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#### Factors influencing global equitable access to COVID-19 vaccines for Low-and Middle-Income Countries: A scoping review

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Complete List of Authors:	Peacocke, Elizabeth; Norwegian Institute of Public Health, Division for Health Services Frønsdal, Katrine; Norwegian Institute of Public Health Knowledge Centre for the Health Services, Division for Health Services Heupink, Lieke; Folkehelseinstituttet, Global Health; Chola, Lumbwe; Norwegian Institute of Public Health,
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### FACTORS INFLUENCING GLOBAL EQUITABLE ACCESS TO COVID-19 VACCINES FOR LOW-AND MIDDLE-INCOME COUNTRIES: A SCOPING REVIEW

#### Authors: Elizabeth Peacocke, Katrine Frønsdal, Lieke Fleur Heupink, Lumbwe Chola

Corresponding author: Elizabeth Peacocke, DPH, Norwegian Institute of Public Health, Division for Health Services (a) <u>Elizabeth.Peacocke@fhi.no</u>, t. +47 941 60 559

Katrine Bjørnebek Frønsdal, PhD. <u>Katrine.Fronsdal@fhi.no</u>, Norwegian Institute of Public Health (a) Lieke Fleur Heupink, MSc. <u>LiekeFleur.Heupink@fhi.no</u>, Norwegian Institute of Public Health (a) Lumbwe Chola, PhD. <u>Lumbwe.Chola@fhi.no</u>, Norwegian Institute of Public Health (a)

iez

(a) Norwegian Institute of Public Health

Division for Health Services

Postbox 222 Skøyen, 0213 Oslo, NORWAY

Visiting address: Sandakerveien 24C, entrance D11, 0473 Oslo, NORWAY

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#### Abstract

Background: In the last months of 2020 several COVID-19 vaccines reached the stage of development where they could be introduced as a public health measure to help curb the pandemic. With one vaccine receiving the Emergency Use Listing from the World Health Organization in December, the international community is now facing the challenge of how to ensure equitable distribution and access to COVID-19 vaccines globally. Historic approaches indicate that possible inequities in distribution and access are more likely to affect countries with less resources. In this scoping review, we have systematically reviewed the literature to identify factors that can influence the equitable access of COVID-19 vaccines relevant for Low- and middle- income countries.

Methods: The review followed the PRISMA guidelines for scoping reviews and a five-stage framework for scoping studies. Searches in four databases of peer-reviewed journals resulted in 1,492 unique citations screened to the topic based on titles and abstracts. 78 citations were considered relevant and further reviewed in full text, of which 13 were selected as meeting our predefined inclusion criteria, with no limitations based on study design nor publication type.

Results: Through our analysis of identified factors, we derived six key messages: 1) Collectively agreed global mechanisms or frameworks may facilitate equitable access to COVID-19 vaccines, 2) Financial mechanisms such as collective Advanced Purchase Agreements may favor fair allocation, 3) Large-scale vaccine manufacturing and distribution can support fair allocation, 4) Sharing manufacturing know-how with Middle income countries can support supply of COVID- 19 vaccines, 5) Reciprocity facilitates equitable access, and 6) Countries' strength in implementing vaccination programs may influence their populations access to vaccines.

Conclusion: This scoping review determines the main challenges facing equitable access to COVID-19 vaccines, but does not aim to provide solutions on how to overcome these challenges. However, the majority of the articles pointed to collectively agreed and legally binding mechanisms as likely to be essential for the fair allocation and equitable access to COVID-19 vaccines between countries.

Strengths and limitations of the study

- Literature was exclusively chosen based on relevance to the topic of identifying and describing factors related to equitable access as identified in peer-reviewed journals, no additional quality assessment of the articles was completed.
- The search was completed once (28 August 2020), in light of the numerous papers published related to the COVID-19 pandemic on a daily basis, there may be relevant articles published after our search that should have been included in this brief.
- We followed the Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) and were guided by the Arksey and O'Malley's five-stage framework through the steps of the review.

#### **Key questions**

What is already known?

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• The international community is facing the challenge of how to ensure a fair and transparent global distribution and equitable access to COVID-19 vaccines. There continues to be a need for action related to equity considerations and ensuring global coordination and distribution mechanisms of vaccines for Low- and middle- income countries.

• Countries' tendencies to control the global supply of personal protective equipment and ventilators at the beginning of the COVID-19 pandemic are proving to continue with those pandemic vaccines that received regulatory approval.

• Historic approaches to vaccine distribution indicate that possible inequities in distribution and access are more likely to affect countries with less resources.

What are the new findings?

• This scoping review indicates that collectively agreed global mechanisms or frameworks may facilitate equitable access to COVID-19 vaccines; Financial mechanisms such as collective Advanced Purchase Agreements may favor fair allocation; Large-scale vaccine manufacturing and distribution can support fair allocation; Sharing manufacturing know-how with Middle income countries can support supply of COVID-19 vaccines; Reciprocity facilitates equitable access; and Countries' strength in implementing vaccination programs may influence their populations access to vaccines.

What do new findings imply?

• There are lessons to be learnt from previous experiences and support the understanding of principles related to equitable access to a COVID-19 vaccine, and through determining these key

factors, which can potentially guide implementation of future initiatives to ensure equitable access.

#### **INTRODUCTION**

The Coronavirus Disease of 2019 (COVID-19) was declared a pandemic by the World Health Organization (WHO) on March 11, 2020. Considerable efforts have been mobilized in developing vaccines and investing in manufacturing capacity, for which there is unprecedented demand. The manufacturing capacities and infrastructure requirements for vaccine production and distribution will depend on the type of vaccine candidates that prove to be most successful in combating the pandemic, and will in turn determine the necessary manufacturing capacity<sup>2</sup>. The demand for safe, affordable, and effective COVID-19 vaccines is expected to outstrip supply for a considerable period of time<sup>3</sup>.

The lesson from previous pandemics is that the benefit of new vaccines is not shared equally across countries. Low- and middle- income countries (LMICs) face unique challenges in accessing vaccines as they do not have the same resources to purchase vaccines and are less likely to have the know-how and technological capacity to be able to manufacture their own vaccines. They are therefore more reliant on multilaterally agreed frameworks or bilateral support to access new technologies<sup>4</sup>. Within the LMIC group of countries there are unique considerations for Middle income countries (MICs). Some MICs are established vaccine manufacturing nations whose expertise can support the scale-up of vaccine manufacturing. In addition for those MICs that have the financial means to purchase COVID-19 vaccines, they may

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face uncertainty in their ability to obtain vaccines, as was experienced by Mexico, which were marginalized in the 2009 influenza A (H1N1) ("Swine flu") pandemic<sup>5</sup>.

The global community has previously in part responded to the abovementioned shortcomings with mechanisms designed to promote equitable access. The 2006 WHO Global pandemic influenza action plan, for instance, which was produced to support increased vaccine supply and the global vaccine manufacturing capacity by enabling technology transfer to MICs<sup>6</sup>. The Pandemic Influenza Preparedness (PIP) Framework developed following the H5N1 outbreak in Indonesia 2005 triggered increased interest in the Global Influenza Surveillance and Response System (GISRS), which in turn lead to the WHO intergovernmental process and further scrutiny of the GISRS and its influence related to the development of influenza vaccines<sup>7</sup>. Following the Swine flu in 2009, this pressure increased, and it was acknowledged that the lacking vaccine distribution system was associated with the failure to ensure fairness, transparency and equity in access to vaccines for LMIC<sup>478</sup>.

Specifically for COVID-19, WHO has led the Access to COVID-19 Tools (ACT) Accelerator global collaboration, designed to fast-track development, production, and equitable access to COVID-19 tests, treatments and vaccines<sup>9</sup>. COVAX, the vaccines pillar of the ACT, is an initiative whose role is proving to be integral in the equitable distribution and access to COVID-19 vaccines<sup>10</sup>. COVAX is co-led by the Coalition for Epidemic Preparedness Innovations (CEPI), a vaccine funding initiative, and Gavi, the vaccine alliance (Gavi). Member countries of COVAX include those that are self-financing investments but also others that are being supported through aid. Figure 1 provides an overview including timeline of introduced

mechanisms and guidelines before and following relevant pandemic events, as identified in our scoping review.

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These introduced mechanisms and guidelines are as identified in the 13 articles included in the scoping review

[attached as a .jpg file]

Most support the idea that access and distribution of COVID-19 vaccines should be equitable across countries, but what "equity" means in this context is often not specified. From the perspective of LMICs, equitable access to a vaccine is fundamentally linked to a fair and transparent global distribution framework. There are, however, different views of what equitable access to a COVID-19 vaccine for LMICs will mean. For the purpose of this review, equitable access is interpreted as all countries, and their populations, having equal access to COVID-19 vaccines, irrespective of the income status of the country in which they reside. Further, we considered a COVID-19 vaccine as an essential medicine\* and we have used the WHO definition of health equity^11 <sup>12</sup>. Several proposals have been made for equitable access of a COVID-19 vaccine between countries. In its first phase, COVAX plans to allocate vaccines in proportion to countries' total population so that all countries receive doses to cover 20% of their population<sup>13 14</sup>. Alternative proposals exist, including The Fair Priority Model proposed by a group of ethicists. This model goes beyond proportional allocation by proceeding with allocation of vaccines in three phases, that would in the first instance prioritize the prevention of more urgent harms earlier<sup>15</sup><sup>16</sup>. The ethical rationale behind this model argues that proportional allocation, as suggested by WHO and COVAX, is not the fairest solution as it implies that some

countries that have a relatively lower risk of death and disease from COVID-19, would receive access to vaccines at the expense of other countries that are facing more exposure<sup>16</sup>.

The aim of this scoping review is to identify and summarize the factors related to the equitable access of a COVID-19 vaccine for LMICs. To our knowledge, the literature related to the equitable access of a COVID-19 vaccine relevant for LMIC has not been systematically investigated. The review is considered highly relevant to the current situation as it can provide lessons from previous experiences and support the understanding of principles related to equitable access to a COVID-19 vaccine, and through determining these key factors, further potentially guide implementation of future initiatives to ensure equitable access.

\*Essential medicines are those that satisfy the priority health care needs of the population ^Health equity or "equity in health" implies that ideally everyone should have a fair opportunity to attain their full health potential and that no one should be disadvantaged from achieving this potential

#### **METHODS**

To enable replication of the search strategy and increasing the reliability of the study findings we performed systematic scoping searches for publications following the Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) and we were guided by the Arksey and O'Malley's five-stage framework through the steps of the review<sup>17 18</sup>. The study protocol was peer reviewed by methodological and subject experts at the Norwegian Institute of Public Health (NIPH).

Based on predefined inclusion criteria (Table 1), we systematically searched in the following four databases: Medline (PubMed and Ovid), EMBASE (Ovid), Global Index Medicus, WHO

https://www.globalindexmedicus.net/ and Web of Science Core Collection Clarivate Analytic. An information specialist in collaboration with co-authors developed the search strategies for the different databases (for complete search strategies, see Appendix 1). The searches were performed on 28 August 2020, and limited to published literature, with no limitations based on study design or publication type. The articles were exclusively chosen based on relevance to the topic of identifying and describing factors related to equitable access to vaccines, with no additional quality assessment of the publications selected.

Table	1:	Incl	usion	criteria

Criterion	Inclusion
Time	01 January 2002 - 28 August 2020
Language	English
Type of	Published in peer reviewed journals
article	1
Article focus	Pandemic vaccines incl. influenza or COVID-19 vaccine
Outcomes	Factors influencing equitable access to a pandemic vaccine
	including COVID-19 vaccines

Publications were first screened based on title and abstract according to the inclusion criteria. Two reviewers independently selected articles to be considered for full text screening. Selected articles were then read in full and considered for inclusion or exclusion by two different reviewers. Final decision of inclusion of relevant articles was determined through consultation between three of the reviewers. Any disagreements were resolved through discussions to reach consensus. See Appendix 2 for a list of the excluded articles and reason for exclusion.

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Data extraction was performed by one reviewer and verified by a second. Standard data extraction templates were used and adapted to extract information related to: the equitable access of a COVID-19 vaccine relevant for LMICs, global initiatives addressing equitable access to pandemic vaccines, challenges in implementing equitable access to vaccination, and recommendations for strengthening the equitable access to vaccination. Data were extracted and analyzed using a combination of adapting the multi-value ethical framework proposed by Liu et al. and inductive reasoning based on the findings from the literature<sup>19</sup>.

#### **RESULTS**

Excluding duplicates, we identified 1,492 potentially relevant articles (Figure 2). Screenings first based on title and abstract then on full text resulted in the final inclusion of 13 publications. See Appendix 3 for a description of the papers included in the review.

#### Figure 2: PRISMA flow-chart for selection of articles

[attached as a .jpg file]

We categorized the identified issues from the included citations into six thematic areas of factors potentially influencing access to COVID-19 vaccines in LMIC as presented below in a summary of the main findings (Table 2).

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### Table 2: Summary of main findings

Theme categorization	Scoping review finding	Articles contributing to the finding
Collectively agreed global mechanisms or frameworks may	Acting collectively and coordinated efforts across countries will facilitate equitable allocation of pandemic vaccines	20-23
facilitate equitable access to COVID-19	Global frameworks and multilateral organisations facilitate solidarity	4 21 24
vaccines	Examples of failures in collective action related to pandemic vaccines	5 25
	Historical vaccine donation and pledging systems have proven to be insufficient	20 24 26
Financial mechanisms such as collective	Financing mechanisms such as advanced purchase agreements (APA) can facilitate access in LMIC	4 21 26 27
Advanced Purchase Agreements may favor fair allocation	Place of vaccine manufacturing influences exporting of vaccines e.g. through national sovereignty over national borders	4 27-29
	Pandemic vaccines will largely be purchased by, and for use in, High income countries (HICs)	20 22 24 30
	Nationalistic ideologies can conflict with greater good of the world	1 5 22 24
	LMICs cannot procure or negotiate the purchase of pandemic vaccines at the same level as HICs	4 30
Large-scale vaccine manufacturing and	Substantial investment is required to finance global vaccine manufacturing	5 21-23 31
distribution can support fair allocation	Disparity between countries that have the capacity to produce vaccines and those that use vaccines	5 21 24 28
Sharing manufacturing know-how with MICs	Capacity building for technology transfer will support vaccine manufacturing and technology transfer in LMIC	4
can support supply of COVID-19 vaccines	Technology transfer of vaccine manufacturing (especially to MIC) supports increased supply	4 20
Reciprocity facilitates equitable access to vaccines	Historical attempts at equitable distribution of vaccines have disproportionately supported HIC and have not secured those benefits for LMIC	1 4 20 26 31
	Manufacturers have historically not reliably committed to reserving production of vaccines to LMIC	4 24
Countries' strength in implementing	A country's ability to vaccinate should be a consideration in equitable distribution	22
vaccination programs may influence their	Influenza vaccination has not been prioritized in LMIC compared to HIC	20
populations access to vaccines	A countries' regulatory approval and market authorization processes for vaccines can facilitate the distribution of vaccines	20 28

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## 1. Collectively agreed global mechanisms or frameworks may facilitate equitable access to COVID-19 vaccines

The COVID-19 pandemic is a global crisis, the included articles suggest that collective efforts are therefore warranted to curb its most devastating effects. Global collective agreements on how to achieve this would need to take into account diverging perspectives of a complex global governance architecture and need to be negotiated between various interest groups, including national governments, the pharmaceutical industry, small biotechnology firms, and multilateral institutions. It is multilateral institutions, such as the United Nations or WHO, that have the global mandate to convene interest groups, advocate for collective response measures, as well as the investment, procurement and distribution of pandemic vaccines. Such measures may be facilitated by prompt agreement on equitable access frameworks<sup>20-23</sup>. However, the Swine flu pandemic showed that even affirmed global principles, such as the 2003 World Health Assembly (WHA) declaration on the prevention and control of influenza pandemics, did not prevent a MIC (Mexico) being adversely affected from accessing vaccines<sup>5 25</sup>. The 2011 PIP Framework, developed to enhance countries' response to pandemic influenza, has facilitated a collective approach<sup>8</sup>. However, again, vaccine donation and pledging systems, as indicated under the PIP Framework, have proven to be insufficient, mainly due to the lack of legal obligation to act, or penalty for parties who breach conditions, as is the case of current global allocation frameworks<sup>1</sup> <sup>20 24 26 30</sup>. Implementation of and adherence to global frameworks could aid the realization of fair distribution and access to medicines, like the Pan American Health Organization Strategic Fund, where pooled procurement is used as a mechanism to support access to essential medicines<sup>32</sup>.

## 2. Financial mechanisms such as collective Advanced Purchase Agreements may favor fair allocation

Several of the papers reviewed warn that most COVID-19 vaccines will be purchased by, and for use in, High income countries (HICs)<sup>20 22 24 30</sup>. HICs have a track-record of dominating the global supply of vaccines, through greater advanced purchasing power, and their proximity to vaccine manufacturing<sup>20 24</sup>. Fair vaccine allocation is hindered by the inability of a LMIC to procure or negotiate access to pandemic vaccines at the same level as HICs<sup>4 30</sup>. Structural market-based inequalities are embedded in the R&D of vaccines, including that vaccine manufacturing is led by multi-national pharmaceutical companies who are incentivized by intellectual property rights and return on investment<sup>27 33</sup>. Advance Purchase Agreements (APAs), where a party commits to buy a specific number or percentage of doses prior to development, may influence equitable access to vaccines, as they secure priority access for the purchaser<sup>20</sup>. Financing mechanisms, such as APAs, may exacerbate or facilitate equity depending on whether they promote the interests of one country or collectively for several countries, and if they include LMICs<sup>4 21 26 27 34</sup>. This highlights the significance of single party contractual agreements between a funder and a vaccine producer, which often lack transparency, and are critical in determining the price and delivery conditions of vaccines<sup>34</sup>.

#### 3. Large-scale vaccine manufacturing and distribution can support fair allocation

Much of the initial funding raised for COVID-19 vaccines has been channeled towards early stage research and development costs to support the identification of safe and effective vaccines. However, multiple articles in this review suggest that substantial additional investment is required to further global vaccine manufacturing<sup>5</sup> <sup>21-23</sup> <sup>31</sup>. Large-scale manufacturing and

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distribution will facilitate equitable access by addressing scarcity challenges and increasing production. Vaccine development is intricate and to manufacture during a pandemic faces unprecedented challenges in scale and complexity. A limited number of HICs, and some MICs, have vaccine manufacturing capacity, therefore there is a disparity between countries that have the capacity to produce vaccines and those that need access to those vaccines<sup>5</sup> <sup>21</sup> <sup>24</sup> <sup>28</sup>. The dependence that the world has on a limited number of countries to manufacture vaccines affects the global availability of pandemic vaccines for two reasons. Firstly, the world is unable to manufacture the quantity of vaccines demanded, and secondly, a manufacturing country has the sovereign authority over goods produced within its borders, and in cases where it is enforced, government intervention may hinder global distribution<sup>27</sup> <sup>28</sup>. A collective global allocation framework for the collective financing of both R&D and manufacturing and the related distribution of COVID-19 vaccines, such as COVAX, offers an approach that could reduce the impact of nationalistic approaches<sup>3</sup>.

*4. Sharing manufacturing know-how with MICs can support supply of COVID-19 vaccines* Our findings suggest that MICs with vaccine manufacturing capability can support filling the forecasted gap in international vaccine manufacturing capacity<sup>28</sup>. The Serum Institute of India is a manufacturer based in a MIC that has pledged 1 billion doses of a COVID-19 vaccine to LMICs<sup>35</sup>. Vaccine manufacturing know-how could include vaccine developers sharing intellectual property of vaccine manufacturing processes, or relaxing patent rights<sup>4 20</sup>. Given the world's limited manufacturing capacity, the use of technology transfer and pooling could help to alleviate a massive shortage of vaccines given the scale of the need<sup>23 36</sup>. Fifteen MICs have vaccine production capacity to support the global supply of vaccines (of which 12 have WHO

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prequalification status)<sup>35</sup>. Technology transfer to MIC has significantly contributed to increasing the global vaccine supply, through the sharing of knowledge of those who own the know-how to recipient sites to enable the recipient developer to produce a vaccine that will support local production. Enabling the transfer of the technology, with limited royalty payments, may facilitate manufacturing in MICs<sup>23</sup>. Two noteworthy current initiatives are, firstly, the COVID-19 Technology Access Pool (2020), proposed by Costa Rica and adopted by WHO (endorsed by 35 mainly MICs and five HICs), calls for the voluntary sharing of knowledge, intellectual property, and data as well as a guarantee of free access and use by WHO member countries of drugs and vaccines that are developed<sup>31,37</sup>; and, secondly, the Global pandemic influenza action plan to increase vaccine supply (GAP) (2006-2016), a strategy to reduce global shortages of influenza and pandemic vaccines that supports technology transfer<sup>6</sup>.

#### 5. Reciprocity facilitates equitable access to vaccines

In the context of equitable access, reciprocity is the principle of sharing benefits equally with a mutual commitment between those who control the supply of vaccines and those who have a right to access vaccines. The shared benefits principle is a long-standing commitment included in the Global Influenza Surveillance and Response System (GISRS), where countries who participated in joint infectious disease preparedness and surveillance activities, including the sharing of genetic resources, benefited from the access to technologies that will facilitate the management of diseases<sup>21</sup>. The articles included in this review that mentioned this issue suggested that benefit sharing as a potential solution to incentivize countries to support collaborative infectious disease responses and measures, and in return be granted eligibility to real-time access of pandemic response products, like vaccines<sup>4</sup><sup>21</sup>. The principle of countries

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sharing virus samples was endorsed at the World Health Assembly in 2003 where member states supported further influenza vaccine research and development (R&D) to enable the supply of medical countermeasures<sup>25</sup>. Despite such agreements there is a weariness of the reliability of commitments made by vaccine manufacturers, as there are examples of manufacturers not reserving the agreed quota of vaccine production to LMICs as stipulated under the PIP Framework<sup>4 21</sup>.

# 6. Countries' strength in implementing vaccination programs may influence their population's access to vaccines

The findings from this research further suggest that the ability of a country to implement a mass vaccination program is an important factor to influence equitable access<sup>1</sup>. Vaccination programs are resource intensive; to maximize the benefit of COVID-19 vaccines, and reduce waste due to improper implementation, it has been suggested that allocation frameworks should consider a country's ability to vaccinate<sup>1</sup>. Most LMICs have well-structured vaccination programs, facilitated by organizations such as UNICEF and Gavi which could support a large pandemic vaccination program. However, few LMICs routinely roll out mass seasonal influenza vaccination, and as older populations may be a prioritized group for COVID-19, this could be a liability in a COVID-19 vaccination program<sup>20</sup>. Another important aspect that is likely to facilitate the distribution of vaccines is the countries' regulatory approval and market authorization processes for vaccines<sup>20 28</sup>. Finally, although perhaps not simply nor immediately solved, though nonetheless an important issue, overall strengthening of countries' health systems will support global efforts to distribute the vaccine. This issue is also identified and prioritized in the ACT accelerator collaboration<sup>9</sup>.

#### DISCUSSION

This study reviewed the literature on access to pandemic vaccines, with the aim to identify factors that can potentially influence equitable access to a COVID-19 vaccine for LMICs. We identified 13 articles that give insight into issues to consider in ensuring that all countries have equitable access to vaccines. Our results report that the following facilitators can broadly support fair allocation of vaccines: (1) collectively agreed mechanisms or frameworks that are legally binding, (2) financial mechanisms such as collective Advanced Purchase Agreements, (3) large-scale vaccine manufacturing and distribution, (5) ensuring reciprocity between countries' in their access to, and those who control vaccine distribution, and (6) strengthening implementation of vaccination programs. All of these factors have the potential to promote fairer global access to COVID-19 vaccines.

As suggested in our review findings, one of the biggest threats to the fair distribution of COVID-19 vaccines to LIMCs are countries nationalistic interests and the hoarding of vaccines. Experiences during previous pandemics loom as a threat for populations access to vaccines in LMICs; the scrutiny on the GISRS processes following H5N1 in Indonesia and the asymmetry in the distribution of pandemic vaccines for Mexico during Swine flu is an example of unfair vaccine distribution <sup>7 29 38 39</sup>. Still today, there continues to be a need for action related to equity considerations and ensuring global coordination and distribution mechanisms of vaccines for LMICs. There are several examples of threats to equitable distribution of essentials earlier in the pandemic, with countries' tendencies to control the global supply of personal protective equipment and ventilators<sup>22 40</sup>. And more recently with Israel's large investment in COVID-19

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vaccines, enabling the largest proportion of a country to be vaccinated, and confusion from India about their willingness to internationally distribute vaccines manufactured in country<sup>41 42</sup>.

Several publications in our review suggested that collectively agreed and legally binding mechanisms would likely be the basis to facilitate the fair allocation of COVID-19 vaccines between countries. Previous attempts at agreement on joint principles, such as the *Bellagio* Statement of Principles on Social Justice and Influenza to Africa, have not gained traction<sup>43</sup>. Numerous WHO resolutions endorsed by member states indicate that there is broad support the principles of equitable distribution of pandemic vaccines to all countries, however there remains uncertainty if enough governments would be willing join binding mechanisms<sup>44-48</sup>. It is unclear whether there would be any value in a new international or multilateral agreement in this area. In addition, WHO has faced questions about its authority, which was undermined during H1N1 when it called for vaccine donations to LMICs. Despite this, it is the multilateral system that has the mandate to play this role, and to date has prioritized the COVAX facility<sup>20 21</sup>. In terms of the role of vaccine manufacturers as a broker for fair distribution, a recently published report cites the example of Moderna whose vaccine (approved for use in USA and the European Union), have publicly implied that vaccines will merely be prioritized and sold to countries which are able to pay by entering into APAs with HICs and setting high course-prices for low-volume deals49.

In many ways, the COVAX facility embodies the equity principles highlighted in our review and seeks to reduce the short-term barriers to access to COVID-19 vaccines discussed here. COVAX is committed to, and leading an effort to distribute 20% of doses to the member states of the

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initiative. Vaccines will be allocated between 78 HICs and 92 LMICs who have joined COVAX<sup>3</sup> <sup>13 14</sup>. Co-lead by CEPI and Gavi, both organizations were established with a commitment of equitable access to medicines in their ethos<sup>10 50 51</sup>. CEPI, most notably, created a vaccine portfolio to which countries participating in COVAX have access. CEPI invested in11 COVID-19 vaccine candidates often in the earliest R&D phases, nine of these vaccines are still further developed<sup>52 53</sup>. These beneficiaries are required to uphold CEPI's equitable access policy that among other things emphasizes that vaccines should be made available for the lowest prices possible to maximize access for all populations during, but also still after, an epidemic, disregarding countries ability to pay<sup>51 54</sup>. However, precise wordings for access distribution are determined during the contract negotiations - an analysis of published contracts and associated files shows a lack of transparency, and COVAX has been criticized by civil society for negotiating vaccine prices that include profit<sup>34 49</sup>.

The GAVI-COVAX Advance Market Commitment (AMC) is in addition to COVAX and aims to protect the interest of HICs and LMICs by using Official Development Assistance (ODA) to invest in vaccines on behalf of LMICs, offering volume guarantees to specific manufacturers before licensure of the vaccine candidates. It has pledged almost 1.2 of two billion doses available to the 92 poorest economies<sup>55</sup>. When the vaccines are licensed and prequalified by the WHO, it will purchase and distribute it equitably between participating countries<sup>56</sup>. The GAVI-COVAX AMC also ensures that vaccines supplies are secured for manufacturers for countries which otherwise would not be able to participate in such financing mechanisms. It remains to be seen whether COVAX will be a success, but already it is an example of how the global

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community can come together to circumvent the challenges of equitable access to pandemic vaccines.

Another key and long-term solution to equitable access highlighted in our findings is that broadening the basis of the manufacturing of vaccines. Local production facilities are critical, but it will take time to build enough of these facilities that meet the necessary quality standards in LMICs. These are therefore so far limited to 12 MICs that have WHO prequalification<sup>35</sup>. Steps are currently being taken by WHO to strengthen local production of medicines and other health technologies, with a consultation of a resolution amongst member states during December 2020<sup>57</sup>. However scaling up the manufacturing of COVID-19 vaccines will likely impact on the production of other vaccines such as influenza, measles, mumps and rubella<sup>2</sup>.

Despite the length of time it takes to build and certify vaccine manufacturing facilities, steps can be taken now to share the know-how of the manufacturing of effective vaccines, mainly through the relaxing of patent and intellectual property rights. It is argued that the management of intellectual property principles can be a strategic tool to support the affordability of availability of vaccines, and also balancing incentives for innovators<sup>34 49 58</sup>.

#### CONCLUSION

The COVID-19 pandemic is unprecedented, and the simultaneous impact on the whole world has placed significant strain on the fair distribution of vaccines to all countries, which will in particular affect resource limited settings. The consequential global demand for a scarce good will take several years to resolve, until vaccine production meets the global demand. This

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scoping review provides valuable insights from the past, many of which are pertinent today, at a time when there is scarce evidence or examples of equitable distribution of pandemic vaccines.

Through this scoping review, vaccine manufacturing was deemed to be of the high importance in the supply of vaccines, future scoping reviews could explore factors related to vaccine manufacturing in MICs to facilitate vaccine supply in a pandemic, including questions related to intellectual property. Another issue discussed in the literature, but beyond the scope of this review is the role of vaccine stockpiles as a means to address urgent needs for LMIC, this was deemed more relevant for the management if COVID-19 becomes endemic, but may be an for further research<sup>4 5 20</sup>. important issue for further research<sup>4 5 20</sup>.

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Article summary

Strengths and limitations of the study

The main limitation of this scoping review is that literature was exclusively chosen based on relevance to the topic of identifying and describing factors related to equitable access, as identified in peer-reviewed journals with no additional quality assessment of the publications done (see Appendix 3 that describes the underlying basis for the papers included in the review). Moreover, in light of the numerous papers published related to the COVID-19 pandemic on a daily basis, there may be relevant publications published after our search that should have been included in this brief. The identified factors are based on empirical observations in the reviewed literature, although we applied the framework proposed by Liu et al. 2020 as a foundation for our analysis<sup>1</sup>. We followed the Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) and were guided by the Arksey and O'Malley's five-stage framework through the steps of the review.

Contributor statement

Elizabeth Peacocke - Study conception, Title, abstract and full-text review, Data extraction, Data analysis, Writing.

Katrine Frønsdal - Methods, Full-text review, Data analysis, Writing.

Lieke Heupink - Data analysis, Writing.

Lumbwe Chola - Study conception, Title, abstract and full-text review, Data extraction, Data analysis, Writing.

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design, data collection and analysis, decision to publish, or preparation of the manuscript.

Competing interests: All authors have completed the ICMJE uniform disclosure form at <u>www.icmje.org/coi\_disclosure.pdf</u> and declare no relationships or activities that could appear to have influenced the submitted work.

Ethical approval: Was not necessary as we used published data, and did not complete primary data collection.

Patient and public involvement: Patients were not involved in this study.

Data availability statement: All data relevant to the study are included in the article or uploaded as online supplementary information.

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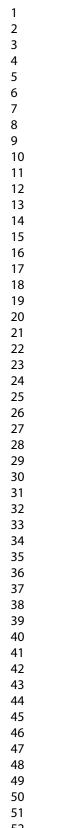
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# **Figure legends**

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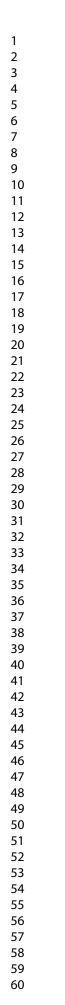
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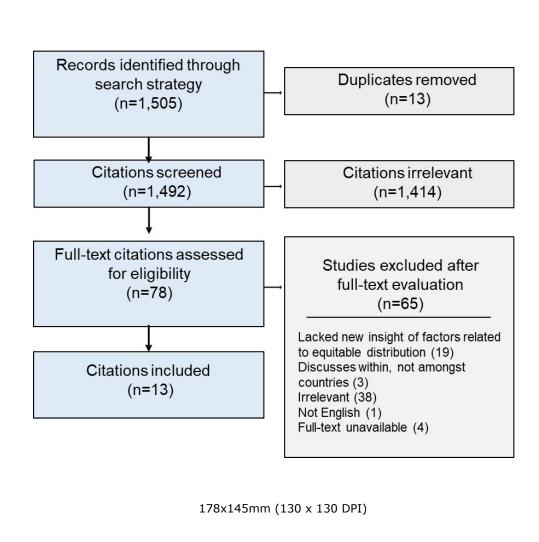




Event Year **Global Guidelines or Mechanisms** 1952 Global Influenza Surveillance and Response System (GISRS) International Health Regulations (IHR) 1969 Agreement on Trade-Related Aspects of Intellectual Property 1995 Rights (TRIPS) WHO Influenza Pandemic Preparedness Plan in WHO Global 1999 Agenda on Influenza Surveillance and Control World Health Assembly adopted Resolution WHA 54.14 member states pledged to strengthen their capacity to detect and respond rapidly to communicable disease threats and emergencies 2001 SARS Coronavirus 2002 (H5N1) epidemic Indonesia refuses International Health Regulations (IHR) updated to include global to share virus 2005 outbreak alert system; better international surveillance samples of H5N1 during outbreak Global Action Plan for Influenza Vaccines strategy to reduce global shortage of influenza vaccines for pandemic influenza; 2006 included Technology Transfer Initiative. GAP II updated after H1N1 World Health Assembly adopted Resolution WHA 60.28 enabled 2007 local manufacturing; enhanced local surveillance; financing for procurement of pandemic vaccines; and access to stockpiles Swine Flu 2009 nfluenza A (H1N1) Pandemic Influenza Preparedness (PIP) Framework granted pandemic researchers and industry access to biological samples in exchange for financial or in-kind donation of products 2012 Pilot Advanced Market Commitment Gavi and World Bank initiative for pneumococcal vaccines 2014 Nagoya Protocol Coronavirus-19 **COVAX the ACT-Accelerator Vaccines Pillar** 2019 (COVID-19) Serum Institute of India manufacturers committed to vaccines for pandemic LMIC 2020 Centre for Global Development Benefit-Based Advanced Market Commitment The COVID-19 Technology Access Pool Inclusive Vaccine Alliance (European Union lead) Operation Warp Speed (United States of America lead) AMC Concept (America First, Harvard Academics lead)

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Supplementary Material

# Appendix 1: Search strategies for each of the four databases *MEDLINE*, *PubMed* (searched 28.08.2020)

MeSH: "COVID-19 vaccine" [Supplementary Concept]

Ovid MEDLINE(R) and Epub Ahead of Print, In-Process & Other Non-Indexed Citations and Daily 1946 to August 27, 2020 (searched 28.08.2020)

#	Searches	Results
1	Coronavirus/	3244
2	Betacoronavirus/	16530
3	Coronavirus Infections/	24138
4	Coronaviridae Infections/	906
5	Severe Acute Respiratory Syndrome/	4873
6	Pandemics/	24349
7	(COVID-19 or COVID 19 or COVID19 or 2019-nCoV or SARS2 or SARS-CoV or	91205
	SARS-CoV-2 or SARS-Cov-19 or coronavirus* or corona or pandemic?).ti,ab,kf.	
8	(BNT162 or BNT-162 or mRNA-1273 or mRNA1273 or INO-4800 or INO4800 or	51
	ChAdOx1 or Ad5-nCoV).ti,ab,kf,hw.	
9	or/1-8	97109
10	Vaccines/	21690
11	Viral Vaccines/	25884
12	Vaccination/	81687
13	Vaccination Coverage/	1160
14	Mass Vaccination/	3038
15	Immunization/	50752
16	Immunization Programs/	10877
17	(vaccin* or immuni*).ti,ab,kf.	546309
18	or/10-17	579947
19	"Delivery of Health Care"/	91173
20	"Health Services Needs and Demand"/	53044
21	Resource Allocation/	8501
22	Health Care Rationing/	11514
23	Health Services Accessibility/	74764
24	Health Equity/	1291
25	Right to Health/	75
26	Universal Health Care/	80
27	Healthcare Disparities/	17030
28	Socioeconomic Factors/	157123
29	Social Justice/	12160
30	Global Health/	47402
31	Human Rights/	14384
32	((equit* or equal* or fair* or inequit* or unequal or unfair* or global*) adj3 (access* or allocat* or distribut* or deliver* or provision or supply or supplies)).ti,ab,kf.	29976
33	(right to health* or universal health*).ti,ab,kf.	7053
<u>33</u>	((health* or health care) adj (rationing or disparities)).ti,ab,kf.	13345
<u>34</u> 35	or/19-34	466021
<u>35</u> 36	9 and 18 and 35	632

### Embase 1974 to 2020 Week 34, Ovid (searched 28.08.2020)

#	Searches	Results
1	coronavirinae/	2268
2	betacoronavirus/	4632
3	coronavirus infection/	8485
4	coronaviridae infection/	166
5	pandemic/	30028
6	(COVID-19 or COVID 19 or COVID19 or 2019-nCoV or SARS2 or SARS-CoV or	103695
	SARS-CoV-2 or SARS-Cov-19 or coronavirus* or corona or pandemic?).mp.	

8	ChAdOx1 or Ad5-nCoV).mp. or/1-7	103962
9	vaccine/	60026
10	virus vaccine/	19609
11	severe acute respiratory syndrome vaccine/	385
12	vaccination/	140276
13	vaccination coverage/	2060
14	immunization/	94131
15	mass immunization/	3511
16	(vaccin* or immuni*).ti,ab,kw,ot.	643022
17	or/9-16	689815
18	health care delivery/	174154
19	resource management/	10271
20	resource allocation/	20867
21	health care access/	62445
22	health care quality/	241073
23	health equity/	3269
24	right to health/	105
25	universal health care/	155
26	health care disparity/	15646
27	socioeconomics/	140163
28	social justice/	10427
29	global health/	9804
30	human rights/	24894
31	((equit* or equal* or fair* or inequit* or unequal or unfair* or global*) adj3 (access* or allocat* or distribut* or deliver* or provision or supply or supplies)).ti,ab,kw,ot.	38602
32	(right to health* or universal health*).ti,ab,kw,ot.	8082
33	((health* or health care) adj (rationing or disparities)).ti,ab,kw,ot.	16415
34	or/18-33	670545
	8 and 17 and 34	672
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vaccine OR vaccines OR vaccination OR immunization OR immunisation AND equity OR equitable OR equal OR equally OR inequity OR inequitable OR unequal OR unequally OR unfair OR unfairly OR disparity OR disparities OR global OR globally

# Web of Science, Clarivate Analytics (searched 28.08.2020)

COVID-19 OR "COVID 19" OR COVID19 OR 2019-nCoV OR "2019 nCoV" OR SARS2 OR SARS-CoV OR "SARS CoV" OR SARS-CoV-2 OR "SARS CoV 2" OR SARS-Cov-19 OR "SARS Cov 19" OR coronavirus OR corona OR pandemic OR pandemics AND vaccin\* OR immuni\* AND equity OR equitable OR equal OR equally OR inequity OR inequitable OR unequal OR unequally OR unfair OR unfairly OR "right to health" OR "right to healthcare" OR "universal health" OR "universal healthcare ationing" OR "healthcare disparities"

# Appendix 2: Excluded articles and reason for exclusion

**Reason for exclusion key:** 1: mentions issue but lacks detail or did not add new insight to factors related to equitable access, 2: discusses within, not amongst countries, 3: irrelevant, 4: not English, 5: full-text unavailable.

Author	Title	Year	Reason
Hay, A. J. and J. W. McCauley	The WHO global influenza surveillance and response system (GISRS)-A future perspective	2018	1
Bennett, B. and T. Carney	Law, ethics and pandemic preparedness: the importance of cross-jurisdictional and cross-cultural perspectives	2010	1
Fisher, D., D. S. Hui, Z. Gao, C. Lee, M. D. Oh, B. Cao, T. T. Hien, K. Patlovich and J. Farrar	Pandemic response lessons from influenza H1N1 2009 in Asia	2011	1
Friede, M., L. Palkonyay, C. Alfonso, Y. Pervikov, G. Torelli, D. Wood and M. P. Kieny	WHO initiative to increase global and equitable access to influenza vaccine in the event of a pandemic: supporting developing country production capacity through technology transfer	2011	1
Hessel, L.	Pandemic influenza vaccines: Meeting the supply, distribution and deployment challenges	2009	1
Ho, A. and I. Dascalu	Global Disparity and Solidarity in a Pandemic	2020	1
Haaheim, L. R., A. S. Madhun and R. Cox	Pandemic influenza vaccines - the challenges	2009	1
Kamradt-Scott, A.	Evidence-based medicine and the governance of pandemic influenza	2012	1
Megiddo, I., J. Nonvignon, R. Owusu, K. Chalkidou, A. Colson, M. Gad, P. Klepac, F. Ruiz and A. Morton	Fairer financing of vaccines in a world living with COVID-19	2020	1
Milstien, J.	Emergency response vaccines: Lessons learned in response to communicable diseases	2003	1
Nannei, C., S. Goldin, G. Torelli, H. Fatima, K. Kumar, O. Bubb-Humfryes, B. Stenson and E. Sparrow	Stakeholders' perceptions of 10years of the Global Action Plan for Influenza Vaccines (GAP) - Results from a survey	2016	1
Muula, A. S.	How relevant is Bellagio statement of principles on social justice and influenza to Africa?	2007	2
Ogbogu, U. and L. Hardcastle	Bioethics and practical justice in the post-COVID-19 era	2020	1
Rodríguez Mega, E.	Latin American scientists join the coronavirus vaccine race: 'No one's coming to rescue us'	2020	1
Ropero-Alvarez, A. M., A. Whittembury, H. J. Kurtis, T. dos Santos, M. C. Danovaro- Holliday and C. Ruiz-Matus	Pandemic influenza vaccination: lessons learned from Latin America and the Caribbean	2012	1
Schwartz, B. and W. A. Orenstein	Prioritization of pandemic influenza vaccine: Rationale and strategy for decision making	2009	1
Yamada, T.	Poverty, wealth, and access to pandemic influenza vaccines	2009	1

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Yen, C., T. B. Hyde, A. J. Costa, K. Fernandez, J. T S. Tam, S. Hugonnet, A. M. Huvos, P. Duclos, V. J. Dietz and B. T. Burkholder	The development of global vaccine stockpiles	20
	Rationing of influenza vaccine during a pandemic: ethical analyses	2
	Preparedness for influenza vaccination during a pandemic in the World Health Organization Western Pacific Region	2
Edwards, K. M., A. Sabow, A. Pasternak and J. S. W. Boslego	Strategies for broad global access to pandemic influenza vaccines	2
Hadler, J. L.	Public health strategies for distribution of influenza vaccine during an influenza pandemic	2
Bhatia, P. T	The H1N1 influenza pandemic: need for solutions to ethical problems	2
Gerberding, E. Hanon, S. Ivol, J. W. Shiver, J. A. P Spencer and J. Van Hoof	Developing Vaccines for SARS-CoV-2 and Future Epidemics and Pandemics: Applying Lessons from Past Outbreaks	2
Briand, S. F	Future developments in global influenza surveillance	þ
Elbe, S. H	Haggling over viruses: the downside risks of securitizing infectious disease	4
	Agreement on a pandemic influenza preparedness framework for the sharing of viruses and benefit haring	2
Fedson, D. S.	Vaccine development for an imminent pandemic: why we should worry, what we must do	2
Gostin, L. O.	Medical countermeasures for pandemic influenza: ethics and the law	2
Gronvall, G. K. and L. L. Borio	Removing barriers to global pandemic influenza vaccination	1
	The consequence of COVID-19 on the global supply of medical products: Why Indian generics matter for he world?	2
and W. Luytjes	An international technology platform for influenza vaccines	2
g	Allocation criteria for an initial shortage of a future SARS-CoV-2 vaccine and necessary measures for global immunity	2
and R. Hatchett	Finding equipoise: CEPI revises its equitable access policy	2
Haaheim, L. R. V	/accines for an influenza pandemic: scientific and political challenges	f
Kamradt-Scott, A.	The politics of medicine and the global governance of pandemic influenza	
Karim, S. A.	COVID-19 vaccine affordability and accessibility	
	An appeal for practical social justice in the COVID-19 global response in low-income and middle-income countries	

Khamsi, R.	If a coronavirus vaccine arrives, can the world make enough?	2020	3
Kieny, M. P.	WHO supports fair access to influenza A (H1N1) vaccine	2009	3
Kyd, J. M.	3rd Global Vaccine Congress	2010	3
McLachlan, H. V.	A proposed non-consequentialist policy for the ethical distribution of scarce vaccination in the face of an influenza pandemic	2012	3
McLachlan, H. V.	On the random distribution of scarce doses of vaccine in response to the threat of an influenza pandemic: a response to Wardrope	2015	3
Monto, A. S., S. Black, S. A. Plotkin and W. A. Orenstein	Response to the 2009 pandemic: effect on influenza control in wealthy and poor countries	2011	3
Nguyen, T. and S. Briand	The influenza challenge	2010	3
Pagliusi, S., M. Dennehy, H. Kim and D. A. O.	Vaccines, inspiring innovation in health	2018	3
Palkonyay, L. and H. Fatima	A decade of adaptation: Regulatory contributions of the World Health Organization to the Global Action Plan for Influenza Vaccines (2006-2016)	2016	3
Ruscio, B., A. Bolster, J. Bresee, A. Abelin, P. Boutet, H. Christiansen, P. Etholm, Sand A. Xeuatvongsa	Shaping meeting to explore the value of a coordinated work plan for epidemic and pandemic influenza vaccine preparedness	2020	3
Stohr, K., M. P. Kieny and D. Wood	Influenza pandemic vaccines: How to ensure a low-cost, low-dose option	2006	3
Straetemans, M., U. Buchholz, S. Reiter, W. Haas and G. Krause	Prioritization strategies for pandemic influenza vaccine in 27 countries of the European Union and the Global Health Security Action Group: a review	2007	3
Wardrope, A.	Scarce vaccine supplies in an influenza pandemic should not be distributed randomly: reply to McLachlan	2012	3
Wynia, M. K.	Ethics and public health emergencies: rationing vaccines	2006	3
Anderson, Tatum	Intensifying vaccine production	2020	3
Coleman, C. H.	Allocating vaccines and antiviral medications during an influenza pandemic	2009	3
Lee, B. Y., S. T. Brown, R. R. Bailey, R. K. Zimmerman, M. A. Potter and D. S. Burke	The Benefits To All Of Ensuring Equal And Timely Access To Influenza Vaccines In Poor Communities	2011	3
Li, Y., E. B. Hsu and J. M. Links	Healthcare system cost evaluation of antiviral stockpiling for pandemic influenza preparedness	2010	3
Mukherjee, R.	Global efforts on vaccines for COVID-19: Since, sooner or later, we all will catch the coronavirus	2020	3
Saunders, B.	EQUALITY IN THE ALLOCATION OF SCARCE VACCINES	2018	3
L. Hites and C. M. Singleton	Lessons about the state and local public health system response to the 2009 H1N1 pandemic: a workshop summary	2013	3
Wong, G. and X. Qiu		2018	3

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C. Yingyao and L. U. Yihan	Expanding the pandemic influenza preparedness framework to the epidemic of COVID-19	2020	
Collin, N. and S. Briand	[Influenza vaccine: globalization of public health stakes]	2009	
Donatelli, I. and F. Pregliasco	[WHO Influenza Global Agenda]	2003	
Jorgensen, P., A. Wasley, J. Mereckiene, S. Cotter, J. T. Weber and C. S. Brown	Unequal access to vaccines in the WHO European Region during the A(H1N1) influenza pandemic in 2009	2013	
Lopalco, P. L. and L. Tan	Pandemic vaccines: Are we prepared for the next pandemic?	2016	

# Appendix 3: Papers underlying this brief

List of the 13 papers included in the review, including the reference, type of publication and context is shown in the table below.

Reference	Туре	What is the context of the paper?
Bollyky TJ, Gostin LO, Hamburg MA: <i>The Equitable Distribution of COVID-</i> <i>19</i> Therapeutics and Vaccines. Jama 2020, 07:07. (1)	Viewpoint	Discusses experiences and suggestions for a future framework to the distribution of vaccines.
Eccleston-Turner M: <i>The pandemic</i> <i>influenza preparedness framework: A</i> <i>viable procurement option for</i> <i>developing states?</i> Medical Law International 2017, 17(4):227-248. (2)	Article	Examines the Pandemic Influenza Framework and the content of the Obligations of the Company which have been secured by the World Health Organization.
Fedson DS: <i>Pandemic influenza and</i> <i>the global vaccine supply</i> . Clin Infect Dis 2003, 36(12):1552-1561. (3)	Article	The article explores several issues related to the global supply of vaccine during influenza pandemics
Fedson DS: <i>Preparing for pandemic</i> <i>vaccination: an international policy</i> <i>agenda for vaccine development.</i> J Public Health Policy 2005, 26(1):4-29. (4)	Commentary	Focuses on the trivalent vaccines currently available contain inactivated viruses.
Fedson, D. S., & Dunnill, P. (2007). Commentary: from scarcity to abundance: pandemic vaccines and other agents for "have not" countries. Journal of Public Health Policy, 28(3), 322-340. (5)	Commentary	Discusses that access to supplies of pandemic vaccine for most countries is a problem of scarcity and how to ensure the "have not" countries will get access to pandemic vaccines.
Fidler DP: Negotiating Equitable Access to Influenza Vaccines: Global Health Diplomacy and the Controversies Surrounding Avian Influenza H5N1 and Pandemic Influenza H1N1. Plos Medicine 2010, 7(5). (6)	Article	Examines the diplomatic negotiations surrounding influenza virus sharing as an example of the core tensions characterizing multilateralism and emerging forms of global health governance.
Kamradt-Scott A, Lee K: The 2011 Pandemic Influenza Preparedness Framework: Global Health Secured or a Missed Opportunity? Political Studies 2011, 59(4):831-847.(7)	Article	Investigates the events that prompted the re- examination of a technical cooperation system that has provided effective global health security on influenza for 60 years, and evaluates the PIP framework.
The Lancet: <i>Global governance for</i> <i>COVID-19 vaccines</i> . Lancet (London, England) 2020, 395(10241):1883 (8)	Editorial	Discusses the danger of a vaccine bidding war and the need for new arrangements at the global level to facilitate the development, finance, production, and equitable distribution of COVID-19 vaccines.
Liu Y, Salwi S, Drolet BC: <i>Multivalue</i> <i>ethical framework for fair global</i> <i>allocation of a COVID-19 vaccine</i> . J Med Ethics 2020, 46(8):499-501. (9)	Article	Analyses four allocation paradigms: ability to develop or purchase; reciprocity; ability to implement; and distributive justice, and synthesizes their ethical considerations to develop an allocation model to fit the COVID-19 pandemic.
Rourke MF: Access by Design, Benefits if Convenient: A Closer Look at the Pandemic Influenza Preparedness Framework's Standard Material	Article	Analyses the PIP Framework, its Standard Material Transfer Agreements (SMTAs), and secondary sources to determine whether the PIP Framework will effectively function as an access and benefit-sharing (ABS) instrument during an influenza pandemic.

<i>Transfer Agreements</i> . Milbank Q 2019, 97(1):91-112. (10)		
Turner M: Vaccine procurement during an influenza pandemic and the role of Advance Purchase Agreements: Lessons from 2009-H1N1. Glob Public Health 2016, 11(3):322-335. (11)	Article	A case study on the procurement of pandemic influenza vaccines during 2009-H1N1, and the likely manner in which procurement will occur during future pandemics.
Usher AD: <i>COVID-19 vaccines for all?</i> Lancet (London, England) 2020, 395(10240):1822-1823(12).	World report	Provides an assessment of the initiatives being planned to ensure equitable access, and their shortcomings.
Yamey G, Schäferhoff M, Hatchett R, Pate M, Zhao F, McDade KK: Ensuring global access to COVID-19 vaccines. Lancet (London, England) 2020, 395(10234):1405-1406. (13)	Comment	Discusses the development of COVID-19 vaccines as a means to be used globally to end the COVID-19 pandemic. This vaccine effort should be guided by three imperatives: speed, manufacture and deployment at scale, and global access.

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# Factors Influencing Global Equitable Access to COVID-19 Vaccines for Low-and Middle-Income Countries: A Scoping Review

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# FACTORS INFLUENCING GLOBAL EQUITABLE ACCESS TO COVID-19

# VACCINES FOR LOW-AND MIDDLE-INCOME COUNTRIES: A SCOPING

# REVIEW

# Authors: Elizabeth Peacocke, Lieke Fleur Heupink, Katrine Frønsdal, Elin Hoffmann Dahl, Lumbwe Chola

Corresponding author: Elizabeth Peacocke, DPH, Norwegian Institute of Public Health, Division for Health Services (a) <u>Elizabeth.Peacocke@fhi.no</u>, t. +47 941 60 559

Lieke Fleur Heupink, MSc. LiekeFleur.Heupink@fhi.no, Norwegian Institute of Public Health (a) Katrine Bjørnebek Frønsdal, PhD. <u>Katrine.Fronsdal@fhi.no</u>, Norwegian Institute of Public Health (a)

Elin Hoffmann Dahl, MD. <u>elin.hoffmann.dahl@helse-bergen.no</u> Haukeland Universitetssjukehus (b)

Lumbwe Chola, PhD. Lumbwe.Chola@fhi.no, Norwegian Institute of Public Health (a)

(a) Norwegian Institute of Public Health
Division for Health Services
Postbox 222 Skøyen, 0213 Oslo, NORWAY
Visiting address: Sandakerveien 24C, Entrance D11, 0473 Oslo, NORWAY

(b) Department of Medicine, Haukeland Universitetssjukehus, Bergen, Norway

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List of attachments:

- 1. Figure 1: Timeline of relevant events and initiatives
- 2. Figure 2: PRISMA
- 3. Appendix 1: Articles underlying this brief
- 4. Appendix 2: Updated protocol
- 5. Appendix 3Updated search strategies
- 6. Appendix 4: Data extraction template
- 7. Appendix 5: Excluded articles and reason for exclusion

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# Abstract

Objective: To identify the key factors influencing equitable access to Coronavirus Disease 2019 (COVID-19) vaccines for Low-and middle-income countries (LMIC). Methods: We searched for published literature (through May 2021) and conducted a Scoping Review following the guidelines for Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews and a five-stage framework for scoping studies.

Results: Systematic searches in five databases (Medline, Embase, Web of Science, Global Index Medicus, and COVID-19 Evidence Epistemonikos) resulted in the selection of 45 peerreviewed articles that met our predefined inclusion criteria, with no limitations based on study design nor publication type. We derived five key factors that influence equitable access to COVID-19 vaccines in LMICs: (1) collectively agreed global mechanisms or frameworks; (2) bilateral purchasing, contractual arrangements, and price of vaccines; (3) large-scale vaccine manufacturing that is supported by sharing know-how; and (4) countries' strength in implementing vaccination programs.

Conclusions: This scoping review highlights the ongoing challenges for the international community in ensuring equitable access to COVID-19 vaccines for vulnerable countries. Vaccine manufacturing was deemed to be of the high importance in the supply of vaccines, as was the role of patent holders who influence global governance through their role in the distribution of COVID-19 vaccines. Our review shows the importance of including the principles of equitable access throughout vaccine research and development, procurement, scale-up, and distribution processes. Finally, advances made with mRNA vaccines may have additional benefits in relation to expanding the manufacturing of other vaccine. The exploration and scale-up of such capacities of LMICs are likely to prove to be a valuable investment, even after the pandemic.

# Strengths and limitations of this study

- To our knowledge, this is the first systematic scoping review of factors influencing equitable access to COVID-19 vaccines.
- A limitation was that literature, provided that it was published in a peer-reviewed journal, was only chosen based on relevance to the topic of identifying factors related to equitable access, with no further quality assessment (see Appendix 1 describing the 45 articles underlying this review).
- In light of the numerous articles being published on a daily basis related to the COVID-19 pandemics, there might be additional relevant articles that should have been included in this review.
- We used the framework proposed by Liu et al. (2020) as a basis for our analysis.
   However, the identified factors are based on empirical observations in the reviewed literature.

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### BACKGROUND

The Coronavirus Disease of 2019 (COVID-19) is a global crisis; hence, collective efforts are essential to curb its most devastating effects. The unprecedented demand for a vaccine has mobilized rapid vaccine development and large-scale investment in manufacturing capacity. The outlay of capital from investors for the scale-up and production of early candidate vaccines has contributed to rapid advances in vaccine science<sup>1</sup>. Despite these investments, the demand for safe, affordable, and effective COVID-19 vaccines is expected to outstrip supply for a considerable period of time<sup>2</sup>. To realize the maximum benefit of these vaccines, vaccines should be shared fairly between all nations of the world, otherwise there will continue to be differential morbidity and mortality with increased risk of virus mutations leading to even more death and disease from COVID-19, not to mention the indirect consequences to the global development and economy<sup>3</sup>.

In relation to the management of communicable disease outbreaks, the principle of shared benefits is a long-standing commitment of the World Health Organization (WHO)<sup>4</sup>. The Global Influenza Surveillance and Response System (GISRS) suggests benefit sharing as a potential solution to incentivize global collaborative infectious disease responses and measures, and in return members have real-time access to pandemic response products, like vaccines<sup>56</sup>. Low- and middle-income countries (LMIC) face unique challenges in accessing vaccines as they do not have the same resources to purchase vaccines and are less likely to have the know-how and technological capacity to be able to manufacture their own vaccines. They may also face uncertainty in their ability to obtain vaccines due to reduced purchasing power compared to high income countries (HIC) when negotiating with vaccine manufacturers<sup>7</sup>. They are therefore more reliant on multilaterally agreed frameworks or bilateral support to access new technologies<sup>6</sup>. The global community has previously in part

managed this with non-binding mechanisms designed to promote equitable access. The 2006 WHO Global pandemic influenza action plan, for instance, was designed to support increased vaccine supply and global vaccine manufacturing capacity, by promoting technology transfer to middle income countries (MICs)<sup>8</sup>. As established vaccine manufacturing nations, some MICs' expertise can support the scale-up of vaccine production.

Ineffective institutional mechanisms for pandemic vaccine distribution were exposed during the influenza A (H1N1) ("Swine flu") pandemic in 2009<sup>6</sup>, despite embedded principles of reciprocity and equity for the prevention and control of influenza pandemics affirmed by member states at 2003 World Health Assembly. Swine flu and the COVID-19 pandemic are reminders that there is no institutional mechanism to effectively distribute global goods such as COVID-19 vaccines<sup>4</sup>. The Pandemic Influenza Preparedness (PIP) Framework that was developed following the H5N1 outbreak in Indonesia in 2005, triggering increased interest in the GISRS, which in turn lead to the WHO intergovernmental process and further scrutiny its influence on the development of influenza vaccines, and recognition of failures to ensure fairness, transparency and equity in access to vaccines for LMICs <sup>6910</sup>.

Specifically for COVID-19, the WHO led the Access to COVID-19 Tools Accelerator (ACT-A) global collaboration designed to fast-track development, production, and equitable access to COVID-19 tests, treatments and vaccines<sup>11</sup>. COVAX, the vaccines pillar of the ACT-A, is an initiative whose role is proving to be integral in the equitable distribution and access to COVID-19 vaccines, by providing an alternative for LMICs that have been failed by historical bilateral vaccine donation systems<sup>1 12</sup>. COVAX is co-led by the Coalition for Epidemic Preparedness Innovations (CEPI), a vaccine funding initiative, Gavi, the vaccine alliance, and WHO. Member countries of COVAX include those that have self-financing

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investments, but also others that are being supported through aid. COVAX aims to coordinate the vaccination of high risk and vulnerable populations, including frontline healthcare workers, across the world through distributing by the end of 2021 two billion vaccine doses. These will be shared between the member countries, of which 78 are HICs, and 92 are LMICs<sup>13</sup>. Figure 1 lists events and a timeline of introduced initiatives before and following relevant pandemic events, as identified in our scoping review.

# Figure 1: Timeline of events and relevant initiatives

See attached as a .png file

The idea that access and distribution of COVID-19 vaccines should be equitable across countries is widely supported, but what *equity* means in this context is often not specified. From the perspective of LMICs, equitable access to a vaccine is fundamentally linked to a fair and transparent global distribution framework<sup>14</sup>. For the purpose of this review, equitable access is interpreted as all countries, and their populations, having equal access to COVID-19 vaccines irrespective of the income status of the country. Further, we considered a COVID-19 vaccine as an essential medicine\*. And we have used the WHO definition of health equity^1<sup>5</sup> <sup>16</sup>. In its first phase, COVAX plans to allocate vaccines in proportion to countries' total population so that all countries receive doses to cover 20% of their population<sup>17 18</sup>. Alternative proposals exist, including The Fair Priority Model proposed by a group of ethicists. This model goes beyond proportional allocation by proceeding with allocation of vaccines in three phases, that would in the first instance prioritize the prevention of more urgent harms earlier<sup>19</sup> <sup>20</sup>. The ethical rationale behind this model argues that proportional allocation, as suggested by WHO and COVAX, is not the fairest solution, as it implies that some countries with relatively

lower risk of death and disease from COVID-19 would receive access to vaccines at the expense of other countries that are facing more exposure<sup>20</sup>.

The objective of this scoping review is to identify and summarize the factors related to the equitable access of COVID-19 vaccines for LMICs. To our knowledge, the literature related to the equitable access of COVID-19 vaccines relevant for LMICs has not been systematically investigated. The review is considered highly relevant as it can provide lessons from previous experiences and perspectives on equitable access to pandemic vaccine, and identifying key factors that could guide implementation of future initiatives to ensure equitable access.

\*Essential medicines are those that satisfy the priority health care needs of the population ^Health equity or "equity in health" implies that ideally everyone should have a fair opportunity to attain their full health potential and that no one should be disadvantaged from achieving this potential

# **METHODS**

We performed systematic scoping searches following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) as indicated in Figure 2 and were guided by Arksey and O'Malley's five-stage framework for scoping studies through the steps of the review<sup>21 22</sup>. The study protocol was peer reviewed by methodological and subject experts at the Norwegian Institute of Public Health (NIPH) (see Appendix 2).

Based on predefined inclusion criteria (Table 1), we systematically searched the following five databases: Medline (PubMed and Ovid), Embase, Web of Science, Global Index Medicus (WHO), and COVID-19 Evidence Epistemonikos. An information specialist, in collaboration with co-authors, developed the search strategies for the different databases (see Appendix 3). The search was performed on 28 August 2020 and updated on 12 May 2021. Only published

literature in peer-reviewed journals was eligible for inclusion, with no limitations on study design nor publication type. The articles for extraction were exclusively chosen based on relevance to the topic of identifying, describing factors related to equitable access to pandemic or COVID-19 vaccines, with no further quality assessments.

Criterion	Inclusion		
Time	01 January 2002 – 12 May 2021		
Language	English		
Type of article	Published in peer reviewed journals		
Article focus	Pandemic vaccines incl. influenza or COVID-19 vaccine		
Outcomes	Factors influencing equitable access to a pandemic vaccine		
	including COVID-19 vaccines		

Table 1: Inclusion criteria

Publications were screened based on title and abstract according to the inclusion criteria (Table 1). Two reviewers independently selected articles to be considered for full text screening. The selected articles were then read in full and considered for inclusion or exclusion by two different reviewers. Final decisions of inclusion of relevant articles were determined through consultation between three of the reviewers. Any disagreements were resolved through discussions to reach consensus. See Appendix 4 for the list of the excluded articles and reason for exclusion.

Data extraction was performed by one reviewer and verified by a second. We used a data extraction form designed specifically for this scoping review. We extracted information on the setting; discussion on equity, access, allocation or prioritization of pandemic vaccines; other equity aspects; challenges in implementing equitable access to vaccination between countries; and recommendations for strengthening equitable access to vaccination (Appendix 5). The analytic process followed the principles of thematic synthesis. Liu et al. was identified as an index paper as it closely reflected the focus of our scoping review<sup>23</sup>. The themes identified in

this article were used as the basis for our analysis and further refined through an iterative process as we identified factors influencing equitable access to COVID-19 vaccines in LMIC.

# RESULTS

Excluding duplicates, our search identified 3,025 unique citations (Figure 2). Screenings first based on title and abstract then on full text resulted in the final inclusion of 45 articles. See Appendix 1 for a description of the articles included in the review.

# Figure 2: PRISMA flow-chart for selection of articles

See attached .png file

We categorized the identified themes from the included citations into four factors influencing access to COVID-19 vaccines in LMICs: (1) collectively agreed global mechanisms or frameworks can contribute to equitable access to COVID-19 vaccines; (2) bilateral purchasing, contractual arrangements, and price influence fair allocation of vaccines; (3) large-scale vaccine manufacturing that is supported by sharing know-how can facilitate increased supply and allocation of COVID-19 vaccines; and (4) countries' strength in implementing vaccination programs may influence their populations access to vaccines (Table 2).

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# Table 2: Summary of main factors influencing equitable access to COVID-19 vaccines

Factors	Scoping review findings	Articles contributing to the finding
Collectively agreed global mechanisms or	Establishing a collective and coordinated COVID-19 donation process will facilitate equitable allocation of pandemic vaccines	1 5 13 24-41
frameworks can	Global solidarity is facilitated by multilateral organizations and agreed frameworks	1 5 25 28 30 33 34 36 42
contribute to equitable access to	Previous collective action has been inadequate with examples of deficient vaccine donation and pledging systems related to pandemic vaccines	1 7 26 30-35 37 42-47
COVID-19 vaccines	Vaccine patent holders play a pivotal role in global the prices and distribution of vaccines	6 30 46 48-51
	Financing mechanisms that facilitate collective purchasing or pooled procurement favor	1 5 6 25 28 29 33 34 40 43 47 48
Bilateral purchasing,	fairer allocation	52-54
contractual	Nationalistic approaches, where bilateral rather than collective purchasing is pursued,	1 7 23-27 29 31-34 36-38 41 42
arrangements, and	contribute to hoarding or supply inefficiencies, limiting the global supply of vaccines	44 50 54-58
price influence the	Pandemic vaccines will largely be purchased by, and for use in, high income countries	25 27-30 32-38 40-42 44-47 54-
fair allocation of	(HICs)	57 59
vaccines	LMICs cannot procure or negotiate the purchase of pandemic vaccines at the same level	1 6 25 29 32 33 37 56 59
	as HICs, and can therefore be disadvantaged by bilateral deals	
	The price and affordability of vaccines influences equitable access	7 27-29 33 47 48 53
	Substantial investments are required to finance and support global vaccine manufacturing	5 7 29 32 33 37-39 41 46 49 53
Large-scale vaccine manufacturing that is	There is disparity between countries that have the capacity to produce vaccines and those that use vaccines	5 7 24 42 51 56
supported by sharing know-how can	Technology transfer of vaccine manufacturing (especially to MICs) supports increased supply favoring fairer allocation	1 6 27-30 35-37 46 48-50 54 56
facilitate increased	Intellectual property rights influence domestic manufacturing	6 29 33 36 37 46 48 51
supply and allocation of COVID-19	Capacity building for technology transfer can support vaccine manufacturing and technology transfer in LMIC	1 6 27 29 32 33 48 53 56
vaccines	Place of vaccine manufacturing influences exporting of vaccines, such as through a nation's sovereignty over national borders	1 6 27 29 42 48 51-53 56

Factors	Scoping review findings	Articles contributing to the finding
Countries' strength in implementing vaccination programs	A country's ability to vaccinate should be a consideration in equitable distribution	1 13 24 27 41 60 61
	Management of logistical and administrative components facilitate distribution of vaccines	5 13 27 28 37 47
may influence their	A countries' regulatory approval and market authorization processes for vaccines	30 33 37 51 58 61
populations access to vaccines	influences the distribution of vaccines	
	peer review only	

# Collectively agreed global mechanisms or frameworks can contribute to equitable access to COVID-19 vaccines

Most articles included in the review indicated that collective action as a key factor that contributes to equitable access <sup>1 5 6 13 24-35 37-40 42-52</sup>. Global collective agreements should be driven by multilateral agencies that have the global mandate to convene interest groups, advocate for collective response measures, as well as the investment, procurement and distribution of pandemic vaccines<sup>58</sup>. These measures may be addressed by prompt agreement on equitable access <sup>5 30 39 41</sup>.

Historic vaccine donation and pandemic influenza pledging systems, have been insufficient, mainly due to the lack of legal obligation to act or the lack of penalty for parties who breach conditions <sup>12627 30-35 37 42-45 47</sup>. It is suggested that collective approaches need to be binding <sup>35</sup>. Actually, such a legal framework that has been ratified by 171 countries already exists, the International Covenant on Economic, Social, and Cultural Rights (1966), however, it has not achieved its intended purpose for countries to take steps to ensure the right to health and the benefits of scientific research, without discrimination <sup>34 44</sup> Nevertheless, and in spite of these so-called failures of collective action, there is wide acceptance of the moral argument that HICs should support LMICs in equitable access to pandemic vaccines, recognizing that any collective purchasing will have inherent inequalities related to existing power dynamics between the Global North over the Global South, and this status quo historically favored HICs over LMICs <sup>25 35</sup>. Specifically for vaccine allocation, there are examples of manufacturers historically not reliably committed to reserving production of pandemic vaccines to LMICs <sup>6</sup> <sup>26 42</sup>.

Bilateral solutions threaten collective action by enabling some countries to queue jump <sup>1 29</sup>. These approaches will always be pursued during global crises, as has been demonstrated during COVID-19, and as such cannot be avoided <sup>32</sup>. McAdams et al. therefore suggests that it comes down to how these bilateral arrangements are structured, using two deals from different US government agencies the Biomedical Advanced Research and Development Authority (BARDA), who has a deal with AstraZeneca, and the US Department of Health and Human Services (HHS), who secured 100 million doses of Pfizer, as examples<sup>32</sup>. The authors suggest that the deal negotiated by BARDA benefits US, AstraZeneca and the rest of the world by supporting the gaining, and sharing, of knowledge through its funding of advanced clinical studies, vaccine manufacturing technology transfer, process development and scaled-up manufacturing, which in turn supports more vaccines and increased availability. Where the Pfizer deal only supports US and Pfizer interests. The article concludes that BARDA's deal will result in more vaccines for LMICs, regardless of whether HICs vaccinate their own populations first<sup>32</sup>.

COVAX is the supported mechanism that has been widely promoted in the literature included in this review, yet the facility has faced criticisms related to transparency, limited knowledge sharing, and that it has needed more political and financial commitment <sup>31,55</sup>. It has also faced challenges related to managing the role of patent holders who have played a determining role in distribution of their medical countermeasures. This affects global governance, with patent holders holding influence over the distribution of patented technologies during a pandemic, a power that rests with few pharmaceutical companies controlling the global supply and distribution of vaccines<sup>48,50</sup>.

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The global prices of respective vaccines are not uniform across setting, wih the price of a COVID-19 vaccine influenced by its patent<sup>29 47 50</sup>. To counteract the inequality in global distribution, in October 2020, a proposal was made by India and South Africa to the World Trade Organization (WTO) requesting a temporary waiver of certain provisions of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement, on the basis of a need to prevent, contain, and treat COVID-19 <sup>46 50</sup>. There is no consensus in the literature included in this review on the benefits of the waiving of intellectual property rights (IPR), with those against the waiver, arguing that it is not patent protection that is the barrier to introducing generic vaccines<sup>44 46 49</sup>, but rather the lack of knowledge in the public domain and shortages of vaccine supplies<sup>1</sup>. The implications on national manufacturing, including a countries' ability to enact compulsory licensure under TRIPs is discussed later in this article.

# • Bilateral purchasing, contractual arrangements, and price influence the fair allocation of vaccines

HICs have a track-record of dominating the global supply of pandemic vaccines, through greater advanced purchasing power, and their ability (including proximity) to vaccine manufacturing. In 2021, 51% of the initial supply of COVID-19 vaccines had been purchased for 13% of the world's population, mostly residing in HICs <sup>28 30 42</sup>, indicating that fair vaccine allocation is hindered by the inability of LMICs to procure or negotiate access to pandemic vaccines at the same level as HICs<sup>6 59</sup>.

Vaccine development under the COVID-19 pandemic has highlighted the conflicting roles between the role of private capital and access to essential health care technologies. Final stage R&D of vaccines (and other medical technologies) are largely led by multi-national pharmaceutical companies who are incentivized by IPR and return on investment, thus

perpetuating structural market-based inequalities of supply and demand. This affects the total quantity of vaccines produced, which, in the case of influenza vaccines, has affected LMIC as it has been perceived that there is "lower demand" in these markets<sup>35 52</sup>.

Pooled procurement is mentioned in the literature of this review as a means to support equity, with Advanced Purchase Agreements (APA) and Advanced Market Commitments (AMC), the most common mechanisms identified in our review to facilitate access in LMIC<sup>5 6 25 28 29 33</sup> <sup>34 40 47 48 52-54</sup>. APAs being those contracts with a specific product developer, whereas an AMC is a global market commitment rather than to any particular company or product<sup>40</sup>. The AMC was first introduced in 1999 for the development of a late-stage pneumococcal vaccine, identified as shortening the time to introduction of a vaccine to LIMCs.<sup>40</sup> Under COVID-19, APAs have been widely used to secure priority access to a scarce resource (when one party has committed to buy a specific number or percentage of doses prior to development), and the influential factor for equitable access being whether they promote the interests of one country or several, and if they include LMICs <sup>5 6 30 34 43 52</sup>.

Bilateral deals contribute to supply inefficiencies, and threaten collective approaches to the procurement of vaccines, e.g. National APAs initiated by countries that are also members of COVAX (not exclusively, but mainly HICs)<sup>32 37 38 54 55</sup>. At the beginning of the COVID-19 pandemic, HICs went ahead purchasing large quantities of COVID vaccines<sup>31</sup>. The necessity for transparency of contractual clauses, especially relating to pricing, licensing and purchase commitments, was identified in the review – finding that global coordination efforts will suffer unless vaccine manufacturers can be trusted to responsibly decide which countries' vaccine orders should be prioritized<sup>34 37</sup>.

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Bilateralism is not limited to relationships between countries and vaccine manufacturers. Through COVID-19 bilateral deals have also been struck between countries, to directly distribute vaccines. For example, both the Russian and Chinese government owned and operated vaccine manufacturers have bilateral arrangements with other countries, such as India, Vietnam, Mexico, Brazil, and Ethiopia to guarantee the supply of vaccines<sup>28 29 54 56</sup>.

# • Large-scale vaccine manufacturing that is supported by sharing know-how can facilitate increased supply and allocation of COVID-19 vaccines

Several articles included in this review suggest that substantial additional financial and capacity investment is required to further global vaccine manufacturing<sup>5 7 29 32 33 37 39 41 46 49 53</sup> <sup>62</sup>. Vaccine development is multifaceted, and manufacturing during a pandemic faces unprecedented challenges in scale and complexity<sup>58</sup>. A limited number of HICs, and some MICs, have vaccine manufacturing capacity, resulting in a disparity between countries that have the capacity to produce vaccines and those that need access to those vaccines<sup>5 7 24 42 51 56</sup>. Nhamo et al. reported that development activity for COVID-19 vaccines is almost nonexistent in LMICs<sup>33</sup>. The majority of development activity is in Asia, with 12 (52%) COVID-19 vaccine development programs, followed by Europe (17%) and North America with four programs each (17%)<sup>33</sup>. A few MICs (Brazil, India and Peru) have capitalized on their clinical testing and/or manufacturing capacity efforts by leveraging these for purchase agreements with vaccine manufacturers<sup>29</sup>. Limited capacity affects the global availability of pandemic vaccines for two reasons. Firstly, the world is unable to manufacture the quantity of vaccines demanded, and secondly, a manufacturing country has the sovereign authority over goods produced within its borders with most countries in the world having legislation in place that require companies to manufacture and prioritize domestic consumption<sup>33 51 52</sup>. In situations where it is enforced, government intervention may hinder global distribution.

For technology transfer to work there needs to be a patent holder that is willing to share the intellectual property and a manufacturing facility that is able to receive it. The findings from this review suggest that MICs with vaccine manufacturing capability can play an important role to support filling the forecasted gap in international vaccine manufacturing capacity, but this requires technology transfer and capacity building to manufacture vaccines that meet the same efficacy and quality standards as the original vaccine<sup>1 6 27-30 35-37 46 48-51 54 56</sup>. Vaccine manufacturing know-how can include vaccine developers sharing the intellectual property of vaccine manufacturing processes, or relaxing patent rights<sup>6 29 33 36 37 46 48</sup>. One article included in the scoping review suggests that for viral vector vaccines (e.g. AstraZeneca and Johnson & Johnson), MICs with less advanced manufacturing capacity can contribute with the fill-and-finish stage of the process, rather than producing the active solution of the vaccine<sup>49</sup>.

Under the WTO TRIPS Agreement, counties' have a right for the compulsory licensure of products in certain circumstances. In practice, this means that a country can produce a patented product or process without the consent of the patent owner, as demonstrated by Canada, Chile and Ecuador in their pandemic response<sup>29</sup>. The discussion related to the TRIPS waiver is especially important to LMICs who recall recent historical experiences from South Africa where patents obstructed access to life-saving medicines for the treatment of HIV/AIDS<sup>44</sup>. Advocates for the COVID-19 products TRIPS waiver argue that significant public monies has contributed to the development of these patents, waiving IPR will support vaccine development and manufacturing, and that some countries are already undermining existing TRIPS flexibilities through restrictive free trade agreements<sup>36 44 54 55</sup>. Proponents against governments' enacting patent waivers claim that they contribute to inefficiencies by diverting raw materials and supplies away from effective manufacturers<sup>49</sup>. Compulsory

Page 19 of 60

### **BMJ** Open

licenses are not considered by these proponents as being a practical tool to rapidly expand access to vaccines, instead they support voluntary licensure, e.g. AstraZeneca's arrangements with Indian and Brazilian manufacturers<sup>1 46 49</sup>. A related issue impacting on manufacturing capacity is the use of limited manufacturing capacity on all vaccine candidates. So et al. caution that a weakness of prematurely exhausting capacity for vaccines that show early safety and efficacy promise is that manufacturing capacity will then be locked into first generation vaccines, and may be a bottleneck for manufacturing capacity for second generation, more effective, vaccines<sup>54</sup>.

Finally, two noteworthy initiatives are identified in the literature reviewed, the Global pandemic influenza action plan to increase vaccine supply (GAP) (2006-2016), a strategy to reduce global shortages of influenza and pandemic vaccines that supports technology transfer<sup>30 44</sup>. And, secondly, the recent COVID-19 Technology Access Pool (C-TAP) (2020) proposed by Costa Rica and adopted by WHO (endorsed by 35 mainly MICs and five HICs). It calls for the voluntary sharing of knowledge, intellectual property, and data as well as a guarantee of free access and use by WHO member countries for drugs and vaccines that are developed<sup>29 35 37</sup>. Given the world's limited manufacturing capacity, the use of technology transfer and pooling of vaccines could help to alleviate a massive shortage of vaccines given the scale of the need<sup>39</sup>.

# • Countries' strength in implementing vaccination programs may influence their populations access to vaccines

The findings from this scoping review further suggest that the ability of a country to implement a mass vaccination program is an important factor to influence equitable access<sup>23</sup>. Vaccination programs are resource intensive; therefore, to maximize the benefit of COVID-19

vaccines, and reduce waste due to improper implementation, it has been suggested that allocation frameworks should consider a country's ability to vaccinate<sup>1 13 23 24 27 41 60 61</sup>. Most LMICs have well-structured immunization programs e.g. for polio, measles and smallpox etc., facilitated by organizations such as UNICEF and Gavi which could support a large-scale pandemic vaccination program. It has been reported that Gavi, for example, has sought to expand its Cold Chain Equipment Optimization Program<sup>27</sup>. More than half of the countries in the world lack robust seasonal influenza programs to tackle influenza, despite most associated death and severe disease from influenza occurring in countries of the Global South<sup>61</sup>. The down prioritization of seasonal influenza vaccination for older populations in LMICs, compared to HICs is a vulnerability for the roll out of COVID-19 vaccines<sup>30 33 60 61</sup>. Ruscio et al. noted that this gap has been attempted to be filled by the recently published WHO Global Influenza Strategy 2019–2030<sup>61</sup>.

Vaccine roll-out requires stable cold chain and supply processes for the necessary logistical and administrative components to facilitate distribution of vaccines, including financing the in-country deliver of vaccines, from cold chain to administration<sup>13 27 28 37 47 62</sup>. Different vaccines have different temperatures for deployment, which will influence supply of vaccine to communities<sup>13 27 47 49 62</sup>, this is a particular challenge in Sub-Saharan Africa, where only 28% of health care facilities have a reliable energy supply<sup>13</sup>. In this context, vaccines that require only one dose, or those that can be stored at room temperature, are more likely to facilitate equitable access<sup>47</sup>. There is also an opportunity to explore the use of new containers and packaging, that already support distribution, e.g., pre-formed plastic vials are being successfully used for oral rotavirus and cholera vaccines<sup>60</sup>. Data solutions should also be considered, these could support alternative vaccine delivery systems for target groups, as well as being an important tool to capture the populations vaccination history<sup>28</sup>.

#### **BMJ** Open

Smooth regulatory and market authorization processes for vaccines can facilitate the distribution of vaccines<sup>30 33 37 51 61</sup>. One article from this scoping review highlighted the importance clinical vaccine studies in LMIC and HIC alike, to support the fast-tracking of market authorization as local clinical trial data is a recognized grounds for delay to introduce some vaccines into countries' immunization programs<sup>33</sup>. Delays for products preventing or treating infectious diseases are cited at being between 4 to 7 years from first approval in a high-income country and final approval in a country in Sub-Saharan Africa<sup>37</sup>.

### DISCUSSION

This study identified four key factors that have the potential to promote fairer global access to COVID-19 vaccines. Our findings show that an international approach is necessary to minimize the spread of a pandemic. A priori of this review was that there is broad international support for the principles of equitable distribution of medical countermeasures, as demonstrated by universal support for WHO resolutions<sup>4 8 9 14 63-66</sup>. COVID-19 has been no exception, with relevant commitments passed in months following declaration of the pandemic<sup>17 67-70</sup>. This, however, has not translated into binding commitments. The establishment ACT-A and COVAX, was partly a recognition of historic failures, as highlighted in the findings of this review. Co-lead by CEPI and Gavi (in partnership with WHO), both organizations were established with a commitment of equitable access to medicines in their ethos. As multi-country endorsed initiatives, they can be considered good candidates to lead the process for equitable distribution of COVID-19 vaccines<sup>12 71-73</sup>.

The risks that sovereign states pose to equitable access by acting in their national interest, including bilateral agreements with pharmaceutical companies, buying up vaccine stocks

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during clinical development phases and vaccine hoarding, were anticipated in our findings, and have, largely, been realized<sup>31</sup>.

COVAX's pooled procurement through APAs have faced challenges, initially in accessing the necessary financing, which in turn delayed securing supply against other HIC purchasers<sup>1 14 27</sup><sup>29</sup>. In addition, it has also faced critique on how price has been determined and whether any costs can be recovered if vaccine candidates fail<sup>34 40 74</sup>. While COVAX has attempted to meet foreseen gaps<sup>14</sup>, it has been challenged by national interests, highlighted recently with announcements that Australia is purchasing booster shots<sup>75</sup>, and that several HICs plan to donate parts of their surplus vaccines to LMICs directly<sup>76</sup>, rather than through the COVAX facility (regardless of membership), making vaccines a tool of geopolitics.

The pandemic has shown several examples of countries enacting their sovereign authority over goods produced within its borders; one example being the USA's invocation of the Defense Production Act reducing export of Active Pharmaceutical Ingredients<sup>77</sup>, which slowed the production of the AstraZeneca vaccine by its collaborator Serum Institute in India<sup>78</sup>. More recently, in response to a devastating second wave of COVID-19 infections, the Indian government imposed an export ban on vaccines, re-directing these to the domestic market, leading to a further slowdown in doses available to the COVAX facility<sup>79</sup>. Additionally, the redirection of vaccine manufacturing capacity to scale up production of COVID-19 vaccines will likely impact on the production of other vaccines such as influenza, measles, mumps and rubella with a disproportionate impact on the global poor<sup>80</sup>.

The rollout of a population wide immunization program has put most governments to the test, with many being critiqued for botched rollouts. Australia and Japan are two HICs that have

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faced criticism over the delays related to the logistical issues of setting up such a large vaccination program<sup>81 82</sup>. In June 2020, it was reported that less than 15% of imported vaccine doses in Japan had been used so far<sup>82</sup>. In addition, Japan is one example of a country whose vaccine implementation was interrupted by national regulatory requirements for domestic clinical trials, that could not be undertaken due to low numbers of COVID-19 cases. This prevented Japan from registering for international clinical trials to meet national requirements related to safety and efficacy<sup>82</sup>. LMICs face similar regulatory delays<sup>27 33</sup>, seemingly a bureaucratic hurdle that could be planned for, especially given the public health emergency of the situation, and that these vaccines have already met stringent regulatory standards (i.e. the US Food and Drug Administration or European Medicines Agency).

For LMICs the well-established child immunization programs have targeted parts of the population, however few LMICs have extensive experience with vaccination of the general adult population. This makes the COVID-19 the "first" adult vaccination program aiming at a high coverage rate <sup>83 84</sup>. To facilitate implementation, COVAX has integrated a "Country Readiness and Delivery (CRD) work stream" to support the introduction of COVID-19 vaccines into national vaccination programs<sup>85</sup>. However, lack of infrastructure, short shelf life and vaccine hesitancy challenge the vaccine uptake and distribution of vaccines, which has led to vaccine wastage (e.g. South Sudan and Malawi) or re-deployment to avoid this outcome (e.g. the Democratic Republic of Congo to Ghana and Madagascar)<sup>86</sup>. Other countries, such as Bhutan, have impressed with their swift implementation strategies vaccinating 90% of their eligible adult population in two weeks<sup>87</sup>.

The key and long-term solution to equitable access highlighted in our scoping review finding is the need to broaden the basis of manufacturing of vaccines. A success of the COVID-19

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response has been the high effectiveness of novel mRNA vaccines that (pre-COVID-19) were yet to enter human clinical trials. However few manufacturers have the necessary know-how to set up mRNA manufacturing capacity, resulting in the centralized production in a few locations in the Global North. WHO has relaunched C-TAP to support a "global one-stop shop for developers" following nothing being shared by any pharmaceutical company within the first 12 months of the launch of the C-TAP open platform in mid 2020 <sup>88 89</sup>. The TRIPS patent waiver of COVID-19 products received historical support from the incoming US Government Administration in May 2021, and has since moved into text-based discussions<sup>90</sup>.

Our review acknowledged that ramping up production in LMICs while meeting the necessary quality standards takes time and will require extensive knowledge transfer from pharmaceutical companies. Globally, fifteen MICs have vaccine production capacity to support the global supply of vaccines but only 12 have WHO prequalification status, which is instrumental for quality assured generic vaccine candidates<sup>2</sup> <sup>7</sup>. The pandemic has further uncovered the need for more vaccine manufacturing capacity across the whole world. The acknowledgment of the incommensurable role of manufacturing capacity is captured in a project led by CEPI project to map out manufacturing capacity for use in future pandemics<sup>91</sup>. Also, to counteract this, the African Union and African CDC launched a partnership to increase future vaccine production in Africa<sup>92</sup>.

A limitation of this Scoping Review is that literature was exclusively chosen based on relevance to the topic of identifying and describing factors related to equitable access of COVID-19 vaccines, meaning that we have included commentaries, editorials, essays and viewpoints. We determined that these perspectives to be of importance to our research aim, regardless of the type of publication. Many of the authors are established academics or

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practitioners in their field, and usual original research and journal publication timeframes are not appropriate. To manage this limitation, articles were only included if they were published in a peer reviewed journal.

#### CONCLUSION

According to current available published peer-reviewed literature, equitable access to vaccines proves to be an ongoing challenge. The uneven global distribution of vaccines is starkly shown in the current divide of vaccine coverage where the wealthiest nations have received more than 87% of the vaccines whilst LMICs just 0.2%<sup>93</sup>. Altogether, findings identified in this scoping review converge towards vaccine manufacturing being of the high importance in the supply of vaccines. Future attention could explore the contribution of MICs to facilitate vaccine supply in a pandemic, including some of the challenges of maintaining these facilities outside of a pandemic. Building on its COVID-19 success, mRNA technologies will be used for other vaccines in the future, thus the exploration and scale-up of such capacities on the African continent is likely to prove to be a valuable investment, even after the pandemic. Moreover, despite the length of time it takes to build and certify vaccine manufacturing facilities, steps can be taken to share the know-how of the manufacturing of effective vaccines, although the full possibilities of relaxing of patent and IPR are yet to be realized and can contribute to equitable access.

Another identified issue was the role that patent holders play in global governance through influencing the distribution of COVID-19 vaccines, this needs more transparency. In the search of factors influencing equal access, the importance of including equitable access principles to in all levels of development seemed to be relevant, e.g., throughout vaccine research and development, procurement, scale-up and distribution.

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#### ETHICS STATEMENT

Ethical clearance was not required as the review used secondary data that is available in the public domain.

#### **CONTRIBUTERS**

EP and LC: Developed the concept, drafted the protocol, data extraction, analysis, writing and review. LH: Data extraction, supported with analysis, writing and review. KF: Methodology, review of extraction, writing and review. EHD: Writing and review.

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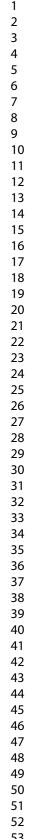
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**BMJ** Open



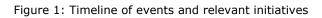


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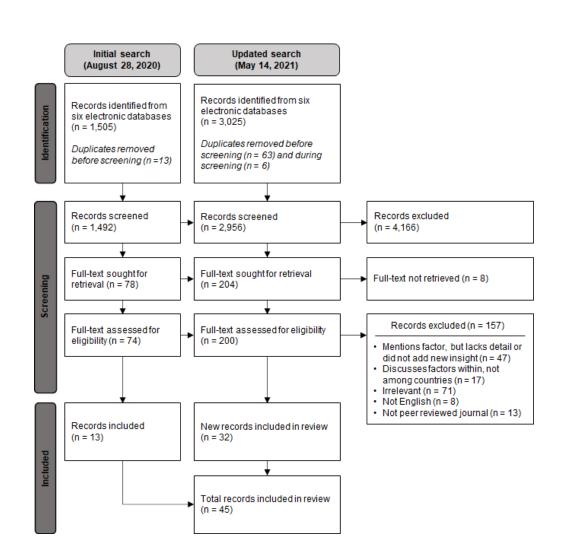
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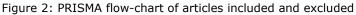
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**Event** Timeline Initiative or mechanism identified in review 1952 Global Influenza Surveillance and Response System (GISRS) 1969 International Health Regulations (IHR) The World Trade Organization (WTO) Agreement on Trade-1995 Related Aspects of Intellectual Property Rights (TRIPS) WHO Influenza Pandemic Preparedness Plan in WHO Global 1999 Agenda on Influenza Surveillance and control World Health Assembly (WHA) adopted resolution WHA 54.14 2001 member states pledged to strengthen their capacity to detect and respond rapidly to communicable disease threats and emergencies SARS coronavirus 2002 (H5N1) epidemic donesia refuses International Health Regulations (IHR) updated to include global to share virus 2005 outbreak alert system; better international surveillance samples of H5N1 during outbreak Global Action Plan for Influenza Vaccines strategy to reduce global shortage of influenza vaccines for pandemic influenza; includes Technology Transfer Initiative. GAP II updated after H1N1 2006 World Health Assembly adopted resolution WHA 60.28 enabling 2007 local manufacturing; enhance local surveillance; financing for procurement of pandemic vaccines; and access to stockpiles Swine flu Influenza A (H1N1) 2009 Pandemic Influenza Preparedness (PIP) Framework granted pandemic researchers and industry access to biological samples in exchange for financial or in-kind donation of products 2012 Pilot Advanced Market Commitment (AMC) Gavi and World Bank initiative for pneumococcal vaccines 2014 Nagoya Protocol signed on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization Coalition for Epidemic Preparedness Innovation (CEPI), a fund 2017 for clinical vaccine development for emerging infectious diseases Coronavirus-19 2019 COVAX & ACT-Accelerator vaccines pillar established COVID-19 pandemic Serum Institute of India manufacturers committed to distributing vaccines to low-and middle-income countries December: WHO issues first The COVID-19 Technology Access Pool for developers to share emergencyuse validation for 2020' intellectual property and know-how with other developers COVID-19 vaccine South Africa and India propose to WTO for a waiver of Pfizer/BioNTech intellectual property rights for COVID-19 medicine, vaccines, and other technologies; was supported by United States in 2021



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#### Appendix 1: Papers underlying this Scoping Review

List of the 44 papers included in the review, including the reference, type of publication and a short summary of the focus of the paper is shown in the table below.

No	Reference (BMJ style)	Study design	Focus of paper
1	Abbott FM, Reichman JH. Facilitating Access to Cross-Border Supplies of Patented Pharmaceuticals: The Case of the COVID-19 Pandemic. <i>Journal of International Economic</i> <i>Law</i> 2020;23(3):535-61.	Article	Proposes legal mechanisms for addressing critical issues facing the international community in terms of providing equitable access to vaccines, treatments, diagnostics, and medical equipment.
2	Bollyky TJ, Gostin LO, Hamburg MA. The Equitable Distribution of COVID-19 Therapeutics and Vaccines. Jama-Journal of the American Medical Association 2020;323(24):2462-63. doi: 10.1001/jama.2020.6641	Viewpoint	Discusses experiences and suggestions for a future framework to the distribution of COVIE 19 vaccines.
3	Choi EM. COVID-19 vaccines for low- and middle-income countries. <i>Transactions of the</i> <i>Royal Society of Tropical Medicine &amp; Hygiene</i> 2021;115(5):447-56.	Review	Discusses low- and middle-income countries access COVID-19 vaccines, what is being dom to distribute vaccines fairly, as well as the challenges ahead
4	DeFrancesco L. Whither COVID-19 vaccines? <i>Nature Biotechnology</i> 2020;38(10):1132-45.	Article	Insights from seven experts on the developmen of the COVID-19 vaccines.
5	Eccleston-Turner M. The pandemic influenza preparedness framework: A viable procurement option for developing states? <i>Medical Law</i> <i>International</i> 2017;17(4):227-48.	Article	Examines the Pandemic Influenza Framework and the content of the Obligations of the Company which have been secured by the World Health Organization.
6	Eccleston-Turner M, Upton H. International Collaboration to Ensure Equitable Access to Vaccines for COVID-19: The ACT-Accelerator and the COVAX Facility. <i>Milbank Quarterly</i>	Original Scholarship	Analysis of the COVAX Facility and its aim and ensure equitable availability of the vaccine in low and middle-income countries.
7	Fedson DS. Pandemic influenza and the global vaccine supply. <i>Clin Infect Dis</i> 2003;36(12):1552-61.	Article	The article explores several issues related to the global supply of vaccine during influenza pandemics
8	Fedson DS. Preparing for pandemic vaccination: an international policy agenda for vaccine development. <i>J Public Health Policy</i> 2005;26(1):4-29.	Commentary	Focuses on the trivalent vaccines currently available that contain inactivated viruses.
9	Fedson DS, Dunnill P. Commentary: From scarcity to abundance: pandemic vaccines and other agents for "have not" countries. <i>J Public</i> <i>Health Policy</i> 2007;28(3):322-40.	Commentary	Discusses that access to supplies of pandemic vaccine for most countries is a problem of scarcity and how to ensure the "have not" countries will get access to pandemic vaccines
10	Felicitas H, Florencia L, Manriquez RT, et al. A matter of priority: equitable access to COVID-19 vaccines. <i>Swiss Med Wkly</i> 2021;151	Viewpoint	Highlights inequality in current vaccination rates between some high income countries (HIC) and low income countries (LIC) provide arguments for HIC to support distribution to LIC
11	Fidler DP. Negotiating Equitable Access to Influenza Vaccines: Global Health Diplomacy and the Controversies Surrounding Avian Influenza H5N1 and Pandemic Influenza H1N1. <i>Plos Medicine</i> 2010;7(5)	Article	Examines the diplomatic negotiations surrounding influenza virus sharing as an example of the core tensions characterizing multilateralism and emerging forms of global health governance.
12	Fidler DP. Vaccine nationalism's politics. <i>Science</i> 2020;369(6505):749.	Editorial	Discusses global politics and the burden of global equitable COVID-19 vaccine access issues, historically and now.
13	Forman R, Anderson M, Jit M, et al. Ensuring access and affordability through COVID-19 vaccine research and development investments: A proposal for the options market for vaccines. <i>Vaccine</i> 2020;38(39):6075-77.	Commentary	Discusses existing financing mechanisms and proposal for vaccine development, referred to as Options Market for Vaccines (OMV).
14	Forman R, Shah S, Jeurissen P, et al. COVID-19 vaccine challenges: What have we learned so far and what remains to be done? <i>Health Policy</i> 2021;125(5):553-67.	Review	Offers a framework for understanding remaining and new policy challenges for globa vaccine campaigns against COVID-19 and potential solutions.

No	Reference (BMJ style)	Study design	Focus of paper
	Gray G, van der Heever A, Madhi S, et al. The	U	
	Scientists' Collective 10-point proposal for	( <b>C</b> t)	
15	equitable and timeous access to COVID-19	(Guest)	Proposes a ten-point plan for equitable and
	vaccine in South Africa. Samj South African	Editorial	timely access to COVID-19 vaccine in South
	Medical Journal 2021;111(2):89-94.		Africa.
	Guzman J, Hafner T, Maiga LA, et al. COVID-		
	19 vaccines pricing policy options for low-		Discusses four pricing strategies to address
16	income and middle- income countries. <i>BMJ</i>	Commentary	high prices and obtain COVID-19 vaccines
	Global Health 2021;6(3):03.		(and other medical products) at affordable rat
	Herlitz A, Lederman Z, Miller J, et al. Just		Offers three suggestions to strengthen how to
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17	allocation of COVID-19 vaccines. <i>BMJ Global</i>	Editorial	achieve the greatest health impact with
	Health 2021;6(2):02.		authorized COVID-19 vaccines.
	Iacobucci G. Covid-19: How will a waiver on		Presents responses from experts and
18	vaccine patents affect global supply? BMJ	News	organizations after Biden administration (US)
	2021;373:n1182.	analysis	announced to support a proposal to waive
			patents on covid-19 vaccines.
	Kamradt-Scott A, Lee K. The 2011 Pandemic		Investigates the diplomatic negotiations
19	Influenza Preparedness Framework: Global	Article	surrounding influenza virus sharing, and
17	Health Secured or a Missed Opportunity?	Anticle	evaluates the Pandemic Influenza Preparedne
	Political Studies 2011;59(4):831-47.		(PIP) framework.
	Kupferschmidt K. Global plan seeks to promote		
20	vaccine equity, spread risks. Science	News	Discusses the COVAX facility and its
	2020;369(6503):489-90.		challenges.
	Liu Y, Salwi S, Drolet BC. Multivalue ethical		Analyses and synthesizes the ethical
	framework for fair global allocation of a		considerations of four allocation paradigms:
21	COVID-19 vaccine. <i>Journal of medical ethics</i>	Article	ability to develop or purchase; reciprocity;
	2020;46(8):499-501.		ability to implement; and distributive justice.
	The Lanclet. Global governance for COVID-19		Discusses the COVID-19 vaccine bidding wa
	vaccines. Lancet (London, England)		and the necessary global level arrangements t
22	2020;395(10241):1883.	Editorial	for development, finance, production, and
	2020,373(10271),1003.		distribution.
	The Lancet. Access to COVID-19 vaccines:		usulouion.
23	looking beyond COVAX. Lancet	Editorial	Calls for a strong political leadership to suppo
20	2021;397(10278):941.	Lanonal	equitable access to vaccines
	McAdams D, McDade KK, Ogbuoji O, et al.		equitable access to vaccines
	Incentivising wealthy nations to participate in the		Discusses how maximizing the benefit of
24	COVID-19 Vaccine Global Access Facility	Commentary	bilateral deals to support COVAX, and
24		Commentary	explores how such deals can improve the glob
	(COVAX): a game theory perspective. <i>BMJ</i>		
	Global Health 2020;5(11):11.		supply of vaccines.
	McMahon A. Global equitable access to	Coor é	
25	vaccines, medicines and diagnostics for COVID-	Current	Discusses the role of patents and highlights th
	19: The role of patents as private governance.	controversy	during the COVID-19 pandemic the power of
	Journal of Medical Ethics 2020;30:30.		patent holders should be questioned.
	Nhamo G, Chikodzi D, Kunene HP, et al.		
_	COVID-19 vaccines and treatments nationalism:		Discusses the 2030 Agenda for Sustainable
26	Challenges for low-income countries and the	Article	Development and calls stakeholders for their
	attainment of the SDGs. Global Public Health		continued support to Gavi and COVAX 'to
	2021;16(3):319-39.		leave no one behind' and eliminate inequalitie
	Pagliusi S, Hayman B, Jarrett S. Vaccines for a		Summary of a meeting where public and
	healthy future: 21st DCVMN Annual General	Monting	private sector participants presented challenge
27	Meeting 2020 report. Vaccine 2021;39(18):2479-	Meeting	and opportunities related to vaccine R&D,
	88.	Report	supply chain, global policies, financing, healt
			objectives, and supporting access for LMIC.
	Phelan AL, Eccleston-Turner M, Rourke M, et		Discusses role of law on equitable access to
		a	COVID-19 vaccines, highlighting challenges
	al. Legal agreements: barriers and enablers to	Commentary	bilateral agreements, advanced purchasing, ar
28	al. Legal agreements: barriers and enablers to global equitable COVID-19 vaccine access.		
28	global equitable COVID-19 vaccine access.		COVAX
28	global equitable COVID-19 vaccine access. Lancet 2020;396(10254):800-02.		COVAX.
28	global equitable COVID-19 vaccine access. Lancet 2020;396(10254):800-02. Rourke MF. Access by Design, Benefits if		Analyses the PIP Framework, its Standard
28	global equitable COVID-19 vaccine access. Lancet 2020;396(10254):800-02. Rourke MF. Access by Design, Benefits if Convenient: A Closer Look at the Pandemic		Analyses the PIP Framework, its Standard Material Transfer Agreements (SMTAs), and
	global equitable COVID-19 vaccine access. Lancet 2020;396(10254):800-02. Rourke MF. Access by Design, Benefits if Convenient: A Closer Look at the Pandemic Influenza Preparedness Framework's Standard	Article	Analyses the PIP Framework, its Standard Material Transfer Agreements (SMTAs), and secondary sources to determine whether the P
	global equitable COVID-19 vaccine access. Lancet 2020;396(10254):800-02. Rourke MF. Access by Design, Benefits if Convenient: A Closer Look at the Pandemic Influenza Preparedness Framework's Standard Material Transfer Agreements. <i>Milbank Q</i>	Article	Analyses the PIP Framework, its Standard Material Transfer Agreements (SMTAs), and secondary sources to determine whether the P Framework will effectively function as an
28 29	global equitable COVID-19 vaccine access. Lancet 2020;396(10254):800-02. Rourke MF. Access by Design, Benefits if Convenient: A Closer Look at the Pandemic Influenza Preparedness Framework's Standard	Article	Analyses the PIP Framework, its Standard Material Transfer Agreements (SMTAs), and secondary sources to determine whether the P

No	Reference (BMJ style)	Study design	Focus of paper
30	Ruscio BA, Hotez P. Expanding global and national influenza vaccine systems to match the COVID-19 pandemic response. <i>Vaccine</i> 2020;38(50):7880-82.	Commentary	Discusses the double burden synergies of Influenza and COVID 19 in the Global South, and proposes how a way to address both issues
31	Saksena N. Global justice and the COVID-19 vaccine: Limitations of the public goods framework. <i>Global Public Health</i> 2021	Article	Focuses on global access, discussing the limitations of the global public good framewor in addressing the problem of distribution COVID-19 vaccines.
32	Sawal I, Ahmad S, Tariq W, et al. Unequal distribution of COVID-19 vaccine: A looming crisis. <i>Journal of Medical Virology</i> 2021;03:03.	Letter to Editor	Argues for the promotion of equitable access to COVID-19 vaccines to benefit the whole world.
33	Sharma S, Kawa N, Gomber A. WHO's allocation framework for COVAX: is it fair? <i>Journal of Medical Ethics</i> 2021;09:09.	Article	Explores comparing COVAX allocation mechanisms to a targeted allocation system, based on need. Arguing that this could maximize well-being and align with principles of equity.
34	Sehovic AB, Govender K. Addressing COVID- 19 vulnerabilities: How do we achieve global health security in an inequitable world. <i>Global</i> <i>Public Health</i> 2021	Commentary	Discusses the particular challenges of COVID- 19 for LMICs, and the inequities being perpetuated in the COVID-19 Pandemic and the suggestions in how to address these challenges.
35	So AD, Woo J. Reserving coronavirus disease 2019 vaccines for global access: cross sectional analysis. <i>Bmj-British Medical Journal</i> 2020;371	Special paper	Analyzes premarket purchase commitments for COVID-19 vaccines from leading manufacturers to recipient countries.
36	So AD, Woo J. Achieving path-dependent equity for global COVID-19 vaccine allocation. <i>Medicina Intensiva</i> 2021;2(4):373-77.	Commentary	Discusses the interdependence of equitable allocation based on three policy levers: Development and Production, Procurement, and Healthcare Delivery.
37	Torres I, Artaza O, Profeta B, et al. COVID-19 vaccination: returning to WHO's Health For All. <i>The Lancet Global Health</i> 2020;8(11):e1355- e56.	Commentary	Promotes the perspective of World Health Organization, calling for inclusion of all member states, and transparency.
38	Towse A, Chalkidou K, Firth I, et al. How Should the World Pay for a Coronavirus Disease (COVID-19) Vaccine? <i>Value in Health</i> 2021;24(5):625-31.	Article	Proposes the Benefit-Based Advance Market Commitment as a collaborative, market-based financing mechanism for the world to incentivize and pay for the development and provide equitable access to second and third generation COVID-19 vaccines.
39	Turner M. Vaccine procurement during an influenza pandemic and the role of Advance Purchase Agreements: Lessons from 2009- H1N1. <i>Glob Public Health</i> 2016;11(3):322-35.	Article	A case study on the procurement of pandemic influenza vaccines during 2009-H1N1, and the likely manner in which procurement will occur during future pandemics.
40	Usher AD. COVID-19 vaccines for all? <i>Lancet</i> ( <i>London, England</i> ) 2020;395(10240):1822-23.	World report	Provides an assessment of the initiatives being planned to ensure equitable access to COVID- 19 vaccines, and shortcomings.
41	Usher AD. CEPI criticised for lack of transparency. <i>Lancet</i> 2021;397(10271):265-66.	World Report	Provides insights and perspectives on CEPI contracts for COVID-19 vaccines.
42	Usher AD. South Africa and India push for COVID-19 patents ban. <i>Lancet</i> 2020;396(10265):1790-91.	World Report	Report on the proposal by India and South Africa to waiver Intellectual Property Rights to COVID-19 products (incl. vaccines).
43	Wouters OJ, Shadlen KC, Salcher-Konrad M, et al. Challenges in ensuring global access to COVID-19 vaccines: production, affordability, allocation, and deployment. <i>Lancet</i> 2021;397(10278):1023-34.	Article	Reviews potential challenges and policy implications for the production, afforable pricing, and global allocation of Covid-19 vaccines.
44	Yamey G, Schäferhoff M, Hatchett R, et al. Ensuring global access to COVID-19 vaccines. <i>Lancet (London, England)</i> 2020;395(10234):1405-06.	Commentary	Discusses how COVID-19 vaccines can be used globally to end the COVID-19 pandemic, arguing for three imperatives: speed, manufacture and deployment at scale, and global access.

Appendix 2: Updated protocol

# Factors influencing global equitable access to a COVID-19 vaccine for Low- and Middle- Income Countries (LMICs)

Proposal for scoping review

24 September 2020

Elizabeth Peacocke, Lumbwe Chola, Katrine Frønsdal and Marita Fønhus, Norwegian Institute Public Health.

Updated 24 July 2021

Elizabeth Peacocke, Lieke Fleur Heupink, Katrine Frønsdal, Elin Hoffmann Dahl and Lumbwe Chola.

## Summary

Vaccines are important medical countermeasures to prevent the spead of infectious diseases. The World Bank forecasts a 5.2% contraction in global GDP in 2020, and long-term negative impacts are expected in terms of lower investment, an erosion of human capital through lost work and schooling, and fragmentation of global trade and supply linkages (1) Without effective vaccines, diagnostics, and therapeutics, COVID-19 will continue to spread and have severe health and socio-economic consequences. The UN's Framework for the Immediate Socio-Economic Response to the COVID 19 Crisis warns "The COVID-19 pandemic is far more than a health crisis: it is affecting societies and econ-omies at their core. While the impact of the pandemic will vary from country to country, it will most likely increase poverty and inequalities at a global scale, making achievement of SDGs even more urgent." (2)

This project includes a scoping review that identifies and characterizes the factors influencing global equitable access to COVID-19 vaccines among countries, and contextualizes these factors with global mechanisms or guidelines that address global equitable access to pandemic vaccines. The documentation of these factors will offer decision makers lessons from previous experiences and information to support the understanding of principles related to equitable access to a COVID-19 vaccine.

This scoping review was conducted during August-November 2020, with a draft report for Norad, who commissioned and partly financed the report. This draft report was then submitted as a manuscript for publication. During the review process, in May 2021, the authors updated the search. This protocol has been updated to reflect the methods used in this Scoping Review.

To our knowledge, such a scoping review has not been systematically investigated.

## Title:

Factors influencing global equitable access to a COVID-19 vaccine for Low- and Middle- Income Countries (LMICs)

Proposal for scoping review

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**Commissioned by:** Commissioned by the Norad Evaluation Department

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Start date: 24.07.2020. End date: 19.07.2021

### Project Team:

Elizabeth Peacocke, Senior Advisor, NIPH Lieke Fleur Heupink, Advisor, NIPH Elin Hoffmann Dahl, MD, Haukeland Universitetssjukehus, Norway Katrine Frønsdal, Senior Researcher, NIPH

Lumbwe Chola, Senior Advisor, NIPH

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Internal peer review: Maria Fønhus, Senior researcher, NIPH

**Approved by:** Ingvil Sæterdal, Department Director, NIPH, Global Health

## Background

## New Corona Virus: SARS-CoV-2 (COVID-19) Pandemic

The world is currently facing a global public health emergency with the emergence of the Severe acute respiratory syndrome coronavirus 2 discovered in 2019 (COVID-19), an infectious acute respiratory disease caused by a novel coronavirus. A race to increase access to existing health technologies – including diagnostics - and find new and effective treatments and vaccine is underway, and with this the international community is faced with the challenge of how to ensure equitable access of essential medicines<sup>1</sup> to all populations. In this scoping review, we will systematically review the literature and summarize factors pertaining to the equitable access of a COVID-19 vaccine relevant for low- and middle- income countries (LMICs). For the purpose of this study, we are using the WHO definition of equity,<sup>2</sup> and we take the principle that the COVID-19 vaccine is an essential medicine<sup>3</sup>, and that access to essential medicines is part of the right to health which is well founded in international law (4).

# The challenge with global equitable availability and access to pandemic vaccines

COVID-19 has seen a large effort and investment in vaccines, and diagnostics, with 22 manufacturers that have applied for and Emergency Use Listing under the WHO Pre-Qualification, 10 of which have been approved (5). Shortly following these rapid advances and regulatory approvals, questions began to be raised about the availability and access of vaccines in LMIC, and as global public goods (6, 7).

The 2005 experience with the sharing of avian influenza A (H5N1) and the 2009 influenza A (H1N1) pandemic made apparent the need for equity considerations and ensuring that global coordination and distribution mechanisms are in place and adhered to, supporting equitable access to scarce vaccines. During H5N1, concerns raised by LMICs about the lack of mechanisms for ensuring global equitable access to vaccines prompted Indonesia to refuse to share H5N1 virus samples with the World Health Organization (WHO) (8). With Asia being the epicenter of the outbreak, fears were raised by the international community that Indonesia's refusal to share virus samples would impede the research and development, surveillance and response efforts, and made the response to the global health emergency more difficult. Ensuing negotiations with the

<sup>3</sup> WHO (2020)

<sup>&</sup>lt;sup>1</sup>Essential medicines are those that satisfy the priority health care needs of the population 3.World Health Organization. Essential medicines and health products. Essential medicines definition 2020 [cited 2020 August 13]. Available from: https://www.who.int/medicines/services/essmedicines\_def/en/. <sup>2</sup> Equity is the absence of avoidable, unfair, or remediable differences among groups of people, whether those groups are defined socially, economically, demographically or geographically or by other means of stratification. "Health equity" or "equity in health" implies that ideally everyone should have a fair opportunity to attain their full health potential and that no one should be disadvantaged from achieving this potential (World Health Organization. Health Topics: Health Equity. 2020 [cited 2020 August 12]; Available from: https://www.who.int/topics/health\_equity/en/).

WHO and its member states to create a new system of influenza virus sharing and vaccine availability did not immediately yield consensus.

During the 2009 pandemic, high income countries (HIC) bought virtually all vaccine supplies, leaving limited supplies for LMICs. One prominent example for this asymmetry was Mexico. Despite it being one of the first nations affected by H1N1 (concurrently with Canada and the United States), Mexico gained access to vaccines much later than the two other countries (9). The WHO intervened to mediate this potential challenge, engaging in talks with manufacturers and LMIC governments to secure equitable access to the vaccine for LMIC (10). Consequently, donation pledges to LMIC were made by manufacturers and HICs, with the exception of Canada (10, 11). These pledges from manufacturers were made without a fixed delivery date and were perceived to leave HICs with more than enough vaccines for full coverage in their own countries, leaving LMICs with limited access to timely supplies (11).

## Lessons from previous collective responses to support global equitable access to vaccines

In response to the H5N1 and H1N1 experiences, WHO and member states developed and adopted the Pandemic Influenza Preparedness (PIP) framework in 2011, a global approach to pandemic influenza preparedness and response (12). The intention of PIP was to improve and strengthen the sharing of influenza viruses with human pandemic potential; and to share the benefit of, which is to increase the access of LMICs to vaccines and other pandemic related supplies. There are, however, several gaps in the framework, not least, that it is not legally binding (13).

There are other relevant frameworks and mechanisms, such as establishing the Advanced Market Commitment for AMC for Pneumonia Vaccine, and the Pan Americal Health Organisation's Revolving Fund for Vaccines. Much can be learnt from these initiatives that is relevant to the current COVID-19 pandemic. Recent events related to COVID-19 have shown some countries and technology holders' tendencies to control the global supply of personal protective equipment, ventilators, diagnostics and therapeutic medicines and reserve supply to HIC, as well as the challenges with limited manufacturing capacity and access to know-how, intellectual property and data; indicating that it is highly likely that similar controls will be placed on a vaccine that meets the necessary safety, efficacy and regulatory standards, to be used for mass vaccination (14).

To manage anticipated issues with the distribution of COVID-19 vaccine, the WHO is convening the Access to COVID-19 Tools (ACT) Accelerator, which brings together governments, scientists, businesses, civil society, and philanthropists and global health organizations (the Bill & Melinda Gates Foundation, CEPI, FIND, Gavi, The Global Fund, Unitaid, Wellcome, the World Bank and Global Financing Facility), in efforts to support the development and equitable distribution of the tests, treatments and vaccines. The ACT-Accelerator is organized into four pillars of work: diagnostics, treatment, vaccines and health system strengthening (15). Gavi and CEPI are leading implementation of the vaccines pillar, "the COVID-19 vaccine global access (COVAX) facility", which is committed to supporting the acute phase of the pandemic through the appropriate allocation of safe and effective doses of a vaccine (16, 17).

The barriers in access to medicines to COVID-19 vaccines relate the demand and the supply of the vaccine, and there continues to be unprecedented demand for a safe and effective vaccine (18, 19). The supply of this vaccine is hampered by complex vaccine

innovation and manufacturing processes. Depending on the candidates that prove to be the most effective, the approach used will determine the necessary manufacturing capacity and length of time for development, (19). In terms of the quantity of the vaccine needed to be produced, this is also influenced by whether one or two does are necessary, in addition other challenges including e.g. with lack or insufficient global vaccine manufacturing capacity & access to know-how and implementation in LMIC countries are also essential for access to vaccines for many. All of these factors will limit the supply of vaccines.

## Importance of the project

The access to, and distribution of a scarce vaccine is one of the pegged solutions to enable the world to return some semblance of life pre-COVID 19. With COVID-19 affecting the world, the equitable distribution of this vaccine is important because the virus will cause unnecessary disability and loss of life unless the benefit of a vaccine is distributed fairly among and within countries. To our knowledge, a scoping review of the the factors for the equitable access of a COVID-19 vaccine relevant for LMIC has not been systematically investigated. The project is considered highly relevant to the current situation as it aims at identifying and describing of these factors which can inform decision makers in terms of lessons from previous experiences and supporting the understanding of principles related to equitable access to a COVID-19 vaccine, and further potentially guide implementation of future initiatives to ensure equitable access.

### Objective

This objective of this scoping review is to identify and summarize the factors for the equitable access of a COVID-19 vaccine relevant for LMICs. We will address the following question: What are the factors influencing global equitable access to a COVID-19 vaccine among countries?

## Methods

## **Scoping searches**

We will perform systematic scoping searches for publications according to PRISMA-ScR (Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews) (20).

## Inclusion criteria

We aim to identify and describe factors influencing global equitable access to a COVID-19 vaccine among countries as identified in our search (see the manuscript supplementary material), following the inclusion criteria shown in Table 1.

Table 1. Inclusion criteria

Торіс	Pandemic vaccines incl. influenza or COVID-19 vaccine	
Outcomes	The factors influencing equitable access to a pandemic vaccine incl. COVID-19 vac-	
	cine	
Type of publica-	Primary studies, systematic reviews	
tion		
Language	English	
Publication date	2002-2021	

Restriction to publications from 2002 are made as a pragmatic choice from the date of the 2003-04 SARS pandemic. Furthermore, the limitation to English language journal articles in scientific databases was balancing completeness with the resources available.

## Search strategy and Information sources:

An information specialist at NIPH will develop the search strategies together with the project leader, and another information specialist will review the search strategy. The literature search will be conducted in the following databases: Medline (PubMed and Ovid), EMBASE (Ovid), Global Index Medicus, WHO <u>https://www.globalindexmedi-cus.net/</u> and Web of Science Core Collection Clarivate Analytics (see supplementary information for updated search strategies and databases).

Additional relevant information will be searched from websites of multilateral agencies and international philanthropic agencies identified in the literature through the database search (e.g. WHO Pandemic Influenza Preparedness Framework) as a means to understand the particular framework or initiative.

## Selection of literature

## **First screening**

**BMJ** Open

We will first review articles that are determined to be relevant (according to predefined inclusion criteria described above). Three project team members (EP, LF and LC) will independently go through all identified titles and abstracts and determine if articles should be included for full-text review.

Where there are divergent views, inclusion will be determined through discussion and consensus between the reviewers or by consulting a fourth team member (KF). Records not fulfilling the inclusion criteria will be excluded.

#### Full text review

Given time constraints, the review group will divide the studies by two and each study will be read in full and assessed for inclusion by one reviewer. This is verified by a second reviewer. Disagreement over exclusion or inclusion will be handled in the same way as for the first screening.

## Extraction and presentation of data

Data to be extracted are mainly qualitative data on the predefined outcomes. Standard data extraction templates were designed, and piloted specifically for this scoping review (see the manuscript supplementary material for a copy of the data extraction form).

The predefined outcomes for extracting data include: the setting (LMIC or globally focused or normative guidance that affects LMIC), and argument/ discussion on equity, access, allocation or prioritization of pandemic vaccines, other aspects that article tells us about the knowledge in this topic area, challenges in implementing equitable access to vaccination between countries, and recommendations for strengthening the equitable access to vaccination. In addition, we collected names of relevant global initiatives and mechanisms as identified in our search. Data is to be extracted by one team member and a second reviewer will review the data extraction.

#### Analysis of data

The analysis of the data collected will provide information on the body of research and evaluations related to the factors influencing global equitable access to a COVID-19 vaccine among countries. Our analysis will include how factors influencing global equitable access to a COVID-19 vaccine among countries pertain to global frameworks and mechanisms identified in our searches.

We will consider using the following framework for analysis, adapted from Liu et al (21), which includes three main areas related to:

- A country's ability to develop or to purchase pandemic vaccines
- Reciprocity
- A country's ability to implement or vaccinate.

### Reporting, submission of manuscript and updating of search

A draft report based on the findings from the scoping review was prepared and presented to Norad and two external peer reviewers. A manuscript was then prepared and submitted to BMJ Open in January 2021. Based on feedback from peer review, the search was updated in May 2021.

#### **Risk of bias and limitations**

Due to time constraints we are extracting data directly related to our topic of interest. This will mean that some papers are excluded due to their lack of direct relevance to our question, and will not be included in the analysis.

Only one reviewer will complete the full-text review and data extraction, to limit the risk of bias, one reviewer will peer review the full-text categorisation and data extraction.

#### **Peer -review**

External and internal peer review is being used to strengthen the methods and improve the rigor of this scoping review.

#### Internal:

The project plan (this document) has been reviewed by all authors and peer reviewed internally at NIPH. Internal reviewers at NIPH will also review any publication of results presented to Norad.

#### External:

Two external peer reviewers will be used in addition before publication of results.

#### Acronyms

CEPI	Coalition for Epidemic Preparedness Innovations
COVAX the C	OVID-19 vaccine global access (COVAX) facility
COVID-19	2019 Pandemic corona virus strain
CIS	Critical Interpretive Synthesis
DNA	Deoxyribonucleic acid
Gavi	Gavi, the Vaccine Alliance
FIND the F	oundation for Innovative New Diagnostics
HIC	High income countries
H1N1	2009 influenza A
H5N1	2006 avian influenza A
LMIC	Low- and Middle- income countries

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for open teries only

## Appendix 3: Search strategies for each of the five databases (*Initially searched for the period* 01.01.2002 - 28.08.2020, updated to include12.05.2021)

Databases searched

- MEDLINE ALL 2002 to May 11, 2021
  - Ovid MEDLINE, PubMed (only 28.082020);
  - Ovid MEDLINE(R) and Epub Ahead of Print, In-Process & Other Non-Indexed Citations and Daily 2002 to August 27, 2020
- Embase 2002 to 2021, Ovid
- Web of Science Core Collection, Clarivate Analytics
- Global Index Medicus, WHO
- COVID-19 Evidence, Epistemonikos Foundation

## Updated search <u>12.05.2021</u>

We searched:

• PubMed, US National Library of Medicine (NLM): <u>pubmed.ncbi.nlm.nih.gov/</u>

Only 28.08.2020 as string was not available in 2021.

#### • MEDLINE ALL 1946 to May 11, 2021, Ovid (searched <u>12.05.2021</u>)

#	Searches	Results
1	COVID-19 Vaccines/	2510
2	Coronavirus/	4692
3	Betacoronavirus/	33218
4	Coronavirus Infections/	44847
5	Coronaviridae Infections/	919
6	Severe Acute Respiratory Syndrome/	5545
7	Pandemics/	56289
8	(COVID-19 or COVID 19 or COVID19 or 2019-nCoV or SARS2 or SARS-CoV or	177584
	SARS-CoV-2 or SARS-Cov-19 or coronavirus* or corona or pandemic?).ti,ab,kf.	
9	(BNT162 or BNT-162 or mRNA-1273 or mRNA1273 or INO-4800 or INO4800 or	218
	ChAdOx1 or Ad5-nCoV).ti,ab,kf,hw.	
10	or/2-9	184722
11	Vaccines/	22577
12	Viral Vaccines/	27055
13	Vaccination/	85401
14	Vaccination Coverage/	1540
15	Mass Vaccination/	3208
16	Immunization/	51563
17	Immunization Programs/	11524
18	(vaccin* or immuni*).ti,ab,kf.	576919
19	or/11-18	610926
20	"Delivery of Health Care"/	95912

21	"Health Services Needs and Demand"/	54005		
22	Resource Allocation/	8895		
23	Health Care Rationing/	11853		
24	Health Services Accessibility/			
25	Health Equity/	1805		
26	Right to Health/	131		
27	Universal Health Care/	149		
28	Healthcare Disparities/	18787		
29	Socioeconomic Factors/	162607		
30	Social Justice/	12551		
31	Global Health/	50200		
32	Human Rights/	14729		
33	((equit* or equal* or fair* or inequit* or unequal or unfair* or global*) adj3	32465		
	(access* or allocat* or distribut* or deliver* or provision or supply or			
	supplies)).ti,ab,kf.			
34	(right to health* or universal health*).ti,ab,kf.	7779		
35	((health* or health care) adj (rationing or disparities)).ti,ab,kf.	15193		
36	or/20-35	488375		
37	10 and 19 and 36	1157		
38	1 and 36	280		
39	37 or 38	1194		
40	(202008* or 202009* or 202010* or 202011* or 202012* or 2021*).dt,dp,ed,ep,yr.	180573		
41	39 and 40	588		
	38 or 41	608		

#### Embase 1974 to 2021 Week 18 (searched 12.05.2021) •

#	Searches	Results
1	SARS-CoV-2 vaccine/	2292
2	coronavirus disease 2019/	106145
3	coronavirinae/	3003
4	betacoronavirus/	7651
5	coronavirus infection/	12666
6	coronaviridae infection/	187
7	pandemic/	65235
8	(COVID-19 or COVID 19 or COVID19 or 2019-nCoV or SARS2 or SARS-CoV or	195467
	SARS-CoV-2 or SARS-Cov-19 or coronavirus* or corona or pandemic?).mp.	

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9	(BNT162 or BNT-162 or mRNA-1273 or mRNA1273 or INO-4800 or INO4800 or ChAdOx1 or Ad5-nCoV).mp.	355
10	or/3-9	195821
11	vaccine/	63516
12	virus vaccine/	20586
13	severe acute respiratory syndrome vaccine/	453
14	vaccination/	151179
15	vaccination coverage/	2788
16	immunization/	98822
17	mass immunization/	3739
18	(vaccin* or immuni*).ti,ab,kw,ot.	685955
19	or/11-18	736294
20	health care delivery/	184159
21	resource management/	10987
22	resource allocation/	22438
23	health care access/	69640
24	health care quality/	250577
25	health equity/	4605
26	right to health/	214
27	universal health care/	337
28	health care disparity/	17595
29	socioeconomics/	147326
30	social justice/	11121
31	global health/	12881
32	human rights/	26721
33	((equit* or equal* or fair* or inequit* or unequal or unfair* or global*) adj3	42137
	(access* or allocat* or distribut* or deliver* or provision or supply or	
	supplies)).ti,ab,kw,ot.	
34	(right to health* or universal health*).ti,ab,kw,ot.	9211
35	((health* or health care) adj (rationing or disparities)).ti,ab,kw,ot.	19032
36	or/20-35	714178
37	10 and 19 and 36	1372
38	1 and 36	266
39	2 and 19 and 36	692
40	or/37-39	1423
41	limit 40 to (conference abstracts or embase)	1129
42	limit 37 to (conference abstracts or embase)	1078

43	(202008* or 202009* or 202010* or 202011* or 202012* or 2021*).dd,em,yr.	1850404
44	42 and 43	439
45	limit 38 to (conference abstracts or embase)	259
46	limit 39 to (conference abstracts or embase)	652
47	44 or 45 or 46	751
48	47 use oemez	751

#### • Web of Science, Clarivate Analytics (searched <u>12.05.2021</u>)

Advanced search - Topic

COVID-19 OR "COVID 19" OR COVID19 OR 2019-nCoV OR "2019 nCoV" OR SARS2 OR SARS-CoV OR "SARS CoV" OR SARS-CoV-2 OR "SARS CoV 2" OR SARS-Cov-19 OR "SARS Cov 19" OR coronavirus OR corona OR pandemic OR pandemics

AND

vaccin\* OR immuni\*

AND

equity OR equitable OR equal OR equally OR inequity OR inequitable OR unequal OR unequally OR fair\* OR unfair\* OR "right to health" OR "right to healthcare" OR "universal health" OR "universal healthcare" OR "healthcare rationing" OR "healthcare rationing" OR "healthcare disparity" OR "healthcare disparities" OR "healthcare disparities"

## • Global Index Medicus, WHO: <u>www.globalindexmedicus.net</u> (searched <u>14.05.2021</u>)

Advanced search in Title, abstract, subject

COVID-19 OR "COVID 19" OR COVID19 OR 2019-nCoV OR "2019 nCoV" OR SARS2 OR SARS-CoV OR "SARS CoV" OR SARS-CoV-2 OR "SARS CoV 2" OR SARS-Cov-19 OR "SARS Cov 19" OR coronavirus OR corona OR pandemic OR pandemics

AND

vaccine OR vaccines OR vaccination OR immunization OR immunisation

AND

equity OR equitable OR equal OR equally OR inequity OR inequitable OR unequal OR unequally OR fair\* OR unfair\* OR "right to health" OR "right to healthcare" OR "universal health" OR "universal healthcare" OR "healthcare rationing" OR "healthcare disparity" OR "healthcare disparities" OR "healthcare disparities" OR global OR globally

• COVID-19 Evidence, Epistemonikos Foundation: app.iloveevidence.com/loves/5e6fdb9669c00e4ac072701d?utm=epdb\_en (searched 14.05.2021)

(vaccin\* OR immuniz\* OR immunis\*) AND (equity OR equitable OR equal OR equally OR inequity OR inequitable OR unequal OR unequally OR fair\* OR unfair\* OR "right to health" OR "right to healthcare" OR "universal health" OR "universal healthcare" OR "healthcare rationing" OR "health care rationing" OR "healthcare disparity" OR "healthcare disparities" OR "healthcare disparities" OR global OR globally) AND (access\* or allocat\* or distribut\* or deliver\* or provision or supply or supplies)

LIMITED TO Type of publication: Pre-print

## Original search of databases: 28.08.2020

• MEDLINE, PubMed (searched 28.08.2020)

MeSH: "COVID-19 vaccine" [Supplementary Concept]

Ovid MEDLINE(R) and Epub Ahead of Print, In-Process & Other Non-Indexed Citations and Daily 1946 to August 27, 2020 (searched 28.08.2020)

#	Searches	Results
1	Coronavirus/	3244
2	Betacoronavirus/	16530
3	Coronavirus Infections/	24138
4	Coronaviridae Infections/	906
5	Severe Acute Respiratory Syndrome/	4873
6	Pandemics/	24349
7	(COVID-19 or COVID 19 or COVID19 or 2019-nCoV or SARS2 or SARS- CoV or SARS-CoV-2 or SARS-Cov-19 or coronavirus* or corona or pandemic?).ti,ab,kf.	91205
8	(BNT162 or BNT-162 or mRNA-1273 or mRNA1273 or INO-4800 or INO4800 or ChAdOx1 or Ad5-nCoV).ti,ab,kf,hw.	51
9	or/1-8	97109
10	Vaccines/	21690
11	Viral Vaccines/	25884
12	Vaccination/	81687
13	Vaccination Coverage/	1160
14	Mass Vaccination/	3038
15	Immunization/	50752
16	Immunization Programs/	10877
17	(vaccin* or immuni*).ti,ab,kf.	546309
18	or/10-17	579947
19	"Delivery of Health Care"/	91173
20	"Health Services Needs and Demand"/	53044
21	Resource Allocation/	8501
22	Health Care Rationing/	11514
23	Health Services Accessibility/	74764
24	Health Equity/	1291
25	Right to Health/	75
26	Universal Health Care/	80
27	Healthcare Disparities/	17030
28	Socioeconomic Factors/	157123
29	Social Justice/	12160
30	Global Health/	47402
31	Human Rights/	14384

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32	((equit* or equal* or fair* or inequit* or unequal or unfair* or global*) adj3 (access* or allocat* or distribut* or deliver* or provision or supply or supplies)).ti,ab,kf.	29976
33	(right to health* or universal health*).ti,ab,kf.	7053
34	((health* or health care) adj (rationing or disparities)).ti,ab,kf.	13345
35	or/19-34	466021
36	9 and 18 and 35	632

## • Embase 1974 to 2020 Week 34, Ovid (searched <u>28.08.2020</u>)

	mbase 1774 to 2020 Week 34, Ovid (searched <u>20.00.2020</u> )	
#	Searches	Results
1	coronavirinae/	2268
2	betacoronavirus/	4632
3	coronavirus infection/	8485
4	coronaviridae infection/	166
5	pandemic/	30028
6	(COVID-19 or COVID 19 or COVID19 or 2019-nCoV or SARS2 or SARS-	103695
	CoV or SARS-CoV-2 or SARS-Cov-19 or coronavirus* or corona or	
	pandemic?).mp.	
7	(BNT162 or BNT-162 or mRNA-1273 or mRNA1273 or INO-4800 or	85
	INO4800 or ChAdOx1 or Ad5-nCoV).mp.	
8	or/1-7	103962
9	vaccine/	60026
10	virus vaccine/	19609
11	severe acute respiratory syndrome vaccine/	385
12	vaccination/	140276
13	vaccination coverage/	2060
14	immunization/	94131
15	mass immunization/	3511
16	(vaccin* or immuni*).ti,ab,kw,ot.	643022
17	or/9-16	689815
18	health care delivery/	174154
19	resource management/	10271
20	resource allocation/	20867
21	health care access/	62445
22	health care quality/	241073
23	health equity/	3269
24	right to health/	105
25	universal health care/	155
26	health care disparity/	15646
27	socioeconomics/	140163
28	social justice/	10427
29	global health/	9804
30	human rights/	24894
31	((equit* or equal* or fair* or inequit* or unequal or unfair* or global*) adj3	38602
	(access* or allocat* or distribut* or deliver* or provision or supply or	
	supplies)).ti,ab,kw,ot.	
32	(right to health* or universal health*).ti,ab,kw,ot.	8082
33	((health* or health care) adj (rationing or disparities)).ti,ab,kw,ot.	16415
34	or/18-33	670545
35	8 and 17 and 34	672
36	limit 35 to (conference abstracts or embase)	529

Adva	anced search in Title, abstract, subject
COV	/ID-19 OR "COVID 19" OR COVID19 OR 2019-nCoV OR "2019 nCoV" OR SARS2 OR
SAR	S-CoV OR "SARS CoV" OR SARS-CoV-2 OR "SARS CoV 2" OR SARS-Cov-19 OR "SARS
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unfa	ir OR unfairly OR disparity OR disparities OR global OR globally
•	Web of Science, Clarivate Analytics (searched <u>28.08.2020</u> )
COV	/ID-19 OR "COVID 19" OR COVID19 OR 2019-nCoV OR "2019 nCoV" OR SARS2 OR
SAR	S-CoV OR "SARS CoV" OR SARS-CoV-2 OR "SARS CoV 2" OR SARS-Cov-19 OR "SARS

Cov 19" OR coronavirus OR corona OR pandemic OR pandemics

AND

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AND

equity OR equitable OR equal OR equally OR inequity OR inequitable OR unequal OR unequally OR unfair OR unfairly OR "right to health" OR "right to healthcare" OR "universal health" OR "universal healthcare" OR "healthcare rationing" OR "healthcare rationing" OR "healthcare disparity" OR "healthcare disparities" OR "healthcare disparities"

#### Appendix 4: Excluded articles and reason for exclusion

**Reason for exclusion key:** 1: mentions issue but lacks detail or did not add new insight to factors related to equitable access, 2: discusses within, not amongst countries, 3: irrelevant, 4: not English, 5: full-text unavailable, 6: not in peer reviewed journal.

Nr*	First author, year	Title	Reason excluded
1	Acharya, 2021	Access to and equitable distribution of COVID-19 vaccine in low-income countries	1
2	Anonymous, 2021	Why a pioneering plan to distribute COVID vaccines equitably must succeed	1
3	Anonymous, 2021	It's time to consider a patent reprieve for COVID vaccines	1
4	Aryeetey, 2021	A step backwards in the fight against global vaccine inequities	1
5	Bennett, 2010	Law, ethics and pandemic preparedness: the importance of cross-jurisdictional and cross-cultural perspectives	1
6	Binagwaho, 2021	Equitable and Effective Distribution of the COVID-19 Vaccines - A Scientific and Moral Obligation	1
7	Burki, 2021	Equitable distribution of COVID-19 vaccines	1
8	Burki, 2021	Challenges in the rollout of COVID-19 vaccines worldwide	1
9	Cohen, 2021	As vaccines emerge, a global waiting game begins	1
10	Emanuel, 2020	An ethical framework for global vaccine allocation	1
11	Ferguson, 2020	Love thy neighbour? Allocating vaccines in a world of competing obligations	1
12	Fisher, 2011	Pandemic response lessons from influenza H1N1 2009 in Asia	1
13	Friede, 2011	WHO initiative to increase global and equitable access to influenza vaccine in the event of a pandemic: supporting developing country production capacity through technology transfer	1
14	Garfinkel, 2020	Survival of the Wealthiest?	1
15	Gostin, 2020	Facilitating Access to a COVID-19 Vaccine through Global Health Law	1
16	Haaheim, 2009	Pandemic influenza vaccines - the challenges	1
17	Hay, 2018	The WHO global influenza surveillance and response system (GISRS)-A future perspective	1
18	Herzog, 2021	Covax must go beyond proportional allocation of covid vaccines to ensure fair and equitable access	1
19	Hessel, 2009	Pandemic influenza vaccines: Meeting the supply, distribution and deployment challenges	1
20	Но, 2020	Global Disparity and Solidarity in a Pandemic	1
21	Hurley, 2021	It's self-interest to share our vaccines globally	1
22	Kamradt-Scott, 2012	Evidence-based medicine and the governance of pandemic influenza	1
23	Kim, 2021	Operation Warp Speed: implications for global vaccine security	1
24	Kimble, 2021	Considerations on the distribution and administration of the new COVID-19 vaccines	1
25	Kupferschmidt, 2020	Despite obstacles, WHO unveils plan to distribute vaccine	1
26	Lie, n.d.	Allocating a COVID-19 Vaccine: Balancing National and International Responsibilities	1
27	Lomazzi, 2020	Equitable access to COVID-19 vaccination: a distant dream?	1
28	Megiddo, 2020	Fairer financing of vaccines in a world living with COVID- 19	1
29	Meyer, 2020	After a COVID-19 vaccine: Collaboration or competition?	1
30	Milstien, 2003	Emergency response vaccines: Lessons learned in response to communicable diseases	1
31	Munguia-Lopez, 2021	Fair Allocation of Potential COVID-19 Vaccines Using an Optimization-Based Strategy	1
32	Nannei, 2016	Stakeholders' perceptions of 10years of the Global Action Plan for Influenza Vaccines (GAP) - Results from a survey	1

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	N. 2020		
33	Nazar, 2020	All for vaccine, vaccine for all	<u>l</u>
<u>34</u> 35	Nkengasong, 2020 Ogbogu, 2020	COVID-19 vaccines: how to ensure Africa has access	1
	Oglogu, 2020 Orit Fischman, 2021	Bioethics and practical justice in the post-COVID-19 era	1
<u>36</u> 37	Punjabi, 2021	A Global Pandemic Remedy to Vaccine Nationalism Vaccine is health and health is wealth	1
57	Fulljabl, 2021	Latin American scientists join the coronavirus vaccine race:	1
38	Rodríguez Mega, 2020	'No one's coming to rescue us'	1
		Pandemic influenza vaccination: lessons learned from Latin	
39	Ropero-Alvarez, 2012	America and the Caribbean	1
		The commitment for fair distribution of COVID-19 vaccine	
40	Sadeghi, 2021	among all countries of the world.	1
		Prioritization of pandemic influenza vaccine: Rationale and	
41	Schwartz, 2009	strategy for decision making	1
42	Schwartz, 2020	Equitable global access to coronavirus disease 2019 vaccines	1
42	Schwartz, 2020	COVID-19 vaccine diplomacy and equitable access to	1
43	Sharun, 2021	vaccines amid ongoing pandemic	1
44	The Lanclet, 2020	Global collaboration for health: rhetoric versus reality	1
		After the Coronavirus Vaccine's Discovery: Concerns	1
45	Usman, 2020	Regarding a COVID-19 Vaccination's Distribution	1
46	Yamada, 2009	Poverty, wealth, and access to pandemic influenza vaccines	1
47	Yen, 2015	The development of global vaccine stockpiles	1
47	1 cii, 2015	Rationing of influenza vaccine during a pandemic: ethical	1
48	Zimmerman, 2007	analyses	1
		Transparent, equitable, safe, and effective use of COVID-19	
49	Abramowitz, 2020	vaccines: A societal imperative	2
		Intellectual Property Rights, Pharmaceutical Patents and	
50	Adebambo Anthony, 2020	Public Health: Adopting Compulsory and Government Use	2
50	Adebailioo Antiloliy, 2020	Licenses in the COVID-19 Emergency in Nigeria	2
		Comments on the Preliminary Framework for Equitable	
51	Ana Santos, 2020	Allocation of COVID-19 Vaccine	2
		ASHP principles for COVID-19 vaccine distribution,	
52	Anonymous, 2020	allocation, and mass immunization	2
		Disparities in H1N1 Vaccination Rates: a Systematic Review	
53	Ayers, 2021	and Evidence Synthesis to Inform COVID-19 Vaccination	2
55	riyeis, 2021	Efforts	2
		Preparedness for influenza vaccination during a pandemic in	
54	Bell, 2018	the World Health Organization Western Pacific Region	2
		Analysing the interplay between the right to health and	
55	Cerilles, n.d.	pharmaceutical patent rights in the introduction of a COVID-	2
	,,	19 vaccine into the Philippines	_
		Strategies for broad global access to pandemic influenza	
56	Edwards, 2009	vaccines	2
		Public health strategies for distribution of influenza vaccine	
57	Hadler, 2005	during an influenza pandemic	2
		Last-Mile Logistics of Covid Vaccination - The Role of	_
58	Lee, 2021	Health Care Organizations	2
	1 : 2021	Jeremy Farrar: Make vaccine available to other countries as	2
59	Looi, 2021	soon as our most vulnerable people have received it	2
		Maintaining a Focus on Health Equity During the COVID-19	2
60	Martin, 2021	Vaccine Rollout	2
- 1		What It Will Take to Equitably Distribute a COVID-19	2
61	Medina-Walpole, 2021	Vaccine	2
	March 2007	How relevant is Bellagio statement of principles on social	2
62	Muula, 2007	justice and influenza to Africa?	2
<u> </u>	0.11 0000	Who gets a COVID vaccine first? Access plans are taking	2
63	Subbaraman, 2020	shape	2
	Todd 2021	Learning from past mistakes? The COVID-19 vaccine and	2
64	Todd, 2021	the inverse equity hypothesis	2
<i></i>	Marchana 2021	Vaccine diplomacy: Exploring the benefits of international	2
65	Varshney, 2021	collaboration	2
	A day 2020	Distribution equality as an optimal epidemic mitigation	2
66	Adar, 2020	strategy	3
		Uneven power dynamics must be levelled in COVID-19	
67	Alaran, 2021	Uneven power dynamics must be revened in COVID-19	3

68	AlKhaldi, 2021	Rethinking and strengthening the Global Health Diplomacy through triangulated nexus between policy makers, scientists	3
	······································	and the community in light of COVID-19 global crisis	
(0)	A1 Orribi 2021	Migrant health is public health: a call for equitable access to	2
69	Al-Oraibi, 2021	COVID-19 vaccines	3
70	Anderson, 2020	Intensifying vaccine production	3
71	Anonymous, 2021	COVID-19 Vaccine: Development, Testing, and Distribution	3
72	Bartovic, 2021	Ensuring equitable access to vaccines for refugees and	3
12	Buito (10, 2021	migrants during the COVID-19 pandemic	5
73	Bhatia, 2013	The H1N1 influenza pandemic: need for solutions to ethical	3
	,	problems	_
74	Billington, 2020	Developing Vaccines for SARS-CoV-2 and Future Epidemics	3
75	-	and Pandemics: Applying Lessons from Past Outbreaks	2
75	Boulton, 2021	Advancing Global Vaccination Equity           How to ensure a needs-driven and community-centred	3
76	Boum Ii, 2021	vaccination strategy for COVID-19 in Africa	3
77	Briand, 2010	Future developments in global influenza surveillance	3
11		WTO Waiver from Intellectual Property Protection for	
78	Bryan, 2021	COVID-19 Vaccines and Treatments: A Critical Review	3
		Unequal Access to Vaccines Will Exacerbate Other	
79	Cheong, 2020	Inequalities	3
		Allocating vaccines and antiviral medications during an	
80	Coleman, 2009	influenza pandemic	3
		Human rights and fair access to COVID-19 vaccines: the	
81	Commissioners, 2021	International AIDS Society-Lancet Commission on Health	3
		and Human Rights	5
00	D. 1. : 2021	Pro-equity immunization and health systems strengthening	2
82	Dadari, 2021	strategies in select Gavi-supported countries	3
02	Ell- 2010	Haggling over viruses: the downside risks of securitizing	2
83	Elbe, 2010	infectious disease	3
84	Eurosurveillance editorial,	Agreement on a pandemic influenza preparedness framework	3
04	2011	for the sharing of viruses and benefit sharing	5
85	Fedson, 2006	Vaccine development for an imminent pandemic: why we	3
05		should worry, what we must do	
86	Gladas, 2021	Supporting efforts for a global COVID-19 vaccine	3
87	Goh, 2021	Covid-19 vaccination: the dangers of "values" imperialism	3
88	Gostin, 2006	Medical countermeasures for pandemic influenza: ethics and	3
	,	the law	
89	Griffin, 2020	Covid-19: Governments should demand transparency on	3
00		vaccine deals, says MSF	2
90	Gronvall, 2006	Removing barriers to global pandemic influenza vaccination	3
91	Cuerin 2020	The consequence of COVID-19 on the global supply of	2
91	Guerin, 2020	medical products: Why Indian generics matter for the	3
		world? Ethical tradeoffs in SARS-CoV-2 vaccine development:	
92	Gurwitz, 2021	Assuring fair availability for low-income countries	3
		Vaccines for an influenza pandemic: scientific and political	
93	Haaheim, 2007	challenges	3
		No-Fault Compensation for Vaccine Injury - The Other Side	
94	Halabi, 2020	of Equitable Access to Covid-19 Vaccines	3
95	Hendriks, 2011	An international technology platform for influenza vaccines	3
		Allocation criteria for an initial shortage of a future SARS-	
96	Henn, 2020	CoV-2 vaccine and necessary measures for global immunity	3
97	Huneycutt, 2020	Finding equipoise: CEPI revises its equitable access policy	3
		Out of Africa: A Solidarity-Based Approach to Vaccine	
98	Jecker, 2021	Allocation	3
00	L 1 2021	Vaccine ethics: an ethical framework for global distribution	~
99	Jecker, 2021	of COVID-19 vaccines	3
100		The politics of medicine and the global governance of	
100	Kamradt-Scott, 2013	pandemic influenza	3
101	Karim, 2020	COVID-19 vaccine affordability and accessibility	3
		From Vaccine Nationalism to Vaccine Equity - Finding a	
	Katz, 2021	Path Forward	3
102	· · · · · · · · · · · · · · · · · · ·	1 uli 1 of Muld	
102 103	Kelley, 2020	An appeal for practical social justice in the COVID-19 global	3

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104	Kelley, 2021	Process and operations strategies to enable global access to antibody therapies	3
105	Khamsi, 2020	If a coronavirus vaccine arrives, can the world make enough?	3
106	Kieny, 2009	WHO supports fair access to influenza A (H1N1) vaccine	3
107	Koff, 2021	A universal coronavirus vaccine	3
108	Kyd, 2010	3rd Global Vaccine Congress	3
109	Lee, 2011	The Benefits To All Of Ensuring Equal And Timely Access To Influenza Vaccines In Poor Communities	3
110	Li, 2010	Healthcare system cost evaluation of antiviral stockpiling for pandemic influenza preparedness	3
111	McLachlan, 2012	A proposed non-consequentialist policy for the ethical distribution of scarce vaccination in the face of an influenza pandemic	3
112	McLachlan, 2015	On the random distribution of scarce doses of vaccine in response to the threat of an influenza pandemic: a response to Wardrope	3
113	Monto, 2011	Response to the 2009 pandemic: effect on influenza control in wealthy and poor countries	3
114	Mukherjee, 2020	Global efforts on vaccines for COVID-19: Since, sooner or later, we all will catch the coronavirus	3
115	Nguyen, 2010	The influenza challenge	3
116	Pagliusi, 2018	Vaccines, inspiring innovation in health	3
		A decade of adaptation: Regulatory contributions of the	5
117	Palkonyay, 2016	World Health Organization to the Global Action Plan for Influenza Vaccines (2006-2016)	3
118	Peters, 2021	Ensuring vaccine supply meets global needs	3
119	Rastegar, 2021	An inventory-location optimization model for equitable influenza vaccine distribution in developing countries during	3
120	Roope, 2020	the COVID-19 pandemic           How Should a Safe and Effective COVID-19 Vaccine be           Allocated? Health Economists Need to be Ready to Take the           Baton	3
121	Ruscio, 2020	Shaping meeting to explore the value of a coordinated work plan for epidemic and pandemic influenza vaccine preparedness	3
122	Sabri, 2020	Solidarity in the time of covid-19 pandemic	3
123	Saunders, 2018	EQUALITY IN THE ALLOCATION OF SCARCE VACCINES	3
124	Shretta, 2021	Vaccinating the world against COVID-19: getting the delivery right is the greatest challenge	3
125	Smith, 2021	Top five ethical lessons of COVID-19 that the world must learn	3
126	Snyder, 2020	Designing Pull Funding For A COVID-19 Vaccine	3
127	Stohr, 2006	Influenza pandemic vaccines: How to ensure a low-cost, low- dose option	3
128	Stoto, 2013	Lessons about the state and local public health system response to the 2009 H1N1 pandemic: a workshop summary	3
129	Straetemans, 2007	Prioritization strategies for pandemic influenza vaccine in 27 countries of the European Union and the Global Health Security Action Group: a review	3
130	Tatar, 2021	The Role of Good Governance in the Race for Global Vaccination during the COVID-19 Pandemic	3
131	Wardrope, 2012	Scarce vaccine supplies in an influenza pandemic should not be distributed randomly: reply to McLachlan	3
132	Wong, 2018	Funding vaccines for emerging infectious diseases	3
133	Wynia, 2006	Ethics and public health emergencies: rationing vaccines	3
134	Yau, n.d.	Mapping the inequality of the global distribution of seasonal influenza vaccine	3
135	Zard, n.d.	Leave no one behind: ensuring access to COVID-19 vaccines for refugee and displaced populations	3
136	Aranzazu, 2013	The WHO influenza surveillance network. Modes of circulation of viruses strains, knowledge and technologies, 1947-2007	4

		BMJ Open	
137	Bingzhe, 2020	Expanding the pandemic influenza preparedness framework to the epidemic of COVID-19	4
38	Leineweber, 2021	The influence of the U.S. response to COVID-19 in Global Health	4
139	Collin, 2009	[Influenza vaccine: globalization of public health stakes]	5
.40	Donatelli, 2003 Iacob, 2020	[WHO Influenza Global Agenda]The Role of the Joint Procurement Agreement during the COVID-19 Pandemic: Assessing Its Usefulness and Discussing Its Potential to Support a European Health Union	5
42	Jorgensen, 2013	Unequal access to vaccines in the WHO European Region during the A(H1N1) influenza pandemic in 2009	5
43	Lopalco, 2016	Pandemic vaccines: Are we prepared for the next pandemic?	5
44	Mark, 2020	The Procurement of a COVID-19 Vaccine in Developing Countries: Lessons from the 2009-H1N1 Pandemic	5
45	Mendes, 2021	Tackling inequitable distribution of the COVID-19 vaccine	5
46 47	Saransh, 2021	Building Resilient Vaccine Distribution           The COVID-19 Vaccine Race: Intellectual Property,	5
	Ana Santos, 2020	Collaboration(s), Nationalism and Misinformation	
<u>48</u> 49	Ana Santos, 2020 Ana Santos, 2020	The Reemergence of Vaccine Nationalism The Intellectual Property of COVID-19	<u>6</u> 6
<del>5</del> 0	Armin von, 2020	The Role of International Law in Vaccinating Against COVID-19: Appraising the COVAX Initiative	6
51	Benjamin, 2020	COVID-19 Vaccine Research, Development, Regulation and Access	6
52	François, 2020	Spatial Allocation of Scarce Vaccine and Antivirals for COVID-19	6
53	Goldstein, 2021	Failure to achieve global vaccine equity will have dire consequences	6
54	Jorge, 2021	US Support for a WTO Waiver of COVID-19 Intellectual Property – What Does it Mean?	6
55	Mohamed Mustafa, 2021	The Cost of Procuring and Delivering COVID-19 Vaccines in Low- and Middle-Income Countries: A Model of Projected Resource Needs	6
56	National Academies of Sciences Engineering and Medicine, 2020	Framework for Equitable Allocation of COVID-19 Vaccine	6
57	Shlomit, 2021	Intellectual Property Laws in the Digital Era: An International Distributive Justice Perspective	6
58	Simon, 2021	The Covid-19 Vaccine Production Club: Will Value Chains Temper Nationalism?	6
59	Viviana Munoz, 2020	The COVID-19 Pandemic: R&D and Intellectual Property Management for Access to Diagnostics, Medicines and Vaccines	6
		21	

## Appendix 5: Data extraction form for factors influencing global equitable access to COVID-19 vaccines for Low-and Middle-Income Countries

- 1. Name of reviewer
- 2. First author and year of publication (Date) e.g. Li (2011)
- 3. Title
- 4. Inclusion criteria (all must be selected):
  - LMIC or globally focussed or normative guidance that affects LMIC
  - Published between 2005-2021
  - Discusses influenza/pandemic/COVID-19 vaccine(s)
  - Contains arguments/discussion on equity, access, allocation or prioritization of influenza/pandemic/COVID-19vaccine(s)
  - Published in English

Findings related to our Scoping Review research objective: What are the factors influencing global equitable access to a COVID-19 vaccine among countries?

- 5. Summarise: What does this article tell us about the knowledge related to allocation and pandemic vaccine(s)?
- 6. Key examples or illustrations from publication (including page numbers)
- 7. Summarise: What does this article tell us about the knowledge related to allocation and pandemic vaccine(s)?
- 8. Key examples or illustrations from publication (including page numbers)
- 9. Summarise: What does this article tell us about the knowledge related to allocation and pandemic vaccine(s)?
- 10. Key examples or illustrations from publication (including page numbers)
- 11. Summarise: What does this article tell us about the knowledge related to allocation and pandemic vaccine(s)?
- 12. Key examples or illustrations from publication (including page numbers)
- 13. Is there anything else that this study tells us about the knowledge in this topic area?
- 14. Challenges in implementing equitable access to vaccination
- 15. List any global initiatives/mechnasims/frameworks identified in our search that address equitable access to pandemic vaccine(s)?
- 16. Recommendations for strengthening equitable access to vaccination

Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) Checklist

SECTION	ITEM	PRISMA-ScR CHECKLIST ITEM	REPORTED ON PAGE #
TITLE			
Title	1	Identify the report as a scoping review.	1
ABSTRACT	1		
Structured summary	2	Provide a structured summary that includes (as applicable): background, objectives, eligibility criteria, sources of evidence, charting methods, results, and conclusions that relate to the review questions and objectives.	2
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known. Explain why the review questions/objectives lend themselves to a scoping review approach.	4, 5, 6
Objectives	4	Provide an explicit statement of the questions and objectives being addressed with reference to their key elements (e.g., population or participants, concepts, and context) or other relevant key elements used to conceptualize the review questions and/or objectives.	7
METHODS			
Protocol and registration	5	Indicate whether a review protocol exists; state if and where it can be accessed (e.g., a Web address); and if available, provide registration information, including the registration number.	7
Eligibility criteria	6	Specify characteristics of the sources of evidence used as eligibility criteria (e.g., years considered, language, and publication status), and provide a rationale.	8
Information sources*	7	Describe all information sources in the search (e.g., databases with dates of coverage and contact with authors to identify additional sources), as well as the date the most recent search was executed.	7
Search	8	Present the full electronic search strategy for at least 1 database, including any limits used, such that it could be repeated.	8
Selection of sources of evidence†	9	State the process for selecting sources of evidence (i.e., screening and eligibility) included in the scoping review.	8
Data charting process‡	10	Describe the methods of charting data from the included sources of evidence (e.g., calibrated forms or forms that have been tested by the team before their use, and whether data charting was done independently or in duplicate) and any processes for obtaining and confirming data from investigators.	8
Data items	11	List and define all variables for which data were sought and any assumptions and simplifications made.	8
Critical appraisal of individual sources of evidence§	12	If done, provide a rationale for conducting a critical appraisal of included sources of evidence; describe the methods used and how this information was used in any data synthesis (if appropriate).	N/A



SECTION	ITEM	PRISMA-ScR CHECKLIST ITEM	REPORTED ON PAGE #
Synthesis of results	13	Describe the methods of handling and summarizing the data that were charted.	8
RESULTS			
Selection of sources of evidence	14	Give numbers of sources of evidence screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally using a flow diagram.	9
Characteristics of sources of evidence	15	For each source of evidence, present characteristics for which data were charted and provide the citations.	9-20
Critical appraisal within sources of evidence	16	If done, present data on critical appraisal of included sources of evidence (see item 12).	9-20
Results of individual sources of evidence	17	For each included source of evidence, present the relevant data that were charted that relate to the review questions and objectives.	9-20
Synthesis of results	18	Summarize and/or present the charting results as they relate to the review questions and objectives.	9-20
DISCUSSION			
Summary of evidence	19	Summarize the main results (including an overview of concepts, themes, and types of evidence available), link to the review questions and objectives, and consider the relevance to key groups.	9 & 20-23
Limitations	20	Discuss the limitations of the scoping review process.	23
Conclusions	21	Provide a general interpretation of the results with respect to the review questions and objectives, as well as potential implications and/or next steps.	24
FUNDING			
Funding	22	Describe sources of funding for the included sources of evidence, as well as sources of funding for the scoping review. Describe the role of the funders of the scoping review.	3

JBI = Joanna Briggs Institute; PRISMA-ScR = Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews.

\* Where *sources of evidence* (see second footnote) are compiled from, such as bibliographic databases, social media platforms, and Web sites.

† A more inclusive/heterogeneous term used to account for the different types of evidence or data sources (e.g., quantitative and/or qualitative research, expert opinion, and policy documents) that may be eligible in a scoping review as opposed to only studies. This is not to be confused with *information sources* (see first footnote).
‡ The frameworks by Arksey and O'Malley (6) and Levac and colleagues (7) and the JBI guidance (4, 5) refer to the

process of data extraction in a scoping review as data charting. § The process of systematically examining research evidence to assess its validity, results, and relevance before using it to inform a decision. This term is used for items 12 and 19 instead of "risk of bias" (which is more applicable to systematic reviews of interventions) to include and acknowledge the various sources of evidence that may be used in a scoping review (e.g., quantitative and/or qualitative research, expert opinion, and policy document).

*From:* Tricco AC, Lillie E, Zarin W, O'Brien KK, Colquhoun H, Levac D, et al. PRISMA Extension for Scoping Reviews (PRISMAScR): Checklist and Explanation. Ann Intern Med. 2018;169:467–473. doi: 10.7326/M18-0850.



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### GLOBAL ACCESS TO COVID-19 VACCINES: A SCOPING REVIEW OF FACTORS THAT MAY INFLUENCE EQUITABLE ACCESS FOR LOW-AND MIDDLE-INCOME COUNTRIES

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## **GLOBAL ACCESS TO COVID-19 VACCINES: A SCOPING REVIEW OF FACTORS**

# THAT MAY INFLUENCE EQUITABLE ACCESS FOR LOW-AND MIDDLE-

### **INCOME COUNTRIES**

# Authors: Elizabeth Peacocke, Lieke Fleur Heupink, Katrine Frønsdal, Elin Hoffmann Dahl, Lumbwe Chola

Corresponding author: Elizabeth Peacocke, DPH, Norwegian Institute of Public Health, Division for Health Services (a) <u>Elizabeth.Peacocke@fhi.no</u>, t. +47 941 60 559

Lieke Fleur Heupink, MSc. LiekeFleur.Heupink@fhi.no, Norwegian Institute of Public Health (a)

Katrine Bjørnebek Frønsdal, PhD. <u>Katrine.Fronsdal@fhi.no</u>, Norwegian Institute of Public Health (a)

Elin Hoffmann Dahl, MD. elin.hoffmann.dahl@helse-bergen.no, Haukeland University Hospital (b)

Lumbwe Chola, PhD. Lumbwe.Chola@fhi.no, Norwegian Institute of Public Health (a)

(a) Norwegian Institute of Public Health 🥖

Division for Health Services

Postbox 222 Skøyen, 0213 Oslo, NORWAY

Visiting address: Sandakerveien 24C, Entrance D11, 0473 Oslo, NORWAY

(b) Department of Medicine, Haukeland University Hospital, Bergen, Norway

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List of attachments:

- 1. Figure 1: Timeline of relevant events and initiatives
- 2. Figure 2: PRISMA flow-chart for selection of articles
- 3. Appendix 1: Updated protocol
- 4. Appendix 2: Updated search strategies
- 5. Appendix 3: Data extraction template
- 6. Appendix 4: Excluded articles and reason for exclusion
- 7. Appendix 5: Articles underlying this brief

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#### Abstract

Objective: To identify the factors contributing to equitable access to coronavirus disease 2019 (COVID-19) vaccines for low-and middle-income countries (LMIC).

Methods: We conducted a scoping review following the guidelines for Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews and a fivestage framework for scoping studies. We performed systematic searches for published peerreviewed literature in the five databases Medline, Embase, Web of Science, Global Index Medicus, and COVID-19 Evidence Epistemonikos (August 2020, updated May 2021). Results: Systematic selection according to predefined criteria resulted in the final inclusion of 45 peer-reviewed articles , with no limitations on study design or publication type. We derived four key factors that potentially can influence equitable access to COVID-19 vaccines in LMICs: (1) collectively agreed global mechanisms or frameworks; (2) bilateral purchasing, contractual arrangements, and price of vaccines; (3) large-scale vaccine manufacturing that is supported by sharing know-how; and (4) countries' strength in implementing vaccination programs.

Conclusions: This scoping review highlights the ongoing challenges for the international community in ensuring equitable access to COVID-19 vaccines for LMICs. The literature suggests that vaccine manufacturing can influence the supply of vaccines, as can the role of patent holders who influence global governance through their role in the distribution of COVID-19 vaccines. Our findings indicate that including the principles of equitable access throughout vaccine research and development (R&D), procurement, scale-up, and distribution processes can ensure equitable access for LMICs. Advances made with mRNA vaccines may have additional benefits in relation to expanding the manufacturing of other vaccine. Finally, the exploration and scale-up of such capacities of LMICs are likely to prove to be a valuable investment, even after the pandemic.

### Strengths and limitations of this study

- To our knowledge, this is the first systematic scoping review of factors influencing equitable access to COVID-19 vaccines.
- Included literature was selected exclusively based on relevance to the topic (according to predefined criteria), provided that it was published in peer-reviewed journals with no further quality assessment.
- In light of the numerous daily published articles related to the COVID-19 pandemic, there might be additional relevant articles that should have been included. Hence, the list of identified factors might not be exhaustive nor completely cover the full? complexity of how various factors interact.

We used the framework proposed by Liu et al. (2020) as basis for our analysis, which we further refined through an iterative process during the analyses.

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#### BACKGROUND

The coronavirus disease 2019 (COVID-19) is a global crisis, and collective efforts are essential to curb its most devastating effects. The unprecedented demand for a vaccine has mobilized rapid vaccine development and large-scale investment in manufacturing capacity. The outlay of capital from investors for the scale-up and production of early candidate vaccines has contributed to rapid advances in vaccine science<sup>1</sup>. Despite these investments, the demand for safe, affordable, and effective COVID-19 vaccines is expected to outstrip supply for a considerable period of time<sup>2</sup>. To realize the maximum benefit, vaccines should be shared fairly between all nations of the world, otherwise there will continue to be differential morbidity and mortality with increased risk of virus mutations leading to even more death and disease from COVID-19, not to mention the indirect consequences to the global development and economy<sup>3</sup>.

In relation to the management of communicable disease outbreaks, the principle of shared benefits is a long-standing commitment of the World Health Organization (WHO)<sup>4</sup>. The Global Influenza Surveillance and Response System (GISRS) suggests benefit sharing as a potential solution to incentivize global collaborative infectious disease responses and measures, and in return members have real-time access to pandemic response products, like vaccines<sup>56</sup>. Low- and middle-income countries (LMIC) face unique challenges in accessing vaccines as they do not have the same resources to purchase vaccines and are less likely to have the know-how and technological capacity to be able to manufacture their own vaccines. They may also face uncertainty in their ability to obtain vaccines due to reduced purchasing power compared to high income countries (HIC) when negotiating with vaccine manufacturers<sup>7</sup>. Therefore, they are more reliant on multilaterally agreed frameworks or bilateral support to access new technologies<sup>6</sup>. The global community has previously in part

managed this with non-binding mechanisms designed to promote equitable access. The 2006 WHO Global pandemic influenza action plan, for instance, was designed to support increased vaccine supply and global vaccine manufacturing capacity, by promoting technology transfer to middle income countries (MICs)<sup>8</sup>. As established vaccine manufacturing nations, some MICs' expertise can support the scale-up of vaccine production.

Ineffective institutional mechanisms for pandemic vaccine distribution were exposed during the influenza A (H1N1) ("Swine flu") pandemic in 2009<sup>6</sup>, despite embedded principles of reciprocity and equity for the prevention and control of influenza pandemics affirmed by member states at 2003 World Health Assembly. Swine flu and the COVID-19 pandemic are reminders that there is no institutional mechanism to effectively distribute global goods such as COVID-19 vaccines<sup>4</sup>. The Pandemic Influenza Preparedness (PIP) Framework was developed following the H5N1 outbreak in Indonesia in 2005, triggering increased interest in the GISRS, which in turn lead to the WHO intergovernmental process and further scrutiny of its influence on the development of influenza vaccines, and recognition of failures to ensure fairness, transparency and equity in access to vaccines for LMICs <sup>6910</sup>.

Specifically, for COVID-19, the WHO led the Access to COVID-19 Tools Accelerator (ACT-A) global collaboration designed to fast-track development, production, and equitable access to COVID-19 tests, treatments and vaccines<sup>11</sup>. COVAX, the vaccines pillar of the ACT-A, is an initiative whose role is proving to be integral in the equitable distribution and access to COVID-19 vaccines, by providing an alternative for LMICs that have been failed by historical bilateral vaccine donation systems<sup>1 12</sup>. COVAX is co-led by the Coalition for Epidemic Preparedness Innovations (CEPI), a vaccine funding initiative, Gavi, the vaccine alliance, and WHO. Member countries of COVAX include those that have self-financing investments, but also others that are being supported through aid. COVAX aims to coordinate

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the vaccination of high risk and vulnerable populations, including frontline healthcare workers across the world, through distributing two billion vaccine doses by the end of 2021. These vaccines will be shared between the member countries, of which 78 are HICs, and 92 are LMICs<sup>13</sup>. Figure 1 lists events and a timeline of initiatives introduced before and following relevant pandemics, as identified in our scoping review.

#### Figure 1: Timeline of events and relevant initiatives

See attached as a .jpg file

The idea that access and distribution of COVID-19 vaccines should be equitable across countries is widely supported, but what *equity* means in this context is often not specified. From the perspective of LMICs, equitable access to a vaccine is fundamentally linked to a fair and transparent global distribution framework<sup>14</sup>. Hence, for the purpose of this review, equitable access is interpreted as all countries, and their populations, having equal access to COVID-19 vaccines irrespective of the income status of the country. Further, we considered a COVID-19 vaccine as an essential medicine\*. We have used the WHO definition of health equity<sup>15 16</sup>. In its first phase, COVAX plans to allocate vaccines in proportion to countries' total population so that all countries receive doses to cover 20% of their population<sup>17 18</sup>. Alternative proposals exist, including The Fair Priority Model proposed by a group of ethicists. This model goes beyond proportional allocation by proceeding with allocation of vaccines in three phases, which would in the first instance prioritize the prevention of more urgent harms <sup>19 20</sup>. The ethical rationale behind this model argues that proportional allocation, as suggested by WHO and COVAX, is not the fairest solution, as it implies that some countries with relatively lower risk of death and disease from COVID-19 would receive access to vaccines at the expense of other countries that are facing more exposure<sup>20</sup>.

The objective of this scoping review was to identify and summarize those factors that contribute to the equitable access of COVID-19 vaccines for LMICs. To our knowledge, the literature related to the equitable access of COVID-19 vaccines relevant for LMICs has not yet been systematically investigated. The review is considered highly relevant as it can provide lessons from previous experiences and perspectives on equitable access to pandemic vaccine, by identifying key factors that could guide implementation of future initiatives to ensure equitable access.

\*Essential medicines are those that satisfy the priority health care needs of the population ^Health equity or "equity in health" implies that ideally everyone should have a fair opportunity to attain their full health potential and that no one should be disadvantaged from achieving this potential

#### **METHODS**

We performed systematic scoping searches following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) as indicated in Figure 2, and were guided by the Arksey and O'Malley's five-stage framework for scoping studies through the steps of the review<sup>21 22</sup>. The study protocol was peer reviewed by methodological and subject experts at the Norwegian Institute of Public Health (NIPH)

(Appendix 1).

Based on predefined inclusion criteria (Table 1), we systematically searched in the following five databases: Medline (PubMed and Ovid), Embase, Web of Science, Global Index Medicus (WHO), and COVID-19 Evidence Epistemonikos. Search strategy was based on following key words and terms and combinations of these, i.e. coronavirus, COVID-19, SARS-CoV, equity, LMIC, pandemic, and (influenza) vaccine (Appendix 2). An information specialist, in collaboration with co-authors, developed the search strategies for the different databases. The

 search was performed on 28 August 2020 and updated on 12 May 2021. Only published literature in peer-reviewed journals was eligible for inclusion, with no limitations on study design nor publication type. The articles for extraction were exclusively chosen based on relevance to the topic of identifying and describing potential factors related to equitable access to pandemic or COVID-19 vaccines, with no further quality assessments.

Criterion	Inclusion
Time	01 January 2002 – 12 May 2021
Language	English
Type of article	Published in peer reviewed journals
Article focus	Pandemic vaccines including influenza or COVID-19 vaccine
Outcomes	Factors influencing equitable access to a pandemic vaccine
	including COVID-19 vaccines

 Table 1: Inclusion criteria

Publications were screened based on title and abstract according to the inclusion criteria (Table 1). Two reviewers independently selected articles to be considered for full text screening. Selected articles were then read in full and considered for inclusion or exclusion by two different reviewers. Final decisions on inclusion of relevant articles were determined through consultation between three of the reviewers. Disagreements were resolved through discussions to reach consensus. See Appendix 3 for the list of the excluded articles and reasons for exclusion.

Data extraction was performed by one reviewer and verified by a second. We used a data extraction form designed specifically for this scoping review. We extracted information on the setting; discussion on equity, access, allocation or prioritization of pandemic vaccines; other equity aspects; challenges in implementing equitable access to vaccination between countries; and recommendations for strengthening equitable access to vaccination (Appendix 4). The analytic process followed the principles of thematic synthesis. The article by Liu et al. was identified as an index paper as it suggested a framework that closely reflected the focus of our

scoping review<sup>23</sup>. The themes identified in this article were used as basis to extract and categorize our findings, and was further refined during the analysis through an iterative process as we identified potential factors influencing equitable access to COVID-19 vaccines in LMICs.

#### RESULTS

Excluding duplicates, our search identified 3,025 unique citations (Figure 2). Screenings first based on title and abstract, then on full text resulted in the final inclusion of 45 articles (described in Appendix 5).

### Figure 2: PRISMA flow-chart for selection of articles

#### See attached .jpg file

We categorized the identified themes from the included citations into four factors influencing access to COVID-19 vaccines in LMICs: (1) collectively agreed global mechanisms or frameworks can contribute to equitable access to COVID-19 vaccines; (2) bilateral purchasing, contractual arrangements, and price can influence fair allocation of vaccines; (3) large-scale vaccine manufacturing that is supported by sharing know-how can facilitate increased supply and allocation of COVID-19 vaccines; and (4) countries' strength in implementing vaccination programs may influence their populations access to vaccines (Table 2).

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<b>Table 2: Summary</b>	of identified factors	contributing to	equitable acc	ess to COVID-19 vaccines
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Factors	Scoping review findings	Articles contributing to the finding
Collectively agreed global mechanisms or	Establishing a collective and coordinated COVID-19 donation process will facilitate equitable allocation of pandemic vaccines	1 5 13 24-41
frameworks can	Global solidarity is facilitated by multilateral organizations and agreed frameworks	1 5 25 28 30 33 34 36 42
contribute to equitable access to	Previous collective action has been inadequate with examples of deficient vaccine donation and pledging systems related to pandemic vaccines	1 7 26 30-35 37 42-47
COVID-19 vaccines	Vaccine patent holders play a pivotal role in global the prices and distribution of vaccines	6 30 46 48-51
	Financing mechanisms that facilitate collective purchasing or pooled procurement favor	1 5 6 25 28 29 33 34 40 43 47 48
	fairer allocation	52-54
Bilateral purchasing,	Nationalistic approaches, where bilateral rather than collective purchasing is pursued,	1 7 23-27 29 31-34 36-38 41 42
contractual	contribute to hoarding or supply inefficiencies, limiting the global supply of vaccines	44 50 54-58
arrangements, and	Pandemic vaccines will largely be purchased by, and for use in, high income countries	25 27-30 32-38 40-42 44-47 54-
price influence the	(HICs)	57 59
fair allocation of	LMICs cannot procure or negotiate the purchase of pandemic vaccines at the same level	1 6 25 29 32 33 37 56 59
vaccines	as HICs, and can therefore be disadvantaged by bilateral deals	
	The price and affordability of vaccines influences equitable access	7 27-29 33 47 48 53
	Substantial investments are required to finance and support global vaccine manufacturing	5 7 29 32 33 37-39 41 46 49 53
Large-scale vaccine manufacturing that is	There is disparity between countries that have the capacity to produce vaccines and those that use vaccines	5 7 24 42 51 56
supported by sharing know-how can	Technology transfer of vaccine manufacturing (especially to MICs) supports increased supply favoring fairer allocation	1 6 27-30 35-37 46 48-50 54 56
facilitate increased	Intellectual property rights influence domestic manufacturing	6 29 33 36 37 46 48 51
supply and allocation of COVID-19	Capacity building for technology transfer can support vaccine manufacturing and technology transfer in LMICs	1 6 27 29 32 33 48 53 56
vaccines	Place of vaccine manufacturing influences exporting of vaccines, such as through a nation's sovereignty over national borders	1 6 27 29 42 48 51-53 56

Factors	Scoping review findings	Articles contributing to the finding
Countries' strength in	A country's ability to vaccinate should be a consideration in equitable distribution	1 13 24 27 41 60 61
implementing vaccination programs	Management of logistical and administrative components facilitate distribution of vaccines	5 13 27 28 37 47
may influence their	A countries' regulatory approval and market authorization processes for vaccines	30 33 37 51 58 61
populations' access to	influences the distribution of vaccines	
vaccines		
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• Collectively agreed global mechanisms or frameworks can contribute to equitable access to COVID-19 vaccines

Most articles indicated collective action ias being key fto contribute to equitable access <sup>1 5 6 13</sup> <sup>24-35 37-40 42-52</sup>. Global collective agreements should be driven by multilateral agencies that have the global mandate to convene interest groups, advocate for collective response measures, as well as the investment, procurement and distribution of pandemic vaccines<sup>58</sup>. These measures may be addressed by prompt agreement on equitable access <sup>5 30 39 41</sup>.

The reviewed literature suggests that historic vaccine donation and pandemic influenza pledging systems, have been insufficient, mainly due to the lack of legal obligation to act or the lack of penalty for parties who breach conditions <sup>1 26 27 30-35 37 42-45 47</sup>. To mitigate this, it is proposed that collective approaches need to be binding <sup>35</sup>. Actuallysuch a legal framework that has been ratified by 171 countries already exists, the International Covenant on Economic, Social, and Cultural Rights (1966), however, it has not achieved its intended purpose for countries to take steps to ensure the right to health and the benefits of scientific research, without discrimination <sup>34 44</sup> In spite of these so-called failures of collective action, there is wide acceptance of the moral argument that HICs should support LMICs in equitable access to pandemic vaccines, recognizing that any collective purchasing will have inherent inequalities related to existing power dynamics between the Global North and the Global South, and recognizing that the status quo historically favored HICs over LMICs <sup>25 35</sup>. Specifically, for vaccine allocation, there are historical examples of manufacturers not reliably commiting to reserving production of pandemic vaccines to LMICs <sup>6 26 42</sup>.

Bilateral solutions threaten collective action by enabling some countries to queue jump <sup>1 29</sup>. These approaches will always be pursued during global crises, as has been demonstrated

during COVID-19, and as such cannot be avoided <sup>32</sup>. McAdams et al. therefore suggest that it comes down to how these bilateral arrangements are structured, using two deals from different US government agencies, the Biomedical Advanced Research and Development Authority (BARDA) who has a deal with AstraZeneca, and the US Department of Health and Human Services (HHS) who secured 100 million doses of Pfizer, as examples<sup>32</sup>. The authors suggest that the deal negotiated by BARDA benefits US, AstraZeneca and the rest of the world by supporting the gaining, and sharing, of knowledge through its funding of advanced clinical studies, vaccine manufacturing technology transfer, process development and scaled-up manufacturing, which in turn supports more vaccines and increased availability. In contrast, the Pfizer deal only supports US and Pfizer interests. The article concludes that BARDA's deal will result in more vaccines for LMICs, regardless of whether HICs vaccinate their own populations first<sup>32</sup>.

COVAX is the supported mechanism and widely promoted in the literature included in this review, yet the facility has faced criticisms related to transparency, limited knowledge sharing, and need for more political and financial commitment<sup>31 55</sup>. It has also faced challenges related to managing the role of patent holders who have played a determining role in distribution of their medical countermeasures. This affects global governance, with patent holders maintaining influence over the distribution of patented technologies during a pandemic, a power that rests with few pharmaceutical companies controlling the global supply and distribution of vaccines<sup>48 50</sup>.

The global prices of respective vaccines are not uniform across settings, with the price of a COVID-19 vaccine influenced by its patent<sup>29 47 50</sup>. To counteract the inequality in global distribution, in October 2020, a proposal was made by India and South Africa to the World

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Trade Organization (WTO) requesting a temporary waiver of certain provisions of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement, based on the need to prevent, contain, and treat COVID-19<sup>46 50</sup>. There is no consensus in the literature included in this review on the benefits of the waiving of intellectual property rights (IPR), with those against the waiver, arguing that it is not patent protection that is the barrier to introducing generic vaccines<sup>44 46 49</sup>, but rather the lack of knowledge in the public domain and shortages of vaccine supplies<sup>1</sup>. The implications on national manufacturing, including a countries' ability to enact compulsory licensure under TRIPS is discussed later in this article.

# Bilateral purchasing, contractual arrangements, and price can influence the fair allocation of vaccines

HICs have a track-record of dominating the global supply of pandemic vaccines, through greater advanced purchasing power and their ability (including proximity) to vaccine manufacturing. In 2021, 51% of the initial supply of COVID-19 vaccines had been purchased for 13% of the world's population, mostly residing in HICs<sup>28 30 42</sup>, indicating that fair vaccine allocation is hindered by the inability of LMICs to procure or negotiate access to pandemic vaccines at the same level as HICs<sup>6 59</sup>.

Vaccine development under the COVID-19 pandemic has highlighted the conflicting roles between private capital and access to essential health care technologies. Final stage R&D of vaccines (and other medical technologies) are largely led by multi-national pharmaceutical companies who are incentivized by IPR and return on investment, thus perpetuating structural market-based inequalities of supply and demand. This affects the total quantity of vaccines produced, which, in the case of influenza vaccines, has affected LMICs as it has been perceived that there is "lower demand" in these markets<sup>35 52</sup>. During this recent pandemic, substantial public funding, that has historically been targeted more towards early- stage development, has also been invested in the late-stage development of multiple COVID-19 vaccines contributing to global market distortions<sup>32 37 38 54</sup>.

Pooled procurement is mentioned in the literature of this review as a means to support equity, with Advanced Purchase Agreements (APA) and Advanced Market Commitments (AMC) being the most common mechanisms identified in our review to facilitate access for LMIC<sup>5 6</sup> <sup>25 28 29 33 34 40 47 48 52-54</sup>. APAs are contracts with a specific product developer, whereas an AMC is a global market commitment <sup>40</sup>. The AMC was first introduced in 1999 for the development of a late-stage pneumococcal vaccine, with the intention to shorten the time to introduction of a vaccine to LIMCs<sup>40</sup> Under COVID-19, APAs have been widely used to secure priority access to a scarce resource (when one party has committed to buy a specific number or percentage of doses prior to development), the influential factor for equitable access being whether they promote the interests of one country or several, and if they include LMICs<sup>5 6 30 34</sup> <sup>43 52</sup>

Bilateral deals contribute to supply inefficiencies and threaten collective approaches to the procurement of vaccines, e.g., National APAs initiated by countries that are also members of COVAX (not exclusively, but mainly HICs)<sup>32 37 38 54 55</sup>. At the beginning of the COVID-19 pandemic, HICs went ahead to purchase large quantities of COVID vaccines<sup>31</sup>. The necessity for transparency of contractual clauses, especially relating to pricing, licensing and purchase commitments, was identified in the review as potentially negative as/since? global coordination efforts will suffer unless vaccine manufacturers can be trusted to responsibly decide which countries' vaccine orders should be prioritized<sup>34 37</sup>.

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Bilateralism is not limited to relationships between countries and vaccine manufacturers. During the COVID-19 pandemic, bilateral deals have also been struck between countries to directly distribute vaccines. For example, both the Russian and Chinese government owned and operated vaccine manufacturers have bilateral arrangements with other countries, such as India, Vietnam, Mexico, Brazil, and Ethiopia to guarantee the supply of vaccines<sup>28 29 54 56</sup>.

# • Large-scale vaccine manufacturing that is supported by sharing know-how can facilitate increased supply and allocation of COVID-19 vaccines

Several articles included in this review suggest that substantial additional financial and capacity investment is required to further global vaccine manufacturing<sup>5 7 29 32 33 37 39 41 46 49 53</sup> <sup>62</sup>. Vaccine development is multifaceted, and manufacturing during a pandemic faces unprecedented challenges in scale and complexity<sup>58</sup>. A limited number of HICs, and some MICs, have vaccine manufacturing capacity, resulting in a disparity between countries that have the capacity to produce vaccines and those that need access to those vaccines<sup>5 7 24 42 51 56</sup>. Nhamo et al. reported that development activity for COVID-19 vaccines is almost nonexistent in LMICs<sup>33</sup>. The majority of development activity is in Asia, with 12 (52%) COVID-19 vaccine development programs, followed by Europe (17%) and North America with four programs each (17%)<sup>33</sup>. A few MICs (Brazil, India and Peru) have capitalized on their clinical testing or manufacturing capacity efforts by leveraging these for purchase agreements with vaccine manufacturers<sup>29</sup>. Limited capacity affects the global availability of pandemic vaccines for two reasons. Firstly, the world is unable to manufacture the quantity of vaccines demanded, and secondly, a manufacturing country has the sovereign authority over goods produced within its borders with most countries in the world having legislation in place that require companies to manufacture and prioritize domestic consumption<sup>33 51 52</sup>. In situations where it is enforced, government intervention may hinder global distribution.

For technology transfers to work, there needs to be a patent holder that is willing to share the intellectual property and a manufacturing facility that can receive it. The findings from this review suggest that MICs with vaccine manufacturing capability can play an important role to support and fill the forecasted gap in international vaccine manufacturing capacity, but this requires technology transfer and capacity building to manufacture vaccines that meet the same efficacy and quality standards as the original vaccine<sup>1 6 27-30 35-37 46 48-51 54 56</sup>. Vaccine manufacturing know-how can include vaccine developers by sharing the intellectual property of vaccine manufacturing processes or relaxing patent rights<sup>6 29 33 36 37 46 48</sup>. One article included in this scoping review suggests that for viral vector vaccines (e.g., AstraZeneca and Johnson & Johnson), MICs with less advanced manufacturing capacity can contribute with the fill-and-finish stage of the process, rather than producing the active solution of the vaccine<sup>49</sup>.

Under the WTO TRIPS Agreement, countries have a right for the compulsory licensure of products in certain circumstances. In practice, this means that a country can produce a patented product or process without the consent of the patent owner, as demonstrated by Canada, Chile and Ecuador in their pandemic response<sup>29</sup>. The discussion related to the TRIPS waiver is especially important to LMICs, who recall recent historical experiences from South Africa where patents obstructed access to life-saving medicines for the treatment of HIV/AIDS<sup>44</sup>. Advocates for the COVID-19 products TRIPS waiver argue that significant public monies have contributed to the development of these patents thus waiving IPR will support vaccine development and manufacturing, but that some countries are already undermining existing TRIPS flexibilities through restrictive free trade agreements<sup>36 44 54 55</sup>. Proponents against governments' enacting patent waivers claim that they contribute to

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inefficiencies by diverting raw materials and supplies away from effective manufacturers<sup>49</sup>. Compulsory licenses are not considered by these proponents as being a practical tool to rapidly expand access to vaccines, instead they support voluntary licensure, for instance, AstraZeneca's arrangements with Indian and Brazilian manufacturers<sup>1 46 49</sup>. A related issue impacting on manufacturing capacity is the use of limited manufacturing capacity on all vaccine candidates. So et al. caution that a weakness of prematurely exhausting capacity for vaccines that show early safety and efficacy promise, is that manufacturing capacity will then be locked into first generation vaccines, and may be a bottleneck for manufacturing capacity for second generation more effective vaccines<sup>54</sup>.

Finally, two noteworthy initiatives are identified in the literature reviewed: 1) the global pandemic influenza action plan to increase vaccine supply (GAP) (2006-2016), a strategy to reduce global shortages of influenza and pandemic vaccines that supports technology transfer<sup>30 44</sup>; and, 2) the recent COVID-19 Technology Access Pool (C-TAP) (2020) proposed by Costa Rica and adopted by WHO (endorsed by 35 mainly MICs and five HICs). C-TAP calls for the voluntary sharing of knowledge, intellectual property, and data as well as a guarantee of free access and use by WHO member countries for drugs and vaccines that are developed<sup>29 35 37</sup>. Given the world's limited manufacturing capacity, the use of technology transfer and pooling of vaccines could help to alleviate a massive shortage of vaccines given the scale of the need<sup>39</sup>.

# • Countries' strength in implementing vaccination programs may influence their populations access to vaccines

The findings from this scoping review further suggest that the ability of a country to implement a mass vaccination program is an important factor that may influence equitable

access<sup>23</sup>. Vaccination programs are resource intensive, therefore, to maximize the benefit of COVID-19 vaccines and reduce waste due to improper implementation, it has been suggested that allocation frameworks should consider a country's ability to vaccinate<sup>1 13 23 24 27 41 60 61</sup>. Most LMICs have well-structured immunization programs, for polio, measles and smallpox etc., facilitated by organizations such as UNICEF and Gavi, which could support a large-scale pandemic vaccination program. It has been reported that Gavi, for example, has sought to expand its Cold Chain Equipment Optimization Program<sup>27</sup>. More than half of the countries in the world lack robust programs to tackle seasonal influenza, despite most associated death and severe disease from influenza occurring in countries of the Global South<sup>61</sup>. The down prioritization of seasonal influenza vaccination for older populations in LMICs compared to HICs, is a vulnerability for the roll out of COVID-19 vaccines<sup>30 33 60 61</sup>. Ruscio et al. noted that an attempt to fill this gap has been made by the recently published WHO Global Influenza Strategy 2019–2030<sup>61</sup>.

Vaccine roll-out requires stable cold chain and supply processes for the necessary logistical and administrative components to facilitate distribution of vaccines, including financing the in-country delivery of vaccines, from cold chain to administration<sup>13 27 28 37 47 62</sup>. Different vaccines have different temperatures for deployment, which influences supply of vaccine to communities<sup>13 27 47 49 62</sup>. This is a particular challenge in sub-Saharan Africa, where only 28% of health care facilities have a reliable energy supply<sup>13</sup>. In this context, vaccines that require only one dose or those that can be stored at room temperature, are more likely to facilitate equitable access<sup>47</sup>. There is also an opportunity to explore the use of new containers and packaging that support distribution. For example, pre-formed plastic vials are being successfully used for oral rotavirus and cholera vaccines<sup>60</sup>. Data solutions should also be

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considered, as these could support alternative vaccine delivery systems for target groups, as well as being an important tool to capture the populations vaccination history<sup>28</sup>.

Smooth regulatory and market authorization processes for vaccines can facilitate the distribution of vaccines<sup>30 33 37 51 61</sup>. One article from this scoping review highlighted the importance of clinical vaccine studies in LMICs and HICs alike, to support the fast-tracking of market authorization, as local clinical trial data is a recognized grounds for delay to introduce some vaccines into countries' immunization programs<sup>33</sup>. Delays for products preventing or treating infectious diseases are cited at being between 4 to 7 years from first approval in a high-income country and final approval in a country in sub-Saharan Africa<sup>37</sup>.

#### DISCUSSION

This study identified four key factors that carry the potential to promote fairer global access to COVID-19 vaccines. Our findings suggest that an international approach is necessary to minimize the spread of a pandemic. A priori of this review, there has been broad international support for the principles of equitable distribution of medical countermeasures, as demonstrated by universal support for WHO resolutions<sup>4 8 9 14 63-66</sup>. COVID-19 is no exception, with relevant commitments passed in months following the declaration of the pandemic<sup>17 67-70</sup>. This has however not translated into binding global commitments. The establishment ACT-A and COVAX was partly a recognition of historic failures, as highlighted in the findings of this review. Co-led by CEPI and Gavi (in partnership with WHO), both were established with a commitment of equitable access to medicines in their ethos. As multi-country endorsed initiatives, they can be considered good candidates to lead the process for equitable distribution of COVID-19 vaccines<sup>12 71-73</sup>.

The risks that sovereign states pose to equitable access by acting in their national interest, including bilateral agreements with pharmaceutical companies, buying up vaccine stocks during clinical development phases and vaccine hoarding, were anticipated in our findings, and have, largely, been realized<sup>31</sup>.

COVAX's pooled procurement through APAs have faced challenges, initially in accessing the necessary financing, which in turn delayed securing supply against other HIC purchasers<sup>1 14 27</sup><sup>29</sup>. In addition, it has also faced critique on how price has been determined and whether any costs can be recovered if vaccine candidates fail<sup>34 40 74</sup>. While COVAX has attempted to meet foreseen gaps<sup>14</sup>, it has been challenged by national interests, highlighted recently with announcements that Australia is purchasing booster shots<sup>75</sup>, and that several HICs plan to donate parts of their surplus vaccines to LMICs directly<sup>76</sup>, rather than through the COVAX facility (regardless of membership), making vaccines a tool of geopolitics.

The pandemic has shown several examples of countries enacting their sovereign authority over goods produced within its borders, one example being the USA's invocation of the Defense Production Act reducing export of Active Pharmaceutical Ingredients<sup>77</sup>, which slowed the production of the AstraZeneca vaccine by its collaborator Serum Institute in India<sup>78</sup>. More recently, in response to a devastating second wave of COVID-19 infections, the Indian government imposed an export ban on vaccines, re-directing these to the domestic market, leading to a further slowdown in doses available to the COVAX facility<sup>79</sup>. Additionally, the redirection of vaccine manufacturing capacity to scale up production of COVID-19 vaccines will likely impact on the production of other vaccines such as influenza, measles, mumps and rubella with a disproportionate impact on the global poor<sup>80</sup>.

Page 23 of 61

#### **BMJ** Open

The rollout of population wide immunization programs has put most governments to the test, with many being critiqued for botched rollouts. Australia and Japan are two HICs that have faced criticism over the delays related to the logistical issues of setting up such a large vaccination program<sup>81 82</sup>. In June 2020, it was reported that less than 15% of imported vaccine doses in Japan had been used<sup>82</sup>. In addition, Japan is one example of a country whose vaccine implementation was interrupted by national regulatory requirements for domestic clinical trials, which could not be undertaken due to low numbers of COVID-19 cases. This prevented Japan from registering international clinical trials to meet national requirements related to safety and efficacy<sup>82</sup>. LMICs face similar regulatory delays<sup>27 33</sup>, seemingly a bureaucratic hurdle that could be planned for, especially given the public health emergency of the situation, and that these vaccines have already met stringent regulatory standards (i.e., the US Food and Drug Administration or European Medicines Agency).

For LMICs, the wellestablished child immunization programs have targeted parts of the population, however few LMICs have extensive experience with vaccination of the general adult population. This makes the COVID-19 the "first" large-scale adult vaccination program aiming to achieve high coverage rates<sup>83 84</sup>. To facilitate implementation, COVAX has integrated a "Country Readiness and Delivery (CRD) work stream" to support the introduction of COVID-19 vaccines into national vaccination programs<sup>85</sup>. However, lack of infrastructure, short shelf life and vaccine hesitancy challenge the vaccine uptake and distribution of vaccines, which has led to vaccine wastage (e.g., South Sudan and Malawi) or re-deployment to avoid this outcome (e.g., the Democratic Republic of Congo to Ghana and Madagascar)<sup>86</sup>. Other countries, such as Bhutan, have impressed with their swift implementation strategies vaccinating 90% of their eligible adult population in two weeks<sup>87</sup>.

The potential long-term solution to equitable access highlighted in our scoping review is the need to broaden the basis of manufacturing of vaccines. A success of the COVID-19 response has been the high effectiveness of novel mRNA vaccines that (pre-COVID-19) were yet to enter human clinical trials. However, few manufacturers have the necessary know-how to set up mRNA manufacturing capacity, resulting in centralized production in a few locations in the Global North. The WHO has relaunched C-TAP to support a "global one-stop shop for developers" following nothing being shared by any pharmaceutical company within the first 12 months of the launch of the C-TAP open platform in mid 2020<sup>88 89</sup>. The TRIPS patent waiver of COVID-19 products received historical support from the incoming US Government Administration in May 2021, and has since moved into text-based discussions<sup>90</sup>.

It is widely acknowledged in the literature that ramping up production in LMICs while meeting the necessary quality standards takes time and will require extensive knowledge transfer from pharmaceutical companies. Globally, 15 MICs have vaccine production capacity to support the global supply of vaccines, but only 12 have WHO prequalification status which is instrumental for quality assured generic vaccine candidates<sup>2</sup><sup>7</sup>. The pandemic has further uncovered the need for more vaccine manufacturing capacity across the whole world. The acknowledgment of the incommensurable role of manufacturing capacity is captured in a project led by CEPI to map out manufacturing capacity for use in future pandemics<sup>91</sup>. Further, to counteract this, the African Union and African CDC launched a partnership to increase future vaccine production in Africa<sup>92</sup>.

A limitation of this scoping review is that literature was exclusively chosen based on relevance to the topic of identifying and describing potential factors influencing equitable access to COVID-19 vaccines, meaning that we have included commentaries, editorials,

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essays and viewpoints. We determined that these perspectives were of importance to our research aim, regardless of the type of publication, as the aim was to identify factors and not to assess or evaluate them or compare their relative importance. In light of the nature of the current situation and the topic, restricting the review to only include publications of original research with journal publication timeframes did not seem appropriate. Although many of the authors of the included literature are established academics or practitioners in their field, this is a limitation. To manage this , articles were only included if they were published in a peer-reviewed journal.

#### **CONCLUSION**

According to current available published peer-reviewed literature, equitable access to vaccines proves to be an ongoing challenge. The uneven global distribution of vaccines is starkly shown in the current divide of vaccine coverage where the wealthiest nations have received more than 87% of the vaccines whilst LMICs just 0.2%<sup>93</sup>. Altogether, findings identified in this scoping review converge towards vaccine manufacturing being of high importance in the supply of vaccines. Future research could explore the contribution of MICs to facilitate vaccine supply in a pandemic, including some of the challenges of maintaining these facilities outside of a pandemic. Building on COVID-19 success, mRNA technologies will be used for other vaccines in the future, thus the exploration and scale-up of such capacities on the African continent is likely to prove to be a valuable investment, even after the pandemic. Moreover, despite the length of time it takes to build and certify vaccine manufacturing facilities, steps can be taken to share the know-how of the manufacturing of effective vaccines, although the full possibilities of relaxing of patent and IPR are yet to be realized and can contribute to equitable access.

Another issue identified in the literature was the role that patent holders play in global governance through influencing the distribution of COVID-19 vaccines, this needs more transparency. The importance of including equitable access principles to all levels of development also seemed to be relevant, e.g., throughout vaccine R&D, procurement, scale-up and distribution.

#### ETHICS STATEMENT

Ethical clearance was not required as the review used secondary data that is available in the public domain.

#### CONTRIBUTORS

EP and LC: Developed the concept, drafted the protocol, data extraction, analysis, writing and review. LH: Data extraction, supported with analysis, writing and review. KF: Methodology, review of extraction, writing and review. EHD: Writing and review.

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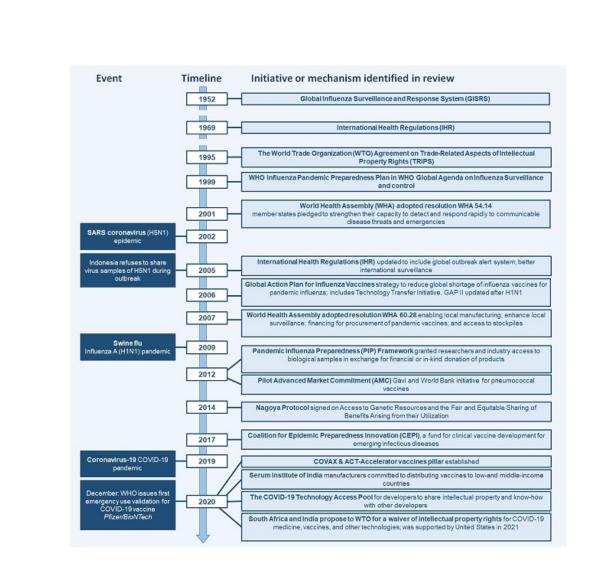
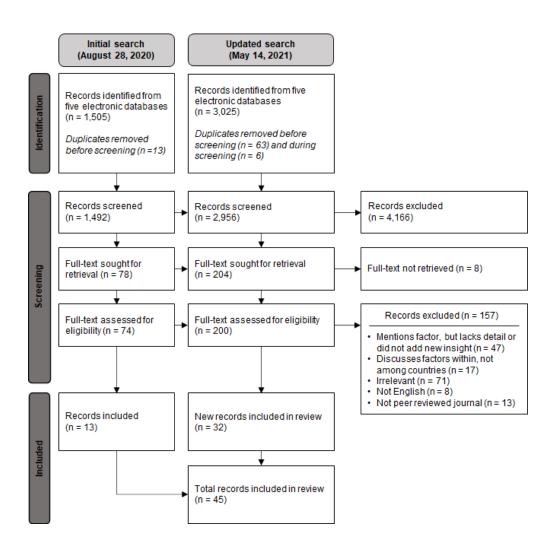


Figure 1: Timeline of events and relevant initiatives

127x122mm (130 x 130 DPI)

For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml





327x321mm (51 x 51 DPI)

Appendix 2: Updated protocol

# Factors influencing global equitable access to a COVID-19 vaccine for Low- and Middle- Income Countries (LMICs)

Proposal for scoping review

24 September 2020

Elizabeth Peacocke, Lumbwe Chola, Katrine Frønsdal and Marita Fønhus, Norwegian Institute Public Health.

Updated 24 July 2021

Elizabeth Peacocke, Lieke Fleur Heupink, Katrine Frønsdal, Elin Hoffmann Dahl and Lumbwe Chola.

## Summary

Vaccines are important medical countermeasures to prevent the spead of infectious diseases. The World Bank forecasts a 5.2% contraction in global GDP in 2020, and long-term negative impacts are expected in terms of lower investment, an erosion of human capital through lost work and schooling, and fragmentation of global trade and supply linkages (1) Without effective vaccines, diagnostics, and therapeutics, COVID-19 will continue to spread and have severe health and socio-economic consequences. The UN's Framework for the Immediate Socio-Economic Response to the COVID 19 Crisis warns "The COVID-19 pandemic is far more than a health crisis: it is affecting societies and econ-omies at their core. While the impact of the pandemic will vary from country to country, it will most likely increase poverty and inequalities at a global scale, making achievement of SDGs even more urgent." (2)

This project includes a scoping review that identifies and characterizes the factors influencing global equitable access to COVID-19 vaccines among countries, and contextualizes these factors with global mechanisms or guidelines that address global equitable access to pandemic vaccines. The documentation of these factors will offer decision makers lessons from previous experiences and information to support the understanding of principles related to equitable access to a COVID-19 vaccine.

This scoping review was conducted during August-November 2020, with a draft report for Norad, who commissioned and partly financed the report. This draft report was then submitted as a manuscript for publication. During the review process, in May 2021, the authors updated the search. This protocol has been updated to reflect the methods used in this Scoping Review.

To our knowledge, such a scoping review has not been systematically investigated.

#### Title:

Factors influencing global equitable access to a COVID-19 vaccine for Low- and Middle- Income Countries (LMICs)

Proposal for scoping review

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**Commissioned by:** Commissioned by the Norad Evaluation Department

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Start date: 24.07.2020. End date: 19.07.2021

#### Project Team:

Elizabeth Peacocke, Senior Advisor, NIPH Lieke Fleur Heupink, Advisor, NIPH Elin Hoffmann Dahl, MD, Haukeland Universitetssjukehus, Norway Katrine Frønsdal, Senior Researcher, NIPH

Lumbwe Chola, Senior Advisor, NIPH

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Internal peer review: Maria Fønhus, Senior researcher, NIPH

**Approved by:** Ingvil Sæterdal, Department Director, NIPH, Global Health

### Background

#### New Corona Virus: SARS-CoV-2 (COVID-19) Pandemic

The world is currently facing a global public health emergency with the emergence of the Severe acute respiratory syndrome coronavirus 2 discovered in 2019 (COVID-19), an infectious acute respiratory disease caused by a novel coronavirus. A race to increase access to existing health technologies – including diagnostics - and find new and effective treatments and vaccine is underway, and with this the international community is faced with the challenge of how to ensure equitable access of essential medicines<sup>1</sup> to all populations. In this scoping review, we will systematically review the literature and summarize factors pertaining to the equitable access of a COVID-19 vaccine relevant for low- and middle- income countries (LMICs). For the purpose of this study, we are using the WHO definition of equity,<sup>2</sup> and we take the principle that the COVID-19 vaccine is an essential medicine<sup>3</sup>, and that access to essential medicines is part of the right to health which is well founded in international law (4).

# The challenge with global equitable availability and access to pandemic vaccines

COVID-19 has seen a large effort and investment in vaccines, and diagnostics, with 22 manufacturers that have applied for and Emergency Use Listing under the WHO Pre-Qualification, 10 of which have been approved (5). Shortly following these rapid advances and regulatory approvals, questions began to be raised about the availability and access of vaccines in LMIC, and as global public goods (6, 7).

The 2005 experience with the sharing of avian influenza A (H5N1) and the 2009 influenza A (H1N1) pandemic made apparent the need for equity considerations and ensuring that global coordination and distribution mechanisms are in place and adhered to, supporting equitable access to scarce vaccines. During H5N1, concerns raised by LMICs about the lack of mechanisms for ensuring global equitable access to vaccines prompted Indonesia to refuse to share H5N1 virus samples with the World Health Organization (WHO) (8). With Asia being the epicenter of the outbreak, fears were raised by the international community that Indonesia's refusal to share virus samples would impede the research and development, surveillance and response efforts, and made the response to the global health emergency more difficult. Ensuing negotiations with the

<sup>3</sup> WHO (2020)

<sup>&</sup>lt;sup>1</sup>Essential medicines are those that satisfy the priority health care needs of the population 3.World Health Organization. Essential medicines and health products. Essential medicines definition 2020 [cited 2020 August 13]. Available from: https://www.who.int/medicines/services/essmedicines\_def/en/. <sup>2</sup> Equity is the absence of avoidable, unfair, or remediable differences among groups of people, whether those groups are defined socially, economically, demographically or geographically or by other means of stratification. "Health equity" or "equity in health" implies that ideally everyone should have a fair opportunity to attain their full health potential and that no one should be disadvantaged from achieving this potential (World Health Organization. Health Topics: Health Equity. 2020 [cited 2020 August 12]; Available from: https://www.who.int/topics/health\_equity/en/).

WHO and its member states to create a new system of influenza virus sharing and vaccine availability did not immediately yield consensus.

During the 2009 pandemic, high income countries (HIC) bought virtually all vaccine supplies, leaving limited supplies for LMICs. One prominent example for this asymmetry was Mexico. Despite it being one of the first nations affected by H1N1 (concurrently with Canada and the United States), Mexico gained access to vaccines much later than the two other countries (9). The WHO intervened to mediate this potential challenge, engaging in talks with manufacturers and LMIC governments to secure equitable access to the vaccine for LMIC (10). Consequently, donation pledges to LMIC were made by manufacturers and HICs, with the exception of Canada (10, 11). These pledges from manufacturers were made without a fixed delivery date and were perceived to leave HICs with more than enough vaccines for full coverage in their own countries, leaving LMICs with limited access to timely supplies (11).

#### Lessons from previous collective responses to support global equitable access to vaccines

In response to the H5N1 and H1N1 experiences, WHO and member states developed and adopted the Pandemic Influenza Preparedness (PIP) framework in 2011, a global approach to pandemic influenza preparedness and response (12). The intention of PIP was to improve and strengthen the sharing of influenza viruses with human pandemic potential; and to share the benefit of, which is to increase the access of LMICs to vaccines and other pandemic related supplies. There are, however, several gaps in the framework, not least, that it is not legally binding (13).

There are other relevant frameworks and mechanisms, such as establishing the Advanced Market Commitment for AMC for Pneumonia Vaccine, and the Pan Americal Health Organisation's Revolving Fund for Vaccines. Much can be learnt from these initiatives that is relevant to the current COVID-19 pandemic. Recent events related to COVID-19 have shown some countries and technology holders' tendencies to control the global supply of personal protective equipment, ventilators, diagnostics and therapeutic medicines and reserve supply to HIC, as well as the challenges with limited manufacturing capacity and access to know-how, intellectual property and data; indicating that it is highly likely that similar controls will be placed on a vaccine that meets the necessary safety, efficacy and regulatory standards, to be used for mass vaccination (14).

To manage anticipated issues with the distribution of COVID-19 vaccine, the WHO is convening the Access to COVID-19 Tools (ACT) Accelerator, which brings together governments, scientists, businesses, civil society, and philanthropists and global health organizations (the Bill & Melinda Gates Foundation, CEPI, FIND, Gavi, The Global Fund, Unitaid, Wellcome, the World Bank and Global Financing Facility), in efforts to support the development and equitable distribution of the tests, treatments and vaccines. The ACT-Accelerator is organized into four pillars of work: diagnostics, treatment, vaccines and health system strengthening (15). Gavi and CEPI are leading implementation of the vaccines pillar, "the COVID-19 vaccine global access (COVAX) facility", which is committed to supporting the acute phase of the pandemic through the appropriate allocation of safe and effective doses of a vaccine (16, 17).

The barriers in access to medicines to COVID-19 vaccines relate the demand and the supply of the vaccine, and there continues to be unprecedented demand for a safe and effective vaccine (18, 19). The supply of this vaccine is hampered by complex vaccine

innovation and manufacturing processes. Depending on the candidates that prove to be the most effective, the approach used will determine the necessary manufacturing capacity and length of time for development, (19). In terms of the quantity of the vaccine needed to be produced, this is also influenced by whether one or two does are necessary, in addition other challenges including e.g. with lack or insufficient global vaccine manufacturing capacity & access to know-how and implementation in LMIC countries are also essential for access to vaccines for many. All of these factors will limit the supply of vaccines.

#### Importance of the project

The access to, and distribution of a scarce vaccine is one of the pegged solutions to enable the world to return some semblance of life pre-COVID 19. With COVID-19 affecting the world, the equitable distribution of this vaccine is important because the virus will cause unnecessary disability and loss of life unless the benefit of a vaccine is distributed fairly among and within countries. To our knowledge, a scoping review of the the factors for the equitable access of a COVID-19 vaccine relevant for LMIC has not been systematically investigated. The project is considered highly relevant to the current situation as it aims at identifying and describing of these factors which can inform decision makers in terms of lessons from previous experiences and supporting the understanding of principles related to equitable access to a COVID-19 vaccine, and further potentially guide implementation of future initiatives to ensure equitable access.

#### **Objective**

This objective of this scoping review is to identify and summarize the factors for the equitable access of a COVID-19 vaccine relevant for LMICs. We will address the following question: What are the factors influencing global equitable access to a COVID-19 vaccine among countries?

### Methods

### **Scoping searches**

We will perform systematic scoping searches for publications according to PRISMA-ScR (Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews) (20).

#### Inclusion criteria

We aim to identify and describe factors influencing global equitable access to a COVID-19 vaccine among countries as identified in our search (see the manuscript supplementary material), following the inclusion criteria shown in Table 1.

Table 1. Inclusion criteria

Торіс	Pandemic vaccines incl. influenza or COVID-19 vaccine	
Outcomes	The factors influencing equitable access to a pandemic vaccine incl. COVID-19 vac-	
	cine	
Type of publica-	Primary studies, systematic reviews	
tion		
Language	English	
Publication date	2002-2021	

Restriction to publications from 2002 are made as a pragmatic choice from the date of the 2003-04 SARS pandemic. Furthermore, the limitation to English language journal articles in scientific databases was balancing completeness with the resources available.

#### Search strategy and Information sources:

An information specialist at NIPH will develop the search strategies together with the project leader, and another information specialist will review the search strategy. The literature search will be conducted in the following databases: Medline (PubMed and Ovid), EMBASE (Ovid), Global Index Medicus, WHO <u>https://www.globalindexmedi-cus.net/</u> and Web of Science Core Collection Clarivate Analytics (see supplementary information for updated search strategies and databases).

Additional relevant information will be searched from websites of multilateral agencies and international philanthropic agencies identified in the literature through the database search (e.g. WHO Pandemic Influenza Preparedness Framework) as a means to understand the particular framework or initiative.

#### Selection of literature

#### **First screening**

**BMJ** Open

We will first review articles that are determined to be relevant (according to predefined inclusion criteria described above). Three project team members (EP, LF and LC) will independently go through all identified titles and abstracts and determine if articles should be included for full-text review.

Where there are divergent views, inclusion will be determined through discussion and consensus between the reviewers or by consulting a fourth team member (KF). Records not fulfilling the inclusion criteria will be excluded.

#### Full text review

Given time constraints, the review group will divide the studies by two and each study will be read in full and assessed for inclusion by one reviewer. This is verified by a second reviewer. Disagreement over exclusion or inclusion will be handled in the same way as for the first screening.

#### Extraction and presentation of data

Data to be extracted are mainly qualitative data on the predefined outcomes. Standard data extraction templates were designed, and piloted specifically for this scoping review (see the manuscript supplementary material for a copy of the data extraction form).

The predefined outcomes for extracting data include: the setting (LMIC or globally focused or normative guidance that affects LMIC), and argument/ discussion on equity, access, allocation or prioritization of pandemic vaccines, other aspects that article tells us about the knowledge in this topic area, challenges in implementing equitable access to vaccination between countries, and recommendations for strengthening the equitable access to vaccination. In addition, we collected names of relevant global initiatives and mechanisms as identified in our search. Data is to be extracted by one team member and a second reviewer will review the data extraction.

#### Analysis of data

The analysis of the data collected will provide information on the body of research and evaluations related to the factors influencing global equitable access to a COVID-19 vaccine among countries. Our analysis will include how factors influencing global equitable access to a COVID-19 vaccine among countries pertain to global frameworks and mechanisms identified in our searches.

We will consider using the following framework for analysis, adapted from Liu et al (21), which includes three main areas related to:

- A country's ability to develop or to purchase pandemic vaccines
- Reciprocity
- A country's ability to implement or vaccinate.

#### Reporting, submission of manuscript and updating of search

A draft report based on the findings from the scoping review was prepared and presented to Norad and two external peer reviewers. A manuscript was then prepared and submitted to BMJ Open in January 2021. Based on feedback from peer review, the search was updated in May 2021.

#### **Risk of bias and limitations**

Due to time constraints we are extracting data directly related to our topic of interest. This will mean that some papers are excluded due to their lack of direct relevance to our question, and will not be included in the analysis.

Only one reviewer will complete the full-text review and data extraction, to limit the risk of bias, one reviewer will peer review the full-text categorisation and data extraction.

#### **Peer -review**

External and internal peer review is being used to strengthen the methods and improve the rigor of this scoping review.

#### Internal:

The project plan (this document) has been reviewed by all authors and peer reviewed internally at NIPH. Internal reviewers at NIPH will also review any publication of results presented to Norad.

#### External:

Two external peer reviewers will be used in addition before publication of results.

#### Acronyms

CEPI	Coalition for Epidemic Preparedness Innovations
COVAX the C	OVID-19 vaccine global access (COVAX) facility
COVID-19	2019 Pandemic corona virus strain
CIS	Critical Interpretive Synthesis
DNA	Deoxyribonucleic acid
Gavi	Gavi, the Vaccine Alliance
FIND the F	oundation for Innovative New Diagnostics
HIC	High income countries
H1N1	2009 influenza A
H5N1	2006 avian influenza A
LMIC	Low- and Middle- income countries

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for open teriew only

### Appendix 3: Search strategies for each of the five databases (*Initially searched for the period* 01.01.2002 - 28.08.2020, updated to include12.05.2021)

Databases searched

- MEDLINE ALL 2002 to May 11, 2021
  - Ovid MEDLINE, PubMed (only 28.082020);
  - Ovid MEDLINE(R) and Epub Ahead of Print, In-Process & Other Non-Indexed Citations and Daily 2002 to August 27, 2020
- Embase 2002 to 2021, Ovid
- Web of Science Core Collection, Clarivate Analytics
- Global Index Medicus, WHO
- COVID-19 Evidence, Epistemonikos Foundation

#### Updated search <u>12.05.2021</u>

We searched:

• PubMed, US National Library of Medicine (NLM): <u>pubmed.ncbi.nlm.nih.gov/</u>

Only 28.08.2020 as string was not available in 2021.

#### • MEDLINE ALL 1946 to May 11, 2021, Ovid (searched <u>12.05.2021</u>)

#	Searches	Results
1	COVID-19 Vaccines/	2510
2	Coronavirus/	4692
3	Betacoronavirus/	33218
4	Coronavirus Infections/	44847
5	Coronaviridae Infections/	919
6	Severe Acute Respiratory Syndrome/	5545
7	Pandemics/	56289
8	(COVID-19 or COVID 19 or COVID19 or 2019-nCoV or SARS2 or SARS-CoV or	177584
	SARS-CoV-2 or SARS-Cov-19 or coronavirus* or corona or pandemic?).ti,ab,kf.	
9	(BNT162 or BNT-162 or mRNA-1273 or mRNA1273 or INO-4800 or INO4800 or	218
	ChAdOx1 or Ad5-nCoV).ti,ab,kf,hw.	
10	or/2-9	184722
11	Vaccines/	22577
12	Viral Vaccines/	27055
13	Vaccination/	85401
14	Vaccination Coverage/	1540
15	Mass Vaccination/	3208
16	Immunization/	51563
17	Immunization Programs/	11524
18	(vaccin* or immuni*).ti,ab,kf.	576919
19	or/11-18	610926
20	"Delivery of Health Care"/	95912

21	"Health Services Needs and Demand"/	54005
22	Resource Allocation/	8895
23	Health Care Rationing/	11853
24	Health Services Accessibility/	78488
25	Health Equity/	1805
26	Right to Health/	131
27	Universal Health Care/	149
28	Healthcare Disparities/	18787
29	Socioeconomic Factors/	162607
30	Social Justice/	12551
31	Global Health/	50200
32	Human Rights/	14729
33	((equit* or equal* or fair* or inequit* or unequal or unfair* or global*) adj3	32465
	(access* or allocat* or distribut* or deliver* or provision or supply or	
	supplies)).ti,ab,kf.	
34	(right to health* or universal health*).ti,ab,kf.	7779
35	((health* or health care) adj (rationing or disparities)).ti,ab,kf.	15193
36	or/20-35	488375
37	10 and 19 and 36	1157
38	1 and 36	280
39	37 or 38	1194
40	(202008* or 202009* or 202010* or 202011* or 202012* or 2021*).dt,dp,ed,ep,yr.	180573
41	39 and 40	588
42	38 or 41	608

#### Embase 1974 to 2021 Week 18 (searched 12.05.2021) ٠

#	Searches	Results
1	SARS-CoV-2 vaccine/	2292
2	coronavirus disease 2019/	106145
3	coronavirinae/	3003
4	betacoronavirus/	7651
5	coronavirus infection/	12666
6	coronaviridae infection/	187
7	pandemic/	65235
8	(COVID-19 or COVID 19 or COVID19 or 2019-nCoV or SARS2 or SARS-CoV or	195467
	SARS-CoV-2 or SARS-Cov-19 or coronavirus* or corona or pandemic?).mp.	

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9	(BNT162 or BNT-162 or mRNA-1273 or mRNA1273 or INO-4800 or INO4800 or	355
	ChAdOx1 or Ad5-nCoV).mp.	
10	or/3-9	195821
11	vaccine/	63516
12	virus vaccine/	20586
13	severe acute respiratory syndrome vaccine/	453
14	vaccination/	151179
15	vaccination coverage/	2788
16	immunization/	98822
17	mass immunization/	3739
18	(vaccin* or immuni*).ti,ab,kw,ot.	685955
19	or/11-18	736294
20	health care delivery/	184159
21	resource management/	10987
22	resource allocation/	22438
23	health care access/	69640
24	health care quality/	250577
25	health equity/	4605
26	right to health/	214
27	universal health care/	337
28	health care disparity/	17595
29	socioeconomics/	147326
30	social justice/	11121
31	global health/	12881
32	human rights/	26721
33	((equit* or equal* or fair* or inequit* or unequal or unfair* or global*) adj3	42137
	(access* or allocat* or distribut* or deliver* or provision or supply or	
	supplies)).ti,ab,kw,ot.	
34	(right to health* or universal health*).ti,ab,kw,ot.	9211
35	((health* or health care) adj (rationing or disparities)).ti,ab,kw,ot.	19032
36	or/20-35	714178
37	10 and 19 and 36	1372
38	1 and 36	266
39	2 and 19 and 36	692
40	or/37-39	1423
41	limit 40 to (conference abstracts or embase)	1129
42	limit 37 to (conference abstracts or embase)	1078

43	(202008* or 202009* or 202010* or 202011* or 202012* or 2021*).dd,em,yr.	1850404
44	42 and 43	439
45	limit 38 to (conference abstracts or embase)	259
46	limit 39 to (conference abstracts or embase)	652
47	44 or 45 or 46	751
48	47 use oemez	751

#### • Web of Science, Clarivate Analytics (searched <u>12.05.2021</u>)

Advanced search - Topic

COVID-19 OR "COVID 19" OR COVID19 OR 2019-nCoV OR "2019 nCoV" OR SARS2 OR SARS-CoV OR "SARS CoV" OR SARS-CoV-2 OR "SARS CoV 2" OR SARS-Cov-19 OR "SARS Cov 19" OR coronavirus OR corona OR pandemic OR pandemics

AND

vaccin\* OR immuni\*

AND

equity OR equitable OR equal OR equally OR inequity OR inequitable OR unequal OR unequally OR fair\* OR unfair\* OR "right to health" OR "right to healthcare" OR "universal health" OR "universal healthcare" OR "healthcare rationing" OR "healthcare rationing" OR "healthcare disparity" OR "healthcare disparities" OR "healthcare disparities"

#### • Global Index Medicus, WHO: <u>www.globalindexmedicus.net</u> (searched <u>14.05.2021</u>)

Advanced search in Title, abstract, subject

COVID-19 OR "COVID 19" OR COVID19 OR 2019-nCoV OR "2019 nCoV" OR SARS2 OR SARS-CoV OR "SARS CoV" OR SARS-CoV-2 OR "SARS CoV 2" OR SARS-Cov-19 OR "SARS Cov 19" OR coronavirus OR corona OR pandemic OR pandemics

AND

vaccine OR vaccines OR vaccination OR immunization OR immunisation

AND

equity OR equitable OR equal OR equally OR inequity OR inequitable OR unequal OR unequally OR fair\* OR unfair\* OR "right to health" OR "right to healthcare" OR "universal health" OR "universal healthcare" OR "healthcare rationing" OR "healthcare disparity" OR "healthcare disparities" OR "healthcare disparities" OR global OR globally

• COVID-19 Evidence, Epistemonikos Foundation: app.iloveevidence.com/loves/5e6fdb9669c00e4ac072701d?utm=epdb\_en (searched 14.05.2021)

(vaccin\* OR immuniz\* OR immunis\*) AND (equity OR equitable OR equal OR equally OR inequity OR inequitable OR unequal OR unequally OR fair\* OR unfair\* OR "right to health" OR "right to healthcare" OR "universal health" OR "universal healthcare" OR "healthcare rationing" OR "health care rationing" OR "healthcare disparity" OR "healthcare disparities" OR "healthcare disparities" OR global OR globally) AND (access\* or allocat\* or distribut\* or deliver\* or provision or supply or supplies)

LIMITED TO Type of publication: Pre-print

#### Original search of databases: 28.08.2020

• MEDLINE, PubMed (searched 28.08.2020)

MeSH: "COVID-19 vaccine" [Supplementary Concept]

Ovid MEDLINE(R) and Epub Ahead of Print, In-Process & Other Non-Indexed Citations and Daily 1946 to August 27, 2020 (searched 28.08.2020)

#	Searches	Results
1	Coronavirus/	3244
2	Betacoronavirus/	16530
3	Coronavirus Infections/	24138
4	Coronaviridae Infections/	906
5	Severe Acute Respiratory Syndrome/	4873
6	Pandemics/	24349
7	(COVID-19 or COVID 19 or COVID19 or 2019-nCoV or SARS2 or SARS- CoV or SARS-CoV-2 or SARS-Cov-19 or coronavirus* or corona or pandemic?).ti,ab,kf.	91205
8	(BNT162 or BNT-162 or mRNA-1273 or mRNA1273 or INO-4800 or INO4800 or ChAdOx1 or Ad5-nCoV).ti,ab,kf,hw.	51
9	or/1-8	97109
10	Vaccines/	21690
11	Viral Vaccines/	25884
12	Vaccination/	81687
13	Vaccination Coverage/	1160
14	Mass Vaccination/	3038
15	Immunization/	50752
16	Immunization Programs/	10877
17	(vaccin* or immuni*).ti,ab,kf.	546309
18	or/10-17	579947
19	"Delivery of Health Care"/	91173
20	"Health Services Needs and Demand"/	53044
21	Resource Allocation/	8501
22	Health Care Rationing/	11514
23	Health Services Accessibility/	74764
24	Health Equity/	1291
25	Right to Health/	75
26	Universal Health Care/	80
27	Healthcare Disparities/	17030
28	Socioeconomic Factors/	157123
29	Social Justice/	12160
30	Global Health/	47402
31	Human Rights/	14384

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32	((equit* or equal* or fair* or inequit* or unequal or unfair* or global*) adj3 (access* or allocat* or distribut* or deliver* or provision or supply or supplies)).ti,ab,kf.	29976
33	(right to health* or universal health*).ti,ab,kf.	7053
34	((health* or health care) adj (rationing or disparities)).ti,ab,kf.	13345
35	or/19-34	466021
36	9 and 18 and 35	632

#### • Embase 1974 to 2020 Week 34, Ovid (searched <u>28.08.2020</u>)

#	Searches	Results
1	coronavirinae/	2268
2	betacoronavirus/	4632
3	coronavirus infection/	8485
4	coronaviridae infection/	166
5	pandemic/	30028
6	(COVID-19 or COVID 19 or COVID19 or 2019-nCoV or SARS2 or SARS-	103695
	CoV or SARS-CoV-2 or SARS-Cov-19 or coronavirus* or corona or	
	pandemic?).mp.	
7	(BNT162 or BNT-162 or mRNA-1273 or mRNA1273 or INO-4800 or	85
	INO4800 or ChAdOx1 or Ad5-nCoV).mp.	
8	or/1-7	103962
9	vaccine/	60026
10	virus vaccine/	19609
11	severe acute respiratory syndrome vaccine/	385
12	vaccination/	140276
13	vaccination coverage/	2060
14	immunization/	94131
15	mass immunization/	3511
16	(vaccin* or immuni*).ti,ab,kw,ot.	643022
17	or/9-16	689815
18	health care delivery/	174154
19	resource management/	10271
20	resource allocation/	20867
21	health care access/	62445
22	health care quality/	241073
23	health equity/	3269
24	right to health/	105
25	universal health care/	155
26	health care disparity/	15646
27	socioeconomics/	140163
28	social justice/	10427
29	global health/	9804
30	human rights/	24894
31	((equit* or equal* or fair* or inequit* or unequal or unfair* or global*) adj3	38602
	(access* or allocat* or distribut* or deliver* or provision or supply or	
	supplies)).ti,ab,kw,ot.	
32	(right to health* or universal health*).ti,ab,kw,ot.	8082
33	((health* or health care) adj (rationing or disparities)).ti,ab,kw,ot.	16415
34	or/18-33	670545
35	8 and 17 and 34	672
36	limit 35 to (conference abstracts or embase)	529

Adv	vanced search in Title, abstract, subject
CO	VID-19 OR "COVID 19" OR COVID19 OR 2019-nCoV OR "2019 nCoV" OR SARS2 OR
SA	RS-CoV OR "SARS CoV" OR SARS-CoV-2 OR "SARS CoV 2" OR SARS-Cov-19 OR "SARS
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equ	ity OR equitable OR equal OR equally OR inequity OR inequitable OR unequal OR unequally O
unf	air OR unfairly OR disparity OR disparities OR global OR globally
•	Web of Science, Clarivate Analytics (searched 28.08.2020)
CO	VID-19 OR "COVID 19" OR COVID19 OR 2019-nCoV OR "2019 nCoV" OR SARS2 OR
	RS-CoV OR "SARS CoV" OR SARS-CoV-2 OR "SARS CoV 2" OR SARS-Cov-19 OR "SARS

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AND

vaccin\* OR immuni\*

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equity OR equitable OR equal OR equally OR inequity OR inequitable OR unequal OR unequally OR unfair OR unfairly OR "right to health" OR "right to healthcare" OR "universal health" OR "universal healthcare" OR "healthcare rationing" OR "healthcare disparity" OR "healthcare disparities" OR "healthcare disparities"

#### Appendix 4: Excluded articles and reason for exclusion

**Reason for exclusion key:** 1: mentions issue but lacks detail or did not add new insight to factors related to equitable access, 2: discusses within, not amongst countries, 3: irrelevant, 4: not English, 5: full-text unavailable, 6: not in peer reviewed journal.

Nr*	First author, year	Title	Reason excluded
1	Acharya, 2021	Access to and equitable distribution of COVID-19 vaccine in low-income countries	1
2	Anonymous, 2021	Why a pioneering plan to distribute COVID vaccines equitably must succeed	1
3	Anonymous, 2021	It's time to consider a patent reprieve for COVID vaccines	1
4	Aryeetey, 2021	A step backwards in the fight against global vaccine inequities	1
5	Bennett, 2010	Law, ethics and pandemic preparedness: the importance of cross-jurisdictional and cross-cultural perspectives	1
6	Binagwaho, 2021	Equitable and Effective Distribution of the COVID-19 Vaccines - A Scientific and Moral Obligation	1
7	Burki, 2021	Equitable distribution of COVID-19 vaccines	1
8	Burki, 2021	Challenges in the rollout of COVID-19 vaccines worldwide	1
9	Cohen, 2021	As vaccines emerge, a global waiting game begins	1
10	Emanuel, 2020	An ethical framework for global vaccine allocation	1
11	Ferguson, 2020	Love thy neighbour? Allocating vaccines in a world of competing obligations	1
12	Fisher, 2011	Pandemic response lessons from influenza H1N1 2009 in Asia	1
13	Friede, 2011	WHO initiative to increase global and equitable access to influenza vaccine in the event of a pandemic: supporting developing country production capacity through technology transfer	1
14	Garfinkel, 2020	Survival of the Wealthiest?	1
15	Gostin, 2020	Facilitating Access to a COVID-19 Vaccine through Global Health Law	1
16	Haaheim, 2009	Pandemic influenza vaccines - the challenges	1
17	Hay, 2018	The WHO global influenza surveillance and response system (GISRS)-A future perspective	1
18	Herzog, 2021	Covax must go beyond proportional allocation of covid vaccines to ensure fair and equitable access	1
19	Hessel, 2009	Pandemic influenza vaccines: Meeting the supply, distribution and deployment challenges	1
20	Но, 2020	Global Disparity and Solidarity in a Pandemic	1
21	Hurley, 2021	It's self-interest to share our vaccines globally	1
22	Kamradt-Scott, 2012	Evidence-based medicine and the governance of pandemic influenza	1
23	Kim, 2021	Operation Warp Speed: implications for global vaccine security	1
24	Kimble, 2021	Considerations on the distribution and administration of the new COVID-19 vaccines	1
25	Kupferschmidt, 2020	Despite obstacles, WHO unveils plan to distribute vaccine	1
26	Lie, n.d.	Allocating a COVID-19 Vaccine: Balancing National and International Responsibilities	1
27	Lomazzi, 2020	Equitable access to COVID-19 vaccination: a distant dream?	1
28	Megiddo, 2020	Fairer financing of vaccines in a world living with COVID- 19	1
29	Meyer, 2020	After a COVID-19 vaccine: Collaboration or competition?	1
30	Milstien, 2003	Emergency response vaccines: Lessons learned in response to communicable diseases	1
31	Munguia-Lopez, 2021	Fair Allocation of Potential COVID-19 Vaccines Using an Optimization-Based Strategy	1
32	Nannei, 2016	Stakeholders' perceptions of 10years of the Global Action Plan for Influenza Vaccines (GAP) - Results from a survey	1

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Drit Fischman, 2021 Punjabi, 2021 Rodríguez Mega, 2020 Ropero-Alvarez, 2012 Sadeghi, 2021 Schwartz, 2009 Schwartz, 2020 Sharun, 2021 The Lanclet, 2020 Jsman, 2020 Yamada, 2009 Yen, 2015 Zimmerman, 2007 Abramowitz, 2020 Adebambo Anthony, 2020	A Global Pandemic Remedy to Vaccine Nationalism         Vaccine is health and health is wealth         Latin American scientists join the coronavirus vaccine race:         'No one's coming to rescue us'         Pandemic influenza vaccination: lessons learned from Latin         America and the Caribbean         The commitment for fair distribution of COVID-19 vaccine         among all countries of the world.         Prioritization of pandemic influenza vaccine: Rationale and         strategy for decision making         Equitable global access to coronavirus disease 2019 vaccines         COVID-19 vaccine diplomacy and equitable access to         vaccines amid ongoing pandemic         Global collaboration for health: rhetoric versus reality         After the Coronavirus Vaccine's Discovery: Concerns         Regarding a COVID-19 Vaccination's Distribution         Poverty, wealth, and access to pandemic influenza vaccines         The development of global vaccine stockpiles         Rationing of influenza vaccine during a pandemic: ethical analyses         Transparent, equitable, safe, and effective use of COVID-19 vaccines: A societal imperative         Intellectual Property Rights, Pharmaceutical Patents and Public Health: Adopting Compulsory and Government Use	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1
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	Distribution equality as an optimal epidemic mitigation	3
Adar, 2020		3
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Health       Health         30       Collin, 2009       [Influenza vaccine: globalization of public health stakes]       5         40       Donatelli, 2003       [WHO Influenza Global Agenda]       5         41       Iacob, 2020       COVID. 19 Pandemic: Assessing Its Usefulness and 5       5         42       Jorgensen, 2013       Unequal access to vaccines in the WHO European Region 4       4         43       Lopalco, 2016       Pandemic vaccines: Are we prepared for the next pandemic?       5         44       Mark, 2020       The Procurement of a COVID-19 Vaccine in Developing 5       5         45       Mendes, 2021       Tackling inequitable distribution of the COVID-19 vaccine       5         46       Saransh, 2021       Building Resilient Vaccine Distribution       5         47       Ana Santos, 2020       The Remergence of Vaccine Nationalism       6         48       Ana Santos, 2020       The Remergence of Vaccine Nationalism       6         50       Armin von, 2020       The Role of International Law in Vaccinating Against COVID-19       6         51       Benjamin, 2020       Spatial Allocation of Scarce Vaccine and Antivirals for COVID-19       6         53       Goldstein, 2021       Failure to achieve global vaccine equity will have dire consequences       6				
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# Appendix 5: Data extraction form for factors influencing global equitable access to COVID-19 vaccines for Low-and Middle-Income Countries

- 1. Name of reviewer
- 2. First author and year of publication (Date) e.g. Li (2011)
- 3. Title
- 4. Inclusion criteria (all must be selected):
  - LMIC or globally focussed or normative guidance that affects LMIC
  - Published between 2005-2021
  - Discusses influenza/pandemic/COVID-19 vaccine(s)
  - Contains arguments/discussion on equity, access, allocation or prioritization of influenza/pandemic/COVID-19vaccine(s)
  - Published in English

Findings related to our Scoping Review research objective: What are the factors influencing global equitable access to a COVID-19 vaccine among countries?

- 5. Summarise: What does this article tell us about the knowledge related to allocation and pandemic vaccine(s)?
- 6. Key examples or illustrations from publication (including page numbers)
- 7. Summarise: What does this article tell us about the knowledge related to allocation and pandemic vaccine(s)?
- 8. Key examples or illustrations from publication (including page numbers)
- 9. Summarise: What does this article tell us about the knowledge related to allocation and pandemic vaccine(s)?
- 10. Key examples or illustrations from publication (including page numbers)
- 11. Summarise: What does this article tell us about the knowledge related to allocation and pandemic vaccine(s)?
- 12. Key examples or illustrations from publication (including page numbers)
- 13. Is there anything else that this study tells us about the knowledge in this topic area?
- 14. Challenges in implementing equitable access to vaccination
- 15. List any global initiatives/mechnasims/frameworks identified in our search that address equitable access to pandemic vaccine(s)?
- 16. Recommendations for strengthening equitable access to vaccination

#### Appendix 1: Papers underlying this Scoping Review

List of the 44 papers included in the review, including the reference, type of publication and a short summary of the focus of the paper is shown in the table below.

No	Reference (BMJ style)	Study design	Focus of paper
1	Abbott FM, Reichman JH. Facilitating Access to Cross-Border Supplies of Patented Pharmaceuticals: The Case of the COVID-19 Pandemic. <i>Journal of International Economic</i> <i>Law</i> 2020;23(3):535-61.	Article	Proposes legal mechanisms for addressing critical issues facing the international community in terms of providing equitable access to vaccines, treatments, diagnostics, and medical equipment.
2	Bollyky TJ, Gostin LO, Hamburg MA. The Equitable Distribution of COVID-19 Therapeutics and Vaccines. <i>Jama-Journal of the</i> <i>American Medical Association</i> 2020;323(24):2462-63. doi: 10.1001/jama.2020.6641	Viewpoint	Discusses experiences and suggestions for a future framework to the distribution of COVII 19 vaccines.
3	Choi EM. COVID-19 vaccines for low- and middle-income countries. <i>Transactions of the</i> <i>Royal Society of Tropical Medicine &amp; Hygiene</i> 2021;115(5):447-56.	Review	Discusses low- and middle-income countries access COVID-19 vaccines, what is being don to distribute vaccines fairly, as well as the challenges ahead
4	DeFrancesco L. Whither COVID-19 vaccines? <i>Nature Biotechnology</i> 2020;38(10):1132-45.	Article	Insights from seven experts on the development of the COVID-19 vaccines.
5	Eccleston-Turner M. The pandemic influenza preparedness framework: A viable procurement option for developing states? <i>Medical Law</i> <i>International</i> 2017;17(4):227-48.	Article	Examines the Pandemic Influenza Framework and the content of the Obligations of the Company which have been secured by the World Health Organization.
6	Eccleston-Turner M, Upton H. International Collaboration to Ensure Equitable Access to Vaccines for COVID-19: The ACT-Accelerator and the COVAX Facility. <i>Milbank Quarterly</i>	Original Scholarship	Analysis of the COVAX Facility and its aim and ensure equitable availability of the vaccine in low and middle-income countries.
7	Fedson DS. Pandemic influenza and the global vaccine supply. <i>Clin Infect Dis</i> 2003;36(12):1552-61.	Article	The article explores several issues related to the global supply of vaccine during influenza pandemics
8	Fedson DS. Preparing for pandemic vaccination: an international policy agenda for vaccine development. <i>J Public Health Policy</i> 2005;26(1):4-29.	Commentary	Focuses on the trivalent vaccines currently available that contain inactivated viruses.
9	Fedson DS, Dunnill P. Commentary: From scarcity to abundance: pandemic vaccines and other agents for "have not" countries. <i>J Public</i> <i>Health Policy</i> 2007;28(3):322-40.	Commentary	Discusses that access to supplies of pandemic vaccine for most countries is a problem of scarcity and how to ensure the "have not" countries will get access to pandemic vaccines
10	Felicitas H, Florencia L, Manriquez RT, et al. A matter of priority: equitable access to COVID-19 vaccines. <i>Swiss Med Wkly</i> 2021;151	Viewpoint	Highlights inequality in current vaccination rates between some high income countries (HIC) and low income countries (LIC) provide arguments for HIC to support distribution to LIC
11	Fidler DP. Negotiating Equitable Access to Influenza Vaccines: Global Health Diplomacy and the Controversies Surrounding Avian Influenza H5N1 and Pandemic Influenza H1N1. <i>Plos Medicine</i> 2010;7(5)	Article	Examines the diplomatic negotiations surrounding influenza virus sharing as an example of the core tensions characterizing multilateralism and emerging forms of global health governance.
12	Fidler DP. Vaccine nationalism's politics. Science 2020;369(6505):749.	Editorial	Discusses global politics and the burden of global equitable COVID-19 vaccine access issues, historically and now.
13	Forman R, Anderson M, Jit M, et al. Ensuring access and affordability through COVID-19 vaccine research and development investments: A proposal for the options market for vaccines. <i>Vaccine</i> 2020;38(39):6075-77.	Commentary	Discusses existing financing mechanisms and proposal for vaccine development, referred to as Options Market for Vaccines (OMV).
14	Forman R, Shah S, Jeurissen P, et al. COVID-19 vaccine challenges: What have we learned so far and what remains to be done? <i>Health Policy</i> 2021;125(5):553-67.	Review	Offers a framework for understanding remaining and new policy challenges for globa vaccine campaigns against COVID-19 and potential solutions.

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No	Reference (BMJ style)	Study design	Focus of paper
	Gray G, van der Heever A, Madhi S, et al. The	U	
	Scientists' Collective 10-point proposal for	( <b>C</b> t)	
15	equitable and timeous access to COVID-19	(Guest)	Proposes a ten-point plan for equitable and
	vaccine in South Africa. Samj South African	Editorial	timely access to COVID-19 vaccine in South
	Medical Journal 2021;111(2):89-94.		Africa.
	Guzman J, Hafner T, Maiga LA, et al. COVID-		
16	19 vaccines pricing policy options for low-	C ·	Discusses four pricing strategies to address
16	income and middle- income countries. BMJ	Commentary	high prices and obtain COVID-19 vaccines
	Global Health 2021;6(3):03.		(and other medical products) at affordable rat
	Herlitz A, Lederman Z, Miller J, et al. Just		Offers three suggestions to strengthen how to
17	allocation of COVID-19 vaccines. <i>BMJ Global</i>	Editorial	achieve the greatest health impact with
- '	Health 2021;6(2):02.	Lanonai	authorized COVID-19 vaccines.
	Iacobucci G. Covid-19: How will a waiver on		Presents responses from experts and
	vaccine patents affect global supply? <i>BMJ</i>	News	organizations after Biden administration (US)
18	2021;373:n1182.	analysis	announced to support a proposal to waive
	2021,373.11102.	anary 515	patents on covid-19 vaccines.
	Kamradt-Scott A, Lee K. The 2011 Pandemic		Investigates the diplomatic negotiations
	Influenza Preparedness Framework: Global		surrounding influenza virus sharing, and
19		Article	
	Health Secured or a Missed Opportunity? <i>Political Studies</i> 2011;59(4):831-47.		evaluates the Pandemic Influenza Preparedne (PIP) framework
	Kupferschmidt K. Global plan seeks to promote		(PIP) framework.
20	vaccine equity, spread risks. <i>Science</i>	News	Discusses the COVAX facility and its
20	2020;369(6503):489-90.	THEMS	challenges.
	Liu Y, Salwi S, Drolet BC. Multivalue ethical		Analyses and synthesizes the ethical
	framework for fair global allocation of a		considerations of four allocation paradigms:
21		Article	
	COVID-19 vaccine. <i>Journal of medical ethics</i>		ability to develop or purchase; reciprocity;
	2020;46(8):499-501. The Lanclet. Global governance for COVID-19		ability to implement; and distributive justice. Discusses the COVID-19 vaccine bidding wa
	-		and the necessary global level arrangements t
22	vaccines. Lancet (London, England)	Editorial	for development, finance, production, and
	2020;395(10241):1883.		distribution.
	The Lancet. Access to COVID-19 vaccines:	~ / /	and to uton.
23	looking beyond COVAX. Lancet	Editorial	Calls for a strong political leadership to suppo
	2021;397(10278):941.		equitable access to vaccines
	McAdams D, McDade KK, Ogbuoji O, et al.		•
	Incentivising wealthy nations to participate in the		Discusses how maximizing the benefit of
24	COVID-19 Vaccine Global Access Facility	Commentary	bilateral deals to support COVAX, and
	(COVAX): a game theory perspective. <i>BMJ</i>		explores how such deals can improve the glob
	Global Health 2020;5(11):11.		supply of vaccines.
	McMahon A. Global equitable access to		
25	vaccines, medicines and diagnostics for COVID-	Current	Discusses the role of patents and highlights the
25	19: The role of patents as private governance.	controversy	during the COVID-19 pandemic the power of
	Journal of Medical Ethics 2020;30:30.		patent holders should be questioned.
	Nhamo G, Chikodzi D, Kunene HP, et al.		
	COVID-19 vaccines and treatments nationalism:		Discusses the 2030 Agenda for Sustainable
26	Challenges for low-income countries and the	Article	Development and calls stakeholders for their
	attainment of the SDGs. <i>Global Public Health</i>		continued support to Gavi and COVAX 'to
	2021;16(3):319-39.		leave no one behind' and eliminate inequalitie
	Pagliusi S, Hayman B, Jarrett S. Vaccines for a		Summary of a meeting where public and
	healthy future: 21st DCVMN Annual General		private sector participants presented challeng
27	Meeting 2020 report. Vaccine 2021;39(18):2479-	Meeting	and opportunities related to vaccine R&D,
- '	88.	Report	supply chain, global policies, financing, healt
			objectives, and supporting access for LMIC.
	Phelan AL, Eccleston-Turner M, Rourke M, et		Discusses role of law on equitable access to
	al. Legal agreements: barriers and enablers to		COVID-19 vaccines, highlighting challenges
28	global equitable COVID-19 vaccine access.	Commentary	bilateral agreements, advanced purchasing, ar
	<i>Lancet</i> 2020;396(10254):800-02.		COVAX.
	Rourke MF. Access by Design, Benefits if		Analyses the PIP Framework, its Standard
	Convenient: A Closer Look at the Pandemic		Material Transfer Agreements (SMTAs), and
	Influenza Preparedness Framework's Standard		secondary sources to determine whether the F
29	Material Transfer Agreements. <i>Milbank Q</i>	Article	Framework will effectively function as an
<i>27</i>	mathar fransier Agreements. Willburk U		
			access and banafit sharing (ADC) instanton
	2019;97(1):91-112.		access and benefit-sharing (ABS) instrument during an influenza pandemic.

No	Reference (BMJ style)	Study design	Focus of paper
30	Ruscio BA, Hotez P. Expanding global and national influenza vaccine systems to match the COVID-19 pandemic response. <i>Vaccine</i> 2020;38(50):7880-82.	Commentary	Discusses the double burden synergies of Influenza and COVID 19 in the Global South, and proposes how a way to address both issues
31	Saksena N. Global justice and the COVID-19 vaccine: Limitations of the public goods framework. <i>Global Public Health</i> 2021	Article	Focuses on global access, discussing the limitations of the global public good framewor in addressing the problem of distribution COVID-19 vaccines.
32	Sawal I, Ahmad S, Tariq W, et al. Unequal distribution of COVID-19 vaccine: A looming crisis. <i>Journal of Medical Virology</i> 2021;03:03.	Letter to Editor	Argues for the promotion of equitable access to COVID-19 vaccines to benefit the whole world.
33	Sharma S, Kawa N, Gomber A. WHO's allocation framework for COVAX: is it fair? <i>Journal of Medical Ethics</i> 2021;09:09.	Article	Explores comparing COVAX allocation mechanisms to a targeted allocation system, based on need. Arguing that this could maximize well-being and align with principles of equity.
34	Sehovic AB, Govender K. Addressing COVID- 19 vulnerabilities: How do we achieve global health security in an inequitable world. <i>Global</i> <i>Public Health</i> 2021	Commentary	Discusses the particular challenges of COVID- 19 for LMICs, and the inequities being perpetuated in the COVID-19 Pandemic and the suggestions in how to address these challenges.
35	So AD, Woo J. Reserving coronavirus disease 2019 vaccines for global access: cross sectional analysis. <i>Bmj-British Medical Journal</i> 2020;371	Special paper	Analyzes premarket purchase commitments fo COVID-19 vaccines from leading manufacturers to recipient countries.
36	So AD, Woo J. Achieving path-dependent equity for global COVID-19 vaccine allocation. <i>Medicina Intensiva</i> 2021;2(4):373-77.	Commentary	Discusses the interdependence of equitable allocation based on three policy levers: Development and Production, Procurement, and Healthcare Delivery.
37	Torres I, Artaza O, Profeta B, et al. COVID-19 vaccination: returning to WHO's Health For All. <i>The Lancet Global Health</i> 2020;8(11):e1355- e56.	Commentary	Promotes the perspective of World Health Organization, calling for inclusion of all member states, and transparency.
38	Towse A, Chalkidou K, Firth I, et al. How Should the World Pay for a Coronavirus Disease (COVID-19) Vaccine? <i>Value in Health</i> 2021;24(5):625-31.	Article	Proposes the Benefit-Based Advance Market Commitment as a collaborative, market-based financing mechanism for the world to incentivize and pay for the development and provide equitable access to second and third generation COVID-19 vaccines.
39	Turner M. Vaccine procurement during an influenza pandemic and the role of Advance Purchase Agreements: Lessons from 2009- H1N1. <i>Glob Public Health</i> 2016;11(3):322-35.	Article	A case study on the procurement of pandemic influenza vaccines during 2009-H1N1, and the likely manner in which procurement will occu during future pandemics.
40	Usher AD. COVID-19 vaccines for all? <i>Lancet</i> ( <i>London, England</i> ) 2020;395(10240):1822-23.	World report	Provides an assessment of the initiatives being planned to ensure equitable access to COVID- 19 vaccines, and shortcomings.
41	Usher AD. CEPI criticised for lack of transparency. <i>Lancet</i> 2021;397(10271):265-66.	World Report	Provides insights and perspectives on CEPI contracts for COVID-19 vaccines.
42	Usher AD. South Africa and India push for COVID-19 patents ban. <i>Lancet</i> 2020;396(10265):1790-91.	World Report	Report on the proposal by India and South Africa to waiver Intellectual Property Rights to COVID-19 products (incl. vaccines).
43	Wouters OJ, Shadlen KC, Salcher-Konrad M, et al. Challenges in ensuring global access to COVID-19 vaccines: production, affordability, allocation, and deployment. <i>Lancet</i> 2021;397(10278):1023-34.	Article	Reviews potential challenges and policy implications for the production, afforable pricing, and global allocation of Covid-19 vaccines.
44	Yamey G, Schäferhoff M, Hatchett R, et al. Ensuring global access to COVID-19 vaccines. <i>Lancet (London, England)</i> 2020;395(10234):1405-06.	Commentary	Discusses how COVID-19 vaccines can be used globally to end the COVID-19 pandemic arguing for three imperatives: speed, manufacture and deployment at scale, and global access.

Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) Checklist

SECTION	ITEM	PRISMA-ScR CHECKLIST ITEM	REPORTED ON PAGE #
TITLE			
Title	1	Identify the report as a scoping review.	1
ABSTRACT			
Structured summary	2	Provide a structured summary that includes (as applicable): background, objectives, eligibility criteria, sources of evidence, charting methods, results, and conclusions that relate to the review questions and objectives.	2
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known. Explain why the review questions/objectives lend themselves to a scoping review approach.	4, 5, 6
Objectives	4	Provide an explicit statement of the questions and objectives being addressed with reference to their key elements (e.g., population or participants, concepts, and context) or other relevant key elements used to conceptualize the review questions and/or objectives.	7
METHODS			
Protocol and registration	5	Indicate whether a review protocol exists; state if and where it can be accessed (e.g., a Web address); and if available, provide registration information, including the registration number.	7
Eligibility criteria	6	Specify characteristics of the sources of evidence used as eligibility criteria (e.g., years considered, language, and publication status), and provide a rationale.	8
Information sources*	7	Describe all information sources in the search (e.g., databases with dates of coverage and contact with authors to identify additional sources), as well as the date the most recent search was executed.	7
Search	8	Present the full electronic search strategy for at least 1 database, including any limits used, such that it could be repeated.	8
Selection of sources of evidence†	9	State the process for selecting sources of evidence (i.e., screening and eligibility) included in the scoping review.	8
Data charting process‡	10	Describe the methods of charting data from the included sources of evidence (e.g., calibrated forms or forms that have been tested by the team before their use, and whether data charting was done independently or in duplicate) and any processes for obtaining and confirming data from investigators.	8
Data items	11	List and define all variables for which data were sought and any assumptions and simplifications made.	8
Critical appraisal of individual sources of evidence§	12	If done, provide a rationale for conducting a critical appraisal of included sources of evidence; describe the methods used and how this information was used in any data synthesis (if appropriate).	N/A



#### St. Michael's

SECTION	ITEM	PRISMA-ScR CHECKLIST ITEM	REPORTED ON PAGE #
Synthesis of results	13	Describe the methods of handling and summarizing the data that were charted.	8
RESULTS			
Selection of sources of evidence	14	Give numbers of sources of evidence screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally using a flow diagram.	9
Characteristics of sources of evidence	15	For each source of evidence, present characteristics for which data were charted and provide the citations.	9-20
Critical appraisal within sources of evidence	16	If done, present data on critical appraisal of included sources of evidence (see item 12).	9-20
Results of individual sources of evidence	17	For each included source of evidence, present the relevant data that were charted that relate to the review questions and objectives.	9-20
Synthesis of results	18	Summarize and/or present the charting results as they relate to the review questions and objectives.	9-20
DISCUSSION			
Summary of evidence	19	Summarize the main results (including an overview of concepts, themes, and types of evidence available), link to the review questions and objectives, and consider the relevance to key groups.	9 & 20-23
Limitations	20	Discuss the limitations of the scoping review process.	23
Conclusions	21	Provide a general interpretation of the results with respect to the review questions and objectives, as well as potential implications and/or next steps.	24
FUNDING			
Funding	22	Describe sources of funding for the included sources of evidence, as well as sources of funding for the scoping review. Describe the role of the funders of the scoping review.	3

JBI = Joanna Briggs Institute; PRISMA-ScR = Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews.

\* Where *sources of evidence* (see second footnote) are compiled from, such as bibliographic databases, social media platforms, and Web sites.

† A more inclusive/heterogeneous term used to account for the different types of evidence or data sources (e.g., quantitative and/or qualitative research, expert opinion, and policy documents) that may be eligible in a scoping review as opposed to only studies. This is not to be confused with *information sources* (see first footnote).
‡ The frameworks by Arksey and O'Malley (6) and Levac and colleagues (7) and the JBI guidance (4, 5) refer to the

process of data extraction in a scoping review as data charting. § The process of systematically examining research evidence to assess its validity, results, and relevance before using it to inform a decision. This term is used for items 12 and 19 instead of "risk of bias" (which is more applicable to systematic reviews of interventions) to include and acknowledge the various sources of evidence that may be used in a scoping review (e.g., quantitative and/or qualitative research, expert opinion, and policy document).

*From:* Tricco AC, Lillie E, Zarin W, O'Brien KK, Colquhoun H, Levac D, et al. PRISMA Extension for Scoping Reviews (PRISMAScR): Checklist and Explanation. Ann Intern Med. 2018;169:467–473. doi: 10.7326/M18-0850.

