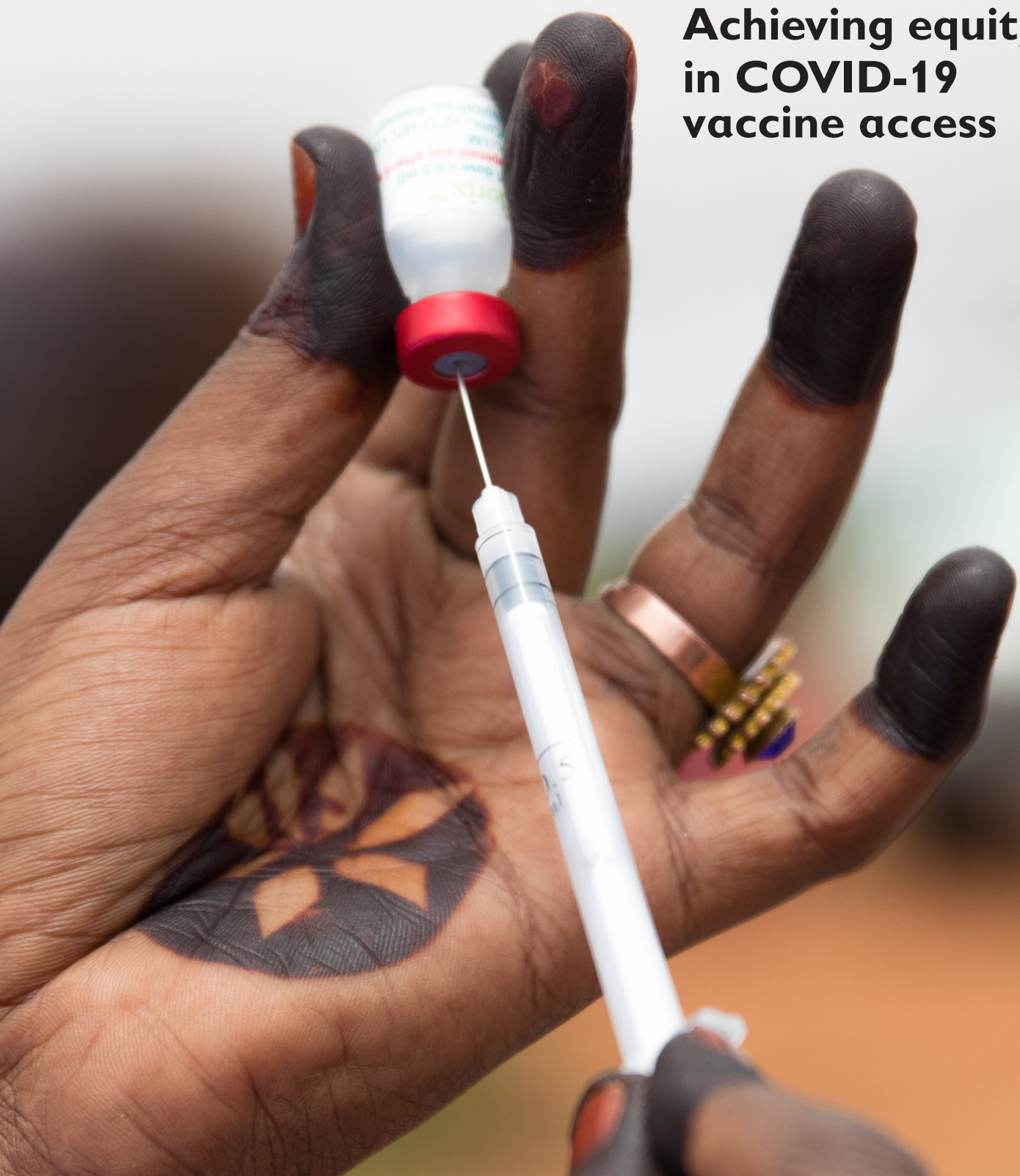




Save the Children

A CHANCE TO GET IT RIGHT

Achieving equity
in **COVID-19**
vaccine access



Save the Children exists to help every child reach their potential.

In more than 100 countries, we help children stay safe, healthy and keep learning. We lead the way on tackling big problems like pneumonia, hunger and protecting children in war, while making sure each child's unique needs are cared for.

We know we can't do this alone. Together with children, partners and supporters, we work to help every child become whoever they want to be.

This report has been written by Karrar Karrar, Kirsten Mathieson and Lenio Capsaskis.

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Cover photo: A health worker prepares a pneumonia vaccine during a community outreach session in Ethiopia's Somali region. (photo: Hanna Adcock/Save the Children)

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ACHIEVING EQUITY IN COVID-19 VACCINE ACCESS

COVID-19 THREATENS CHILDREN'S RIGHT TO SURVIVE, THRIVE, LEARN AND BE PROTECTED

1.2B

CHILDREN IN MULTIDIMENSIONAL
POVERTY – UP 15%

80M

CHILDREN AT RISK OF VACCINE-
PREVENTABLE DISEASES

168K

MORE CHILDREN COULD DIE
DUE TO MALNUTRITION

1.6B

LEARNERS AFFECTED BY
SCHOOL CLOSURES

2 DECADES OF PROGRESS IN POVERTY ERADICATION AT RISK

\$28TN LOSS IN GLOBAL OUTPUT OVER THE NEXT FIVE YEARS

GUARANTEEING EQUITABLE ACCESS TO COVID-19 VACCINES IS A
HUMAN RIGHTS + PUBLIC HEALTH AND ECONOMIC IMPERATIVE



GLOBAL SOLIDARITY

- Donors must invest now to fully finance the COVAX facility
- Prioritise fair global allocation and distribution of vaccines
- Governments must not engage in vaccine nationalism – it will cost the world **US\$9.2 trillion**
- Governments must urgently redistribute a proportion of secured doses to COVAX



ACCOUNTABILITY FOR ACCESS

- Governments have spent **€88.3 billion** of public funds on COVID-19 vaccines – accountability for this money is critical
- Public funds must come with conditions on transparency and fair access
- Accountability requires meaningful multi-stakeholder engagement, including civil society



EXPAND GLOBAL VACCINE SUPPLY

- Up to **15.6 billion doses** could be needed worldwide – business as usual will not meet this demand
- Support the COVID-19 Technology Access Pool (C-TAP) and share technology, know-how and licensing
- Invest in manufacturing capacity in low- and middle-income countries



NATIONAL ROLL-OUT

- Governments must follow WHO guidance for vaccine prioritisation and have a responsibility to vaccinate all vulnerable groups, without discrimination
- Decision-making must be inclusive with communities at the centre
- Continue to prioritise routine immunisation services

AN EPIDEMIC ANYWHERE COMPROMISES VACCINATION EVERYWHERE

Introduction: COVID-19 and vaccine access

THE IMPACT OF COVID-19 ON CHILDREN'S LIVES

A year on from being declared a global pandemic, COVID-19 has claimed the lives of more than 2.5 million people.¹ The secondary impacts of the pandemic on people's lives and wellbeing have been far-reaching and devastating. It is estimated that nearly 150 million people could be pushed into extreme poverty by the end of 2021, potentially reversing two decades of progress in global poverty eradication.² The International Monetary Fund has projected that as a result of the pandemic and its associated economic impact, there will be a cumulative loss in global output over 2020–25 of \$28 trillion.³

For children, this pandemic has led to the violation of their rights by threatening every aspect of their lives.⁴ Family incomes have been drastically cut, schools closed, often-fragile health systems stretched to breaking point. Joint analysis by UNICEF and Save the Children revealed that the number of children living in multidimensional poverty (without access to education, health, housing, nutrition, sanitation or water) has increased by 15%, soaring to approximately 1.2 billion since the start of the pandemic.⁵ COVID-19 has exacerbated inequalities, leaving the most marginalised children and families worst affected.

Our research found that over 90% of households that have lost half their income during the pandemic experienced challenges in accessing healthcare and medicines.⁶ According to the World Health Organization (WHO), 90% of countries have faced disruptions to essential health services during the pandemic, with low- and middle-income countries (LMICs) worst affected. UNICEF, WHO and Gavi, the Vaccine Alliance, warn that COVID-19 related disruptions to immunisation services could leave 80 million children at risk of vaccine-preventable

diseases. The WHO's Director-General has warned that the risk of deaths due to vaccine-preventable diseases because of children missing out on routine immunisations could exceed those from COVID-19.⁷

More than two-thirds of households surveyed by Save the Children reported issues accessing nutritious food.⁸ It is estimated that 9.3 million more children could suffer from wasting, 2.6 million more could suffer stunting and 168,000 more children under five could die due to malnutrition by 2022.⁹ Furthermore, more than 1.6 billion learners¹⁰ have been affected by school closures with Save the Children research finding a doubling of rates reported by children of household violence when schools were closed, compared with when children were attending school in person.¹¹ This pandemic has further exacerbated impacts of gender inequality, with up to an additional 2.5 million girls at risk of child marriage over the next five years.¹²

Amid this global crisis for children and their families, the rollout of COVID-19 vaccines offers the potential for real hope. Getting vaccines to all countries would have a direct impact on the lives of children, their families and caregivers. Ensuring global equitable access to COVID-19 vaccines is a matter of rights, public health and economics. But as we face the greatest threat to global health in our generation, we must ensure existing inequities are addressed head on. Currently, the opposite is happening. Millions of doses are being rolled out in high-income countries with very few in low-income countries,¹³ exacerbating the divide between rich and poor countries, to the detriment of children.

If we are to make real progress on ending the pandemic – and minimise its impact on children – this equity gap must be addressed as a matter of urgency. We need a global response and the global, equitable distribution of vaccines.

THE FRAMEWORK FOR GLOBAL VACCINE COORDINATION AND MULTILATERALISM

The global community has been scrambling to find ways to protect against COVID-19 and to treat those who are infected.¹⁴ The lack of pre-existing vaccines and medicines meant there was no distinction in prevention and treatment between rich and poor countries, or according to background or wealth. This has pushed the debate about access to medicines to the top of agendas and the forefront of public discourse.

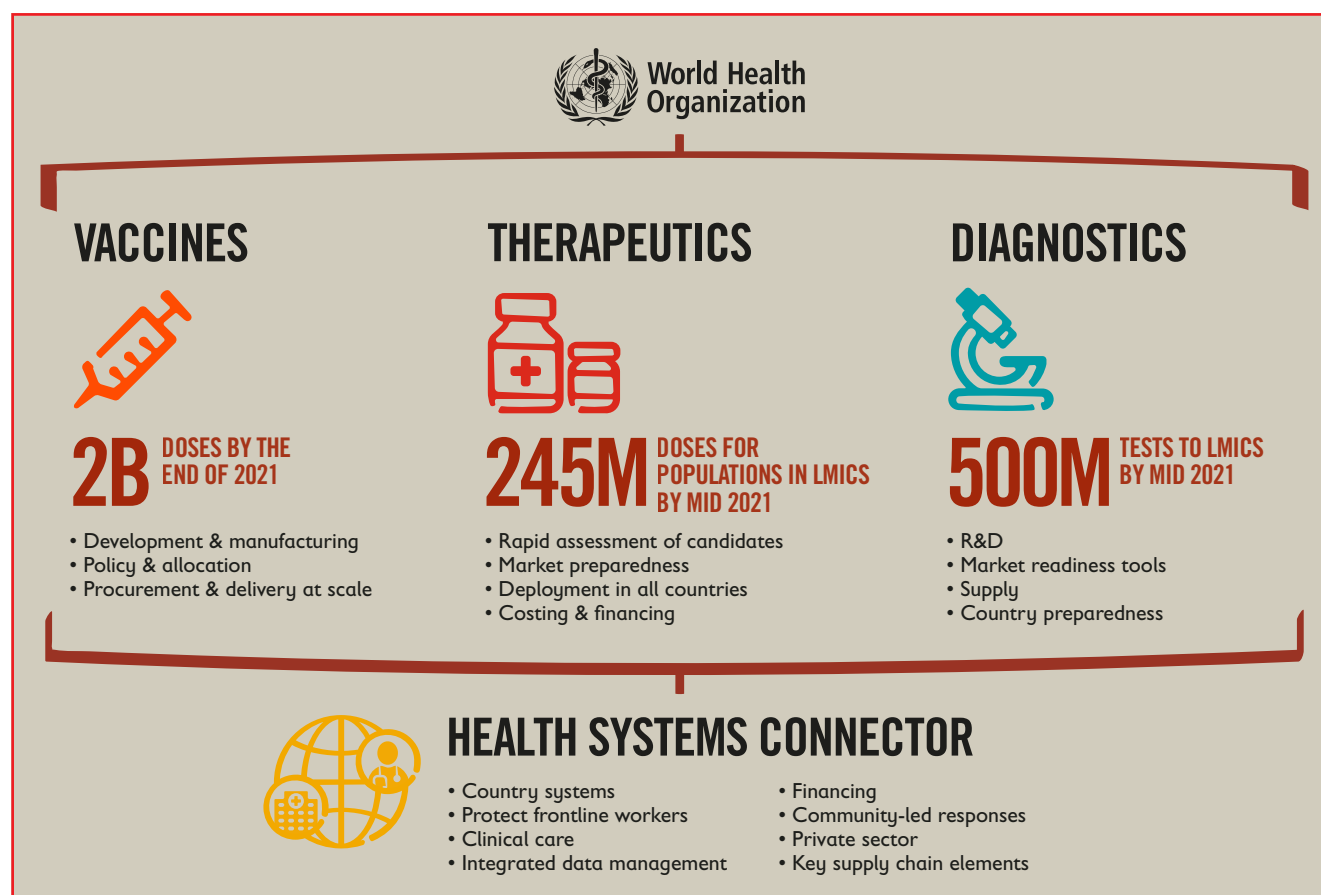
To address this huge gap in available medical tools to tackle COVID-19, billions of dollars have been pumped into research and development (R&D) of new vaccines and treatments. In order to coordinate global efforts, WHO, together with partners, launched the Access to COVID-19 Tools Accelerator (ACT-A; see Figure 1).¹⁵ The intention behind this global collaboration is to accelerate the development, production and equitable access to new COVID-19 diagnostics, therapeutics and vaccines, so that all people have access to the tools needed to defeat COVID-19 and end the acute

phase of the pandemic by the close of 2021. ACT-A has the potential to showcase the power of global coordination and provide a vision for equity through a coordinated multilateral effort.

GETTING VACCINES TO THE WORLD

The world urgently needs safe and effective COVID-19 vaccines to protect the most vulnerable, stop transmission and prevent the resurgence of COVID-19. Although other interventions, including therapeutics, diagnostics and public health measures, have critical roles to play and should continue to be prioritised, global population coverage with effective vaccines is considered the linchpin intervention to sustainably restore health and societal stability. COVID-19 vaccine development is advancing at an unprecedented pace: as of 1 March 2021, there are more than 300 candidates across at least eight different technology platforms in development with around 80 candidates already in human clinical trials.¹⁶ As of 18 February 2021, at least seven different vaccines across three platforms have been rolled out in some countries.¹⁷ Beyond developing vaccines quickly, it is critical that there is sufficient supply

FIGURE 1. ACT-A: MULTILATERALISM AT ITS BEST



of the most suitable (safe, effective, appropriate) COVID-19 vaccines as soon as possible and that supply, when available, is prioritised equitably based on public health need. This prioritisation exercise for what will inevitably be a finite supply of future COVID-19 vaccines should be governed by WHO's allocation framework.¹⁸

The 73rd session of the World Health Assembly saw the endorsement by Member States of the COVID-19 response resolution.¹⁹ In addition to calls for solidarity, there was acknowledgment that a future COVID-19 vaccine should be a global public good with equitable access.

The vaccine pillar of ACT-A, also known as the COVAX Facility²⁰ aims to accelerate the development and manufacture of COVID-19 vaccines and to guarantee fair and equitable access for every country around the world.²¹ The ambition is to make 2 billion vaccine doses available by the end of 2021 so that participating countries can protect high-risk and vulnerable people and healthcare and other frontline workers.²² In order to ensure equitable access irrespective of a country's ability to pay, the COVAX Advance Market Commitment (AMC) was set up to support 92 low- and middle-income countries through donor-funded doses.²³

COVAX now has agreements in place to access close to 2 billion doses of several vaccine candidates, including at least 1.3 billion donor-funded doses for 92 low- and middle-income countries eligible under the AMC, thereby allowing them to cover 20% of their populations by the end of 2021.

However, to deliver on this goal, COVAX estimates it needs to raise an additional US\$6.8 billion in 2021: \$800 million for R&D, at least \$4.6bn for the COVAX AMC and \$1.4bn for delivery support.²⁴

It is critical that this funding gap is filled to allow COVAX to procure doses and fulfil the agreements signed with manufacturers. Ultimately, COVAX provides a practical way for governments to turn sentiments of solidarity into action by ensuring that everyone globally has access to safe and effective vaccines.

To ensure fair and equitable distribution between countries, the WHO allocation framework aims to guide global allocation decisions and supply agreements in order to prioritise finite supply. Allocation prioritisation across countries is set to be introduced in two phases. During phase 1, doses will be allocated to cover 20% of the population of each country – an initial tranche of doses will cover 3% of the population (namely frontline workers in health and social care settings), with additional doses until 20% of the population is covered (eg, older people, adults with comorbidities and others depending on locally relevant risk factors – countries are encouraged to follow SAGE's policy recommendations). Phase 2 will progressively expand access to continue to cover a larger portion of the population in all countries.²⁵ Governments must not engage in vaccine nationalism that undermines the global COVID-19 response or stockpile vaccines beyond the equitable allocation quota.

“COVAX has now built a platform that offers the world the prospect, for the first time, of being able to defeat the pandemic on a global basis, but the work is not done: it's critical that both governments and industry continue to support our efforts to achieve this goal.”

Dr Seth Berkley, CEO of Gavi, the Vaccine Alliance

1 Build global vaccine solidarity



OUR RECOMMENDATIONS

WE CALL ON:

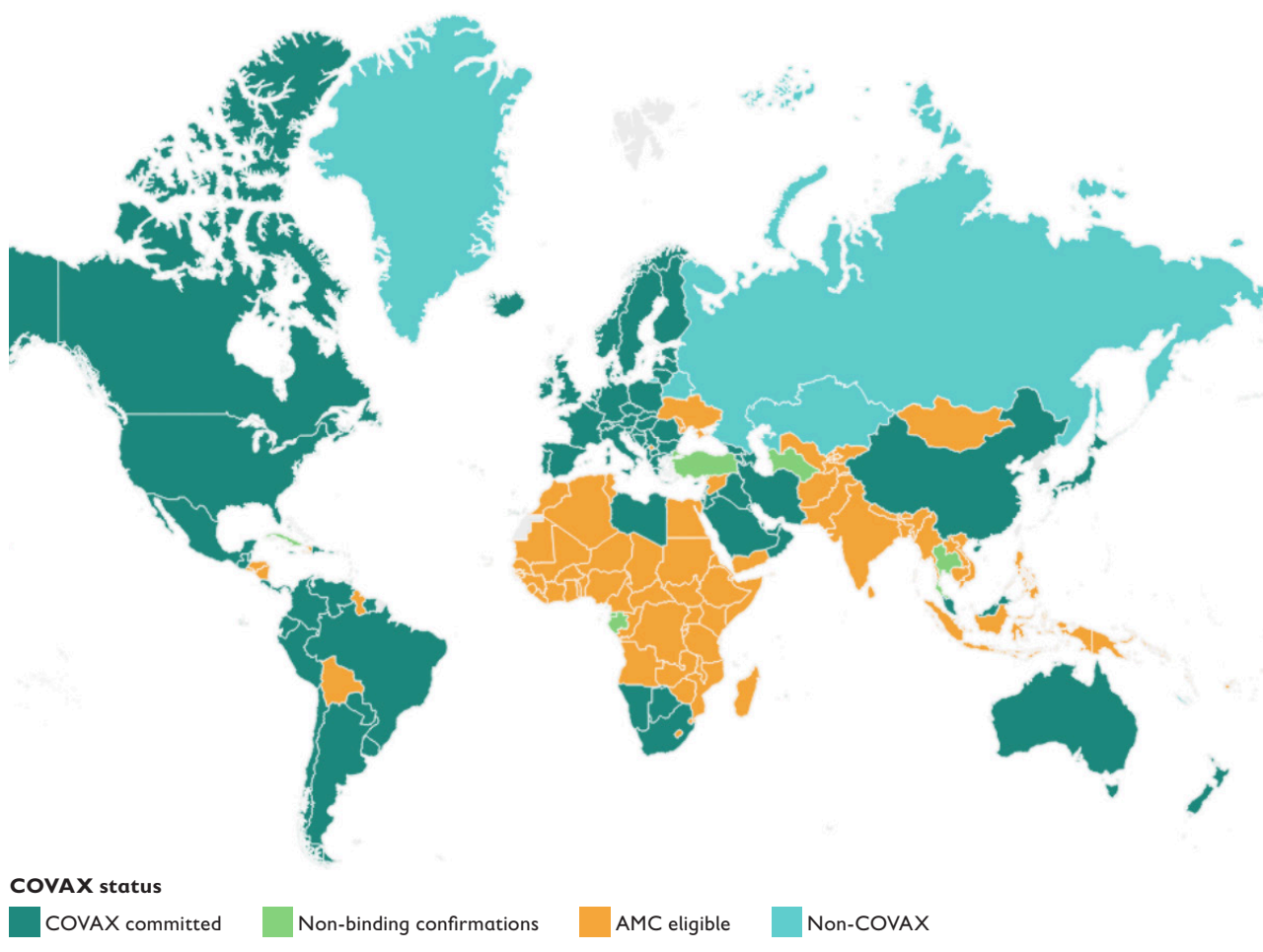
- governments and global stakeholders to guarantee equitable access to COVID-19 vaccines, including through COVAX.
- donors to fully resource global efforts to tackle COVID-19, including ACT-A and COVAX. Donor government pledges must come from different budget lines (eg, domestic health and research budgets) to ensure that official development assistance (ODA) is not over utilised. After all, these initiatives benefit all countries, not just countries eligible for ODA.
- all stakeholders to future-proof strategies developed to improve equitable allocation during the height of the crisis as an integral part of building back better, including developing a more sustainable and equitable approach to resource mobilisation.
- governments not to engage in nationalism that undermines global equitable allocations of COVID-19 vaccines. Countries that have already entered into bilateral agreements with manufacturers should contribute a proportion of these doses to COVAX, following the Principles for sharing COVID-19 vaccine doses with COVAX.²⁶ They should also not impose export controls on commodities for COVID-19.

THE ECONOMIC ARGUMENT FOR A GLOBAL APPROACH

While this virus continues to circulate anywhere in the world, efforts to open up society and economies, resume international travel and restore global trade will be significantly hindered. Without an equitable approach to vaccine rollout, the global economy will continue to take a hit: a recent analysis by the International Chamber of Commerce Research Foundation estimates that vaccine nationalism could cost the global economy \$9.2 trillion a year.²⁷ While the funding gaps for the global response may seem big, especially with many donors facing fiscal challenges due to the pandemic, recent

analysis highlights that global solidarity makes good economic sense. An analysis by RAND shows that even if ensuring vaccine access to the world's poorest countries would cost up to \$25 billion, the USA, UK, EU and other high-income countries could lose a combined \$119 billion a year if low- and middle-income countries are not able to access vaccines. For every \$1 spent on ensuring global equitable access, high-income countries would see a nearly five-fold return.²⁸ Ensuring COVAX is fully financed is not only the right thing to do to ensure all countries can access vaccines to protect the health of their populations, it makes financial sense and will support global economic recovery.

FIGURE 2. COUNTRIES UNITE AND COMMIT TO COVAX



Source: Duke Global Health Innovation Center (2020) Launch and Scale Speedometer, Duke University, retrieved from: <https://launchandscalefaster.org/covid-19>

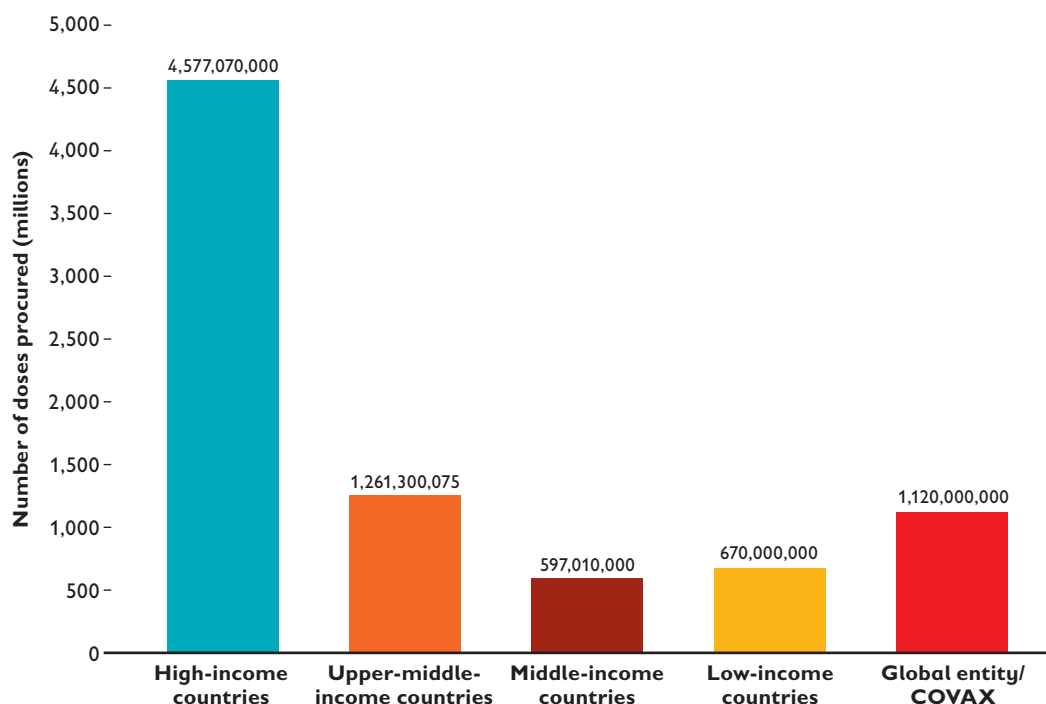
THE THREAT OF VACCINE NATIONALISM TO PUBLIC HEALTH

Due to the high failure rates associated with vaccine R&D,²⁹ some high-income countries have made bilateral deals with a number of vaccine manufacturers to secure a portfolio of vaccines in order to mitigate against the risk of one or more vaccine candidates not being successful. However, we now have several successful candidates proving to be safe and effective. This means that a number of high-income countries that secured pre-purchase agreements are now sitting on enough vaccine doses to vaccinate their whole population several times over.³⁰ To date, this group of high-income countries, representing 16% of the global population, have

secured approximately 4.6 billion doses, which accounts for at least 70% of doses of five leading vaccine candidates available in 2021.³¹ This represents vaccine injustice and is exacerbating global inequity.³²

While national governments have a responsibility to protect their people, COVID-19, like all pandemics, continues to teach us that only by ensuring everyone is safe can we ensure our own safety. As such, our response to this pandemic must be rooted in solidarity and collaboration. Short-sighted vaccine nationalism will only prolong the human and financial cost of COVID-19. From a public health and epidemiological perspective, if the pandemic continues to rage in some parts of the world, new strains and virus mutations will continue to occur.

FIGURE 3. HIGH-INCOME COUNTRIES' VACCINE DEALS: A THREAT TO GLOBAL ACCESS



Source: Duke Global Health Innovation Center (2020) Launch and Scale Speedometer, Duke University, retrieved from: <https://launchandscalefaster.org/covid-19>

This will render unilateral vaccination efforts in a select number of high-income countries futile: an epidemic anywhere will threaten the impact of immunisation everywhere.^{33,34}

COVAX has released a Principles for Dose-Sharing framework³⁵ for countries to direct surplus doses

secured through bilateral pre-purchase agreements to COVAX. This must be done as a matter of urgency so that countries around the world can, in the immediate term at least, vaccinate their health workers and most vulnerable people.

“In an interconnected world, it is high time to recognize a simple truth: solidarity is self-interest. If we fail to grasp that fact, everyone loses. ... Populism and nationalism have failed. Those approaches to contain the virus have often made things manifestly worse.”

António Guterres, UN Secretary-General³⁶

2 Ensure accountability for vaccine access



OUR RECOMMENDATIONS

WE CALL ON:

- donors to incorporate pro-public safeguards on public contributions for vaccine R&D, including to ACT-A, such as conditionalities of full transparency on clinical trial data, cost of R&D and price.
- manufacturers to ensure accessibility and affordability through flexible intellectual property management approaches, such as non-exclusive licences, and technology and know-how transfers to expand the global supplier base.
- governments to ensure they have and use legal instruments to ensure intellectual property does not impede access to vaccines, including not undermining countries' rights to utilise flexibilities highlighted in the Doha Declaration on TRIPS and Public Health.
- governments to enable World Trade Organization members (as well as countries that are not members) to import vaccines under a compulsory licence from another country; this could be critically important during the COVID-19 pandemic, as well as under future health emergencies.
- multilateral mechanisms and partners to meaningfully engage low- and middle-income countries, civil society, and communities in their governance and decision-making structures and to exercise standards of full transparency and stakeholder consensus. We call on the Boards of these multilateral organisations to hold their leadership to account for delivering on this.

EMBEDDING ACCESS IN PUBLIC FUNDING OF RESEARCH AND DEVELOPMENT

Healthcare funding pressures, in addition to access and affordability challenges due to high-cost pharmaceuticals, has brought into question the role of public funding in pharmaceutical R&D.³⁷ This is compounded by our inability to validate the cost of medicines due to a lack of transparency on the cost of bringing a new medicine to market. Furthermore,

a lack of transparency around the final negotiated prices of many pharmaceuticals leaves countries in a disadvantaged position when engaging in price negotiations with industry due to informational asymmetries.³⁸ This issue was hotly debated during the passing of a landmark resolution 'Improving the transparency of markets for medicines, vaccines and other health products'³⁹ at the 2019 World Health Assembly.⁴⁰ Given the challenges in ensuring timely equitable access to COVID-19 vaccines, the pandemic has reopened many of these

debates, with many calling for public contracts with pharmaceutical companies to be made public⁴¹ to allow the assessment of public industry commitments on access and affordability.⁴²

So far, €88.3bn in public sector contributions has gone to vaccine companies for the research and development of COVID-19 vaccines.⁴³ The major donors are the USA (32%), the EU (24%), and Japan and South Korea (a total of 13%).⁴⁴ Public funding into key early R&D efforts⁴⁵ has been instrumental in achieving the current pipeline of COVID-19 vaccine candidates. With such huge sums of public money being committed, public interest conditions for equitable access must be embedded into agreements to ensure resulting vaccines are made available widely and fairly based on needs rather than means.

These conditions can include:

- **Commitments to open licensing** – eg, preventing exclusive licensing or ensuring licensing to a pooling mechanism such as the Medicines Patent Pool or the COVID-19 Technology Access Pool (C-TAP).⁴⁶
- **Commitments on transparency** – eg, uploading clinical trial results onto a WHO primary clinical trial registry or any accessible public domain; ensuring full transparency on prices and R&D costs (eg, through WHO's Global Observatory on Health R&D); sharing patent information through the Medicine Patent Pool's patents and licences database,⁴⁷ MedsPaL or the Pat-INFORMED database.⁴⁸
- **'Step-in rights'** – for donor governments to issue non-exclusive licenses⁴⁹ if a licensing partner fails to comply with the requirements of providing the health technology at an affordable and fair price or due to supply constraints.

“The large public funding going into health innovation means governments should govern the process to ensure prices are fair, patents are not abused, medicine supply is safeguarded...”

Mariana Mazzucato, Professor of Economics at UCL,
Director of the Institute for Innovation and Public Purpose⁵⁰

3 Expand vaccine supply



OUR RECOMMENDATIONS

TO UNLEASH VACCINE SUPPLY, WE CALL ON:

- donors (both governments and philanthropists) to prioritise investment in manufacturing capacity and strengthening sustainable and quality-assured supply chains globally, especially in low- and middle-income countries, working with local stakeholders.
- donors and the pharmaceutical industry to collaborate with vaccine manufacturers in low- and middle-income countries through open licensing to unleash supply and help the world prepare for the next global health challenge.

TO ADDRESS INTELLECTUAL PROPERTY BARRIERS, WE CALL ON:

- governments to support C-TAP, including ensuring their domestic manufacturers do the same, to share COVID-19 health-technology-related knowledge, intellectual property and data, which are critical to expanding supply and driving equitable access.
- multilateral organisations, like WHO and Gavi, the Vaccine Alliance, to push for action on issues around patents, know-how and technology transfer, including the use of C-TAP.
- the pharmaceutical and medical devices industry to:
 - engage in open innovation to expedite the research and development of COVID-19 vaccines, including sharing platform technologies, compound libraries and intellectual property rights with third party researchers and ensuring full transparency around clinical trials data, cost of R&D and prices.
 - operationalise access principles of product development partnerships, such as the Coalition for Epidemic Preparedness Innovations (CEPI) and the Biomedical Advanced Research and Development Authority (BARDA); register products in low- and middle-income countries; use non-exclusive voluntary licences; and apply differential pricing that captures ability to pay of different countries.
 - use flexible intellectual property management, including intellectual property waivers, non-exclusive licensing, technology and know-how transfers with manufacturers in low- and middle-income countries, and supporting mechanisms like C-TAP.

Only through population coverage with safe and effective vaccines can we end the global pandemic. This means vaccinating enough people globally to achieve herd immunity. Even though this threshold is not yet known for COVID-19, considering the world's 7.8 billion people⁵¹ are affected by the disease and its wider impacts, the scale of the challenge becomes immediately clear.⁵² No one company will have the manufacturing capacity to produce or supply the volumes of doses needed to meet global demand.

If we assume a two-dose vaccine schedule, it is estimated that approximately 15.6 billion doses of vaccines will be required by the 194 WHO member states for a universal COVID-19 vaccination programme. If only targeted occupational or high-risk groups were prioritised for vaccination, then 10.3 billion doses would be needed.⁵³

Furthermore, the production of COVID-19 vaccines must not disrupt the production of other life-saving vaccines. Therefore, producing COVID-19 vaccines at the necessary volumes and speed requires unleashing manufacturing capacity at a scale not before imagined – let alone operationalised.

UNLEASHING GLOBAL SUPPLY

Vaccine supply constraints in the short term remain the Achilles heel in our global efforts to end the pandemic. The traditional pharmaceutical business model is based on granting intellectual property rights to innovators, thereby allowing investments to be recouped during a period of exclusive selling rights or monopolies. Given the pressing need, a business-as-usual approach to intellectual property only limits global manufacturing and supply capacities. To overcome this and help expand supply of COVID-19 vaccines – expanding the pie instead of having countries fighting over a limited supply of vaccines in the short term – the COVID-19 Technology Access Pool (C-TAP)⁵⁴ was launched in May 2020 as a pooled mechanism for innovators to openly share intellectual property and other forms of knowledge, clinical data and know-how relevant to the development and manufacture of diagnostics, devices, therapeutics and vaccines for COVID-19.

This will allow other prequalified manufacturers to manufacture COVID-19 commodities, thereby expanding supply and facilitating timely, equitable and affordable access for all.

Flexible approaches to the intellectual-property-based model are also being proposed. For example, the governments of India and South Africa submitted a proposal for a temporary waiver of certain Trade-Related Aspects of Intellectual Property Rights (TRIPS) obligations to facilitate an appropriate response to COVID-19. This would be a time-bound proposal related to the acute phase of the pandemic, recognising that these are exceptional times that warrant exceptional solutions. It is not uncommon for the pharmaceutical industry to adopt flexible intellectual property approaches to different markets and therapeutic areas, including intellectual property waivers and voluntary licensing. Numerous companies choose to waive or not enforce patents in certain low- and middle-income countries. The Access to Medicine Index⁵⁵ includes this in its assessment of companies and many companies make these commitments public on their websites. For example, Moderna made a public commitment to not enforce patents on its mRNA-based vaccine during the pandemic⁵⁶ and expressed a willingness to license out the intellectual property for the post-pandemic period, which will enable other manufacturers to produce the vaccine.

SUPPORTING VACCINE MANUFACTURING CAPACITY IN LOW- AND MIDDLE-INCOME COUNTRIES

The vaccine market is dominated by a handful of companies, the majority of which are large research-based pharmaceutical companies in high-income countries. Unleashing supply will be achieved by facilitating smaller vaccine manufacturers in low- and middle-income countries to engage in R&D into COVID-19 vaccines. This is critical for improved and safe supply and affordability, and will leave a legacy of health security preparedness.

FIGURE 4: THE DEVELOPING COUNTRIES VACCINE MANUFACTURERS NETWORK



Source: Developing Countries Vaccine Manufacturers Network. 2020. (webpage). <https://www.dcvmn.org/-About->

The Developing Countries Vaccine Manufacturers Network⁵⁷ is an alliance of 41 vaccine manufacturers in 14 countries and territories across Latin America, Africa, the Middle East and Asia, working to ensure high-quality vaccines are available and affordable to all. 37 out of the 41 alliance members collectively supply around 3.5 billion vaccine doses annually for other diseases. 13 members already supply WHO-prequalified vaccines around the world and 19 developing-country vaccine manufacturers are engaged in R&D into 22 COVID-19 vaccine candidates.⁵⁸

Engaging vaccine manufacturers in low- and middle-income countries through providing financial and technical expertise as well as capacity building will help resolve COVID-19 vaccine supply bottlenecks⁵⁹ and help strengthen global vaccine supply chains in the long term. Investments and partnerships fostered during this pandemic can lead to a transformative change in our global emergency preparedness as well as ending vaccine preventable diseases.

“C-TAP is a sister initiative of the ACT Accelerator and offers concrete actions to achieve the objective of the ACT Accelerator, which is equitable access ... WHO recognizes the important role that patents play in fuelling innovation. But this is a time when people must take priority. Tools to prevent, detect and treat COVID-19 are global public goods that must be accessible by all people”

Dr Tedros Adhanom Ghebreyesus, WHO Director-General⁶⁰

4 Achieve equitable national vaccine roll-outs



OUR RECOMMENDATIONS

WE CALL ON GOVERNMENTS TO:

- adequately prepare for the introduction of a COVID-19 vaccine. Governments must ensure multi-stakeholder representation, including civil society, in their national vaccine task force and in all decision-making.
- follow the WHO SAGE Roadmap guidance as they make decisions on vaccine prioritisation within their country, including prioritising frontline health workers and high-risk populations.
- include all population groups in their country in their national COVID-19 vaccination and allocation plans, including refugees, internally displaced people, migrants, asylum-seekers, stateless people, and other marginalised, vulnerable and neglected communities and groups, regardless of legal status or documentation.
- strengthen national and regional regulatory systems, and ensure they have the required indemnification legislation in place, which is critical to achieving timely access to high-quality vaccines. High-income-country drug regulatory authorities should support authorities in low- and middle-income countries as cross-country collaboration will be important to strengthen regional and global regulatory networks and systems.
- ensure that routine services are not interrupted by the introduction of the COVID-19 vaccine and that COVID-19 vaccine investment supports long-term sustainability and reach of other routine immunisations and health services.

PREPARING FOR NATIONAL VACCINE ROLL-OUT

Technical partners, such as WHO, UNICEF, Gavi and the COVAX Country Readiness and Delivery workstream and subgroups, are working with countries to prepare for COVID-19 vaccine introduction,⁶¹ including adaptable guidance, tools, training and advocacy materials. These include guidance on developing a national deployment and

vaccination plan (NDVP) for COVID-19 vaccines⁶² and the COVID-19 Vaccine Introduction Readiness Assessment Tool,⁶³ which provides a roadmap for countries to plan for COVID-19 vaccine introduction in addition to a structured framework to self-monitor readiness progress against key milestones. Countries are encouraged to establish a national task force and coordinating committee (eg, coordination/advisory groups), with multi-sectoral representation, including civil society.

Countries will need to invest in reaching communities through two-way communication to create demand and promote uptake of COVID-19 vaccines, to continue to promote COVID-19 prevention behaviours and to maintain demand for routine immunisation. Civil society and communities play a critical role in supporting vaccine roll-out and community uptake and acceptance; they must therefore be included as an essential stakeholder in vaccine decision-making, planning and roll-out.

Ensuring a successful roll-out of a COVID-19 vaccine within a country will require a coherent whole-of-government approach. Countries must also ensure they have the systems in place⁶⁴ to ensure they can receive their allocation of vaccine through the COVAX Facility. This includes:

- a) having financing in place to either procure (self-financing payers) or fulfil cost-sharing obligations of the COVAX AMC⁶⁵ – ensuring this is not diverted from budgets for other essential health services, including routine immunisation
- b) regulatory systems and frameworks for swift COVID-19 vaccines approvals in country⁶⁶
- c) appropriate liability and indemnification⁶⁷ systems in place.⁶⁸

EQUITABLE ALLOCATION OF VACCINES

To ensure equity and fair distribution of vaccines within each country, national governments must follow the WHO SAGE Roadmap guidance as they make decisions on vaccine prioritisation within their country and develop national plans.⁶⁹ In settings with community transmission, this prioritises:

- First stage (up to 10% of population): frontline health workers and older people
- Second stage (11–20% of population): other vulnerable and high-risk groups.

It is important that essential workers who are not formally employed and/or salaried by government ministries, including community-based teachers, community health workers, community care personnel and other people engaged in social and protective service provision, are also considered.

National governments are responsible for ensuring that all population groups in their country are

included in their national COVID-19 vaccination and allocation plans, including refugees, internally displaced people, migrants, asylum-seekers, stateless people, and other marginalised, vulnerable and neglected communities and groups, regardless of legal status or documentation. National governments must also address barriers that these population groups may face in safely accessing vaccinations, including addressing demand issues. This is in line with humanitarian principles and international human rights law, under which host countries are responsible for providing healthcare to people who live within their borders, including migrants, refugees and asylum-seekers, whether documented or not. Civil society organisations should play a critical advocacy and accountability role with national governments and decision-makers to ensure adherence to WHO SAGE guidance and to ensure vaccines are prioritised where needed most.

STRENGTHENING ROUTINE IMMUNISATION

Even as countries prepare for the roll out of COVID-19 vaccines, children need to continue to receive life-saving immunisation. Routine services must not be interrupted by the introduction of the COVID-19 vaccine and any investment for the roll out should support long-term sustainability and reach of other routine immunisations and health services. Naturally, the activities carried out to prepare, implement and monitor the introduction of COVID-19 vaccination should leverage and strengthen existing immunisation systems through integration into and support for a country's national primary healthcare. This includes establishing operational working groups and processes; strengthening human resource capacity and training for new vaccine introduction; ensuring traceability systems and efficiency of supply chains; enhancing integrated disease surveillance and surveillance of adverse events following immunisation; and key advocacy and communications activities to promote demand for vaccination and to improve health literacy around COVID-19. This will ultimately lead to increased demand and acceptability of general essential primary healthcare services.⁷⁰

Conclusion: A chance to get it right

The global community has the chance to adopt a lesson-learning approach from previous pandemics and to ensure solidarity and equity are at the heart of our COVID-19 response. ACT-A and COVAX provide practical solutions for countries to put sentiments of solidarity into actions. The spread of COVID-19 has highlighted how interconnected we all are. The virus has shown no regard for borders, race, wealth or status, with this pandemic having caused loss of life, livelihoods, and freedoms – and changed how we, as 7.8 billion people globally, live our lives. COVID-19 has disproportionately affected the most marginalised groups globally. And in

threatening every aspect of children's lives, it has resulted in the violation of their rights to survive, thrive, learn and be protected.

Yet, the emergence of safe and effective COVID-19 vaccines offers hope. However, only through ensuring fair global and equitable access to these vaccines can we end this pandemic. This is a moral, public health and economic imperative. We must realise that our own protection is rooted in the protection of others and that we can only ensure our own safety by ensuring the safety of everyone.

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