

# Pandemic Preparedness and Response: Key Provisions for a New Treaty

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## 1. Overview

The global response to the COVID-19 pandemic has been far from satisfactory. It has been characterized by tribalism, nationalism and ensuing unnecessary loss of life as well as inequities [1]. Some estimate that the chance of another pandemic as disruptive as COVID-19 or worse is about 22-28% in the next 10 years [2]. Climate change and antimicrobial resistance are predicted to further contribute to rising risks for emergency mass critical care events and resulting hospital surges [3]. Better scientific, technological, and ethical preparation could not be more important for addressing future pandemic threats [4, 5].

In this ongoing pandemic, we have seen how nationalism has trumped cosmopolitan solidarity and impeded equitable access to vaccines and therapeutics [6]. The World Health Organization (WHO) - with a mandate to ensure "Health for All" - found itself unable to protect everyone's health despite a multitude of existing treaties and agreements with its member states and collaborations with other international organizations [7]. None of the existing mechanisms have the power of law and none can trump sovereignty of the self-interested country. Even the International Health Regulations (2015), which are legally binding on all 194 WHO member states, have poor compliance due to ineffective instruments to monitor and enforce the regulations [8]. Existing intellectual property regimes, under which pharmaceutical firms operate, have also been obstacles to the adequate supply, affordable pricing, and equitable access to COVID-19 vaccines and other health products [9]. Although it is important to expand manufacturing capacity in developing countries, patents, trade secrets, data rights and other intellectual property protections also pose barriers to accessing such essential health technologies [19].<sup>1</sup>

The new multi-stakeholder mechanisms put in place by the WHO and other global actors to guide innovation, develop pandemic related health technologies including vaccines, diagnostics, and therapeutics, and equitably distribute them globally - the Access to COVID-19 Tools Accelerator (ACT-A) and COVID-19 Vaccines Global Access (COVAX) pillar - failed to meet even their partial, acute-phase objectives [86]. COVAX allowed countries to pool buying power to invest in the development and distribution of new vaccines. Unfortunately, because of bilateral competition and inadequate funding, the ACT-A and COVAX have been unable to meet global demand for essential health technologies. COVAX is the best funded and largest component of the ACT-A, yet only aims to distribute vaccines to 20% of the world's population by the end of 2021 and is off track to meet even this unambitious target [19]. More generally, the ACT-A did not secure sufficient funding for development, manufacture, and distribution of

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<sup>1</sup> Moreover, in its first phase COVAX distributes vaccines equally to all participating countries, even though some have been able to purchase the vaccine directly from the manufacturer, often at very high prices, disadvantaging poorer/less well developed countries that are not able to procure vaccinations either directly through pharmaceutical firms or through bilateral deals and depend only on COVAX [19,87].

diagnostics, therapeutics, and other essential health technologies. It did not help countries secure the resources necessary to invest in the basic health systems required to deliver essential health technologies.<sup>2</sup> It did not foster the kind of collaboration necessary to ensure adequate demand for, and

uptake of, these technologies such as investments in additional recruitment and salaries of healthcare workers especially in countries already facing severe human resources for health shortages. Finally, without a binding commitment, the WHO's attempt to get companies to share data and research results has not been successful to date and we lack sufficient knowledge, intellectual property, and technology transfer initiatives to support generic companies in less advanced economies in making vaccines [9].<sup>3</sup>

In our opinion, the ACT-A was not fit for purpose from the beginning, its goals were too modest, and the international community's assumption that it could adequately address the COVID-19 pandemic was unrealistic. It naively depended on the private sector without sufficiently safeguarding the interests of those in low- and middle-income countries (LMICs) and its governance, transparency, and accountability structures were too colonialist and charity-based, with decisions primarily led by the global North [10, 11]. It did not have the representation and feedback mechanisms in place needed to ensure that countries could deploy new technologies as they received access. The loosely governed, multi-stakeholder "collaboration", where key decisions are made in part by industry representatives with clear conflicts of interest, and without sufficiently clear lines of accountability – is a weak foundation for the institutional response needed for ongoing and future pandemic risks [10, 11]. Without greater cosmopolitan solidarity, a spirit of benefit sharing, and cooperation, we cannot fight the current pandemic, never mind future pandemics, efficiently or effectively [13, 88, 89, 18].<sup>4</sup>

Although adequate pandemic preparation and response requires many things, the international community must come together to create a globally acceptable regime for the development of, and access to, health technologies, including diagnostics, vaccines and therapeutics and should enable health systems strengthening. This regime should reward innovation while ensuring robust supplies, affordable and perhaps differential pricing, equitable access and distribution of public health related technologies. It should explicitly embrace needed patent waivers and technology transfer requirements and a shift away from nationalism to 'globalism'. During this pandemic, in the face of national demands, without a binding pre-existing commitment, national governments often reneged on bilateral or multilateral rhetorical commitments, since there were no enforceable legal requirements. Therefore, for future pandemics, it is necessary to institute an accountable global structure governed by international law. We believe that without such significant global obligations, adequate pandemic preparedness will remain a distant hope, and securing equitable distribution of pandemic related health technologies to all people of the world, a dream. The current pandemic has amply demonstrated the epidemiology of pandemic infectious diseases that can, and will, mutate in unvaccinated and untreated populations presenting ongoing risk even in islands of pseudo-immunity [15].

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<sup>2</sup> "High income countries only have to increase healthcare spending by 0.8% to vaccinate 70% of the population, whereas low income countries have to increase their healthcare spending by 56.6%" and the ACT-A's health connector does not provide the requisite support [10, 12].

<sup>3</sup> Although we focus primarily on what is necessary to allocate essential health technologies below, we should buttress many other aspects of pandemic preparation and response as well – from surveillance to testing, tracing, and isolation capacity for a variety of potential pandemic threats.

<sup>4</sup> To its credit, the ACT-A interim review recognizes some of these failings but does not address the fundamental representation and governance issues e.g. embodied in its Facilitation Council. Nor does it set concrete goals for the kinds of health systems and other investments we advocate [14].

The call for a re-look at the current legal landscape and the consideration of a legally binding convention on pandemic preparedness and response is not new. As early as January 2021, the WHO Director-General issued a call for the formulation of a legally binding treaty for enhancing political commitment to pandemic preparedness and response, which itself built on earlier calls for new international legal agreements governing global health security challenges such as antimicrobial resistance [16, 17, 18]. Some recommend a top-down approach that includes strengthening global public health governance and promoting compliance with existing global health security regulations as part of that treaty [13]. It has become increasingly clear in this current pandemic that this top-down approach must be accompanied by technology development and transfer, and that access is an equally important pillar of any pandemic response and must be the driving aim of any global treaty [16].

## 2. Our Proposal

How can we promote research and development on innovations for pandemics that may never happen or on pathogens whose nature we do not yet know? And if such technology is available during a future pandemic, how can we enable fast and equitable access at a global level? We propose an enhanced global response mechanism to speed up research and development of, and fair access to, essential health technologies that might be embodied in a new global agreement for better pandemic preparedness and response [19]. Fair access to these technologies requires ensuring that they are adequate, affordable, available, acceptable, accessible, and equitably distributed.

More precisely, we propose: 1) implementing alternative incentive and funding mechanisms for new scientific and technological innovations that contribute to the understanding or control of infectious diseases with pandemic potential on the condition that, 2) companies pool intellectual property and other data to speed up research and development and vest the licenses for resulting products in the WHO (or other relevant governing body per the agreement) to allow low-cost (e.g. generic) production. Moreover, this governing body - or Independent Secretariat - would provide 3) transparent, accountable, collective procurement to 4) support efforts to expand equitable access to essential health technologies by investing in manufacturing, distribution, and basic health systems. Furthermore, the international community should 5) explicitly embrace needed patent waivers and technology transfer requirements. Finally, the international community must 6) enshrine all these provisions in international law through a global convention. We discuss how such an agreement might be instituted and governed below, but first review its contours.

***Implementing alternative incentive and funding mechanisms:*** The basic idea is to provide alternative incentives and funding for innovations (diagnostics, therapeutics, vaccines and other essential health technologies) instead of patents, for priority conditions where current incentives and funding are insufficient to generate sufficient research and development and equitable access to resulting products [20, 21].<sup>5</sup> Priority conditions might include all major diseases on the WHO list of pandemic threats - COVID-19, Ebola, Marburg, Lassa fever, Crimean-Congo haemorrhagic fever, MERS-CoV, SARS, Rift Valley fever, Nipah and henipaviral diseases, Zika and “Disease X” (pandemic threats of unknown origin) -, and influenza [22, 23].<sup>6</sup> We also believe it is appropriate to include interventions to prevent and address

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antibiotic resistance arising for many pandemic pathogens [24]. Moreover, the list might extend to ongoing (e.g. HIV/AIDS, tuberculosis and malaria) pandemics where existing incentives do not suffice to adequately address these problems. The WHO, Coalition for Epidemic Preparedness Innovations (CEPI), or other international global health institution might provide target product profiles for pandemic disease counter-measures, but all pandemic diseases on which there is insufficient innovation should automatically gain eligibility for alternative funding and incentives, even where no products were originally solicited [25]. These profiles might specify different conditions for products at various stages of development. The incentives might come in the form of advance market commitments for companies with manufacturing capacity but can be provided in alternative funding for those without sufficient capacity.

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<sup>5</sup> There are many other proposals for expanding access to essential health technologies in the literature [27].

<sup>6</sup> This can be expanded to other existing or future pandemics as the threats evolve.

The initial incentives might be garnered in many ways and our proposal is compatible with many different innovative financing mechanisms. One possibility is to link incentives for new technology development to a global financial transactions or technology tax currently under deliberation [26]. Voluntary contributions from philanthropic organizations and compulsory contributions from signatories to any agreement implementing this proposal might also suffice to generate the needed funds.

Some suggest a total pool of US\$50bn for these kinds of efforts - enough to purchase a vaccine for 70% of the global population (5 billion people) at US\$10/dose or multiple treatments at a lower price point - and much less than the estimated cost of the pandemic (we discuss below how to decide on incentives for particular innovations) [28]. Such investments are in line with other proposals for research and development (R&D) and access initiatives for pandemic preparation and response may also suffice to produce and distribute many medicines to significant portions of the global population [29, 30, 31].

To compete only for products developed from smaller companies and organizations' R&D efforts (>30% of pharmaceutical R&D is simply acquired by larger companies), smaller pools will suffice [32]. New products typically receive up-front payments of between a few hundred thousand and a few million dollars (averaging around 800 thousand USD) and royalties for subsequent disbursement [33]. Here the upfront payments would likely need to be higher given that the need for any particular product to prevent or combat a future pandemic may not be very likely to materialize (though this would not be the case for existing pandemics), but it is also possible to provide some rewards once technologies reach patients [34].

***Pooling intellectual property, sharing data, & vesting licence for resulting products in the Independent Secretariat:*** As a condition of receiving the incentives companies would vest the licence for manufacturing resulting products for specific conditions or uses in the Independent Secretariat as specified by a global agreement, which would then be able to licence out production to (e.g. generic) manufacturers. These licenses should allow unrestricted sub-licensing of new technologies for production and distribution in all locations. Where the Independent Secretariat can ensure sufficient supply, it should simply allow generic or generic equivalent production and competitive sale of new medicines and technologies (and pool patents, data, know-how, and other essential knowledge required for production). This will encourage companies to build on each other's scientific research when they develop new technologies. About 80% of global drug manufacturing is in the generics sector and generic production will greatly lower costs [35, 36, 37]. When supply is constrained, companies can receive licenses from the Independent Secretariat to produce the drugs only on specified (cost and provision) conditions.

Companies must also agree to share data and knowledge to speed up the development of safe and effective products around the world as proposed through C-TAP, the WHO Tech Transfer Hubs, and the Medicines Patent Pool for COVID technologies [38]. To ensure that the rewards are large enough to provide investments for future R&D, companies must share (current) data on R&D costs. We should also require them to make public their pre-clinical and clinical trial results and data within a reasonable time period to speed up the production of new vaccines and technologies, which many studies have shown does not consistently happen, especially for technologies developed by small and medium sized companies [39, 40, 41]. Finally, it is essential that companies share knowledge and other data that will support the manufacturing and provision of the medicines by other firms [9].

The Independent Secretariat may agree to pay a price per estimated (disability adjusted) life saved that is sufficient for companies to recoup costs plus optimal R&D investment. Current estimates of R&D drug

costs range from \$43.4 to \$4,200 million [42, 43, 44, 45, 46, 47, 48]. Incentives for new innovations must cover these costs and risks of not being the first to produce a product fulfilling a specific profile and be commensurate with acceptable and affordable market value for new products. They might also be in line with the estimated health impacts of new technologies - considering total disease burden alleviated by effective treatment [49]. Modelling of disease infectivity rates and estimates of pandemics' likelihood may inform rewards for preventative treatments along with information on interventions' effectiveness from clinical trials and treatment access [49]. When the WHO, CEPI, or another international organization is tasked with developing target product profiles, they might also estimate R&D costs and risks given pharmaceutical company data. Net incentives might fall in line with reasonable profits of other pharmaceutical products to ensure sufficient investment. Incentivising companies in this way delinks companies' profits from sales and ties them to good health consequences instead.<sup>7</sup>

***Transparent and Accountable Collective procurement to enable equitable distribution:*** We propose countries implement an international agreement that requires them to purchase only through the Independent Secretariat, which can price products differentially (charging more in rich than in poor countries), to ensure equitable access and sufficient funding for future investments in R&D [49].<sup>8 9</sup> Procurement efforts should at least involve pooled contracted negotiation on prices of essential health technologies globally as this will reduce transaction costs even for rich country public sector procurement organizations that regulate prices. They should also include information sharing on budgeting, pricing, forecasting, and the legal landscape [52, 53]. However, collective procurement may also include pooled contracting, acquisition, logistics, and delivery of these technologies where helpful to support country efforts and may involve a gradual scale up of UNICEF, regional procurement organizations, and/or related distribution efforts [53]. The funds saved may suffice to support the development of new manufacturing capacity, investments in cold chains, and other aspects of demand and supply development necessary for vaccine deployment and uptake [54].<sup>10 11</sup>

***Investments in manufacturing, distribution and basic health systems to expand equitable access to essential health technologies:*** Future pandemic preparedness response should not just focus on technologies and vaccines but include significant investments in manufacturing and distribution capacity and health systems strengthening. Investments in the training and recruitment of health care workers (both skilled and community health care workers) and equipping them with the right tools, and technologies to prevent, contact trace, diagnose, treat, and support clients is critical. Priority in many LMICs should go to expanding, and strengthening, community systems and community-led interventions such as health information, education and communication strategies, demand generation, and outreach.

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<sup>7</sup> Some suggest rewarding pharmaceutical companies and other R&D organizations for new innovations based on their health consequences. To this end, good measures of health impact exist (see below for further discussion) [49, 50].

<sup>8</sup> Measures exist to combat parallel importation of cheaper technologies from poorer to richer countries should this problem arise.

<sup>9</sup> Others are advancing closely related ideas as well: [44] also see redacted [55]. However, our proposal goes beyond those in the literature to discuss ways of making this kind of mechanism actionable.

<sup>10</sup> Some "analysis of pharmaceutical prices suggests that monopsony power can reduce the price paid by a pooled procurement agency by as much as 50 percent" [53, 56, 57].

<sup>11</sup> It is essential to invest "in in-country capacity for making informed procurement decisions through strengthening local institutions and supply chains... [and implementing pooled procurement mechanisms requires] political will, funding, and an operating model that takes into account barriers countries will likely face. With their technical expertise, infrastructure, and long-cultivated supplier relationships, donor organizations could help develop such a model" [53]

We should scale up manufacturing and delivery capacity in all regions and ensure sufficient technology transfer. It is essential to build countries' supply and coordinate, harmonise and align donor's supply and distribution channels well before the onset of a new pandemic [54]. This will require improving, and potentially linking, international distribution channels like the WHO Procurement platform and regional ones like the African Medicines and Supplies Platform (potentially to manufacturers in different regions with appropriate technology transfer). Technology transfer is essential to overcome the monopolies and high prices that make new tools, technologies, diagnostics, and vaccines inaccessible [54]. It is also important to strengthen and build country level capacities for distribution and that they lead this process.

Strong health systems can play a critical role in preventing and mitigating adverse impacts of future pandemics. Even before essential tools and technologies are accessible, affordable, and available, the international community must prepare and invest in health systems at the country and implementation level [54]. Strong health systems require a robust policy environment, robust health governance and leadership, and coordination mechanisms at country and global levels. They also require investments in data, monitoring, evaluation and surveillance systems. Most importantly, the international community must invest in training, recruitment, and remuneration of health workers to deliver a robust pandemic response. We should also invest in education and uptake initiatives partnering with civil society and other community organizations and avoid duplicating existing efforts.

***Intellectual Property Waivers and Technology Transfer:*** The international community should explicitly embrace needed intellectual property waivers and technology transfer requirements along the lines of the India/South Africa proposal for a temporary waiver on intellectual property protections on COVID-19-related health technologies.<sup>12</sup> The Trade Related Intellectual Property Rights (TRIPs) agreement instituted by the World Trade Association allows compulsory licensing of patents on multiple grounds, including, with expedited procedures, for public health emergencies [58]. It should be interpreted to allow compulsory licenses on trade secrets and confidential information as well. It is possible to provide compensation for IP-free technology acquisition at reasonable rates to preserve incentives for innovation even with compulsory licensing. However, country-by-country, product-by-product compulsory licenses are often administratively burdensome [59]. So, countries should commit to assisting other countries in securing the knowledge and technology necessary to produce essential health technologies where necessary not only by waiving IP barriers and mandating technology transfer, but also by reducing restrictions on the importation and exportation of components and products. When voluntary efforts fail to ensure equitable access, intellectual property barriers and technology transfer refusals should not stand in the way. Instituting the other portions of the agreement we propose will help the international community scale up manufacturing capacity that will support access as long as the international community requires pharmaceutical companies and other organizations to share the relevant intellectual property, knowledge, and technology.

Given the large public investments in essential technology development it is reasonable to require good access conditions for the provision of property rights [60]. COVID-19 has shown how much the development of essential pandemic preparation and response technologies depend on public financing

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<sup>12</sup> Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19, IP/C/Wi669/Rev.1 (May 25, 2021), <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669R1.pdf&Open=True>.

and de-risking. US taxpayers essentially paid for, and took on all financial risks associated with, developing/trialing the Moderna vaccine, yet only Moderna shareholders and executives have received a direct financial return on this investment [61]. The international community should collaborate to require good access terms for such non-market interventions where needed.

Good examples exist of organizations implementing something along the lines of each of the components of our proposal above. The Medicines Patent Pool helps companies share intellectual property and other information and UNICEF already collectively procures 45% of the vaccines for children under 5 [62, 63]. The Affordable Medicines Facility-Malaria (AMFm) is an example of a global subsidization mechanism that effectively provides lower prices for medicines in poorer countries and differential pricing is practiced effectively by many individual corporations [64]. Countries often compulsorily license medicines - though they require more support for manufacturing, distribution, and uptake of new technologies and our proposal provides a way of securing the needed funds [65].

***Convention on pandemic preparedness and Response:*** We support the development of an international agreement with good governance and enforcement mechanisms to create the proposed incentives for new product development and ensure collective procurement and access (e.g. through an international treaty) [66, 67]. This may require modifying existing laws and policies, where needed, to make the provisions we propose actionable. Moreover, as part of this agreement, all countries should commit to strengthening their health systems and increasing capacities in research and manufacturing with available funds.

The governance for the coordination mechanism, or Independent Secretariat, we propose need not rely on the existing response architecture and could well be under the purview of the WHO alone but, in any case, should better represent the interests of all those affected by the pandemic – including patient groups, health care provider representatives, civil society, philanthropic organizations, policy makers, both in high and those in low- and middle- income countries [68].<sup>13</sup> Discussions and debates in the Secretariat should be conducted in an international fora in an inclusive manner, keeping in mind that the outputs of the discussions will be relevant for the whole world, not only the high income countries (HICs). Thus, LMICs must be involved in all discussions at all levels and as early on in the process not just as tokens but in ways that are meaningful and numbers that are representative. Relevant stakeholders must be included in the discussions at an early stage prior to designing the criteria for calculating rewards (and specifying their conditions), as well as for distributing essential health technologies.<sup>14</sup> Terms of reference should be devised for this purpose, stating clearly who will be entitled to participate in the mechanism's design, as well as how the processes of deliberation will take place and who decides and has a final say.

Our proposal embraces decolonisation at its core in specifying that the Secretariat should fully represent the interests of the global population, especially the LMICs. The Secretariat must include LMICs in setting priorities for an effective pandemic response. The Secretariat must have proportional representation of LMIC experts in leadership roles and throughout the governance structure and be responsive to

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<sup>13</sup> Countries negotiating such an agreement should be bound to act in the common interest rather than as representatives of only the interests of their own populations.

<sup>14</sup> This is essential for many reasons but one is to ensure adequate trust, demand for, and uptake of new technologies.

indigenous knowledge to be equitable and effective [69].<sup>15</sup>

Moreover, it is essential that any agreement implementing this proposal be transparent, accountable, and backed by appropriate enforcement mechanisms. Enforcement mechanisms might include benefits, or incentives, for participation, if not penalties for countries refusing to comply with the agreement. Although all countries will benefit if the agreement saves lives and prevents the loss of a great deal of economic activity, additional incentives for participation might include foreign aid, technical assistance, data and information sharing, policy guidance, and other help with pandemic preparation and response. LMICs should receive capacity building support in setting up manufacturing, distribution, and basic health system capacity and technology transfer before the onset of major pandemics so that they are prepared to respond. Given that countries not participating in international pandemic preparedness and response mechanisms pose a public health threat, responsive measures might include restrictions to protect public health and ensure collaboration in pandemic times.<sup>16</sup> Other measures might also include naming/shaming via soft law and moral suasion. Civil society may help secure countries' participation and address breaches of the agreement by informing public opinion as long as they are part of key decision-making processes and have the requisite information [13].

It is important to design enforcement mechanisms that are in line with existing international law. Trade restrictions on the movement of goods and people are allowed under the General Agreement on Tariffs and Trade and other international regimes to protect public health, for instance [58]. Although the TRIPs provisions would not be altered simply by the creation of another treaty, implementing one detailing conditions under which compulsory licenses on all forms of intellectual property should be issued to protect public health might tame the implementation of the TRIPs agreement if it is not modified as well [70], though it would surely be preferable for the Agreement to be modified to allow more directly for an effective pandemic response. Moreover, the processes of deliberation proposed above could involve input by multiple intergovernmental organizations with a mandate in different areas. They could verify the legality of enforcement mechanisms. For instance, if sanctions are explored, due regard should be paid to the United Nations (UN) Security Council as an international organ with unique powers under the UN Charter [71]. At the outset, this will require the political will of all five veto-holding members.<sup>17</sup>

It might be harder to get countries to abide by the terms of an agreement along the lines we propose at the start of a major pandemic than to get countries to sign on, but even if cooperation is not sustainable during a major pandemic, cooperation to develop preventative measures and treatments in non-pandemic times may suffice to prevent, and help address, future pandemics. Moreover, instituting mechanisms that work in normal circumstances may make it easier to sustain cooperation during crises [72]. Appraising the participatory criteria in ordinary times, as well as reviewing the implementation difficulties in other fields of international law, could help devise commitments that can aspire to be both legally sound and reasonably effective [18].

Even aspirational or normative agreements that are not fully effective, such as an ideal of collective

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<sup>15</sup> If the Secretariat is within the WHO, then the terms of reference of the Secretariat can build on these requirements.

<sup>16</sup> Though implementing barriers to the movement of some goods or people may require modifying existing rules under the WTO and require countries willing and able to enforce such measures. See discussion below.

<sup>17</sup> Namely, the United States, China, Russia, France and the United Kingdom.

procurement and R&D guided by global health interests, can be important in practice. When powerful countries feel aggrieved, they will often adjudicate in political as opposed to legal fora, but an existing agreement can provide a pressure point, and process, for resolving disagreements helping to get people to the table. Moreover, it may be more difficult to deviate from procedures as they become ingrained, or enmeshed, in many other systems. So, a well-designed legal agreement can help provide clarity on which states are conducting themselves in line with their commitments, and possibly even foster avenues for correcting deviations.

It is essential that country-level participation, coordination, and support mechanisms are put in place and that health system strengthening is not viewed as under the purview of countries alone - the mechanisms we propose might generate the necessary resources necessary to provide this support. The international community cannot wait until the next pandemic to invest in this effort. Access to medicine and other essential health technology requires more than research and development. Health systems need to be strengthened and funded to support surveillance, and early detection. Testing capacities need to be universally available. People need to actually receive essential technologies through good quality and equitable health and community services. Beyond vaccines, personal protective equipment, basic medical supplies, testing, diagnosis and treatment are also essential [54, 73]. To ensure access to all of these things, countries need sufficient manufacturing, transportation, distribution, cold chains, and other health care infrastructure [50]. Health care systems also need sufficient health workforce and supplies of essential medical equipment. We must equitably test and quickly approve safe technologies that can serve the majority of the world's population [74]. We must work on building demand for new technologies to ensure uptake [75].

One legal possibility is to expand the current obligations in the International Health Regulations to develop so-called minimum core capacities [8]. These provide for a series of areas where states commit themselves to strengthen their healthcare systems. Considering the objectives of the regulations, mostly geared towards disease surveillance and response, the IHR has not included securing medicines as the means to protect the population's health. So far, these capacities remain underdeveloped in several countries throughout the world. Any new mechanism should include concrete roadmaps and commitments supporting the effective distribution of essential health technologies from their locations of manufacture to the point of care in all countries. A repeat of the underwhelming fulfilment of obligations to collaborate under the International Health Regulations should be avoided [8].

### 3. Defending the Proposal: Global Cooperation, Solidarity & Human Rights

There are good moral as well as prudential and legal reasons for countries to come together to implement a proposal along the lines articulated above. Ethical principles of reciprocity, solidarity, fair distribution (justice), and human rights all provide strong ethical reasons to implement our proposal [49, 50, 51]. As the recent pandemic has shown, the lack of preparedness and cooperation lead to wildly unequal distributions of diagnostics, therapeutics, vaccines and, partly for this reason, terrible inequities in the health impact of the disease [76]. In order to avoid such outcomes in the future, it is essential that we strengthen our pandemic preparedness and response in a way that recognizes the obligations and responsibilities of all stakeholders. Our proposal provides a path forward for such preparations.

Some might object that there are other actions the international community could take which would have a higher impact. Why should countries such as Sweden, the United States, and France devote financial resources and efforts to prepare for future pandemics that might not even occur when the very same resources with certainty could have high impact battling existing diseases (e.g., cancer or diabetes)?

This objection relies on a false dichotomy. Rich countries do not face a choice between mitigating the global burden of disease or preparing for future pandemics. Rich countries face two different choices: (i) to mitigate the global burden of disease or not, (ii) to prepare for future pandemics or not. Making the right choice in the first instance does not mean one can make the wrong choice in the second instance.

Others might suggest that instead of supporting our proposal, the international community could just provide more funds to CEPI for new research and development or better fund the current ACT-A [77]. CEPI, like many other global health research and development organizations, simply pays for Phase 1 and 2 clinical trials and then pharmaceutical companies keep the patents on their technologies [78]. Access provisions are negotiated on a case-by-case basis [78].

This is not acceptable. The rhetoric is that the research and development system works well so we should only focus on expanding access [27]. But we do not believe this is the case. The research and development system works well for the wealthy, it simply fails to serve the global poor at all in many cases [27]. Moreover, we can greatly improve the research and development systems by requiring knowledge and data sharing and doing so provides the key to improving access. But we cannot leave it up to companies whether or not to share their technology and data. We must make the rewards we provide them conditional on their providing this information to ensure adequate supply, affordable pricing, and equitable access [79]. Because doing so was entirely voluntary and companies lacked the requisite incentive, they simply did not join C-TAP, the WHO Tech Transfer Hubs, or the Medicines Patent Pool for COVID technologies [79]. Companies are perfectly willing to accept public funds to de-risk their pandemic-related R&D through CEPI and to take additional government money to expand fill and finish capacity that they control. The problem is that these public funds should not be given to companies without stringent access conditions. We have also provided significant reason to worry about continuing with the ACT-A architecture especially given its loose governance structure and lack of ability to ensure equitable access to resulting products.

Yet others might argue for alternatives to our proposal that we believe are demonstrably worse. For instance, some may advocate for allowing bilateral deals within limits [80]. These authors might suggest that countries should reallocate vaccines to help the global poor when they are not able to utilize them or when they have their own pandemics under control.

Bilateral deals lead to highly inequitable outcomes, and perpetuate the colonial model of global health [6, 81]. They also withhold agency from the low and middle income countries to develop capacities for innovation and manufacturing, which our model successfully supports. Moreover, it is not clear that widespread access will ever materialise in poor countries if rich countries continually offer boosters to their populations, buying up available supply [82].

A worry about our proposal might be that a fully multilateral approach along the lines we advocate might require too much cooperation [83, 80]. There are no completely global procurement institutions in place to date. Rich countries have undue influence over international health organizations because they pay a great proportion of their budgets and can also exercise significant influence over pharmaceutical companies within their boundaries. They may simply exit or renege on international agreements and when it is in their best interest to engage in bilateral deals, pressure pharmaceutical companies to provide them priority access, or issue export prohibitions to secure scarce supplies. Finally, collective procurement may not suffice to secure sufficient innovation in the future if the prices paid for new innovations are not in line with current prices.

While we share some of these worries, we believe that it is in the interest of all countries to collaborate, because as we have amply seen in this pandemic - “No one is safe till everyone is safe” [84]. This is also an opportune moment to push for positive change in the pharmaceutical sector. Whether our proposal is feasible will depend on countries’ and pharmaceutical companies’ buy in.<sup>18</sup> If the rewards are sufficient, pharmaceutical companies are likely to support the proposal. For countries, feasibility will be determined by the terms of any new treaty or agreement to implement the mechanism proposed here.<sup>19</sup> It is important to take into account the potential economic costs prevented as well as lives saved from better pandemic preparation and response and the need for global coordination in pandemic control and prevention efforts. To date, 4.6 million people have died from the pandemic (with Covid-period excess mortality much higher) and some estimate that the Covid-19 crisis costs the world US\$375 billion monthly and will cost US\$8.5 trillion over the next two years [85, 55, 30]. Others estimate that vaccine nationalism alone is costing the world US\$1.2 trillion [30]. So, moving beyond bi-lateral deals and greatly enhancing the global response architecture had the potential to save millions of lives and trillions of dollars.

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<sup>18</sup> Some simply assume that the approach we advocate is not feasible, but we believe that what we can achieve together as an international community is up to us and even these authors highlight the importance of many parts of the proposal we articulate acknowledging that it is important to articulate principles for good bilateral deals that include reasonable access conditions, especially given the public funding provided for these technologies. They also stress the importance of transparency in negotiations, ensuring productive investments are made in manufacturing capacity, supply chain resilience, and sharing technical knowledge. We likewise acknowledge their suggestion that an agreement should at least help ensure that extra products are donated to poorer countries [83].

<sup>19</sup> Our proposal makes actionable the ideas in section 5 of the International Panel on Pandemic Preparation and Response's recommendations: [48].

## 4. Conclusion

In the current pandemic, wealthy nations have bought most of the world's Covid-19 vaccine and therapeutics supplies despite having a small proportion of the global population leaving many countries without access to any vaccines at all, and even those who can access the vaccines often lack other resources they need to effectively combat the virus. From a human rights perspective, this is entirely unacceptable. Moreover, future pandemics may prove much more devastating without global cooperation. We have argued for an equitable, transparent, accountable new global agreement to provide rewards for research and development but only on the condition that pharmaceutical companies share knowledge, data, and intellectual property rights necessary to produce and distribute them globally. Moreover, if countries commit to collective procurement and fair pricing resulting products, we have argued that we can greatly improve our ability to prepare for and respond to pandemic threats. We must work together to overcome the kind of vaccine/therapeutic/diagnostic/PPE nationalism undermining our current global response plans to adequately address and prevent future pandemics.<sup>20</sup>

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<sup>20</sup> Our proposal provides a way of realizing the IPPPR's fifth recommendation to "Establish a pre-negotiated platform for tools and supplies" and more specifically to:

- I. Transform the current ACT-A into a truly global end-to-end platform for vaccines, diagnostics, therapeutics, and essential supplies, shifting from a model where innovation is left to the market to a model aimed at delivering global public goods. Governance to include representatives of countries across income levels and regions, civil society and the private sector. R&D and all other relevant processes to be driven by a goal and strategy to achieve equitable and effective access.
- II. Ensure technology transfer and commitment to voluntary licensing are included in all agreements where public funding is invested in research and development.
- III. Establish strong financing and regional capacities for manufacturing, regulation, and procurement of tools for equitable and effective access to vaccines, therapeutics, diagnostics and essential supplies, and for clinical trials:
  - a. based on plans jointly developed by WHO, regional institutions, and the private sector;
  - b. with commitments and processes for technology transfer, including to and among larger manufacturing hubs in each region; and
  - c. supported financially by International Financial Institutions and Regional Development Banks and other public and private financing organization [45].

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