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Securing trust in the global COVID-19 supply chain



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## From development and delivery to acceptance and administration

Scientists have come together in an unparalleled worldwide collaboration and sharing of data to advance a COVID-19 vaccine.<sup>1</sup> As rollouts become reality, stakeholders from across the globe will need to collaborate to ensure these vaccines are available and accepted. Vaccines will need a high level of trust for a return to normal. Trust will be a cornerstone for the successful launch, distribution, and acceptance of vaccines.

Initially, government leaders and regulators will be making life-saving decisions for limited supplies of vaccines, while production gears up to meet demand. Each vaccine has its own specialized requirements, and each country has varying resources to accommodate them—making an already complex supply chain, even more complex and uncertain.

Life science leaders will need to focus on the areas they can control, such as product integrity, behaving ethically, and communicating transparently.<sup>2</sup> Transparency will help to instill confidence that vaccines are safe and genuine, and that allocation is being done fairly and equitably worldwide.

Trust is the belief that another will behave with integrity and consistency—and cannot only be embodied by individuals and institutions—but also by standards, processes, and technology. To secure public trust, organizations will need to:

- Advance industry collaboration across the value chain
- Embrace and promote global standards for supply chain security
- Anticipate challenges for safe and efficacious delivery of vaccines
- Use clear and transparent communications for vaccine confidence

Being proactive is key.<sup>3</sup> Those who achieve a strong degree of public trust will have successfully conveyed their humanity and transparency, while meeting uncertainty head-on in the global COVID-19 supply chain.<sup>4</sup>

## Advancing industry collaboration

According to organizations like ClinicalTrials.gov and FasterCures, there are approximately 4,000 studies underway globally for vaccines and therapies related to COVID-19.<sup>5</sup> More than 200 trials are specific to vaccine development and vary by technology, conditions for storage, location, and size of clinical trial.<sup>6</sup> The World Health Organization (WHO) tracks progress on the development of vaccine candidates around the world.<sup>7</sup>

#### Key trials open to public scrutiny

Transparency helps to build trust. When organizations are transparent and openly share information, they instill confidence.<sup>8</sup> Every interaction either gains or loses trust, and one bad player may negate the efforts of many.<sup>9</sup>

Due to the unprecedented demand for openness and transparency, a few companies with leading COVID-19 vaccines (e.g., Oxford/AstraZeneca, Johnson & Johnson's Janssen Pharmaceuticals, Moderna, and Pfizer/BioNTech) are providing far greater detail about critical trial protocols than was previously available. Industry cooperation created a rare opportunity for a "real time" exchange on the scientific, deliberative, and inclusive trial process—a great win for public trust.<sup>10</sup>

Likewise, partnerships in vaccine development and trials with universities or other unaffiliated organizations create trust. According to Johnson & Johnson's Chairman and CEO Alex Gorsky, pharmaceutical companies are not competing against each other on the development of a vaccines but collaborating with the world's top scientists to save lives.<sup>11</sup>

#### "The best possible position we could be in is where we have four or five or six of these vaccines available in the year 2021."

- Alex Gorsky, Chairman and CEO, Johnson & Johnson<sup>12</sup>

Early information sharing between all stakeholders, including the pharmaceutical industry, was unusually open and transparent—driving rapid development of COVID-19 vaccines. Vaccines moved from concept to Phase 3 trials to Emergency Use Authorization (EUA) in a record-breaking 11 months. Leading candidates are already demonstrating exceptional efficacy rates from clinical trials, and vaccines will continue to be robustly tested and monitored for safety as they are administered in real world conditions.<sup>13</sup>

#### The difference between efficacy and effectiveness

With such high degrees of efficacy being achieved for early vaccine candidates, it is important to communicate that efficacy is not the same as effectiveness. According to Gavi, the Vaccine Alliance, efficacy is the degree to which a vaccine prevents disease, and possibly also transmission, under ideal and controlled circumstances, i.e., comparing a vaccinated group with a placebo group in a clinical trial. Effectiveness refers to how well the vaccine performs in the real world. It will require several months after a vaccine is administered to a population to demonstrate its effectiveness.14

#### Worldwide demand for billions of vaccine doses

Multiple vaccines will be necessary to meet the need for worldwide vaccination, and the initial supply of successful vaccines may be limited.<sup>15</sup> As production ramps up, countries and groups have secured their supply with contracts from multiple vaccine manufacturers (Figure 1).

Figure 1: Vaccine manufacturers and number of doses contracted by country or group\*

	Vaccine Manufacturers & Doses Contracted*									
Country / Group	Pfizer/ BioNTech	Moderna	JNJ	AstraZeneca	Sanofi / GSK	Novavax / Takeda	CureVac	Valneva	Sinovac	
USA	100M (initial purchase w/ opp to buy add'l 500M)	100M (initial purchase w/ opp to buy add'l 400M)	100M	300M	100M	100M	n/a	n/a	n/a	
European Union (EU)	200M (initial purchase w/ opp to buy add'l 100M)	160M	200M (initial purchase w/ opp to buy add'l 200M)	400M	300M	n/a	225M (initial purchase w/ opp to buy add'l 180M)	n/a	n/a	
Japan	120M	50M	n/a	120M	n/a	250M	n/a	n/a	n/a	
United Kingdom	40M	5M		100M	60M	60M	n/a	60M (initial purchase w/ opp to buy add'l 130M)	n/a	
Latin America (excluding Brazil)	n/a	n/a	n/a	250M	n/a	n/a	n/a	n/a	n/a	
Brazil	n/a	n/a	n/a	100M	n/a	n/a	n/a	n/a	120M	
Canada	20M	56M	38M	n/a	72M	76M	n/a	n/a	n/a	
Australia	10M	n/a	n/a	33.8M	n/a	40M	n/a	n/a	n/a	
Indonesia	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	40M	

\*Data as of November 25, 2020

Source: Deloitte Analysis

For most COVID-19 vaccine products, two doses of vaccine, separated by 21 or 28 days, will be needed from the same manufacturer. This adds a significant degree of complexity to an already complex supply chain. Not only does a vaccine need to be available for a patient at a specific time interval, it will need to be the same vaccine.

As part of the doses secured in Figure 1, the US Department of Health & Human Services (HHS) expects to have 40 million COVID-19 vaccine doses available in December 2020—enough for 20 million people designated high-priority, such as frontline health care workers and nursing home residents and staff. The general public will likely start receiving vaccines in the spring 2021.<sup>16</sup>

The EU Commission has secured vaccines for 430 million people—enough for virtually every EU resident. Priority access for the initial supply will likely go to health workers, and experts say it is essential to develop a policy for allocation supported by the general public.<sup>17</sup>

Successful and equitable vaccination strategies will need to consider many factors and ethical tradeoffs. For example, some countries may have high transmission of the COVID-19 virus, while others may only have local outbreaks.<sup>18</sup>

#### No dose wasted, everyone's goal

As the industry prepares for the global storage and distribution of vaccines against COVID-19, it is critical that stakeholders work together to identify all possible logistics requirements and bottlenecks across the end-to-end supply chain.<sup>19</sup> From laboratory to patient, extraordinary collaboration will be required between governments, NGOs, private companies, not-for-profit organizations, and health care providers to ensure that no single dose is wasted and to enable pharmacovigilance.<sup>20</sup>

#### Supply chain will rely on public-private partnerships and institutional trust

As a leading public-private partnership, Gavi has been a very effective collaborator between multi-lateral organizations—especially the World Health Organization (WHO), the UN Children's Fund (UNICEF), and the World Bank. The Bill and Melinda Gates Foundation is a key Gavi partner in vaccine market shaping, and the organization plays both a technical and financial role in the Vaccine Alliance's efforts. Vaccines have become the Gates Foundation's biggest investment.<sup>21</sup>

COVAX is the third pillar of the ACT Accelerator focused on vaccines, and the initiative is being coordinated by Gavi, the WHO, and the Coalition for Epidemic Preparedness Innovations (CEPI).<sup>23</sup> More than 180 countries have joined the COVAX initiative, and COVAX is working with manufacturers towards an initial aim of 2 billion COVID-19 vaccine doses by the end of 2021.<sup>24</sup>

## What is the ACT Accelerator?

In response to the pandemic, the Access to COVID-19 Tools (ACT) Accelerator was launched by the WHO, the European Commission, and France, to provide innovative and equitable access to COVID-19 diagnostics, treatments and vaccines. ACT brings together governments, global health organizations, manufacturers, scientists, the private sector, civil society, and philanthropy.<sup>22</sup>

"Our belief in a fast-moving pandemic is you're not safe unless everyone is safe. What the COVAX Facility (Figure 2) is trying to do is to get a vaccine out to all countries, rich and poor, at the same time."<sup>25</sup>

- Dr. Seth Berkley, Chief Executive Officer, Gavi

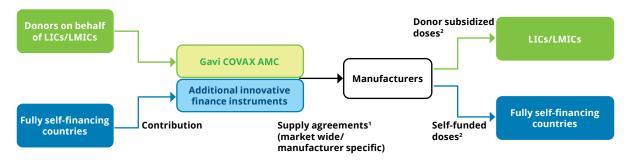


Figure 2: The COVAX Facility, coordinated by Gavi Secretariat, implemented by ACT Accelerator actors

1. Agreements with manufacturers would be unified across full scope of countries participating in the Facility, but ODA funding will only be used to support LICs and LMICs

2. Financing for procurement incremental to contributions

Source: Gavi COVAX Facility, Preliminary Technical Design<sup>26</sup>

Protecting supply chain integrity is an important aspect of ACT's broader multi-agency effort,<sup>27</sup> and all coordinating members of COVAX have extensive experience in resolving logistics challenges. Collectively, these organizations also represent a high degree of institutional trust.<sup>28</sup>

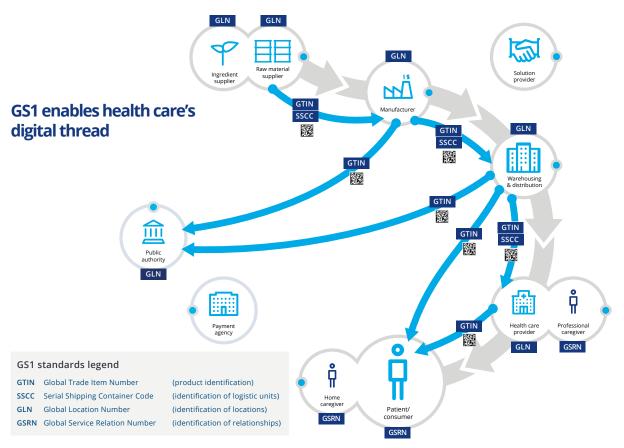
Institutional trust is a critical factor in influencing preventive behavior during an outbreak.<sup>29</sup> Past experience with the Ebola vaccine shows that engaging locally trusted leaders and service providers can help to build trust, while a lack of institutional trust and widespread misinformation can undermine vaccine efforts.<sup>30</sup>

## Embracing global standards

#### Minimizing supply chain hiccups, advancing interoperability

COVID-19 vaccines and therapeutics, plus associated medical devices and consumables, present an urgent need for a system of traceability built around globally identified products. The not-for-profit global standards organization GS1 (Figure 3)<sup>31</sup> has developed the most widely utilized supply chain standards.<sup>32</sup>

Figure 3: GS1 Global Digital Thread in Supply Chain



Source: GS1

Use of global GS1 standards means that every product, at every level of packaging, is uniquely identified. This identification information is captured in a standardized barcode that is able to be read by all supply chain partners.<sup>33</sup> In addition to vaccines, standards provide a level of trust for:

- The medical supplies needed to administer vaccines
- The medicines and medical devices required to treat COVID patients
- The personal protective equipment needed to protect clinical caregivers and the population

Information is able to be shared in a standardized way with health authorities and up and down the supply chain throughout manufacturing, shipping, distribution, and use processes. This standardization also benefits post market and pharmacovigilance activities.

Using existing standards for harmonized implementation of regulatory requirements will further patient safety goals. Embracing GS1 standards adds an element of trust at all levels of the supply chain—a trust that ultimately extends to the patients themselves.<sup>34</sup>

#### Marking vaccines with GS1's DataMatrix

Vaccine identification information (like product identifier, lot number, and expiration date) is essential for health care providers to administer vaccines with confidence and improve the supply chain. For this reason, the WHO recommends that all vaccines be identified with this data in a standardized barcode.<sup>35</sup>

More than 70 countries have health care regulations or trading partner requirements for which industry uses GS1 standards. Today, these countries, as well as Gavi and UNICEF, rely on GS1's DataMatrix two-dimensional (2D) barcodes that can encode vaccine information to reduce errors and improve efficiency and safety.<sup>36</sup>

Manual processes to record product information are still in use today, especially in many low- to middle-income countries.<sup>37</sup> But the drive to health care digitization, accelerated by COVID-19, may help increase the capability to leverage global standards and barcode scanning—not only for vaccines but for all health care products. For these countries, using mobile phones for scanning DataMatrix barcodes might be a good option to consider.

#### Scaling up product identification and traceability

Traceability is the ability to track forward the movement through specified stages of the extended supply chain, and trace backward the history, application, or location of that which is under consideration. Different traceability models can be established. Today, more than 70 countries today have track and trace systems, while the EU has established an end-to-end verification system. Both of these traceability systems are intended to ensure that the correct product reaches the patient and is able to be trusted.

GS1 standards for product identification are used as the foundation of these traceability systems. For effective traceability to occur, each product being traced will need to have a unique identifier. Application of GS1 standards enables harmonized implementation and fosters global interoperability.

Serialization is a form of product identification whereby a specific drug pack has a globally unique number. This number is used to confirm its authenticity along the supply chain prior to sale, dispensing, return, or recall. Although not every country with traceability requirements has serialization requirements, many countries and regions have established traceability systems or are developing them.<sup>38</sup> Low- and middle-income countries are also sensitive to the importance of serialization and are expected to be part of the next wave of regulatory requirements.

In the first wave of the pandemic, hoarding was, and may continue to be, an issue. Traceability allows health care providers and authorities to have better visibility and control of stock and inventory. It also provides the necessary data that allows manufacturers and health authorities to accurately plan. It gives those who rely on that inventory a sense of trust in the supply processes and ensures that the products they need are available and not expired.

Building a traceability system now, not only addresses immediate challenges, but is an investment for the future. Traceability systems for vaccines can also be used for any other medicinal products when using standardized product identification and processes.

#### **Global harmonization approach**

Following the WHO's recommendations, a DataMatrix should be applied on the secondary packaging (carton boxes), and if possible, also on the primary packaging (vial or prefilled syringe). UNICEF recently announced it will utilize GS1 barcodes on packaging beyond primary level to improve traceability of vaccines (see Annex E). The DataMatrix is able to encode:

- The vaccine identification code
- Date of expiration
- Lot number
- Serialization (depending of the packaging level)

The European Medicines Agency (EMA) and EU Member States agree that COVID-19 vaccines will have to meet the requirements for the EU Falsified Medicine Directive for identification and labeling. In practice, all of the COVID-19 vaccines supplied to the EU will need to be marked on the secondary packaging with:

- A DataMatrix encoding a Global Trade Identification Number (GTIN)
- Lot number
- Expiry date

In the US, the requirements for drug identification and labeling for the COVID-19 vaccines will require:

- A 2D barcode containing the National Drug Code (NDC) embedded in the GTIN
- The lot number
- A placeholder expiration date of 12/31/2069 on secondary level packaging

In Russia, the COVID-19 vaccines will fall under the scope of the current system of medicines traceability based on a DataMatrix, with GTIN and related identification attributes. Health authorities in some low- and middle-income countries may have divergent requirements despite their intention to align with global standards.<sup>39</sup>

This global alignment on the use of global standards for identification and barcoding of the vaccines will enable traceability across borders to reduce falsification, enable precise product identification in patient health records, and facilitate recalls or adverse event reports.

#### Tracking vaccinations with a digital health passport

G20 leaders recently discussed the need for a uniform set of policies and standards to ensure smooth functioning of the world economy during the pandemic. Experts agree that once vaccines are available, there may be a need for some type of international "digital health passport" and multiple initiatives are underway.<sup>40</sup> Such international, regional, or even national health passports would enable free movement of people again by providing trusted electronic information on who has been vaccinated.

## Anticipating challenges for safe and efficacious delivery of vaccines

#### Product integrity and safety monitoring

In the US, the Vaccines and Related Biological Products Advisory Committee (VRBPAC) provides outside guidance to instill confidence in the authorization process.<sup>41</sup> The US Food & Drug Administration's (FDA) goal is also to be as transparent as possible about the scientific basis for recommending that a drug or biological product is authorized for emergency use.<sup>42</sup> After randomized trials determine vaccine efficacy and a vaccine is approved, effectiveness will be tracked by safety monitoring.

Globally unique identification and barcoding of the vaccines will not only be critical for clinical trials and distribution, but for administration sites. It is important to identify and label the vaccines, capturing precisely which patient, received which vaccine, and when. Visibility enabled by aggregating global data will engender a higher degree of trust.

While controlled randomized trials may reveal some side effects, adverse reactions that are uncommon, or that occur in subpopulations, may not emerge until the vaccine is widely distributed. Rapid, rigorous science is necessary to determine if these events stem from the vaccine, or if they would have occurred regardless.<sup>43</sup> Given the sheer number of vaccinations planned to be administered, the scope and volume of reported adverse events will be unprecedented, and require the coordinated application of people, process, and technology to capture and address relevant safety signals. It will need to be possible to contact the affected patients quickly and efficiently. As a result, a robust patient contact protocol is essential.

"Nothing would undermine delivery of successful COVID-19 vaccines and therapeutic treatments faster than the emergence of fake vaccines."

> Tom Woods, Chairman of the Global Steering Committee for Quality Assurance of Health Products for the World Bank<sup>44</sup>

As this COVID-19 vaccination program is expected to be one of the most challenging and complex ever faced worldwide, leveraging current best practices (e.g., embracing global standards) and ensuring that all stakeholders are moving towards the same direction will be critical. During the first few months of the pandemic, an 18 percent increase in counterfeit products was observed, and the first fake COVID-19 vaccines already came onto the market in South America.

It is expected that the highly anticipated vaccines, needed by so many people, will have the highest risk of being falsified. This should be monitored and prevented to avoid significantly undermining public trust in safe vaccines. This is where track and trace plays a critical role.

#### Optimizing delivery and last mile cold chain challenges

The cold chain requirements for these vaccines are an unprecedented logistical challenge on a global scale.<sup>45</sup> Administration sites will need to have capabilities for storing, handling, and administering vaccine products, each with its own distribution and administration requirements. Health care workers may not be equipped to deal with these special requirements, and vaccine administration will need to be organized in such a way that vaccines are tracked and not wasted. Multi-dose vials, once opened, may expire within hours.<sup>46</sup>

The Pfizer/BioNTech vaccine requires "ultra-cold" storage at minus 70° Celsius ±10°C (-94° F) and can be kept up to 15 days. Once thawed, the vaccine vial can be stored for up to 5 days at refrigerated (2 - 80C, 36°- 46°F) conditions.<sup>48</sup> Moderna's vaccine requires standard refrigerator temperatures and can be kept up to 30 days.<sup>49</sup> CureVac says its mRNA vaccine, currently in Phase 1 trials, could be stored for up to three months under normal refrigeration.<sup>50</sup>

According to German logistics company DHL, only 25 countries have the necessary ultra-cold storage infrastructure, and remote areas throughout the world are not likely to receive some of these vaccines. Refrigeration is already limited in most of Africa, central and southeast Asia, India, and smaller countries in Latin America, and minus 70° Celsius, in particular, cannot be accommodated. The necessary type of air transportation is also very limited in these countries.<sup>51</sup>

Vaccines being developed via traditional methods and with less stringent refrigeration requirements, like the Oxford/AstraZeneca and Johnson & Johnson vaccines, will be critical for low- to middle-income countries with limited cold chain capabilities, extreme weather conditions, or very remote populations.<sup>52</sup>

## What is a "cold chain"?

Delivering vaccines around the world takes a chain of precisely coordinated events in temperature-controlled environments. Vaccines need to be continuously stored and transported in a specific temperature range, that varies by vaccine—from the time they are manufactured until the moment of vaccination. To keep vaccines at specific cold temperatures requires special equipment like cold rooms, refrigerators, freezers, cold boxes, and vaccine carriers. For example, the Pfizer/BioNTech mRNA vaccine needs to be stored at "ultra-cold" temperatures.47

In the US, most COVID-19 vaccines will be delivered from the Centers for Disease Control and Prevention's (CDC) centralized distributor directly to the location where the vaccine will be stored and administered. In many European countries vaccination centers are planned. However, even in the developed world, rural areas will be disadvantaged.<sup>53</sup>

Technologies, such as barcodes and Vaccine Vial Monitors (VVM), will be critical to ensure that product integrity is preserved and the cold chain has not been broken. Trust at the last mile will also mean that patient safety protocols are followed, and patients can be assured that vaccines are safe and not counterfeit.

#### Anticipating alternative administration sites for marginalized populations

Vulnerable, remote, and minority populations need to be engaged earlier to earn and build trust. Vaccine manufacturers are already trying to educate the public and are creating vaccine content especially targeted to minority communities most impacted by the virus.<sup>54</sup>

Individuals may be fearful or wary of seeking vaccination at sites that have historically caused mistrust or are otherwise unsafe. Experts suggest public health agencies should consider taking vaccinations out of medical settings and into places where people work or shop. Alternative sites should be considered that may also provide urgently needed services, like food aid, employment aid, or other preventive health services.<sup>55</sup>

Planning for a satellite, temporary, or off-site vaccination clinic requires additional considerations during the pandemic.<sup>56</sup> Social distancing, masks, and other precautions will be necessary to protect caregivers and patients, and to ensure trust. Public health workers will need to be culturally competent. Culturally appropriate, translated materials for education should be available to clinicians tasked with vaccinations.<sup>57</sup>

Vaccine expert Dr. Walter Orenstein suggests that primary care providers be paid for vaccine counseling.<sup>58</sup> He also suggests collaborating with trusted leaders of culturally diverse groups to disseminate information and to reassure people. These communications need to be transparent and include:

- Information on vaccine development, including criteria for approval
- Strength of the data for each vaccine's safety and effectiveness
- Information on how side effects and adverse events will be monitored<sup>59</sup>

#### Lessons learned from past vaccine experiences

The H1N1 vaccine program in 2009-2010 provides a model for a safe and transparent vaccine monitoring system. In the US, the National Vaccine Program office was solely tasked with looking at the safety data of the H1N1 vaccine, independent of outside interests. Notably, the group's plans were made available to raise awareness with the public and all stakeholders, including the media, state and local health departments, and medical associations.<sup>60</sup>

There is also a concern that different types of vaccines may be mixed and matched depending on availability and effectiveness. Francis Collins, the director of the US National Institutes of Health (NIH), says that when the shingles vaccine was introduced, people got vaccinated. But years later, a better one came along, and many took both.<sup>61</sup>

Unexpected side effects of mixing vaccines may occur if taken within a short period of time. If an initial vaccine has unexpected side effects, or is not effective, the experience may deter people from getting the next vaccine—even though the new vaccine may provide better protection. Many of the vaccines will require two doses. If a patient is not tracked, or skips the second dose, they may not reap the full benefit of immunization.<sup>62</sup> The use of barcodes, linking the product to the patient, can address these concerns.

# Using clear and transparent communication to build vaccine confidence

For vaccine developers, health care stakeholders, and society at large, the level of transparency and public trust will determine COVID-19 vaccine acceptance and confidence.<sup>63</sup> Vaccine uptake will need to be facilitated by clear, evidence-based, and tested communications.

#### Achieving herd immunity and vaccine uptake

Some experts are optimistic that multiple vaccines could represent a return to normalcy and an end to the pandemic.<sup>64</sup> Others are concerned that people will be reluctant to take the vaccines, especially in rural or remote areas.<sup>65</sup> Herd immunity cannot be achieved without sufficient uptake of COVID-19 vaccines.

#### "Vaccines don't save lives. Vaccinations save lives. Persons for whom vaccines are recommended need to receive them if there is to be a benefit to the individual as well as society."

— Walter Orenstein, MD, Professor and Associate Director, Emory Vaccine Center<sup>66</sup>

Experts are still not sure what the sweet spot for herd immunity to COVID-19 will be. Professor Ali Mokdad of the Institute for Health Metrics and Evaluation (IHME) at the University of Washington predicts it will be higher than 70 percent.<sup>67</sup>

#### **Tracking vaccine confidence**

Confidence in the safety of vaccines fluctuates around the world.<sup>68</sup> In September 2020, the World Economic Forum and Ipsos conducted a global survey of nearly 20,000 adults across 27 countries (Figure 4). The survey found that an average of 74 percent of people say that they are willing to get a COVID-19 vaccine when it is available, while 26 percent are not.<sup>69</sup>

The 26 percent shortfall in confidence is significant enough to compromise the effectiveness of rolling out a COVID-19 vaccine. Therefore, experts say it is critical that governments and the private sector come together to build confidence and ensure that patients have trust in the newly developed vaccines—especially since vaccination may be voluntary in many parts of the world.<sup>70</sup>

	Total Agree							ſ	Total Disagree
Global Average	74%	37%		37%		15	5%	12%	26%
China	97%	38%			59%			2%1%	3%
Brazil	88%		64%			25%		8% 4%	12%
Australia	88%	5	9%			28%		8% 5%	12%
India	87%	44%			44%			9% 4%	13%
Malaysia	85%	35%		51	%			11% 4%	15%
Great Britain	85%	52%			33%		99	6 7%	15%
South Korea	84%	27%		58%				15% 1 <mark>%</mark>	16%
Saudi Arabia	84%	39%			45%		1	2% 4%	16%
Peru	79%	48%			31%		11%	10%	21%
Canada	76%	48%			29%		13%Canada	11%	24%
Argentina	76%	47%			29%		14%	10%	25%
Mexico	75%	38%		37%			3%	12%	25%
Japan	75%	24%		51%			20%	5%	25%
Spain	72%	38%		34%		17	%	11%	28%
Netherlands	71%	38%		33%		16%		13%	29%
Turkey	70%	42%		28%		14%		16%	30%
Belgium		34%		36%		17%		13%	30%
Chile		40%		30%		14%		16%	30%
Sweden		34%		33%		20%		13%	33%
United States	67%	35%		32%		17%		16%	33%
Germany	67%	36%		31%		20%		13%	33%
Italy		37%		29%		17%		17%	33%
South Africa		29%		35%		19%		18%	36%
France		22%	37%		21%	b		20%	41%
Hungary		19%	37%		17%		28%		44%
Poland		18%	37%		27%			18%	45%
Russia	54%	19%	34%		22%		24%	b	47%
		Strongly Agree	Somewhat Agree	Somewhat Dis	sagree	Strongly Disa	gree		

#### Figure 4: Interest in getting a COVID-19 vaccine\*

\*Data as of September 1, 2020 Source: World Economic Forum

Many people are undecided, and sentiments fluctuate over time and with media influence. If the "wait and see" group sits out the early months of a widespread vaccine rollout, achieving high population coverage will be delayed.<sup>71</sup>

Trends in public sentiment around the globe are being tracked by the Vaccine Confidence Project at the London School of Hygiene and Tropical Medicine (LSHTM). This project seeks to monitor public confidence in immunization programs by listening for early signals of public distrust.<sup>72</sup>

Through population surveys and social media analysis, data is being collected on attitudes towards potential COVID-19 treatments and vaccines. The project' goal is to build preparedness for introducing a COVID-19 vaccine and support public engagement strategies.<sup>73</sup>

According to Director Dr. Heidi Larson, the project's founder, dispelling vaccine hesitancy means building trust, not taking down misinformation. "It will just move," she says, as an advisor to health ministries, pharmaceutical companies, NGOs, and social media companies.<sup>74</sup>

#### **Overcoming vaccine hesitancy**

Vaccine hesitancy is a complex, rapidly changing global problem that varies widely. Vaccine uptake may be threatened in any country, region, or community where there is waning confidence in the government, doctors, or public health officials who recommend, oversee, and mandate vaccination.<sup>75</sup>

## What is vaccine hesitancy?

The WHO defines vaccine hesitancy as 'the delay in acceptance or refusal of vaccines despite the availability of vaccination services'. In 2019, vaccine hesitancy was already identified by the WHO as one of the top ten health threats to the world.<sup>76</sup>

Prominent messaging from anti-vaccination groups and concerns about the speed of the vaccine development process have led to wider skepticism of COVID-19 vaccines.<sup>77</sup> Any falsified or substandard product, as well as a unplanned side effects and serious adverse events, may increase doubts even more and could be very dangerous.

Another problem may be the unavailability of vaccines or associated products when needed. Establishing an interoperable traceability system that ensures product integrity is key for both worldwide perception of trust and the actual trustworthiness of vaccines, as well as other medicinal products.

The CDC will make use of its strategic framework, Vaccinate with Confidence, to strengthen public trust in vaccines.<sup>78</sup> Trusted voices and immunization of community leaders and celebrities could play a role in compelling members of the public to vaccinate. The motivation to be vaccinated results in actual vaccination only if practicalities of availability, accessibility, cost, convenience, service quality, and incentives are all addressed.<sup>79</sup>

Public health authorities should fund research and innovation to advance the behavioral and social science of COVID-19 vaccine acceptance. Strategies include:

- Engagement and support of community leaders
- Mass media campaigns to build vaccine confidence
- Training and tools for health care professionals<sup>80</sup>

According to Dr. Anthony Fauci, director of the US National Institute of Allergy and Infectious Diseases (NIAID), overcoming vaccine hesitancy requires considerable community engagement, trust, and consistent messaging from the government, especially for minority populations. He says that vaccine confidence could be raised by informing people about the criteria used for vaccine safety and highlighting the independent organizations and career scientists that play a pivotal role.<sup>81</sup>

#### Networked monitoring and communications for safety and effectiveness

In a global pandemic, what one country does may affect another. Dr. Orenstein says that it is critically important to establish national and international networks for monitoring potential rare side effects, and for health care providers to report these events to their reporting system. The reporting systems would then compare these adverse events with other vaccines to see if they are more prevalent for the COVID-19 vaccine.<sup>82</sup>

Whether the new vaccines will stop transmission, or how long immunity may last, is still unknown. With such high efficacy rates in clinical trials, expectations for effectiveness in populations may be high. Global access to reporting information and tools will be necessary. Dr. Orenstein says communications should be prepared in advance, using focus groups and scenario planning, to anticipate challenges of rare adverse events and to maintain trust.<sup>83</sup>

#### Vaccine risk communications and community engagement

Effective communication is key to dispelling fears, addressing concerns, and promoting vaccine acceptance.<sup>84</sup> While good communication can build confidence in care providers and public health authorities, the wrong type of messaging can erode trust. For example, some scientists have been critical about pharmaceutical companies making vaccine predictions.<sup>85</sup>

According to the Framework for Equitable Allocation of COVID-19 Vaccine, those responsible for vaccination risk communication and community engagement programs need to have:

- Agility, to respond rapidly to changing circumstances and feedback
- Competence, to apply relevant risk communication research
- Diversity, to involve needed perspectives
- Independence, to secure trust and provide candid feedback<sup>86</sup>

Experts say that communications developed for the public need to be consistent with evidence and tested before being disseminated. People overestimate how well they understand another's perspective or how well they themselves are understood. Unless messages are tested, audiences may be frustrated by not getting the information they need, or feel misled, if information is not interpreted as intended. Either way, trust can become compromised.<sup>87</sup>

## Building public trust through messaging

Health care stakeholders and vaccine developers need to know that is much easier to build trust when you're the first to articulate a message. It's equally important for people to hear the same message multiple times from a variety of sources. People respond to storytelling, and supplying a narrative provides value. People trust those in their networks, and act when they trust the messenger. They are less likely to trust a vaccine, if they question the motives of the those advocating for them to take it. People's choices are affected by how they see the world.88

"As the world gears up for the largest deployment of vaccines in history, it is more important than ever that supply chains are up to the task of maintaining trust and ensuring effective, timely delivery. We need to be able to trace every vaccine dose—from shipping to delivery and finally administration—using technologies such as 2D DataMatrix barcodes, and we need better adoption of common standards across to optimize cost and product visibility."

- Dr. Seth Berkley, Chief Executive Officer, Gavi

In an unprecedented way, the world has come together quickly for the fair and equitable distribution of vaccines to conquer the largest disease threat of our time, COVID-19. How we continue to respond and collaborate will define the world we continue to inhabit. Health care providers have been tasked with the biggest burden. Government leaders, regulators, and public health authorities need to continue to be sensitive to their safety and the resources they need. Leaders need to behave ethically and reassure the communities they represent.

The life science industry's innovation is on a world stage, and the pandemic has accelerated adoption of new technologies. We need to not step back, but collectively move the world forward. Global standards, like GS1, ensure supply chain security, increase patient safety, and provide trust in the vaccines, medicines, and medical products distributed.<sup>89</sup>

Health care workers will need to be trained and equipped to handle the massive undertaking of vaccine administration. Public-private partnerships should be maximized, and community leaders and influencers engaged. Raising immunization levels will depend on product integrity and transparent, culturally appropriate communications. Public health authorities will need to reduce vaccine hesitancy and build vaccine confidence. Public trust is paramount.

#### Everyone deserves to be safe. Meeting this challenge depends on all of us.

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