

# COVID-19 VACCINE ACCESS

Achieving equitable access to  
quality COVID-19 vaccines, using  
digital, AI, and GIS tools



January 2022

## Workshop organisers

This workshop was organised by the Global Health Strategy Group for Digital Health and AI for Health, an initiative of the University of Oxford, and by the Supply & Market Dynamics and Medicine Quality Working Group of the COVID-19 Clinical Research Coalition in partnership with:



## Executive Summary

This report synthesises the thoughts that emerged from a workshop hosted by the Global Health Strategy Group for Digital Health and AI for health, an initiative of the University of Oxford. It captures the challenges affecting the supply, distribution, and access to authentic COVID-19 vaccines for people in low- and middle-income countries, with a special focus on Africa. Moreover, it provides real-life case studies of organisations and initiatives that exemplify how digital, Artificial Intelligence (AI), and Geographic Information Systems (GIS) technologies can be implemented to strengthen vaccine access, traceability, and product safety.

COVID-19 has shaped the world in unprecedented ways. Hallmarks of “ordinary” life like commerce, employment, education, and travel have been disrupted for over two years now. As the world begins to re-open, vaccines for COVID-19, which were developed with unparalleled speed and global cooperation, remain our best chance of returning to pre-pandemic life. Yet, access to these vaccines remains a preeminent challenge for the majority of the world’s population. Vaccine nationalism has led to significant immunisation disparities between high-income countries and low- and middle-income countries. By early September 2021, for example, only 2% of the population of people in low-income countries had received one vaccine dose compared with 65% of people in high-income countries.<sup>1</sup> Countries like the US, UK, and Canada have secured enough vaccines to cover multiples of their populations<sup>2</sup> and have moved on to giving boosters while billions of other people barely have access to these life-saving vaccines.

Such disparities have accelerated the emergence and proliferation of both substandard and falsified (SF) and diverted COVID-19 vaccines. Constrained supply of vaccines, poor traceability of medical products, weak infrastructure, and inadequate tracking across borders have all worsened the situation. As of July 2021, for example, approximately 150 unique reports of SF vaccines had been published in the lay literature, highlighting the breath and complexity of the challenge.<sup>3</sup>

<sup>1</sup> Duke Global Health Institute. 2020. *Will Low-Income Countries Be Left Behind When COVID-19 Vaccines Arrive?*. Available at: <https://globalhealth.duke.edu/news/will-low-income-countries-be-left-behind-when-covid-19-vaccines-arrive>

<sup>2</sup> Rouw, A., Kates, J., Wexler, A. and Michaud, J., 2021. Tracking Global COVID-19 Vaccine Equity: An Update. Available at: <https://www.kff.org/coronavirus-COVID-19/issue-brief/tracking-global-COVID-19-vaccine-equity-an-update/>

<sup>3</sup> Medicine Quality Research Group, University of Oxford. Medical Product Quality Report – COVID-19 Issues. Issue 12, June & July 2021. Available at: <https://www.iddo.org/document/medical-product-quality-report-covid-19-issues-issue-12-october-2021-data-june-july-main>

# The Abuja Principles

The Abuja Principles were developed from the insights that emerged during the Vaccine Access Workshop, to guide the deployment of digital, Artificial Intelligence (AI), and Geographic Information Systems (GIS) technologies to ensure access to quality COVID-19 vaccines for all people, in all places, at all times. They are intended to be guidelines that support those developing these technologies and those who implement such technologies within various public health capacities.

Below, we present ten principles that developers, implementers of these technologies, and policy makers should adhere to:

## Approach vaccine access and quality challenges from the bottom-up, not just top-down

A major shortcoming of the global response to the COVID-19 pandemic has been the failure to prepare, provide, and coordinate adequate resources at the country-level, often because of too much reliance on top-down thinking. Investments in community-level health-surveillance capacity strengthening will be key to tackling this and future pandemics. Top-down models and agreements to shape responses must be grounded firmly in local communities and value their engagement, risk ownership, and anxieties.

## Apply a holistic, systemic, non-siloed approach to the development and implementation of digital/AI/GIS technologies

It is not enough to develop technologies that address one aspect of a problem. All stakeholders need to work together to develop the necessary supporting infrastructure for the optimal deployment of new technologies. Without traceability solutions, reference labs, screening tools, and other such supporting infrastructure and tools, risks of substandard and falsified COVID-19 vaccines and medical products will remain, if not proliferate.

## Develop tools that are infrastructure-agnostic and cater to diverse local contexts

Digital and AI technology should be designed to fit the context for which they are to be used, informed by local data and tailored to the available resources in-country, bearing in mind that infrastructure and data accessibility can vary starkly at the subnational level, even within the same neighbourhood, city, district or province. From the start, tools must be designed to work across all possible infrastructures.

## Pursue joined-up responses across public and private sectors and civil society, including establishing new Public-Private Partnerships

Fragmentation of sectors continues to be a major challenge of global vaccine access especially in Africa. Partnerships, such as that between NAFDAC, GS1, mPedigree and others, have been critical to the success of vaccine access so far. Stronger intersectoral, public-private partnerships should be encouraged, as these have the potential to expand vaccine access, encourage further research, and harmonise regulation of activities to avoid duplication of efforts. Through collaboration, the functions of different digital tools can be integrated into single multi-functional tools.

## Pursue data-driven scalable solutions based on human-centred design principles

As technologies are rolled out to improve vaccine access, successful scaling up and sustainability hinge on human-centred design, on digital innovations tailored to users and their needs. Pilot studies can assess the viability of new technologies especially in resource limited settings, and data from these pilots should inform the path to scale-up. Where pilots are successful, stakeholders (donors, implementers, and regulators) should align themselves to accelerate the scale-up of these solutions.

## Build technologies that factor in and address in-country immunisation dynamics

Many of the tools in development currently focus on the supply-side reaching from the manufacturer to the national cold store. However, there is a need for technologies that help optimise on the supply side and uptake of vaccines within countries so as to minimise vaccine wastage at the last mile. Such technologies should focus on important considerations such as digitising microplans and predicting vaccine absorption.

## Shore up in-country standardisation and regulation measures and set the goal of data interoperability

Global guiding minimum standards for digital tools and products are needed, and countries should be encouraged to adopt these minimum standards so that data can be exchanged across systems (interoperability). Harmonisation of data standards and regulation will not only foster greater efficiency, but add accountability, transparency, and traceability — all essential for delivering safe and trusted vaccines and medical products.

## Share data and develop trusted knowledge repositories

International and national-level data management and data-sharing systems need to be strengthened, or set up where they currently do not exist, to unclog bottlenecks and guard against risks. The adoption of GS1 standards and traceability technologies can create process efficiencies that ensure product quality and patient safety. The development and adoption of innovative means of sharing information from trusted sources with lay audiences can help fight vaccine hesitancy and provide countermeasures to protect against misinformation. In a digital world, removing as many barriers as possible to accessing data/knowledge is a linchpin strategy that all developers and policy makers should adopt to maximise public health.

## Strengthen the overall ecosystem across manufacturers, private digital/AI/GIS innovators, regulators, and health-service providers

More critical thought needs to be given to building an ecosystem of support for all digital health solutions across all stakeholders, including technology partners, implementing agencies, NGOs, civil society, country partners, and donors. No one group — especially donor groups — should have a monopoly on decision-making. Incentives and the right remuneration structures need to be devised to encourage and reward enterprising solutions in Global Health, especially those emanating from the global south, and financing should be put in place to support the roll-out of digital solutions. No one stakeholder can achieve this, it requires the entire stakeholder ecosystem.

## Invest in digital and AI skills development and education at all levels

While macro-indicators highlight the momentum with which Africa is pivoting towards digital tools, there are still many challenges which impede this transition. One of the biggest is that many African countries lack sufficient human capital to drive the digital agenda. If the poorest members of society are to truly benefit from hands-on access to digital and AI tools and be the drivers of the take-up and use of such tools for the equitable delivery of health interventions such as quality COVID-19 vaccines, they will need the skills to do so. Part of the supportive ecosystem includes investment in education and training and skills capacity strengthening, reaching right back into schools, with greatly improved foundational literacy and numeracy,<sup>4</sup> and forward into universities and technical colleges so that there is a continuous supply of people well-equipped in the skills necessary to develop and deploy such tools. Africa, in particular, has a very young and entrepreneurial population, presenting it and the world with a huge potential opportunity in the innovation and scale-up of digital and AI tools — as many of the case studies in the workshop illustrated — and in leadership in their deployment to tackle global health challenges such as COVID-19. All that is needed is investment.

<sup>4</sup> Beeharry, G., 2021. The pathway to progress on SDG 4 requires the global education architecture to focus on foundational learning and to hold ourselves accountable for achieving it. *International Journal of Educational Development*, 82, p.102375. Available at: <https://www.sciencedirect.com/science/article/pii/S0738059321000286>

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## Acronyms

ACDC	Africa Centres for Disease Control and Prevention
AI	Artificial Intelligence
AMA	African Medicines Agency
APOC	African Programme for Onchocerciasis Control
CDC	Centres for Disease Control and Prevention
CDD	Community Directed Distributors
CEPI	Coalition for Epidemic Preparedness Innovations
COVAX	COVID-19 Vaccines Global Access
COVID-19	Coronavirus disease 2019
DHIS2	District Health Information Software 2
DPT	Diphtheria, Pertussis and Tetanus
FCT	Federal Capital Territory
GS1	Global Systems 1
GIS	Geographic Information System
IDDO	Infectious Disease Data Observatory
LGA	Local Government Area
LMIC	Low- and Middle-Income Countries
MAS	Mobile Authentication Service
ML	Machine Learning
MORU	Mahidol Oxford Research Unit
MOU	Memorandum of Understanding
MQM	Medicine Quality Monitor
NAFDAC	Nigeria Agency for Food and Drug Administration and Control
NAPAMS	National Automated Product Administration and Monitoring System
PIDCARMS	Ports Inspection Data Capture and Risk Management System
PV	Pharmacovigilance
SF	Substandard and Falsified
SMS	Short Messaging Service
UNICEF	United Nations Children's Emergency Fund
USSD	Unstructured Supplementary Service Data
WHO	World Health Organisation

## Background and Purpose

The Supply and Market Dynamics and Medicine Quality Working Group, part of the COVID-19 Clinical Research Coalition, focuses on a range of issues, including: substandard and falsified (SF) COVID-19 products of all kinds; the production and distribution capacity for medicines and vaccines to ensure adequate supply of effective interventions; the conduct of market dynamics analyses and evaluations of interventions to scale up production; the monitoring and analysis of medicine quality reports during the COVID-19 pandemic response, and dissemination of SF alerts. As part of its activities, the Working Group tabulated a list of measures needed to achieve equitable access to vaccines and to tackle SF vaccines, and concluded that putting those measures in place was taking far too long. Noting that global efforts have concatenated the timelines of vaccine development from years to less than a year, the Working Group wanted to know how to concatenate timelines, from 10 years to 1 year, of this other package of measures also needed for successful delivery of COVID-19 vaccines. From this came the notion of convening this workshop. It then became possible to incorporate the lessons from Nigeria and other early movers. Following the formation of the Global Health Strategy Group for Digital Health and AI for health, there was an opportunity to also focus the expertise of many other global partners on this priority challenge.

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### Purpose to workshop

COVID-19 vaccines, combined with other public health interventions, are vital to ending the pandemic. Their storage and distribution are a major logistical challenge. Additional, but so far neglected, issues are substandard and falsified (SF) and diverted COVID-19 vaccines, fuelled especially when access to vaccines is heavily constrained. The problem stems first and foremost from poor traceability, which is exacerbated by weak infrastructure and inadequate tracking across borders. To complicate future challenges, there will be markets in richer parts of the world for booster COVID-19 vaccines and vaccines reconfigured for new variants absorbing available supply, the proliferation of different types of vaccines and of 'new' and 'superseded' generations of vaccines, spare-doses redistribution/reallocation, and many competing products.

When vulnerable communities think that they are protected when they are not, this risks impairing the effectiveness of vaccination programs. Falsified, degraded, and diverted vaccines risk speeding the emergence and spread of viral variants, undermining vaccines, and prolonging the pandemic. Efforts to set up new vaccine manufacturing facilities in low-resource settings are undermined if vaccine supply chains and vaccine reputation cannot be protected.

Digital, Artificial Intelligence (AI), Geographic Information Systems (GIS) and similar tools are important parts of a package of joined-up interventions for tracking COVID-19 vaccines and securing quality all along the supply chain, and for more quickly identifying and managing the risks of SF and diverted COVID-19 vaccines. Success depends on creating a supportive ecosystem of interested parties with shared goals, aligning manufacturers, private digital/AI/GIS innovators, regulators, and health-service providers, and efficiently deploying already available technology that is adapted for the needs of users and workable in even the toughest of low-resource settings. If the world is to finally exit from the pandemic, like the successful development of the vaccines themselves, we need a sense of urgency and the same can-do attitude and resources to concatenate the timeline for putting together a joined-up set of inventions for delivery of COVID-19 vaccines to all populations that need them, from ten years to less than a year.

The workshop was organised with five specific objectives in mind, namely to:

- Share best practices on improving traceability of COVID-19 vaccines all along the supply chain so as to more quickly identify substandard and falsified (SF) and diverted COVID-19 vaccines and to better manage 'new' and 'superseded' generations of vaccines and spare-doses redistribution;
- Align manufacturers, private digital/AI/GIS innovators, regulators, and health-service providers around common goals to improve COVID-19 vaccine access;
- Discuss strategies to efficiently deploy available technology by adapting it to the needs of users in the toughest of low-resource settings;
- Identify measures to prevent falsified, degraded and diverted vaccines from speeding the emergence and spread of viral variants;
- Formulate the 'Abuja Principles' for deploying digital/AI/GIS tools to ensure access to quality COVID-19 vaccines for all, in all places, at all times.

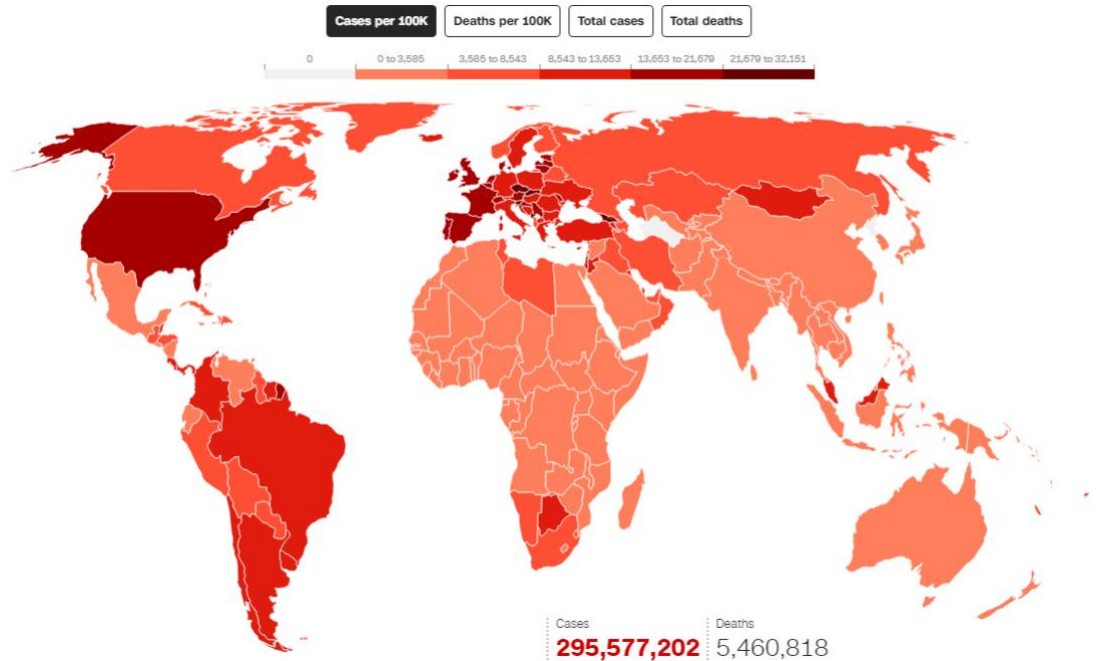


## Section 1: Challenges and Context



## 1.1 The Scale of the Challenge

Even though more than 8.7 billion COVID-19 vaccine doses having been administered worldwide by the end of 2021,<sup>5</sup> billions of people around the world are going without. Time is not on our side. We are not responding efficiently or equitably. By the early January 2022, there had already been about 295 million reported cases and approximately 5.4 million reported deaths from COVID-19 globally (see Figure 1),<sup>6</sup> with some estimates suggesting that, based on excess-deaths, the true death toll could be closer to 16.3 million (95% confidence interval from 10 and 19 million).<sup>7</sup> Without equitable access to vaccines, the number of those dying will likely go up multiple more fold. Many millions of lives depend on us improving our performance quickly.



**Figure 1. Cumulative confirmed COVID-19 cases per hundred thousand, as of 5 January 2022<sup>8</sup>**

New variants are proving much more transmissible than the initial strain of the virus. The average number of people a single infected individual can infect in a population that has not previously encountered the virus, the  $R_0$  number, varies across different SARS-CoV-2 strains, and has risen significantly since the virus emerged. Estimates for the delta variant show that it has a  $R_0$  number closer to 5 suggesting that it is twice as transmissible as the original strain of the virus (see Figure 2).<sup>9</sup> In December 2021 a report from the Imperial College London COVID-19 response team estimated that the risk of reinfection with the Omicron variant was 5.4 times greater than that of the Delta variant, which suggested already low remaining levels of immunity from prior infection.<sup>10</sup>

<sup>5</sup> World Health Organisation. 2021. *WHO Coronavirus (COVID-19) Dashboard*. [online] Available at: <https://covid19.who.int/> Figures as of 29 December 2021.

<sup>6</sup> Map extracted from CNN. 2021. *Tracking Covid-19's global spread*. Available at: <https://edition.cnn.com/interactive/2020/health/coronavirus-maps-and-cases/>. Original source is Dong E, Du H, Gardner L. An interactive web-based dashboard to track COVID-19 in real time. *Lancet Infect Dis*; published online Feb 19. [https://doi.org/10.1016/S1473-3099\(20\)30120-1](https://doi.org/10.1016/S1473-3099(20)30120-1).

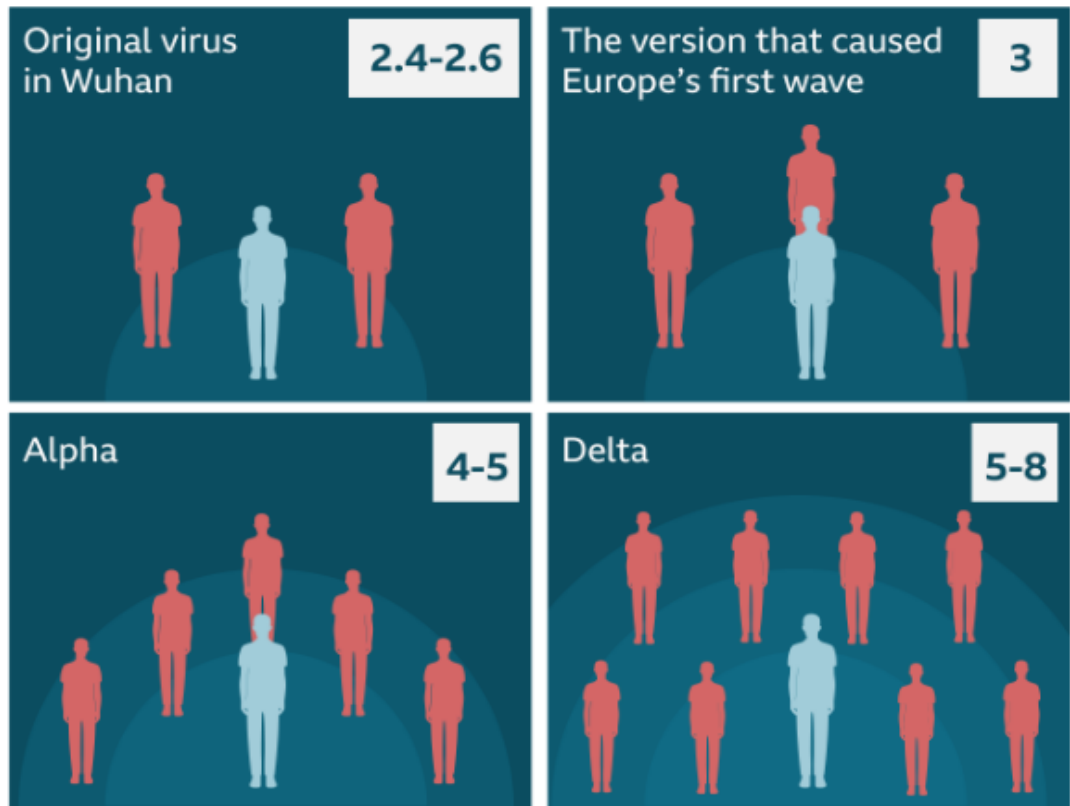
<sup>7</sup> The Economist. 2021. *The pandemic's true death toll*. Available at: <https://www.economist.com/graphic-detail/coronavirus-excess-deaths-estimates>

<sup>8</sup> Map extracted from CNN. 2021. *Tracking Covid-19's global spread*. Available at: <https://edition.cnn.com/interactive/2020/health/coronavirus-maps-and-cases/>. Original source is Dong E, Du H, Gardner L. An interactive web-based dashboard to track COVID-19 in real time. *Lancet Infect Dis*; published online Feb 19. Available at: [https://doi.org/10.1016/S1473-3099\(20\)30120-1](https://doi.org/10.1016/S1473-3099(20)30120-1).

<sup>9</sup> Liu, Y. and Rocklöv, J., 2021. The reproductive number of the Delta variant of SARS-CoV-2 is far higher compared to the ancestral SARS-CoV-2 virus. *Journal of travel medicine*. Available at: <https://academic.oup.com/jtm/article/28/7/taab124/6346388>

<sup>10</sup> Ferguson, N., Ghani, A., Cori, A., Hogan, A. and Hinsley, W., Report 49: Growth, population distribution and immune escape of Omicron in England. *Imperial College London (2021-12-20)*. Available at: <https://www.imperial.ac.uk/mrc-global-infectious-disease-analysis/covid-19/report-49-Omicron/>.

## The more contagious, the higher the R0 number



**Figure 2. How the R0 numbers of COVID-19 variants compare<sup>11</sup>**

One way of reducing the rate of transmission is through vaccination.<sup>12</sup> Estimates show that to combat the Delta variant, an immunisation rate of 80-90 percent is needed, either through natural infection or vaccination, whereas the threshold for the original COVID-19 variant lay at around 67 percent.<sup>13</sup> Distributing COVID-19 vaccines fast and equally is more important than ever, and it is imperative the international community cooperates.

## 1.2 Substandard and Falsified Vaccines

Just as it is important to accelerate the equal distribution of vaccines so too is it vital to stop the spread of substandard and falsified (SF) vaccines.

As the global need for vaccines has increased drastically, a situation of excess demand has led to a market for SF vaccines. This presents a series of threats to global health. First, through failing to stimulate immunity in recipients, SF vaccines jeopardise the safety of entire communities. We have seen this before. In 1995, for example, 2,500 to 3,000 preventable deaths occurred after 60,000 Nigerians were injected with water disguised as a meningitis vaccine.<sup>14</sup>

Second, SF vaccines cause indirect harm by eroding public trust in vaccination programmes. Public trust in China in the vaccination programme plummeted in 2018 after several prominent vaccine manufacturers were involved in SF vaccine-related scandals. More than 200,000 children were vaccinated with substandard diphtheria, pertussis, and tetanus (DPT) vaccines produced by Changsheng Biotechnology. Similarly, 400,520 substandard DPT vaccines produced by the Wuhan Institute of

<sup>11</sup> BBC, 2021. *Covid: Is there a limit to how much worse variants can get?*. Available at: <https://www.bbc.co.uk/news/health-57431420>

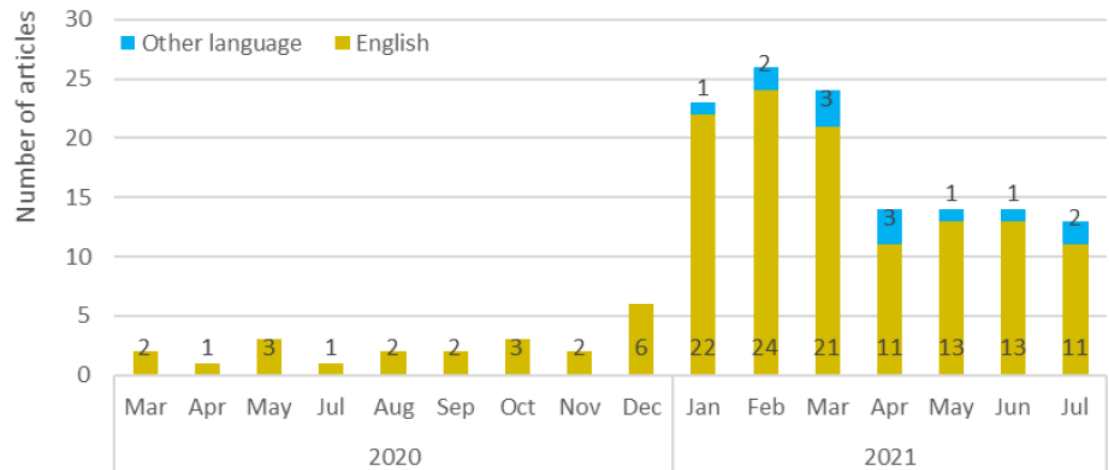
<sup>12</sup> Eyre, D.W., Taylor, D., Purver, M., Chapman, D., Fowler, T., Pouwels, K., Walker, A.S. and Peto, T.E., 2021. The impact of SARS-CoV-2 vaccination on Alpha and Delta variant transmission. *medRxiv*. Available at: <https://www.medrxiv.org/content/10.1101/2021.09.28.21264260v1>

<sup>13</sup> MISHRA, S., 2021. *Why is Delta more infectious and deadly? New research holds answers.*. National Geographic. Available at: <https://www.nationalgeographic.com/science/article/why-is-delta-more-infectious-and-deadly-new-research-holds-answers>

<sup>14</sup> Borse, N.N., Cha, J., Chase, C.G., Gaur, R., Koduri, C.K., Kokai-Kun, J.F., Kwan, D.C., Lee, R., Moore, J.C., Raghavendran, V. and Takara, L.S., 2021. Responding to the surge of substandard and falsified health products triggered by the Covid-19 pandemic. Available at: <https://www.usp.org/sites/default/files/usp/document/our-impact/covid-19/surge-of-substandard-and-falsified-health-products.pdf>

Biological Products were sold in Hebei and Chongqing, China.<sup>15</sup> SF vaccines impact vaccine hesitancy very negatively, at a time when such hesitancy has the potential to kill in large numbers.

SF vaccines are a global problem. In early 2021, the German news broadcaster Deutsche Welle warned that SF versions of COVID-19 vaccines were assumed to be on the European market.<sup>16</sup> As of 30 September 2021, the Food and Drug Administration in the United States had issued a total of 198 warning letters concerning fraudulent COVID-19 products.<sup>17</sup> Moreover, by July 2021, the Infectious Disease Data Observatory, based at the Centre for Tropical Medicine and Global Health at the University of Oxford, had identified more than 150 unique reports of SF vaccines in the lay literature across 41 countries (see Figure 3).<sup>18</sup>



**Figure 3. Articles on quality issues with COVID-19 vaccines by language of the article**

### 1.3 Vaccine Inequity

There is a vast disparity between high-income and low- and middle-income countries with respect to vaccine access and immunisation rates.<sup>19</sup> Whereas the first high-income countries were purchasing vaccines in May 2020 and had secured enough doses for well over 100% of their population by November 2020, the African continent, for example, had barely secured enough doses by September 2021 to cover 25% of its population.

Even though global stakeholders have recognised the need for equitable access, vaccine nationalism has thwarted efforts to promote equity. International initiatives such as the COVID-19 Vaccines Global Access (COVAX) Facility have been debilitated and the people most in need of vaccines cannot in fact access them in a timely manner.

Unsurprisingly and as a consequence of inequitable vaccine access, the number of doses administered across countries is widely skewed, with high-income countries vaccinating more of their populations compared to low-income countries. Based on data compiled by the Our World in Data group based at the Oxford Martin School, most high-income countries who purchased their own vaccines have achieved coverages of greater than 70% of their populations for the first dose, whereas many African countries are yet to reach the 20% mark that COVAX had promised to cover (see Figure 4). Indeed, a WHO report showed that as of 1 October 2021 only 15 African countries had managed to fully vaccinate 10% or more of their populations.<sup>20</sup>

<sup>15</sup> The Lancet. Vaccine scandal and confidence crisis in China. Lancet (London, England). Available at: [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(18\)31695-7/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(18)31695-7/fulltext)

<sup>16</sup> Deutsche Welle., 2021. Officials warn of fake COVID-19 vaccines | DW | 04.01.2021. Available at:

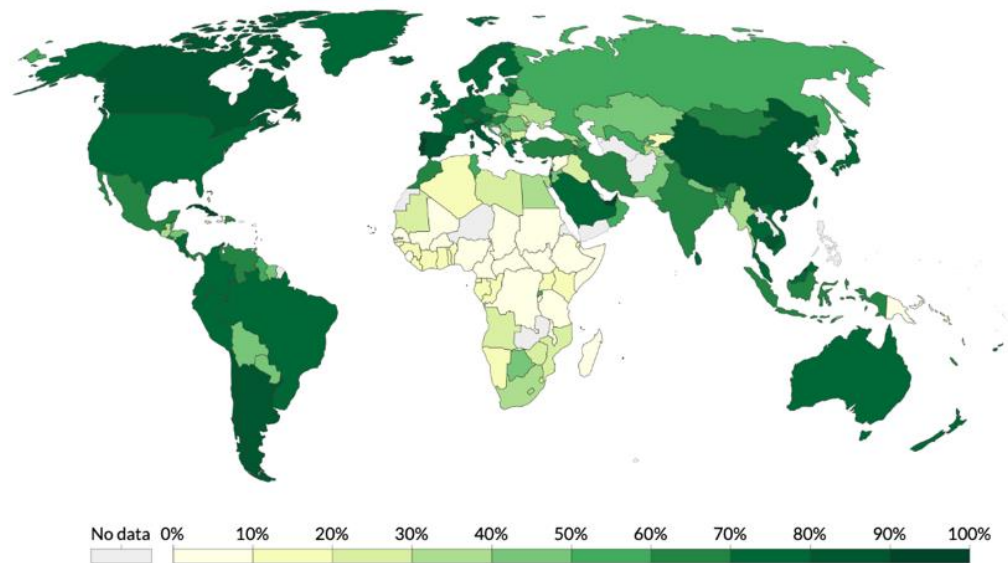
<https://www.dw.com/en/officials-warn-of-fake-covid-19-vaccines/a-56123830>

<sup>17</sup> U.S. Food and Drug Administration. 2021. Fraudulent COVID-19 Products. Available at: <https://www.fda.gov/consumers/health-fraud-scams/fraudulent-coronavirus-disease-2019-covid-19-products>

<sup>18</sup> Medicine Quality Research Group, University of Oxford. Medical Product Quality Report – COVID-19 Issues. Issue 12, June & July 2021. Available at: <https://www.iddo.org/document/medical-product-quality-report-covid-19-issues-issue-12-october-2021-data-june-july-main>

<sup>19</sup> UNDP Covid-19 Data Futures Platform. 2021. Global Dashboard for Vaccine Equity - UNDP Covid-19 Data Futures Platform. Available at: <https://data.undp.org/vaccine-equity/>

<sup>20</sup> World Health Organisation| Regional Office for Africa. 2021. Fifteen African countries hit 10% COVID-19 vaccination goal. Available at: <https://www.afro.who.int/news/fifteen-african-countries-hit-10-covid-19-vaccination-goal>



Source: Official data collated by Our World in Data – Last updated 3 January 2022, 11:00 (London time)

OurWorldInData.org/coronavirus • CC BY

**Figure 4. Share of people of who have received at least one dose of COVID-19 vaccine, as of 2 January 2022<sup>21</sup>**

## 1.4 Bottom-up, not top-down, is key

In the face of the COVID-19 pandemic, good global health governance is as important as ever. Throughout the Vaccine Access Workshop, the group voiced strong support for a bottom-up philosophy concerning global health activities, including initiatives to achieve vaccine access. Many examples of past successes indicate that a bottom-up, community-based approach might prove more efficient at combating outbreaks and diseases than an approach based on top-down infrastructure. For example, the African Programme for Onchocerciasis Control (APOC) set up a community-directed programme to combat river blindness, which “has brought continent-wide success for onchocerciasis control in Africa while other health initiatives have floundered and failed.”<sup>22</sup>

Given the wide-ranging challenges of the 21st century — from the COVID-19 pandemic to antimicrobial resistance, and from climate-change impacts on health to the long-term consequences of ageing populations — community-directed intervention strategies provide a basis on which to tackle these challenges.

“A renewed emphasis on local resilience may therefore find a much more receptive audience in communities around the world. One of the shortcomings of international health regulations during the COVID-19 pandemic has been the failure to prepare, provide, and coordinate adequate resources at the country level. A bottom-up approach could change this...investments in community-level health-surveillance capacity will likely be key to tackling this and future pandemics...Historically, global health and environmental cooperation has reflected various combinations of top-down and bottom-up measures...To be better prepared for future pandemics, our top-down models and agreements must shape responses that are grounded firmly in local communities and value their engagement, risk ownership, and anxieties”.

Excerpt from *Global Health Governance from the Grassroots* by Ngairé Woods & Ok Pannenberg. Available at Project Syndicate ([link](#))

<sup>21</sup> Roser, M., Ritchie, H., Ortiz-Ospina, E. and Hasell, J., 2020. Coronavirus pandemic (COVID-19). *Our world in data*. Published online at OurWorldInData.org. Retrieved from: <https://ourworldindata.org/covid-vaccinations>.

<sup>22</sup> World Health Organisation, 2007. Revitalising health care delivery in sub-Saharan Africa: the potential of community-directed interventions to strengthen health systems. Available at: <https://apps.who.int/iris/bitstream/handle/10665/275498/275498-eng.pdf?sequence=1&isAllowed=y>

## Section 2: Vaccine Access



As of January of 2022, the world is in a fourth wave of the pandemic (see Figure 5), with the Delta then Omicron variants having driven the latest waves of infections. WHO warns that the pandemic will drag on deep into 2022<sup>23</sup> as more than 50 nations globally missed the WHO milestone of fully vaccinating at least 10% their populations by September 2021.<sup>24</sup>

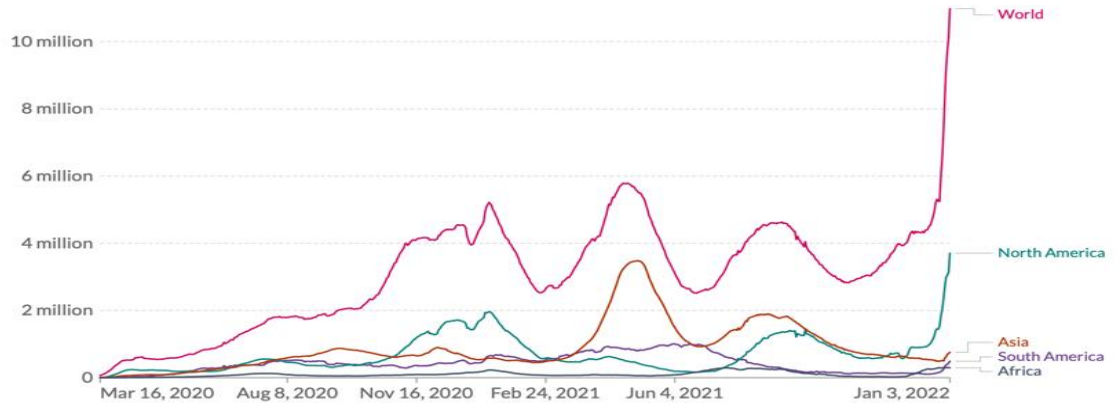


Figure 5. Weekly confirmed COVID-19 cases<sup>25</sup>

In some countries like those in Southeast Asia, government restrictions on travel movement, office and public space closures, etc., are still imposed at the strictest levels. Conversely, in many places in Europe, life was returning to something like it was before the pandemic with restrictions easing before the Omicron variant sent some countries back towards more restrictive measures. The single greatest tool that has helped usher in any semblance of a return to pre-pandemic life has been access to vaccines.

## 2.1 Vaccine Development Landscape

COVID-19 vaccine development is a global public health triumph that is unrivalled in vaccine development history. From the first injections in the vaccine trials to the first COVID-19 vaccines being granted emergency approval, it took just eight months. Typically, vaccines take 10 to 15 years to be developed, but an extraordinary effort went on through the international community to develop vaccines such that we now have the tools we need to curtail the pandemic (see Figure 6).

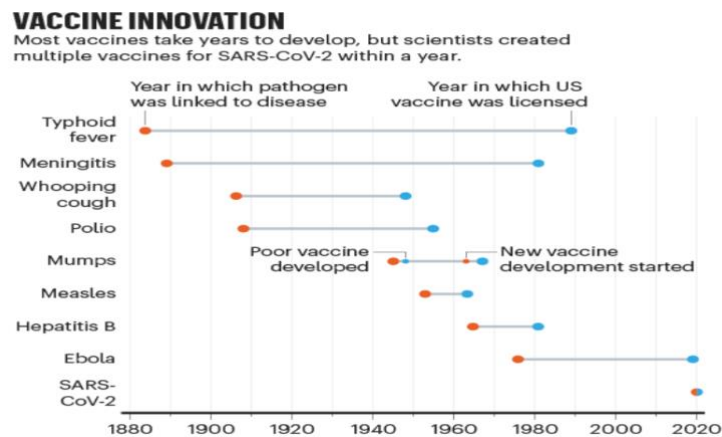


Figure 6. Vaccine development timelines for different diseases<sup>26</sup>

<sup>23</sup> Baker, F., 2021. The Covid Pandemic Could Continue Well Into 2022. Here's Why. [online] HuffPost UK. Available at: [https://www.huffingtonpost.co.uk/entry/covid-pandemic-to-run-into-2022\\_uk\\_61712e22e4b093143206bb67](https://www.huffingtonpost.co.uk/entry/covid-pandemic-to-run-into-2022_uk_61712e22e4b093143206bb67)

<sup>24</sup> Mwai, P., 2021. Covid-19 vaccinations: More than 50 nations have missed a target set by the WHO. [online] BBC News. Available at: <https://www.bbc.co.uk/news/56100076>

<sup>25</sup> Hannah Ritchie, Edouard Mathieu, Lucas Rod s-Guirao, Cameron Appel, Charlie Giattino, Esteban Ortiz-Ospina, Joe Hasell, Bobbie Macdonald, Diana Beltekian and Max Roser (2020) - "Coronavirus Pandemic (COVID-19)". Published online at OurWorldInData.org. Available from: [https://ourworldindata.org/grapher/weekly-covid-cases?tab=chart&country=OWID\\_WRL~North+America~South+America~Africa~Asia~Europe](https://ourworldindata.org/grapher/weekly-covid-cases?tab=chart&country=OWID_WRL~North+America~South+America~Africa~Asia~Europe)

<sup>26</sup> Ball, P., 2021. What the lightning-fast quest for Covid vaccines means for other diseases. *Nature*, 589. Available at <https://www.nature.com/articles/d41586-020-03626-1>

Astonishingly, even now, there are currently over 300 vaccines at different stages of development. However, only a very small number have gone through the full process of development, authorisation, and distribution, and an even smaller number are being distributed at any scale around the world. The Oxford-AstraZeneca vaccine is the most distributed, followed by Pfizer, Moderna and then the vaccines from Sinopharm and Sinovac in China, and the vaccine of the Gamaleya Research Institute of Epidemiology and Microbiology, Russia.

But most vaccines, other than the Oxford-AstraZeneca vaccines, are very limited in their number of doses available and the geographies they cover (see Figure 7). Africa, in particular, has limited access to the vaccines that have been developed, and many of the shortages are a result of supply limitations and other failures. Many big pharma companies do not have a product; of all of those companies that are recognised as global vaccine manufacturers, only Pfizer has a vaccine that has been successful.



**Figure 7. Locations where each vaccine is being used<sup>27</sup>**

#### **Developing a global COVID-19 vaccine: Spotlight on the Oxford-AstraZeneca Vaccine**

From the start of the development process, the Oxford group was very keen to ensure that its vaccine was a global vaccine. Trial sites for the early phases were intentionally situated in the UK, Brazil, and South Africa ensuring that trial participants were diverse and that the results of the trial were generalizable to people who lived in different places.

By the time the AstraZeneca collaboration was finalised, the team had already been working to set up trials in Asia. AstraZeneca took over the next phases of global trials in North America, Russia, Japan, and, through a partnership with the Serum Institute of India, ran the Asian trials. This meant that the development of the vaccine happened in different geographies, in different societies and also across all of the major global ethnicities. This was essential to building confidence amongst recipients and the certainty that the vaccine induces similar immune response across the world.

<sup>27</sup> Hadler, J., 2021. *Tracking Coronavirus Vaccinations Around the World*. [online] Nytimes.com. Image extracted on 5 January 2022. Available at: <https://www.nytimes.com/interactive/2021/world/covid-vaccinations-tracker.html>



## 2.2 Vaccine Access: Approaches and Challenges

In mid-2020, global stakeholders came together and formed COVAX, a multilateral initiative that worked with governments and manufacturers to ensure that COVID-19 vaccines would be available worldwide to both high-income and low- and middle-income countries. COVAX is co-led by Gavi, the Vaccine Alliance, the Coalition for Epidemic Preparedness Innovations (CEPI), the World Health Organisation (WHO), and the United Nations Children’s Emergency Fund (UNICEF).

The idea was that by pulling demand and resources together, both high-income and low-and-middle-income countries (LMICs) participating in COVAX, would have better negotiating power with manufacturers to access lower prices for some of the vaccines they would need. Additionally, another arm of the organisation would help to mobilise vaccine donations for LMICs. The strategy aimed early on to maximise access to different suppliers of vaccines, since no one vaccine candidate had received approval by then, and to help LMICs achieve access to up to 20% of the vaccines they would need at more or less the same time as wealthier countries.<sup>28</sup>

However noble an idea, COVAX has suffered many setbacks. First, COVAX, struggled to raise support and the funds that it needed. A few large countries, especially the US and China, were slow to endorse the program, and others, including in particular Russia, declined to participate.<sup>29</sup> Moreover, even though other stakeholders pledged to give funds to the program, it still took time for the committed funds to come through. As of September 2021, the platform under which COVAX is housed — the Access to COVID-19 Tools Accelerator — had a funding gap of \$1.6 billion for all of its planned activities for 2021, and nearly a \$800 million deficit for the purchase of vaccines.<sup>30</sup> The world had come together on many things, but that collaborative spirit was still lacking in some critical areas.

By the time COVAX had begun to negotiate deals with manufacturers, many wealthier countries had already formed bilateral deals that crowded out COVAX. Many countries, such as the UK, the US, and Canada, secured deals for vaccine supplies that would cover multiple fold their own populations, so much so that even where COVAX had mobilised the money to pay for vaccines, supply to COVAX could not be guaranteed in a timely manner.<sup>31,32</sup>

Compounding the effects of vaccine nationalism were export bans on Oxford-AstraZeneca vaccines from the Serum Institute of India. The Oxford-AstraZeneca vaccine had formed the backbone for most of COVAX’s supply and had become the de facto primary vaccine for most LMICs. However, due to its own crippling second wave of COVID-19 cases, India banned exports of COVID-19 vaccines in an effort to free-up local manufacturing capacity to meet its own demands.<sup>33</sup> This destabilised global supply and soured relationships with stakeholders such as the EU who later sued AstraZeneca for breaching the terms of its supply agreement.<sup>34</sup>

Because of supply-side limitations and internal bottlenecks, COVAX had managed to deliver only 378 million doses as of October 2021, significantly below its intended quantities.<sup>35</sup> The program has since revised its supply forecast and now aims to deliver its initially projected 2 billion doses by the first quarter of 2022 instead of year-end 2021.<sup>36</sup>

Looking at COVAX’s performance so far, it is easy to assume that the failures are a result only of supply-side constraints. Indeed, many bottlenecks occurred with supplying the vaccines. Given the focus here on digital, AI, and GIS tools, it is salient to note that there have been also great challenges with demand and uptake of the delivered vaccines (see Figure 8). An internal analysis conducted by Gavi shows that substantive risks from low vaccine uptake within countries has been a major challenge to COVAX. For the purposes of this report, we highlight three key risks that offer a complementary view to the supply-side issues discussed above and that might be the focus of digital, AI, and GIS innovations; vaccine absorption; vaccine wastage; and the impact of COVID-19 on routine immunisation.

<sup>28</sup> Ducharme, J., 2021. *What Went Wrong with COVAX, the Global Vaccine Hub*. Time. Available at: <https://time.com/6096172/covax-vaccines-what-went-wrong>

<sup>29</sup> Edgeway, E., 2021. *Documents Leaked to Reuters Raise Concerns about COVAX | Global Risk Insights*. Global Risk Insights. Available at: <https://globalriskinsights.com/2021/02/documents-leaked-to-reuters-raise-concerns-about-covax/>

<sup>30</sup> World Health Organisation, 2021. Access to COVID-19 tools funding commitment tracker. available at: <https://www.who.int/publications/m/item/access-to-covid-19-tools-tracker>

<sup>31</sup> Cohen, R., 2021. *COVID vaccines: rich countries have bought more than they need – here’s how they could be redistributed*. The Conversation. Available at: <https://theconversation.com/covid-vaccines-rich-countries-have-bought-more-than-they-need-heres-how-they-could-be-redistributed-153732>

<sup>32</sup> Financial Times. 2021. *‘Vaccine nationalism’ delays WHO’s struggling Covax scheme*. [online] Available at: <https://www.ft.com/content/502df709-25ac-48f6-ae1-ae7ac03c759>

<sup>33</sup> Beaubien, J., 2021. *It’s The Vaccine That’s Lost A Lot Of Trust. But AstraZeneca Still Has Its Fans*. [online] NPR. Available at: <https://www.npr.org/sections/goatsandsoda/2021/06/01/1002067808/astrozenecas-rocky-rollout-the-woes-of-the-vaccine-of-the-world?t=1634911160508>

<sup>34</sup> France 24. 2021. *EU, AstraZeneca strike deal to settle vaccine supply dispute out of court*. [online] Available at: <https://www.france24.com/en/europe/20210903-eu-astrazeneca-strike-deal-to-settle-vaccine-supply-dispute-out-of-court>

<sup>35</sup> Gavi. 2021. *COVAX vaccine roll-out*. Available at: <https://www.gavi.org/covax-vaccine-roll-out>

<sup>36</sup> World Health Organisation. 2021. *Joint COVAX Statement on Supply Forecast for 2021 and early 2022*. Available at: <https://www.who.int/news/item/08-09-2021-joint-covax-statement-on-supply-forecast-for-2021-and-early-2022>

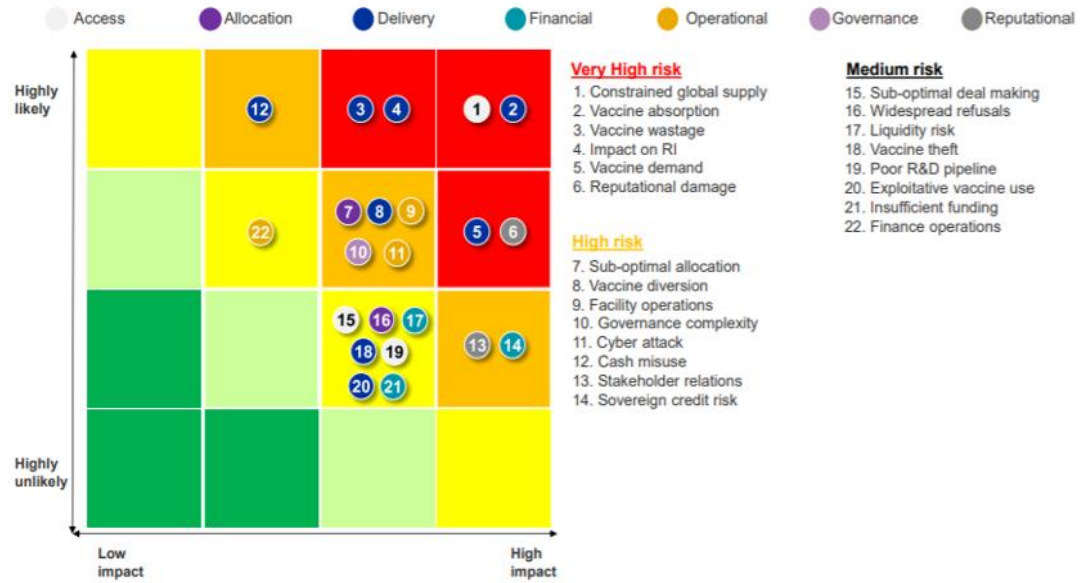


Figure 8. COVAX Risk Mapping<sup>37</sup>

**Vaccine absorption:** This refers to the ability of countries to optimally use the vaccine doses they receive, and it has been low in many instances. Some countries have not able to use the doses they have received under COVAX and have struggled with disposing of expired doses. South Sudan, for example, destroyed 59,000 doses and returned 72,000 of the 132,000 doses it had received through COVAX. The Democratic Republic of Congo was unable to use most of the 1.7 million doses it received and was forced to redistribute them to other countries. Even though the supply of vaccines has been constrained, there have been challenges in countries with making sure that vaccines get to the groups that need them.<sup>38</sup>

**Vaccine Wastage:** Defined by the WHO as the sum of vaccines discarded, lost, damaged or destroyed,<sup>39</sup> this is a significant risk for GAVI/COVAX. While the actual data on the extent of the problem is unavailable, the limited evidence available shows that this is a challenge for both high-income and lower-income countries, and that key drivers for this include vaccine hesitancy and poor supply-chain visibility and traceability. Some African countries like Malawi, South Sudan and Liberia, among others, had to destroy at least 450,000 doses as of mid-July 2021.<sup>40</sup> Stockpiling of vaccines by rich countries has also put at risk of wastage an estimated 241 million doses of vaccines, especially if these high-income countries are unable to donate the vaccines.<sup>41</sup> Even as donations increased, they were often being delivered with short shelf lives and at little notice. The WHO and Africa Centres for Disease Control and Prevention (CDC) requested a minimum of two and a half months shelf life on arrival and a month notice.

**Impact on Routine Immunisation and Delivery:** Granular data from country registries for immunisation show that, during the pandemic, there has been a lower delivery of routine vaccines. In 2020, global routine immunisation coverage dropped from 86% to 83% and the number of completely unvaccinated children increased by 3.4 million — the highest number since 2009.<sup>42</sup> At site level, service delivery and access to vaccines has been impacted in inconsistent ways, with some sites having additional demand for vaccines while other sites have had no one attending at all. These trends show that routine immunisation delivery is fragile and that COVID-19 has led to a reduction in uptake of many other vaccines.

<sup>37</sup> Gavi, 2021. *Annex C: COVAX Risk Report*. p.2. Available at: <https://www.gavi.org/sites/default/files/board/minutes/2021/23-june/06%20-%20Annex%20C%20-%20COVAX%20Risk%20Report.pdf>

<sup>38</sup> Global Health Security Consortium, 2021. *The Absorption Capacity Challenge*. Global Health Security Consortium. Available at: <https://institute.global/sites/default/files/2021-08/Global%20Health%20Security%20Consortium%2C%20The%20Absorption-Capacity%20Challenge%2C%20August%202021.pdf>

<sup>39</sup> World Health Organisation, 2019. *Revising global indicative wastage rates: a WHO initiative for better planning and forecasting of vaccine supply needs. Concept Note, 2019*, pp.1-6. Available at [https://www.who.int/immunization/programmes\\_systems/supply\\_chain/resources/Revising\\_Wastage\\_Concept\\_Note.pdf](https://www.who.int/immunization/programmes_systems/supply_chain/resources/Revising_Wastage_Concept_Note.pdf)

<sup>40</sup> Duke Global Health Innovation Center. 2021. *Looking into Vaccine Wastage*. Available at: <https://dukeghic.org/2021/08/13/looking-into-vaccine-wastage/>

<sup>41</sup> BBC News. 2021. *Covid vaccine stockpiles: Could 241m doses go to waste?*. Available at: <https://www.bbc.co.uk/news/world-us-canada-58640297>

<sup>42</sup> World Health Organisation. 2021. *Immunisation Coverage Fact Sheet*. Available at: <https://www.who.int/news-room/fact-sheets/detail/immunisation-coverage>

## 2.3 Vaccine Production in Africa

In the wake of delays with COVAX, many African countries, and the African Union at large, have undertaken a new commitment to strengthen vaccine manufacturing on the continent. As of 2021, only 1% of vaccines used in Africa were being manufactured on the continent.<sup>43</sup> Moreover, most vaccines on the continent are procured via UNICEF and are not directly imported by the countries themselves. Through a drive led by the African Centres for Disease Control and Prevention (ACDC), African leaders have committed to ramp up local production so that 60% of vaccines consumed in Africa will be manufactured in Africa by 2040.<sup>44</sup>

However, 2040 is clearly too far to wait to address the current pandemic in Africa. More urgent solutions are needed. Neither COVAX nor the African Union are on track to meeting their goals of vaccinating 20% of the population of Africa by 2022 and 60% of the population by 2023.

New partnerships are starting to form between leading global pharmaceutical companies and African manufacturers. However, questions arise as to how long it would take to accelerate the production and whether scaling up of local production for COVID-19 is an effective solution for the immediate challenges that COVID-19 presents.

Currently, 12 COVID-19 vaccine production facilities have been set up on the continent or are in the pipeline (see Figure 9). Of these, four manufacturers — the Pasteur Institute of Dakar in Senegal, the Pasteur Institute of Tunis in Tunisia, Biovac in Cape Town, and the Pasteur Institute of Algeria in Algiers — have the capacity to manufacture the substance that a vaccine is made of. Two others — Ethiopia Public Health Institute in Addis Ababa and Biovaccines in Lagos, Nigeria — have announced plans to reach that point. Two manufacturers are, or plan to be, involved in only 'fill and finish' processes or packaging and labelling.<sup>45</sup>

Despite these investments, the new plants will still need to overcome operational hurdles before they can produce COVID-vaccines.<sup>46</sup> They will, at the very least, face time-to-build constraints and need substantial investment and physical capital. Where these constraints have been overcome, manufacturers will still need to deal with operational delays. It will take time to organise intellectual property waivers, and even after manoeuvring the complex legal processes involved with undertaking this, there is still a 12-month process for selecting sites and then doing the necessary technology and know-how transfers.

In light of these delays, most manufacturers will start to scale up production only from 2022 onwards. Aspen Pharmacare in South Africa, for example, will be able to produce up to 500 million doses of the Johnson & Johnson vaccine by the end of 2022. Similarly, the Biovac Institute, also in South Africa, will ramp up its ability to package imported vaccines from 2022 onwards.<sup>47</sup>

As local vaccine manufacturing is starting to take-off, important considerations surrounding traceability and vaccine regulations are also emerging. National regulatory authorities across the continent range in quality from robust and functional to the "virtually non-existent."<sup>48</sup> Given this variability, the African Union has recently moved to form the African Medicines Agency (AMA), which will help to harmonise medical product regulatory processes across the continent. Similar to the new facilities, the AMA is also expected to be up and running in 2022.<sup>49</sup>

<sup>43</sup> Irwin, A., 2021. How COVID spurred Africa to plot a vaccines revolution. *Nature*. Available at <https://www.nature.com/articles/d41586-021-01048-1>

<sup>44</sup> Irwin, A., 2021. Ibid

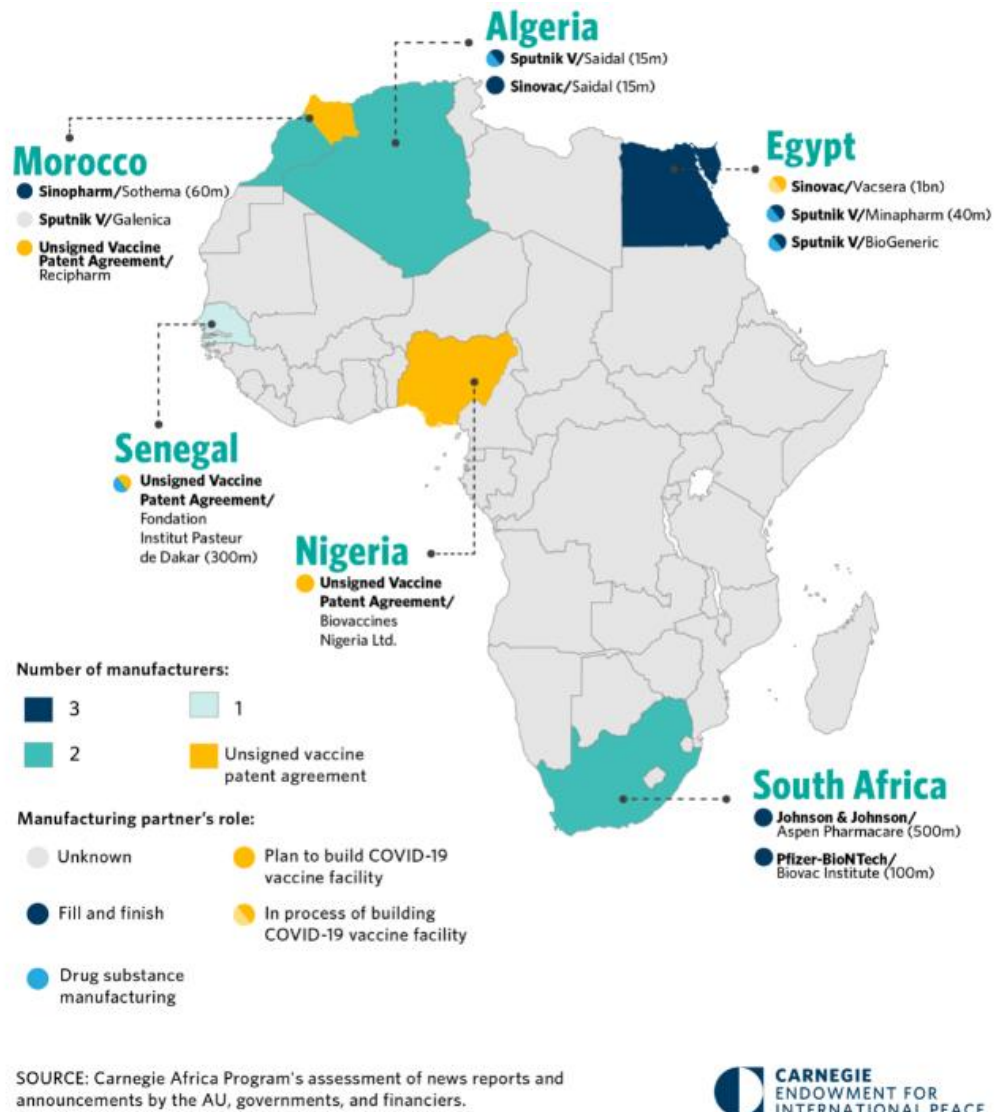
<sup>45</sup> Irwin, A., 2021. Ibid

<sup>46</sup> Meyer, K., 2021. *A COVID-19 vaccine plant in Africa? This is what it would take to build one*. [online] The Conversation. Available at: <https://theconversation.com/a-covid-19-vaccine-plant-in-africa-this-is-what-it-would-take-to-build-one-162778>

<sup>47</sup> Ovadia, J. and Usman, Z., 2021. *Is There Any COVID-19 Vaccine Production in Africa?*. Carnegie Endowment for International Peace. Available at: <https://carnegieendowment.org/2021/09/13/is-there-any-covid-19-vaccine-production-in-africa-pub-85320>

<sup>48</sup> Irwin, A., 2021. How COVID spurred Africa to plot a vaccines revolution. *Nature*. Available at [How COVID spurred Africa to plot a vaccines revolution \(nature.com\)](https://www.nature.com/articles/d41586-021-01048-1)

<sup>49</sup> van der Merwe, C., 2021. *AU expects African drug agency to be a reality in 2022 - Research Professional News*. [online] Research Professional News. Available at: <https://researchprofessionalnews.com/rr-news-africa-pan-african-2021-10-au-expects-african-drug-agency-to-be-a-reality-in-2022/>



**Figure 9. African Vaccine Manufacturing Centres<sup>50</sup>**

Given this evidence, and the reality on the ground, accelerating the manufacturing of vaccines in Africa is not likely to be a solution for the immediate challenges that COVID-19 places on the continent and the current limitation in Africa's access to COVID-19 vaccines. It is, however, an important step in the right direction to protect Africans from future pandemics and to help prevent future gross inequities in access to vaccines. In the interim, global efforts to redistribute available vaccines and to prioritise groups who desperately need access to vaccines should be pursued. It may be the only realistic way to address the major challenges that COVID-19 presents on the most vulnerable and disadvantaged populations.

#### Decentralized Vaccine Production in Latin America

Latin America accounts for just 2% of global vaccine production, and urgent calls have been made to accelerate vaccine production in the region. Similar to ongoing efforts to boost vaccine production in Africa, global stakeholders are also working to decentralize and increase vaccine production in Latin America. PAHO/WHO have launched a new platform that will support collaboration across countries and agencies to amplify local production of COVID-19 vaccines in Latin America and the Caribbean (more on this [link](#)). Partner manufacturers in the region, like the Oswaldo Cruz Foundation (FioCruz) in Brazil, have been selected and will become a WHO hub in Latin America for developing and producing messenger RNA vaccines (more on this [link](#)).

<sup>50</sup> Ovadia, J. and Usman, Z., 2021. Ibid

## 2.4 Variants, Boosters and the New Frontier for Inequality

### 2.4.1 Variants

The WHO and global partners have been tracking COVID-19 variants and have been paying particular attention to “variants of concern”, in particular the Alpha, Beta, Gamma, Delta, and Omicron variants.<sup>51</sup> Such variants are associated with the following: (i) increase in transmissibility or detrimental change in COVID-19 epidemiology; or (ii) change in virulence or in clinical disease presentation; or (iii) change in effectiveness of public health and social measures or available diagnostics, vaccines, therapeutics.

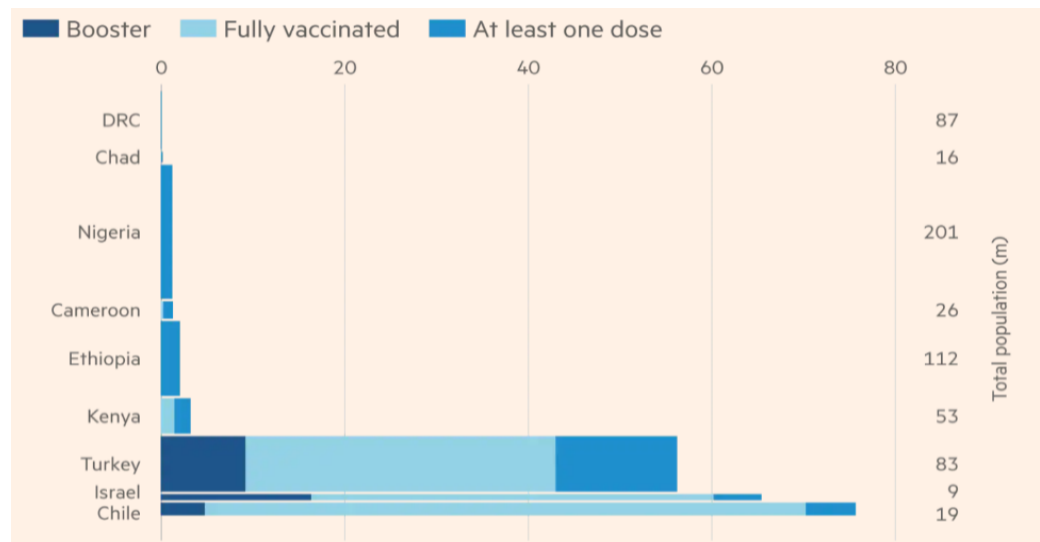
The WHO is also tracking other variants of interests (Lambda and Mu).<sup>52</sup> These variants have: (i) genetic changes that are predicted or known to affect virus characteristics such as transmissibility, disease severity, immune escape, diagnostic or therapeutic escape; and are (ii) identified to cause significant community transmission or multiple COVID-19 clusters, in multiple countries with increasing relative prevalence alongside increasing number of cases over time, or other apparent epidemiological impacts to suggest an emerging risk to global public health.

Lessons learned from the Beta, Delta, and now Omicron variants are that the new variants can infect vaccinated people, and that future variants will likely be more adept at doing so.

*“The critical thing we have taken from all the studies taken together is that the vast majority of people who have been vaccinated do not end up in hospital or die. And so, infection, which is the focus of the data collection around the world at the moment, is actually not important in the future. The future is whether vaccines continue to protect against hospitalisations and death, and all the current data from all the variants shows that this is extremely good news. We have to keep watching that to see what happens next.” Professor Andy Pollard, Director of Oxford Vaccine Group*

### 2.4.2 Boosters

As of early September 2021, Turkey, Israel, and Chile had given more booster doses than all doses that had been given in half a dozen African countries put together including Nigeria, Ethiopia and the DRC which collectively make up 6% of the world’s population (see Figure 10).<sup>53</sup> Such surprising dynamics raise important questions regarding how doses should be distributed and prioritized especially when national needs in countries with new variant outbreaks contend with global equity issues.



**Figure 10. Booster shots in Israel, Turkey and Chile vs vaccines administered in DRC, Chad, Cameroon, Nigeria, Ethiopia, and Kenya<sup>54</sup>**

<sup>51</sup> World Health Organisation. 2021. *Tracking SARS-CoV-2 variants*. Available at: <https://www.who.int/en/activities/tracking-SARS-CoV-2-variants>.

<sup>52</sup> World Health Organisation. 2021. *Ibid*

<sup>53</sup> Barnes, O. and Elliott, O., 2021. *Western states finalise Covid booster plans as developing world left behind*. Financial Times. Available at: <https://www.ft.com/content/e126f315-9ebe-4677-8dc5-ad5fdea8abbe>

<sup>54</sup> Extracted from Barnes, O. and Elliott, O., 2021. *Western states finalise Covid booster plans as developing world left behind*. Financial Times. Available at: <https://www.ft.com/content/e126f315-9ebe-4677-8dc5-ad5fdea8abbe>

Three key arguments have been put forward to recommend boosters namely: waning immunity (protection against infection or disease over time); reduced protection against variants of concern and; the need to protect groups that were not represented in Phase 3 clinical trials of the vaccines.

When the WHO Strategic Advisory Group of Experts on Immunisation gathered in December 2021 to review the evidence, they concluded that the waning effectiveness of vaccines had “minimal to modest reduction” on the protective effect of vaccines against severe disease over 6 months after the primary series. Moreover, they went on to warn that “broad-based administration of booster doses risks exacerbating vaccine access by driving up demand in countries with substantial vaccine coverage and diverting supply while priority populations in some countries, or in subnational settings, have not yet received a primary vaccination.”<sup>55</sup>

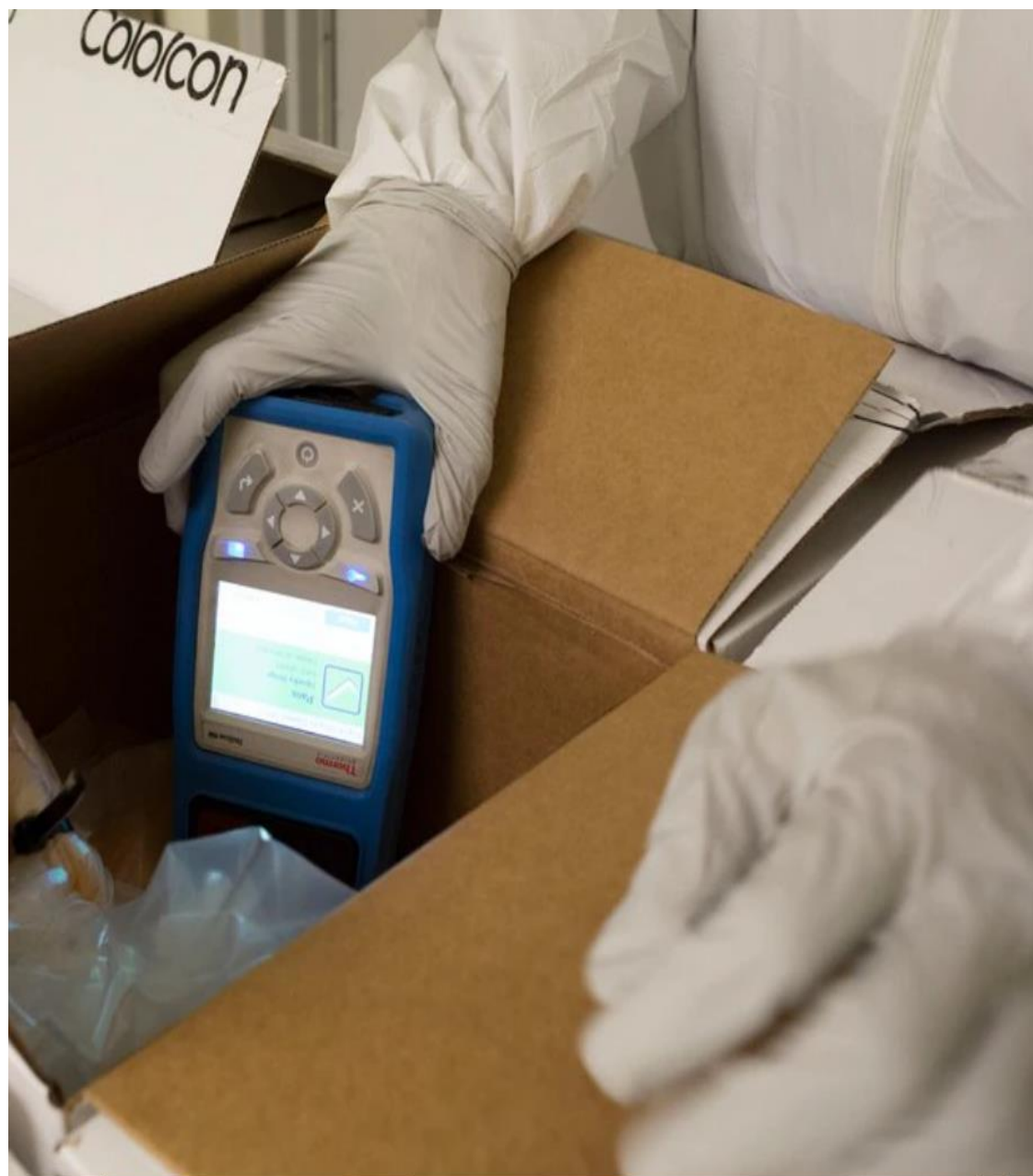
*“It is particularly chilling to think that we have now distributed enough doses worldwide that we could prevent almost all future deaths, if we had done an equitable distribution of those doses. Instead, most of those doses have gone to rich countries for people who are at very low risk of dying. And so, we will see over the rest of this year probably several million more deaths that could have been prevented.”*

Professor Andy Pollard, Director of Oxford Vaccine Group

By the end of 2021, global supply had improved markedly (indeed, the Serum Institute of India announced a cut back of production as orders declined), but distribution and uptake were seriously lagging in some countries. Nigeria, Ethiopia, and the DRC had fully vaccinated just 2.1%, 4.5%, and 0.1% of their populations respectively. The issue was shifting from the supply of vaccines themselves to the logistics of their delivery, health infrastructure, training and deployment of medical staff, vaccine storage, and tackling vaccine hesitancy. The role of digital, AI, and GIS tools was becoming ever more important.

<sup>55</sup> World Health Organisation. 2021. *Interim statement on COVID-19 vaccine booster doses: Update 22 December 2021*. Available at: <https://www.who.int/news/item/22-12-2021-interim-statement-on-booster-doses-for-covid-19-vaccination---update-22-december-2021> .

## Section 3: Case Studies on Digital Solutions for Vaccine Access and Product Safety



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### 3.1 Framing Thoughts for Artificial Intelligence and Digital Health Solutions for Vaccine Delivery in Low- and Middle-Income Countries

According to Villgro Africa, members of the Global Health Strategy Group for Digital Health and AI for Health, more than 50% of AI professionals globally work for tech companies but only 3% currently work for health organisations, and there are very few applications of AI in the vaccine supply chain. Usage of AI of pharmaceutical companies is mostly based in the area of drug discovery and development and very little in the area of supply chains.

Yet, there are multiple AI-driven interventions within the vaccines space and even more opportunities for AI and other digital solutions to transform vaccine delivery and supply chains. AI has a role to play in areas like demand forecasting, quality monitoring and tackling the dangers of SF vaccines, fighting misinformation, and also with the storage of vaccines in order to reduce wastage.

With regards to demand forecasting, the demand for specialised pharmaceuticals in most sub-Saharan Africa countries is low and unpredictable. Even with COVAX, a large number of poorer countries receiving vaccines through the global sharing scheme do not have enough doses to continue programmes while other countries are already considering vaccinating adolescents because uptake by vulnerable/high priority groups has been low. Utilising health information systems like the District Health Information Software 2 (DHIS2) which contains subnational data is essential to predicting and forecasting demand for vaccination to make sure that appropriate doses of vaccines reach the people who need them.

For quality monitoring, there have been a number of cases where vaccines have been rejected because of contamination issues. While AI can also be used, we can learn from the regulatory authorities like those in Nigeria (see NAFDAC case study) on how to develop solutions to strengthen the regulation of these vaccines and to protect high product quality. Moreover, the use of AI in traceability can help to pinpoint exactly where contamination and SF problems originated in the supply chain and further protect medical product users.

Another area where digital solutions can play a critical role is in combatting misinformation. The challenge of misinformation is both local and global, and around one in three people in some countries have reported seeing false or misleading information about COVID-19 vaccines.<sup>56</sup> COVID-19 is overwhelmingly mentioned in social and popular media, and it is difficult to quantify the exact amount of misinformation there is. Sprinklr, an online analytics company in the US, reported that COVID-19 had been mentioned nearly 20 million times on social and traditional media in the US on one day.<sup>57</sup> AI and Machine Learning (ML) solutions can be helpful for analysing such volumes of data and tracking misinformation across media platforms.

There are other vital areas for which AI/ML and digital solutions can play potent roles. There is space for such tools in the storage and handling of vaccines (see case study below on mPedigree), with personalised vaccination, with tracking substandard and falsified (SF) medicines (see case study below on IDDO), and in many other areas. The case studies in this report present powerful examples of organisations innovating within the digital health space, doing work to strengthen vaccine access, traceability, and product safety.

<sup>56</sup> Scott, M., POLITICO. 2021. *One-third of people have seen misleading info on COVID-19 on social media: report*. Available at: <https://www.politico.eu/article/one-third-of-people-have-seen-misleading-info-on-covid-19-on-social-media-report/>

<sup>57</sup> Mola, R., 2021. *How coronavirus took over social media*. [online] Vox. Available at: <https://www.vox.com/recode/2020/3/12/21175570/coronavirus-covid-19-social-media-twitter-facebook-google>



### **Gavi, the Vaccine Alliance Guiding Insights on the use of Digital Solutions for Vaccines**

The investments and technologies that are being set up today for COVID-19 will need to be sustainable for routine immunisation in the longer term. Rather than one-off response to the pandemic, Gavi's view is that investments should be positioned from the perspective of both the immediate response and the longer-term health system strengthening objectives.

In terms of routine immunisation, we need to have a balance between the needs and the demands that are emanating from people on the front lines in countries with what is technologically possible, and to find a feasible median. In some ways we have to be needs-driven but we also need to be exposed to what's out there, and there are hidden spots around what is happening. Some technologies are being developed with focused applications outside the global health space and the question is how do we apply these to COVID-19 which is the biggest challenge of our time.

As we think through these technologies, we should also consider the sort of technological environment they will be implemented in. There needs to be more emphasis on capability enhancement programmes within countries, and how we think about the users of this technology (i.e., national governments and potentially other partners). We need to think of stakeholders beyond just technological partners and countries but also think more about the ecosystem of people involved in the deployment and sustainability of such technology. In addition to technological partners and countries, we need to think about including implementing agencies, NGOs, civil society organisations, and donors as well.

Lastly, we have to think more rigorously around the business model, the cost of implementation, the ongoing tech-transfer and ownership issues surrounding the use of these technologies. We must be sensitive both to the public-sector needs and constraints, but also to the private-sector needs and constraints, and looking at a whole-system approach.

## **3.2 Case Study: Nigeria Agency for Food and Drug Administration and Control**

### **3.2.1 Background**

The Nigeria Agency for Food and Drug Administration and Control (NAFDAC) was instituted in 1993 with a mandate to regulate and control the manufacture, importation, exportation, distribution, advertisement, sale and use of foods, drugs, cosmetics, chemicals, detergents, medical devices and packaged water in Nigeria. NAFDAC has approximately 2,200-2,500 staff members and has a presence in 36 States including the Federal Capital Territory (FCT).

Prior to 2001, it was reported that 40% of medicines circulating in the Nigerian pharmaceutical supply chain were substandard, fake, or counterfeited. By 2005, this had reduced to 16.7%. To achieve its mandate and drive down the prevalence of SF drugs in the supply chain, NAFDAC deploys a range of strategies such as sustaining public engagement, utilising cutting-edge technologies, and strengthening supply chain regulations and laws.

### **3.2.2 NAFDAC's Distribution and Product Quality Work**

Nigeria, through NAFDAC, was the first country in the world to use the TruScan™ Handheld Analyser strictly for the detection of fake or counterfeit drugs; the device was hitherto used in the US by pharmaceutical companies to verify the quality of their active ingredients.<sup>58</sup>

An early investigation in 2011 using the technology found that 20% of retail products in forty drug stores in Oyo, the capital city of Ibadan, failed to pass quality tests.<sup>59</sup> Following the investigation, which involved six groups of agents at various locations in the city, the regulator advised pharmacists to check product batch numbers before accepting deliveries from sellers.

<sup>58</sup> Ojeme, V., 2011. *War Against Fake Drugs: NAFDAC's Truscan to the rescue*. Vanguard News. Available at: <https://www.vanguardngr.com/2011/11/war-against-fake-drugs-nafdac%E2%80%99s-truscan-to-the-rescue/>

<sup>59</sup> FiercePharma. 2010. *Nigerian agents detect fake drugs using Raman units*. [online] Available at: <https://www.fiercepharma.com/manufacturing/nigerian-agents-detect-fake-drugs-using-raman-units>

### Thermo Scientific TruScan™ Handheld Raman Analyser

The TruScan™ is a handheld spectrometer used to analyse the quality of pharmaceutical and biotechnical products. It delivers reliable material identity verification through sealed packaging in seconds, right at the point-of-need.

The unit is built for users having little understanding of chemistry. The TruScan™ analyses the chemical composition of an authentic product and can then be used to compare this against that of retail products. TruScan then provides a pass or fail indication. More on how Nigeria has used the TruScan™ can be found on this news article ([link](#)).



To further strengthen its distribution work, NAFDAC also uses the Minilab for field screening, and utilises a Mobile Authentication Service (MAS). The MAS scheme uses scratch codes and Short Messaging Service (SMS) to empower consumers to verify the authenticity of medicines at the point of purchase.

### Global Pharma Health Fund-Minilab

The Minilab™ contains the essential components and apparatus needed for reference testing. It is a complete laboratory that fits in one suitcase.

The kit contains a manual with simple operation procedures, a complete set of glassware and a collection of reference agents for up to 102 active pharmaceutical ingredients. The suitcase is accompanied by a set of chemicals that allows the immediate use of Minilabs in any corner of the world. Click [here](#) to read more about it.



More recently, NAFDAC, has been shoring up its information and communication technology infrastructure, using software it has developed such as the Ports Inspection Data Capture and Risk Management System (PIDCARMS), and the National Automated Product Administration and Monitoring System (NAPAMS) for e-registration of regulated products. As a result of these innovations, in 2017 and 2018, NAFDAC managed to identify and destroy SF medical products worth more than N3.226 billion (USD 7.7 million).<sup>60</sup>

### 3.2.3 NAFDAC's Traceability Work

Building on the above, NAFDAC has also intensified its work on traceability, and strengthened efforts to improve visibility of the history, location, and use of products once they have left the manufacturer. This work is essential given that one in ten medical products in developing countries is SF and that more than 100,000 deaths a year in Africa are linked to the counterfeit drug trade.<sup>61</sup>

Recognising the immense need for traceability, NAFDAC commenced work in the area in 2018 by attending the 1<sup>st</sup> African GS1 Healthcare Conference held in Addis Ababa in May of that year (see box on GS1 below for more information on GS1). In June 2019, NAFDAC and USAID held a collaborative workshop to launch the pharmaceutical traceability initiative with the main outcome being the establishment of a vision statement, strategy, and five-year roadmap for implementing pharmaceutical traceability using global standards.

<sup>60</sup> THIS DAY LIVE. 2021. NAFDAC Destroys N3bn Fake Drugs. [online] Available at:

<https://www.thisdaylive.com/index.php/2019/11/12/nafdac-destroys-n3bn-fake-drugs/>

<sup>61</sup> WHO. 2017. 1 in 10 medical products in developing countries is substandard or falsified. Available at:

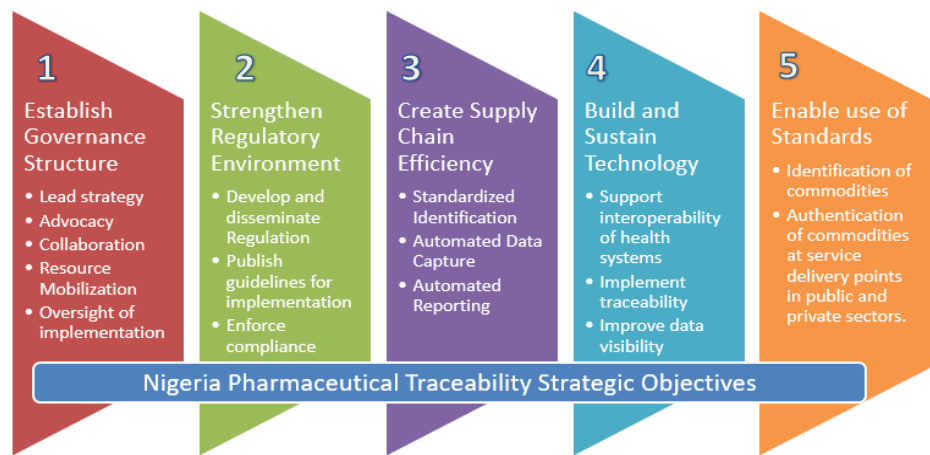
<https://www.who.int/news/item/28-11-2017-1-in-10-medical-products-in-developing-countries-is-substandard-or-falsified>

### GS1 and work in Nigeria

GS1 is a not-for-profit organisation that was formed in 1973 to develop and maintain global traceability standards. The organisation has more than 2 million members, and helps stakeholders involved with making, moving, and trading goods to automate and standardise their supply chain processes using a common language. GS1 global standards are the global common language for traceability solutions. (More about GS1 can be found [here](#))

GS1 provides the global framework and local implementation services in more than 100 countries to ensure that traceability systems are interoperable and scalable, where trading partners can easily collaborate and share information across the entire supply chain.

NAFDAC's strategy focuses on five strategic objectives ranging from establishing governance structures for traceability to enabling the use of standards. See Figure 11 for an overview of the strategy, and follow this [link](#) to read more in-depth on the strategy:



**Figure 11. NAFDAC National Pharmaceutical Traceability Strategic Objectives<sup>62</sup>**

In 2019, the second GS1 Africa Summit was held in Lagos, Nigeria. This historic conference welcomed over 300 participants. 25 African regulatory authorities and 6 health-financing and donor organisations signed a call to action to pursue pharmaceutical traceability by adopting global supply chain standards (see Figure 12).<sup>63</sup> African representatives from national and regional economic communities agreed to work with one another to create sustainable governance structures, strengthen regulatory policies and procedures, implement automatic identification and data-capture technologies, and invest in the underlying health-system infrastructure that enables verification and track and trace of pharmaceuticals through the supply chain.



**Figure 12. Attendees of second GS2 summit and signatories of the call to action<sup>64</sup>**

<sup>62</sup> Picture extracted from presentation given by Professor Adeyeye during the Vaccine Access Workshop. Reference: Adeyeye, M., 2021. *Traceability of COVID-19 Vaccines using GS1 standards: the Nigeria experience*.

<sup>63</sup> GS1. 2019. *The power of standards at the 2nd African GS1 Healthcare Conference in Lagos, Nigeria*. Available at:

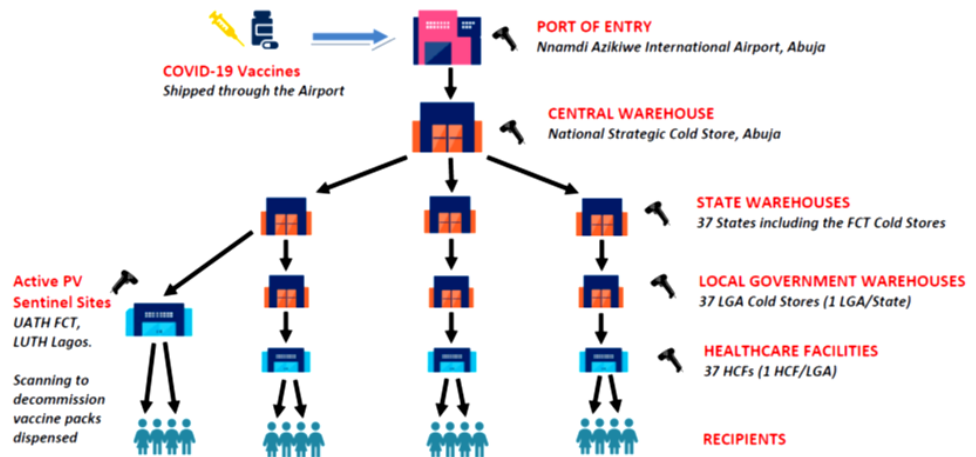
<https://www.gs1.org.sg/SolutionPartners/Articles/the-power-of-standards-at-the-2nd-african-gs1-healthcare-conference-in-lagos-nigeria>

<sup>64</sup> GS1. 2019. Ibid

### 3.2.4 COVID-19 Vaccine Pilot in Nigeria

Nigeria was the first country in Africa to have preparedness guidelines for COVID-19 vaccines. It was able to do so because NAFDAC collaborated with healthcare supply chain actors and used GS1 standards early on to carry out a pilot that enabled it to prepare for the arrival of COVID-19 vaccines.

Control of the supply of COVID-19 vaccines was highly regulated. The vaccines arrived at only one port of entry, Nnamdi Azikiwe International Airport in Abuja. From there the vaccines went to the central warehouse and then to different state warehouses and local government healthcare facilities. NAFDAC assigned Global Location Numbers (GS1 standards) to more than 400 facilities in 36 states including the FCT, and conducted barcode scans across 34 states, at the port of entry and at selected Local Government Area (LGA) stores and Health Facilities. The goal was to identify any possible point of infiltration into the supply chain, and also to support pharmacovigilance activities for COVID-19 vaccines.



**Figure 13. COVID-19 Vaccines Traceability Pilot: Supply Chain Map<sup>65</sup>**

As a pilot, it generated many lessons. For example, a total 7,672 packs of multidose vials were successfully commissioned, but it took NAFDAC staff more than 10 hours at the port to sort this because manufacturers and the Marketing Authorisation Holders had not shared event data which would — and it is hoped, in future, will — make it easier to verify the product at the port.

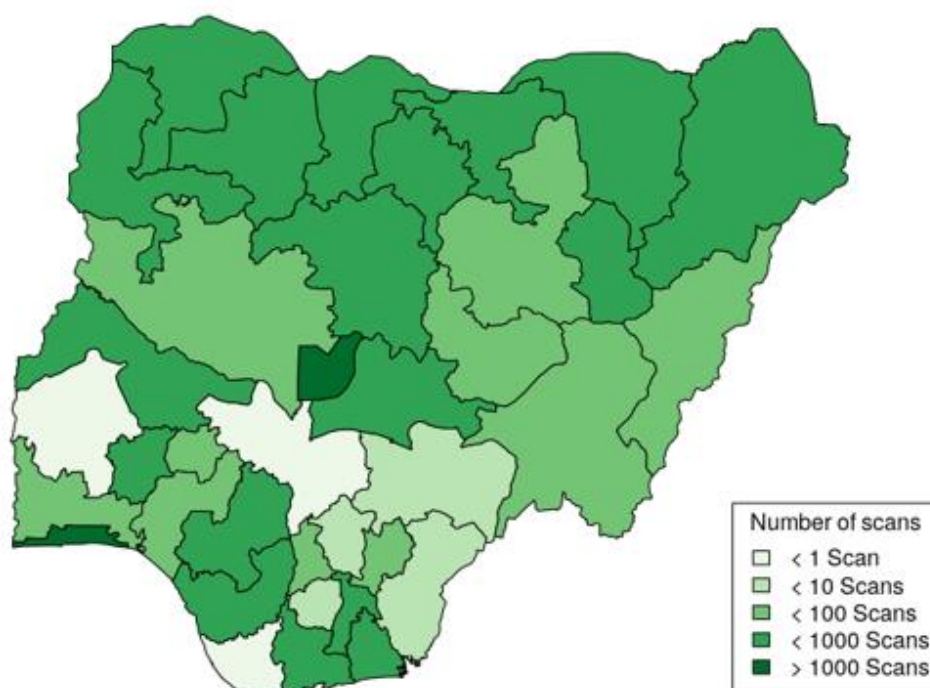
For the second phase of the pilot, NAFDAC introduced active pharmacovigilance (PV) Sentinel Scanning. Scanning was done upon entry at the airport and across 34 States and also at selected LGA Cold Stores (see Figure 13).

Including data from the second phase of the pilot, a total, 15,997 scans were completed in the pilot with 83% of scans being valid (see Figure 14). Furthermore, the batch distribution detected by the scans at state level were largely as expected. Invalid scans were attributed to the unavailability of mobile scanners in some locations, and insufficient time to test the tracking app and train the people scanning in how to properly capture scan data. Hopefully, such problems would be ironed out in future. Despite these localised challenges, overall, the pilot was successful and prepared Nigeria for the eventual arrival of more COVID-19 vaccines later in the year.<sup>66</sup>

<sup>65</sup> NAFDAC, 2021. *Report of the Traceability Implementation for Covid-19 Vaccines Distributed In Nigeria*. NAFDAC. Available at: <https://www.nafdac.gov.ng/wp-content/uploads/Files/Resources/Traceability/NAFDAC-TrackTrace-COVID-19-Report-4.pdf>

<sup>66</sup> NAFDAC, 2021. *ibid*

### Barcode Scanning Activity for COVID-19 Vaccine Traceability Pilot in Nigeria



**Figure 14. Pharmacovigilance scanning conducted as part of COVID-19 vaccine rollout pilot<sup>67</sup>**

Looking back at the pilot a few key lessons emerge:

- **Incremental improvements lead to remarkable results:** NAFDAC was able to build on its ongoing institutional strengthening, implementation of cutting-edge technology, and workforce capacity building to successfully implement the pilot;
- **Infrastructure and funding deficits, nevertheless, threaten traceability objectives.** Despite the successful implementation of the pilot, insufficient funding and equipment as well as the absence of bar codes on primary packages led to failed scans;
- **There are plenty of opportunities to further improve performance.** Further strengthening and standardising regulations and processes, improving stakeholder engagement and awareness, and developing interoperable systems are key next steps for improving traceability endeavours in Nigeria. **Developing and adopting tools and applications that involve AI and GIS technology are the next frontiers for fortifying traceability.**

### 3.3 Case Study: Infectious Disease Data Observatory

Despite supply-chain challenges, COVID-19 Vaccines have been introduced in 191 countries so far.<sup>68</sup> Much attention has been devoted to recognising, and rightfully criticising, challenges and the inequitable distribution of vaccines,<sup>69</sup> but more limited focus has been given to issues surrounding substandard and falsified (SF) vaccines.

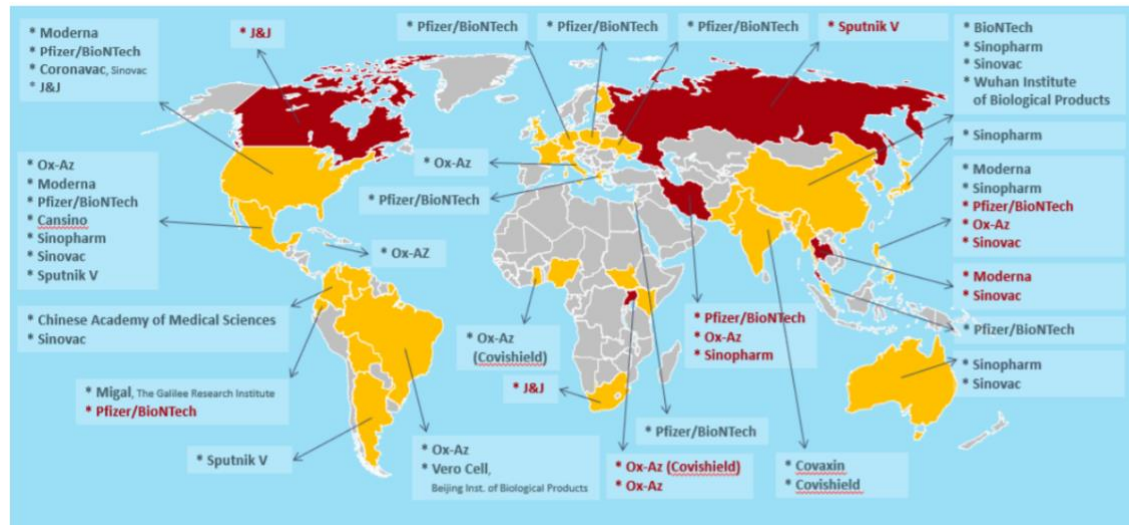
The Medicine Quality Research Group at the Infectious Disease Data Observatory (IDDO) at the University of Oxford has been gathering information on diverted, substandard and falsified (SF) COVID-19 vaccines and putting it in the public domain. Based on their tracker, as of the end of July 2021, there have been 150 reports of SF vaccines gathered from public sources in 41 countries.<sup>70</sup>

<sup>67</sup> Extracted from above referenced NAFDAC report

<sup>68</sup> International Vaccine Access Center (IVAC), Johns Hopkins Bloomberg School of Public Health. Available at <https://view-hub.org/covid-19/?set=current-vaccine-intro-status&group=vaccine-introduction&category=covid>

<sup>69</sup> WHO. 2021. *Vaccine inequity undermining global economic recovery*. Available at: <https://www.who.int/news/item/22-07-2021-vaccine-inequity-undermining-global-economic-recovery>

<sup>70</sup> Medicine Quality Research Group, University of Oxford. Medical Product Quality Report – COVID-19 Issues. Issue 12, June & July 2021. Available at: <https://www.iddo.org/document/medical-product-quality-report-covid-19-issues-issue-12-october-2021-data-june-july-main>



**Figure 15. Countries with public reports on diverted, substandard or falsified (SF) COVID-19 vaccines in the press<sup>71</sup>**

The group uses a Google News search tool and an algorithm to search online and sort articles. Trained analysts then correct or refine automated labels and add further categorisation information to content in the database through a web-based interface. The labelled data then serve as training data for a machine learning algorithm that applies tentative labels to new data as it enters the system.

Results from the search are populated on the Medicine Quality Monitoring (MQM) Globe ([link to resource](#)), a web-based application that allows users to search and visualise reports by country. The MQM Globe has “smart” features such as synonym content to help users find content when they do not know the strict medical terminology.

The major advantage of this tool is that it automatically finds articles related to poor quality medicines and medical products in several languages. The disadvantage, however, is that the information from the different sources is taken as is, and is not verified by the tool, such that the results should be taken with caution. Additionally, the tool captures only reports that are in the lay domain (see Figure 15), and does not capture reports in other domains. As such, the abundance or absence of reports in a particular geographical area has no direct correlation with the extent of SF medical products in that area

#### Overview of Infectious Diseases Data Observatory (IDDO), University of Oxford

IDDO’s vision is to ensure effective treatment for patients affected by neglected and emerging infections. Amongst many other objectives, IDDO aims to undertake collaborative data analysis to address priority questions and to deliver trusted and accessible data on infectious disease areas such as Ebola, malaria, and COVID-19.

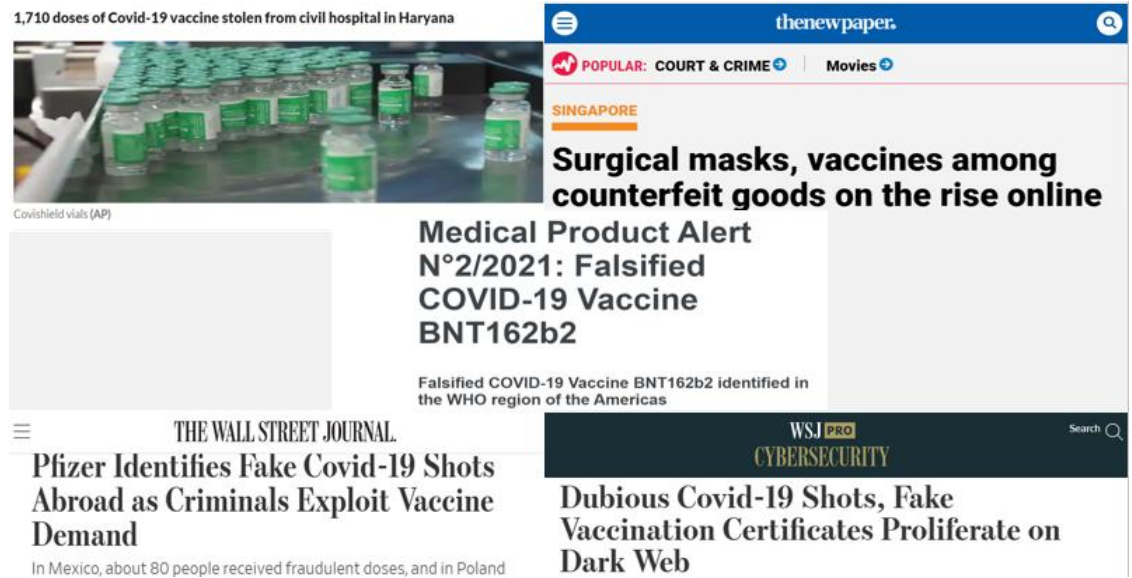
One group at IDDO, the Medicine Quality Report Group, shares expertise and collates information to increase understanding of the prevalence and distribution of substandard and falsified (SF) medical products around the world. Their work on COVID-19 vaccines, for example, has led them to track reports in the public domain. For more information on their methodology, [click here](#). The group publishes their findings on a bimonthly basis as a Medical Product Quality Report which can be found [here](#). It, and similar resources, are shared on the COVID-19 Clinical Research Coalition website [here](#)

### 3.3.1 Risks Assessment for SF Vaccine Occurrence and Impact

Prior to the pandemic, there had been many cases of SF vaccines globally but these had not really hit the global public-health consciousness needed to incentivise interventions to prevent, detect, and respond to them. With COVID-19 vaccines in such limited supply, however, this risk has been a concern since the start of the pandemic.

<sup>71</sup> Main citation same as above. Countries linked to incidents are indicated in orange. If a public report mentions a product name or a company, these details are indicated on the map, with in red the information that was added specifically in the June-July 2021 issue. Ox-Az: Oxford-AstraZeneca, and J&J: Johnson & Johnson

The current grossly inequitable distribution of vaccines is fuelling the profit-motive for SF vaccines (see Figure 16). Errors in cold chain also risk vaccine degradation and reduced vaccine potency. Diverted and stolen vaccines, taken from those who were the intended recipients, will lead to degradation. Adulteration and falsified vaccines risk upsurge in vaccine hesitancy unless action is taken to stop people being concerned about taking genuine vaccines. Together, these risks have many public health consequences that will reduce the speed at which we can exit from the pandemic.



**Figure 16. Featured articles in the lay domain related to falsified or substandard vaccines<sup>72</sup>**

The key to counteracting the use of SF vaccines is to engage with different communities when we do have SF vaccine problems on a large scale. In this case, bottom-up, and not just top-down, engagement is essential. Publications such as Fight the Fakes ([link](#) to their website) and Medicines We Can Trust ([link](#) to their website) are examples of pioneering organisations working to raise awareness and prevention of SF medicines.

Another potent lever is using joined-up stakeholder data sharing and risk analysis to inform policymakers. To help drive this kind of data sharing, Gavi, the Vaccine Alliance was working to make GS1 compliance compulsory for globally-sourced products by the end of 2021.<sup>73</sup> Lessons learned from countries like Nigeria and their work on traceability can provide vital insights in to how to achieve joined-up stakeholder data sharing. One essential ingredient to facilitate data sharing for both imported and locally-produced products is to introduce penalties for making SF products; however, in many countries there is neither the regulatory infrastructure nor political will to implement this.<sup>74</sup>

An additional intervention is making sure countries have rapid access to reference labs. If a country has vaccine it is suspicious of, who do they send it to? How quickly do results come back? What do they do in the meantime? How is the data shared? Which actions are taken? Reference laboratories that are too far away are, in effect, inaccessible and create counterproductive bottlenecks in the fight against SF vaccines. Making reference labs accessible is an important and powerful mechanism to detect and prevent the proliferation of SF vaccines.

One final intervention is to either develop new, or repurpose existing, screening devices for COVID-19 vaccines. Currently, there are no available devices for screening vaccines along the supply chain. IDDO and other groups have a collaborative project to see if it is possible to repurpose existing devices to look for SF vaccines in supply chains.

<sup>72</sup> This picture references different news headlines. The top left article can be [found here](#); top right article can be [found here](#), centre article can be [found here](#), bottom left article can be [found here](#) and the bottom right image is [here](#).

<sup>73</sup> Stone, J., 2021. How Counterfeit Covid-19 Vaccines and Vaccination Cards Endanger Us All. Forbes. Available at:

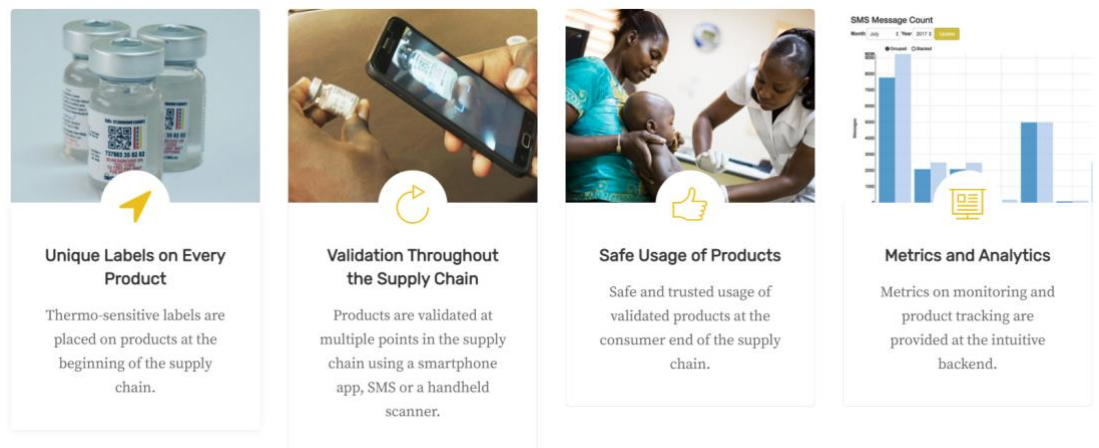
<https://www.forbes.com/sites/judystone/2021/03/31/how-counterfeit-covid-19-vaccines-and-vaccination-cards-endanger-us-all/>

<sup>74</sup> Stone, J., 2021. *ibid*

### 3.4 Case Study: mPedigree

Africa is very diverse, and mPedigree has worked to develop solutions that are applicable to different contexts and geographies on the continent: from Kenya and Tanzania in the east, to Malawi in the south to countries like Ghana and Nigeria in the west. mPedigree provides joined-up services across the ecosystem in order to address not only counterfeiting, product security and brand protection issues, but also consumer safety and regulatory integrity solutions.

In 2017 mPedigree launched Koldchain (see Figure 17), a spin-off that has extended these capabilities beyond verification of products into the cold chain, with radical implications for vaccines. Their new sensory technology empowers frontline health professionals to validate important data on traceability and vaccine potency in one go (Click [here](#) to read more about KoldChain).



**Figure 17. How KoldChain technology is applied to vaccines**

One of the key inventions that fuels this advancement is the Thermocycler system which combines the ability to detect breaches in the cold chain with anti-counterfeiting and regulatory notifications. The system uses polymer-based sensors placed on vaccine vials which respond to environmental stimuli. When the vaccines are tampered with, this creates a pattern on the polymer-based label. Scanning these patterns with a machine learning algorithm based on a dataset held by mPedigree can indicate whether or not there has been a breach in the supply chain. With one scan of the primary vial, a frontline health worker is not only told whether or not there has been a breach in the cold chain but he/she can also validate whether that particular product came from a verified source. By using the one scan, a frontline health worker — or anyone for that matter — can address multiple issues.

#### 3.4.1 mPedigree's Key Working Principles

Because of the diversity of locations where mPedigree works, they develop technology that caters to contexts with both advanced and limited infrastructure, and have come to promote an infrastructure-agnostic principle. mPedigree operates in a such a way that they can provide a solution regardless of the infrastructural context of a particular location.

*"So, we have countries where people don't have smartphones, they don't have internet-enabled devices, we are able to use SMS and USSD all the way to advanced smartphone capabilities including track and trace across the supply chain. This is very different to what is often offered in the West, where you need to have a smartphone and an internet-enabled device to use such kinds of systems"*  
*Bright Simons, Founder and President of mPedigree*

In addition, mPedigree develops integrated solutions that track products from the manufacturer to the point of care or points of administration. mPedigree believes that creating integrated solutions can help address overlooked challenges in the supply chain. They therefore design technologies that include regulatory integrity and involve joined-up responses from the private sector, government, and civil society.



### 3.5 Case Study: United Nations children's emergency fund

SF medicines are a \$30 billion problem in low-and-middle-income countries alone, and globally this toll rises to more than \$200 billion. Data obtained by the United Nations Children's Fund (UNICEF) indicate that fake certificates, vaccines, and other COVID-19-related supplies have gone up from 20% to 50% in the last nine to ten months, posing a serious challenge for vaccine uptake and confidence. In 80% of cases, in-country data systems do not reach the district level health systems, making it impossible to currently trace COVID-19 vaccines. UNICEF procures half of all the vaccines produced globally and therefore has an advantage in partnering with manufacturers and also in fostering partnerships between the public and private sectors, and regulators working together to ensure that SF vaccines are not introduced into the supply chain.

*"The vast majority of the lower middle-income countries do not have a fully functioning track and trace system in place, and developing one will take anything up to three or five years" Zabi Kamran  
Immunisation Specialist, UNICEF*

UNICEF and its partners are co-leading the development of an end-to-end track and trace system for COVID-19 vaccines. This system will help strengthen in-country stock management and vaccine consumption practices, map digital investments, and help harmonise the bespoke systems that countries currently use. The problem of SF vaccines in the supply chain and falsification of vaccine certificates highlights the need for development of a global trust mechanism that works with manufacturers in countries.

To address this need, UNICEF and partners have started work on a Global Trust Repository, which will be based on GS1-enabled traceability standards. The repository will rely on a barcode system and will monitor vaccines as they move across the supply chain; scanning the barcode allows the vaccines to be verified and to have their origin identified. This will help with the immediate issue of COVID-19 vaccine safety and help prevent the distribution of SF products in national immunisation programmes.

Beyond introducing the Global Trust Repository, UNICEF will work with country stakeholders to ensure that the implementation of the Repository is effective. UNICEF will provide technical assistance to countries and engage national institutes to operate tools at service-delivery points to monitor consumption and vaccine stock throughout the supply chain. Moreover, they will also proffer guidance on how to standardise in-country logistics management systems. They are currently mapping the different types of logistical management systems that countries use, and they are encouraging the adoption of minimum standards to make these systems interoperable. So far, this mapping exercise has provided an understanding of the concentration and maturity of these systems and of their capacity to incorporate the demands that COVID-19 vaccines are placing on supply chains.

### 3.6 Case Study: Africa Centre for Disease Control and Prevention

The Africa Centre for Disease Control and Prevention (ACDC) is the premiere public health agency of the African Union that was set up in 2016 to ensure disease control and prevention within the continent. Regarding vaccines, the ACDC is involved with procurement, deployment, and increasing vaccine manufacturing capacities within the member states.

Trusted Vaccines is a specialised unit within the ACDC that partners with the private sector and non-governmental agencies on a continental basis to rapidly transform the African vaccination system using modern technology. The objectives of Trusted Vaccines are to: (i) develop the capability of countries to digitise their entire vaccine management systems; (ii) provide an intergovernmental means to verify that citizens of African member states receive genuine vaccines; and (iii) allow member states to deploy these solutions on a timely basis. (More on the Trusted Vaccines objectives and model can be found [here](#))

Achieving all of these will require action across four key domains (see Figure 18):

- I. Cross border travel solutions that will provide and streamline inter-country support and vaccination documentation for member states;
- II. Vaccine record management and tracking of all vaccination data across health systems and prevention of poor data management;
- III. Vaccine allocation & administration Scheduling that which ensure fairness and equity in vaccine distribution across member states;

- IV. Post-vaccine administration and feedback management for monitoring, reporting, and recording of side effects and personalised risk communications through to enhanced transparency to address vaccine hesitancy.

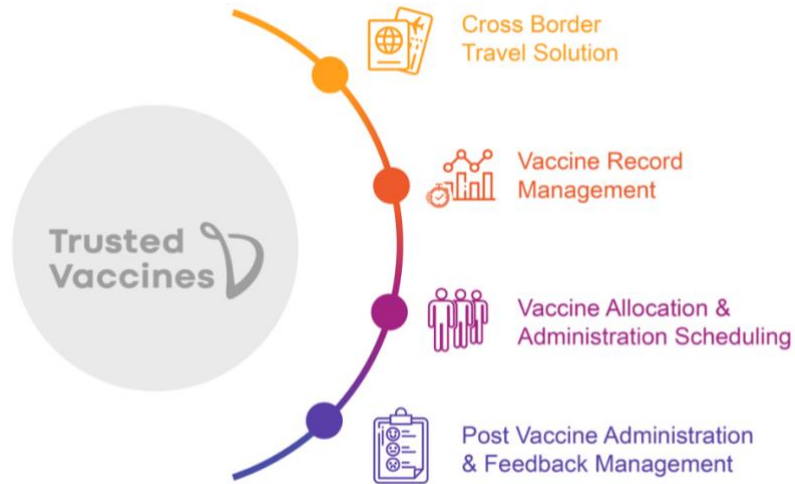


Figure 18. Africa CDC's Trusted Vaccines Model

### 3.7 Case Study: Zenysis

The Global Health Strategy Group for Digital Health and AI for health is keen to hear from, and work with, innovative private-sector companies who share their vision to make digital and AI tools available across the world and to support the needs especially of the poor. Zenysis is a 'Big Data' and Artificial Intelligence (AI) company that builds advanced analytics software for public health entities in low- and middle-income countries. Their software helps break down silos between data systems and collates data together in one space to enhance insights and decision-making. Their software is currently used in 10 countries in Africa, Asia, and Latin America to support national health programmes and emergency vaccination campaigns in an equitable, efficient, and data-driven way.

Zenysis' system works on top of existing data systems to safely and securely integrate data from any source. The integration process harmonises data in a new common format so that clients can conduct fast and easy analyses (see Figure 19). Zenysis' data quality tools help clients identify and address data-quality problems, and Zenysis' delivery model incorporates intensive capacity building and the option of an open-source software solution.

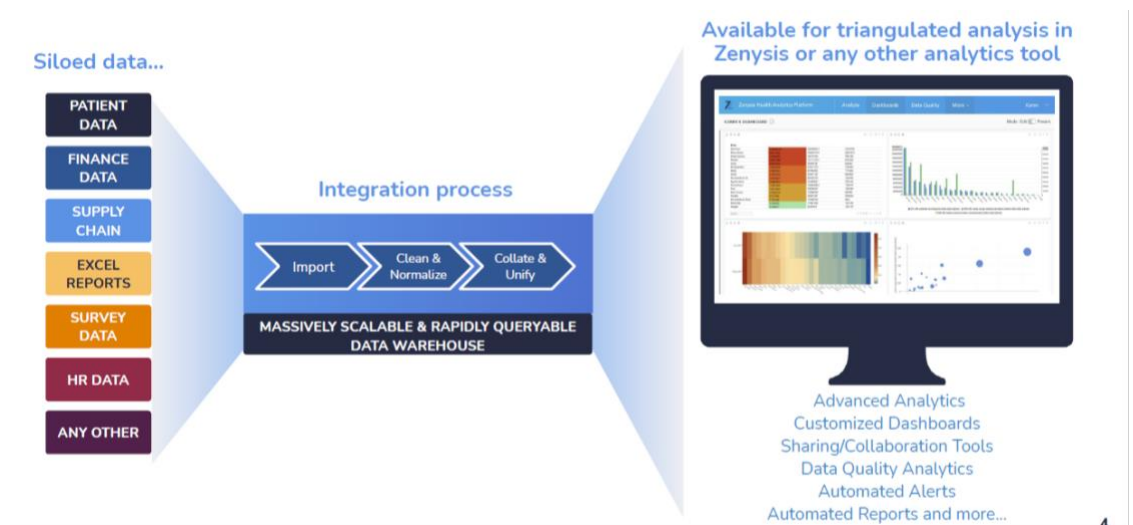


Figure 19. Zenysis Value Proposition

Because the Zenysis system allows decision makers to access real-time high-resolution analytics, it has been used in the vaccine space by countries to manage their COVID-19 response, to monitor supply chains, and to enhance transparency. In Mozambique, Rwanda, South Africa, and Zambia, for example, program managers have used the software to reduce vaccine stockouts, to reduce wastage, and to improve allocation of scarce resource to high-impact areas.

### 3.8 Case Study: Centrale Humanitaire Médico-Pharmaceutique

Centrale Humanitaire Médico-Pharmaceutique (CHMP) is a non-profit humanitarian pharmaceutical wholesaler, founded in 1992 by Pharmacists without Borders. Their mission is mainly to ensure the availability of high-quality health products to populations in Kenya and neighbouring regions.

CHMP pursues a four-pronged strategy to achieve its goals:

- i) Provide health product supply-chain solutions that work in changing and complex environments;
- ii) Ensure compliance of health products with national and international standards;
- iii) raise awareness about health product quality;
- iv) Ensure value for money for products.

Their quality assurance work spans three levels. They provide staff training for quality assurance, developing laboratory controls, and they carry out validation of product sources using international best practices.

Over the next five years, CHMP aims to significantly enhance the innovation aspect of their work. Currently, they are already implementing an M&E system, which is a real-time dashboard that allows them to track data within their organisation. Moreover, they are finalising an electronic data management system that will allow them to track the flow of documents across the organisation itself. Finally, they have an online shopping cart which makes it easier for their clients to interact with them.

They are also developing three apps that will be operationalised within the next 5 years. These apps will automate the quality assurance audit process, enhance real-time inventory checks, and empower consumers to trace where products are coming from based on barcodes.

### 3.9 Case Study: minoHealth AI Labs

Recognising that there is a shortage of clinicians globally, minoHealth works to develop scalable AI for health solutions for infectious diseases, looking especially at radiology and more broadly biomedical research and health (see Figure 20 as an example). They focus on digital diagnostics for diseases like COVID-19 and Malaria, and work to develop handheld lab-on-a-chip molecular diagnostics systems that can be used for point-of-care diagnosis.

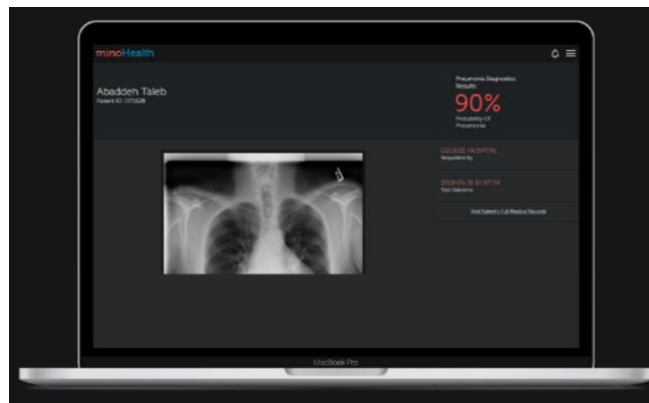


Figure 20. minoHealth AI Diagnostic Tool

They also started the AI4COVID-19 Initiative and developed the first real-time dashboard which tracked COVID-19 cases across Africa. Additionally, they ran a hackathon which put together developers with the Runmila AI Institute and developed solutions for analysing medical images and applied those to COVID-19.

Currently, they are working on a number of other projects including the use of AI in Malaria immunology, and to combat vaccine misinformation.

## Conclusion

It is now more important than ever to ensure that all people in need of COVID-19 vaccines, regardless of where they live, have access to them. The pandemic continues to be a complex challenge and our strategies to address it require new approaches. We have seen rich countries amassing stockpiles of vaccines in competition with, and to the detriment of, low- and middle-income countries, but the available evidence shows that this is not a long-term viable solution and, ultimately, is to the detriment of all.

The world is far too interconnected for COVID-19 to be addressed effectively through nationalistic approaches. It is not sufficient for richer countries to introduce booster vaccines while paying insufficient attention to the fact that many countries are struggling to immunise just 10% of their populations with the first dose. Indeed, and as this report shows, such disparities lead to harmful outcomes; they drive the proliferation of substandard and falsified (SF) vaccines and risk the spread of viral variants prolonging the pandemic.

Beyond improving the supply of vaccines, we need to be quicker in the delivery of safe vaccines and to improve collaboration and funding for cross-cutting innovations. We need to introduce, scale-up, and sustain the use of digital technologies to ensure the delivery of authentic vaccines. The Abuja Principles provide guidelines for how we can better design, develop, and implement such technologies, while the case studies presented highlight how we can operationalise them. The world came together to develop the vaccines. What is needed now is a commensurate level of commitment, investment, and buy-in from all stakeholders necessary to tackle the pandemic with the urgency it deserves. No one is safe until we are all safe. The world needs to come together to get the job done.

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## Appendix: Organisations and Speakers

The Vaccine Access meeting was co-chaired by **Andrew Farlow** and **Paul Lotay**, co-chairs of the Supply & Market Dynamics and Medicine Quality Working Group of the COVID-19 Clinical Research Coalition



Prof. Mojisola Adeyeye,  
NAFDAC, Director-General



Prof. Paul Newton,  
IDDO and MORU, Head



Bright Simons,  
Mpedigree, CEO



Prof. Andy Pollard,  
Oxford Vaccine Group, Director



Hamidreza Setayesh,  
COVAX, Senior Country Manager



Zabi Kamran, UNICEF,  
Immunization Specialist



Deogratias Mzurikwao,  
Villgro Africa, AI lead



Harriet Teare,  
RAND Europe, Research leader



Paul Lotay, CHMP, CEO, **Co-chair of the workshop**



Darlington Akogo,  
minoHealth AI Labs, Founder and Director



James Bolster,  
Zenysis Technologies, Manager



Moz Siddiqui,  
Gavi, Head of Strategic Innovation and Partnerships



Elvis Sedah,  
Africa CDC, Trusted Vaccines Cluster Coordinator



Laila Pelletier,  
Harras-Covid-19 Clinical Research Coalition, Project Associate



Prof. Anurag Agrawal,  
Lancet-Financial Times Commission, Co-chair



Folasade Osho  
NAFDAC, Assistant Chief Regulatory Officer



Saleem Sayani, Aga Khan Development Health Resource Centre, Director



Andrew Farlow,  
Oxford in Berlin, Head of Global Health Initiatives, **Co-chair of the workshop**