recommended in this framework are described in Box 4.

Box 4 Scoping stages used in this review

Stage 1:	identifying the research question
Stage 2:	identifying relevant studies
Stage 3:	study selection
Stage 4:	charting the data
Stage 5:	collating, summarising, and reporting the results

Stage 1. Identifying the research question

The main research question was: What lessons can we learn from the previous experience with vaccine global health partnerships?

Stage 2. Identifying relevant sources

First, six databases (i.e., MEDLINE, EMBASE, Global Health, EconLit via Ovid, Web of Science, Scopus) and Google Scholar were systematically searched in November 2021. These databases were selected to be comprehensive and cover a broad range of disciplines capturing the multidisciplinary nature of GHPs. For instance, EconLit was searched to capture economic perspectives, a crucial feature of GHPs and their role in the innovation system relating to push and pull mechanisms.

Keywords and related MeSH terms and subject headings related to global health partnerships and vaccines were used: (global public private partnership* or global health partnership* or global health initiative* or public private cooperation* or public private partnership* or public private sector cooperation* or public private sector partnership* or public private alliance* or private finance initiative* or product development partnership* or project finance*) AND (vaccin* or immuni* or immunization programs/ or vaccination coverage/). The terms public private partnership* and project finance* were both used as keywords, as project financing is one of the most popular types of partnerships (Petersen, 2019, Roehrich et al., 2014, Torchia et al., 2014).

Appendix I includes the complete MEDLINE search strategy and filters, serving as an example search query for all database searches. I developed a Google Scholar search based on terms related to 'public-private partnerships' and 'vaccines', which was refined based on the

relevance of initial results. A snowball approach was also employed, where the references of retrieved studies were reviewed for additional articles (Wohlin, 2014). Most of these reviews were identified during screening. I screened all the records, and no automation tools were used in the process. A broad search was employed to ensure as many relevant search results as possible while clearly articulating eligibility criteria for the aims, objectives, and research questions (Armstrong et al., 2011).

Stage 3. Study selection

Appendix J lists the eligibility criteria. After removal of duplicates, title and abstracts of all potential sources identified were screened by one reviewer in EndNote 20 against eligibility criteria. Remaining full texts were then screened to identify the final number eligible for inclusion.

Publications were eligible to be included in this review if they critically reviewed the strengths and weaknesses of GHPs' vaccine innovation strategies, including any financial mechanisms employed such as AMCs or reviewed the experiences of GHPs about their achievements or failures in promoting vaccine production or delivery. Given the focus on global vaccine coverage, studies examining country-specific case studies were excluded but those that discussed or compared multiple regions or countries were included. Eligible material included discussion papers, observational studies, cross-sectional surveys, systematic reviews, and meta-analyses in peer-reviewed journals. Editorial material such as interviews, forum/symposium and meeting minutes, comments and profile articles were excluded. All remaining records were included in this review. There was no restriction on the geographical scope of the review. However, studies were limited to those published in English and French.

Stage 4. Charting the data

Relevant data were extracted from each eligible source to an Excel file under the following headings: lead author, publication year, study location, Intervention type, and comparator (if any); duration of the intervention, (3) Study populations (carer group; care recipient group), (4) Aims of the study, (5) Methodology, (6) Outcome measures, (7) results.

Stage 5. Collating, summarising, and reporting the results

First, I summarised the number of sources in a table or graphs by publication year, where accessed (i.e., database, journal, website, reference list), type (i.e., article, report),

distribution (i.e., publication language), and nature (i.e., topic, outcomes included, study design, participant characteristics, time-period of data collection).

Second, I analysed data thematically as described by Braun and Clarke (2019). Arksey and O'Malley's framework does not specify how to summarise and report results (Levac et al., 2010, Westphaln et al., 2021), suggesting researchers, may consider using qualitative analytical techniques. As such, I synthesised data thematically as described by Braun and Clarke (2019). I coded the data myself and reported inductive and deductive themes, guided by research objectives, and discussed implications for policy, practice, and future research.

Third, I report themes arising from the analysis. Results will be reported according to the Preferred Reporting Items for Systematic Literature Reviews and Meta-Analyses (PRISMA) Extension for Scoping Reviews flow diagram (Tricco et al., 2018).

2.6.2 Document review

The second research question was addressed by analysing relevant documents and interviews with key informants involved in the creation and operation of COVAX. The documents primarily revealed the extent to which the lessons learnt, as identified in answer to the first question, were addressed in the process of creating COVAX.

Document review or analysis is a systematic procedure for reviewing or evaluating documents. As Dalglish et al (2020) explain "the purpose of conducting such a review is to provide context, generate questions, supplement other types of research data, track change over time and corroborate other sources". Though this can include qualitative and quantitative-based documents, this document review examined qualitative documents more adapted to the socially constructed meaning-making inherent to collaborative exercises like policymaking (Dalglish et al., 2020). As with any research method, document review must adhere to standards to ensure validity and reliability, achieved by techniques to enhance qualitative rigour, such as triangulation within documents across methods and theoretical perspectives. Though document review can be used as a standalone research method, it can also be combined with other qualitative research methods such as different types of interviews or observation (Berner-Rodoreda et al., 2020, Dalglish et al., 2020).

Dalglish et al. (2020) note that there is little guidance available for health policy researchers on conducting a document review. Accordingly, they propose the READ approach, an

overarching method for conducting document review in a systematised method that enhances procedural rigour. This approach is a systematic procedure for collecting documents and extracting information from health policy studies at any level of policymaking, such as global, national, or local. The approach consists of 4 steps, each defined and summarised in Box 5.

Box 5 The READ approach's steps to document review

Step 1: Ready your materials

Set parameters based on the study's research question, such as types of documents or the number of documents to be reviewed. Accordingly, criteria should be established around (1) the topic (whether it is a policy or programme which will be investigated in accordance with the study's research questions); (2) dates of inclusion and (3) an indicative list of places to search for documents. This is an iterative process which may evolve as data collection starts. The types of documents analysed can vary by study and include formal documents, such as official policies, laws or strategies, grey literature such as organisational reports evaluations or white papers or working documents such as meeting minutes. The prioritisation of document types depends on the research question and the focus of the study, such as prioritising informal documents for studies looking at the policy process or formal documents for studies looking at policy content.

Step 2: Extract data

Data are extracted using an Excel spreadsheet, where each row is a document, and each column is a category of information the researcher seeks to extract. Proposed categories include the document title, author, date, theoretical or conceptual categories deriving from the research question, and operating theory or analytical framework. The extraction of data is an exercise in close reading, where the researcher will begin to build working theories about observations in the data. The authors suggest capturing these emerging theories in extended notes, such as those used in Grounded Theory methodology. During the extraction phase, the researcher may modify the document inclusion criteria.

Step 3: Analyse data

In this step, the researcher considers the "full picture" such as reflections on expectations to find certain documents, missing documents, evolutions over time, or any noticeable patterns. The authors suggest applying specific analysis methodologies such as policy analysis, case study methodology, thematic content analysis or discourse analysis. Analysis may be structured according to the chosen theoretical approach. In this step, the author should also consider their positionality to the documents and consider how their personal characteristics or views may influence analysis.

Step 4: Distil findings

Document review results can be grouped by theoretical or analytic category or presented as a policy narrative that interweaves strands from other methods used in the study, such as interviews or observation. The distillation process allows the researcher to state findings relative to the research question and to draw policy-relevant conclusions.

The objective of this review was to collect documents from various sources to generate a clear understanding of the policies and policy environment related to the COVAX Facility. This included understanding COVAX's approach to achieving vaccine equity, when key policy reforms or events occurred, which policies hindered or supported interventions and programmes related to vaccine equity and mapping the key actors and pieces of evidence about COVAX's vaccine equity policy. This information informed the development of the interview guide and fed directly into the final analysis.

I analysed public documents to explore key findings from the scoping review of literature related to what is stated in COVAX organisational policy documents. Table 2 summarises the types of documents consulted in this document review. Dalglish et al. (2020) propose a non-exhaustive list of the types of documents that can be included in document review of health policy issues, such as (1) official documents; (2) implementation documents; (3) legal documents; (4) working documents; (5) scholarly work; (6) media and communications; (7) other such as promotional material nutritional labels or floor plans. The categories summarised in Table 2 have been included in the review as they are relevant to my research question. Other categories, such as promotional material, were less relevant to this study and were excluded. Scholarly work was not consulted in this document review as a scoping

literature review has already been conducted, and its findings are discussed in Chapter 3. Documents were obtained from COVAX's website and the websites of its main coordinators (Gavi, CEPI, WHO and UNICEF) April 2020 to December 2021. The inclusion dates were selected to correlate with the launch of COVAX in 2020 and when the document review was conducted in 2021.

Table 2 ***Types of documents consulted in document review***

Category	**Type of document**
Official documents	- Policies or policy directives - Strategies - Official statements and declarations - Position papers - Surveys
Implementation documents	- Organisational reports or evaluations - Financial analyses - Operational plans - Funding requests
Legal documents	- Laws - Regulations - Memorandums of understanding - Cooperation agreements
Working documents	- Meeting report or minutes - Committee reports - PowerPoint Presentations - Mission reports
Media and communications	- Websites - News releases

I reviewed all available documents relating to COVAX and published by COVAX's four leading partners in their online report repositories. Most of COVAX's official reports or documents are hosted on the Gavi website. I reviewed a total of 109 documents, which included board and committee meeting minutes, reports, terms of reference, information documents, distribution forecasts and policy and framework documents. Documents which met the

inclusion criteria were downloaded and read in full. Their details were recorded in an Excel spreadsheet, and categories of information were extracted. The categories included document title, date of publication, author(s), publisher/journal title, source (i.e., website), document type, summary or document type and objective, a summary of document analysis findings, research evidence cited or discussed, mention of international recommendations or decisions, vaccine equity focus, keywords, potential interview respondent names, and data extracted. In line with the theoretical framework used in this study, particular attention was paid to the different actors involved, such as the public and private sectors, the nature of partnerships, and how they framed vaccine equity.

In analysing the documents I employed a reflexive thematic analysis approach (Braun and Clarke, 2019). Data were analysed inductively to identify core meanings using a coding scheme to index, search, summarise and analyse. Further details on the analysis are provided in the following chapter. The findings of the document review were triangulated with results from the semi-structured interviews with key informants. Given the iterative nature of document review, I included any relevant documents which interviewees mentioned during interviews. These were also recorded in the same Excel spreadsheet.

2.6.3 Key informant interviews

The interviews were used to confirm or refute findings from the document review and seek explanations for why issues were addressed or not. This data generation method was appropriate as I could identify key topics for discussion during the interview. However, interviewees determined the scope of the information they provided, and the level of importance afforded to the topic. Triangulation with interviews allowed for critical reflection on findings and facilitated the exploration of themes which may not have arisen in the scoping or document review. My chosen data analysis framework (below) allowed for the emergence of additional themes based on key informants' lived experiences or beliefs.

2.6.4 Sampling and recruitment

I invited 37 participants for interviews via email, 28 responded, and I interviewed 23. As I am bilingual, I offered participants the option of interviews being conducted in either English or French. Including both English and French speakers in this study expanded the diversity of the participant sample. Additionally, this strengthens the transferability of the research by

including people from different language groups (Fryer, 2019). Information about the study and interviews was sent via email. Participants were purposively sampled based on their current or past involvement with ACT-A, COVAX or vaccine global health partnerships: academics, civil society organisations or policymakers. Members of civil societies included NGOs, activist groups, and professional associations. Policymakers included individuals involved in national or global policymaking. The information being sought pertained to agenda setting and decision-making processes relating to factors addressing global health policy creation within COVAX and global vaccine equity during the COVID-19 pandemic.

Purposive sampling is a method which allows recruitment of study participants based on their level of expertise or interest in the chosen subject area (Etikan, 2016). Online searches of the main COVAX website were used to identify appropriate individuals. In addition, snowball sampling was used to recruit participants. Snowball sampling allows experts (those recruited through purposive sampling) to identify individuals with relevant insights and knowledge who can help answer chosen research questions (Etikan, 2016, Valerio et al., 2016). One of the benefits of this approach is the identification of hard-to-reach individuals. Both methods were used to maximise the number of study participants and increase the breadth of discussion. Interviewees were asked about issues related to the policy process leading to the creation of COVAX, the vaccine ecosystem within which it operates and any relevant recommendations for COVAX and future global health partnerships. Interviews were conducted via Zoom Meeting. Access to Zoom is granted via LSHTM, and end-to-end encryption was enabled. Participants were given instructions on how to re-join the meeting should there be unstable WIFI.

2.6.5 Consent processes

Participants were provided with an information sheet and written consent was obtained before participating. Inclusion was not limited by age or gender. Participants were recruited based on their professional status and involvement with COVAX. There was no stipulation limiting the ethnic backgrounds of respondents. Table 3 outlines the eligibility criteria.

Table 3 Participant eligibility criteria

Inclusion criteria	**Exclusion criteria**
Speaks English or French	Stakeholders involved in domestic distribution or local supply chain management of vaccines
Academics or professionals currently or previously involved in global health partnership finance or planning	
Stakeholders from global economies that have joined the COVAX facility as a "self-financing country", "financed country", or opted not to join or purchase vaccines through COVAX	

Each interview lasted approximately 30 to 45 minutes. Upon signing onto Zoom, oral information and verbal consent were also provided to enable full accessibility, however, all participants provided written consent. The information sheet and consent form were written in English and French (Appendices K to N). Consent forms included permission to use direct quotes anonymously. I attempted to mitigate any harm to participants by being as clear as possible about the study's aims and objectives and reminded them about the consent process throughout the interview. I also allowed as much time as possible during the interview for participants to ask questions and seek clarification about any concerns before starting discussions. All interviews were audio recorded and transcribed.

During the interview, I used open-ended questions to explore the participants' experiences or views on COVAX's financial platform and proposals for potential strategies to overcome the identified barriers. Interview questions have been developed based on the findings from the scoping review of literature, this study's theoretical framework and consultations with academic advisors from LSHTM and the University of Sheffield. A complete summary of the interview questionnaire is provided in Appendix O.

2.7 Analysis

I used reflexive thematic analysis (RTA) for all data sources, i.e. literature, documents, and transcripts (Braun and Clarke, 2019). An RTA seeks to identify patterns of meaning across a dataset. Such patterns are identified through data familiarisation, data coding, theme development, defining and naming themes and contextualising themes in relation to existing literature (Braun and Clarke, 2006). An advantage of this approach is that it is theoretically flexible and is not linked to an epistemological position. This does not imply that this approach is atheoretical; instead, it can be applied across a range of theoretical and epistemological approaches.

Data from the document review were analysed inductively to identify core consistencies and meanings using a coding scheme to index, search, summarise and analyse (Braun and Clarke, 2006). Thematic analysis of documents was conducted by hand. The initial codes were identified based on my aims, objectives, findings from the scoping review of literature, and main theoretical framework; however, the coding process became iterative based on the data presented. Initial coding of the qualitative data continued in parallel with the semi-structured interviews. This allowed the coding and analysis process to remain open to what was being discussed and what was happening with data. By adopting this iterative process of analysing data, triangulating findings from literature, documents, and interviews contemporaneously I was able to interrogate in increasing detail the themes relating to the role of GHPs in stimulating vaccine innovation and achieving global vaccine equity. No analytical distinction was made between data generated from the different sources given this ongoing interplay between data gathering and analysis, so the findings are presented together.

All interview recordings, translations, transcriptions, and notes have been kept confidential and stored in password-protected files on the LSHTM server, in accordance with the data protection measures specified in my ethics approvals. Identifiers for each participant were assigned and kept separate from names. Names were only present on consent forms. All interview discussions were transcribed from the recordings taken during each session then coded anonymously. I will keep the anonymised transcripts from the interviews and my notes for ten years on the secure LSHTM server. Audio recordings will be destroyed upon completion of the study.

I transcribed interviews myself using Microsoft Word for Mac (version 16.43). I transcribed interviews myself to ensure that the familiarisation process began as soon as possible in the data analysis process. Following this, I coded transcripts myself to identify comments and suggestions with similar themes and produce a list of core codes. The coding scheme emerged mainly through inductive approaches based on the interview guide, literature review, and reading of the interviews. Interview transcripts were analysed inductively using a reflexive thematic analysis approach.

A complete list of codes was developed during the interviews and the entire analysis process following data collection. New codes were added when none of the existing codes fit the data point in question. The descriptive codes were then clustered into categories to detect patterns of frequency and interrelationships. Appendix P provides a complete list of codes developed through the analysis. During the data analysis process following data collection, translation and complete transcription, the taxonomy of themes was developed according to the clustering of codes described above. The overarching "parent" themes were established based on the coding in line with my research questions and theoretical framework, particularly the keywords used in that process. I developed a systematic process of organising and analysing the data through thematic codes, with guidance from my supervisors and advisory committee.

2.8 Data management

I managed data in accordance with requirements set out in the LSHTM Data Management Policy. All interviews were recorded, transcribed verbatim, and I analysed transcripts myself. Interview data were anonymised using ID codes and stored in a password-protected folder in my private LSHTM server space. The home drive was accessed remotely using the Horizon Remote Desktop and only accessible to me. Key informant personal identifiable data were anonymised during analysis and discussion with my supervisors. Organisational identifiers, such as names, have been changed.

2.9 Reflexivity

In qualitative research, it is important to take a reflexive stance. This includes considerations of how personal views, prior assumptions, and experience can influence the study by shaping data collection or interpretation of results (Mays and Pope, 1995). Reflexivity involves actively

reflecting on “how” and “why” a researcher comes to a decision and disclosing accordingly (Tremblay et al., 2021).

Qualitative research is also characterised by extensive time in the field and proximity between participants and researchers to establish trust and rapport. This is particularly relevant in interpretivist and constructivist orientations, which seek to “understand phenomena that are rooted in the subjective and contextualised experiences of individuals or groups living in it” (Tremblay et al., 2021). However, this was hampered by COVID-19, with social distancing measures when in the presence of others.

Given this reality, I recognise my position as an “outsider”, as I am not an “active participant” of any of the organisations or have “natural access” to any of the participants who may be included in this study (Bruskin, 2019). Additionally, given the ongoing pandemic restrictions, I could not conduct research in person, thus hindering my ability to create an in-depth rapport with participants. As such, I employed additional strategies for facilitating rapport with participants. This included being transparent with participants about my objectives and reminding the participant of their rights throughout the interview. In addition, I also employed “informal, impromptu interactions” that promoted familiarisation between the participant and me (Tremblay et al., 2021). This included “chats” or informal discussions conducted via Zoom.

2.10 Ethics

I received ethics approval from the LSHTM Observational Research Ethics Committee (LSHTM Ethics ref: 26297). Before starting the study, I also completed the LSHTM Research Ethics training course to become familiar with key ethical guidelines and principles and how they can be applied to support ethical research (certificate of completion in Appendix Q).

I contemplated several ethical considerations in developing this study, where the primary objective was to maintain complete confidentiality and anonymity of the interview participants. Before their participation, all participants were provided with a study information sheet, available in English and French, depending on their preference. Due to the ongoing pandemic and restrictions on travel and social distancing measures, conducting interviews in person was impossible. Therefore, all interviews were conducted via Zoom to

maintain a COVID-19 secure environment. Participants were also provided guidance on how to use Zoom, data encryption measures and steps to take should there be Wi-Fi interruptions.

2.11 Summary

This chapter has summarised the methods used in this thesis. This study uses an explorative single case study design, using qualitative methods, with a constructivist international relations framework by Rushton and Williams (2012). The research questions were answered using a combination of methods such as scoping review of literature, document review and key informant interviews. Data was analysed thematically, using inductive coding. Ethics approval was provided by the Research Ethics Committee at LSHTM.

The following chapter presents the findings of a scoping review of literature on global vaccine GHPs, looking at the reasons why they are used to respond to global health challenges, their historical and sustained authority in global health decision making, whether COVAX crystallises existing strengths and weaknesses of GHPs and how this will impact its ability to achieve its intended goal of global vaccine equity.

Chapter 3 Lessons from previous global health partnerships: a scoping review

3.1 Overview

In this chapter, I report on the findings of a scoping review of relevant literature on collaborations between the public and private sectors designed to increase vaccine uptake in LMICS. This review provides context for the empirical component of my thesis. It begins by providing background information (section 3.2) on the role of global health partnerships (GHPs) in achieving global immunisation mandates. This is followed by a summary of the review's main aims and objectives (section 3.3). I can situate my subsequent research on COVAX within the available literature by meeting the review's objectives. Before describing the methods (section 3.4), I have employed in the review and its findings, and I set out the parameters within which my review is set. The main research question was: "What lessons can we learn from the previous experiences with vaccine global health partnerships?" The findings (section 3.5) are organised into three inductive themes as per my stated objectives. Section 3.5.2 discusses the emergence of GHPs in supporting historical immunisation goals and programmes, section 3.5.3 identifies the different forms of partnerships for vaccine innovation and access and finally, section 3.5.4 summarises the main critiques of GHPs' influence on decision making processes in global health governance. In section 3.6 I discuss the review's main findings (section 3.6.1), study implications (section 3.6.2) and study limitations (section 3.6.3). Finally, I conclude (section 3.7) and provide a summary (section 3.8).

3.1.1 Abstract

Background

The emergence of GHPs towards the end of the 20th century, especially in the vaccine field, responded to concerns that uptake of existing vaccines was plateauing in many parts of the world. These partnerships bring together a range of organisations, including governments, private philanthropic foundations, NGOs, and international agencies. GHPs act, to a greater or lesser extent, to incentivise the development and manufacture of new vaccines, raise funds to pay for them, and develop and support delivery systems to ensure they reach the

population in need. This model has become even more critical during the COVID-19 pandemic, particularly with the launch of the COVAX Facility Initiative, with its goal of global vaccine equity. I ask what experiences with previous GHPs tell us about the ability to achieve vaccine equity and what needs to be done to make this successful.

Methods

I conducted a scoping review of lessons learnt with existing GHPs, using Arksey and O'Malley's 2005 framework, answering the question: "What lessons can we learn from the previous experience with vaccine global health partnerships?" I synthesised data thematically.

Results

I included 66 literature sources from 3,219 identified. Most (64 [95%]) were discussion papers or review articles describing GHPs or GHP-supported programmes, and three [5%] were commentaries. Emerging themes included policy responses (e.g., immunisation mandates), different forms of partnerships arising in the vaccine innovation system (e.g., product development partnerships, public-private partnerships for access) and GHPs' influence on global governance decision-making processes (e.g., the rising influence of Foundations, diminishing the authority of WHO, GHPs' lack of accountability and transparency, GHPs' creation of disease funding silos).

Conclusions

GHPs alone cannot achieve global vaccine equity but make some contribution. GHPs attempt to achieve global immunisation goals by focusing on innovation. Though this approach is cost-effective, it is donor-dependent, and neglects broader systems approaches which ensure sustainability and equity. GHPs address market failure and rely on specific tools such as push and pull mechanisms, which increase access to vaccines to some extent but do not spur innovation or achieve equity. To achieve equity and sustain long-term goals, GHPs should (1) increase transparency to provide opportunities for performance and impact evaluation; (2) ways to refocus interventions to include both health systems strengthening and cost-effectiveness and (3) examination of incentives for cooperative vaccine R&D partnerships and expansion of manufacturing capacity to achieve global immunisation goals.

3.2 Background

Although programmes to deliver vaccines in all countries have always involved some degree of engagement between the private sector, in the form of vaccine manufacturers (there are some state-owned manufacturers, but even they work with the private sector in, for example, purchase of raw materials and manufacturing equipment) and the public sector, with mass vaccination almost invariably delivered by government agencies even when other aspects of health care are privately funded or provided, in recent decades these arrangements have been formalised within a variety of new structures (Buse and Walt, 2000a, Buse and Walt, 2000b, Buse and Harmer, 2004, Rushton and Williams, 2011, Andonova, 2017). These structures act, to a greater or lesser extent, to incentivise the development and manufacture of new vaccines, raise funds to pay for them and develop and support the necessary delivery systems to ensure they reach the population.

Those structures active in increasing vaccine uptake fall within what have been termed public-private partnerships (PPPs). In the health field, they provide a mechanism by which public and private partners can collaborate to achieve specified health goals by sharing resources, risks, responsibilities, and rewards (Buse and Walt, 2000a, Buse and Walt, 2000b, Schäferhoff et al., 2009). PPPs can be created at any level, but here we are interested in those acting globally, embracing countries at all levels of development, typically with the wealthier ones acting as donors and the poorer ones as recipients. As they have developed over time, commentators have argued that the terminology "public-private" is oversimplistic when applied to those acting in global health, given the wide range of organisations involved, including private for-profit and private non-profit organisations (such as private philanthropic foundations and NGOs), and international agencies (Buse and Walt, 2000a, Widdus, 2001, Widdus, 2005). These organisations can adopt various roles. For example, while philanthropic foundations and NGOs are often categorised under the same non-profit making banner, Rushton and Williams (2011) distinguish them thus: a foundation's source of money is typically from an individual with private wealth or from a corporate initiative, whereas an NGO's source of money is usually from a more diverse stream of donations. This thesis uses a broader definition of PPPs than what is proposed by Buse and Walt (2000a). It is aligned with the definition provided by the UK Department for International Development (DFID) and others such as Rushton and Williams (2011), as the latter also includes private for-profit and private

non-profit-making organisations. Foundations are often formal partners in PPPs whilst also providing funding to such initiatives.

In 2004, DFID introduced the expression "global health partnerships" (GHPs), defined as a "collaborative relationship among multiple organisations in which risks and benefits are shared in the pursuit of a shared goal" (Carlson, 2004, Bartsch, 2011). Thus, those involved collaborate because they believe they cannot achieve the desired outcomes independently. These GHPs have proliferated, with some seeing them as essential contributors to "collaborative trans-national research and action for promoting health for all" (Beaglehole and Bonita, 2010). They typically fall into categories of "advocacy partnerships", "R&D partnerships", "access partnerships", and financing partnerships" and have a specific focus, for example, on access to medicines and vaccines.

The rise of such partnerships in global health was driven mainly by philanthropic foundations such as the Rockefeller Foundation and the BMGF around the turn of the millennium. Both foundations advocated for the creation and sustained support of various types of partnerships like the International AIDS Vaccine Initiative (IAVI), the Malaria Vaccine Initiative (MVI), the Global Alliance for Vaccines and Immunisation (Gavi), the Global Alliance for Improved Nutrition and the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM). Their entry into the vaccine field was in response to concerns that, towards the end of the 20th century, immunisation rates were beginning to plateau in many parts of the world (Ruckert and Labonté, 2014).

Although beyond the scope of this thesis, it is important to be aware of the contested role of philanthropic bodies in the global health arena. Much recent attention has focused on the BMGF. Thus, McCoy and McGoey have set out the case that it lacks transparency and accountability and distorts funding priorities (McCoy and McGoey, 2011). It and others have also been criticised for a focus on technological solutions that ignore context, especially the need for health systems strengthening, although Hill, using the example of Gavi, an organisation that has prioritised this activity, shows how complicated this can be (Hill, 2011). More generally, Moran has argued that many of the main philanthropic foundations, which are based in the USA, have acted as vehicles to spread American ideals, in particular the importance of capital as a force for change (Moran, 2011).

Gavi is the best known of these partnerships and the one with the broadest remit. It was created in 2000 to increase access to vaccines in lower MICs and LICs. Gavi is a GHP, with 80% of its finances paid by donor states such as Canada, the USA, the UK, and the European Commission. 20% of contributions come from private sector donors such as the BMGF (Gavi, 2020k). Gavi sought to incentivise the development of new vaccines using AMCs. Gavi's strategy ensured sufficient demand to incentivise a steady supply of vaccines to low-income countries (LICs). This funding model was launched in 2009 by the BMGF, Canada, Italy, Norway, the Russian Federation, and the UK and involved donors committing funds to guarantee the price of a vaccine once it was developed. In exchange, vaccine manufacturers were incentivised to provide the vaccine at a lower price for MICs and LICs by signing an AMC, which is legally binding.

Another more limited model of GHP in the vaccine field concentrates on vaccine discovery and development, the product development partnership. These seek to accelerate research and development of new technologies such as vaccines, mainly intended for use and access in LMICs. For example, the Rockefeller Foundation first embraced the product development partnership model in the mid-1990s to support the development of an HIV vaccine (Widdus, 2005, Widdus, 2001). This led to the creation of IAVI in 1996, an independent non-profit organisation that coordinated clinical trials for potential vaccine candidates. Outside the vaccine field, the Drugs for Neglected Disease Initiative (DNDi), the Medicines for Malaria Venture (MMV) and the Tuberculosis (TB) Alliance fill a similar niche. Appendix R summarises the remit of some of the GHPs mentioned in this scoping review and their role in the vaccine innovation system.

Perhaps inevitably, in a developing field, there is some variation in the use of terminology. Thus, the WHO has used the term "global health initiative", which can include predominantly bilateral arrangements (at least initially, GHPs were envisaged as bringing together multiple actors), such as the USA's President's Emergency Plan for AIDS Relief (PEPFAR) or looser arrangements, such as the World Bank's Multi-Country HIV/AIDS Program. These often lack the same degree of executive decision-making structures (Brugha and Walt, 2001, Brugha et al., 2008). However, as Bartsch (2011) notes, "the fact that a political actor like WHO, which was among the first to introduce the partnership idea into global health a decade ago, today

prefers to talk merely about 'initiatives' rather than 'partnerships' has cognitive, normative, and practical repercussions for policy-making processes in global health".

3.3 Aim and objectives

As this thesis is concerned with the governance arrangements for COVAX, this review will focus mainly on GHPs with formal structures for bringing various actors together to achieve global immunisation mandates. I conducted this review to answer the research question, "What lessons can we learn from the previous experience with vaccine global health partnerships?". The main objectives were to:

1. Describe the emergence of GHPs in global health and identify why these partnerships were used as a model to achieve goals;
2. Identify the different forms GHPs take in this field and examine their strengths, limitations, and drawbacks, paying particular attention to the balance of costs and benefits to the parties involved;
3. Summarise fundamental critiques of GHPs' influence on global health decision-making processes.

3.4 Methods

The methods used in the scoping review of literature are outlined in Chapter 2: Methodology.

3.5 Results

3.5.1 Scope of the literature

Appendix S shows the Preferred Reporting Items for Systematic Literature Reviews and Meta-Analyses (PRISMA) Extension for Scoping Reviews diagram for this review (Tricco et al., 2018). In total, 66 sources were included of 3219 identified, 56 from databases and ten from Google scholar and citations. Sources included in this analysis are tabulated in Appendix I. All publications were in English. Most (63 [95%]) were discussion papers or review articles describing GHPs or GHP-supported initiatives and programmes, and three (3 [5%]) were commentaries or editorials. All focused on GHPs working in different stages of the vaccine innovation system. None of the sources focused on regional partnerships. Findings are

organised under three deductive themes from my objectives, including eight inductive sub-themes.

3.5.2 The emergence of global health partnerships in supporting historical global immunisation goals or programmes

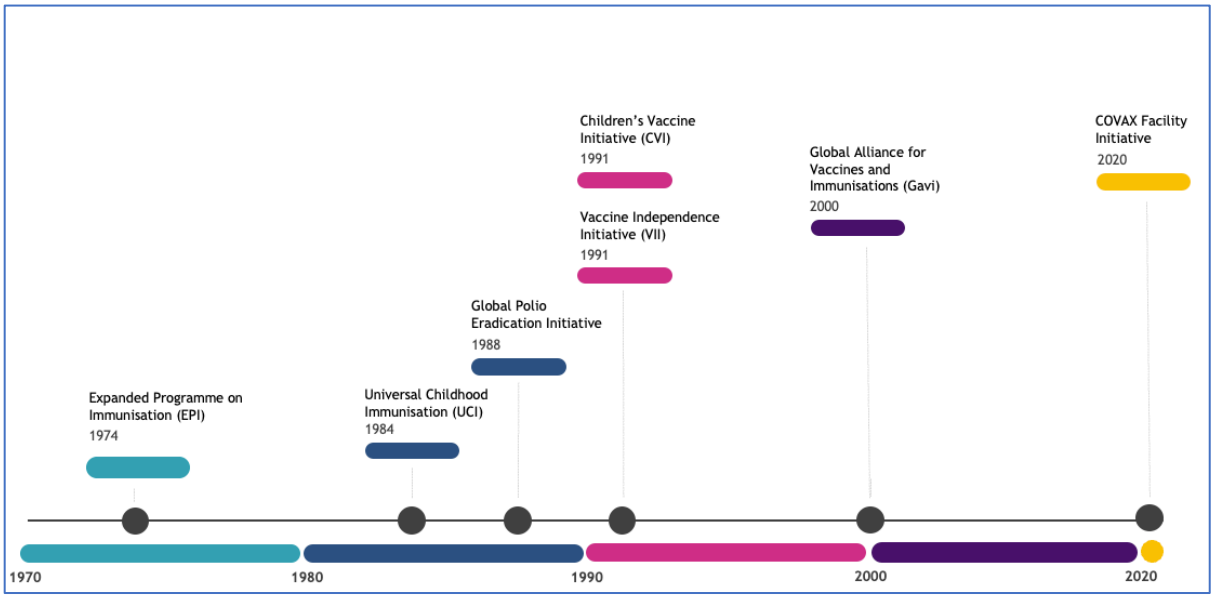
The evolution of global immunisation mandates and growing donor fatigue

Four sources discussed historical global immunisation policies and programmes and identified shifts in global immunisation goals, the actors involved in increasing immunisation coverage, and any possible unintended effects (Hardon and Blume, 2005, Chataway and Smith, 2006, Muraskin, 2004, Ahonkhai et al., 2016). Notably, the Expanded Programme on Immunisation (EPI) was launched by the WHO in 1974 to accelerate immunisation rates for six target diseases: diphtheria, tetanus, whopping cough, polio, measles, and TB. At this time, less than 5% of the world's children were immunised against these diseases. The EPI built on the gains made by the global smallpox eradication programme. By 1990, the EPI successfully provided 80% of the world's children under 13 months with the Bacille-Calmette-Guerin (BCG, used against TB), polio and measles vaccines (Hardon and Blume, 2005, Chataway and Smith, 2006).

Building on the EPI, Hardon and Blume (2005) discuss what they deem to be the five most crucial global immunisation initiatives formulated during the past 20 years: (1) the Universal Childhood Immunisation (UCI) launched in 1984 by the WHO and UNICEF to accelerate the EPI; (2) the Global Polio Eradication Initiative launched in 1988 and adopted by the World Health Assembly with the aim of eradicating polio; (3) the Vaccine Independence Initiative (VII) launched in 1991 by UNICEF and was a financial mechanism that enables governments to manage temporary budget shortfalls and facilitate timely procurement of essential supplies; (4) the Children's Vaccine Initiative (CVI) also launched in 1991, which sought to develop and implement new vaccine technologies and to conduct research to determine the feasibility of a single-dose multivalent vaccine; (5) the Global Alliance for Vaccines and Immunisations (now officially known as Gavi, the Vaccine Alliance) launched in 2000 and supported by public and private actors such as the WHO, UNICEF, the World Bank and the BMGF with the goal of extending the reach of the EPI and improving access to sustainable immunisation services, accelerating the introduction of new vaccines and making immunisation a central part of international development goals. Figure 12 provides a timeline

of global immunisation mandates, summarising the launch of all the initiatives above, ending with the launch of COVAX in 2020.

Figure 12 Timeline of global immunisation mandates



The UCI and the Eradicate Polio campaign had unintended effects. Both programmes skewed health services by encouraging health workers to focus on routine immunisations, potentially compromising or neglecting other preventative and curative health services (Hardon and Blume, 2005). Both initiatives focused on achieving specific targets, though they did not acknowledge the sustainability of such interventions (Siagian and Osorio, 2018). For example, the UCI achieved its target of 80% vaccine coverage at the aggregate level. However, this figure does not reveal that universal coverage was not reached in 107 countries and that coverage rates differed significantly between the six antigens (Hardon and Blume, 2005). Additionally, there was reason to believe that there was systematic overestimation of the percentages of children immunised in some countries.

Donor fatigue exacerbated challenges in the 1990s, prompting UNICEF to introduce the VII (Hardon and Blume, 2005, Muraskin, 2004). In contrast to the two previous initiatives, the VII encouraged LMIC governments to become gradually more independent and assume financial responsibility for their vaccine needs. This initiative supported LMIC governments in procuring vaccines through subsidised purchases. Governments had to establish a budget for vaccinations as a condition of participating in the pooled procurement mechanism, set up to help countries pay for vaccine needs in the local currency. Though the initiative encouraged

financial independence, UNICEF absorbed the risk of defaulting on payments. The VII was considered a success in increasing the self-reliance of middle-income countries; however, less so for low-income countries.

The rise of global health partnerships as brokers between public and private actors

Three sources noted the historical origins of global health partnerships around the end of the Cold War in the late 1980s (Hardon and Blume, 2005, Ruckert and Labonté, 2014, Stevenson, 2017). This was a time when several developments were coming together, including the end of superpower rivalry in many parts of the world, in which the major powers contributed, in money or in-kind, to exert influence on their client states and others, the emergence of HIV and its recognition as a global health crisis, and the increasing use of innovative financing schemes involving public-private partnerships in areas such as health and education in high-income countries.

Consequently, a focus on cost-effective interventions became prominent in the 1990s, when donor countries increasingly viewed innovative vaccine technologies as the answer to immunisation problems (Hardon and Blume, 2005, Ruckert and Labonté, 2014, Stevenson, 2017). This meant that GHPs would undertake large-scale resource mobilisation for LMICs. This focus on new technologies meant that equity issues became less prominent. The CVI was co-sponsored by the United Nations Development Programme (UNDP), WHO, the World Bank, UNICEF, and the Rockefeller Foundation. In comparison with previous initiatives, the CVI had an increased private sector involvement with the goal of establishing a programme to develop a single children's vaccine.

This approach to vaccine innovation provided a new and more appealing focus for donor commitment, thus complementing existing immunisation mandates. However, the CVI led to various tensions between European and American donors. European donors felt this initiative was too focused on finding technical solutions for health issues in LMICs and highlighted how commercial interests dominated this focus (Hardon and Blume, 2005). Though the CVI successfully developed new and improved vaccine technologies through PDPs, it did not sufficiently mobilise the resources needed to deliver and sustain immunisation programmes (Hardon and Blume, 2005, Stevenson, 2017). The VII and the CVI received limited donor funds and reflected a time when the emphasis on global health was not on equity or health rights but on cost-effective interventions (Ruckert and Labonté, 2014).

Together, these factors, such as the increasing focus on investment in health as a contributor to sustainable development after 2000, in the Millennium Development Goals, led governments to look at new ways of paying for development, particularly those that involve the private sector. Thus, several private sector organisations gained a seat at the table of global health policy, with a space for them to occupy various roles (Ruckert and Labonté, 2014, Chataway and Smith, 2006). Increasingly, partnership models in which they partnered with the public sector were viewed as an essential component of any response to a global problem.

Four sources considered that this new worldview led to GHPs acting as either integrators or knowledge brokers to create long-term partnerships, mainly between the public and private sectors, working toward a common technological goal to achieve vaccine mandates (Chataway et al., 2007, Huzair et al., 2011, Huzair, 2012, Moran and Stevenson, 2013). This role as a broker is particularly prominent in issues relating to intellectual property, which describes the GHPs' position as "mediating asymmetric economic relationships between HICs and LMICs" and further indicate that "these initiatives do not seek to explicitly challenge the rules of international trade, global finance or the [IP] rights regime that underpin the neoliberal system of economic governance, viewed by many as the basis of continuing North-South intra-country inequities" (Moran and Stevenson, 2013). Instead, such initiatives work within the "rules of the game", by adopting push and pull mechanisms to develop products or increase access to health technologies.

When Gavi was launched in 2000 as a successor to the CVI, its strategy embodied and reinforced previous priorities to expand the use of cost-effective vaccines, improve access to sustainable immunisations, and accelerate the development and introduction of new vaccine technologies using pull mechanisms. At the time, countries became eligible for Gavi support if their Gross National Income (GNI) per capita was ≤ US$ 1,000 over the past three years (Hardon and Blume, 2005). Unlike the previous programmes, Gavi is not an UN-led initiative and is governed by a board of 16 institutional members. Five are permanent, and 11 rotate. The permanent seats are reserved for the BMGF, the Vaccine Fund, WHO, UNICEF, and the World Bank. The 11 rotating seats reflect different constituencies: LMICs (2 seats), HICs (3), NGOs (1), LMIC industry (1), HIC industry (1), foundations (1), technical health institutes (1) and research and academia (1). Jean Stephenne, former president of SmithKline Biologicals

(the company that produced the combination DTP-hepatitis B combination vaccine), outlined the conditions for industry participation in the Alliance at the first Gavi Partners' meeting held in Noordwijk, the Netherlands, in 2000. The requirements include a guarantee for "'reasonable prices', support for a credible and sustainable market, respect for international property rights, a tiered pricing system including safeguards against re-export of products back from developing countries to high-priced markets and a prohibition on compulsory licensing" (Hardon and Blume, 2005).

Gavi sought to make aid contingent on performance, incorporating incentive systems. Increased immunisation coverage was used to measure performance. However, this reliance on performance indicators overlooks the absence of health information systems in most countries applying for support. This is compounded by problems calculating coverage and echoes the issues highlighted in the UCI initiative. For example, Hardon and Blume (2005) highlighted that there were reporting problems in three African countries under the UCI: Ghana, Mozambique, and Tanzania, where they could not provide the required DTP3 data and reported difficulties in recording valid and reliable data.

3.5.3 Different forms of partnerships for vaccine innovation and access

Product development partnerships

Six sources indicated that the collaborative approach taken by GHPs in the form of Product Development Partnerships (PDPs) for product R&D increases innovation in health technologies, such as vaccines, for diseases which affect LMIC populations (Mrazek and Mossialos, 2003, Brooke et al., 2007, De Pinho Campos et al., 2011, Stevenson, 2017, Jahn et al., 2020, Sunyoto, 2020). PDPs are another GHP model which involves placing public money in disease-specific capital funds created to reduce the risk of private companies undertaking high-cost research and subsidising the development and commercialisation process (Mahoney, 2011, Stevenson, 2017). Some examples of PDPs are the Drugs for Neglected Diseases Initiative (DNDi), International AIDS Vaccine Initiative (IAVI) and the Malaria Vaccine Initiative (MVI). Though vaccine discovery and development partnerships have shown success, many studies indicated a continued need to transform the current R&D system, particularly if there are continued unmet health needs in some regions (Sunyoto, 2020).

The most significant criticism of the PDP model is that it seeks to reconcile what are, in theory, two conflicting organisational purposes; where the public sector has the responsibility to address population-wide needs at a low cost and within a specified budget, the private sector is required to maximise profits (De Pinho Campos et al., 2011, Mrazek and Mossialos, 2003, Jahn et al., 2020). The model further strengthens the intellectual property regime, which awards private sector actors long-term rights over pricing (Mrazek and Mossialos, 2003, Sunyoto, 2020). In some cases, this results in limited access to health technologies in LMICs, so other financial mechanisms are needed to procure products for LMIC markets (Ahonkhai et al., 2016, Gilchrist and Nanni, 2013). Paradoxically, the current PDP model is also an opportunity for private sector actors to make reputational gains, with some authors portraying them as acting in the public interest to solve complex problems; however, because of conflicting goals, the PDP model tends to dimmish the ability of public sector actors to credibly claim that they are also acting in the public interest (Stevenson, 2017, Sunyoto, 2020). Findings from the literature review indicated that the PDP model was not the most cost-effective approach to vaccine R&D if it acts as a push scheme through grants.

In response to criticisms that PDPs have limited local stakeholder engagement, some have attempted to build capacity within the areas most affected by target diseases, especially in public health, regulatory expertise, and clinical trial management (Chataway and Smith, 2006, Hayter and Nisar, 2018). The gradual growth of globally competitive vaccine manufacturers in LMICs is primarily supported by PDPs (Bishai et al., 2011, Mahoney, 2011, Moran and Stevenson, 2013, Hayter and Nisar, 2018). The expansion of manufacturing capacity in LMICs facilitates regional development of vaccine technologies, prompting LMICs to partner in the vaccine innovation process (Hayter and Nisar, 2018). This occurs through public- and private-sector investments, and PATH and BMGF play essential roles in this process as committed supporters and facilitators (Mahoney et al., 2007b). The Serum Institute of India (SII), for example, is now the largest producer of vaccines in the world by volume. The BMGF has subsidised much of the SII portfolio, including their rotavirus, human papillomavirus (HPV) and pneumococcal programmes (Moran and Stevenson, 2013). Based on key informant interviews, Moran and Stevenson (2013) indicate that, “the Foundation’s leadership believes the world needs several companies like the SII with global distribution capacity to meet demand projections and diversify risks”.

Five sources contend that PDPs are fulfilling their intended purpose by developing new drugs, vaccines, and other technologies in the face of longstanding state and market failures (Chataway et al., 2007, Hanlin et al., 2007, Huzair et al., 2011, Huzair, 2012, Hayter and Nisar, 2018). For example, by the end of 2004, global health partnerships, including PDPs, were responsible for nearly 75% of neglected disease drug development projects and negotiated conditions for IP rights (Moran and Stevenson, 2013, Mrazek and Mossialos, 2003, Chataway et al., 2007). They also noted that DNDi developed eight new treatments for malaria, leishmaniasis, Chagas, sleeping sickness, paediatric HIV, and hepatitis C. Indeed, Hayter and Nisar (2018) noted that PDPs had developed strategies to motivate company and university participation in instances where IP protection act as a barrier to collaborative governance. Licensing plans include co-assigning patents with commercial partners or not patenting at all. Chataway et al. (2007) and Moran and Stevenson (2013) noted IAVI's attempt to monitor how the costs of intellectual property should be shared between public and private actors by brokering a negotiated agreement where the private sector retains IP rights and IAVI has the right to obtain licences to contract other vaccine manufacturers if the original company should decline to produce the vaccine for LMICs in reasonable quantities and at affordable prices.

Two sources proposed alternatives to the PDP model, such as redirecting PDP funds away from partnerships to build up existing public sector pharmaceutical manufacturing capacities in LMICs. Both Stevenson and Youde (2021) and Stevenson (2017) note how doing so eliminates the profit motive inherent in PDPs and ensures that demand is met. This approach has been leveraged by the DNDi, which combines resources of existing public-sector research institutions from HICs, using pharmaceutical firms only as contractors where necessary (Stevenson, 2017). From this perspective, PDPs have duplicated pre-existing public-sector research organisations that share similar mandates yet have been starved of funds. As noted by Stevenson (2017), by declaring access to preventative and therapeutic health technologies a fundamental tenet of global health policy, governments and enablers of global health partnerships have made manufacturers vital to the functioning of global public health. Efforts could, in theory, be re-directed to support scaling up the public-sector health technology production capabilities that already exist, for example, in Brazil and Cuba. Until this comes to pass, however, PDPs operating outside of the direct control of governments and the UN

system will continue to be relied upon to produce needed health technologies for LMIC populations.

Global health partnerships for access

Access partnerships refer to GHPs, such as Gavi, that focus on procuring and delivering vaccine technologies. Four sources discussed Gavi's accomplishments in increasing access to vaccine technologies in LMIC settings through AMCs (Gandhi, 2015, Jaupart et al., 2019, Hayter and Nisar, 2018, Mahoney, 2011). Jaupart et al. (2019) found that Gavi had a substantial impact in the fight against communicable diseases LICs, noting a 12.02 percentage point increase in diphtheria, pertussis, and tetanus (DPT) coverage (95% CI 6.56 to 17.49) and an 8.81 percentage point increase in measles immunisation coverage (95% CI 3.58 to 14.04) from its inception until 2016. This was consistent with findings from a study by Gandhi (2015); however, this study also concluded that GAVI has had mixed results in addressing between-country inequities in utilising immunisation services.

Six articles argued that market-oriented incentives like AMCs are necessary to ensure that vaccines are provided to LMICs in adequate quantity, quality, affordability and programmatic sustainability (Cernuschi et al., 2011, Jahn et al., 2020, Mahoney et al., 2007a, Mrazek and Mossialos, 2003, Sunyoto, 2020, Aerts et al., 2017). Thus, HIC donors channelled development financing into specialised programmes that included AMCs, which they saw as a means to address between-country inequities in access to vaccines and which "[they] have been best positioned to operate" (Gandhi, 2015). This funding model was initially embraced in 2007 by the BMGF, Canada, Italy, Norway, Russia, and the UK. They pledged US$ 1.5 billion to accelerate the development of a new pneumococcal vaccine (Cernuschi et al., 2011). The premise behind AMCs is that they tackle static and dynamic distortions in the vaccine market through a legally binding commitment to purchase vaccines on predetermined terms. This reduces the risks taken by the pharmaceutical industry and aims to stimulate the development and manufacturing of such health technologies (Mrazek and Mossialos, 2003).

The AMC model sought to address market failure but continues to experience shortcomings in supporting innovative new vaccine technologies and price regulation. Though the AMC model successfully incentivises pharmaceutical companies to engage with issues relating to the supply and demand of vaccines, it has been less successful in convincing companies to develop new technologies (Siagian and Osorio, 2018, Gilchrist and Nanni, 2013). This failure

is explained by the AMC's shift from its original intention of developing new vaccine technologies to focusing on increasing production capacity and the purchase and distribution of existing vaccines. This shift effectively locked in a price to be paid to vaccine manufacturers, thus providing two multinational producers (GSK and Pfizer, as opposed to vaccine manufacturers located in LMICs such as the Serum Institute in India) with a fixed profit level and no incentive to reduce unit prices, with consequences for vaccine accessibility in LMICs (Hayter and Nisar, 2018).

Cernuschi et al. (2011) and Siagian and Osorio (2018) discuss some of the challenges with the AMC model, such as the lack of long-term competition between first- and second-generation vaccine manufacturers. Second-generation suppliers have little incentive to participate as they face technical barriers to market entry (Cernuschi et al., 2011). Though supporters of the AMCs intended that the model would promote competition to ensure lower prices and avoid supply interruptions, donors did not want to establish differential terms for different suppliers, opting for a "one size fits all" contract (Siagian and Osorio, 2018).

Several articles questioned the sustainability of partnerships. They highlighted their heavy donor dependence, especially on Gavi, despite attempting to reassure industry partners about the long-term viability of sustaining vaccine markets in LMICs (Aerts et al., 2017, Gilchrist and Nanni, 2013, Siagian and Osorio, 2018). The authors suggest exploring less pro-cyclical funding sources and finding ways in which the AMC design can match long-term, predictable donor commitments with the final buyer's budgetary capacity.

3.5.4 Critiques of GHPs' influence on decision-making processes in global governance

The creation of the BMGF

Several studies identify the creation of the BMGF in 2000 as an essential step in the growing role of non-state actors in global health (Ruckert and Labonté, 2014, Stevenson, 2017, Stevenson and Youde, 2021, Moran and Stevenson, 2013). The enormous resources it commands, dwarfing those from many donor countries, and the budgets of some international agencies gave it vast influence. For example, in 2018, its endowment had already reached US$ 46.8 billion, and it had awarded a cumulative US$ 50 billion in grants and provided US$ 3.24 billion in development assistance for health (DAH) in that year. This accounted for more than 8% of the global total that year, making it the third-largest single

source of DAH funds after the United States and the United Kingdom (Stevenson and Youde, 2021). Inevitably, the BMGF is not a passive donor, and its support has focused, to a considerable extent, on specific, often technological innovations rather than broader health system strengthening.

Six articles examined the work of the BMGF, highlighting their material, ideational and agenda-setting influence on global health policymaking (Mrazek and Mossialos, 2003, Hanlin et al., 2007, Ruckert and Labonté, 2014, Stevenson, 2017, Legge and Kim, 2021, Stevenson and Youde, 2021). Several commentators argue that its status and activities contribute to a weakening of international bodies such as the WHO and the UN, thus "rendering less relevant multilateral fore where [LMICs] have a voice". For example, the WHO was marginalised in the design and governance of the Access to COVID-19 Tools Accelerator (ACT-A), while traditional multilateral governance involving WHO member states gave way to multi-stakeholder oversight (Legge and Kim, 2021). Yet, while some have criticised this development on the grounds of transparency, others have argued that it is an understandable response to the "glacial speed" with which many multilateral initiatives progress. In contrast, some GHPs, such as the International AIDS Vaccine Initiative (IAVI), are praised for their more agile response, drawing on techniques more usually associated with the private sector (Hardon and Blume, 2005, Chataway and Smith, 2006, Ahonkhai et al., 2016).

Stevenson and Youde (2021) argue that the influence that BMGF can exert in the governance of global health is less a reflection of its ability to usurp state power than the abdication of states' responsibilities. From this perspective, partnerships involving major philanthropic organisations have brought urgently needed resources to bear on complex problems that have long stymied individual governments and the existing international order. This has led governments to look to these arrangements to achieve goals that have proven elusive for the international system. This is exemplified by the support given to an organisation such as Gavi.

Diminishing authority of the WHO

Several authors considered the impact of GHPs on the role and influence of the WHO (Ruckert and Labonté, 2014, Stevenson, 2017, Legge and Kim, 2021, Stevenson and Youde, 2021). As an organisation accountable to its member states, the WHO is, in effect, constrained in what it can do, even if it has the resources necessary to act. Although there have been periodic attempts to strengthen it, for example, by the 2005 revision of the International Health

Regulations, these have had limited success (Ruckert and Labonté, 2014, Legge and Kim, 2021). In contrast, private philanthropic organisations have much greater freedom, especially those where the authority is concentrated in one or two individuals, as has been the case with the BMGF. In some respects, this freedom makes the BMGF well-suited to act as an honest broker to resolve global health challenges. However, the idea that a private foundation and, in this case, in effect, the decisions by two individuals should drive global health policy is deeply offensive to many, given that WHO's legitimacy is derived from formulating policies which are backed by the agreement of its 194 members (Stevenson and Youde, 2021).

The perceived weakness of UN organisations, such as the WHO, has created a gap that non-state actors can fill. Such moves are often welcomed both by the organisations themselves, whose staff are all too aware of the opportunities they provide for additional resources and by the donor governments, who see an opportunity to restrain their contributions. As a leading donor and regular partner, BMGF has demonstrated that it will work through WHO and will not wait for an invitation or defer to WHO to create new programmes it would support. It justifies this approach by pointing to the success of entities like Gavi and the GFATM as evidence that alternative organisational structures can provide financial support, promote drug and vaccine development, and build necessary health infrastructure (Stevenson and Youde, 2021). At the same time, BMGF's adoption of a public-private partnership model means the realisation of its goal largely depends on whether its public sector partners can mainly fulfil their commitments. Stevenson and Youde (2021) go on to indicate that one of the biggest threats to this model as the unwillingness of BMGF's government partners to adequately complement its activities, for example, by scaling up technologies that have been developed or by delivering and implementing these technologies because of a lack of the necessary infrastructure on the ground. Given its limited capacity and, in some cases, the enormous imbalance in available resources, it has been argued that WHO has been ill-equipped to enter sustained collaborations with non-state actors, especially when working with the pharmaceutical industry, as is the case with access to vaccines.

Several of the articles note how the resources available to GHPs have led to their presence at high-level decision-making fora becoming institutionalised (Buckup, 2008, Hanlin et al., 2007, Huzair, 2012, Mahoney et al., 2007a, Naimoli, 2009), despite the previously noted concerns about their democratic legitimacy and accountability (Stevenson and Youde, 2021).

Commentators differentiate the authority they wield, derived from their resources, which contrasts with their weak claims to legitimacy. Authority implies a degree of power; legitimacy refers to the normative right to exercise that authority, which means the assent of those directly impacted. In this respect, some commentators have questioned the assumption that private participation in global health is necessary for complex problems to be solved, given the absence of any mechanism for democratic or population oversight of internal decision-making in BMGF (Stevenson and Youde, 2021).

GHPs are not accountable to the public and lack transparency

Numerous commentators noted a lack of transparency and accountability by GHPs (Mrazek and Mossialos, 2003, Chataway and Smith, 2006, Ruckert and Labonté, 2014, Stevenson, 2017, Legge and Kim, 2021, Stevenson and Youde, 2021). They noted, in particular, concerns about transparency of decision-making processes and the lack of mechanisms at the global level to hold GHPs accountable. Combined, this lack of transparency and accountability makes it difficult to examine the successes and failures of specific interventions or programmes. Some also saw the lack of accountability and transparency as an opportunity for increased representation of private interests in decision-making processes. Ruckert and Labonté (2014) report how, in an analysis of 23 global health GHPs, most decision makers were from the corporate sector. Commentators argue that this can create potential conflicts of interest. For example, the BMGF maintains substantial equity in the Coca-Cola Corporation (Ruckert and Labonté, 2014). At the same time, its grants encourage communities in low- and middle-income countries to become business affiliates of Coca-Cola, even though the high-energy products of Coca-Cola are significant drivers of the growing burden of obesity and diabetes in these countries. Sources have even argued that this could partially explain the focus on infectious diseases by BMGF, even though NCDs now constitute more than half of all deaths in LMICs (Ruckert and Labonté, 2014, Stevenson and Youde, 2021).

Funding and programmes have taken a vertical business-like approach to tackle global health challenges. Such approaches to global health have not been compatible with more horizontal and health systems-oriented approaches endorsed by the WHO, which have a primary focus on achieving vaccine equity. Consequently, evidence suggests that the continued usage of GHPs in global health decision-making has resulted in the gradual relegation of the WHO to the peripheries of decision-making, acting as a coordinator rather than a leader in governance

(Stevenson, 2017, Stevenson and Youde, 2021). Adopting a business model is seen by many as excluding LMICs from decision-making processes, further exacerbating issues relating to lack of access to health technologies (Ruckert and Labonté, 2014, Stevenson, 2017, Legge and Kim, 2021).

One concern, identified by several sources, related to the ability of American dollars to set philanthropic contributions against their tax liabilities (Buckup, 2008, Naimoli, 2009, Huzair, 2012, Stevenson and Youde, 2021). This, in effect, allows money that would otherwise go to general government revenues, some of which could be spent on development assistance by elected politicians, to be channelled by individual donors. Thus, it can be argued that some private foundations benefit from significant public subsidies. Three studies estimated the scale of this subsidy, with one claiming that 45% of the US$ 500 billion that foundations hold actually 'belongs to the American public' in the sense that it is money foregone by the state through tax exemptions (Ruckert and Labonté, 2014, Hayter and Nisar, 2018, Stevenson and Youde, 2021). Yet, this means that even though almost half of the funds controlled by private foundations are public money, there is no democratic oversight of how it is spent. Data published by the BMGF suggest that this subsidy is somewhat lower than the overall figure, amounting to only 9% of their total contributions, according to their Foundation's website. Nevertheless, even that would amount to a government contribution of US$ 2.2 billion annually.

GHPs creating disease funding silos

Further critiques of GHPs' involvement in global health decision-making processes indicate that their rise has had implications for the WHO's agenda-setting capacity, where its regular budget funds were frozen and prompted to use extra-budgetary funding to prioritise individual disease-specific programmes over more general health systems capacity building programmes. Indeed, this singular focus on product development and delivery of specific illnesses undermines more horizontal and systems-oriented efforts to reduce the spread of disease. Two articles portrayed the GHP model as a barrier to addressing the social determinants of health (SDH), such as poverty or social exclusion, resulting in "agenda skewing" (Mrazek and Mossialos, 2003, Ruckert and Labonté, 2014). Many GHPs do not focus on the role of SDH in the distribution of the global disease burden. For example, TB shows a

strong socioeconomic gradient, where poor and vulnerable populations have a higher risk of contracting TB due to malnutrition or inadequate access to health services.

One article commented on how few GHPs have explicit objectives for poverty alleviation or robust means to demonstrate that their interventions benefit poorer populations, despite having equity objectives (Stevenson and Youde, 2021). This is important as certain GHPs working in TB-specific interventions have been successful in reducing mortality rates; they have been less successful in reducing incidence rates (Stevenson and Youde, 2021). Consequently, there are disease funding silos and segmentation of health financing, where most international funding is directed towards infectious diseases instead of non-communicable diseases (NCDs), which now outpace the burden of infectious diseases globally. For example, the BMGF directs approximately 97% of its financial disbursements towards infectious diseases, with less than 3% to NCDs. 45% of total PDP funding continues to be derived from the BMGF, resulting in the model's financial reliance on the Foundation (Ruckert and Labonté, 2014). Currently, PDPs remain the primary means for incentivising technical innovation in the face of market failure and transferring proprietary technologies to actors' intent on strengthening public health in LMICs through science-enabled innovation.

Three sources referred to the increased "financialisaton" of the vaccine ecosystem and GHP initiatives' heightened focus on the financial risks of the pharmaceutical industry rather than global public health risks (Legge and Kim, 2021, Storeng et al., 2021, Stein, 2021). Consequently, this approach has informed how COVAX approaches vaccine production and distribution. Both Stein (2021) and Storeng et al. (2021) indicate that COVAX's focus on "financialisation" and corporate risk management has undermined its goals of achieving global vaccine equity. Financialisation refers to, "the rise of financial concepts, motives, practices and institutions" (Stein, 2021). Both studies also consider that this focus could be the reason behind its refusal to consider and support global health policies which challenge the global IP regime or corporate privileges, despite providing pharmaceutical companies with both push and pull subsidies. However, this approach has not benefitted COVAX, indicating that vaccine manufacturers have consistently prioritised bilateral deals with wealthier countries instead of supplying COVAX at a fair price. This was illustrated with vaccine manufacturer Moderna, which reserved most of its doses for bilateral deals with HICs, despite receiving funding from CEPI, which included conditions on equitable access (Storeng

et al., 2021). However, Moderna only entered an agreement with COVAX in May 2020 for approximately 500 million doses to be delivered in the second half of 2021, and "only after committing to delivering billions of doses first in bilateral deals" (Storeng et al., 2021).

One group of commentators, reflecting on the increasing role played by global health partnerships but also voicing concern about the fragmentation of global governance, has suggested that the COVID-19 pandemic offers an opportunity for different organisations to work together, invoking the concept of a "super-PPP", an alliance of existing GHPs intended to "benefit not just [LMICs], but the entire world" (Storeng et al., 2021). The authors present COVAX as a super-PPP and argue that the emergence of this new model provides a means to facilitate coordination of global health actors. By conceptualising ACT-A as an institutional frame and attempting to coordinate a highly fragmented and competitive governance field, this study portrays each constituent GHP as competing with others to attract investment. They argue that a symptom of this problem is how ACT-A's separate pillars received different levels of international support, with COVAX the most successful in attracting funding. This, it is argued, highlights another problem of many existing partnerships: they tend to take a siloed approach that prioritises individual diseases over broader health system development (Storeng et al., 2021). However, they also note that this super-GHP has not been able to resolve global health governance challenges and continues to suffer from a lack of transparency, with little publicly available information about vaccine R&D costs and profit margins for vaccine manufacturers, thus replicating existing shortcomings of GHPs.

3.6 Discussion

3.6.1 Key findings

This review provides an overview of the role of GHPs in supporting global immunisation mandates, examining their strengths and limitations. Only a few original studies were identified, with even fewer generating empirical data that could shed light on characteristics associated with particular outcomes. This lack of empirical studies was particularly notable for partnerships seeking to improve access to medicines, such as Gavi, or those involved more generally in pandemic preparedness or response. This scarcity may reflect an inherent lack of accountability of GHPs, with little transparency about decision-making processes. Much literature comprised case studies, discussion papers, or narrative descriptions.

The studies identified looked at GHPs from different perspectives. Some used an economic lens, seeing GHPs as a response to market failure, with success measured as the ability to stimulate innovation and reduce prices. Examples include Mrazek and Mossialos (2003), Chataway et al. (2007), Hanlin et al. (2007) (Bishai et al., 2011), Cernuschi et al. (2011), and (Mahoney, 2011). Others took a political science perspective, examining GHPs' role in global health discourse and governance, including associated power dynamics. Examples include Moran and Stevenson (2013), Ruckert and Labonté (2014), Stevenson and Youde (2021), Legge and Kim (2021) and Storeng et al. (2021).

Studies applying a political science perspective observed a general lack of engagement with LMIC stakeholders. This was seen in both partnerships for access and PDPs; however, PDPs have responded to such criticisms by attempting to work with local communities in areas most affected by target diseases. Authors generally commended the PDPs' support of building capacity in regulatory expertise, clinical trial management and expanding vaccine manufacturing capacity in LMICs. Indeed, this is a step in the right direction; however, I have made two observations.

First, studies highlighting PDP strengths mainly outlined their successes in supporting regulatory pathways for country-level vaccine approvals, where many of the vaccine technologies already existed were not accessible. The studies acknowledged that research, including clinical trials, were ongoing for various vaccine candidates (Chataway and Smith, 2006, Gilchrist and Nanni, 2013, Ahonkhai et al., 2016, Hayter and Nisar, 2018). However, few identified the PDP model as the successful driver in bringing new successful vaccines to the market. PDPs achieved some successes, such as DNDi, which bought eight new treatments to the market. However, the production of vaccines remains much more complex. The literature does not examine whether such vaccines were successfully administered at a population level. Second, despite including LMIC stakeholders in their activities, there remains limited evidence to suggest that they have the ability to propose alternative interventions for speeding up vaccine innovation, improving access, or creating interventions that may be more suitable to their local needs. For example, several authors expressed concern about Gavi's mixed results in addressing between-country inequities in utilising immunisation services because of a lack of the necessary infrastructure on the ground.

Sources considered PDPs to have duplicated the work of some existing public-sector research organisations that share similar mandates yet have limited funding in the neoliberal era (Mrazek and Mossialos, 2003, De Pinho Campos et al., 2011, Stevenson, 2017, Jahn et al., 2020, Sunyoto, 2020). This underlines an inherent conflict in organisational goals, where public sector partners aim to address population needs within a specific budget, and private sector partners aim to maximise stakeholder profits (Mrazek and Mossialos, 2003, De Pinho Campos et al., 2011, Jahn et al., 2020). Indeed, a public consortium may seem a logical pathway to circumventing market failure. Still, well-founded doubts about the usefulness of such a strategy constrain such an arrangement from coming into existence. Essentially states would have to replicate the billions that firms invest in basic research, clinical trials, manufacturing, and distributing end products (Mrazek and Mossialos, 2003, Stevenson, 2017). Their unwillingness to do so underpins the existing division of labour, whereby basic research is currently funded publicly. In contrast, the private (though not always for-profit) sector does the rest (Stevenson, 2017).

Another significant finding relates to using AMCs to spur vaccine innovation and promote competition between first- and second-generation vaccine manufacturers in LMIC markets. The AMC has not been able to promote R&D into new vaccines, where its fundamental flaw is that it was based on the PCV vaccine, which was already available in the market in some form. Like other GHP approaches to initiating vaccine R&D, the AMC model does not sufficiently create opportunities for new technological diffusions for second-generation manufacturers. Sources examining the AMC's successes and failures also noted that it had played a role in expanding access to certain vaccines in LMIC markets; however, gaps remain regarding limited global vaccine manufacturing capacity or innovative new vaccine technologies. A lack of transparency on GHP decision-making processes further hampered the AMC model's successful appraisal. Though GHPs have an increasing influence in policymaking, they act as brokers between states and vaccine manufacturers, representing both parties' interests in accelerating access and R&D, mainly in LMIC settings. There was no evidence to suggest that such models work for HIC markets. Understanding how the GHP model can be leveraged in high-income economies, relating to their role in negotiating prices on behalf of such economies with vaccine manufacturers, will be crucial to understanding whether this model helps achieve global vaccine equity.

The findings of this review leave several questions outstanding on the structural factors that influence COVAX's ability to achieve its goals of global vaccine equity. Though COVAX is a new initiative aiming to increase vaccine availability globally, it has applied existing GHP methods and tools, all of which have only been used in LMIC settings. By contrast, there are numerous other barriers facing COVAX, such as supply shortages and vaccine nationalism. Unlike previous GHP initiatives, COVAX involves close collaboration with GHPs and international organisations such as the WHO, UNICEF, and public and private sector actors to achieve global vaccine equity. COVAX's mission is to serve both LMIC and HIC populations. However, more research is needed to understand the nature of this partnership, the different levels of power and influence each partner holds, and how they exert such influence to achieve the desired outcome. None of the studies included in this study examined how individual goals of partners within a GHP may either undermine or support its intended purpose.

Though COVAX exhibits the same business approach to global vaccinations as its predecessors, further research is needed to understand how actors have collaborated and which tactics they have employed to influence policy outcomes. This is inclusive of understanding how concepts of corporate risk management remain dominant despite the barriers it creates to access to health technologies across various global regions. Notably, Stevenson (2017) set out a framework by Rushton and Williams (2012) based on the competing frames, paradigms and power dynamics in global health. For the reasons outlined above, this framework helps conceptualise how different actors involved in COVAX project other ideas or concepts to support their relative positions in global health policymaking or governance. Additionally, it helps address the outstanding research questions relating to the structural determinants that may prevent COVAX from achieving its primary goal of vaccine equity. Finally, it encompasses the main findings of this scoping literature review relating to economic and governance factors influencing GHPs.

Similarly, Hayter and Nisar (2018) propose using an integrative framework for collaborative governance presented by Emerson et al. (2012). This framework addresses many of the issues outlined in the findings of this scoping review, relating to the relationship of actors involved in PDPs and the conditions that either promote or hinder vaccine innovation, such as limited financial or technical resources. It outlines a series of dimensions encompassing a more extensive system context, a collaborative governance regime, and internal collaborative

dynamics and actions that can produce impacts across the system. Analysts can apply this framework across a broad set of issues relating to public administration involving various actors at various levels of governance. It considers individual actors' incentives and barriers to collective action. This framework helps identify and describe dimensions that affect governance, particularly, it is useful in conceptualising how different organisations, mainly non-profit or private partnerships, can play a primary leadership role in innovation. However, it is less helpful in understanding how these factors interact and why such factors persist amidst changes in policymaking processes.

This framework does not require or focus on the role of the public sector to initiate collective action. Indeed, the public sector has heavily invested and funded R&D into many COVID-19 vaccine candidates. Lastly, this framework also does not address the different power dynamics which could arise in a governance regime. Though the focus of a collaborative regime is on engaging with actors with shared interests, there is limited scope on how to engage with actors who do not share such interests and may prevent collaborative action. The findings of this scoping review have provided insight into the conditions giving rise to GHPs and the factors which affect their performance. However, more research is needed on the relationships between actors and how specific power dynamics are sustained or undermined. For such reasons, the framework by Emerson et al. (2012) is not useful, as it does not provide further insight into the dynamic nature of policy framing and power relations which influence COVAX.

Other studies proposed frameworks relating to vaccine innovation and knowledge generation. For example, Mahoney (2011) presents a new framework that identifies the six determinants of innovation that are needed to promote the creation of health technologies, summarised in Box 6. The authors apply this framework in various case studies such as the Medicines for Malaria Venture, PATH, and the Japanese encephalitis project, among others, to determine whether the initiatives addressed all six components of innovation and go on to provide recommendations accordingly.

Box 6 The six determinants of innovation

The following determinants are necessary to promote innovation in health technologies and involve collaboration between public and private sector organisations:

1. The design and execution of research and development programs from preclinical studies to licensure;
2. Analysis and planning for the marketing and distribution of new technologies in individual developing countries;
3. Analysis and planning for the procurement and supply of new health technologies by the global health community;
4. Planning and implementation of manufacturing capabilities;
5. Establishment and implementation of regulatory systems to ensure safe and effective products;
6. Establishment and implementation of intellectual property rights (IPR) management systems

Source: Mahoney (2011)

Though this framework helps guide analyses of how PDPs should collaborate, it does not sufficiently engage with other important factors highlighted in this scoping review relating to the collaborative nature of actors' partnerships influenced by individual interests. Indeed, promoting innovation of new vaccine technologies is essential to address global health challenges; however, as noted in this scoping review, innovation alone is insufficient to achieve global vaccine equity. Other factors such as building vaccine manufacturing capacity in LMICs and reforming the current vaccine ecosystem are necessary to address the systematic inequities arising in the COVID-19 pandemic.

3.6.2 Implications

The critiques of existing GHPs included in this review lead me to consider that they offer numerous advantages over the traditional development process used by the pharmaceutical industry. However, challenges remain as global vaccine equity is yet to be realised. Both PDPs and access GHPs provide an excellent opportunity to tackle the gaps in the vaccine innovation system. Such partnerships are an opportunity to grow and leverage the comparative skills and experiences each partner is uniquely positioned to bring to the table. To make the best of

these alliances, I propose that the following issues require attention: (1) increased transparency to provide opportunities for performance and impact evaluation; (2) ways to refocus interventions to include both health systems strengthening and cost-effectiveness and (3) examination of incentives for cooperative vaccine R&D partnerships and expansion of manufacturing capacity to achieve global immunisation goals.

Many studies highlighted the lack of transparency of GHPs related to their geographic coverage, funding, governance structures and stakeholder involvement. Notably, GHPs have been characterised by a scarcity of civil society organisations (CSO) or LMIC stakeholders in decision-making processes, leaving decisions in the hands of HICs and private sector actors. The lack of transparency reduces opportunities to evaluate GHPs' impact and how such characteristics affect their performance and impact. There is a shortage of standardised, consistent data and routinely collected measures of progress in pharmaceutical innovation. As such, GHPs should consider being more transparent by making information about decision-making processes publicly available, thus prompting opportunities for evaluation. As pointed out by Aerts et al. (2017) , no single routinely updated, publicly available database exists to map and evaluate GHP's progress on innovation, along with GHP-specific characteristics related to funding arrangements, geographical scope or R&D costs and profit margins. To deal with this, donors could create a single platform, where GHPs would have to declare details such as, but not limited to, all funding received, investments made, and dates of each clinical step.

Private sector involvement in the pursuit of global vaccination goals is essential. However, their inclusion in global health decision-making processes has resulted in a greater focus on narrow technical interventions rather than systematic approaches to strengthening health systems. Appreciating the influence of donor expectations, particularly given previous donor fatigue, evaluations of GHPs' should include their success in achieving vaccine equity. To incentivise this, particularly in cases where partnerships are recipients of public funds, funding arrangements should be subject to a commitment to principles of equity and cost-effectiveness. Just as GHPs currently employ corporate-style incentive systems, where aid is contingent on performance, further research is required on whether donors can do this for monitoring and achievement of vaccine equity. There was a lack of studies on the role of GHPs in achieving vaccine equity, suggesting that an investigation into their role in promoting

equitable access to vaccines is urgently needed, which could provide vital knowledge to inform the development of future approaches to global public health policymaking.

Finally, the inclusion of equity in funding arrangements will require GHPs to consider incentives for data sharing and cooperative research, addressing the political aspects of the vaccine innovation system. This relates to technology transfer and manufacturing capacity conditions in the LMIC setting, prompting GHPs to treat LMICs as partners rather than aid recipients. Solutions addressing gaps in the innovation system should consider the aims of all the parties involved, not favouring only private sector interests. The precedence for this is evidenced by IAVI's experience providing the basis for future access through innovative IP arrangements. Greater attention should be given to systematic approaches to strengthening global vaccine manufacturing capacity, ultimately increasing availability, linked to better procurement strategies for all global economies. Though there is evidence to suggest that GHPs have increased vaccination campaigns in some countries, there is limited evidence to suggest they have contributed to health systems strengthening or increasing vaccine manufacturing capacity, both of which are essential factors in achieving global vaccine equity.

3.6.3 Limitations

The reliability of this study is limited by the fact that one researcher searched the literature. As such, this may have resulted in some bias in interpretation. However, I took measures to mitigate or reduce any form of bias, following the rigorous methodological approach proposed by Arksey and O'Malley (2005). The research is limited by the absence of a counterfactual against which GHPs could be compared. It is unknown whether, without GHPs, the global community would have developed vaccines to the extent it did, how push and pull factors would have operated, and what prices would have been set. Additionally, this review did not include grey literature. Grey literature refers to print and electronic documents produced by government, not-for-profit, academic, business, and industry sources that are not controlled by commercial publishers (Schopfel, 2010). Indeed, the inclusion of such documents would have provided details of GHPs' organisational planning and policy related activities. While it would be appropriate to include it in a review seeking to answer a narrowly focused question, such as "how did the policies of a specific organisation X (or issue Y) evolve over time", when the literature to be included could be clearly defined. Recent examples include a review of the use of German Social Law to support people with dementia (Manietta

et al., 2022). This is not the case with a scoping review such as this, that examines a large number of partnerships, each with their own extensive bibliography.

3.7 Conclusion

My findings in this scoping literature review contribute to a clearer understanding of the emergence of GHPs, the mechanisms they have leveraged to support global access to vaccines and the inherent challenges associated with their implementation. There is little evidence to suggest that GHPs alone can address broader issues relating to global vaccine equity, where studies indicate that GHPs are part of the solution and should not be considered the sole solution. By design, GHPs do not explicitly seek to challenge the current economic governance system; instead, they work within its confines to develop products or increase access. Consequently, GHP initiatives produce technical solutions to political problems. As such, further research is needed to identify opportunities for collaboration across all actors involved in global health governance and to identify which mechanisms should be implemented to ensure successful action towards achieving global vaccine equity. Findings from this scoping literature review also indicated that the framework by Rushton and Williams (2012) would help understand how COVAX crystallises the institutional design of existing GHPs.

3.8 Summary

This chapter reports the findings of a scoping review of literature on GHPs. It asked why GHPs are used, discussed their emergence and institutionalisation in global health governance, examined their strengths and weaknesses, and asked what this means for COVAX. GHPs have typically applied vertical approaches to tackling global health challenges relating to access to vaccine technologies, an approach that COVAX has also adopted. This approach highlights GHPs' tendency to operate within, and not against, the neoliberal economic system by playing the "rules of the game". Consequently, this has affected how vaccine technologies are perceived as an economic tool for market returns rather than a global health good, which all global populations should access.

Though various studies have sought to understand and examine GHPs as a phenomenon, few have sought to understand the interplay and exchange of ideas from an international relations perspective and why certain actors continue to push specific tactics to realise their interests

and sustain their positions of power in policymaking processes. The following chapter provides the findings from a review of documents and interviews with key stakeholders.

Chapter 4 Findings from the COVAX Facility case study

4.1 Overview

In this chapter, I report on the findings from the document review and key informant interviews, which answer my second research question, "to what extent were those lessons learnt, or not learnt, when creating COVAX and what might explain this?" The document review seeks to understand whether COVAX replicates existing strengths and weaknesses of previous and existing GHPs identified in the previous chapter, with the key informant interviews conducted to either confirm or refute the emerging findings. Section 4.2 provides an overview of key informant characteristics. I have structured my findings following Rushton and Williams (2012) framework for analysing global health policymaking. The first set of findings in section 4.3 describes the "global health policy" component of the framework. Here, I discuss Gavi and CEPIs' role in creating the COVAX Facility (section 4.3.1), followed by emerging observations relating to COVAX's tiered design (section 4.3.2), COVAX governance structure and lack of transparency and accountability on decision making processes (section 4.3.3), and finally, COVAX's limited engagement with civil society organisations (CSOs) and LMIC stakeholders (section 4.3.4). These are followed by a summary of competing frames, consisting of "policy debates" and the underlying "paradigms of global health" (section 4.4). This section is divided into the two main framings of vaccine equity, which were that vaccine equity requires technical solutions and additional financing mechanisms (section 4.4.1) and vaccine equity requires political solutions (section 4.4.2). My findings are presented as a series of themes. The process of producing themes was informed by the reflexive thematic analysis theoretical framework proposed by Braun and Clarke (2019). Finally, I summarise the main findings.

4.1.1 Abstract

Background

The onset of the COVID-19 pandemic led to the creation of COVAX - a novel structure to support the discovery, development, and distribution of COVID-19 vaccines. COVAX's task was to coordinate the resources needed for all countries to achieve equitable access to COVID-19 tests, therapies, and vaccines. It is led by GAVI, the vaccine alliance, the Coalition for Epidemic Preparedness Innovations (CEPI), and the World Health Organization (WHO),

with UNICEF as the primary delivery partner. These organisations all have well-established track records in this field, and, in many respects, COVAX has succeeded in procuring and delivering vast amounts of vaccines. But it has also fallen short of its goals, lagging behind schedule and facing substantial challenges in obtaining and distributing vaccines in circumstances where there was intense competition for the limited qualities available. Ideally, one would have expected that the design of this innovative mechanism would draw on the lessons of the previous global health partnerships operating in the vaccine field. This case study asks to what extent were lessons learnt from previous GHPs considered when creating COVAX and what this tells us about the current state of global health policymaking and the influence of power dynamics between actors.

Methods

I reviewed key organisational documents and key informant interviews to answer the question: "to what extent were those lessons learnt, or not learnt, when creating COVAX and what might explain this?" I synthesised data thematically.

Results

I reviewed 109 documents. Most (64 [59%]) were meeting minutes from either Gavi or CEPI Board or Committee meetings, and 45 [41%] were documents prepared for meetings, including reports to the Board, activity forecasts, terms of reference, and policy or strategy documents. I interviewed 23 stakeholders. Emerging themes included global health policy (e.g., Gavi and CEPI creating the COVAX initiative, COVAX's tiered design, COVAX's governance structure and lack of transparency and accountability in decision-making processes and COVAX's limited engagement with CSOs and LMIC stakeholders) and policy debates (contestation between frames) and paradigms of global health (e.g., achieving vaccine equity requires technical solutions and additional financing mechanisms and achieving global vaccine equity requires political solutions).

Conclusions

COVAX combines an end-to-end approach to vaccine R&D by leveraging both push and pull mechanisms, led by Gavi and CEPI, both highly experienced in their respective fields. However, the leadership of Gavi and CEPI has largely followed the same arrangements as previous GHP initiatives. Despite both organisations acknowledging the pandemic called for a move from "business as usual", their efforts have largely followed the traditional way of

thinking, with the exclusion of CSO and LMIC stakeholders, COVAX's tiered approach to vaccine procurement, and continued lack of transparency in decision making. The document review and interviews reveal two competing frames for achieving vaccine equity, private sector and GHP actors supporting GHPs' continued subsidy-based approach versus CSO and academic actors calling for GHPs to employ systematic approaches to achieving higher vaccination rates.

4.2 Subjects

The methods used to undertake the document review and the interviews were described in Chapter 2. Twenty-three key informants interviewed, and their characteristics are presented in Table 4.

Table 4 Summary of key informant interviews

Role	**Initials**	**Organisation**	**Location**	**Interview language**
Academic	AC-1	Queen Mary University London	UK	English
	AC-2	Georgetown University	USA	English
	AC-3	University College London	UK	English
	AC-4	University of Oslo	Norway	English
	AC-5	University of Oslo	Norway	English
	AC-6	Duke University	UK	English
	AC-7	London School of Economics and Political Science	UK	English
	AC-8	KEMRI Wellcome Trust	Kenya	English
	AC-9	KEMRI Wellcome Trust	Kenya	English

	AC-10	KEMRI Wellcome Trust	Kenya	English
Civil society	CV-1	Médecins Sans Frontiers	UK	English
	CV-2	Oxfam	UK	English
	CV-3	Chatham House	UK	English
	CV-4	Médecins Sans Frontiers	USA	English
Global health partnership	GP-1	Gavi	USA	English
	GP-2	WHO	Switzerland	English
	GP-3	COVAX	Switzerland	English
	GP-4	Global Fund	France	English
Private sector or vaccine manufacturers	PM-1	Deloitte	UK	English
	PM-2	Deloitte	USA	English
	PM-3	Merck	France	English
	PM-4	Deloitte	UK	English
	PM-5	Merck	USA	English

4.3 Global health policy

The themes summarised in this section explore the issues associated with the creation of COVAX, which itself constitutes a global health policy. The themes relate to both the formal elements such as (1) Gavi and CEPI creating the COVAX initiative; (2) COVAX's tiered design, and informal elements such as (3) COVAX's governance structure and lack of transparency and accountability in decision making processes and (4) limited engagement with CSOs and LMICs, which have shaped the creation of COVAX.

4.3.1 Gavi and CEPI creating the COVAX Facility

The COVAX design process was led mainly by Gavi and CEPI. The COVAX Facility was shaped between May and August 2020, when these two organisations presented its design to their

respective boards. This illustrates how both organisations divided institutional arrangements in real time to create a space for international collaboration in development, procurement, and delivery of vaccines. It was agreed that COVAX would have three workstreams. CEPI would lead the development and manufacturing workstream. Gavi would lead on procurement and delivery. WHO would lead policy and allocation.

Gavi and CEPI acknowledged that the COVID-19 pandemic response was not "business as usual" and adapted their core processes when creating COVAX. Minutes of meetings in the first months of 2020 reveal how the governance bodies of each organisation adapted to the needs of the COVID-19 pandemic by increasing the number of meetings and the level of communication across all governance functions. For example, the Gavi Alliance Board Meeting on 19 March 2020 acknowledged that "it is not 'business as usual', and Gavi should be taking some bold and rapid country-responsive actions and be willing to work in new ways while remaining mindful of the need to ensure that Gavi's longer-term ambition and core business is not compromised". Board members initially "expressed support for the potential use of [International Finance Facility for Immunisation] and the AMC in relation to this pandemic response while ensuring that any such use does not undermine Gavi's core business" (Gavi, 2020h). Similarly, on 10 January 2020, CEPI's Scientific Advisory Committee suggested to view the early onset of the pandemic as, "a potential Disease X rehearsal" and to initiate work on, "RNA sequencing and making DNA through rapid response platforms" to develop a targeted vaccine (CEPI, 2020g).

At the same time, a CEPI Mid-Term Review noted that the COVID-19 response was outside of CEPI's organisational mandate (CEPI, 2021b). Noting that CEPI was created to address market failure, the development of a COVID-19 vaccine was not a classic example of such a failure because of the large flows of governmental and private sector investments into R&D. Based on interviews with staff from the CEPI Secretariat (n=15), the report stated:

> *"CEPI's role should primarily focus on the pre-pandemic period, to ensure preparedness when market forces are not put into action. Such perspective, however, does not acknowledge the importance of global reach, equity, and public health impact (ending the pandemic), all dimensions that, even in the event of a global pandemic, are generally not effectively addressed by market forces which tend to focus primarily and at first on the most profitable markets, as the 2009 H1N1 pandemic demonstrated".*

At CEPI's Board meeting on 29 June to 01 July 2020, Richard Hatchett noted, "The concept of COVAX is that it is an end-to-end solution that will provide participant countries the

opportunity to share risk in R&D; access successful vaccine candidates and share costs, including a manufacturing at risk – premium to deliver at speed". Consequently, the focus on end-to-end vaccine development and procurement meant that WHO was primarily involved in norm-setting and developing a vaccine strategy. In this meeting, WHO's Chief Scientist, Soumya Swaminathan, who focused on WHO's relationship with COVAX, noted that WHO was primarily responsible for policy and allocation, established a SAGE working group on COVID-19 vaccines, considering post-marketing surveillance, criteria for efficacy, talking with regulators, and leading work on the principles of fair allocation.

Many interviewees (AC1-3, CV1, 4, PM1, 5) agreed that having both Gavi and CEPI lead the global response seemed natural, given that they were already working within the space of global vaccine procurement and epidemic preparedness. There was a consensus that there was no counterfactual to compare with, as there was no other organisation or group of organisations that were experienced and willing to act and had access to the funds needed to finance a global COVID-19 vaccine response other than Gavi and CEPI. One interviewee explained how donor expectations pointed to Gavi and CEPI leading the response instead of WHO:

> *"CEPI was created to do this. This was disease x. It was normal for me that they would take the lead. CEPI and Gavi, they are both into vaccines, we need diagnostics and treatment […] you can see where is the money, who can move money around. And then for instance, donors were ready to give loads of money and they wanted to give it to initiatives they were confident were doing a good job, [and who were] more operational than WHO. So [these organisations] got plenty of money to setup programmes and shift money through their contacts and channels to help finance their response. These players had access to money in ways that WHO did not have. [Gavi and CEPI] have in their mandates to develop products, clinical trials and procurement, and the things that WHO is not equipped with. This is outside of their role" (CV-1).*

When asked whether donors should have strengthened WHO capacity prior to the pandemic, directing funds towards public sector engagement, there was a consensus amongst interviewees that this would not be suitable for the different actors involved in global health, where there has been a historical shift away from legally binding health equity initiatives typically pursued by WHO to non-binding ones such as those offered by GHPs. Many interviewees (AC2-5, CV1-3, PM1-3) noted that WHO's role in the pandemic response has been hampered by its limited capacity in vaccine R&D and being severely underfunded to deliver on its primary tasks, such as policy and allocation and norm-setting. Interviewees

supported the notion that GHPs such as Gavi have improved the supply and demand of vaccines for preventable diseases by working with public and private sector actors. However, interviewees also argued that other interests were not adequately addressed in the formation of COVAX. One vaccine manufacturer explained:

> *"The reason Gavi was at the core of COVAX was because everyone realised Gavi did a pretty good job in the preceding 20 years of addressing how to improve the supply and distribution of solutions for vaccine-preventable illnesses to people who needed those solutions and could not afford them on their own. The difference with COVAX was, we did not have the technologies on hand in the way that we did with every other technology that Gavi had distributed […] They put together an equity based, solidarity-based platform and everything will be fine, but this didn't do anything to provide the incentives that were needed for the different actors that would actually solve the problem" (PM-5).*

Interviewees argued that COVAX's equity-based model was not as effective as having context or country-specific vaccine goals given countries' varied demographics (i.e., certain regions having a greater proportion of people over 65 years versus regions having a greater proportion of people under 65 years). For example, some interviewees (AC3-5, CV1, GP3) who worked closely with Gavi on the development of ACT-A and COVAX said they did not think that the single goal of vaccinating 20% of the population in every country was appropriate. Many interviewees stated that though the WHO Allocation Framework informed COVAX, a better response would have been to make a country or region-specific responses and put more resources into the entire vaccine supply chain; however, this would have required much more knowledge of each country's health systems. One academic indicated that global aims and goals should be easily measurable, simplistic, broad diverse:

> *"There is a tendency in the international community to shoot for the lowest common denominator, to communicate what is simple – in general, WHO is big on simple messages. This is because countries are diverse, and it needs to resonate. If we say 70% of people over 50, does this mean that young LMICs don't matter because they don't have many people over 50? Does that signpost some inherent racist bias? How do we set a measurable, straightforward target, and easy to communicate, without having the intended effect of making us look [bad]?" (AC-4).*

Another interviewee who worked with COVAX as a consultant noted:

> *"We also learned that allocation does not lead to equity. You cannot send a country like Yemen a bunch of vaccines and expect them to achieve a coverage level at the same rate as Australia. It's unrealistic; the problem in Yemen is partially getting supply; it's more about once the supply is in the country, how do you get it into people's arms? […] You cannot allocate your way to equity; you need to also address all the other barriers that these countries face to moving their coverage rates up" (GP-2).*

4.3.2 COVAX's tiered design

CEPI Board meeting minutes held throughout March 2020 revealed that COVAX's current tiered approach to vaccine access was a departure from the originally proposed model. It did not differentiate between national income levels. Instead, it considered public health factors which could facilitate the design and implementation of national vaccine programmes. A white paper presented by Richard Hatchett on 25 March 2020 outlined the fundamental mechanisms that COVAX would use. This was initially called the "Fair Allocations of Innovations for Pandemic Relief (FAIR) System" (CEPI, 2020e). It acknowledges that *"the international organizations best suited to implement and oversee such a system are Gavi, the Vaccine Alliance (Gavi) and the Global Fund for AIDS, TB, and Malaria (GFATM), working closely in coordination with each other and with WHO. Given their current focus on developing countries, the mandates of these organizations may need to be extended with respect to the COVID-19 response to include the provision of medical material and services to all affected countries"* (CEPI, 2020e).

The proposal goes on to set out how to operationalise a globally fair allocation system by using financial instruments such as advanced purchase commitments to "*provide sufficient regimens to vaccinate healthcare workers, first responders, and high-risk populations worldwide, and after that provide vaccine for a substantial portion of the world's population, contributing to the development of global herd immunity* [within 1-2 years]" (CEPI, 2020e). The proposal further states that an allocation scheme will "[take] *into account the size of the healthcare workforce, populations within identified risk groups, healthcare system capacity, and other factors as appropriate within different countries can be developed in coming months and facilitate the design and implementation of appropriately scaled national vaccination programs*" (CEPI, 2020e).

This corresponds with the meeting minutes of CEPI's Equitable Access Committee, held on 30 April 2020, which state that the intended COVAX model maintained that "equitable access is critical, especially for funders who are using ODA funding" and advised, "*One approach would be to define a large percentage of vaccine for the global stockpile, and within countries where the vaccine is manufactured to ensure a focus on groups that need vaccine first (e.g. health care workers and emergency services workers) – and in doing so reduce the global high priority requirement*" (CEPI, 2020f).

However, in September 2020, the Gavi Alliance board reviewed proposals for COVAX's governance structure, which outlined the design, funding and financing arrangements for participating countries based on income level (Gavi, 2020i). Item 1.4 of the final report to the Board summarised a departure from the original public health considerations to the current COVAX tiered participation model for Self-Financing Participants (SFPs): the "Committed Purchase arrangement or the "Optional Purchase" arrangement, and item 1.6 explained the COVAX AMC for AMC eligible economies (Gavi, 2020d). Seth Berkley describes COVAX as being a "lifeline" for funded participants, and being an "insurance policy" for self-funded participants:

> *"For lower-income funded nations, who would otherwise be unable to afford these vaccines, as well as several higher-income self-financing countries that have no bilateral deals with manufacturers, COVAX is quite literally a lifeline and the only viable way in which their citizens will get access to COVID-19 vaccines. For the wealthiest self-financing countries, some of which may also be negotiating bilateral deals with vaccine manufacturers, it serves as an invaluable insurance policy to protect their citizens, both directly and indirectly" (Berkley, 2020).*

Berkley further explained,

> *"For the Optional Purchase Arrangement, participants can choose to opt out of receiving any vaccine, without jeopardising their ability to receive their full share of doses of other candidates, subject to supply becoming available. This type of agreement may be more attractive to participants that already have bilateral agreements with manufacturers, through which they may already have secured sufficient doses of that particular vaccine" (Berkley, 2020).*

I found few documents outlining how this arrangement was developed. However, an ACT-Accelerator Strategic Review prepared by Dalberg stated, "*While intended to maximise HIC participation and prevent HICs from locking up all early doses, some external commentators believed this tiered approach ran counter to ACT-A and COVAX's underlying equity goals*" (Dalberg, 2021).

There was some disagreement when interviewees were asked about whether COVAX's tiered approach undermined equity. Some (AC2-4, 6-7, CV1-3) considered the tiered approach to have undermined principles of equity, indicating that COVAX was initially set up to avoid the international scramble for vaccines. However, by making concessions, such as the Optional Purchase Agreement, HICs effectively prioritised access by allowing concessions on access and leveraging their purchasing power. One noted the gradual shift in COVAX's design was reflective of existing global health norms, which do not challenge existing structures:

"And so, from the first discussions I had with Richard, he wanted to know if [we were] interested in getting on board with a project like that, which we were, but by the time the next iteration actually first paper came about, it was no longer that ambitious project and had already been diluted as something that would differentiate between rich and poor countries and the whole complicated set of that [which] COVAX started to crystallise. And I think from the beginning the ambitions were compromised because the key people and institutions that were at the driving wheel were not ready to go for the big ambition. Maybe this is realpolitik, but this is never going to fly. But the funny thing is, the reason they wanted to do this, was to avoid the scramble that we have had in the end" (CV-3).

Other interviewees (AC1, 5, GP2-3, PM 3-5) argued that the concessions were necessary for political reasons, as it would not be possible to host one platform for all economies and HICs would not have agreed to the terms and conditions originally proposed. One interviewee justified the rationale behind creating a tiered system and said:

> *"We couldn't have the same model; self-financing countries are not eligible for donor-funded vaccines. Countries that are in the AMC group, got free vaccines. We couldn't send free vaccines to Canada. We needed a model where those who had the means could pay their own way. That was important […] We wanted to make the model attractive, this was a difficult decision. We came up with an attractive model […] you'll see those vaccines from COVAX did go to [LMICs] at much higher rates and higher proportions than to HICs even though they had these different terms. The reality was a couple shipments did go to the UK and Canada, which probably shouldn't have gone there because they had plenty of vaccines, but we made a promise in the beginning that said if you join COVAX the way allocation works is that everyone gets the same rate up until 20%. We set this 20% threshold as this public health-oriented coverage level that would protect your most vulnerable and would have the greatest public health impact, so we said the whole world deserves to get to that place on the same schedule" (GP-2).*

When asked whether Gavi and CEPI were correct in targeting all global economies attempt to achieve global vaccine equity, there was a consensus among all interviewees that COVAX's goal was noble. However, the focus should have been on LMICs, rather than attempting to also cater to HICs in the name of solidarity. One interviewee noted that basing the global response on solidarity was ineffective and idealistic:

> *"Solidarity is not a useful analytical tool in looking at a question like this; some people will think – if it were so important – if we believe in solidarity then that would mean that there are equitable solutions to every global health problem, we would live in a different world than that which we live in. We have people who believe in solidarity, but we still have inequalities. And the reason for that has to do with the pattern of*

interests and the way in which resources are allocated according to those interests" (PM-5).

The "one size fits all" approach that COVAX applied was unsuccessful as every economy has different priorities and needs, which influence their capacity to procure and administer vaccines. This was particularly the case for countries with manufacturing capacity that ultimately prioritised their own citizens before sending vaccines to other countries. Reflecting on COVAX's choice to cater to all global economies on one platform, one interviewee agreed that COVAX was overly idealistic:

> *"We were perhaps optimistic and naïve was thinking that perhaps [HICs] would view COVAX as truly complementary to their own methods of getting access and wouldn't be (whether intentionally or not) trying to undermine COVAX through trying to procure supply directly from manufacturers. And we knew this would happen to some extent, we were not blind to that. There was also this idea that it is better that they are on your team, then not on your team. And so, in a world where we knew the UKs and USs were already striking deals and being very aggressive with trying to secure vaccines, if you could have them be part of your team in some way […] we didn't get it fully right. If we were to do it again, we would have probably required countries like the UK or the US or Canada to provide back to COVAX some portion of supply should they receive supply sooner than COVAX did itself […] If you look at countries that did get vaccines early, they were China, India, Europe, and the US – they all had manufacturing capacity and they all prevented manufacturing capacity from being shared with the world for some period of time. All the major producers restricted exports; how do you compete with that?" (GP-2).*

4.3.3 COVAX's governance structure and lack of transparency and accountability on decision making processes

All interviewees agreed that COVAX's governance structure procedures are characterised by a lack of transparency and inclusiveness, noting COVAX's lack of accountability. COVAX was built on Gavi's existing structure, where the Gavi Board is responsible for overseeing the role of the Gavi Secretariat. The Market-Sensitive Decisions Committee and the Audit and Finance Committee, both within Gavi's regular governance structure, are comprised mainly of Gavi Board members and have also taken a role in overseeing COVAX. Though there are mentions of "decision-making principles," an explanation of how decisions are made, by whom and where the accountability rests are notably absent from the COVAX Structure and Principles document. The only mention of who makes decisions is about the Gavi Board, which has "ultimate responsibility for decisions and effective implementation of the COVAX Facility" (Berkley, 2020, Nguyen, 2020).

The documentation of decisions and their rationale are not always immediately intelligible, and nor is the role of specific governance and advisory bodies, even among many within the system. For example, in the Gavi Alliance Governance Committee meeting held on 08 October 2020, members sought clarification on issues related to "the link between the new COVAX Facility governing groups and the Gavi Board and its Committees, in particular about decision-making; the role if any, of the Gavi Board Committees about COVAX; membership of the different bodies, to ensure inclusion, equity and transparency" (Gavi, 2020j). However, the same issue is raised on 30 September 2021: "Committee members noted that it is clear from the recent Board meeting that Board Members are still at different levels of understanding about COVAX and that it will be important to ensure that there is a common level of understanding on the process and that Board Members understand when and how best they can and should engage" (Gavi, 2021c).

The lack of communication on organisational mandates was also highlighted in CEPI, where interviewees to the CEPI Mid-Term Review provided mixed reviews on CEPI's role as a facilitator of effective partnerships in the coalition and with other stakeholders. The complex global health ecosystem does not simplify CEPI's task of aligning and clarifying the roles and relationships of external stakeholders, many of which have been historically challenging. A comment encapsulating CEPI's challenge in this realm: "CEPI does align well with other global health initiatives, but communication of this could be improved. This would help improve understanding of how CEPI complements existing structures and clarify where CEPI 'hands off' to others" (CEPI, 2021b).

The lack of clarity on organisational mandates is exacerbated by reports of Gavi and CEPI's unwillingness to engage in meaningful self-reflection and implement changes accordingly. For example, Brenda Killen, Director, Governance and Secretary to the Gavi Board, noted, "There is no desire for changes to be made to the COVAX governance model" (Gavi, 2021c). Similarly, CEPI's Joint Coordination Group reviewed CEPI's COVID-19 response and rated CEPI's performance strongly with an average of 8.7 out of 10. They cited CEPI's speed in identifying candidates and success in positioning vaccines as a key element of the response as reasons for rating CEPI so successfully. When asked what could have gone better, the answers varied but included: the need to clarify roles with others (especially Gavi and regional bodies); a need for clarity around vaccine communications in the response; and the need to be sure the right

resources are focused on the suitable topics […] Finally, when asked what changes needed to be made in the next few months: the group did not offer any. Even without suggesting any clear changes that need to be made, the discussion has given CEPI a lot to consider when approaching the response moving forward (CEPI, 2020d).

The lack of clarity around vaccine communications was illustrated by COVAX's decision to rely on the AstraZeneca vaccine. One interviewee responded commented on this and said:

> *"Everything with COVID and the vaccines, there is lack of transparency by the vaccine developer around clinical trials, publication by press release and this is independent of institutions like ACT-A and COVAX, but then why did they decide to put all their eggs in one basket which unfortunately turns out to be the vaccine that wealthy countries, after the UK was initially proud of it, and then kind of switched to mRNA vaccines and then wealthy countries don't want to use anymore, to use that as the one vaccine that was going to – that does not look very good. It was not planned like that and, but this is where is landed. There have been so many mistakes, but again everyone has been building the plane while it was flying, there were no easy things to be done. But what is problematic is that they kept saying they were doing a good job" (CV-1).*

The CEPI Board meeting minutes (15-17 March 2021) noted, "There have been delays in the delivery of anticipated supplies of doses for COVAX. This is partly due to manufacturing bottlenecks but also the worsening epidemic in India and geopolitical considerations elsewhere. CEPI and COVAX mustn't be blamed for the realpolitik of countries focussing on domestic supply". Interviewees from the private sector, including those working in vaccine manufacturing, did not think contractual transparency was an important element of accountable global health governance. One interviewee said:

> *"Contracts are a red herring. If I am a pharmaceutical company and I have a contract with government x to deliver a certain amount of a vaccine by time y, that contract will have specifications that I am obligated to fulfil, or I don't get paid. On the other side, the government or recipient will have a contracting officer, a procurement officer whose job it is to make sure that the government gets exactly what it bought. So, when people say there is no oversight and pharma companies aren't accountable, I think this is nonsense, this is insulting to the governments and the other parties in those contracts that they don't have the width and the ability to hold pharmaceutical companies' feet to the fire as their suppliers […] The transparency question is more an issue of inclusivity and public participation" (PM-2).*

4.3.4 COVAX's limited engagement with CSOs and LMIC stakeholders

On 04 June 2020, Gavi launched the COVAX AMC, where stakeholders such as Gavi, the Gates Foundation, CEPI, WHO, World Bank, UNICEF, PAHO, academics, and McKinsey and Company were consulted (Berkley, 2021). Notably missing from this group and the overall design

process were representatives from AMC countries and civil society organisations. By July 2020, Gavi confirmed the scope of countries to be included in the COVAX AMC. However, there was minimal opportunity for the governments affected by the COVAX AMC to shape its structure.

Civil society started to advocate for a seat at the table in May 2020, before the AMC was launched. However, it was not until October 2020 that civil society organisations were included in the governance structure of the COVAX Initiative. Comparatively, HICs exerted significant influence over the design of COVAX financial mechanisms. When asked why CSOs were omitted from the initial stakeholder discussions of COVAX's structure, a few interviewees (AC1, CV1-4) contended that CSOs' demands would not be adequately addressed by senior governing officials at both Gavi and CEPI, where one interviewee reported:

> *"After that initial convo with the then president of MSF, we said we were very interested, send us a concept note as soon as possible, happy to contribute etc, we never heard back, and I insisted several times […] a few weeks later we received a concept note that was already very different. I think we were not invited to be part of the table because they knew what we would be standing for and fighting for. We know in a way who are the key people who ended up governing COVAX and those groups are on the table. But MSF after that initial exploratory conversation, we were not invited to be part of it. Because it was already going in way that they knew we would resist" (CV-2).*

In the October 2020 Gavi Alliance Governance Committee Meeting, Dr Ngozi Okonjo-Iweala, the Board Chair, highlighted the importance of CSO participation and asked the Board at what stage and where should they participate and in which manner. Committee members agreed that this was an important issue and, following discussion, proposed that CSOs and UN agencies be included in the working versions of the ToRs for both the COVAX Shareholders Council and the COVAX AMC Engagement Group. The Secretariat noted that regional bodies would also be considered for the Engagement Group. However, it clarified that the Gavi Board remained the ultimate decision-making body as Gavi is the legal entity administering the COVAX Facility. The creation of new bodies was to give partners who had not previously been engaged with Gavi a voice to offer opinions and be fully informed about the work being done (Gavi, 2020j).

A review of the Terms of References (ToRs) revealed that government participation in COVAX happens through two groups, the Shareholders Council and the AMC Engagement Group. The

COVAX Shareholders Council represents and is open to all self-financing participants. The AMC Engagement Group is meant to represent COVAX AMC countries and is open to representatives from AMC-eligible countries and AMC-donor countries. According to the COVAX Structure and Principles document, both the Shareholders Council and AMC Engagement Group are "self-organising" and "convene to support real-time information exchange and provide strategic guidance and advice to the Office of the COVAX Facility on the operational aspects of the COVAX Facility" (Gavi, 2020d, Gavi, 2020e).

Despite the Facility's attempt to engage with different stakeholders, Gavi's Governance Committee noted: "Committee Members agreed that some of the areas that need to be addressed are not around the governance model itself. The AMC Engagement Group and Shareholders Council meetings thus far have not generated as much communication and exchange between countries within their meetings as one might expect in such fora. The Secretariat has also organised many workshops and briefing meetings, so it will be important to find the right balance, and clear differentiation, between these and the more formal meetings going forward" (Gavi, 2021c). When asked why there has been limited CSO engagement with COVAX, eight interviewees argued that CSOs were not given adequate resources to participate. Such participants were already stretched with other commitments and worked on different timelines. One interviewee said:

> *"ACT-A could easily give grants to CSOs to act, but they don't like that because they will try to challenge, but these groups don't like to be challenged. It is a full-time job to look at all these documents, these consultancy firms they churn out slide decks and 50-page report, you need to be really on top of your game, and as CSO you need to consult your representatives and other stakeholders. Even though there are a number of seats in a number of committees, it is extremely difficult to make that effective, but who has time and in this capacity? Unless you have specific people and funding" (AC-3).*

The lack of LMIC representation was also observed in CEPI's organisational governance and operations. For example, CEPI's Equitable Access Committee pointed out that CEPI should aim to broaden its engagement and recognised, "the importance of participation of e.g., African, Asian scientists and population in development to build confidence, was pointed out. CEPI should aim at broad engagement" (CEPI, 2020b). Additionally, findings from the CEPI Mid-Term Review indicated that, "*CEPI lacked representation from at-risk countries, where interviewees recommended that improving CEPI's landscape understanding and decision-making requires expertise from both industry and implementers from at-risk countries, which*

is better incorporated in CEPI's governance and operations" (CEPI, 2021b). Some interview (AC5-7, CV3-4, PM4) accounts concurred that the current exclusion of LMIC stakeholders in decision-making processes is problematic and has prompted the development of the African Vaccine Acquisition Trust (AVAT) which was endorsed by the African Union. However, interviewees also agreed that it was too early to determine how AVAT would change decision-making processes and how they would engage with global health partners such as Gavi and CEPI. An over-representation of HIC interests contrast with the lack of LMIC representation.

For example, the CEPI Mid-Term Review's findings also indicate interviewees' concern that investor interests are too influential on CEPI's decision-making processes and state: "The potential impact of investors' interests can be deduced from one document recommending that the U.S. government invest in CEPI, because 'if the United States becomes a coalition partner, it will acquire a seat at the table early in the evolution of this promising new partnership, which will enable it to influence CEPI's decision process' [emphasis added]. This would allow the U.S. government to 'better align CEPI investments with other U.S. programmes and direct bilateral investments and motivate other donors, companies, and philanthropies to join the coalition'" (CEPI, 2021b). The report notes that such instances should be managed by robust transparency and governance processes to address conflicts of interest.

4.4 Policy debates (contestation between frames) and paradigms of global health

The themes summarised in this section explore how global vaccine equity is framed by different actors involved in the policymaking process. The themes arising include two main competing frames: (1) achieving vaccine equity requires technical solutions and additional financial mechanisms; (2) achieving global vaccine equity requires political solutions.

4.4.1 Achieving vaccine equity requires technical solutions and additional financing mechanisms

Technical solutions

The document review highlighted COVAX's technical approach to vaccine equity instead of addressing political issues that affect access. The COVAX Facility is repeatedly described as being committed to the "principle of equity" (Berkley, 2020, CEPI, 2020f, Gavi, 2021b), where the Facility is designed to "promote vaccine multilateralism", given the threat of vaccine

nationalism (CEPI, 2020a). Despite recognising nationalism and vaccine hoarding as a threat, there is limited evidence that either Gavi and CEPI took measures to mitigate this or engage with countries who might engage in "nationalistic" ways (CEPI, 2020f). Gavi and CEPI's main governing bodies consider the political elements related to vaccine access and nationalism to be outside of their respective organisational remits. Vaccine nationalism is recognised as something that lies "beyond the Facility's control" (Gavi, 2021b), where "an international effort to address the drivers of vaccine nationalism is needed, and this could be part of WHO's leadership role" (CEPI, 2020f).

Amongst all interviewees agreed that GHPs should do more to address political drivers of vaccine hoarding. However, four noted the practical limits of attempting to critique donor behaviour. For example, one stated:

> *"Gavi sits in the middle of a lot of competing forces, our core mission is to serve countries who are struggling for whatever reason. To achieve that mission, we work with parties that have other interests, like donors and manufacturers, in the arena you have to do things, where from the outside may not appear all together consistent but are viewed by us worth doing to get to the objective we want to achieve. What I mean by that is for example when you have donors that are the ones who are primarily funding Gavi, we've raised 12-13 billion dollars in the last 2 years, this is a tonne of money, calling them out publicly and saying, 'hey you guys should do a better job [of] sharing vaccines with us', is a good way for that cheque to never show up in your bank account. We work behind the scenes on all that stuff. But in public we were more muted because our hands were a bit tied. We would advocate for vaccine equity, but we would not point fingers so obviously" (GP-3).*

Document review illustrated Gavi and CEPI's tactics for advocating for vaccine equity were mainly technical interventions that operated within existing IP frameworks by including vaccine equity provisions in their contractual agreements. For example, when considering the development of equitable access requirements, CEPI discussed its position on the broader vaccine architecture in the March 2020 Equitable Access Committee, noting that it is not the sole funder of vaccine technologies (CEPI, 2020h). CEO Richard Hatchett went on to say that CEPI's portfolio has been designed around three components: speed, scale, and access, further noting:

> *"In a pandemic there is a need for huge production at pace, at huge scale, and to find a fair way to allocate vaccine when there is massive global simultaneous demand. CEPI's partnership agreements with vaccine developers are one of the keyways CEPI seeks to achieve equitable access, and they build in on ramps and off ramps to consider how and when to proceed. In working on Step 2 agreements with partners, access*

considerations become more pronounced and critical. That noted, CEPI's agreements need to interact with the wider architecture, which CEPI can seek to influence, but goes beyond CEPI's responsibility".

A closer look at how agreements are developed shows CEPI working within the confines of the IP system instead of challenging it. For example, the meeting minutes from CEPI's Equitable Access Committee meeting held on 13 February 2020 stated, "It was also advised that the language of the terms of agreements be amended to include specific requirements relating to producing sufficient quantities for those in need, benchmarking affordability, and termination of breach to set out CEPI's expectations in relation to IP […] Concern was expressed around the IP ownership for the agreements with companies and the view was supported that clear provisions needed to be included in agreements to ensure that IP is subject to an agreement to equitable access" (CEPI, 2020c).

There were no discussions on possible IP waivers in either Gavi or CEPI Board meeting minutes. Interviewees were divided when asked whether IP was a barrier to achieving global equitable vaccine access. Those working in vaccine manufacturing (PM1-5), partnerships (GP1-3) and some academics (AC3 and 7) did not consider IP to be a barrier to access and saw the patent system was an important incentive for innovation and means to engage private, including pharmaceutical sector, partners. One interviewee noted:

"This is a sensitive issue in the industry, there are several bodies or individuals calling for IP waiver, but I think this is simplistic view not taking into consideration the huge amounts of other considerations. You need to protect the ability for organisations to invest in their innovation, and it is the thin edge of a wedge when you start talking about IP waivers […] But when you then look at other considerations around like the quality standards that you need in order to manufacture in our industry, so very tight requirements, GXP, around quality around standing up a manufacturing facility with the requisite quality regulatory standards adherence etc, that is not a simple thing to do […] The [pharmaceutical] industry overtime has always been used as a football, given the cost of healthcare and the cost of pharmaceuticals and some bad examples of profiteering which are well published in the sector. But the [pharmaceutical] industry are on the side of angels with regard to what they are trying to do to promote health in the population. And again, I think it gets politicised and weaponised the cost of bringing a drug to market" (PM-1).

Subsidy-based approach

The reluctance to challenge the IP regime has resulted in a subsidy-based approach. Gavi and CEPI's original white paper outlining the COVAX Initiative committed to the "*coordinated use of financial instruments such as concessional loans, grants, advance purchase commitments*

(APCs), and potentially government-backed vaccine bonds to support the necessary scaling of manufacturing, procurement of vaccine, and delivery of the product. The system should also address the outstanding concerns of private sector partners about liability and indemnification in the event of severe adverse events caused by licensed vaccines procured through the system" (CEPI, 2020e). Private sector and vaccine manufacturer interviewees agreed that Gavi and CEPI's approach to regulatory flexibility had created optimal conditions for innovation, with one interviewee noting:

> *"I think [we should be looking] at vaccines that have been created [and] at the silver linings review of what actually transpired in that 6-month period from the onset of the pandemic to production of that first vaccine. How did we move from creating a vaccine in a 6-month period, when the previous record was 5 years, and the average period is 10 years? How can we actually improve the lifecycle of the development of the vaccine or lifesaving drugs, by taking on board the things we were able to do in a record time when a number of constraints were removed, and the quality of the outcomes was still guaranteed?" (PM-3).*

Regulatory changes are now being incorporated into future pandemic planning, where CEPI Board meeting minutes, (15-17 March 2021), highlight that "*regulatory flexibility is critical and that there are numerous efforts underway to sketch out a fit-for-purpose pandemic preparedness and response architecture for the future, including improved financing mechanisms, with proposals under development by the G7, G20, and others*" (CEPI, 2021a).

By contrast, many interviewees (AC1, 5, CV 1-3, GP4) concurred that the international community's pandemic response should not solely "err on the side of only pumping [manufacturers] with money [to] see what happens" (AC-5). Instead, it should have a more tactical approach knowing that the pandemic was not a usual market failure scenario requiring tools such as AMCs, which have historically been unsuccessful in spurring innovation. Moreover, Gavi and CEPI's concern with corporate financial risk ignores how most vaccine production is also funded publicly and that financial risks are compensated by pharmaceutical industry profits. One interviewee critiqued the AMC model saying:

> *"Gavi's corporate subsidy-based approach to global health, which is what it is, they just don't use the word subsidy, but it's exactly what they do and have been doing for 20 years, also always promises a diversification of corporations in the vaccine market, and that diversification has not happened for 20 years. If you look at their other AMCs they are giving scarce aid money to extremely profitable companies, without having any sense whatsoever whether that is enough money to spur innovation on their end, or without any evidence that this will diversify the market […] This does get us back to the historical study of how prices for generica in the AIDS crisis were brought down - it*

wasn't through subsidies – it was done through generica and LMICs advocating for policy changes (AC-5).

4.4.2 Achieving global vaccine equity requires political solutions

COVAX ignored the realities of international politics

All interviewees agreed that COVAX has not achieved its goal of vaccine equity because of its limited political awareness, at its inception and during ongoing operations. Despite recognising the importance of multilateralism, many said this was "naïve". They did not consider the reality whereby governments see their primary purpose as to provide for and protect their citizens, to whom they are (mostly) accountable. Thus, it was always unlikely that high-income countries with vaccine purchasing, and manufacturing capacity would put the needs of poorer countries above their own in the name of "solidarity".

> *"This was a flaw in the model, this idea that we will suddenly come together. There are two flaws, one is this idea that we will all come together in this global solidarity moment and care about each other – I don't know what is the evidence base for this decision - that's a big experiment to do it on. I don't know what the evidence was to suggest this would be a successful model. The second one is if you look at, if you had done the political economy analysis to inform that, would one have reasonably thought, would any government - even if it had really wanted to – put other people potentially before [its] own citizens" (AC-3).*

Interviewees viewed GHPs as working between the public and private sector actors. However, when considering the state of international politics before the pandemic, Gavi and CEPI did not adequately leverage their positions to address how nationalistic policies can affect global health. Instead, both organisations adopted an apolitical stance. Interviewees referred to "America first" or "Brexit-like" policies as barriers to global access to health technologies. It was insufficient to see COVAX as a model of solidarity and there should have been more political engagement.

> *"What's the bottom line? Those things can make a huge difference when they can be conveyed effectively. And I think often in health equity spaces, when we are doing social justice work, the last thing we think about is quantifying the value of investing in health equity work. But being able to do that makes a really compelling case to governments that are self-interested. [To achieve this] you could do a cost benefit analysis or something of that nature to particularly the government if you invest in this, there are huge benefits. You could do a return on investment to show that you will earn money if you have invested in a particular cause through things like a greater global reputation and there is payback that comes from doing well and doing good. I think governments, the greater level of self-interest can forget that that's there" (PM-2).*

Focus on manufacturing ignores health systems strengthening

Interviewees contended that that increasing global manufacturing capacity is a critical barrier to an effective pandemic response. However, manufacturing was framed in two different ways. First, some interviewees argued that Gavi and CEPI's focus on regional manufacturing ignores systematic issues relating to health systems strengthening and broader issues of IP. Second, other interviewees questioned the politics of manufacturing, asking why GHPs are focusing on expanding manufacturing capacity for mRNA vaccines as opposed to other vaccine technologies.

Both Gavi and CEPI Board meeting minutes portray both organisations as recognising the importance of expanding manufacturing capacity. Ongoing Gavi Board meetings in 2020 mapped out the organisation's strategy, including exploring partnering with "companies with large scale manufacturing capabilities to leverage their skills and expertise, and pairing manufacturers and developers to quickly scale up high-quality manufacturing of COVID-19 vaccines" (Gavi, 2020g). Gavi Board meeting minutes from June 2021 suggests that any longer-term focus on vaccine manufacturing will inform "*the next phase of COVAX in terms of informing portfolio development and recognising other sources of vaccine targets and supply such as the African Union*" (Gavi, 2021b). This phase includes a closer partnership with WHO, where "*the Secretariat highlighted the COVAX Manufacturing Task Force work which focuses, amongst other items on the longer-term expansion and regional diversification and noted the ongoing work with WHO and other partners in this regard. It was also highlighted that new supplier relations might emerge through supply to COVAX, which could represent an opportunity for sourcing future vaccines other than COVID-19 vaccines*" (Gavi, 2021b).

There were mixed responses to the question of whether greater manufacturing capacity was a solution to increasing access to vaccines, most interviewees (AC5-9, CV1-3, PM1, 3, 5) raising concerns that it did not address health systems bottlenecks which have affected uptake in many LMICs. For example, one interviewee spoke about Aspen's experience in South Africa, stating:

> *"Local manufacturing is a red herring, the conditions that are making it difficult to distribute vaccines in those countries are not going to change simply if you have a manufacturing plant which makes vaccines more available. The bottleneck is not supply, the bottleneck is now demand and infrastructure and distribution capacity and all the other things that go into a successful immunisation programme, and people are*

not paying enough attention to that […] The best example of this is Aspen in South Africa, they went on speck and built their own COVID-19 manufacturing plant so they could provide generic vaccines and meet this demand. They built it a year ago and they haven't had one order since" (PM-5).

GHPs should instead look to build health systems capacity:

> *"What are the parts of the global surveillance ecosystem that are really important and that need global coordination? How can organisations like Gavi and CEPI help to become part of those value chains. If they are always just trying to procure in order to provide, without becoming a constituent part of global response in [LMICs] – this might be in the way reporting is done, standards in the way genomic sequencing is done, it might be I think they have to be able to insert themselves into a part of the value chain. That is important for [LMICs] so that [GHPs] are seen not only as value adding and helping to address the problem from an [LMIC] perspective but are a voice at the table in those developed nations and how they do that as well" (PM-1).*

Indeed, COVAX is a pillar in the larger ACT-A consortium of initiatives relating to health systems strengthening, access to therapeutics and diagnostics. Interviewees noted that the other pillars were poorly funded and not well integrated into global responses. COVAX received the majority of funding, limiting the capacity of the other pillars to achieve their main aim.

Manufacturing ignores intellectual property

Though Gavi and CEPI discussed the need to expand manufacturing capacity in LMICs, there was little mention of technology transfer as being part of a longer term manufacturing strategy, simply that "*a number of partnerships with manufacturers are underway as part of a longer-term strategy, including discussions with the Developing Country Vaccine Manufacturers Network (DCVMN)*" (Gavi, 2020i). The December 2020 Board meeting noted, "*on technology transfer, the Secretariat recognised that the Facility is operating at speed, noting that manufacturers are encouraged to facilitate and accelerate technology transfer and other measures to increase vaccine access to all countries. It was also noted that infrastructural capacity and know-how are the real obstacles to vaccine development. The long-term goal is to have manufacturing available for all countries, in high-quality manufacturing facilities*" (Gavi, 2020f). Some interviewees (AC6, 8, 9, CV1, GP4) discussed the importance of technology transfer but acknowledged that it was missing from COVAX's design and inception due to Gavi and CEPI's position on protecting IP.

> *"We have created corporate structures that systematically don't work towards a publicly optimal tech transfer because it is in their interest to hold on to monopoly power and monopoly pricing over their products for as long as possible. That is not*

because people are mean. That is the structural feature of private corporations and the market. So, the question is what limits to this tendency for monopoly power we would like to put in place to increase technology transfer and increase manufacturing capacity overall? Those can be time limits – you can charge anything for a certain time, and then you have to make your patents public" (AC-6).

Some interviewees (AC1, 5, 8, 9, CV1, 3, 4, GP4) described manufacturing as being a bottleneck during the pandemic due to ongoing tensions within the IP system. Many indicated that COVAX realised too late into the pandemic that regional manufacturing is an important aspect of the global pandemic response, particularly with countries choosing to vaccinate their populations or implementing export bans, such as in the case of India. Three interviewees indicated that an expansion of global vaccine manufacturing does not sufficiently address the issue of intellectual property, which ultimately controls global vaccine availability as companies control their clinical data and marketing authorisation.

"In this pandemic, manufacturing was the main bottleneck. It is no longer in the same way. We have realised, maybe too late, manufacturing would be the bottleneck. There is [intellectual property] and sharing of [technology] which you need to boost, but it is not the same. What I fear that there is so much focus on manufacturing that we are no longer talking about IP. We're not talking about how CEPI and Gavi are talking about setting up a network of producers which can be kept lukewarm so that they do not loose capacity so they can be mobilised in epidemic times […]. We often forget that you need to have the marketing authorisation and so what sits in the marketing authorisation dossier is the clinical trial data. But the clinical trial data, companies have preferred to do their own trials because then they own the data […] With the support of the US and European governments, Moderna and Pfizer are now building factories in Africa, that is not going to change who controls where the vaccines are made available first, and at what price. Unless we take away the control from a few monopolies, we will be in exactly the same situation" (CV-1).

Western pharmaceutical dominance

Few interviewees (AC8, 9, CV1, GP 4) also discussed the role of governments in promoting certain vaccine technologies, which they described as being a political barrier to achieving vaccine equity. Four interviewees discussed the politicisation of "using the science", which has influenced how GHPs have operated in the global governance space. This became particularly apparent with stalled WHO approvals of the Russian Sputnik V vaccine amidst international sanctions and the invasion of Ukraine. Historically, GHPs have tended to rely on the Western pharmaceutical industry, and COVAX has replicated this tendency. However, interviewees questioned why Western pharmaceutical industries were the most influential,

despite emerging evidence that other global industries, mainly China, produced equally as effective technologies, though remained side-lined in COVAX's response:

> *"The international system and partnerships have been relying the mRNA vaccines. If we look at the world, a huge proportion of the world geographically has been vaccinated with the Chinese vaccine, some parts of the world have been vaccinated with Sputnik, and we are currently learning that contrary to what has been pushed in our minds in the West, these are good vaccines […] What we are learning now is that three doses of Sinovac is equivalent to 3 doses of mRNA, this is now in the literature. There is not much hierarchy between these vaccines if you go through 3 doses. When you are at two doses it is very different. It took time until this data came, but to me I am saying this- I am saying this because from the beginning and because of the poor state, if not catastrophic state, of multilateralism these days, the dialogue was not global around global access and global access and global R&D and the world was split from the beginning between the West – with the US industry leading, China and to some extent Russia and India – 4 blocks" (GP-4).*

Another researcher from KEMRI-Wellcome noted:

> *"You could blame the American government, particularly the former US President, who made it seem like the pandemic was a conspiracy from China. So, the sentiment then would arise that if they started it, why would they have something to end it? And that I think dealt a blow to a lot of the Chinese products, like Sinopharm never picked up and the same also happened to Sputnik from Russia. The science was probably sound, but geopolitics played a big role in that. And the worst part is that would have denied access to countries who would have really needed it like here in Africa. The US government made it look like a lot of other vaccines were not as efficacious" (AC-9).*

4.5 Summary

This chapter reports on the findings of a case study on COVAX. It considered the existing strengths and weakness of previous GHPs and asked in what ways has COVAX replicated these and to what extent were those lessons learnt when creating COVAX. First, the findings described different issues relating to the creation of COVAX, followed by a summary of competing frames and ideas which underpin the policy. Findings from the document review and key informant interviews indicate that COVAX is not a departure from previous GHPs and employs the same mechanisms to address gaps in the vaccine innovation system. Despite Gavi and CEPI acknowledging the pandemic called for a move from "business as usual", their efforts have largely followed the traditional way of thinking, with the exclusion of CSO and LMIC stakeholders, COVAX's tiered approach to vaccine procurement, and continued lack of transparency in decision making. Thus, COVAX has pursued vaccine equity by a subsidy-based approach, instead of supporting systematic approaches to achieving higher vaccination rates.

The following chapter examines the reasons as to why such lessons were not learnt when creating COVAX and uses Rushton and Williams (2012) framework, an international relations perspective, to understand why certain actors continue to push specific tactics to realise their interests and sustain their positions of power in policymaking processes.

Chapter 5 Discussion

5.1 Overview

My thesis examined the role of global health partnerships in achieving the goal of global vaccine equity. Taking COVAX as a case study, I considered the vaccine innovation system within which it operates and considered the agenda setting and decision-making processes. This considered both the COVAX Facility and the COVAX AMC, examining the COVAX's governance structures and relationships between key stakeholders. I examined the nature of COVAX as a global health partnership using the components of Rushton and Williams (2012) framework for analysing global health policymaking. The case study was conducted to answer my second research question, "to what extent were those lessons learnt, or not learnt, when creating COVAX and what might explain this?". In this chapter, I reflect on the results of my case study, organising them into sub themes under the two components of the framework: (1) power and authority; and (2) the "deep core" of neoliberalism. Power and authority (section 5.2) examine the power relationships that link different actors involved in COVAX, considering how each advance different frames and paradigms (section 5.2.1), and with a focus on material power and on discursive and institutional resources (section 5.2.2), asking how this determines the institutional context within which the policy cycle takes place. The deep core (section 5.3) considers the structural determinants of global health policymaking processes, reflecting on the historical context and, especially, the configurations of power that arises from it.

I conducted a scoping review to understand the origins and persistence of the partnership model in global health, mapping a range of initiatives and mandates and summarising the critiques they had attracted. The scoping review answers my first question, what lessons can we learn from previous experience with vaccine global health partnerships. My main findings, reported in Chapter 3, suggest that GHPs must (1) increase transparency to make it easier to evaluate their impact; (2) revisit their priorities and, especially, the balance between health systems strengthening and technological innovation and implementation and (3) examine incentives to cooperate in vaccine R&D and expansion of manufacturing capacity.

My findings in the case study confirm how COVAX has applied the same mechanisms as in previous GHPs. COVAX was initially a buyer's club, whose operations were underpinned by a

commitment to global solidarity, and which envisaged an end-to-end approach to vaccine R&D, leveraging both push and pull mechanisms. However, as with previous GHPs, COVAX failed to engage adequately with the political context in which the vaccine innovation system was embedded and broader power dynamics arising from the dominance of the countries of the Global North and, especially, the pharmaceutical industry that is concentrated in those countries and is to varying degrees protected by their governments. As a result, it soon became, in effect, another aid project, based on the principle of charity for low-income countries. In the following section I ask why this shift happened, highlighting competing power dynamics against a background of certain assumptions and values that continue to underpin the vaccine innovation system. Finally, I examine the implications of my work (section 5.4) and its limitations (section 5.5) and offer recommendations for COVAX and for other future vaccine global health partnerships (section 5.6) and conclude with reflections on how the study findings offer a useful guide to future discussions on the role of GHPs in achieving global vaccine equity (section 5.7).

5.2 Power and authority: Frames, power, and policy context

5.2.1 Competing framings of global vaccine equity

Rushton and Williams (2012) consider policy framing as an issue of agency which underlines power relations, where the contestation among competing policy frames is shaped by the distribution of power. My case study identifies two competing framings of global vaccine equity, one where it can be achieved largely by technical solutions and innovative financing mechanisms and a second where it requires political solutions. Interviewees working in the private sector or in GHPs were most likely to support the former whereas academics and individuals working with civil society organisations were more likely to favour the latter. The second group also drew attention to the uneven distribution of power within decision-making processes of GHPs and, especially, of material power – where those who lacked it often had little influence on decisions.

The existence of the two framings reflects the findings of my scoping review, which also identified technical and political approaches to achieving global immunisation mandates. Almost two decades ago, Hardon and Blume (2005) noted that the private sector and GHPs were more inclined to adopt approaches based on providing money to those involved in

development, production, and distribution of vaccines, often referred to as a subsidy-based approach, which they see as a means to combat donor fatigue. In contrast, civil society organisations were more inclined to support approaches that addressed structural barriers to greater vaccine uptake, such as inadequate manufacturing capacity, weak health systems, and vaccine hesitancy, which often reflects factors such as trust in authority. However, while the former is easily measured (e.g., how many patents were issued?) while the latter are not (how attitudes have changed?), with the difficulty in demonstrating progress risking donor fatigue.

Subsidy based framing of vaccine equity

As noted above, GHPs have favoured a subsidy-based approach to vaccine R&D. This has been endorsed by Gavi since the early 2000s. Yet there is relatively limited evidence that it works, and many interviewees were sceptical, noting how it had not spurred innovation before the pandemic. There have been widespread concerns about the subsidies that pharmaceutical companies have received for vaccine R&D and the profits they have made during the pandemic, as well as a general lack of transparency of contractual agreements.

The support by GHPs for a subsidy-based approach reflects their willingness to "play the rules of the game", whereby Gavi responds to donor expectations of measurable and quantifiable outputs and an acceptance of the existing IP regime. This willingness can be interpreted as either the acceptance of a market friendly paradigm or a pragmatic response to the power dynamics in the global health space.

The discourse on COVAX is essentially a continuation of earlier debates. My scoping review pointed to GHPs acting, in effect, as a technological solution to global health problems. However, various scholars have argued that this fails to take account of the inherent political and systematic factors influencing global health outcomes. COVAX has crystallised a set of norms that embrace vertical approaches to health, technological solutions, and financialised measures. The AMC model perpetuates a traditional market-based model, whereby the role of donors is to provide funds for an agreed goal and the role of commercial companies is to supply what is needed to achieve that goal. This is based on what is termed "financialisaton" (Muraskin, 2004, Hardon and Blume, 2005, Chataway and Smith, 2006, Ahonkhai et al., 2016, Stein, 2021). COVAX has not departed from this basic model, which is supported by its main stakeholders, who have discursive, resource and material power.

Political based framing of vaccine equity

The second framing, which prioritises the political aspects of global health, asserts that unequal power dynamics will be maintained without transparent discussions on the ownership of intellectual property and the continued exclusion of CSOs and LMICs in decision making. As noted above, this was associated most with academics and CSOs.

Even if CSOs lack material power, they do have "soft power", through their ability to advocate, persuade, and justify certain approaches but this was largely excluded by design in COVAX. They were only involved much later in the pandemic, when they were included in the CSO representation group. This is consistent with the findings of the scoping review, whereby many PDPs initially omitted local stakeholders from decision making processes (Chataway and Smith, 2006, Hayter and Nisar, 2018). Even when they were included, local stakeholders had little opportunity to advocate for changes to the design of PDPs.

Similarly, by the time CSOs were included, the design of COVAX had already been complete, without much appetite by the Gavi Board to change COVAX's fundamental design or governance. This was noted by the Gavi Governance Committee meeting which stated, "There is no desire for changes to be made to the COVAX governance model" (Gavi, 2021c). Moreover, even when CSO's were included in the different Gavi and COVAX committees, the Gavi Board retained decision making powers, only allowing these groups to offer advice. One interviewee said that CSOs were excluded, "because [Gavi and CEPI] knew what we would be standing for and fighting for" (CV-2), which reiterates the competing framings of vaccine equity.

Proponents of the political framing of vaccine equity also highlighted the importance of regionalisation of vaccine manufacturing, noting how supplies were interrupted when India banned vaccine exports during the pandemic. Promotion of regional manufacturing clashed with CEPI's decision to prioritise economies of scale, which led to the concentration of capacity in India. The documents noted how CEPI had spread the risk in one way, by supporting multiple vaccine candidates and technologies but increased it by failing to diversify production, noting "[they] should not be blamed for the realpolitik of countries focusing on domestic supply" (CEPI, 2021a). The Indian example illustrates the role of politics in shaping pandemic responses. There are several interpretations of what happened. Some view it as a domestic issue which should be resolved internally, but in the context of my thesis, it can be

seen to reflect the lack of experience by GHPs in resolving difficult issues that arise from vaccine nationalism. Of course, we do not know what discussions Gavi engaged in behind closed doors and one interviewee commented that "We work behind the scenes on all that stuff. But in public we were more muted because our hands were a bit tied. We would advocate for vaccine equity, but we would not point fingers so obviously" (GP-3). Judging from the duration of India's export ban, such negotiations seemed unsuccessful.

In contrast, proponents of subsidy-based approaches to vaccine equity noted the changing role of manufacturing during the pandemic. For example, during the initial acute phase, bottlenecks in global supply, mainly associated with inadequate manufacturing capacity, were apparent. However, as the initial wave of the pandemic waned, there were additional challenges in increasing both supply and demand, illustrated in the ongoing challenges faced by Aspen. This again points to a failure to engage LMICs in decision making processes, coupled with the lack of regional manufacturing capacity. Increased regionalisation permits regional organisations such as WHO's regional offices or the African Union to establish their own priorities, based on their own understanding of needs in their region.

5.2.2 Discursive, resource, and material power

The adoption of a technical and subsidy-based approach to global vaccine equity has largely been driven by the distribution of discursive, resource, and material power held by GHPs and private sector actors.

Material power

The work of GHPs is heavily influenced by actors with material power, including donor governments and pharmaceutical companies. Both the documents reviewed, and the interviews undertaken revealed the influence of donors and the flow of money in decision-making processes. For example, the documents showed that HIC governments were highly influential in advocating for a tiered approach to countries participating in COVAX – so that HICs could participate in COVAX two ways, either Committed Purchases Agreement or an Optional Purchase Agreement. This left COVAX as an "insurance policy" as opposed to the global procurement mechanism it was originally convened to be (Berkley, 2020).

Interviewees involved in Gavi and COVAX's internal decision-making processes argued that it would be impossible to create a platform that used the same procurement mechanisms for

all global economies. They went on to argue that the choice that was made was necessary and any criticism of donors could have led to funds for COVAX being withheld. These views are consistent with the scoping review and the example of the VII led by UNICEF. The VII encouraged LMIC governments gradually to become more independent, assuming financial responsibility for their vaccine needs. This initiative supported LMIC governments to procure of vaccines through subsidised purchases. Indeed, the VII was considered a success in increasing self-reliance of middle-income countries but less so for low-income countries. This strengthens the argument for measures that can be adapted to economic context of recipients. However, in contrast with the situation facing COVAX, the concessions made for HICs resulted in unequal opportunities favouring materially powerful actors, given the limits of global vaccine manufacturing.

The scoping review revealed the context within which material power was exerted. My literature review noted the initial scepticism of European donors about applying technical solutions in LMICs and raised concerns about commercial interests dominating global health programmes in the 1990s (Hardon and Blume, 2005, Ruckert and Labonté, 2014, Stevenson, 2017). The initial disagreement between American and European donors in the 1990s arose from resistance among the latter to adopting technical approaches to global health issues. Thus, there has been a gradual convergence on an American "world order", which characterises the vaccine innovation as being commercially dominated (Stein, 2021). This includes its competitive nature, where some vaccine technologies, specifically mRNA, have potential that goes far beyond viruses (Storeng et al., 2021). This correlated with findings from the case study. For example, interviewees pointed to what they saw, correctly or not, as "cherry picking" evidence to discredit Chinese or Russian vaccines, thereby focusing support on Western vaccine technology. Yet while GHPs portray themselves as apolitical, multilateralism has been undermined as global rivalries among the "4 blocks", the USA, China, Russia, and India, have grown.

As noted, the distribution of material power has led GHPs to emphasise the use of models based around subsidies. However, many questions remain about how useful this approach is or whether donor funds could be used to greater effect in other ways. Unfortunately, the lack of transparency of contracts makes this is difficult to assess. Although one interviewee considered contracts a "red herring" and noted the numerous governmental and company-

wide oversight mechanisms to ensure contracts were adhered to, they acknowledged concerns about inclusivity. Thus, there was widespread support for at least some greater involvement of different stakeholders in decision-making, with accompanying transparency.

The study by Storeng et al. (2021) noted the limits of policies driven by material power and observed a normative shift in approaches to GHPs. The authors proposed the concept of a super-GHP, of which COVAX is one. However, as with previous GHPs, it has not been able to reconcile the tensions that characterise global governance or engage with existing power dynamics at the global level. Indeed, unlike previous GHP initiatives, which mainly sought to address the needs of LMICs, COVAX marks a shift in supporting financial mechanisms that benefit both HICs and LMICs. The authors concede that COVAX has not been able to achieve its goals of global vaccine equity due to its "financialisation" of global health.

Gavi and CEPI's discursive and institutional resources

Gavi and CEPI have largely framed themselves as technical leaders, exploiting their previous experience with vaccine R&D and procurement and their financial resources to find an appropriate global solution to inadequate vaccine access. They have also largely staked their claim to authority in global health policy on the basis of their ability to act as a successful broker in a complex network of actors. They have succeeded in getting the global community to defer to their judgement, particularly as they are the main organisations working on delivery of vaccine technologies. Interviewees concurred that Gavi's reputation benefits greatly from its record in technical achievements that improve supply and distribution of vaccines in LMICs. Donors were accordingly, "ready to give loads of money and they wanted to give it to initiatives they were confident were doing a good job" (CV-1), highlighting the donor focus on results.

Historically, Gavi has primarily aimed to support LMIC economies to procure and distribute vaccines. Though it would seem logical that it would play a role in pooling procurement and negotiating prices for COVID-19 vaccine in countries where they were already doing this work, doing so for all countries was well beyond their existing mandate. Though both CEPI and Gavi noted that the pandemic was not "business as usual", both organisations have attempted to adopt new processes to meet the demands of the pandemic. For example, both organisations held additional board meetings to speed up decision making, intensified negotiations with

pharmaceutical companies to secure vaccines for the COVAX portfolio and prioritised the expansion of global manufacturing capacity.

Indeed, the sheer volume of both Gavi and CEPI's additional actions shows that it was not "business as usual", where both organisations increased the frequency of meetings in order to respond to the rapidly evolving pandemic. However, I found little evidence that either organisation had experience in dealing with the market conditions that pertained during the pandemic. In fact, as the documents indicate, both organisations were designed to address market failures by creating demand during non-pandemic times. During the pandemic, there was ample demand from the international community, and as interviewees indicated, this was enough to incentivise the pharmaceutical industry to invest and manufacture vaccine technologies. Rather, the problem was a technical, where supply could not be ramped up.

Both interviews and documents pointed to GHPs becoming an important part of global health governance, brokering relationships between public and private entities. This was particularly notable as the authority of WHO has been diminishing, and from a fairly low baseline as it has never been especially active in this area. Consequently, GHPs have attracted many more donor pledges, something that several interviewees attributed to their results-oriented approach. WHO does play an important role in norm setting and advocacy, such as raising awareness of the need for global vaccine equity and establishing the Fair Allocation Framework, which COVAX has adopted, the WHO has provided little in the way of technical outputs.

Partnerships in global health exist to resolve problems in resource constraint environments where the answer requires multiple actors. It is not enough for at Ministry of Health to engage in dialogue with one or more private manufacturers of vaccines. Appropriate solutions require collaboration by all stakeholders who have an influence on the way we do things. Thus, the value of the partnership is the breadth of its community. This is also its greatest problem as the more people involved, the messier it becomes.

From a more ideational perspective, partnerships are a means by which the material power of donor governments and pharmaceutical companies is exerted. This might potentially explain why institutions such as WHO have experienced a gradual reduction in involvement in global health processes. Unlike the WHO, where each country has a single vote in the World Health Assembly (although of course rich countries can influence policy in other ways,

including extra-budgetary contributions), donors have greater sway in GHPs by virtue of the decision-making structures.

The focus on material power has influenced how GHPs approach global immunisation challenges, with a focus on tangible goods such as vaccines rather than on the wider political issues involved in health system strengthening. However, interviewees noted several shortcomings in ACT-A, where most donor funding was given to COVAX leaving the other pillars severely underfunded. In theory, the creation of ACT-A is a progressive act in that it does give greater attention to health systems strengthening and diagnostic development. In addition, COVAX is a procurement mechanism designed to vaccinate the world and not just LMICs. However, many interviewees pointed out how the other pillars in ACT-A were severely underfunded and/or created much later in pandemic, which to them signalled not only the low priority given to what they did but also the priorities that donors gave to technical solutions rather than systematic reform.

Secondly, though COVAX's approach to vaccine procurement was framed as being solidarity driven, there was limited evidence to suggest that either Gavi or CEPI undertook much advocacy to coalesce the different viewpoints around this concept. COVAX's technical orientation means that it works closely with private sector organisations and pharmaceutical companies to develop technologies which can be used in pandemic responses. There was limited evidence to suggest that GHPs have been captured by the pharmaceutical companies, rather, GHPs must rely on their knowledge and experience. GHPs respond to governments and private or philanthropic organisations that fund them. The focus on material power is linked to the technological orientation of GHPs, which means that actors that lack funds have the least influence. This is consistent with a study by Stevenson and Youde (2021) which argued that the rise of the GHP model is less an in indication of a usurping of power but rather an abdication of state leadership. However, this can be interpreted in two ways: first, it reflects the current state of global policymaking whereby donors abide by the "rules of the game" and leverage their material power to ensure optimal financial returns which ultimately bolsters their economic power. Second, it reflects a gradual side lining of UN organisations that are not equipped to "play the game". Comparatively, organisations such as the WHO have limited capacity and technical expertise to collaborate with non-state actors such as the pharmaceutical industry.

5.3 The "deep core" of neoliberalism

The scoping review highlighted GHPs' tendency to operate within a neoliberal system of economic governance, seeking to leverage mechanisms that work within the "rules of the game" as opposed to challenging the rules of international trade. Consequently, this has shaped COVAX's policy preferences on issues relating to the IP regime and vertical approaches to achieving global vaccine equity. The "deep core" is therefore observable in three interrelated areas: governance, market friendly policy preferences and knowledge production and exchange. Regarding governance, the key shift in advancing neoliberalism has been the deliberate shift to decentred regulation and the diffusion of authority away from states and multilateral organisations. With respect to knowledge, neoliberal thought has been espoused by rationalist and technocratic constructions of knowledge, namely from the field of economic science. And finally, in terms of market friendly policy preferences, neoliberalism has been furthered through contemporary policy trends which favour privatisation and the maintenance of the vaccine IP regime. The three areas are elaborated in turn and under separate headings below, in practice they have generated the doctrine together and through their combination. All three aspects, and particularly their interconnectedness, have been crucial to the production and entrenchment of COVAX's neoliberal policies.

Governance

GHPs such as Gavi and CEPI have largely led the global COVID-19 response with the creation of COVAX, however, in doing so they have also consolidated a set of policy preferences and governance models which are characterised by an exclusion of LMIC and CSO stakeholders in decision making processes. Such processes have largely been donor led, which have accordingly favoured private sector interests by adopting market friendly policy templates. Such templates have not only given the private sector additional decision-making powers but have also benefitted private sector partners such as pharmaceutical companies as COVAX have maintained its support for the IP regime and existing innovation system by adopting a subsidy-based approach to achieving vaccine equity. Consequently, the lure of higher profits through the patent system persisted even during the pandemic, with interviewees noting that there is little evidence that this can diversify the market. This lack of evidence is further compounded by an inherent lack of transparency about contractual agreements.

Yet, calls for more transparency were mostly viewed as being a "sensitive" issue (PM-1) or "red herring" (PM-2) by most private sector interviewees. This is another notable characteristic of neoliberal thought, where anything that functions as a collective check on corporate power has become a target of the elite, thereby resulting in a colonisation of specific paradigms and framings of vaccine equity (Rushton and Williams, 2012). Framing of vaccine equity requiring technical and financial solutions remains dominant because of the governance structures in place.

This governance structure has also led to a gradual usurping of the United Nations system, namely WHO. Though WHO was a named partner in COVAX and ACT-A, their role mainly revolved around norm setting by adopting the Fair Allocation Framework. Indeed, many key interview respondents noted that this was an appropriate role, given WHO's limited experience with vaccine R&D and procurement. However, this is a result of the historical trajectory of global health governance under neoliberalism, which has led to WHO's shrinking discretionary budgets from the compulsory contributions of member states. Consequently, this has cut capacities and made program areas beholden to donor preferences – namely cost effective and technical solutions to health issues. WHO and associated global health security apparatus responded to COVID-19 within the parameters of a market friendly and market disciplined approach that have been compromised repeatedly.

Market friendly policy preferences

Gavi reappropriated existing market mechanisms such as the AMC model for COVAX. There was limited evidence from the document review to indicate that Gavi had done any consultations into why the AMC model would be appropriate to use during the pandemic. Initially, the AMC tool was employed to address conditions of market failure, which was not the case during the pandemic when demand was high. Interviewees noted that Gavi adopted a subsidy-based approach to vaccine innovation and equity without a clear idea of whether this approach indeed support innovation of different candidates. The innovation of the companies supported through CEPI, or Operation Warp Speed remains to be proven. There is a need for an economic analysis to determine whether such companies were likely to have acted without demand stimulation subsidies as the demand for a COVID-19 vaccine was high from the beginning of the pandemic.

This finding is consistent with papers identified in the scoping review that critiqued the AMC model. Cernuschi et al. (2011) and Siagian and Osorio (2018) discuss some of the challenges inherent in it, such as the lack of long-term competition between vaccine manufacturers, namely first- and second-generation suppliers and limited innovation. Indeed, market friendly policies have proven to be insufficient during the pandemic, prompting COVAX's pivot to facilitating donations to LICs, a departure from its initial goal of vaccinating the world.

Knowledge production and exchange

The role of GHPs in the pandemic response has overall been characterised by Gavi and CEPI being the technical "experts" within and around the vaccine ecosystem. The very idea of positioning themselves as "technical experts" results in an epistemological critique of the role of the social sciences in global health processes, planning and centralised bureaucracy, all of which are perceived to be incapable of capturing the practical and measurable forms of knowledge that the market can process. In adopting this stance, GHPs are seen to be "legitimate" sources of policy guidance within the neoliberal economic system. This reflects their extensive expertise and knowledge in the form of toolkits and methodologies with which to analyse a problem. Gavi and CEPI have repeatedly championed rationalist approaches to global health policymaking, ignoring the role of different actors' interests. Both organisations view any social or political deliberation as lying outside of their organisational remit.

The argument that GHPs lack legitimacy because they are not democratically elected arose in the scoping review, in a paper by Stevenson and Youde (2021). As such, their institutionalisation in global health decision making processes means there are limited mechanisms for democratic or population oversight (Buckup, 2008, Hanlin et al., 2007, Huzair, 2012, Mahoney et al., 2007b, Naimoli, 2009). However, findings from interviewee interviews noted the rise of populist movements in donor countries, such as Brexit or the impact of American foreign policy changes under President Donald Trump, have exacerbated global vaccine inequities by adopting a "my nation first" approach. There is a tension between balancing democratic representation in global health fora and ensuring that protectionist norms are not privileged. For example, the alternative of having public sector actors lead global responses does not imply a greater move towards global vaccine equity, when elected officials are advocating for protectionist health policies and reduced sharing of global resources.

Indeed, changes of government could bring to power newly elected officials who may advocate for more globalised approaches to health. However, reliance on a publicly led approach to global health is unsustainable. Politicians change frequently, raising the prospect of more nationalistic leaders. For example, as mentioned, many countries will seek to protect patents and intellectual property regimes as it will benefit their economies (Chandrasekharan et al., 2015, Sunyoto, 2020, Boseley, 2021). This is particularly relevant for economies with manufacturing capacity such as Germany, who are home to manufacturers such as Pfizer and who have produced vaccines using mRNA technologies (Feinmann, 2021). It is within the German government's interest to protect this technology as it will help grow the economy. GHPs' limited technical focus ultimately ignores this political reality and undermines their role as an effective knowledge producer and "expert" as they lack diplomatic skills to address nationalistic tendences of donors (Davies and Wenham, 2020).

5.4 Study implications

COVAX has largely replicated approaches adopted in existing GHPs. As with other GHPs, it works within the prevailing economic system, adopting market friendly policies designed to spur vaccine innovation as major means to achieve global vaccine equity. Such mechanisms do not seek to challenge the existing neoliberal economic system, which is ultimately not conducive to achieving global vaccine equity. This is, I contend, an important reason why COVAX has underperformed in relation to global vaccine equity. This should not detract from what it has done, with major contributions to increased vaccine coverage in many LMICs. However, gaps remain. COVAX endorses the assumption that market friendly policies can be leveraged to achieve innovation which ultimately address donor concerns of cost effectiveness, however such measures have proven to be ineffective. This assumption, arising from neoliberal ideas, has resulted in a mismanagement of political externalities which have led to vaccine nationalism and have benefitted a specific set of stakeholders, namely donors and HICs. GHPs like COVAX thus continue to push this illusion of effective market operation.

5.5 Limitations

My research was limited to a case study of one GHP undertaken during the COVID-19 pandemic. Each GHP is different, and hopefully future examples will take account of the lessons from COVAX, although given the apparent lack of learning, coupled with the

continuing distribution of power in the global health policy space, that cannot be assumed. Nonetheless, what is clear is that my findings cannot be easily generalised to other GHPs. Other limitations included the small number of interviewees, limited mainly to stakeholders who have either advised or consulted on COVAX. Finally, this is a rapidly developing area, and the interviews were conducted prior to some more recent developments, such as the Partnership for African Vaccine Manufacturing, launched by African Centres for Disease Control in 2022. This answers the call made by the African Union Commission and the African Centres for Disease Control at a summit in April 2021, with the goal of enabling Africa to manufacture 60 percent of its vaccine needs locally by 2040 (CDC, 2022).

5.6 Recommendations

My thesis adds to our knowledge of the role of GHPs in the quest for global vaccine equity, with a focus on the interests of actor and the power dynamics among them. My analysis was guided by Rushton and Williams (2012) framework, which applies an international relations lens to the role of norms in global health policymaking processes. Findings from my study suggest that COVAX was a step in right direction as it leveraged end-to-end partnerships, employing both push and pull mechanisms. For the COVAX model to become fit for purpose during any future pandemic, such capabilities should be strengthened during non-pandemic times. This means consolidating a networked approach to leverage expertise, resources, and reliable sources of at-risk financing, based on strong stakeholder relationships. Indeed, a key challenge in maintaining end-to-end partnerships within the vaccine innovation system will be to avoid any overlap or duplication of efforts between key stakeholders and/or managing key stakeholders' competing interests. Overcoming this will require robust leadership and governance and transparency in roles, responsibilities, and key expectations.

Vaccine nationalism, hoarding and vaccine export bans remain another key challenge for COVAX, but measures could be taken to plan ahead and mitigate these circumstances. Such measures can include increasing and expanding regional vaccine manufacturing or strengthening multinational trade facilitation measures to ensure the free flow of vaccines and any other associated supplies. However, considering the "rules of the game" and the reality of international relations, the interplay of power dynamics poses many challenges to achieving global vaccine equity. The current neoliberal economic system of governance

prioritises the interests of actors with material power, who have historically exerted their influence to support global immunisation programmes that are technically oriented as opposed to politically driven, thus addressing the systematic barriers inherent in the vaccine ecosystem. The following recommendations are informed by my findings of this thesis and outline actions which GHPs could ideally incorporate should the current norms dominating global health governance change. In each, I set out what should be done and then suggest how GHPs might be able to do it.

5.6.1 Ensure inclusivity in decision making processes

Championing the inclusion of LMICs and CSOs across all decision-making stages will ensure effective organisational collaboration that benefits all partners. Indeed, this approach views LMICs as partners in decision making processes, rather than recipients of aid. This can be achieved through the following actions:

- Partners with more power (including donors) are willing to give up control and incur some risks, this means including LMICs and CSOs in early decision-making stages when governance structures have not been established and consolidated;
- Partners with less power acquire agency and are able to play a bigger role in advancing the partnership's goals.

Making this happen will be difficult, given that existing arrangements reflect global power dynamics that go far beyond considerations of health. It will only come about if those countries that are the beneficiaries of GHPs can work together, something that will be difficult given the ability of some of the more powerful countries, such as the USA and China, to exert pressure on them. At present, there is no obvious structure that can take this forward at a global level. In the past one might have looked to the Non-Aligned Movement, but it is now relatively ineffective. There are, however, some signs for optimism, such as the development of lose coalitions to press home the issue of compensation for "loss and damage" at the COP27 talks on climate change. This will require leadership by regional groupings, such as the African Union.

5.6.2 Diversifying regional manufacturing of vaccines

Expanding regional manufacturing will prevent manufacturing bottlenecks, as we have witnessed during the COVID-19 pandemic. Currently manufacturing is dominated by first

generation vaccine manufacturers such as Pfizer and GSK. Supporting the expansion and market entry of second-generation manufacturers in LMICs will ensure diversification in regional manufacturing. This approach will also be particularly useful in the face of political tensions, such as countries implementing export bans, to maintain a steady global supply of vaccines during a health emergency:

- Work closely with WHO regional offices to scope potential for expanding manufacturing plants;
- Support LMIC governments to expand their technical skills and expertise necessary for vaccine production.

This is beginning to happen, with the creation of the Partnerships for African Vaccine Manufacturing. It will be important to learn from its experience, while seeking other regional structures that might host similar initiatives. A number of regional or other political groupings are taking an increasing interest in health and have sought to improve their national regulatory capacity. These include the European Union, which exemplifies such a grouping with a well-established health policy (Greer et al., 2013), and others such as ASEAN that have come to this more recently (Greer et al., 2022). In addition, the BRICS (Brazil, Russia, India, China, and South Africa) countries, which had already established some basic collaboration on health (Watt et al., 2014), have now launched the BRICS Vaccine R&D Centre. The emergence of regional vaccine manufacturing hubs will have implications for vaccine prices and availability, where China, India and Russia researched, developed, and produced their own vaccines.

This is a step in the right direction and will ensure access to the necessary vaccine technologies when needed. However, such regional groups must also consider the sustainability of such initiatives, including considerations of at-risk financing and infrastructure investment to maintain a resilient and more self-reliant manufacturing system. Here, it is important for GHPs initiatives like COVAX to engage with such regional hubs in order to support the expansion of global manufacturing capacity. This can be achieved in the form of disbursement mechanisms and sharing of expertise, which ensure that systems can start work when needed, ideally on day one of the pandemic. This will require GHPs to have leadership with skills needed to engage in multilateral diplomacy and manage expectations and conflicting interests between different actors. This is particularly important given the

emergence of new mRNA vaccine technologies and the desire by the governments that host manufacturers to protect them.

5.6.3 Diversifying solutions for different economies

One of the main challenges facing COVAX was setting its goal of vaccinating 20% of the global population without any clear consideration of the needs of different economies. Implementing diverse solutions for different economies requires further collaboration with different WHO regional offices and a clear understanding of countries' health systems profiles, this can be achieved through the recommendations relating to increased inclusivity and diversification of vaccine manufacturing. Additional steps include:

- Distinguish between the needs of LICs, lower and upper MICs to consider the different economic issues facing each economic profile;
- Pay particular attention to MICs transitioning out of Gavi supported programmes, undertaking detailed assessments of their financial situation, including cash flow and budget projections, and work with them to identify solutions that reflect their circumstances, which could include underwriting loans, bond guarantees, or direct development assistance, either targeted or as budgetary support. This arrangement can be particularly beneficial for MICs who are unable to procure vaccines in a timely manner particularly when supplies are limited during a pandemic.

Achieving this will require early alignment and coordination with country working groups and broader global stakeholders to manage processes. Such relationships can be developed and strengthened during non-pandemic times to monitor data systems and to ensure countries' preparedness. However, this will incur high costs, requiring staff to remain in constant readiness. This will be even more challenging in conflict-affected countries, which may rely on non-traditional immunisation actors such as humanitarian agencies and CSOs, where communication channels may not always be available. COVAX will need to maintain donor focus and adequate funding to maintain this level of coordination.

5.6.4 GHPs influencing the changes in the vaccine innovation process

Calls to lift IP restrictions raise important observations on vaccine accessibility for LMIC populations such as the tension between protecting global population health and commercial

interests of donors and pharmaceutical companies. The powerful use of market mechanisms at the pursuit of health rights can go hand in hand to a very large extent, they are not perfectly conceptually compatible, but there is a lot of room for serving both purposes at the same time. This will require GHPs to strike a much better balance between what they do for vaccine equity and what they do for corporate power. This can be achieved through the following steps:

- Redesigning GHPs in such a way that the contracts are pre negotiated rather than negotiated after the industry has generated something;
- Working closely with the private sector on R&D processes and maintaining ownership of patents (i.e., issuing patents from universities). Doing so will require GHPs to work closely with educational institutions and universities and accordingly leverage pull mechanisms to fund product development;
- In partnership with universities and private sector, conduct clinical trials and maintain IP over this data. Doing so would allow for better access to data and the ability to compare vaccines in other clinical trials. Currently, there has been limited comparison of any vaccines;
- Where the private sector maintains IP, advocate for a shorter time limit, prompting the sector to make their patents public. This accordingly supports second generation vaccine manufacturers in developing generic vaccine candidates.

It is important for COVAX to maintain its end-to-end approach to vaccine innovation, procurement, and delivery. Challenges remain the vaccine market, however, there is room for GHPs to play a role in addressing these challenges. Indeed, early R&D support with grant funding is important for COVAX's ability to address gaps of evidence or emerging needs relating to new variants. However, it will be necessary to balance the competing interests of pharmaceutical manufacturers and other key stakeholder groups, particularly in relation to IP. Here, technology transfer plays an important role on the innovation process, where COVAX could partner small biotech companies with larger manufacturing companies to facilitate technology transfer. However, during a pandemic, such timelines need to be balanced with the speed at which vaccines will be needed to be manufactured. The capacity of smaller

biotech companies to absorb new technology will be influenced by ongoing work on expanding manufacturing capacity and sharing of expertise.

5.7 Personal reflection

I have learned various new skills while conducting research for the thesis component of the programme, such as how to apply interdisciplinary and multi method approaches to research effectively. This thesis draws from various disciplines, mainly international relations, and applies a qualitative multimethod approach to answer to the research questions, such as a scoping review of literature, document review and interviews with key informants. Learning about international relations theory was very rewarding, albeit challenging, as it provided a lens to understand the dynamic nature of global health politics and its intersection with changing actors' interests and motivations. To fully understand how such interests and motivations are shaped, I also drew from economic theory to understand broad concepts such as market failure and the use economic tools in the vaccine innovation system.

I operationalised an international relations theory framework by Rushton and Williams (2012), which, to the best of my knowledge, has not been previously done in an empirical study. In doing so, I applied various analytical approaches such as the READ (Ready materials, Extract data, Analyse data, Distil) approach by Dalglish et al. (2020) in my document review and reflexive thematic analysis approaches to produce findings from all data sources. This multimethod approach was iterative, where analysis of my interviews was contemporaneous, rather than sequential. Conducting this research has not only enhanced my skills as a qualitative researcher but has also strengthened my experience analysing and disseminating complex sets of information from various data sources.

Drawing from lessons learnt in my OPA and thesis and knowledge I have gained on the nature of evidence translation and stakeholder engagement, I think the main outputs from my DrPH experience will come from my thesis. Outputs of this thesis will be two papers published in academic journals, the first being the findings from my scoping review of literature (incorporating Chapter 3) and the second being findings from my case study of COVAX (incorporating Chapter 4 and 5). Lastly, I plan on contacting my interviewees again to share policy briefs, summarising the main findings from this thesis, in order to further develop this area of research and advance potential changes in policy.

Overall, the LSHTM DrPH experience has done what I had hoped. In particular, it has provided more formal instruction and exploration into policy development and translation of evidence to policy, but more importantly the management and organisation of global and public health organisations. This includes developing a broader understanding of the interplay of political and economic factors, both of which influence health outcomes for global communities differently, in pandemic and non-pandemic times. Broadly, across the degree, I have had the opportunity to explore how to research, develop and hopefully advocate for better, healthier policies through both well-run organisations and creatively examining policy design and implementation.

5.8 Conclusion

I sought to investigate the role of GHPs in achieving global vaccine equity. My line of questioning, which sought to build a better understanding of how different actors in global health conceptualise and make sense of the environment within which they operate, corresponds to interpretive approaches to research which seek to understand, rather than explain, actions or processes. My findings enhance our knowledge about different actors' policy preferences through an examination of how global vaccine equity is framed. The dominance of a particular framing, notably that it requires technical, rather than political solutions, has cognitive, normative, and practical repercussions for policy-making processes in global health.

The insights I gained were derived through an adoption of a constructivist international relations lens, in particular the framework by Rushton and Williams (2012). This framework considers the structural determinants of global health governance and decision-making processes, reflecting on their historical context and, especially, the configurations of power that arise from it. I was able to demonstrate the utility of such theoretical approaches in advancing knowledge and understanding of actors' interests and informing decision making processes, with the ultimate goal of improving global health outcomes. My findings recognise the limits of adopting an exclusively technical approach to vaccine equity. Indeed, while vaccine innovation is a necessary part of achieving vaccine equity, it is not in itself sufficient. Adopting a more nuanced approach, which also encompasses political determinants, helps to understand the barriers to achieving equity that we have seen during the COVID-19 pandemic.

I believe that my findings offer a useful guide to future discussions on the role of GHPs in achieving global vaccine equity. GHPs can achieve global health goals by leveraging their influence to advocate for reforms in the vaccine innovation system and adopt strategies that consider the political aspects of vaccine R&D. My findings may also inform the development of guidance on engaging with private sector actors in other related areas of global health policy, where economic actors are increasingly involved, such as climate change. This includes how contracts are negotiated, the expansion of global manufacturing capacity in LMIC settings, and the balance of corporate interests with public health goals. The private sector has a key role in global health governance processes and GHPs must find ways to reconcile public sector interests with population-wide needs, balancing budgetary pressure with private sector interests in maximising profits.

In conclusion, this study makes an important contribution to knowledge that can inform future policy on vaccine equity, incorporating the principles of inclusivity and strengthening multilateral cooperation to produce global public goods.

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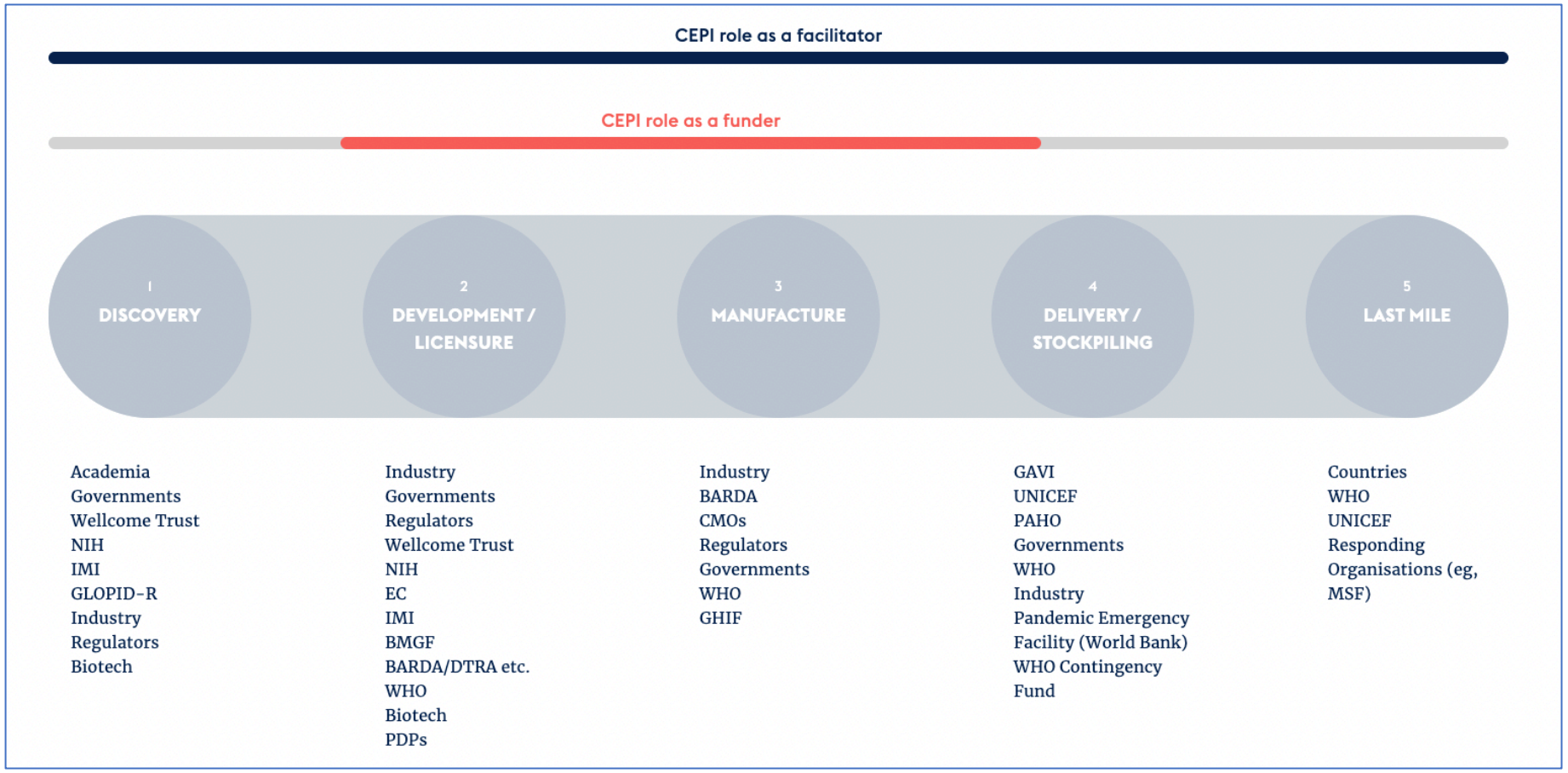
Appendices

Appendix A

CEPI's scope and fit in the vaccine R&D process



Appendix B

The process of declaring a Public Health Emergency of International Concern (PHEIC)

"The International Health Regulations (2005), or IHR (2005), represents a binding international legal agreement involving 196 countries across the globe, including all the Member States of WHO. Their aim is to help the international community prevent and respond to acute public health risks that have the potential to cross borders and threaten people worldwide. The purpose and scope of the IHR (2005) is to prevent, protect against, control, and provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health risks, and which avoid unnecessary interference with international traffic and trade.

The shared global responsibility for responding to major health threats is manifest in the revisions to the IHR agreed in 2005. The revisions championed a new understanding of global shared responsibility and outlined a regulatory framework for state and non-state actors to ensure that they had certain core public health competencies needed to limit transnational spread of infectious diseases. This conceptual shift meant that all states now had a responsibility to develop, strengthen and maintain core capacities required to detect, assess, notify, and report an outbreak to the WHO. The implementation of the IHR involves functions and responsibilities across many ministries, sectors, and governmental levels. These include, but are not limited to, sectors such as transportation, customs, food safety, agriculture, and public health authorities at national, regional, and local levels.

The IHR requires State Parties to notify the WHO of events that may constitute or signify a public health emergency of international concern (PHEIC). A PHEIC is defined in the IHR (2005) as, "an extraordinary event which is determined to constitute a public health risk to other States through the international spread of disease and to potentially require a coordinated international response". This definition implies a situation that is:

- *serious, sudden, unusual or unexpected;*
- *carries implications for public health beyond the affected State's national border; and*
- *may require immediate international action.*

A PHEIC would then notify other State Parties of ongoing public health events and is an opportunity to marshal resources and coordinate global response efforts. A decision instrument was created to guide notifications to the WHO of four specific diseases: smallpox,

wild poliomyelitis, novel human influenza and SARS. The underlining algorithm of the decision instrument also listed pandemic-prone diseases that trigger further assessment such as cholera, pneumonic plague, yellow fever, and viral haemorrhagic fevers. Beyond this list, the IHR requires State Parties to use the decision instrument to assess any event that may lead to the PHEIC, such as unknown or unusual events that may cross borders resulting in travel or trade restrictions. The Director-General has sole power to declare a PHEIC. To do so, the Director-General considers information from the State Party, the information gathered through the decision instrument, the advice of the Emergency Committee, scientific principles and evidence and a human health risk assessment.

The Emergency Committee is made up of international experts who provide technical advice to the WHO Director-General in the context of a "public health emergency of international concern" (PHEIC) The Committee provides views on:

- *whether the event constitutes a public health emergency of international concern (PHEIC);*
- *the Temporary Recommendations that should be taken by the country experiencing an emergency of international concern, or by other countries, to prevent or reduce the international spread of disease and avoid unnecessary interference with international trade and travel; and*
- *the termination of a PHEIC.*

The Director-General makes the final determination of a PHEIC and Temporary Recommendations to address the situation, based on advice from the Emergency Committee, information provided by the State Parties, scientific experts, and an assessment of risk to human health, risk of international spread of disease and of risk of interference with international travel.

Under the IHR (2005), Temporary Recommendations automatically expire three months after their issuance. Emergency Committees are therefore reconvened at least every 3 months to review the current epidemiological situation and to review whether the event continues to be a public health emergency of international concern and whether changes need to be made to the Temporary Recommendations. A statement of the Emergency Committee meeting is published on the WHO website after each meeting of the Committee" (WHO, 2022b).

Appendix C

Characteristics of approved COVID-19 vaccines as of June 2022

Vaccine name	Type of vaccine	Primary developers	Country of origin	Approved by WHO	Available on COVAX portfolio
Ad26.COV2.S	Non Replicating Viral Vector	Janssen Vaccines (Johnson & Johnson)	The Netherlands, USA	Yes	Yes
Abdala	Protein subunit	Center for Genetic Engineering and Biotechnology (CIGB)	Cuba	No	No
BBIBP-CorV	Inactivated	Beijing Institute of Biological Products; China National Pharmaceutical Group (Sinopharm)	China	Yes	Yes
Comirnaty BNT162b2	RNA	Pfizer, BioNTech; Fosun Pharma	Multinational	Yes	Yes
CoronaVac	Inactivated	Sinovac	China	Yes	Yes
Covifenz	Plant based virus like particles	Medicago; GSK; Dynavax	Canada	No	No

Covaxin (BBV152)	Inactivated vaccine	Bharat Biotech, ICMR; Ocugen	India	Yes	No
Corbevax	Adjuvanted protein subunit vaccine	Biological E, Baylor College of Medicine, Dynavax, CEPI	India, USA	No	No
CoviVac	Inactivated	Chumakov Federal Scientific Center for Research and Development of Immune and Biological Products	Russia	No	No
Convidicea (PakVac, Ad5-nCoV)	Recombinant vaccine	CanSino Biologics	China	Yes	No
COVIran Barekat	Inactivated	Shifa Pharmed Industrial Group	Iran	No	No
EpiVacCorona	Peptide vaccine	Federal Budgetary Research Institution State Research	Russia	No	No

		Center of Virology and Biotechnology			
FAKHRAVAC (MIVAC)	Inactivated	Organization of Defensive Innovation and Research	Iran	No	No
MVC-COV1901	Protein subunit	Medigen Vaccine Biologics Corp.; Dynavax	Taiwan, Paraguay	No	No
Noora vaccine	Protein subunit	Bagheiat-allah University of Medical Sciences	Iran	No	No
Nuvaxovid (Covovax in India; previously NVX-CoV2373)	Protein subunit	Novavax; CEPI, Serum Institute of India	US	Yes	No
QazVac	Inactivated	Research Institute for Biological Safety Problems	Kazakhstan	No	No

Sputnik V	Recombinant adenovirus vaccine (rAd26 and rAd5)	Gamaleya Research Institute, Acellena Contract Drug Research and Development	Russia	No	No
Sputnik Light	Recombinant adenovirus vaccine (rAd26)	Gamaleya Research Institute, Acellena Contract Drug Research and Development	Russia	No	No
Spikevax mRNA-1273	RNA	Moderna, BARDA, NIAID	USA	Yes	Yes
Spikogen	Monovalent recombinant protein vaccine	Vaxine Pty Ltd.; CinnaGen	Iran	No	No
Soberana 02	Conjugate vaccine	Finlay Institute of Vaccines; Pasteur Institute	Cuba, Iran	No	No

Soberana Plus	Conjugate vaccine	Finlay Institute of Vaccines; Pasteur Institute	Cuba, Iran	No	No
Turkovac	Inactivated	Health Institutes of Turkey	Turkey	No	No
Unnamed	Inactivated	Minhai Biotechnology Co.; Kangtai Biological Products Co. Ltd.	China	No	No
Unnamed	Inactivated	Chinese Academy of Medical Sciences, Institute of Medical Biology	China	No	No
VLA2001	Inactivated vaccine	Valneva; UK National Institute for Health Research; Dynavax	France, USA	No	No
Vaxzevria AZD1222	Adenovirus	BARDA, OWS, Oxford/AstraZeneca	UK	Yes	Yes

WIBP-CorV	Inactivated	Wuhan Institute of Biological Products; China National Pharmaceutical Group (Sinopharm)	China	No	No
Zifivax	Recombinant	Anhui Zhifei Longcom Biopharmaceutical, Institute of Microbiology of the Chinese Academy of Sciences	China, Uzbekistan	No	No
ZyCov-D	DNA vaccine (plasmid)	Zydus Cadila	India	No	No

Appendix D

WHO Fair Allocation Framework

In a snapshot, fair allocation of vaccines will occur in the following way:

1. An initial proportional allocation of doses to countries until all countries reach enough quantities to cover 20% of their population
2. A follow-up phase to expand coverage to other populations. If severe supply constraints persist, a weighted allocation approach would be adopted, taking account of a country's COVID threat and vulnerability.

Appendix E

The Values Framework for the Allocation and Prioritisation of COVID-19 Vaccines

Overarching Goal COVID-19 vaccines must be a global public good. The overarching goal is for COVID-19 vaccines to contribute significantly to the equitable protection and promotion of human well-being among all people of the world. The main principles are: **Human Well-Being:** Protect and promote human well-being including health, social and economic security, human rights and civil liberties, and child development. **Equal Respect:** Recognize and treat all human beings as having equal moral status and their interests as deserving of equal moral consideration. **Global Equity:** Ensure equity in vaccine access and benefit globally among people living in all countries, particularly those living in low-and middle-income countries. **National Equity:** Ensure equity in vaccine access and benefit within countries for groups experiencing greater burdens from the COVID-19 pandemic. **Reciprocity:** Honour obligations of reciprocity to those individuals and groups within countries who bear significant additional risks and burdens of COVID-19 response for the benefit of society. **Legitimacy:** Make global decisions about vaccine allocation and national decisions about vaccine prioritization through transparent processes that are based on shared values, best available scientific evidence, and appropriate representation and input by affected parties.

Source: (WHO, 2020b)

Appendix F

List of countries participating in the COVAX Facility

As of May 2021, the following countries have signed commitment agreements to the COVAX Facility as a self-financing participant:

Albania Andorra Antigua and Barbuda Argentina Armenia Australia Azerbaijan Bahamas Bahrain Barbados Belize Bosnia and Herzegovina Brazil Brunei Darussalam Canada Chile China Colombia Costa Rica Dominican Republic Ecuador Gabon Georgia Guatemala Iran Iraq Israel Jamaica Japan Jordan Kuwait Libya Mauritius Mexico Monaco Montenegro Nauru New Zealand Oman Palau Panama Paraguay Peru Qatar Saudi Arabia Serbia Singapore South Korea St. Kitts and Nevis Suriname Switzerland Trinidad & Tobago United Arab Emirates United Kingdom, Uruguay and Venezuela

In addition to the above countries, "Team Europe" – the European Commission on behalf of 27 EU member states plus Norway and Iceland – have also joined the COVAX Facility:

Austria Belgium Bulgaria Croatia Cyprus Czech Republic Denmark Estonia Finland France Germany Greece Hungary Iceland Ireland Italy Latvia Lithuania Luxembourg Malta Norway Netherlands Poland Portugal Romania Slovakia Slovenia Spain Sweden

The following countries are eligible to have their participation in the COVAX Facility supported by the COVAX AMC:

Low income: Afghanistan, Benin, Burkina Faso, Burundi, Central African Republic, Chad, Congo, Dem. Rep., Eritrea, Ethiopia, Gambia, The Guinea, Guinea-Bissau, Haiti, Korea, Dem. People's Rep., Liberia, Madagascar, Malawi, Mali, Mozambique, Nepal, Niger, Rwanda, Sierra Leone, Somalia, South Sudan, Syrian Arab Republic, Tajikistan, Tanzania, Togo, Uganda, Yemen, Rep.,

Lower-middle income: Angola, Algeria, Bangladesh, Bhutan, Bolivia, Cabo Verde, Cambodia, Cameroon, Comoros, Congo, Rep. Côte d'Ivoire, Djibouti, Egypt, Arab Rep., El Salvador, Eswatini, Ghana, Honduras, India, Indonesia, Kenya, Kiribati, Kyrgyz Republic Lao PDR, Lesotho, Mauritania, Micronesia, Fed. Sts., Moldova, Mongolia, Morocco, Myanmar, Nicaragua, Nigeria, Pakistan, Papua New Guinea, Philippines, São Tomé and Principe, Senegal,

Solomon Islands, Sri Lanka, Sudan, Timor-Leste, Tunisia, Ukraine, Uzbekistan, Vanuatu, Vietnam, West Bank and Gaza, Zambia, Zimbabwe

Additional IDA eligible: Dominica, Fiji, Grenada, Guyana, Kosovo, Maldives, Marshall Islands, Samoa, St. Lucia, St. Vincent and the Grenadines, Tonga, Tuvalu

Appendix G

List of dose donors and donated doses per manufacturer

- Austria
- Belgium
- Canada
- Croatia
- Cyprus
- Czech Republic
- Denmark
- Estonia
- Finland
- France
- Germany
- Greece
- Hong Kong SAR, China
- Iceland
- Ireland
- Italy
- Japan
- Latvia
- Lithuania
- Luxembourg
- Netherlands
- New Zealand
- Norway
- Portugal
- Slovakia
- Slovenia
- Spain
- Sweden
- Switzerland
- United Kingdom
- United States

Per manufacturer, COVAX has delivered the following donated doses:

- AstraZeneca – 140 million doses
- Johnson & Johnson – 137 million doses
- Moderna – 115 million doses
- Pfizer – 110 million doses

Appendix H

Sample questions provided by authors of the theoretical framework

Relationship between Frames and Paradigms

- Which language is used in discussions of a global health issue (i.e., how is it framed)?
- Which competing frames are brought to bear? How well do they resonate with the major paradigms of global health?
- Who voices particular framings and within which institutional contexts (e.g., particular communities of experts, organisations, the media)?
- Which authorities, texts etc are cited in support of a particular framing?
- How does the audience react to particular framings (do they gain support or are they opposed? Are they repeated in other contexts? etc)?
- Are links drawn between different policy fields/issue areas (e.g., are examples of successes/failures in other areas deployed)?
- How do framings differ at different stages of the policy cycle: are they consistent or do they change?

Power, frames, and policy context

- Which actors, communities and institutions have a visible stake in the outcomes a policy process?
- Who is involved in determining policy outcomes? Which institutions/individuals provide leadership, and who is excluded from the policy process?
- Is the policy process/outcome seen as legitimate or not?
- Which communities of experts are referenced and deployed in policy debates?
- Who provides the resources to implement policy and what conditionalities are attached, if any?
- Is contestation between different frames apparent in the policy cycle, and how is such contestation mediated or settled?
- In which ways is procedural power evident (e.g., through standard operating procedures, policy templates, institutional structures, and hierarchies etc)?

- Is there evidence that actors without traditional material power have influence on policy outcomes?

The "deep core" of neoliberalism

The following questions aim to reveal whether, or how, neoliberalism has structuring power. As such, they focus on the three lines of force: the privileging of certain actors and voices, evidence of distinctive policy templates, and the manner in which it colonises the paradigms of global health.

Actors

- What is the role of global economic actors and private interests in specific global health policy cycles?
- Are particular states or groupings of states (e.g., G8) associated with particular policies, do they promote them internationally, and do they pursue them in their own national policies?
- How does their role relate to that of other global health governance actors? Are they dominant or just another voice?
- How seriously are actors who critically engage with neoliberal policies taken?

Policy Templates

- What particular role is ascribed to states and other international public policy actors in the policy cycle? What roles are assigned to markets and private actors?
- How are competing interests, for example between economic development and individual health status, balanced or reconciled? Does one set of objectives or interests dominate?
- Have policy templates from other regimes or areas of policy been imported into global health policy, and are such templates associated with or indicative of neoliberalism?
- To what extent are private actors and market mechanisms seen as legitimate or useful in securing policy outcomes?

Paradigmatic Effects

- Are successful arguments framed in economic logics (e.g., efficiency, cost- saving) or do they employ economic evidence or methodologies?

- Do certain policy debates/discourses include framings that combine paradigms of health with neoliberal ideas?

- Are arguments put forward which bring together paradigms which may appear to be diametrically opposed (e.g., are policy debates ostensibly about development or public goods for health couched in discourses of market efficiency, consumer power and choice or the failure/inefficiency of public initiatives and interventions)?
- Are policy debates characterised by framings which stress the individual nature of risk, responsibility and (un)healthy behaviour?
- Are regulatory powers or policy interventions challenged on the basis that they infringe on private/individual/market rights?

Appendix I

MEDLINE search strategy used for scoping review of literature

Ovid MEDLINE(R) ALL [1946 to August 10, 2021]

Keyword	Medline search syntax	Result
Global health partnerships	1. (global public private partnership* or global health partnership* or global health initiative* or public private cooperation* or public private partnership* or public private sector cooperation* or public private sector partnership* or public private alliance* or private finance initiative* or product development partnership* or project finance*).mp.	3831
	2. Public-Private Sector Partnerships/	2321
	3. ((PFI* or PDF* or PPP*) and (financ* or partnership*)).mp.	603
	4. 1 or 2 or 3	4145
Vaccines	5. (vaccin* or immuni*).mp.	747214
	6. exp Vaccines/	242895
	7. exp Immunization/	185865
	8. immunization programs/ or vaccination coverage/	12975
	9. 5 or 6 or 7 or 8	764925
	10. 4 and 9	319

Appendix J

Inclusion and exclusion criteria for studies in the scoping review of literature

Criteria	Inclusion	Exclusion
1. Context	• Global or bilateral settings	• Other settings (e.g., subnational, or national. Reviewed or examined country specific PPP case studies and did not compare with another country or region (i.e., focused only on a PPP intervention in one country)
2. Topic	• Examines the role of vaccine global health partnerships in vaccine research, development and delivery	• Reviewed PPPs for addressing animal related diseases • Reviewed non-vaccine PPPs exclusively
3. Outcomes	• Critically reviewed the strengths and weaknesses of vaccine PPPs and their initiatives	• PPPs were only mentioned in the conclusion or as a recommendation • Only reported or summarised a PPP's performance, without critically engaging with processes or outcomes
4. Source type	• Primary research articles • Commentaries/editorials • Book chapters • Conference abstracts	• Non-text materials such as audio/video reports • Social media, blogs, news articles • Conference abstracts covering the same material as an available publication

5. Time-period	• Published between 2000 and 2021	N/A
6. Language	• English or French	N/A
7. Study design	• Any	N/A
8. Participants	• Any	N/A

Appendix K

Participant consent form in English

PARTICIPANT CONSENT FORM

Title of Project: The politics of COVID-19 vaccine equity: A case study of the COVAX Facility Initiative

Name of PI/Researcher responsible for project: Charnele Nunes

Statement	**Please initial or thumbprint* each box**
I confirm that I have read the information sheet dated July 2021 (version 1) for the above-named study. I have had the opportunity to consider the information, ask questions and have these answered satisfactorily. **OR** I have had the information explained to by study personnel in a language that I understand. I have had the opportunity to consider the information, ask questions and have these answered satisfactorily.	
I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.	
I understand that relevant data collected during the study may be looked at by authorised individuals from the London School of Hygiene and Tropical Medicine, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.	
I understand that data about/from me/the participant may be shared via a public data repository or by sharing directly with other researchers, and that I will not be identifiable from this information	
I agree to take part in the above-named study	

Printed name of participant	Signature of participant	Date

I attest that I have explained the study information accurately in _____ to, and was understood to the best of my knowledge by, the participant and that he/she has freely given their consent to participate* in the presence of the above named impartial witness (where applicable).

Printed name of person obtaining consent	Signature of person obtaining consent	Date

A copy of this informed consent document has been provided to the participant.

Centre Number:
Study Number:
Participant Identification Number:

[Informed Consent for Participant with Impartial witness_28.08.21_v2]

Appendix L

Participant consent form in French

FORMULAIRE DE CONSENTEMENT DU PARTICIPANT

Titre du projet: The politics of COVID-19 vaccine equity: A case study of the COVAX Facility Initiative

Chercheur responsable du projet: Charnele Nunes

Déclaration	**Veuillez signer ou empreinte* chaque case**
Je confirme avoir pris connaissance de la fiche d'information en date de juillet 2021 (version 1) de l'étude susnommée. J'ai eu l'occasion d'examiner les informations, de poser des questions et d'obtenir des réponses satisfaisantes. **OU** Le personnel de l'étude m'a expliqué les informations dans une langue que je comprends. J'ai eu l'occasion d'examiner les informations, de poser des questions et d'obtenir des réponses satisfaisantes.	
Je comprends que ma participation est volontaire et que je suis libre de me retirer à tout moment sans donner de raison, sans que mes soins médicaux ou mes droits légaux soient affectés.	
Je comprends que les sections pertinentes de mes notes médicales et des données recueillies au cours de l'étude peuvent être consultées par des personnes autorisées de la London School of Hygiene and Tropical Medicine, lorsque cela est pertinent pour ma participation à cette recherche. J'autorise ces personnes à accéder à mes dossiers.	
Je comprends que les données me concernant/de moi/du participant peuvent être partagées via un référentiel de données public ou en partageant directement avec d'autres chercheurs, et que je ne serai pas identifiable à partir de ces informations.	
J'accepte de participer à l'étude susnommée.	

Nom imprimé du participant	Signature du participant	Date

J'atteste que j'ai expliqué avec précision les informations de l'étude en _____ au participant et qu'il a été compris au meilleur de ma connaissance par le participant et qu'il a librement consenti à participer* en présence du témoin impartial nommé ci-dessus (le cas échéant).

Nom imprimé de la personne qui obtient le consentement	Signature de la personne obtenant le consentement	Date

Une copie de ce document de consentement éclairé a été remise au participant.

Numéro de centre :
Numéro d'étude :
Numéro d'identification du participant :
[Consentement éclairé du participant avec témoin impartial_28.08.21_v2]

Appendix M

Participant information sheet in English

Participant Information Sheet

Title of Project: *The politics of COVID-19 vaccine equity: A case study of the COVAX Facility Initiative*

Introduction
We would like to invite you to take part in a research study. Joining the study is entirely up to you. Before you decide, you need to understand why the research is being done and what it would involve. One of our team will go through this information sheet with you, and answer any questions you may have. Ask questions if anything you read is not clear or you would like more information. Please feel free to talk to others about the study if you wish. Take time to decide whether or not to take part.

What is the purpose of the study?
The London School of Hygiene and Tropical Medicine (LSHTM) are conducting research to understand what problems COVAX faces and how these can be addressed.

Why have I been asked to take part?
You have been invited because you have been involved in research or advocacy related to COVAX and/or policymaking related to your government's choice to join or not to join COVAX.

Do I have to take part?
No. It is up to you to decide to take part or now. If you don't want to take part, that's ok.

We will discuss the study together and give you a copy of this information sheet. If you agree to take part, we will then ask you to sign a consent form.

What will happen to me if I take part?
You will be invited for an interview via Zoom where the Principal Investigator (Charnele Nunes) will ask you questions related to vaccine equity, COVAX as a public, private partnership, and how to manage the global health politics of vaccine distribution and allocation.

What will I have to do?
You will be invited to an interview via Zoom.

What are the possible risks and disadvantages?
There are none. Should you choose to participate in this study, we will ensure that all personal identifiable details (including, but not limited to, name, age or job title) will be anonymised during the data processing to ensure confidentiality is maintained.

What are the possible benefits?
We cannot promise the study will help you but the information we get from the study will help our knowledge and understanding of this research area and how to problems related to COVAX can be addressed.

What if something goes wrong?
If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions +44 (0) 78 4152 3936 . If you remain unhappy and wish to complain formally, you can do this by contacting Patricia Henley at rgio@lshtm.ac.uk or +44 (0) 20 7927 2626

The London School of Hygiene and Tropical Medicine holds insurance policies which apply to this study. If you experience harm or injury as a result of taking part in this study, you may be eligible to claim compensation.

Can I change my mind about taking part?
Yes. You can withdraw from the study at any time.

If you withdraw from the study we will destroy all your digitally recorded interview>, but we will need to use the data collected on you up to your withdrawal.

What will happen to information collected about me?
We will need to use information from you for this research project. All information collected about you will be kept private. Only the study staff and authorities who check that the study is being carried out properly will be allowed to look at information about you. Information will include your initials, name, contact details or other identifiers used for the research project. We will keep all information about you safe and secure.

Data may be sent to other study staff in London, but this will be anonymised. This means that any information about you, will have your name and address removed so that you cannot be recognised and your data will have a code number instead.

Your personal details, meaning your name and other identifiable information, will be kept in a different safe place to the other study information and will be destroyed within 10 years of the end of the study and stored securely in London.

At the end of the project, the study data will be archived on a digital database at the London School of Hygiene and Tropical Medicine. The data will be made available to other researchers worldwide for research and to improve medical knowledge and patient care. Your personal information will not be included and there is no way that you can be identified.

What are your choices about how your information is used?
You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.

We need to manage your records in specific ways for the research to be reliable. This means we won't be able to let you see or change the data we hold about you.

Where can you find out more about how your information is used?
You can find out more about how we use your information

- *At https://www.lshtm.ac.uk/files/research-participant-privacy-notice.pdf*
- *by asking one of the research team*
- *by sending an email to DPO@lshtm.ac.uk*

- *at https://www.hra.nhs.uk/information-about-patients/*

What will happen to the results of this study?
The study results will be published in a medical journal so that other doctors can learn from them. Your personal information will not be included in the study report and there is no way that you can be identified from it.

Who is organising and funding this study?
London School of Hygiene & Tropical Medicine is the sponsor for the research and they have full responsibility for the project including the collection, storage and analysis of your data, and will act as the Data Controller for the study. This means that we are responsible for looking after your information and using it properly.

Who has reviewed this study?
All research involving human participants is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by The London School of Hygiene and Tropical Medicine Research Ethics Committee (<ref:>).

Further information and contact details

Thank you for taking time to read this information sheet. If you think you will take part in the study please read and sign the consent form.

Contact details: Charnele Nunes at charnele.nunes@lshtm.ac.uk or *+44 (0) 78 4152 3936*

Appendix N

Participant information sheet in French

Fiche d'information du participant

Titre du projet: *The politics of COVID-19 vaccine equity: A case study of the COVAX Facility Initiative*

Introduction
Nous aimerions vous inviter à participer à une étude de recherche. Rejoindre l'étude est entièrement à vous. Avant de prendre une décision, vous devez comprendre pourquoi la recherche est effectuée et ce qu'elle impliquerait. Un membre de notre équipe passera en revue cette fiche d'information avec vous et répondra à toutes vos questions. Posez des questions si quelque chose que vous lisez n'est pas clair ou si vous souhaitez plus d'informations. N'hésitez pas à parler de l'étude à d'autres si vous le souhaitez. Prenez le temps de décider de participer ou non.

Quel est le but de l'étude ?
La London School of Hygiene and Tropical Medicine (LSHTM) mène des recherches pour comprendre les problèmes auxquels le COVAX est confronté et comment ils peuvent être résolus.

Pourquoi m'a-t-on demandé de participer ?
Vous avez été invité parce que vous avez participé à des recherches ou à des activités de plaidoyer liées à COVAX et/ou à l'élaboration de politiques liées au choix de votre gouvernement d'adhérer ou de ne pas adhérer à COVAX.

Dois-je participer ?
Non. C'est à vous de décider de participer ou maintenant. Si vous ne voulez pas participer, ce n'est pas grave.

Nous discuterons ensemble de l'étude et vous remettrons une copie de cette fiche d'information. Si vous acceptez de participer, nous vous demanderons alors de signer un formulaire de consentement.

Que va-t-il m'arriver si je participe ?
Vous serez invité à un entretien via Zoom où le chercheur principal (Charnele Nunes) vous posera des questions sur l'équité en matière de vaccins, COVAX en tant que partenariat public et privé, et sur la manière de gérer la politique de santé mondiale de la distribution et de l'allocation des vaccins.

Que vais-je devoir faire ?
Vous serez invité à un entretien via Zoom.

Quels sont les risques et inconvénients possibles ?
Il n'y en a pas. Si vous choisissez de participer à cette étude, nous assurerons que toutes les informations personnelles identifiables (y compris, mais sans s'y limiter, le nom, l'âge ou le titre du poste) soient rendues anonymes pendant le traitement des données afin de garantir la confidentialité.

Quels sont les avantages possibles ?
Nous ne pouvons pas promettre que l'étude vous aidera, mais les informations que nous obtenons de l'étude nous aideront à mieux connaître et comprendre ce domaine de recherche et à résoudre les problèmes liés au COVAX.

Et si quelque chose ne va pas ?
Si vous avez des inquiétudes concernant un aspect de cette étude, vous devez demander à parler aux chercheurs qui feront de leur mieux pour répondre à vos questions +44 (0) 78 4152 3936. Si vous n'êtes toujours pas satisfait et souhaitez-vous plaindre formellement, vous pouvez le faire en contactant Patricia Henley à rgio@lshtm.ac.uk ou +44 (0) 20 7927 2626

Une copie de ce document de consentement éclairé à offrir au participant

La London School of Hygiene and Tropical Medicine détient des polices d'assurance qui s'appliquent à cette étude. Si vous subissez un préjudice ou une blessure à la suite de votre participation à cette étude, vous pourriez être admissible à une indemnisation.

Puis-je changer d'avis pour participer ?
Oui. Vous pouvez vous retirer de l'étude à tout moment.

Si vous vous retirez de l'étude, nous détruirons tous vos entretiens enregistrés numériquement, mais nous devrons utiliser les données collectées sur vous jusqu'à votre retrait.

Qu'adviendra-t-il des informations recueillies à mon sujet ?
Nous aurons besoin d'utiliser vos informations pour ce projet de recherche. Toutes les informations recueillies à votre sujet resteront confidentielles. Seul le personnel de l'étude et les autorités qui vérifient que l'étude est menée correctement seront autorisés à consulter les informations vous concernant. Les informations comprendront vos initiales, votre nom, vos coordonnées ou d'autres identifiants utilisés pour le projet de recherche. Nous conserverons toutes les informations vous concernant en toute sécurité.

Les données peuvent être envoyées à d'autres membres du personnel de l'étude à Londres, mais cela sera anonymisé. Cela signifie que toute information vous concernant aura votre nom et votre adresse supprimés afin que vous ne puissiez pas être reconnu et vos données auront un numéro de code à la place.

Vos données personnelles, c'est-à-dire votre nom et d'autres informations identifiables, seront conservées dans un endroit sûr différent des autres informations de l'étude et seront détruites dans les 10 ans suivant la fin de l'étude et gardées en toute sécurité à Londres.

A la fin du projet, les données de l'étude seront archivées au xxx. Les données seront mises à la disposition d'autres chercheurs dans le monde à des fins de recherche et d'amélioration des connaissances médicales et des soins aux patients. Vos informations personnelles ne seront pas incluses et il n'y a aucun moyen de vous identifier.

Quels sont vos choix sur la façon dont vos informations sont utilisées ?
Vous pouvez arrêter de faire partie de l'étude à tout moment, sans donner de raison, mais nous conserverons les informations vous concernant que nous avons déjà.

Nous devons gérer vos dossiers de manière spécifique pour que la recherche soit fiable. Cela signifie que nous ne pourrons pas vous permettre de voir ou de modifier les données que nous détenons à votre sujet.

Où pouvez-vous en savoir plus sur la façon dont vos informations sont utilisées ?
Vous pouvez en savoir plus sur la façon dont nous utilisons vos informations

- *Sur https://www.lshtm.ac.uk/files/research-participant-privacy-notice.pdf*
- *En demandant à l'un des membres de l'équipe de recherche*
- *En envoyant un email à DPO@lshtm.ac.uk*
- *Sur https://www.hra.nhs.uk/information-about-patients/*

Qu'adviendra-t-il des résultats de cette étude ?

Les résultats de l'étude seront publiés dans une revue médicale afin que d'autres médecins puissent en tirer des enseignements. Vos informations personnelles ne seront pas incluses dans le rapport d'étude et il n'y a aucun moyen de vous identifier à partir de celui-ci.

Qui organise et finance cette étude ?
La London School of Hygiene & Tropical Medicine est le sponsor de la recherche et ils ont l'entière responsabilité du projet, y compris la collecte, le stockage et l'analyse de vos données, et agiront en tant que contrôleur de données pour l'étude. Cela signifie que nous sommes responsables de veiller à vos informations et de les utiliser correctement.

Qui a revu cette étude ?
Toutes les recherches impliquant des participants humains sont examinées par un groupe indépendant de personnes, appelé comité d'éthique de la recherche, afin de protéger vos intérêts. Cette étude a été examinée et a reçu un avis favorable par le comité d'éthique de la recherche de la London School of Hygiene and Tropical Medicine (<ref:>).

Plus d'informations et coordonnées
Merci d'avoir pris le temps de lire cette fiche d'information. Si vous pensez participer à l'étude, veuillez lire et signer le formulaire de consentement.

Coordonnées : Charnele Nunes à charnele.nunes@lshtm.ac.uk ou +44 (0) 78 4152 3936

Appendix O

INTERVIEW GUIDE The politics of COVID-19 vaccine equity: A case study of the COVAX Facility Initiative

Introduction

READ: Interview [add ID code], without saying your name, please confirm that you have been informed about this study, your questions have been answered, you understand that if you wish to avoid a question or stop at any point you may do so, and that you are participating willingly.

1. Could you briefly summarise your professional role or experience in relation to COVAX?

Topic 1: COVAX and its governance structure

2. In what ways has COVAX achieved what it was set up to do? PROBE: has it achieved its goals of vaccinating the world, why/why not?
3. What are the main barriers facing COVAX?
4. COVAX has been critiqued as being a charity project for low and middle-income countries, do you think this is true, why/why not?
5. Why do you think many high-income countries have not procured vaccines via COVAX?
6. Why do you think there was limited CSO/LMIC involvement in the initial COVAX design process?
7. Why do you think many vaccines approved for emergency use are not included in the COVAX portfolio? PROBE: Why might manufacturers have chosen not to make their vaccines available via COVAX, despite creation of the No-Fault Compensation programme?

Topic 2: how ideals of vaccine accessibility interact with the vaccine R&D ecosystem

8. How could the current IP system act as a barrier to global accessibility of vaccines? PROBE: If it is a barrier, what is the role of COVAX in this?

9. Both Gavi and CEPI were created to address market failure, which has not appeared to be a problem during the COVID-19 pandemic, so do you think their preferred approaches to vaccine R&D and delivery were appropriate during the pandemic? PROBE: Why/why not?
10. In what ways have vaccine manufacturers dominated the current innovation system? PROBE: why is it supply led instead of demand led? How does this affect the likelihood of achieving global vaccine equity?
11. How can COVAX adapt to a vaccine system that favours suppliers and their interests?
12. COVAX adopts the GAVI procurement model, despite both facing very different problems, so do you think the GAVI model is appropriate during a global pandemic when countries compete for resources?
13. What is the role of public/private partnerships in a pandemic? PROBE: Are they effective within the context of countries competing for vaccines and resources?
14. Has there been an appropriate focus on global manufacturing capacity, why/why not?

Topic 3: Responding to global health politics

15. If countries are inherently self-interested, as international relations theory describes, how can COVAX address this self-interest and promote more multilateral cooperation?
16. In what ways do you think domestic politics have influenced how countries responded globally to COVID-19 or any other crisis?
17. How can non-state actors influence countries' willingness to work together?
18. How does vaccine nationalism or diplomacy [*EXPLAIN both terms to the participant*], undermine the goal of global vaccine equity? PROBE: How can COVAX respond to this?

Wrap-up

Thank you for your time. We have reached the end of my questions. Is there anything else you would like to add or ask about that you think we didn't discuss sufficiently?

Appendix P

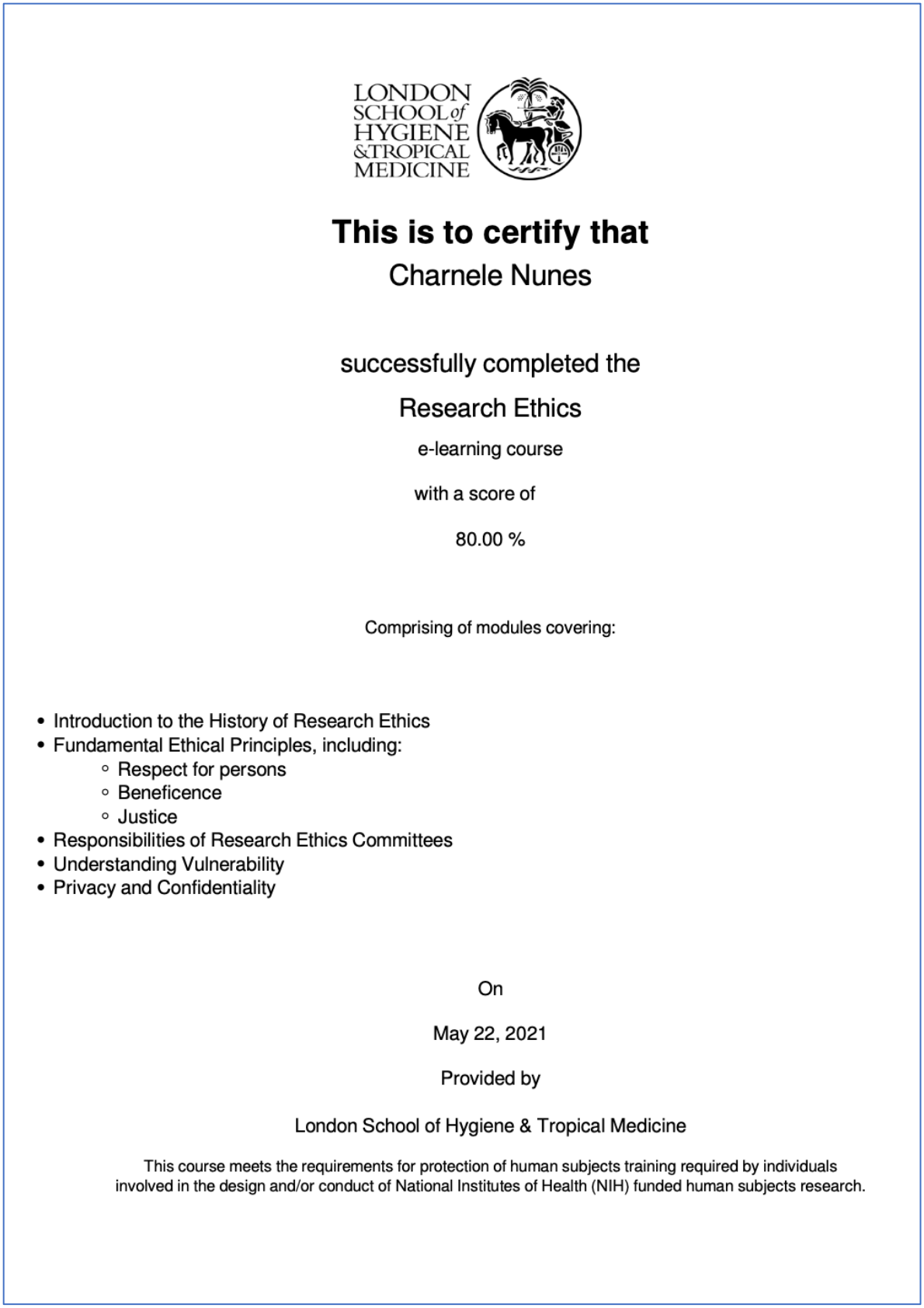
List of codes developed during case study data collection

Parent theme	Themes	Codes
Global health policy	Gavi and CEPI	Global health leaders Institutional leaders Experts in the field Recipient of large funds
	Tiered design	Risk groups Fair allocation system Self-funded participants Funded participants Donor funded
	Transparency and accountability	Decision making processes Clarity on processes Contractual agreements Ownership of clinical trial data
	CSOs and other stakeholders	Inclusivity of stakeholders LMIC stakeholders' involvement Widening participation Donor led agenda

Policy debates and paradigms of global health	Technical solution	Need to maintain the intellectual property regime Subsidies – concessional loan, grants and bonds to innovate Private sector led innovation Private sector expertise Cost effectiveness of interventions Prioritisation of economic policy vs global health policy
	Political solution	Need to expand manufacturing Solidarity as political idealism Value and health system strengthening Intellectual property monopoly Innovation power dynamics Vaccine mRNA technological monopoly

Appendix Q

Certificate of completion of LSHTM Research Ethics training course



LONDON SCHOOL of HYGIENE &TROPICAL MEDICINE

This is to certify that

Charnele Nunes

successfully completed the

Research Ethics

e-learning course

with a score of

80.00 %

Comprising of modules covering:

- Introduction to the History of Research Ethics
- Fundamental Ethical Principles, including:
  - Respect for persons
  - Beneficence
  - Justice
- Responsibilities of Research Ethics Committees
- Understanding Vulnerability
- Privacy and Confidentiality

On

May 22, 2021

Provided by

London School of Hygiene & Tropical Medicine

This course meets the requirements for protection of human subjects training required by individuals involved in the design and/or conduct of National Institutes of Health (NIH) funded human subjects research.

Appendix R

Examples of GHPs in the vaccine innovation system

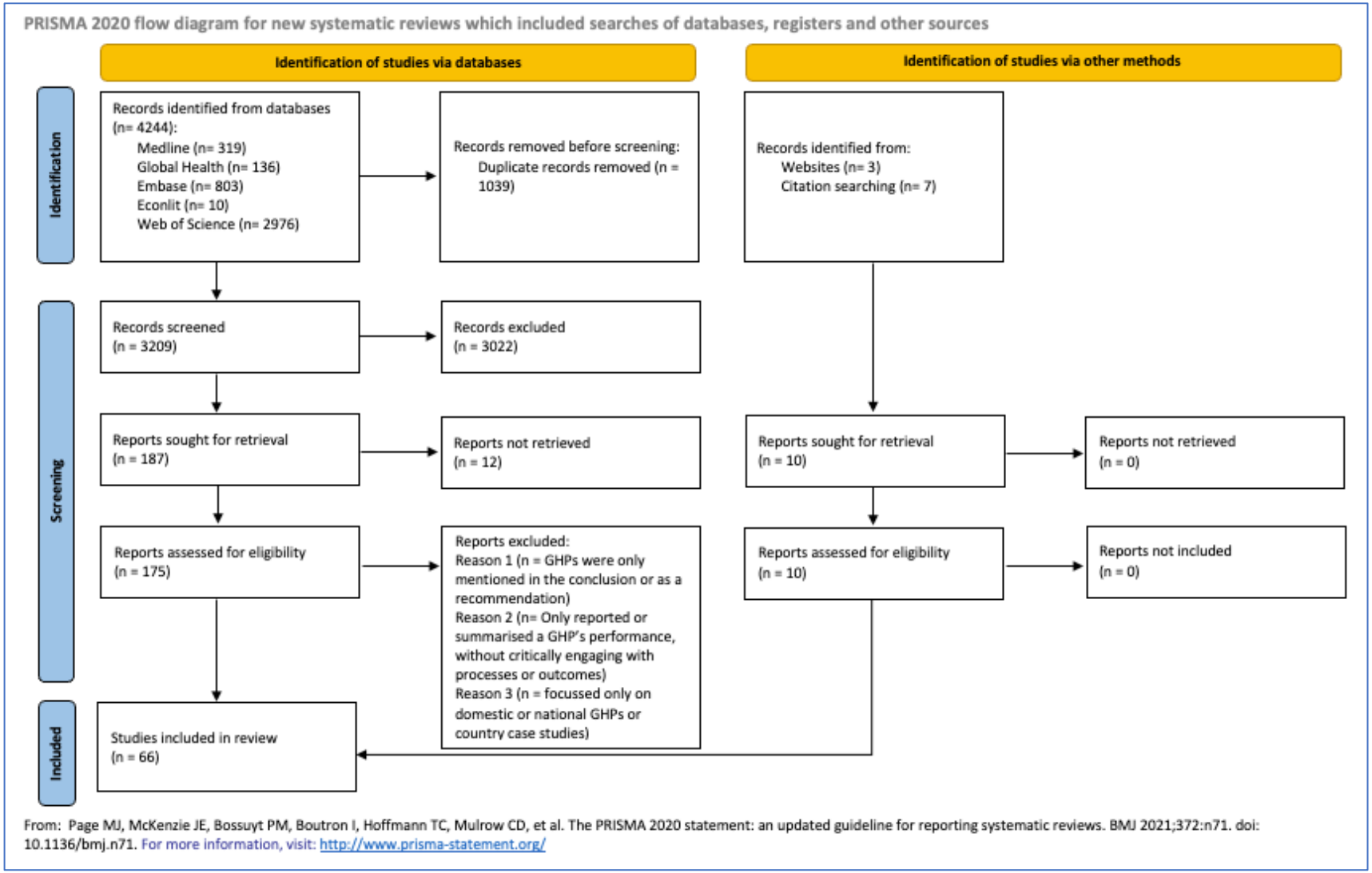
Organisation	Mission	Diseases covered	Governance	Budget	Sources of funding
CEPI	To accelerate the development of vaccines and other biologic countermeasures against epidemic and pandemic threats so they can be accessible to all people in need.	Emerging Infectious Diseases (EIDs)	Governing Board and 2 bodies to guide and support organisational work: the Scientific Advisory Committee and the Joint Coordination Group.	The next business period from 2022-2026 has a budget of BUSD $3.5	Government agencies, international organisations, and other foundations
DNDi	To develop new treatments for people living with neglected diseases.	Neglected diseases such as human African trypanosomiasis (HAT, or sleeping sickness), visceral	Board of Directors that approves project selection and sets policies governing intellectual property,	Since its inception in 2003, DNDi's total expenditure amounted to EUR 548 million by end of 2020.	Government agencies, international organisations, and other foundations

		leishmaniasis (kala-azar), and Chagas disease, while considering engagement in R&D projects for other neglected patients (e.g., malaria, paediatric HIV, filarial infections)	financial control, and ethics.		
Gavi	To save lives and protect people's health by increasing equitable and sustainable use of vaccines	Zero-dose children – defined as children who don't receive a single dose of diphtheria, tetanus, and pertussis-containing vaccine	The Gavi Secretariat oversees the day-to-day operations of the Vaccine Alliance, the Board is responsible for giving strategic direction and policymaking.	US $8.8 billion was raised for the funding cycle 2021 to 2025	Government agencies, international organisations, and other foundations

International Aids Vaccine Initiative	Development of safe, effective and accessible HIV vaccines particularly for developing countries	HIV	A vaccine fund that identifies partners supporting promising vaccine candidates	Invested almost US$20 million in four innovative Vaccine Development partnerships since 1996	Government agencies, international organisations, and other foundations
Medicines For Malaria Venture	Discover, develop and commercialise 1 new antimalarial every 5 years	Malaria	Virtual not-for-profit R&D company	Target fundraising budget US$30 million	Government agencies, public foundations, private companies (drug discovery expertise and related technologies)
TB Alliance	The discovery, development and delivery of better, faster acting and affordable tuberculosis drugs that are available to those who need them.	Tuberculosis	Board of Directors and various Advisory Boards	Funding of up to US$30 million will be administered over a period of 5 years	Government agencies, international organisations, and other foundations

Appendix S

PRISMA chart for scoping review of literature



From: Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. BMJ 2021;372:n71. doi: 10.1136/bmj.n71. For more information, visit: http://www.prisma-statement.org/

Appendix T

The role of Gavi Committees

Audit and Finance Committee: The Audit and Finance Committee assists the Board in fulfilling its responsibilities in respect to the accounting, financing, budgeting, and financial practices of the Vaccine Alliance.

Evaluation Advisory Committee: The Evaluation Advisory Committee assists the Board in fulfilling its responsibilities in respect to the oversight of Gavi's organisational and programmatic evaluation activities.

Governance Committee: The Governance Committee assists the Board in fulfilling its responsibilities relating to developing and implementing sound Governance policies and practices for Gavi.

Investment Committee: The Investment Committee assists the Board in fulfilling its responsibilities in respect to managing of Gavi's investments in a manner consistent with Gavi's operating needs and overall programme goals; asset preservation and growth within Gavi's investment portfolio; prudent maximisation of risk-adjusted returns on investment consistent with objectives stated in the Investment Policy.

Programme and Policy Committee: The Programme and Policy Committee assists the Board in fulfilling its responsibilities in respect to the programmatic and policy oversight of the Vaccine Alliance.

The role of CEPI Committees

The Programme and Policy Committee (PPC) assists the Board in fulfilling its responsibilities in respect to the programmatic and policy oversight of the Vaccine Alliance.

The Research Development and Manufacturing Investment Committee (RDMIC) is also accountable to the CEPI Board. The RDMIC is a multidisciplinary group providing investment

decision recommendations for COVID-19 vaccine projects in the COVAX R&D and manufacturing portfolio.

The Scientific Advisory Committee is an independent body within the CEPI governing structure that provides world-class scientific support, advice, and guidance to CEPI staff and the CEPI Board in responding to the current COVID-19 pandemic.

Joint Coordination Group is a roundtable of independent institutions with an interest in seeing CEPI's vaccines successfully developed and deployed in an outbreak.

Key groups that manage, govern, and support the operations of the COVAX Facility

Facility management

- **Office of the COVAX Facility**: As the legal administrator of the COVAX Facility, Gavi has established the Office of the COVAX Facility within the Gavi Secretariat as a dedicated team to support Facility operations. It will comprise several new teams, including design and operations; deal making and vaccine portfolio management; country engagement; and finance. The Office of the COVAX Facility will also establish Advance Purchase Agreements and propose them to the Market-Sensitive Decisions Committee (MSDC) for approval.

Facility governance

- **Gavi Board**: The Board of Gavi, the Vaccine Alliance is responsible for overseeing the role of the Gavi Secretariat and the Alliance in the COVAX Facility and will have ultimate responsibility for decisions and effective implementation of the Facility. The Gavi Board established the **Audit and Finance Committee (AFC)** to support the Board in fulfilling its oversight responsibilities in a timely manner, in respect of the Vaccine Alliance's financial management; risk and control framework, including internal and external audit; and adherence to appropriate standards of good practices and ethics. The AFC will undertake this function in relation to Gavi's role as the legal administrator of the COVAX Facility. Also, the Gavi Board established the **Market-Sensitive Decisions Committee (MSDC)** to provide oversight and make decisions that are market and/or commercially sensitive. The MSDC is responsible for reviewing business terms of proposed agreements with manufacturers to ensure: (i) reasonableness of terms and

acceptable level of reputational risks; and (ii) availability of resources to back proposed agreements.

- **COVAX Shareholders Council**: In the governance of the COVAX Facility, the COVAX Shareholders Council represents the 90+ higher-income economies that have agreed to self-finance their COVID-19 vaccines. The Council is a self-organising body that will support real-time information exchange, and provide strategic guidance and advice, to the Office of the COVAX Facility on operational aspects of the COVAX Facility.
- **AMC Engagement Group**: The AMC Engagement Group is open to representatives from implementing economies, donors and other parties engaged in the financing and operation of the Gavi COVAX Advance Market Commitment (AMC). This self-organising group will support real-time information exchange, and provide strategic guidance and advice, to the Office of the COVAX Facility on the operational aspects of the COVAX Facility – particularly as it relates to implementation in AMC-eligible countries. Within this body, an **AMC Investors Group** will convene representatives from AMC donors; procurement organisations such as UNICEF and the Pan American Health Organization (PAHO); and representatives of multilateral development banks or regional banks involved in the financing of the AMC. It will discuss its investments in the AMC; options for additional financing; and receive specific reporting on progress achieved against the objectives of the AMC.
- **COVAX Consensus Group**: The COVAX Consensus Group will be established to support effective operation of the COVAX Facility through consensus-based decision-making between various governing bodies, particularly in areas where disagreement may arise.

Technical and advisory bodies

- **Independent Product Group (IPG)**: Considering priority vaccine candidates and portfolio balance, the IPG makes recommendations to the Office of the COVAX Facility on the inclusion of vaccines in the COVAX Facility. The IPG regularly reviews the portfolio for balance; reviews updates on timing and availability of doses; and considers any implications for the COVAX Facility portfolio.
- **Procurement Reference Group (PRG)**: Once vaccine candidates have been selected to be funded by the COVAX Facility, the PRG ensures an appropriately risk managed COVAX portfolio from a commercial perspective, considering the timeline for supply

delivery of vaccine candidates. The PRG provides independent advice to the Facility on its procurement strategy.

Allocation governance

- **Joint Allocation Taskforce (JAT)**: Comprised of Gavi, via the Office of the COVAX Facility, and WHO, the JAT will, based on a data-driven allocation model, prepare a Vaccine Allocation Decision (VAD) proposal for review and validation.
- **Independent Allocation of Vaccines Group (IAVG)**: The IAVG will be established as an independent body to validate VAD proposals put forward by the JAT. Composed of technical experts, the IAVG will validate that the proposed VADs are technically informed, transparent, and free from conflicts of interest. They may also request clarifications from the JAT, and for the model to be rerun if needed, before making their final determination. Once validated by the IAVG, the VAD is passed to the Office of the COVAX Facility for implementation, with support from procurement organisations, such as UNICEF and PAHO.

Operational bodies (e.g., working groups)

The COVAX Coordination Meeting (CCM) is the high-level body that meets to coordinate efforts across the different elements of COVAX. The CCM is chaired by the Board Chairs of CEPI and Gavi, representatives of civil society and industry, and includes the institutional leads of CEPI, Gavi and WHO – providing a link to the established governance of each organisation. It meets to help coordinate, guide, and resolve issues across COVAX.