RESEARCH ARTICLE

The formation of the Coalition for Epidemic Preparedness Innovations (CEPI): An empirical study [version 1; peer review: 1 approved with reservations, 1 not approved]

Kristin Ingstad Sandberg ¹, Steinar Andresen¹, Unni Gopinathan²,
Berit Sofie Hustad Hembre³

¹Fridtjof Nansen Institute, Lysaker, Norway

²Norwegian Institute of Public Health, Oslo, Norway

³University of Oslo/Oslo University Hospital, Oslo, Norway

v1 First published: 07 Dec 2020, 5:284
<https://doi.org/10.12688/wellcomeopenres.16284.1>
 Latest published: 07 Dec 2020, 5:284
<https://doi.org/10.12688/wellcomeopenres.16284.1>

Abstract

Background: The formation of the Coalition for Epidemic Preparedness Innovations (CEPI) sheds light on how conditions for global collaboration are created and sustained. This is a multi-stakeholder initiative whose objective is to be a global financing and coordination mechanism that supports the development of vaccines against epidemic infectious disease.

Methods: The paper reports from an empirical study that documented and analysed CEPI's formation from idea in mid-2015 to its formal launch in January 2017, using a qualitative approach and analytical perspectives from international relations and the governance of socio-technical systems to explain decisions and outcomes.

Results: The accomplishment of forming CEPI in only 15 months was possible due to a substantial operational capacity among founding partners for groundwork and coordinating parallel processes, multiple individuals in leadership roles as well the flexibility offered by an interim phase. Findings also suggest that key alignments needed to be found between diverging positions on collective action for technology development, revealing the complexity and dynamics of interests among actors. The study further identifies key institutional conditions that interests clustered around, which CEPI needed manage in order to become operational.

Conclusions: The study concludes that while successful in developing a new nexus between global public health, vaccine innovation and pandemic response, CEPI was in 2017 still in the process of defining the nature of its authority within that landscape. Finally, the CEPI formation process bears significance for the global coordinated response to the coronavirus (COVID-19) pandemic in 2020. As features of the CEPI formation represent persistent challenges in global health

Open Peer Review

Approval Status

	1	2
version 1 07 Dec 2020	 view	 view
1. Kelley Lee , Simon Fraser University, Burnaby, Canada		
2. Remco van de Pas , Institute of Tropical Medicine, Antwerp, Antwerp, Belgium		
Any reports and responses or comments on the article can be found at the end of the article.		

collaboration, the study offers both a backdrop and lessons learned.

Keywords

Global health, pandemic preparedness, governance, institutional design, vaccines, innovation

Corresponding author: Kristin Ingstad Sandberg (kingstadsandberg@gmail.com)

Author roles: **Ingstad Sandberg K:** Conceptualization, Investigation, Methodology, Project Administration, Writing – Original Draft Preparation, Writing – Review & Editing; **Andresen S:** Conceptualization, Funding Acquisition, Investigation, Project Administration, Supervision, Writing – Original Draft Preparation, Writing – Review & Editing; **Gopinathan U:** Conceptualization, Writing – Original Draft Preparation, Writing – Review & Editing; **Hustad Hembre BS:** Investigation, Writing – Review & Editing

Competing interests: No competing interests were disclosed.

Grant information: This is an independent study, supported by a Wellcome contract with the Fridtjof Nansen Institute. The funders had no role in study design, data collection and analysis. The manuscript was approved by CEPI and a Wellcome representative prior to submission.

The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

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How to cite this article: Ingstad Sandberg K, Andresen S, Gopinathan U and Hustad Hembre BS. **The formation of the Coalition for Epidemic Preparedness Innovations (CEPI): An empirical study [version 1; peer review: 1 approved with reservations, 1 not approved]** Wellcome Open Research 2020, 5:284 <https://doi.org/10.12688/wellcomeopenres.16284.1>

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Introduction

Infectious disease outbreaks that cross borders reveal gaps in global structures for collaboration. The Ebola outbreak in West Africa, 2014–16 was no exception in this regard. In its aftermath, however, a resolve among organisations and individuals representing science, industry, states and civil society, led to the formation of Coalition for Epidemic Preparedness Innovations (CEPI), a new institution that is taking centre-stage in the global response to fight the coronavirus (COVID-19) pandemic. The formation of CEPI sheds light on how the combination of leadership and organisational resources work to establish a new institution. It also illuminates the difficult balance between pragmatic positions and a shared ethos for creating a better system. In short, it tells the story of what it takes to establish a structure for collaboration that everyone has an interest in being part of.

The Wellcome Trust, the World Economic Forum, the Government of Norway, the Government of India and the Bill and Melinda Gates Foundation launched CEPI in Davos in January 2017. CEPI is a multi-stakeholder coalition and a legally independent transnational entity that aims to stimulate, finance, and co-ordinate the development of vaccines against potentially epidemic infectious diseases for which the market potential is limited^{1,2}. This was the first global R&D funding mechanism aiming to enhance coordination of the R&D process for developing vaccines for use in outbreak situations. The ambition, however, required closer alignment between a diverse set of actors across public and private sectors, including also civil society. It so happened around 2016 that representatives from these formed a critical mass of stakeholders who were exhausted from responding to the crisis and motivated to find a new *modus operandi* for global health governance. During its interim phase, the CEPI governing board had representation of states, pharmaceutical industry, Médecins Sans Frontières (MSF) research and academic organisations as well as the WHO.

This paper reports from an empirical study of the formation of CEPI from mid-2015 to its launch in 2017. Employing a combination of analytical frameworks from political science/international relations and the governance of socio-technical systems, we sought to explain how a group of stakeholders, with diverse experience in pandemic response, vaccine R&D, and institution building for global public health crafted an initial idea in 2015 into an actual initiative in the course of only 18 months. CEPI entered a landscape of global health initiatives in 2016 at a time when product-development partnerships established in the early 2000s had gained significant experience and some had demonstrated success. These had aimed at overcoming similar deficiencies, partly driven by new ideas for changing incentive structures for developing and delivering new pharmaceutical technologies³. R&D for epidemic preparedness, however, had so far been national biosecurity projects in high-income countries for developing medical countermeasures with public financing⁴. Bringing the biosecurity agenda to a global arena, CEPI seeks to make epidemic preparedness a shared global responsibility.

From a political science and international perspective, the challenge in achieving cooperation is to steer actors towards common goals: Many global health actors aspire to the same visions, but have differing interests and perspectives as to the best path^{5,6}. This situation is characterised as a commons-dilemma, which challenges the presumption that the prospects of group benefit is sufficient for generating collective action⁷. Negotiations and compromises shape the outcomes of institutional formation, but evolve largely outside the public view. Independent observation and analysis of how actors collaborate in the pursuit of new objectives can shed light on the conditions for collective action. The established tradition of research on global environmental institutions offers theoretical and methodological guidance^{8,9} on which we drew when formulating the two key questions: How did the main actors' interests shape what was possible? What was the role of leadership in crafting sufficient alignment?

From the perspective of governing socio-technical systems, emerging technologies are a key driver of institutional change, enticing key actors to develop new sets of governing instruments. In the area of pandemic preparedness, there has been a persistent lack of tools like vaccines and therapeutics, despite a clear investment case for funding prevention¹⁰. The challenge in bringing a new vaccine from R&D to product development, clinical trials and manufacturing in a global setting, is to create a system for incentives and collaboration between academia, biotechnology firms, pharmaceutical manufacturers, government, regulatory bodies and the World Health Organisation both ahead of outbreaks, and in outbreak-settings¹¹. At the same time, however, CEPI was created a time of uncertainties in the broader vaccine innovation landscape as to what would drive innovation in the near future, with stalling pipeline growth within the large pharmaceutical companies and increased innovation potential in smaller biotech firms, yet doubts about system capacities in bringing R&D projects to fruition¹². Therefore, a new structure for collaboration would have to take into account not only R&D challenges in pandemic preparedness, but characteristics of the vaccine innovation system as a whole.

Within the vaccine innovation system, states have always been an intrinsic part. The role of the public sector has both been to incentivize and support national pharmaceutical R&D, and as a key market actor, procuring vaccines for national immunization programmes. In this way, vaccine R&D epitomizes three generic challenges of the global health system. The first to coordinate the public and private sector in developing new technologies; a second is to address disconnects between anachronistic structures and rapidly changing realities¹³; and a third is to capture lessons learned from institutional innovations of multi-stakeholder collaboration^{14,15}. In addition, the governance of change in socio-technical systems is arguably understudied¹⁶. Therefore, the CEPI case can potentially inform both practical and academic efforts.

This paper first presents the analytical framework from international relations and the governance of socio-technical system,

followed by methodological choices before turning to the unfolding of the CEPI formation process. The focus is on analysing the barriers to cooperation that stakeholders needed to overcome in order for the initiative to become reality. We conclude with reflections on lessons learned.

An analytical framework for studying global institutions

As a global public private partnership that supports the development of new technology, CEPI is a hybrid institution. Positioned outside the realm of any state, within a transnational innovation ecosystem, it is part of a recent phenomenon in international relations. The conceptual starting point of the study is the framework used by international relations scholars to study the formation of international institutions. These are defined as structures for collaboration, or assemblages of rights, rules, and decision-making procedures that give rights to social practices, assign roles to those involved, and regulate interactions among them¹⁷. Regimes, institutions that specialize in an issue area are typically intergovernmental, where the dominant regulatory approach are binding treaties. In global health, states are key actors as WHO member-states, but the past 20 years have seen the rise of initiatives where non-state actors play an instrumental role, often together with states, leading to multi-stakeholder partnerships and new institutions with formalised collaboration, like the Medicines Patent Pool or Gavi, the Vaccine Alliance.

Public-private partnerships in international relations have emerged when states alone are not willing or able to deal effectively with relevant challenges¹⁸. This is also the case in global health, where the complex interdependence of the public sector and private industry gives rise to situations that no actor can solve on their own. This is also why a significant share of partnerships in global health are about technology, whether diagnostics, medicines or vaccines. When analysing the creation of an institution like CEPI, therefore, the pragmatic combination of conceptual insights from both international relations and the governance of socio-technical systems offer the best view to understand the forces at play and optimize lessons learned.

While conceptual frameworks on institutions in international relations were originally crafted with a state-centric focus, they still provide important clues for understanding cooperation. A common combination of explanatory variables that has proved useful in studying environmental and health institutions is a focus on interests and leadership¹⁹. The *Liberal School* of thought emphasizes what actors can gain from cooperation²⁰. Liberalists hold that international institutions can serve as useful vehicles for facilitating cooperation, understood as mutual adjustments among actors. Actors are seen as motivated primarily by self-interest, but experience shows that interests may change, as part of internal adjustments. In considering independent variables that might explain the formation of CEPI, we examined actors' overall interests and motivations, as well as their positions at key junctures in the process. Thus, we could observe the extent to which interests diverged or converged, and if they were redefined along the way.

The second main independent variable, leadership, is based on a more nuanced view of agency in relation to institutional

structures, developed by what is known as the *Social Constructivist School of international relations*. As an analytical starting point, this perspective identifies four types of leaders: power-based leadership, directional leadership (or leadership by example), instrumental leadership, and intellectual leadership^{21,22}. An intellectual leader "...produces intellectual capital or generative systems of thought that shape the perspectives of those who participate in institutional bargaining"²³. The instrumental leader often uses and amplifies the ideas of the intellectual leader in getting ideas onto the political agenda. These actors seek to find means of achieving common goals and convincing others of the substantive merits of specific framing of the solution to the problem at hand²⁴. This type of leadership is often seen as a function of the actors' skills, energy and status. As we will show, the CEPI formation process involved multiple leadership roles that were linked to a broader network of expertise.

As constructivists see politics as a process of social learning, they emphasize ideas and knowledge in the making of international institutions²⁵. This perspective also leads focus towards the role of *epistemic communities*, which are expert networks that generally share values and beliefs about the causes of and solutions to the problems identified²⁶. Furthermore, these networks are typically heterogeneous, often cutting across various interest groups. In CEPI's context, a prominent epistemic community is the international network of vaccine scientists. To identify the involvement and influence of epistemic communities within CEPI was a key starting point for our study.

While the international relations perspectives go a long way to explain processes of institutional formation under conditions where there is no central authority, the kind of issues that interests and leadership revolve around in a multi-stakeholder process to solve R&D challenges are likely to be different. As international relations scholars have adapted analytical frameworks to hybrid forms of transnational governance involving both public and private actors, sets of *rules* and ways to determine them become more salient²⁷. Still, as the methods section will elaborate in further detail, data from this study suggested that interests and leadership as key independent variables clustered around four necessary conditions for CEPI's creation. Making sense of these conditions, or what stakeholders needed to agree about, led to a broadening of the analytical perspective to include emerging work on the governance of socio-technical systems. In this way, the combination of conceptual framework for the study evolved as part of an iterative process and pragmatic approach to understand a new kind of institution.

The socio-technical conceptual lens views technology and social institutions as co-evolving and suggests that a way to analyse the formation of new initiatives is through the relation between the innovation ecosystem and the process of governing a specific change within it. The pillars of that process partly overlap with that of international relations, particularly with regards to the role of agents capable of framing the need for solutions and initiating collective action. The framework also highlights *legitimacy*, defined as the change being accepted and supported, as a key factor because it will inevitably affect the interests and normative preferences of actors within the

system. Equally important, however, are *instruments*, with which actors seek to induce change by addressing specific problems or bottlenecks²⁸. This factor brings us to the heart of institutions cutting across the various social science disciplines; the rules defining the range of actions and outcomes²⁹. Ultimately, the rules and instruments that come into play in the case of CEPI is an empirical question, and reflects the characteristics of the technology in focus.

Methods

The research upon which this paper is based is exempt from requiring formal approval as per Norwegian regulations and law. Its subject matter falls under the remit of the National Committee for Research Ethics in the Social Sciences and the Humanities, its Guidelines for Research Ethics in the Social Sciences, Humanities, Law and Theology, and governed by the law on organisation of work on research ethics (LOC-2017-04-28-23). Authors obtained oral consent from interview subjects following written information about the project. Oral consent was preferred in order to avoid excess transactions of personal information over email with informants interviewed by phone, and adopted as a uniform approach for all interviewees.

As is common in qualitative studies in political science, we used a process-tracing approach. This is a technique for examining intermediary steps in political processes through diverse data sources in order to explain decisions and outcomes, the causal process between hypothesised independent variables (here: actor interests and individual leadership), and the dependent variable (the formation of CEPI). Process-tracing is often more theory-driven and deductive compared to the practice of grounded theory, yet also open to alternative explanations and inductive insights³⁰.

Semi-structured key informant interviews represent our main data source. We identified informants from membership in groups and task forces and other governing bodies of CEPI, seeking to ensure representation of key stakeholders as well as geographic diversity. The initial selection and additional snowballing resulted in a total of 32 participants¹. Twenty-four of the interviews were conducted in person in Oslo, Geneva, and London at interviewee workplaces or public spaces, the remaining by phone, all in the period between June 2017 and June 2018, lasting on average 50 minutes. All interviews were conducted by the authors, where KIS participated in all but one interview, SA in 17 interviews and BSHH in two interviews). All except two were recorded (with permission) and subsequently transcribed. Information from non-recorded interviews were transcribed as field-notes. All informants were invited to comment on the draft report, where they – as in this paper – are anonymised and referred to by a designated number.

Our analysis also draws on documents identified by informants during and after the interviews, including internal papers,

meeting reports, publicly available policy documents and the minutes from meetings of governing bodies, as well as published editorials by stakeholders³¹. This document review provided material for mapping key decisions, and informed the interview guide.

We analysed our data manually, according to themes drawing on the interests of stakeholders and leadership roles as the main hypothesised explanatory variables. Eventually, in seeking to answer the ‘how’ and ‘why’ of the formation process, the data suggested a pattern of key junctures described as ‘make-or-break’ turning points: 1) agreeing on an initial concept; 2) combining broad inclusion and rapid decision-making; 3) finding common ground on policy; and 4) developing the funding instrument. These junctures resonate with an emerging methodological tool, known as Necessary Condition Analysis (NCA). A necessary condition is defined as “...a non-trivial characteristic, event, resource or effort that is relatively unique, scarce or costly and that must be designed/controlled/managed to bring or keep it in place in order to allow a certain desired outcome to occur” (p. 36)³². An inclusion-exclusion criterium is that the condition poses a constraint, and that no other can compensate for it³³.

A key feature of NCA is that while each of the conditions had to be in place, none were in themselves sufficient for CEPI to be established. By following the logic of a Necessary Condition Analysis, the process-tracing method illuminated how interests and leadership came into play as actors worked to manage these conditions for success³⁴. Also, the conditions concretized the relation between the interest- and leadership-variables to the instruments CEPI needed to develop to govern actors’ relations to the effectuated vaccine R&D. A question in NCA is what the minimum values of the conditions are in order to make the desired outcome possible³⁵. While a full-fledged NCA is beyond the scope of the present study, a single case like CEPI, by virtue of having already succeeded in becoming a reality, can nevertheless provide a set of testable propositions of what it takes to craft changes in global health institutions.

In analysing the data, we took as our point of departure Miles’s law: “where you stand depends upon where you sit”³⁶. We expected the differing positions of various actors to be based on the types of interests they represented. Further, since actors tend to exaggerate their own influence³⁷, the *ego-alter approach* was employed³⁸: We assessed the influence of various actors based not only on their own information, but also by relying on viewpoints by other actors and then applying our judgement of the emerging picture. A challenge in tracing political processes is the extent of accurate recall by key informants, or “recall bias”. We achieved strengthened validity through a comprehensive sample that represented the interests of all main players, and through the timing of the study, which started only six months after CEPI was formally launched.

Two factors that might have affected the interpretation of the findings are the background of the research team and the sampling of interviewees. While the team were granted full academic freedom by the Wellcome Trust as funding source for the study, all members of the team are based in Norway, and

¹ Informants came from Germany, India, Japan, Norway, the WHO and GAVI; the Wellcome Trust, the Bill and Melinda Gates Foundation; Médecins Sans Frontières, the World Economic Forum, the US National Academy of Medicine the London School of Hygiene and Tropical Medicine, GlaxoSmith-Kline, Merck, Sanofi, Johnson & Johnson, and the CEPI Secretariat.

one (UG) worked for the CEPI Secretariat, July–December 2016 (though did not conduct any of the interviews). To balance the impact of any connections, the team paid particular attention to the ego-alter approach, asking other respondents to reflect on the role of Norway and the Wellcome Trust in relation to other actors. While being a potential source of bias, the relations also helped secure unprecedented access to interviewees. Against the relatively large sample of individuals of whom most had various degrees of affiliation to the CEPI process, more perspectives from external observers may have balanced any positive bias. Finally, the timing of the study also affects the outcome. This case is the first empirical study of CEPI, with key informant interviews starting only months after the cut-off date for the period being studied. This has some advantages, such as minimising recall bias, but also some drawbacks, including not being able to draw on previous studies to compare our findings. Nonetheless, as the analysis will show, no perspectives or assertions were internally disputed nor disclaimed.

The Coalition for Epidemic Preparedness Innovations

In January 2016, the founding group of CEPI stakeholders set the ambitious goal of launching the coalition within a year. The start of the longer timeline, however, will vary according to when stakeholders got involved in what became the eventual mission of CEPI. A few date it as far back as the SARS-outbreak in 2003 (2, 3), while others referred to the first meetings about R&D during the Ebola outbreak in 2015 (6, 32). The majority, however, point to a WHO-meeting in Oslo October 2015 (7, 9, 29). Within the brief timespan of 15 months to the formal launch in January 2017, the rules and structure for cooperation needed to be in place.

An important point of departure for CEPI was the context of the Ebola-outbreak, where efforts to advance R&D had been part of the outbreak response, showing that solutions were indeed possible. Of the three consortia that carried out vaccine trials in

West Africa, two were unable to determine vaccine efficacy due to a rapid decline in number of cases in Liberia and Sierra Leone³⁹. The trial in Guinea, however, succeeded. It attracted political attention, and its multi-stakeholder consortium featured as a model to learn from⁴⁰. Furthermore, in the midst of the Ebola-effort, WHO convened a broader group of stakeholders in a series of meetings on R&D during the outbreak. These talks, which became the WHO R&D Blueprint for Action to Prevent Epidemics, included not only scientists and member-states, but also industry and philanthropic foundations (17, 7, 3). The above meeting in Oslo in 2015 was originally for the financing stream of the R&D Blueprint. By becoming a venue that started the CEPI process, the Blueprint was one of the paths leading towards the new initiative (7, 3).

In taking a broader view, the R&D response during the Ebola-crisis created what can be thought of as an opportunity structure, where the possibility to test and develop vaccines in outbreak situations represented a breakthrough technological solution for being better prepared (2, 3, 29). Despite the success, the experience also highlighted a void in global coordination. The R&D Blueprint raised this issue, in addition to subsequent panels and reviews as we shall see later. Notably, at this early stage, actors who initiated CEPI were already active in advocating for change and moderating the discourse.

The CEPI timeline until the formal launch in January 2017 provides an overview of the process that will be analysed in the following sections (Figure 1). Starting by developing the initial concept, the core group of founders consulted a broader group of stakeholders through task teams before deciding on the organisational structure and continuing to negotiate policy principles until the self-imposed deadline. Throughout this period, the core group worked to secure financing from their own organisations as well as mobilising additional funders. The events represent key meetings and are not exhaustive. At best, these are indicative of the massive coordination effort that was required within the compressed timeline.

Figure 1. The Coalition for Epidemic Preparedness Innovations timeline.

The phases of the process in the figure mirror the key junctures identified as necessary conditions for CEPI's establishment. The conditions also structure the following analysis, tracing how individual agency and organisational interests influenced the conditions for success, how stakeholders found common ground, and what they managed to achieve within the one-year deadline.

Condition 1: Finding agreement on the initial concept

The initial concept presented as the starting point for CEPI at the Davos meeting in January 2016 was that the new mechanism would be an independent mechanism and focus on vaccine technology with limited market prospects. Furthermore, it combined industry participation with global public health goals. This was essentially an agreement on the scope of the new initiative, constraining the space of outcomes that will be affected by it, or what performance will be judged on⁴¹. Leading up to the meeting, the agreement was built in three steps, involving the linking of existing ideas and proposals, a convening of key actors to probe a unified approach, negotiations among key stakeholders, and finally the first endorsement of the concept.

The first step of linking ideas happened over an extended time-period starting with the emergence of collaboration among scientific networks following the SARS outbreak in 2003. The head of the Wellcome Trust, Jeremy Farrar, was part of establishing The International Severe Acute Respiratory and Emerging Infection Consortium before taking on leadership of the Wellcome Trust (3, 4). Through these engagements, Farrar had multiple tangents with ideas for new mechanisms that were evolving in mid-2015, when the scientific and global health communities were reflecting on the Ebola response. He approached Stanley Plotkin and Adel Mahmoud of the Foundation for Vaccine Research, and together they published a proposal on a new financial mechanism (3, 7, 17)⁴². In addition, the Wellcome Trust was funding partner of the US National Academy of Medicine Commission on a Global Health Risk Framework for the Future, whose recommendations also included the need to coordinate an acceleration of R&D⁴³. Whether through the recent Ebola crisis or the numerous outbreaks of infectious disease with pandemic potential since SARS, the experience was the same: The responses had been ad hoc, and there continued to be no effective therapeutics or vaccines to fight them (3, 5, 12). Furthermore, editorials by high-profile individuals^{44–46} and panels in the global health community echoed the need for a new approach^{47–49}. The challenge was to avoid multiple concepts for initiatives that might end up competing for attention and funding.

The WHO played an important role in the network of scientists and public health practitioners engaged in finding new R&D solutions. Prior to the Oslo-meeting in October 2015, the starting point of the WHO R&D Blueprint involved all technologies. In Oslo, however, the participants agreed to focus the new mechanism on vaccines. More specifically, the meeting decided to narrow focus to vaccines with limited market prospects⁵⁰. Moreover, the role of the independent mechanism would be to fund and coordinate innovation in the pre-clinical to phase II

trials, leveraging funding from multiple sources (7, 27). The transition from a WHO process to operational independence and from medical R&D more broadly to vaccines was a quick and unanimous resolve. While WHO would continue as a central actor for scientific oversight, individuals from the Wellcome Trust, World Economic Forum (WEF), the Gates Foundation, the Norwegian Institute of Public Health (NIPH), and the Norwegian Ministry of Foreign Affairs (MFA) formed a Core Group that further developed the concept to be presented at the closed high-level meeting in Davos, January 2016.

A network of individual leaders partly rooted in R&D response during the Ebola outbreak, and partly in the experience of establishing global health initiatives in the early 2000s were important in the early shaping of the direction of the initiative. On the one hand, CEPI was an extension of the successful Guinea vaccine trial. The steering group for this trial was led by John-Arne Røttingen from the Norwegian Institute of Public Health, under the WHO umbrella headed by Marie Paule Kieny, the WHO Assistant Director-General for Health Systems and Innovation. Røttingen, who would eventually head the CEPI Secretariat during the first phase, and Kieny, who remained the primary WHO contact to CEPI in the same period, were on close terms. In addition to Jeremy Farrar, Tore Godal from the Norwegian Ministry of Foreign Affairs was a lead figure in the background, first as part of the Guinea trials, subsequently in the initiation of the WHO Blueprint and next as CEPI founders. Both had backgrounds as clinicians working to transform their respective fields: R&D during epidemics, and access to global vaccine innovations. In Norway, Godal had direct access to the political leadership, who gave the first financial pledge to CEPI as early as the autumn of 2015 (6, 7). The early instrumental leadership in bringing stakeholders and ideas together as a network with complementary strengths all served as starting point for negotiating a broad spectrum of interests and positions.

Once the basic scope had been set in Oslo, members of the core group had three months to find common ground on the principles of a model that combined public health and industry perspectives. WEF drafted the first concept note for the core group, reflecting its position as a member-based organisation for private companies and wish to involve industry leadership as much as possible in the process (37). As representatives of the Norwegian state, Godal's interest was to take a lead role in the creation of CEPI, capitalizing on Norway's track record as a global health funder and entrepreneur of initiatives like the GAVI Alliance. The NIPH shared that view, but its main role concerned bringing scientific expertise to bear on the process, with an interest in strengthening the innovation eco-system in Norway (7b). Between the industry and public health interests were the two large private philanthropic organisations; The Wellcome Trust and Gates Foundation. The first is the world's second-largest non-governmental funder of biomedical research, well-known as a key player in science policy debates⁵¹. Its interest was to be a neutral broker, building on a long-term view of advancing R&D in the context of epidemics. Finally, the Gates Foundation was initially the most peripheral of the five Core

Group members. Although it was engaged in the Ebola outbreak response in 2015, its main interest lay in fighting infectious disease more broadly, setting precedents by funding and shaping innovative hybrid organisations like GAVI and disease-specific product development partnerships (12). The Foundation held that, if CEPI could close technological gaps and solve regulatory bottlenecks, there would be positive spill-over effects on vaccine innovation in general (29). In this way, while the Core Group members had different starting points, these mirrored the wider group of stakeholders who would engage during the next phase of the formation process

By the time the Core Group presented the concept note at the high-level meeting in Davos January 2016, they had reached further agreement on key stakeholders and operational principles. Starting with a model where industry was at the centre and the WHO was main public stakeholder, the concept presented to the high-level meeting included also governments and civil society. Still, the concept was open as to what kind of entity the mechanism would be, leaving the institutional design pending⁵². What was clear, however, was that it would be a multisectoral partnership based on an innovative approach (ibid). The meeting agreed to aim for a launch of the partnership at the next Davos meeting. In the meantime, there would be a small interim secretariat overseeing a Working Group with representative from all sectors and areas of expertise to develop further options for the mechanism, to be presented in the form of a business plan (ibid). At this point, therefore, the multiple ideas for a new mechanism had merged to become one process, but with principles still broad enough for all participants to envision what they considered an optimal partnership (4, 7, 37).

The significance of the first condition, as the initial hurdle to cooperation, was to get the necessary buy-in for the plan from key stakeholders in order to proceed. The process leading up to the Davos meeting depended on a core group of diverse actors. Their differences in perspectives and positions was coupled with complementary capacities, adding weight to the signals they gave of being willing to convene for, fund, and support a mechanism, should it materialize (3, 5, 37). Furthermore, the Davos meeting itself was important, not only for the agreement it produced to move forward, but also for evoking an ethos, rising from the shared trauma of the Ebola outbreak. This was a chance for a new and different solution. The chairperson of the meeting, Peter Piot, filled an intellectual leadership role in this regard. Piot was among the pioneers in the scientific and clinical responses to Ebola outbreaks in the 1976, and political entrepreneur in the global health community as the first head of UNAIDS. Now, as head of the London School of Hygiene and Tropical Medicine (LSHTM) and having chaired an independent Ebola review panel, many saw him as independent since LSHTM did not have a formal role or interest in relation to the CEPI formation process (2, 5). As these factors came together, industry, states, civil society and the R&D community all had a strong interest in continuing to be part of the discussions (5, 37).

Condition 2: Balance between broad inclusion and rapid decision-making

The second condition to be managed was the transition process from initial concept to an institutional framework. This happened over the course of six months, following the first Davos meeting. Here, the Core Group had been granted the authority to steer the process forward. This would entail making decisions about the structure for cooperation as well as the instruments CEPI would use to make changes to the system⁵³. At the same time, however, there was a growing group of stakeholders representing the vaccine innovation system in which the new initiative would be embedded, ready to continue the discussion about what CEPI would be. By initiating a change in how the R&D of a technology is governed globally, there was no central authority or constituency in the traditional sense. Instead, CEPI depended on stakeholders' readiness to contribute to the process and wield authority over decision-making in a way that stakeholders would support, in other words, the process needed to be seen as legitimate by the stakeholders within the system.

The timeframe for which this condition needed to be managed was about six months, until the transition of CEPI into a formal entity started in June 2016. In this period, the four main topics for consultations were the prioritization of pathogens, manufacturing and legal/regulatory issues, organisational models and funding. The Core Group organized consultations as parallel Task Teams with a total of approximately 60 members, coordinated by a small group of staff from the Wellcome Trust, NIPH, WEF and the Gates Foundation, of whom NIPH was formally the interim secretariat (4, 7). This group also coordinated a growing engagement in steering the process, whereby co-chairs of the Task Teams joined the Core Group in what was known as the Leadership Group (4, 7). This administrative capacity was a key factor in managing the inputs of the consultations, following up by marshalling the range of different processes that followed, e.g. resource mobilization, designing governance structures and drafting guiding policies, drawing from the strengths of their home institutions.

Members of the Task Teams came from both global health and vaccine-development community, representing scientific and academic organisations, in addition to the WHO, multinational pharmaceutical companies and the civil society organisation MSF. Through the consultations, emerging positions revealed a concern with the balance between R&D, industry and public health perspectives. European stakeholders were attentive to CEPI becoming more than a biosecurity organisation, to encompass global public-health goals that might be owned by a coalition broader than trans-Atlantic high-income countries (7, 17). At the same time, it was important to include the vaccine innovation and medical countermeasures expertise, particularly that of US-based institutions (8, 12, 35). Two sets of instruments that galvanized in this phase as the most important were how the pharmaceutical industry would be engaged, and secondly, CEPI's role in setting normative scientific standards, including its division of labour with WHO (11, 15, 18).

A key change in the system that CEPI was aiming for was to target a selection of pathogens with financial incentives in order to strengthen the R&D process. This instrument was primarily concerned with rules for scientific prioritization. The group involved in this aspect of the Task Team deliberations was heterogeneous, with scientific expertise from vaccine innovation, R&D in the context of national biosecurity efforts as well as some with a broader background in public health. The majority were US-based, but included also research and academic organisations in Australia, Brazil, India, Japan, South Africa, and the UK. One perspective within the group was the principle that science should not be politicised, and that the governance of CEPI should be based on the science of vaccine development—understanding the need for long timelines, and the complex interplay of innovating organisations like biotech and multinational pharmaceutical companies (11, 31, 42). Scientists who represented states, on the other hand, often had a broader perspective of the coalition as pursuing a global public health mission (9, 36). Representatives from organisations familiar with balancing the two concerns, for instance from the GAVI Alliance, the International AIDS Vaccine Initiative and the US Biomedical Advanced Research and Development Authority, argued for emphasizing technical expertise and taking a broad view of the evolving R&D ecosystem (8, 31, 41, 35). The interest of the WHO was to preserve its authority in the role of norm setting, and to avoid overlap with CEPI on setting scientific priorities and coordinating with regulators (7, 17, 18). The WHO R&D Blueprint was evolving parallel with the CEPI formation process, and the WHO saw itself as the key institution and most politically neutral arena to guide CEPI (6, 7, 17, 18). Many actors agreed with this normative mandate and saw CEPI as depending on it. Some – and particularly US actors – felt that the WHO lacked authority and capacity in certain areas of the R&D landscape, and that CEPI potential was to step in when needed (11, 31, 35).

New instruments for engaging multinational pharmaceutical companies were premised on an early intent to find a new *modus operandi*. This, however, meant different things to different actors. In the Task Teams, industry was represented by the six key multinational companies in vaccine innovation, GlaxoSmith-Kline (GSK), Merck, Johnson & Johnson (J&J), Sanofi, Pfizer and Takeda. They agreed on the need for a more robust system, as they shared the experience of shouldering heavy costs when called upon in outbreak situations (14, 32, 42). At the same time, industry interests varied according to how they saw the potential of CEPI in relation to their business model. For the majority, this involved preserving existing practices, such as maintaining control of intellectual property (IP) and autonomy to set prices (14, 16, 32). GSK, however, had experimented with more tailored frameworks for specific issues, often part as multi-stakeholder approaches in global health, like the Medicines Patent Pool, and believed that innovation of policy frameworks for specific segments of the health care market would be the future (32). Early in the process, MSF aligned with GSK on this issue. The background for MSF involvement was its activity during the Ebola crisis, treating one-third of the reported cases in West

Africa, and taking on an advocacy role to mobilise a concerted global response⁵⁴. Its interest in CEPI was based on the conviction that vaccines were needed, but also that this would require a different model for vaccine development than practised by industry and the public sector thus far (5). This perspective had roots in MSF's long-standing role as advocate for access to medicines and one of the founders of the Drugs for Neglected Diseases Initiative.

The open-ended consultations through parallel task teams ran their course up to key junctures of decision making on organisational structure in May, June and August. At that point, the range of perspectives among stakeholders was becoming more explicit (4, 6). Although this was a departure from the collective moment of the Davos 2016 meeting, the mapping and conversations had kept the concept open, and a community of stakeholders felt ownership to the initiative. In June the Leadership Group formed an interim Board of Directors and made decisions about formalising governance. This was another critical stage in the formation process, because the decision appeared opaque for those outside the inner circle who still felt that the instruments needed to be worked out (14, 31). A key design feature that resolved this tension was the decision to designate the next 18 months, until the end of 2017, as an interim phase. This allowed decisions to be made quickly without being set in stone, leaving instruments to be further negotiated during the second half of the year (9, 11, 12).

When CEPI was established formally in August as a non-profit international association, the Core Group and the government of India formed a founding group of five. Leadership roles within the network can shed further light on the transition from consultations to decision-making. On the one hand, there were efforts of strategic positioning. As early as February, the NIPH offered to dedicate full-time staff to an interim secretariat (6, 7). In June, Godal followed the same approach as he proposed Røttingen as interim CEO. This was controversial among some because he was known to favour a strong public-sector role in R&D, yet also considered a neutral stakeholder without strong industry ties (3, 4, 7). At the same time, Godal was an instrumental leader precisely because of his sense of timing: He was a driving force in setting up the tight timeline, but also for when to transition from the task-team process to deciding on the structure (4, 7, 12). Yet, Godal was firmly positioned in the public health realm, and the process also depended on someone who could credibly stage the negotiation space between the public and private sectors (31, 32). That person was Jeremy Farrar, who, as an intellectual leader, had summary capabilities within the larger group, supported also by the roles played by other individuals with science backgrounds in the Leadership group, such as Peter Piot or Victor Dzau (4, 31, 37). The representatives from the Wellcome Trust and the Gates Foundation understood the dynamics of the innovation landscape, but also instilled trust that CEPI would be able to navigate in it, which differed from the leadership roles of Norway or the WEF. In this way, the weight and comparative advantages of the

Core Group was also part of making the decision-making acceptable to the broader group, even if it contrasted with the otherwise inclusive process.

The formal institutional structures could accommodate fewer stakeholders than those who had initially engaged in the broader consultation. In order to include the types of actors that were not otherwise involved through the governing and scientific bodies, the CEPI Secretariat initiated what became known as the Joint Coordinating Group (4). This was part of an ambition that CEPI would align efforts of a broader range of actors involved in vaccine development and procurement. In the period leading up to the 2017 launch, it was the largest of the CEPI bodies, counting 53 individuals at its first meeting in November 2016⁵⁵. At the time of the launch in 2017, the purpose and functioning of the group was not yet clearly defined, and it was also unsettled what the appropriate head of such an umbrella would be in the international setting (11). Nevertheless, it signalled an openness and outlet for taking forward topics that had emerged in the consultations, but not yet found a place as part of the nascent instruments (4, 7).

Condition 3: Addressing contestation of instruments (Finding common ground on policy)

The third condition presented itself in the autumn of 2016 when key stakeholders diverged in their positions on the instrument regulating what stakes CEPI and its funders should have in the vaccines that would eventually be developed. In the first draft for consultations, written by the interim secretariat, the most difficult issues were the extent to which CEPI investments should influence the final price of the vaccine, the kind of ownership CEPI should have in the IP generated through its investments, in addition to the geographic scope of equitable access provisions. The institutional bargaining leading to CEPI depended on a consensual approach, and a failure to land it before the formal launch in January 2017 would risk participation of two key stakeholders: industry and civil society.

This situation differed from the instruments being negotiated over scientific prioritization. On that issue, the most challenging aspect was to clarify the role of CEPI in relation to the prioritization by the WHO R&D Blueprint, and thus the boundaries of the WHO norm-setting function. This relation between norms in the broader system and CEPI instruments was settled at the leadership level with a Memorandum of Understanding (7, 17, 18). Within CEPI, members from the scientific community that had engaged in the Task Team process transitioned fast into a Scientific Advisory Committee that advised the CEPI leadership and Board during the interim phase (7, 11). The committee formalised participation and decision making, with industry and WHO as observers, ensuring that the instrument applied principles for securing the legitimacy of the scientific process (11).

The issue of IP ownership, access and prices, however, was an area in which MSF saw an opportunity for CEPI to break with the past. As the only organisation on the Interim Board involved in delivering community health services, MSF took

up the role of maximising public interest. Here, MSF held that, when public institutions pay industry to make a product, there should be a public return on the investment. Thus, when all costs of R&D are paid for by CEPI, the products should be in the public domain⁵⁶. As part of that scenario, CEPI would own all foreground IP, commit industry to ensure vaccines at the lowest possible price, and include all populations in low- and middle-income countries for equitable access, not just 'priority populations'. From the MSF perspective, CEPI represented a new way of thinking, and in the bargaining, all sides would need to give in order to agree on the necessary tools (5).

For the pharmaceutical industry, a key question was the extent to which the precedents to be set by CEPI would inevitably extend beyond CEPI's scope. The fear among the majority was that concessions given to CEPI-funded vaccines would spill over into markets where the same products would be commercially viable. Therefore, a key position was to retain the ability to set prices and make a return on investment, with all IP rights intact (14, 16). For a minority, however, a tailored approach for CEPI-vaccines was an acceptable option. This difference in perspectives depended on the individual company's experience with other forms of public-private partnerships in global health, or in other words; its positioning within the broader global health system.

The institutional bargaining carried on until the formal launch in February 2017, with the Interim Secretariat playing an active role and with its own ambitions. Its interest was to advance the principle of investment in R&D as a global public good⁵⁷. This perspective was a mind-shift from the traditional government subsidiser on a national scale, whose goal is also to advance industrial competitiveness and therefore with no claims to the final product. CEPI, as a global coalition, would not only pool public and philanthropic funds, but also be accountable to its funders that the eventual vaccines would be widely accessible according to need. Seeing these issues as permeating product-development partnerships in global health, the Secretariat viewed CEPI as an opportunity to codify best practice, where funders are in dialogue with awardees about sharing of research data, stakes in clinical trials, affordable pricing and volume guarantees, depending on the stage of development and size of funding (7, 12). Some funders, such as the Gates Foundation, already practise such principles, but they have been part of confidential contract negotiations. CEPI's ambition lay in building on these precedents and bringing the same principles to the public realm (7b).

The perceived extent of change to be brought by CEPI to the system evolved during the bargaining period; from broad ideas to the specific limits of compromise. In the beginning of 2016, MSF, the WHO and selected companies like GSK all supported the open principle of 'no profit, no loss'. This concept acknowledged concerns by industry that their opportunity costs during outbreaks were unsustainable, and that there was a real and justified risk of not being able to count on them in the future. At the same time, however, there was little appetite for tailored approaches by individual companies, such as

a proposal by GSK to dedicate a facility to CEPI for developing vaccines on a cost-coverage basis (15, 32). Instead, companies proceeded to negotiate as a group, and – by the time CEPI had started to formalise its governance structure in June 2016 – would respond collectively to a renewed concept of ‘shared risks, shared benefits’. As soon as the content of this phrase was specified in the autumn of 2016, however, both industry and MSF reacted. In the end, one of the most difficult points of negotiation was how to minimise the risk of public and philanthropic investments going to waste in the case that industry, for scientific, portfolio change or business reasons, proved unable or unwilling to move forward with vaccine development. The Secretariat proposed that CEPI would have “step-in” rights, involving non-exclusive licensing to the foreground IP as well as background IP (7, 14, 16, 42)⁵⁸. Industry actors, however, were in unison about retaining ownership to the background IP, regardless of the fate of CEPI-funded products. This is the know-how that companies bring into vaccine development, known as vaccine platforms, which are firm-specific and take years to develop with significant own investments in addition to other sources of public financing. It thus represents a key company asset (7, 14, 15, 42). The nature of CEPI as a global coalition with an anticipated but uncertain rise in number of public funders made this point particularly contentious. Key uncertainties loomed: Who would be making the decisions within CEPI, and to whom could it further license the rights? (42).

By the time of the formal launch in January 2017, negotiations landed on a consensus whereby details of ownership and control of IP should be left to project-specific contracts for a one-year trial period. This was a position that industry representatives laboured to align on internally yet reached acceptance for in the working group designated by the Interim Board to work on the issue (5, 14, 15, 16). It provided direction for contracts and CEPI default positions but left specific obligations to negotiations with awardees⁵⁹. MSF was the only voice for its position on the interim board, despite its experience of tacit support by some (4, 5, 7). While industry resisted the prescriptive nature of the access policy, MSF had hoped for a stronger sense of public ownership. A revision of the policy at the end of the interim phase was thus on the cards.

The working group responsible for negotiating this instrument demonstrated the interplay of founding members and leaders representing them. While Farrar of the Wellcome Trust headed the group, the Interim CEO Røttingen and Kieny from the WHO saw themselves as brokers of the negotiations between the industry group and MSF (7, 15). Røttingen knew both Farrar and Kieny from his time as chair of the multi-stakeholder process the Consultative Expert Working Group on Research and Development: Finance and Coordination, which aimed for the establishment of an international R&D Convention⁶⁰. Røttingen also knew MSF well from that process and was in a position to argue for a middle ground (7, 7b). Legal expertise from the Gates Foundation and the Wellcome Trust advised on proposals, strengthening procedural legitimacy as founding members with experience in contracts with R&D entities. The roles played by Paul Stoffels from J&J, Andrew Witty and

Moncef Slaoui from GSK, as well as Joanne Liu of MSF, showed how individuals in high-level positions within their organisations shared the challenge of reaching an agreement within the group that did not run counter to core principles of their respective home organisations (4, 5, 32, 42). Thus, while the brokers could draw on the resources of their respective organisations, the involved parties were working to avoid compromising material benefits and value systems of these home organisations. Still, however, all shared an engagement in CEPI from leadership positions, and an affiliation with global vaccine R&D that ran across institutional divides.

Condition 4: Developing the funding instrument

Throughout the year between the Davos meetings, the Core Group worked to develop the funding instrument, primarily by recruiting additional governments as investors. Plans stipulated in the Davos 2016 concept note envisioned a model of combining state and private funding in a “comprehensive financing facility”. In addition to the traditional public sector funder and global foundations making up the core group, they also saw a potential for contributions from non-pharma industry, striving towards further developing the innovative financing concept in global health as part of a public goods-approach (6,7)⁶¹. While the Norwegian government, the Wellcome Trust, and the Gates Foundation gave early indications of funding, a priority from the Leadership Group and later the Interim Board was to mobilise governments from low- and middle-income countries together with the more traditional health aid donors (2, 3, 4, 7). This was a critical barrier not only because CEPI, as a financing mechanism, needed to generate the funding base with which to incentivize vaccine R&D, but also because the aim of becoming a broad global coalition with state engagement beyond the traditional OECD-donor countries.

In the effort to bring funders on board, governments were approached directly, and CEPI was promoted in key international fora. The Core Group invited representatives from the EU, France, Germany, India and the UK to the Davos meeting in 2016. They also targeted established events that year, including the WHO Health Assembly (WHA69) and the 59th Munich Security Conference, as well as the G7 meeting in Japan and the G20 meeting in China (6, 37). The Wellcome Trust’s communications team supported this effort by authoring and timing presentations of CEPI in the mainstream media (39)⁶². Of the countries courted by the core group, several remained engaged, but only Japan and Germany had joined Norway as funding governments by the time of the launch in 2017.

Although there is a convergence of interests among Japan, Germany, and Norway, each process for getting on board shows that CEPI appealed to multiple rationales for engagement, combining biosecurity, innovation, and global public health. Germany’s interest was to serve as an intermediary in the multi-stakeholder coalition, understanding and helping to integrate the positions of industry, science and civil society, with funding and representation through the Ministry of Education and Research (30). From participation in the Ebola response to the G7 Presidency in 2015 and its G20 Presidency in 2017, the

German perspective on global health was evolving from a focus on development cooperation towards health interconnectedness—a broader approach that also encompasses bio-preparedness. This built on Germany's preference for working through the multilateral system (30)⁶³. Japan came on board through its G7 Presidency in 2016. Its interests were grounded in its history of support to the WHO with global health as one of the pillars of its diplomacy, its role in establishing the Global Fund to fight TB, AIDS and Malaria, as donor to the GAVI–Alliance, as well as an engagement in Health Security (36, 7)⁶⁴. In CEPI, Japanese officials saw the opportunity to become involved in shaping a new partnership from the start, also drawing on domestic experience from running successful public–private partnerships, having its own scientists, regulatory authorities and pharmaceutical industry also play a part in global collaboration. Support came through the Ministry of Health (36).

In mobilising Germany and Japan, the Core Group utilised the networks of its members, and capitalised on health security still being high on the global political agenda. For Germany, the Ebola response had led to separate channels of direct relations between the Gates Foundation and between the Norwegian political leadership and Angela Merkel. Tore Godal was engaged in the German–Norwegian co-funding of the UN Ebola High-level Review Panel. For Japan, the network of the WEF and Peter Piot was important. Representatives from Japan and Germany joined the Interim Board in the autumn of 2016, with confirmed funding commitments by the time of the formal launch in 2017⁶⁵.

In addition to funding governments, other states engaged as strategic partners. First came India, which the Wellcome Trust and Norwegian stakeholders had involved since the Blueprint consultation meeting in Oslo in 2015. The original aim was for India to join as the first funding partner from the South, and as its first instance of funding a global health initiative. The Indian government wished to advance the potential of the country's pharmaceutical industry – with the potential of linking Indian large-scale vaccine manufacturing capacity with innovative technologies, thereby contributing to global access (11, 25). The head of the Department for Biotechnology (under the Ministry of Science and Technology) became chair of the interim Board; India also provided the deputy chair of the Scientific Advisory Group, Cherry Gagandeep Kang. Other governments that joined the Interim Board as strategic partners in this period included Australia, Ethiopia, Liberia, South Africa, the UK, and the USA⁶⁶.

Among the public donors that engaged with CEPI in the formation period, the tilted interest towards strategic partnership rather than funding roles had complex reasons. The large traditional donors – the EU, UK and the USA – already had domestic biosecurity initiatives. In the UK, there was government support for CEPI, but Whitehall also sought to re-establish its own national strategic capability on vaccines R&D and manufacturing (32). The US government has its own institutions for medical countermeasures, who – despite their national mandate – had built experience of value to CEPI. Still, initial support for CEPI

was through scientific contributions and strategic advice (35). Of the three, the European Commission committed most tangibly by planning to co-fund activities through its own initiatives, like the Innovative Medicines Initiative⁶⁷. With regards to the non-traditional donor countries, including emerging economies, initial strategic partnership roles rather than funding roles was a way by which CEPI sought to make first steps towards higher involvement of non-OECD donors (6, 25, 17). An incremental expansion of partners and eventually donors would solidify CEPI as truly global, compared to the development aid paradigm on which other global health product development partnerships had relied⁶⁸. Another reason was that for CEPI's own extensive efforts, there was a recognition that the combination of timing and network had to be right, working out on some domestic political arenas, but not on others (37).

The actual pledges by the first five donors were confirmed late in the year 2016. Their total funding commitment totalled USD 540 million over the period from 2017 to 2021, consisting of USD 125 million from the government of Japan, USD 110 million from Germany, USD 200 million from Norway and 100 million each from the Gates Foundation and Wellcome⁶⁹. At the time of its launch in 2017, CEPI therefore was short of its initial USD 1 billion target and had relied on established health aid donors. Still, it had the necessary funding base on which to move forward (3, 6, 25).

Concluding discussion

As the CEPI formation shows, ideas do not spontaneously evolve and alter decision-making by virtue of a shared understanding of their significance or vision of what can be achieved. Even as actors shared the trauma of the Ebola outbreak, agreed on the need for R&D funding and the urgency of a new solution, the change, or the commons – in this instance CEPI – was achieved through a political process where stakeholders worked hard to find agreement on rules and instruments, leaving some options behind. This provides insight for future global collaboration to develop vaccines and other technologies against pandemic infectious disease, in addition to broader lessons of the global health innovation ecosystem.

The four conditions demonstrate the magnitude of the effort that was confined to a period of 15 months. The first condition, gaining wider support for the initial concept, clarified leadership and brought together the various strands of ideas in a crowded landscape, leapfrogging what could easily have become contested issues. The second condition, combining consultations with crafting the institutional design, involved a balancing act of testing and corroborating the extent of change that CEPI would bring to the system, while setting in motion the institutional structure and instruments for making such a shift. The third condition, addressing the contestation of instruments, suggests that the most challenging issues require a formalised setting that an institutional framework offers in order to reach consensus. Finally, the fourth condition of developing the funding instrument points towards the challenges when pushing the frontiers of global health financing. Since CEPI was indeed successfully launched in Davos January 2017, the level at which CEPI managed these conditions met the threshold for becoming operational.

Explaining the CEPI formation

The focus on interests, as one of the main explanatory variables, led to the identification of the above necessary conditions. As we have seen, these were considered junctures, where the direction was staked out through institutional bargaining. In all four, there is a difference in positions on what collective action for technology development entails. Throughout the conditions, this aspect finds various expressions, such as private versus public ownership; scientific versus generalist knowledge; IP versus access; or material benefits versus normative preferences. This is not to suggest a dichotomy, nor a split among actor groups. On the other hand, the CEPI formation reveals the complexity and dynamics of interest configurations, where several of the actors, such as governments and foundations, harbour versions of both. In this setting, the epistemic community – or scientific expertise – was a key group that enhanced problem-solving capabilities. The fact that many had served across these types of organisations was a factor that strengthened a common ground among actor-specific interests.

With regards to leadership and agency, CEPI benefited from the heterogeneity of perspectives within the core group. These individuals also had leadership positions within their home organisations, from which they could access three kinds of resources: funding, convening power as well as operational staff. Together, they formed a network of complementary strengths. As part of the Leadership group that formed after the Davos meeting in 2016, individuals who were institutionally independent, i.e. whose home organisation was not a member or funder of CEPI, played key parts as intellectual leaders, whose moral authority helped draw towards consensus.

The study finds three sets of policy instruments that actors engaged in developing. The first, prioritizing pathogens, concerned the extent to which CEPI should follow existing norms of standard setting by the WHO or use additional criteria. The second, governing IP prices and access, was as a point of contention one of the necessary conditions. The third instrument, the pooling of funding, is a necessary condition in itself, and because of CEPI's mission, arguably the most important of the instruments. The funding instrument affects the others in two ways; first, financially, by determining the extent of R&D endeavours CEPI can support, as well the stake CEPI can claim as share of industry's total investments in a given vaccine; second, politically, as investors ask for influence in how CEPI is governed. This is particularly the case with public funders, who are accountable to taxpayers. These instruments and concomitant dilemmas build on the experiences of nearly two decades of product development partnerships in global health⁷⁰. As precedents and extended processes of collective learning, these may have contributed to the speed with which CEPI was formed.

The concept of legitimacy is inextricably linked to leadership and participation in the process of developing the above instruments. Up until mid-2016, the credibility and operational capacity of the leadership and staff of the Core Group, many of whom became the Interim Secretariat, was an important factor. However, when the leadership group started formalizing the

institutional structure in June 2016, there was a critical moment of procedural opacity. The rapid transformation into the Interim Board, Scientific Advisory Group and Joint Coordinating Committee led to a more transparent structure and enhanced procedural legitimacy during the institutional bargaining that lasted until the official launch in January 2017. In this way, there was a sufficient degree of internal support throughout the formation phase, but the source of legitimacy changed along the way. In terms of external legitimacy, CEPI was at an initial disadvantage because it had fewer public funders on board than planned for, particularly from emerging economies. At the same time, however, the link to the WHO and network of strategic partners compensated to a large extent, affirming CEPI's position within the nexus it had created; between global public health, vaccine innovation and pandemic response.

A feature of the process was that actors engaged selectively, according to where they had the strongest interests. The instrument on prioritization engaged scientific expertise; the funding instrument government and philanthropic actors, and the instrument governing IP, prices and access, industry and civil society. The reason for this may have been the compressed timeline, made possible by the groundwork of Core Group staff/Interim Secretariat, as well as the leadership-roles performed by Core Group members. The pressure and flexibility granted by the interim structure, combined with clear leadership, made it possible to conclude, broadening the range of what stakeholders were willing to accept in order to stay on board. At the same time, however, it may also have contributed to a more segmented processes with less than optimal representation by actor groups on the various arenas. A consequence was that key parts of the institutional design were still in the making by January 2017.

In the end, the CEPI experience can be summarized as four indicators for managing necessary conditions, which translate into broader lessons for solving commons-dilemmas:

- Leadership roles represent the full spectrum of interests and expertise to be involved in the change.
- Credibility and operational effectiveness of leadership prevail as main source of legitimacy in early phases, prior to transparent and representative institutional structures.
- Managed trade-offs between interest representation, time and interim structures in the institutional bargaining over instruments.
- Funding initiated among like-minded investors, capitalizing on ambitions for strategic influence in the process.

Epilogue

Beyond the launch of CEPI in January 2017 — and the scope of this study — a significant amount of work remained in order for CEPI to become fully operational. Since then, CEPI reached a number of milestones: it issued the first calls for proposals on the same day as its launch, setting in motion its core activity. Another important area of progress was an increase in the number of funding governments, as the initial three were joined by Australia, Belgium, Canada and Ethiopia by February 2020.

A further important step beyond the interim phase was a revision of the equitable access-policy, finalized in December 2018. This was in response to concerns among stakeholders, primarily major vaccine manufacturers. They saw key challenges with the interim policy being the limited scope for negotiations as part of individual contracts, misalignment of principles with a competitive business model, and the perception that the policy permitted CEPI to set product prices unilaterally, forming precedents⁷¹. From CEPI's perspective, the subsequent revision did not represent a change in CEPI's access commitments, but rather an attempt to provide greater flexibility in operationalizing them and allowing for cooperation with the widest possible range of development partners⁷². Yet, tensions observed in the interaction between MSF, CEPI and vaccine manufacturers during the interim phase manifested themselves again in MSF's response to the revision, which argued that the resulting policy was a step backwards from CEPI's earlier commitments⁷³. The ensuing public dialogue brought to the fore issues that would soon become pertinent in responding to COVID-19: Are access principles more effective when guiding individual contracts with partners than a proscriptive 'rule-based approach' in terms of keeping on board a diverse range of partners that are needed to advance vaccine development and access?; What kind of mechanisms, for instance for transparency and accountability, should such principles embody?⁷⁴

The COVID-19 pandemic brought CEPI to the forefront of the global coordinated response. Starting with a funding call for the development of vaccines in February 2020, CEPI established a portfolio of nine candidate vaccines within three months⁷⁵. Thus, CEPI demonstrated its position as one of the key actors in a global coordinated response⁷⁶. Time will show how the labour that went into the foundational partnership, and documented here, also prepared the ground for broader institutional collaboration and fair global access in the face of a major pandemic. In the end, the paramount lesson of CEPI may be that in order to create new and different solutions for humanity, you need the combination of slow incremental change, creating a foundation and intellectual underpinning from where fast-paced institutional construction work is possible.

Data availability

Underlying data

The data consists of 32 key informant interviews yielding 350 pages of transcription. These are stored in the archives of the Fridtjof Nansen Institute for a minimum of 10 years, in accordance with Norwegian law and the ethical guidelines for the study. The informed consent by the informants was premised on that recordings and transcripts were for the use of the project team only and therefore, these cannot be made

publicly available, even in an anonymised form. In addition, the content - describing organisational interests and positions and how individuals navigated the political aspects of the formation process in a field with relatively few actors - is of such a nature that the transcripts cannot be meaningfully anonymised. If researchers wish to access these notes for the purposes of further research, they may contact the corresponding study author, Dr. Kristin I. Sandberg, by email (kis@fni.no), providing details of the information required and the intended use of the data. Depending on approval by the National Committee for Research Ethics in the Social Sciences and the Humanities (Norway), Dr. Sandberg will then contact the interview participants in question to seek their permission to share the interview transcripts for the purpose specified.

Intermediary data are available on the Norwegian Centre for Research Data. The DOI directs to a Norwegian language overview of the project. Access to the English language overview and intermediary data documents is via the 'Dokumentasjon' button or [this link](#).

Norwegian Centre for Research Data: The establishment of the Coalition for Epidemic Preparedness Innovations (CEPI): Interests and leadership, 2018. <http://doi.org/10.18712/NSD-NSD2885-V1>⁷⁷.

This project contains the following underlying data:

- CEPI study Analytical Themes (PDF, emergent themes in relation to variables)
- CEPI study Informant typology (PDF, informants categorised by type of organisation and geographic location)

Extended data

Norwegian Centre for Research Data: The establishment of the Coalition for Epidemic Preparedness Innovations (CEPI): Interests and leadership, 2018. <http://doi.org/10.18712/NSD-NSD2885-V1>⁷⁷.

This project contains the following extended data:

- CEPI study Interview guide (PDF, key areas of inquiry)
- CEPI study Variable description (PDF, variables as categorised prior to data collection)

Data are available under the terms of the [Creative Commons Attribution 4.0 International license](#) (CC-BY 4.0).

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Open Peer Review

Current Peer Review Status: ? ✖

Version 1

Reviewer Report 09 August 2021

<https://doi.org/10.21956/wellcomeopenres.17892.r42776>

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Remco van de Pas

Institute of Tropical Medicine, Antwerp, Antwerp, Belgium

Thanks for having me review "The formation of the Coalition for Epidemic Preparedness Innovations (CEPI): An empirical study". Excuse me for the delay in doing so.

The study traces the initiation, development and eventual establishment of CEPI, by conducting actor interviews, tracing policy documents and being informed by political science/ international relations theory, notably liberal school of thoughts, social constructivism (albeit this is hardly touched upon, applied) and the role of epistemic communities. Further more there is reference to notions of rules, legitimacy and how to overcome the commons problem.

(Elaborated) methodology and results then, based on concept above, are rather descriptive in arriving at 4 emerging themes (conditions). Discussion then reflects on the 4 conditions that made CEPI being established (The magnitude of the effort).

I have four major reasons difficulty to see the paper indexed in its current form.

1. While its possible to analyze via one IR theoretic school to analyze the establishment of a Global health partnerships, at the minimum one can expect a discussion noting some considerations from *other* IR schools. For instance, a political-economy analysis, or the Copenhagen critical security school would come to rather different conclusions about CEPI's agency, polity and legitimacy also in relation to diverse and existing critical appraisals of Global health initiatives and actors interests, Drivers and the values pursued. None of these are being addressed in the discussion. Rather, it remains rather limited to the partnership and its establishment itself, without considering context, international political and global health landscape (austerity, growing role of philanthropy, securitization trend etc). The rise of CEPI should also be discussed within this wider trend.
2. The authors take notion of epistemic communities. While they *describe* CEPI as an epistemic community, it is not analyzed as an epistemic community as such and what makes it different or comparative with *other* epistemic communities (see. E.g. Schiffman's work on the emergence of global health networks)

3. There is reference to legitimacy, but not to the political science approach of *input* and *output legitimacy*. Regarding representation, and deliberation one can for instance ask questions about the World Economic Forum being a main venue where CEPI was discussed and established. The economic and policy actors present there share liberal economic drivers and values, but there is questions about democratic legitimacy of the CEPI establishment and how balanced and deliberated (via parliaments, affected communities, with the World Health Assembly) it has been established. Its legitimacy can be defended, specially on effectiveness and transparency, but a more comprehensive picture of legitimacy needs to be provided.
4. Lastly, and authors allude already to it, given that study was funded by Wellcome Trust and authors received a grant as such, and given the cross-funding with the CEPI secretariat, it remains difficult to have an independent, autonomous assessment of its funding. One can read that in the document and likely also in the selection of research participants, who were all close to the CEPI partnership and its epistemic community. This hinders a real dialectic data collection and discussion about its relevance, agency and polity as an innovative global health partnership bringing several actors together.

I hope these 4 points clarify reservations I have justifying publication as such. I hesitate to advise whether these can corrected based on the current methodology, available data set and results. I would advise authors not only to amend manuscript but to restructure in a way that a decent analysis and dialectic in light of CEPI's formation in the (political) context of broader global health governance developments is possible.

Is the work clearly and accurately presented and does it cite the current literature?

Partly

Is the study design appropriate and is the work technically sound?

Partly

Are sufficient details of methods and analysis provided to allow replication by others?

Partly

If applicable, is the statistical analysis and its interpretation appropriate?

Not applicable

Are all the source data underlying the results available to ensure full reproducibility?

Partly

Are the conclusions drawn adequately supported by the results?

Partly

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Health systems and policy, global health governance, political-economy of health.

I confirm that I have read this submission and believe that I have an appropriate level of expertise to state that I do not consider it to be of an acceptable scientific standard, for reasons outlined above.

Reviewer Report 03 February 2021

<https://doi.org/10.21956/wellcomeopenres.17892.r41947>

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Kelley Lee

Faculty of Health Sciences, Simon Fraser University, Burnaby, BC, Canada

Overall comments

I appreciate the opportunity to review this interesting case study documenting the initiation and founding of Coalition for Epidemic Preparedness Innovations (CEPI). There is much need for policy analyses of how different global health initiatives have come about. This is especially welcome at a time when the world needs to figure out how to strengthen collective action to meet critical needs such as vaccines and other global public goods. The story that the paper tells is very organized and provides interesting insights of how different stakeholders came together. The authors bring together concepts and theories from International Relations and innovation thinking, and then apply these to make sense of empirical data on CEPI. The paper's effort to draw lessons from this analysis is a potentially important contribution to global health governance scholarship.

To help to sharpen the presentation of this case study further, there are a few suggestions I would like to offer. First, there are many interesting ideas, theories and concepts set out in the paper but not all of them seem to be used or needed. It is a tall task to apply all of these different ideas in one paper. Thinning them down and focusing on those that advance the analysis would be better and less confusing to the reader. Of particular note is the paper's discussion of social constructivism. The analysis undertaken does not seem to apply social constructivism. Indeed, I am struck in places by language that suggests the contrary (e.g. empirical study, dependent variables, hypotheses). This language made me wonder if the authors were trying to enhance the paper perceived credibility among non-social scientists by using language familiar to the public community. In my view, the paper loses nothing by removing the discussion of social constructivism and, in fact, the presentation of the analytical framework would be more aligned with the approach actually taken.

Second, and related to the previous point, the paper rightfully puts stakeholder interests at the heart of the story it tells. The way in which diverse interests come together, are then overcome or somehow mediated, and then CEPI is formed is the core narrative. If this were an analysis applying social constructivism, then the authors might critically interrogate how perceptions of self-interests are formed, how different stakeholders seek to shape the interests perceived by others, or how definition of an interest is shaped by social context. The paper also assumes that there is no difference between perceived and genuine interests and can we ever know the

difference. None of this is actually done. Given the approach that the authors do take, what they describe as a process tracing approach, interests are taken as “givens”, knowable and constant over time. What would be helpful is for the authors to state explicitly how they define “interests” (i.e. material interests, normative frameworks) and then what different stakeholders’ interests are assumed to be. Did the authors identify the interests of stakeholders or did key informants define their interests? This could then be mapped onto a figure of some kind. This would bring out the process involved in designing and creating CEPI more clearly and enable the reader to understand the importance of the key stages set out.

Third, the methodology needs some clearer discussion and perhaps reflection regarding the core narrative that the process of creating CEPI overcame a diversity of interests. The key informants and stakeholders, as presented, do not seem that diverse. The figure setting out the different stakeholders and interests will help make this clearer. But beyond presentation, I would like more reassurance that there is not a selection bias in how the key informants were selected which leads to a particular story being told? They were all linked to CEPI’s creation in some way. Was there any effort to get the perspective outside of this group? The paper might be open to being criticized for a narrow set of key informants but also range of actors involved in the CEPI process. This, in turn, has implications for the validity of the paper’s claims regarding the “variables” contributing to CEPI’s creation.

Overall, a more selective approach to the analytical framework, tightening up of how interests are defined and studied, and reflection on how methodology might have influenced the resulting narrative would further strengthen the paper’s presentation.

Minor Comments

- Abstract - The methods section needs to state more specifically what methods were used. It current states that "qualitative approach and analytical perspectives from IR". I would also just state the methods used rather than refer to the study upon which the paper is based.
- Abstract - In the Conclusion, the authors again should perhaps just state the conclusion and not write, “The study concludes”. A more direct and active style of writing is recommended. More substantively, I would state here what the lessons here rather than stating there are lessons learned. If the reader only read your abstract, what would you like them to take away?
- Collective action might be added as a keyword.
- This introduction covers quite a bit of ground in locating this paper's analysis of institution building at the intersection of global health governance and innovation. The originality of the paper's analysis is relatively clear in terms of the topic and how it is studied. The gaps in knowledge are set out clearly. However, the significance of the analysis might come through a little stronger. What are the shortcomings of the current institutional arrangements and what practical implications arise from this for pandemic preparedness and response. A sentence or two here and there on implications of the analysis for action and outcome would further get across the importance of the paper.
- P. 3, column 1, line 2: add “international” between “cross” and “borders”.

- P. 3, column 2, line 1: "relations" missing after "international".
- P. 3, column 2, lines 1-3: The definition of collective action in global health could be developed more fully. Presumably, these are agreed common goals of public interest?
- P. 3, column 2, lines 3-5: What happens when there isn't the same vision (e.g. equity of access to vaccines) and differing interests and values?
- The paper states in a few places that CEPI represents a shift in practice and is presented as a kind of breakthrough. This feels right but it would be helpful to set out what practices or institutional arrangements exactly preceded CEPI and why they were unsatisfactory.
- Might anti-microbials be mentioned as similar to vaccines in their under production for global health need under current system.
- International organization theory is a rich body of different approaches. You have chosen liberal internationalism but some explanation of why you think this is the more appropriate approach would be helpful (as opposed to realist theory for example). I think the authors do mean liberal internationalism rather than just liberal theory?
- P. 4, column 1, para 3: The authors provide a particular perspective on why PPPs have emerged. Another is state and market failures. Another is that neoliberal ideology supports a minimalist role for the state and advances the role of the private sector.
- P. 4, column 2, para 1, line 7: If this is the case, does this not negate your previous adoption of liberal internationalism as your analytical framework? How one perceives or defines one's own interests can be socially constructed. This is an example of how the paper feels like a bit of a "pick and mix" analytical approach with basic assumptions underlying these theories are not consistent.
- P. 4, column 2, para 4, line 3: insights rather than clues?
- We don't get enough analysis of the role of epistemic communities in global health governance so I welcome this.
- There are a few points when the language is a little dense and opaque (e.g. p. 4, column 2, para 4). Some rephrasing would be helpful to ensure clarity of meaning.
- P. 5, column 2, para 1, end: There is an opportunity to emphasise why this paper's findings are important. There is a knowledge gap but also why is it significant to address this gap? Given the readership for this journal, this will be important to articulate this significance more explicitly.
- Methods, p. 5: The ethics and consent information might be better placed at the end of this section after the methods are discussed.
- Methods – As noted above, I wonder if there is any selection bias here in terms of who was involved in creating CEPI and who the authors interviewed. It is important to consider

insights from those who were not around the table and voices that were perhaps not heard. Is it possible to provide any general summary of the profile of these key informants? How diverse were their perspectives and interests?

- Methods - What limitations might these documents pose as official records? What was not recorded? The formal process could be traced but what about the informal (in the hallways) negotiations?
- P. 5, column 2, para 2: Very interesting - like a treaty negotiation or labour union talks. What were the key points that needed resolving, what are the deal breakers etc. For me, this is the most interesting part of the paper.
- A single case study can lead you to attribute success to a number of potential variables but without comparative analysis, how can you cannot be sure? Are there examples of failure that you could draw upon to compare? Or perhaps comparable literature to draw upon that can strengthen your conclusions?
- Figure 1 is very helpful. I wonder if another figure could be created mapping the key stakeholders and their identified interests.
- P. 7, column 2, para 2: The point that Tore Godal had direct lines of communication with political leaders seems a very important observation. Indeed, the named individuals are all leading figures in global health with considerable influence. While this is somewhat subsumed under the discussion of leadership, the insider status of many of the players seems a major reason why this initiative got high level buy in. Explaining what caused something to happen in the political domain is notoriously challenging to do. Who had influence and who didn't? How was influence exerted? The authors discuss financial contributions by various stakeholders but what normative influence might individuals or organizations assert? I feel like this aspect of the negotiations are underdeveloped in the paper.
- P. 8, column 1, para 1: This might be a good place to discuss in greater depth the interests of different stakeholders and the mediation that occurred among them.
- P. 8, column 1, para 2: Is multi-sectoral the right word? Different parts of government? Or multi-institutional? Not sure what is right word is but I think you mean state, market and civil society.
- P. 8, column 1, para 2, bottom: What are these principles? What is the "glue" holding this coalition together?
- P. 8, column 1, para 3: In a number of places in the paper, there are statements that part of the success of CIPA is that it put aside politics, that people were "independent", and that scientific considerations drove action. And yet the paper also describes how different interests were mediated, how priorities were set, and different values had to be navigated (e.g. MSF versus pharmaceutical company on equity of access). I wonder if you are equating politics with partisanship or big P politics? Politics is inherent in these negotiations arguably.

- If someone is perceived as “independent,” is this the same as that person actually being relatively independent? This seems a very tight group with close links. Some have occupied leadership positions in government, practice, international organizations, donors over their careers. They all know each other very well. Rather than being independent, I wonder if there is a better way to describe Peter Piot. A respected scientist, academic leader, UN leader etc perhaps? No one is truly independent are they? Relatively independent perhaps but still part of the global health establishment.
- P. 13, column 2, para 1, last lines: To what extent has trust in WHO been enhanced or weakened by what has happened during COVID-19? On vaccine development, perhaps stronger, but geopolitics has been very tough over the past year. Some nod to this might be useful.
- P. 13, column 2, para 3: Was a “full spectrum of interests” really involved in creating CEPI? It would be helpful to set out the stakeholders involved in a figure. As set out in this paper, there were many prominent figures in global health involved and they were able to navigate through and create CEPI. The people that needed to be around the table were around the table to get the job done. But this is a very different conclusion from the argument that the success came from a breadth of representation. The failure to describe interests in any detailed way (as noted above) makes it hard to assess the degree diversity of interests existed here. One might argue that this is the “usual suspects” in global health. What points of divergence needed to be overcome?
- There are missing words here and there in the text. The paper needs a careful proof to fix these.

Is the work clearly and accurately presented and does it cite the current literature?

Yes

Is the study design appropriate and is the work technically sound?

Partly

Are sufficient details of methods and analysis provided to allow replication by others?

Partly

If applicable, is the statistical analysis and its interpretation appropriate?

Not applicable

Are all the source data underlying the results available to ensure full reproducibility?

Partly

Are the conclusions drawn adequately supported by the results?

Yes

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Global health governance, global infectious disease policy, international

political economy, globalization.

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.