

Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.

Elsevier hereby grants permission to make all its COVID-19-related research that is available on the COVID-19 resource centre - including this research content - immediately available in PubMed Central and other publicly funded repositories, such as the WHO COVID database with rights for unrestricted research re-use and analyses in any form or by any means with acknowledgement of the original source. These permissions are granted for free by Elsevier for as long as the COVID-19 resource centre remains active.

### **Health Policy**

## Governing the Access to COVID-19 Tools Accelerator: towards greater participation, transparency, and accountability

Suerie Moon, Jana Armstrong, Brian Hutler, Ross Upshur, Rachel Katz, Caesar Atuire, Anant Bhan, Ezekiel Emanuel, Ruth Faden, Prakash Ghimire, Dirceu Greco, Calvin WL Ho, Sonali Kochhar, G Owen Schaefer, Ehsan Shamsi-Gooshki, Jerome Amir Singh, Maxwell J Smith, Jonathan Wolff

### Lancet 2022; 487–94

Published Online December 10, 2021 https://doi.org/10.1016/ S0140-6736(21)02344-8

International Relations and Political Science Department & Interdisciplinary Programmes, Global Health Centre, Graduate Institute of International and Development Studies, Geneva, Switzerland (S Moon PhD): Independent Global Health Consultant, Geneva, Switzerland (| Armstrong MBA); Johns Hopkins Berman Institute of Bioethics, Johns Hopkins University, Baltimore, MA, USA (B Hutler PhD, Prof R Faden PhD): Department of Family and Community Medicine and Dalla Lana School of Public Health, University of Toronto, Toronto, ON, Canada (Prof R Upshur MD); Faculty of Health Sciences, Western University, London, ON, Canada (R Katz MA M J Smith PhD); Department of Philosophy and Classics, University of Ghana, Accra, Ghana (C Atuire PhD); Department of Community Medicine and Centre for Ethics. Yenepova University. Mangalore, India

The Access to COVID-19 Tools Accelerator (ACT-A) is a multistakeholder initiative quickly constructed in the early months of the COVID-19 pandemic to respond to a catastrophic breakdown in global cooperation. ACT-A is now the largest international effort to achieve equitable access to COVID-19 health technologies, and its governance is a matter of broad public importance. We traced the evolution of ACT-A's governance through publicly available documents and analysed it against three principles embedded in the founding mission statement of ACT-A: participation, transparency, and accountability. We found three challenges to realising these principles. First, the roles of the various organisations in ACT-A decision making are unclear, obscuring who might be accountable to whom and for what. Second, the absence of a clearly defined decision making body; ACT-A instead has multiple centres of legally binding decision making and uneven arrangements for information transparency, inhibiting meaningful participation. Third, the nearly indiscernible role of governments in ACT-A, raising key questions about political legitimacy and channels for public accountability. With global public health and billions in public funding at stake, short-term improvements to governance arrangements can and should now be made. Efforts to strengthen pandemic preparedness for the future require attention to ethical, legitimate arrangements for governance.

### Introduction

Global cooperation collapsed in early 2020 as the emergence of the COVID-19 pandemic prompted governments to close borders and to compete over severe shortages of medical supplies,<sup>1</sup> affecting the most vulnerable within and across countries. To jumpstart a more collaborative and fairer pandemic response, several existing organisations created the Access to COVID-19 Tools-Accelerator (ACT-A) to work collectively towards innovation and globally equitable access to vaccines, therapeutics, and diagnostics.

In global health, ACT-A is unprecedented in its scale, scope, speed of its creation, and complexity. Whether by necessity or design, ACT-A is not an organisation with its own legal status or central governing body, but rather a collaboration of public, private sector, philanthropic, and public-private actors that are relatively autonomous from each other. Official publications state that the explicit intention at the outset of ACT-A was not to develop new governance mechanisms, where possible,<sup>2</sup> and describe the loose governance structure of ACT-A as a benefit, making it nimble3 and flexible; justified because its partner organisations are already well established and the work of ACT-A is time-bound.<sup>2</sup> However, governance arrangements-eg, for participation, decision making, access to information, and accountability-influence whose interests are ultimately reflected in the outcomes. The unclear and unsettled governance arrangements of ACT-A raise important questions, not only for the initiative itself, but also as policy makers consider future pandemic preparedness reforms beyond the COVID-19 pandemic.

We refer to ACT-A as a multistakeholder initiative, "two or more classes of actors engaged in a common governance enterprise concerning issues they regard as public in nature, and characterised by polyarchic authority relations."<sup>4</sup> We prefer the term multistakeholder partnerships over the more commonly used term public– private partnership, both for analytical traction and because of substantial differences in how ACT-A is governed compared with the many pre-existing global health public–private partnerships.<sup>5,6</sup>

Our analysis is based on publicly available documentation of the evolution of ACT-A and its governance arrangements (appendix pp 2–20). We structure our analysis based on three governance principles embedded in the ACT-A founding commitment statement: participation, transparency, and accountability (appendix p 2). We conclude with proposals for strengthening governance arrangements of ACT-A in the immediate

### Search strategy and selection criteria

This Health Policy analyses publicly available data collected from the websites of WHO and partner organisations between May 01, 2021 and June 01, 2021. To construct the dataset, the research team relied on a chronologically organised list of WHO press releases published by the ACT-A publishing office (https://www.who.int/news), and a timeline of the COVID-19 outbreak created by Devex (https://www.devex.com/news/covid-19-a-timeline-of-the-coronavirus-outbreak-96396). Researchers canvassed these websites for English-language press releases and timeline entries that referenced the terms "ACT-A," "accelerator," or "COVAX," between Dec 31, 2019 (first case of pneumonia of unknown cause reported by Chinese officials to the WHO) and May 12, 2021 (the 6th ACT-A Facilitation Council meeting). All press releases and directly referenced primary source documents (where available) were collected into a master spreadsheet. These documents were then coded for their relevance to ACT-A governance and analysed with results described in the article. From this dataset, the research team selected ten key documents, based on their importance to the development of the ACT-A, that together display the evolution of ACT-A's governance structure (figure 1).

(A Bhan MHSc); Global Initiatives and Healthcare Transformation Institute. University of Pennsylvania, Philadelphia, PA, USA (Prof E Emanuel MD). Tribhuyan University, Kirtipur, Nepal (Prof P Ghimire PhD); School of Medicine, Federal University of Minas Gerais, Belo Horizonte, Brazil (D Greco MD); Faculty of Law and Centre for Medical Ethics, University of Hong Kong, Hong Kong Special Administrative Region, China (CWLHoJSD); Department of Global Health, University of Washington, Seattle, WA, USA (S Kochhar MD); Centre for **Biomedical Ethics**, National University of Singapore, Singapore (G O Schaefer PhD); Department of Medical Ethics. Tehran University of Medical Sciences, Tehran, Iran (E Shamsi-Gooshki PhD); University of KwaZulu-Natal. Durban, South Africa (Prof J A Singh PhD); Blavatnik School of Government, University of Oxford, Oxford. UK (Prof J Wolff MPhil)

> Correspondence to: Ms Jana Armstrong, 1227 Carouge, Geneva, Switzerland

jana.armstrong@mac.com

See Online for appendix For more on the Coalition for Epidemic Preparedness

Innovations see https://cepi.net For more on Gavi, the Vaccine

Alliance see

https://www.gavi.org For more on The Global Fund to Fight AIDS, Tuberculosis and Malaria see https://www.

theglobalfund.org For more on **Unitaid** see

https://unitaid.org

For more on **Wellcome** see https://wellcome.org For more on **WHO** see https://www.who.int

For more on the Foundation for Innovative New Diagnostics see https://www.finddx.org

For more on **The World Bank** see https://www.worldbank.org/en/ home



Figure 1: Timeline of ACT-A and its governance arrangements ACT-A=Access to COVID-19 Tools Accelerator.

term, and consider how governance might be addressed in future reforms.

# Evolution of ACT-A and its governance arrangements

Understanding the governance of ACT-A requires a brief review of how it has evolved since its inception and official launch on April 24, 2020, at a virtual event cohosted by WHO, the President of France, the President of the European Commission, and the Bill & Melinda Gates Foundation (figure 1). ACT-A is described as a collaboration between global health actors, private sector partners, and other stakeholders,7 initially including the Gates Foundation, the Coalition for Epidemic Preparedness Innovations (CEPI), Gavi, the Vaccine Alliance, The Global Fund to Fight AIDS, Tuberculosis and Malaria, Unitaid, Wellcome, WHO, and three industry groups (Developing Countries Vaccine Manufacturers Network, International Federation of Pharmaceutical Manufacturers & Associations, and the International Generic and Biosimilar Medicines Association).

The first representation of the collaboration in early May, 2020, shows global stewardship without explanation at the top and places a group of nine highincome countries (donor governments), WHO, two charitable foundations, and one international non-governmental organisation as a facilitation group to oversee ACT-A, implying a hierarchical relationship to the vaccine, therapeutics, and diagnostics partnerships (figure 2A).8 No governments of low-income or middleincome countries (LMICs) seemed to have been involved in the creation or initial governance of ACT-A. WHO occupies various roles, including being a member of the facilitation group, providing coordination between the facilitation group and the then three pillars, and playing specific roles within each pillar.

By late June, 2020, when the first investment cases were published seeking US\$31 billion from donors, the governance structure of ACT-A had evolved to include four pillars: (1) vaccines, headed by CEPI and Gavi; (2) therapeutics, headed by Unitaid and Wellcome; (3) diagnostics, headed by the Foundation for Innovative New Diagnostics (FIND) and The Global Fund; (5) and the Health Systems Connector, headed by the World Bank and The Global Fund.<sup>9</sup> WHO only later became a coconvenor in the Health Systems Connector, and the industry groups (Developing Countries Vaccine Manufacturers Network, International Federation of Pharmaceutical Manufacturers & Associations, and the International Generic and Biosimilar Medicines Association) are not mentioned. Roles of donors, partners, coconveners, and founding member countries are described, but which entity occupies which role, the relationships between entities, and where decision making responsibility lies is unclear.<sup>2,3</sup>

The investment cases appear to be the first public statement of objectives and funding needs by pillar. A section on accountability refers to the plan by the initial facilitation group to set up an ACT-A Facilitation Council, the ACT-A Hub already in place at WHO; and that formal governance of the work of the pillars is provided by the boards and governing bodies of the partner organisations that lead the work of each pillar.<sup>9</sup> Donations are to be made directly to coconvenors, not to ACT-A itself, since there is no ACT-A entity. Donors retain full oversight on the allocation of their pledges, and grant management and financial reporting to donors will be managed by the receiving entity.<sup>2</sup>

In September, 2020, the ACT-A Facilitation Council first met.<sup>10</sup> Although the Facilitation Council appears at the top of the diagram, its terms of reference do not give it decision making or oversight authority. Also in September, just before the UN General Assembly highlevel ACT-A event, an ACT-A Status Report and Plan3 and updated investment cases were published. The authorship is unclear, but it bears eight logos: those of Gavi, CEPI, WHO, Wellcome, the Gates Foundation, FIND, The Global Fund, and Unitaid. The logos of the three industry groups (Developing Countries Vaccine Manufacturers Network, International Federation of Pharmaceutical Manufacturers & Associations, and International Generic and Biosimilar Medicines Association) no longer appear, making them less visible in the collaboration, although they remain listed as part of the Principals Group and as industry representatives that have standing invitations (along with civil society and communities) to the Facilitation Council.

In February, 2021, the ACT-A civil society group wrote in detail to ACT-A leaders requesting increased transparency



Figure 2: The ACT-A model reflecting substantial changes in the public presentation of its composition and structure

(A) Representation of collaboration in May, 2020. Reproduced from reference 8, by permission of the European Union. (B) Representation of collaboration in April, 2021. Reproduced from reference 2, by permission of WHO.

about decision making; meaningful inclusion in ACT-A decisions by countries, communities, and civil society, and accountability of different ACT-A partners.<sup>11</sup> In April, 2021, ACT-A published a report describing what the initiative was.<sup>2</sup> ACT-A collaboration seems to have coalesced into two concentric layers (figure 2B): an inner operational layer of three pillars (vaccines, diagnostics, and therapeutics) and two cross-cutting functional areas (health systems connector, and access and allocation), each led by two to three coconvenors.<sup>2</sup> The outer governing layer of three groups (the Facilitation Council, a new Principals Group, and the ACT-A Hub) collectively provide advice, guidance, fundraising, advocacy, and coordination of the inner layer. Table 1 shows the arrangements of ACT-A governance.<sup>2</sup>

ACT-A released another report in April 2021, this time summarising its efforts, impact, and plans.<sup>12</sup> The report's

cover adds UNICEF to the eight logos from the September, 2020, status update, and acknowledges governments, civil society, and industry. The significance of the inclusion or exclusion of logos is unclear. Further detail of the data evaluated for this summary and analysis can be found in the appendix (pp 14–19).

# Governance challenges arising from the structure of ACT-A

Analysis of ACT-A governance arrangements was done in terms of three principles embedded in the ACT-A founding commitment statement:<sup>7</sup> participation, transparency, and accountability. These principles appear to be widely accepted, as they were also the ones invoked in the February, 2021, civil society letter,<sup>11</sup> and comprise the governance values in the Ethical Framework for WHO's work in the ACT-A.<sup>13</sup> Participation in decision making by those directly affected legitimises decisions on the basis of respect for people and communities.<sup>13</sup> Participation can also serve the instrumental purpose of contributing to broader acceptance and effective implementation. Transparency regarding inputs, processes, and decisions enables more meaningful participation by those affected;<sup>12,13</sup> political theorists note that "the availability of information is crucial for all forms of accountability, but transparency, or the widespread availability of information, is essential to market, peer, and reputational accountability."<sup>14</sup> Finally, accountability is a fundamental characteristic of legitimate governance, and is conceptualised here as when "some actors have the right to hold other actors to a

set of standards, to judge whether they have fulfilled their responsibilities in light of these standards, and to impose sanctions if they determine that these responsibilities have not been met".<sup>14</sup> Notably, accountability featured prominently in the ACT-A founding commitment statement: "We commit to be accountable to the world, to communities, and to one another."<sup>7</sup>

Assessing ACT-A against these three principles, several interrelated challenges were found. First is a lack of clarity on the roles of these organisations in ACT-A governance, which have shifted over the course of its first year, with some actors appearing or disappearing, changing their roles, or playing multiple roles (table 1). For example, governments of high-income countries

Description	Composition	Governance statements
Operational implementation	Eight coconvenors or leads (Gavi, the Vaccine Alliance, Coalition for Epidemic Preparedness Innovations, Unitaid, Wellcome, the Global Fund to Fight AIDS, Tuberculosis and Malaria, WHO, the Foundation for Innovative New Diagnostics, and the World Bank)	Formal governance for each of the Pillars, including transparency of administration, financial management, and accountability for resources raised and used, is provided by the existing Boards and governing bodies of the coconvening and lead organisations <sup>2</sup>
High-level advice and guidance, global leadership and advocacy, to communicate progress, and to act in support of the partners in each pillar <sup>10</sup>	Cochairs are the South African Government and Norwegian Government; cohosts are WHO and the European Commission; members are 27 governments representing regional cooperation groups, donor countries, and market shaping countries; three partners are the Gates Foundation, Wellcome, and World Economic Forum; two WHO Special Envoys, World Bank (as observer); and a standing invitation to civil society, communities, and industry	Four key governance principles: (1) motivated, flexible, agile, and diverse group of influential world leaders who are committed to creative collaboration and supporting the ACT-A vision in the global interest; (2) no legal status and no duplication of existing multilateral bodies; (3) time-limited, outcome focused, and restricted to COVID-19-related products; and (4) subsidiarity applies—the Council acts in support of the partners in each pillar, who are the central actors of the ACT-A framework and are responsible for delivery of their objectives <sup>10</sup>
Discuss key developments and challenges, the overall strategic direction of ACT-A and pillar-specific priorities, and address and align on cross-cutting issues and key bottlenecks <sup>2</sup>	Comprised of the Principals of the coconvening agencies and lead agencies, such as UNICEF, the Gates Foundation, and industry associations <sup>2</sup>	No reference to governance
Plays a central coordination function and aims to facilitate synergies across the partnership; Facilitation Council secretariat, hosts pillar coordination, and Principals Group meetings <sup>2</sup>	WHO staffed	No reference to governance
	Operational implementation High-level advice and guidance, global leadership and advocacy, to communicate progress, and to act in support of the partners in each pillar <sup>10</sup> Discuss key developments and challenges, the overall strategic direction of ACT-A and pillar- specific priorities, and address and align on cross- cutting issues and key bottlenecks <sup>2</sup> Plays a central coordination function and aims to facilitate synergies across the partnership; Facilitation Council secretariat, hosts pillar	Operational implementationEight coconvenors or leads (Gavi, the Vaccine Alliance, Coalition for Epidemic Preparedness Innovations, Unitaid, Wellcome, the Global Fund to Fight AIDS, Tuberculosis and Malaria, WHO, the Foundation for Innovative New Diagnostics, and the World Bank)High-level advice and guidance, global leadership and advocacy, to communicate progress, and to act in support of the partners in each pillar <sup>10</sup> Cochairs are the South African Government and Norwegian Government; cohosts are WHO and the European Commission; members are 27 governments representing regional cooperation groups, donor countries, and market shaping countries; three partners are the Gates Foundation, Wellcome, and World Economic Forum; two WHO Special Envoys, World Bank (as observer); and a standing invitation to civil society, communities, and industryDiscuss key developments and challenges, the overall strategic direction of ACT-A and pillar- specific priorities, and address and align on cross- cutting issues and key bottlenecks <sup>2</sup> Comprised of the Principals of the coconvening agencies and lead agencies, such as UNICEF, the Gates Foundation, and industry associations <sup>2</sup> Plays a central coordination function and aims to facilitate synergies across the partnership; Facilitation Council secretariat, hosts pillarWHO staffed

Table 1: ACT-A	governance	arrangements
----------------	------------	--------------

	WHO	Gavi, the Vaccine Alliance	CEPI	Wellcome	Unitaid	The Global Fund	FIND	The World Bank	The Gates Foundation	UNICEF	Industry associations	The World Economic Forum	Civil society organisations	High- income country donors	LMICs
Pillars	CC (G)	CC (G)	CC (G)	CC (G)	CC (G)	CC (G)	CC (G)	CC (G)	Working group	Working group		Working group	Working group (representation)		
Hub	MPR														
Principals Group	MPR	MPR	MPR	MPR	MPR	MPR	MPR	MPR	MPR	MPR (from April, 2021)	MPR		Standing invitation (from June, 2021)		
Facilitation Council	MPR			MPR				Observer	MPR		Standing invitation	MPR	Standing invitation	MPR	MPR
Logos on publications	MPR	MPR	MPR	MPR	MPR	MPR	MPR (from Sept, 2020)		MPR		MPR (April, 2020 only)				

Respective working groups colead in at least one pillar. CEPI=Coalition for Epidemic Preparedness Innovations. FIND=The Foundation for Innovative New Diagnostics. LMICs=low-income and middle-income countries. CC (G)=coconvenor (governance). MPR=member, partner, or representative.

Table 2: Roles of main actors

were initially conceived as having an oversight role, but they later disappeared. Industry is initially in a leading role, but it becomes unclear how they participate, raising questions regarding potential conflicts of interest when billions in public funding are being allocated to purchase goods from these same industries. Some actors are simultaneously coconvenors, members of the Facilitation Council, and members of the Principals Group (table 2), raising questions about the concentration of power and whether the same actor is expected to hold itself accountable if it is both a governor and implementer. There is little or no explanation of these shifting roles or its effects.

ACT-A is comprised of relatively autonomous organisations that both collaborated and competed for funding and visibility before the COVID-19 pandemic. No two organisations are identical in mission, vision, or values, or in who governs them. In particular, WHO and the World Bank are governed by member governments; Gavi, The Global Fund, and Unitaid are governed by a mix of public and private organisations and individuals; industry associations are governed by for-profit companies; CEPI is governed by investor representatives and individuals; and FIND, Wellcome, the Gates Foundation, and WEF are governed by individuals (appendix pp 3–13). This mix of public and private authority within a multistakeholder initiative raises challenges for ensuring accountability for acting in the public interest. No single organisation is subordinate to any other, speaks for others, nor are the goals of the organisations subsidiary to that of ACT-A. Partners committed publicly to work together within ACT-A (appendix p 2) without establishing clear roles, responsibilities, and decision making processes, and it remains unclear whose interests are taken into account—and ultimately served—in decision making.

Although evolving in response to changing circumstances is both necessary and valuable, shifting, inchoate governance arrangements also make participation very difficult for stakeholders (eg, governments, communities, and civil society) and weakens accountability. Each of the ACT-A participating organisations is legally accountable to its own governing board; we did not find an ACT-Awide accountability framework. Each board might be the appropriate accountability mechanism for each individual organisation but cannot ensure accountability across multiple organisations coleading a pillar or ACT-A as a whole. However, it is important to recognise other non-board levers for accountability. For example, funders can ultimately hold ACT-A organisations accountable by withholding future funding (upward accountability), and partner organisations can ultimately withdraw from a partnership (horizontal accountability).<sup>14</sup> However, arrangements remain inadequate for downward accountability to intended beneficiaries for whom ACT-A decisions have crucial implications.14

In April, 2021, ACT-A issued an impact report on its first anniversary outlining its concrete achievements

regarding the goals and objectives of the partnership. In October, 2021, ACT-A published a strategic review of itself, done by the consulting firm Dalberg.<sup>15</sup> Both reports are important, yet are partial tools for accountability. Beyond the level of any single organisation, the accountability of ACT-A overall is unclear.

A second governance challenge is the absence of a clearly defined decision making body for ACT-A, which is instead currently characterised by multiple centres of formal decision making, and uneven arrangements for information transparency, inhibiting meaningful participation. For example, legal responsibility for use of funds lies with the boards of eight or more organisations (appendix p 12).

The involvement of so many boards in decision making makes meaningful stakeholder participation difficult. The Facilitation Council and the Principals Group do not have explicit decision making roles, but they include powerful actors with large-scale resources and the ability to wield influence. For example, the Gates Foundation is a donor to all coconvenors except Wellcome, sits on the boards of Gavi, The Global Fund, and Unitaid, belongs to both the ACT-A Principals Group and Facilitation Council, and is a colead in several ACT-A working groups. This complex network of private and public actors with roles not always clearly defined can also obscure accountability and is a known governance challenge facing multistakeholder initiatives.<sup>16</sup>

Furthermore, without ACT-A-wide decision making, the work of each pillar risks being siloed, undermining necessary synergies between the delivery of specific health technologies, and achieving public health objectives. For example, resources are unevenly allocated across the pillars. By mid-2021, vaccines had been almost fully funded for the year, whereas diagnostics had only received 10% of the year's funding needs and health systems only 8%.<sup>17</sup> The absence of ACT-A-wide decision making can also concentrate the power of donors and contribute to a logic of competition among the pillars for funding.

In addition, ACT-A does not have a transparency policy. Rather, each of the participating public, private, and public-private organisations have their own approach, and some do not have transparency policies at all. Information is spread across the websites of the various organisations and is not always consistent across organisations, with no clarity on the type of information stakeholders can expect. Delays in accessing information on ACT-A decisions impede meaningful stakeholder participation, especially in emergencies such as largescale country outbreaks. Information should also be as thorough as possible since details (eg, the type, price, quantity, timelines, and legal conditions of products expected in a country) are often crucial. Information should be easily accessible by all stakeholders, including the general public, whose health might be affected by ACT-A decisions.

Transparency has increased as ACT-A has evolved, particularly regarding roles and responsibilities of the various actors involved, objectives, strategies, work-streams, template contracts, budget requirements, and financial contributions, as noted in the evolution of publications and events (appendix pp 14–19). Yet, countries and civil society groups have raised concerns and called for changes in practice to provide more detailed information regarding contracts specifying the prices, terms, and timelines of vaccine supply.<sup>11,18</sup>

Although real-time, full information disclosure might not always be practical and can impede the ability to act quickly, decisions—and the inputs and processes that produced them—should be disclosed rapidly and thoroughly. Otherwise, whether information, processes, and decisions serve the public interest is difficult to assess, and could undermine trust and legitimacy.

A third governance challenge is the changing and receding role of governments in ACT-A governance, raising key questions about its political legitimacy and channels for public accountability. Legitimacy has been referred to as "the set of conditions that must be in place in order for the claims to authority of somebody to be deemed appropriate, and for their claims to compliance to be warranted."19 States remain the main duty-bearers responsible and accountable for the health of their people under international law; states are also mandated to represent their people's interests at the international level. Yet, apart from WHO, the organisations involved in ACT-A are largely private (eg, foundations, not-for-profit organisations, and industry associations) or publicprivate hybrids (eg, Gavi, The Global Fund, and Unitaid), neither mandated nor claiming to act as representatives of the public. In the early weeks of ACT-A, a group of governments from high-income countries conceptually were above ACT-A in the governance structure (figure 2), but by the time governance arrangements had solidified a year later, these governments disappeared, except as members of the Facilitation Council (table 1). LMIC governments only appear several months into the collaboration as members of the Facilitation Council, which as noted has no oversight or decision making authority. The Principals Group includes no governments. A key question remains whether governments have had adequate opportunities to participate in the decisions that ultimately affect their people, and if not, who is to be held accountable for any ACT-A shortcomings, by whom and how.

In theory, WHO might be seen to act on behalf of the governments of its 194 Member States, and its legitimacy as an organisation delegated by governments to act in their interests is a substantial political resource for the ACT-A. Yet, WHO does not exercise oversight over ACT-A, but rather plays varying—often technical advisory—roles in each of the pillars, sharing leadership in specific pillars with non-state actors (figure 2). In some multistakeholder initiatives, public–private actors hold decision making roles, while intergovernmental organisations act as advisors.<sup>16</sup> However, such an exercise of private authority raises fundamental questions regarding legitimacy and accountability of private actors.<sup>20</sup>

In principle, authority might also be delegated by populations through governments that represent them on the boards of coconvening organisations, such as Gavi (five donor country and five implementing country representatives), The Global Fund (eight donor country and seven implementing country representatives) and Unitaid (seven donor governments and one regional intergovernmental organisation), each of which also include non-state actors. But these boards necessarily only include a small subset of governments, and LMIC governments do not hold representational seats on the boards of some coconvenors (Wellcome, CEPI, or FIND), or of the Principals Group, the Gates Foundation, or industry associations.

The extent to which civil society organisations represent constituents is debated, but for those who consider them to represent at least some segments of society, we note that they do hold seats on the boards of three coconvenors (one seat with Gavi, three seats with The Global Fund, and two seats with Unitaid). And after several months of advocating for representation, civil society organisations now have representation in all ACT-A pillars, coordination structures, and working groups, and in the Principals Group as of June, 2021. However, civil society organisations have raised serious concerns about the quality of their participation.<sup>11,21</sup> Furthermore, civil society organisation representation cannot be a systematic replacement for the public accountability expected from and through governments.

### Strengthening ACT-A's governance

ACT-A's governance arrangements were constructed necessarily quickly during a global emergency and have understandably evolved in response to a rapidly shifting terrain. Nevertheless, after 18 months since its creation, limited transparency and clarity on who is deciding what for whom has impeded participation in ACT-A governance and obscured accountability.

In the short to medium term, we do not consider it feasible or necessarily desirable to merge the diverse activities of ACT-A partners into a single organisation, or to create a new one, despite the clarity in governance that a single organisation would offer. Furthermore, in its October, 2021 strategic plan, ACT-A responded to external critiques by committing to strengthen the participation of LMIC governments and civil society, and to increase information sharing. Nevertheless, we conclude it remains necessary and possible to take further steps quickly to strengthen ACT-A's governance, and thereby, the overall initiative.

First, clarification of decision making roles, responsibilities, and processes is needed. Current documents describe the structure of ACT-A and identify

actors but still do not explain who is making which decisions and how. A clear, publicly available description of policies for participation across ACT-A, and the roles of each actor in decision making, would be an important step forward.

Second, a common transparency policy across ACT-A organisations could help a broad range of stakeholders understand the types of information they could expect, the level of detail, and timelines. Transparency policies generally allow the broad public to seek access to information and can thereby strengthen public accountability. These policies can include space for nuance and judgment.22 For example, the World Bank's access to information policy permits both exceptions to disclosure requirements when clearly justified, and channels for appeals when requests for information are denied.<sup>23</sup>

Third, a regular forum for soliciting meaningful, broad-based input from governments and other societal stakeholders on ACT-A overall should be considered. A tailor-made process for regular open public consultation and debate on the ACT-A's activities, policies, decisions, achievements, and struggles could strengthen not only participation and transparency, but also accountability and effectiveness. As political theorists have argued, creating spaces for more democratic deliberation in global governance can strengthen the legitimacy and the quality of decisions, even when systematic representation is infeasible.24

Fourth, an accountability framework for ACT-A should be developed articulating who is responsible for what. Attention to the role of governments, as both agents and recipients of demands for accountability from their citizens, will be particularly important.

These measures would address some of the governance challenges. The stakes remain high with the ongoing COVID-19 pandemic, and the majority of the world's population without secure access to countermeasures.

We have argued that arrangements for decision making and accountability ultimately shape the outcomes of ACT-A. We do not claim that different governance arrangements within ACT-A would have overturned decisions that undermined the initiative, such as wealthy governments bilaterally securing a disproportionate share of global vaccine supply or vaccine producers selling to the most commercially attractive buyers first. Nevertheless, it is worth considering how governance arrangements shape ACT-A strategies. Critics have called for more ambitious coverage targets, more transparency on delays in vaccine deliveries, more emphasis on technology transfer and flexible approaches to intellectual property, and more proportional funding allocation between the pillars.<sup>15,18,21,25-27</sup> Would broader participation, greater transparency, and stronger accountability arrangements in ACT-A decision making have produced different outcomes? Would they have strengthened trust, buy-in, and support for ACT-A? We cannot answer these counterfactual questions, but they are worth debating.

The recommendations above are all partial and shortterm. Therefore, our final recommendation is a longerterm proposal: that governments negotiate international rules, commit financing, and establish governance arrangements that embody the principles of participation, transparency, and accountability to ensure globally equitable innovation and access to countermeasures in future potential pandemics.28 Governments can and should engage in open public consultation and deliberation, at both national and global levels, on such potential reforms.<sup>19</sup> Clear, ethical governance arrangements are not easy to negotiate during a crisis but are necessary for initiatives dealing with the life-or-death issue of access to countermeasures. Doing so in advance of a potential pandemic is a crucial aspect of global preparedness that can no longer be neglected.

### Contributors

The conception for this Health Policy was a collective effort based on group discussion, with many suggestions circulated by email. SM, JA, BH, RU, and RK cowrote the first draft. All other authors contributed further comments and suggestions on three subsequent drafts, which were discussed in at least three further group meetings. SM and RU contributed to the methodology, data analysis, writing, and editing. JA, BH, and RK contributed to the data collection, analysis, writing, and editing. CA, AB, EE, RF, PG, DG, CWLH, SK, ES-G, GOS, JAS, MJS, and JW contributed to the input, review, analysis, and editing. JA managed the process of reviews and edits.

### Declaration of interests

All authors are members of a WHO-led ACT-A Ethics and Governance Working Group set up to advise WHO on ethics and governance issues related to its role as a partner in the ACT-A. SM reports grants paid to her institution from the WHO Regional Office for Europe, UNICEF-UNDP-WB-WHO Special Program for Research and Training in Tropical Disease, and the Bill and Melinda Gates Foundation; reports paid membership with the Unitaid Proposal Review Committee; reports unpaid cochairmanship of the WHO Fair Pricing Forum; and is an unpaid member of the WHO ACT-A Governance and Ethics Working Group. JA reports paid WHO consultancy for work with the ACT-A Ethics and Governance Working Group, a paid consultancy with Wellcome, and unpaid board membership with Médecins sans Frontières Switzerland. EE declares payments, honoraria, or travel fees from Greenwall Foundation, RAND Corporation, Medical Home Network, Healthcare Financial Management Association. Ecumenical Center-UT Health, American Academy of Optometry, Associação Nacional de Hospitais Privados, National Alliance of Healthcare Purchaser Coalitions, Optum Labs, Massachusetts Association of Health Plans, District of Columbia Hospital Association, Washington University, Goldman Sachs, Brown University, The Atlantic, McKay Lab, American Society for Surgery of the Hand, Association of American Medical Colleges, American Essential Hospitals, Johns Hopkins University, National Resident Matching Program, Shore Memorial Health System, Tulane University, Oregon Health & Science University, United Health Group, Blue Cross Blue Shield, Center for Global Development, Informa, and Galien Foundation; and declares a leadership or fiduciary role in VillageMD, Oncology Analytics, Embedded Health Care, Oak HC/FT, and COVID-19 Recovery Partners. RF declares participation as a member of the WHO Strategic Advisory Group of Experts and the Immunization Working Group on COVID-19 Vaccines. GOS reports individual funding from WHO. SK is a member of the WHO Strategic Advisory Group of Experts on Immunization and the WHO SAGE Working Group on COVID-19 vaccines. JAS declares participating as a member of the WHO Technical Advisory Group on COVID-19 vaccines. MJS reports grants paid to their institution from the Canadian Institutes of Health Research (grant number #C150-2019-11), and travel fees to attend WHO and Global Research Collaboration for Infectious Disease Preparedness Global Research and Innovation Forum. All other authors declare no competing interests.

### Acknowledgments

JA, GOS, MJS, RU, and JAS received support for time worked on the subject matter of this article: JA and GOS as consultants for WHO; MJS and RU from a grant from the Canadian Institutes of Health Research, and JAS from the COVID-19 Africa Rapid Grant Fund. AB is the site principal investigator on a US National Institutes of Health grant (1U19MH113211-01) for Mental Health. BH has a postdoctoral fellowship partially funded by a Center for Excellence in ELSI Research grant (SRM1HG009038-03) from the US National Human Genome Research Institute. No authors were employed or funded by the US National Institutes of Health for this work. All authors have had access to the data, research, and analysis used in the preparation of this Health Policy and jointly accept responsibility for its publication.

#### References

- The Independent Panel for Pandemic Preparedness and Response. How an outbreak became a pandemic: the defining moments of the COVID-19 pandemic. Geneva: The Independent Panel for Pandemic Preparedness & Response, 2021.
- 2 WHO. What is the Access to COVID-19 Tools (ACT) Accelerator, how is it structured and how does it work? Geneva: World Health Organization, 2021.
- 3 WHO. ACT-Accelerator: status report and plan. Geneva: World Health Organization, 2020.
- 4 Raymond M, DeNardis L. Multistakeholderism: anatomy of an inchoate global institution. Int Theory 2015; 7: 572–616.
- 5 Buse K, Walt G. Global public-private partnerships: part II—what are the health issues for global governance? Bull World Health Organ 2000; 78: 699–709.
- 6 Andonova LB. The power of the public purse: financing of global health partnerships and agenda setting for sustainability. *Chinese J Popul Resour Environ* 2018; 16: 186–96.
- 7 WHO. Commitment and call to action: Access to COVID-19 Tools (ACT) Accelerator: a global collaboration to accelerate the development, production and equitable access to new COVID-19 diagnostics, therapeutics and vaccines. Geneva: World Health Organization, 2020.
- 8 European Union. Coronavirus global response: a pledging marathon for universal access to vaccines, treatments and tests. Brussels: European Union, 2020.
- 9 WHO. ACT-Accelerator update: publication of investment cases. June 26, 2020. https://www.who.int/news/item/26-06-2020-actaccelerator-update (accessed Dec 1, 2021).
- 10 WHO. Access to COVID-19 Tools Accelerator: Facilitation Council meeting. Sept 10, 2020. https://www.who.int/news-room/events/ detail/2020/09/10/default-calendar/access-to-covid-19-toolsaccelerator-facilitation-council-meeting (accessed Sept 29, 2021).
- 11 The Civil Society and Community Representatives of the ACT-A. More transparency, accountability and inclusion needed in ACT-A: letter to ACT-A leadership and brief from CS and community representatives. Feb 22, 2021. http://covid19advocacy.org/resources/ (accessed Dec 1, 2021).

- 12 WHO. ACT now, ACT together 2020–2021 impact report. Geneva: World Health Organization, 2021.
- 13 WHO. Ethical framework for WHO's work in the ACT-Accelerator. Geneva: World Health Organization, 2021.
- 14 Grant RW, Keohane RO. Accountability and abuses of power in world politics. *Am Polit Sci Rev* 2005; **99**: 29–43.
- 15 Dalberg Advisors. ACT-Accelerator Strategic Review. Geneva: World Health Organization, 2021.
- 16 Gleckman H. Multistakeholder governance and democracy: a global challenge. Oxfordshire: Routledge, 2018.
- 17 WHO. Access to COVID-19 tools funding commitment tracker. Geneva: World Health Organization, 2021.
- 18 Goldhill O, Furneaux R. 'Naively ambitious': how COVAX failed on its promise to vaccinate the world. Oct 8, 2021. https://www. statnews.com/2021/10/08/how-covax-failed-on-its-promise-tovaccinate-the-world/ (accessed Dec 1, 2021).
- Smith MJ, Weinstock D. Political legitimacy and research ethics. *Bioethics* 2019; 33: 312–18.
- 20 Biersteker TJ, Hall RB. Private authority as global governance. In: Hall RB, Biersteker TJ, eds. The emergence of private authority in global governance. Cambridge: Cambridge University Press, 2002: 203–22.
- 21 Platform for ACT-A Civil Society & Community Representatives. Statement on the ACT-Accelerator Strategic Review. Oct 12, 2021. https://covid19advocacy.org/statement-on-the-act-acceleratorstrategic-review/ (accessed Dec 1, 2021).
- 22 Donaldson M, Kingsbury B. The adoption of transparency policies in global governance institutions: justifications, effects, and implications. Annu Rev Law Soc Sci 2013; 9: 119–47.
- 23 The World Bank. Access to information: annual report. Washington, DC: The Work Bank, 2020.
- 24 Curato N, Dryzek JS, Ercan SA, Hendriks CM, Niemeyer S. Twelve key findings in deliberative democracy research. *Daedalus* 2017; 146: 28–38.
- 25 The Lancet. The ACT Accelerator: heading in the right direction? *Lancet* 2021; **397**: 1419.
- 26 Usher AD. Decolonise COVAX: an African critique. July 13, 2021. https://www.development-today.com/archive/dt-2021/dt-5-2021/ decolonising-covax-a-ugandan-epidemiologists-perspective (accessed Dec 1, 2021).
- 27 Cullinan K. African Union special envoy slams COVAX as COVID deaths spike on the continent, urges donors to 'pay up' on vaccine pledges. July 1, 2021. https://healthpolicy-watch.news/africanunion-special-envoy-slams-covax-as-covid-deaths-spike-on-thecontinent-urges-donors-to-pay-up-on-vaccine-pledges (accessed Dec 1, 2021).
- 28 Moon S, Agarwal S, Becker A, Alonso Ruiz A. Embedding global access in development of future pandemic vaccines. *BMJ* 2021; 374: n2256.

Copyright © 2021 Elsevier Ltd. All rights reserved.