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Securing trust in the global supply chain of COVID-19 vaccines

**Moving from development success to
vaccination**





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Introduction

Most relationships depend on trust, and trust is built through actions that reflect both competence and the right intent, which in turn are the products of demonstrated capability; reliability; transparency; and humanity.¹ When it comes to life sciences and new therapies such as the COVID-19 vaccines, our [Securing trust in the global COVID-19 supply chain report](#), published in December 2020, identified four prerequisites to building citizens' trust in the vaccine supply:

- Advancing industry collaboration across the value chain to develop and test vaccines;
- Embracing and promoting global standards to ensure supply chain security, including expiry dates and product traceability protocols;
- Anticipating the challenges for safe and efficacious delivery of vaccines throughout urban and rural regions; and
- Using clear and transparent communications to enhance confidence in and motivate uptake of the new vaccines, including tactics to address vaccine hesitancy.

There has been progress on all these fronts, although it has been uneven.

- Trust in the COVID-19 supply chain has grown and shifted since their release. Many no longer are questioning “will vaccines work?” and “when will they be available?” but are now concerned with ensuring all parts of the world are vaccinated to reduce risk of new variants. Yet, there is still an ongoing need to build trust² in the vaccine supply chain so that citizens believe they are safe and efficacious, especially in countries such as those in Africa where traceability systems vary or do not exist. The lack of a global data repository of product identification information of all vaccines still impedes delivery or effective administration too often, and delays traceability.
- Optimizing in-country administration of the vaccines has met hurdles as well, including the lack of cold chain storage, challenging management of expiry dates, disparate use of serialization to uniquely identify products, and unreliable infrastructure to navigate the last mile. Still, mass vaccination sites in urban areas, public-private partnerships, and innovative community-based initiatives that enlisted contributors to distribute and administer vaccines in a range of settings showed promise.
- Communication campaigns have had varied impact. Significant investment by some governments, health care leaders and leaders of trusted nonprofits and non-governmental organizations successfully raised awareness and interest in the vaccines but fell short in addressing the root causes of vaccine hesitancy. The lack of diversity among communicators and fragmented community-based efforts allowed skepticism and confusion to flourish. In some countries, 15 to 20 percent of citizens decline any vaccination³ (first, second, and booster shots) regardless of proven safety and efficacy.

We have learned more about the complexity of the four critical success factors identified in our initial report. This update explores each factor in three dimensions: we highlight the successes and progress made (what worked); we identify remaining challenges and lessons learned about achieving each success factor; and we offer insights and potential solutions to those challenges.

The magnitude of suffering inflicted by COVID-19 is heartbreaking. Now, more than ever, leaders in the global health community must develop standards, processes, and capabilities that ensure citizens across the globe have access to lifesaving therapies. A transparent, secure, equitable supply chain is a factor in expanding access, which in turn builds trust.



Progress reflects exceptional global collaboration across the value chain

Expedited development of numerous effective vaccines

Nearly 30 vaccines globally were authorized for use by the end of 2021, with another 90 in development⁴—a remarkable achievement made possible by unprecedented data sharing among rival drug manufacturers and support for clinical development by companies and governments. The host of vaccines are based on traditional and new technologies, with some requiring one dose and others more than two. The International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) calculated manufacturers produced 11.2 billion doses of COVID-19 vaccine in 2021,⁵ making it the largest campaign in human history. Figure 1 shows the major vaccine manufacturers and doses shipped and administered after January 1, 2021.

Figure 1. Vaccine manufacturers & doses contracted

Vaccine Manufacturers & Doses Contracted								
Country/Group	Pfizer/BioNTech	Moderna	JNJ	AstraZeneca	Sanofi/GSK	Novavax/Takeda	CureVac	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
European Union	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
Japan	120M	50M	n/a	120M	n/a	250M	n/a	n/a
United Kingdom	40M	n/a	n/a	100M	60M	60M	n/a	n/a
Latin America (excluding Brazil)	5M	n/a	n/a	250M	n/a	n/a	n/a	n/a
Brazil	n/a	n/a	n/a	100M	n/a	n/a	n/a	120M
Canada	20M	56M	38M	n/a	72M	76M	n/a	n/a
Australia	10M	n/a	n/a	33.8M	n/a	40M	n/a	n/a
Indonesia	n/a	n/a	n/a	n/a	n/a	n/a	n/a	40M

Source: Deloitte analysis.

IFPMA found 11.2 billion vaccine doses were produced in 2021 through 300 partnerships that supported production in some way, of which 229 included the voluntary sharing of expertise, technologies, and quality processes to ensure doses met the highest quality standards.

Manufacturers successfully collaborated with governments, NGOs, private companies, nonprofits, and health care providers to increase supply, expedite delivery, and strive for equitable distribution. This collaboration could have led to perceptions of increased reliability and capability, and by extension, increased trust. The results are encouraging. By the end of January 2022, Our World in Data, an aggregator of COVID-19 information, reported that:

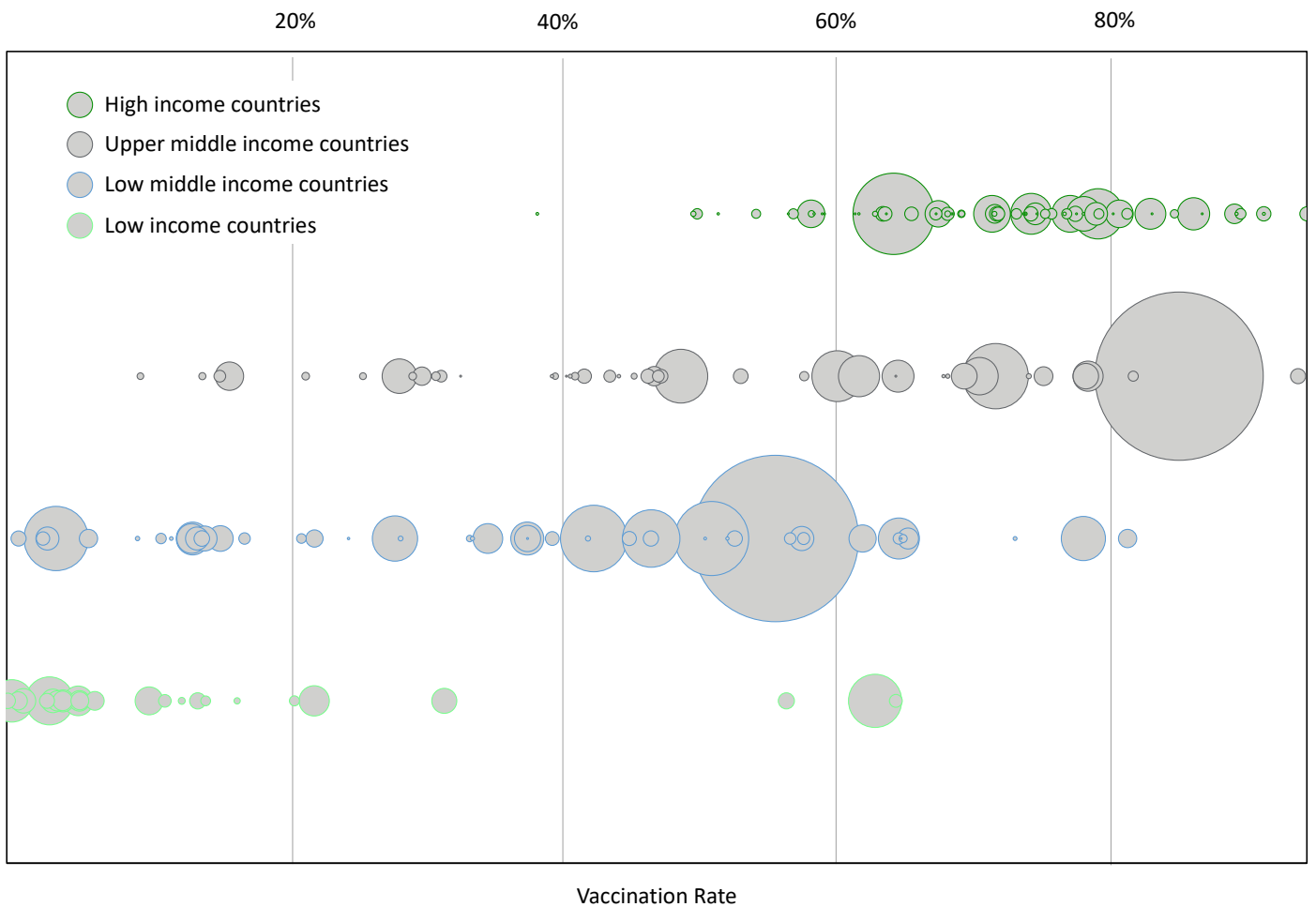
- Over 61 percent of the world population has received at least one dose of a COVID-19 vaccine, and
- More than 23 million doses are now administered each day.⁶

Multilateral organizations such as Gavi (Global Alliance for Vaccines and Immunization), the



World Health Organization (WHO), the World Bank, and the United Nations Children’s Fund (UNICEF) all played a role in understanding and meeting demand for vaccines in different markets. The ACT (Access to COVID-19 Tools) Accelerator launched by COVAX to ensure equitable access and distribution of vaccines facilitated shipments of one billion doses of vaccines to more than 140 countries⁷ working in conjunction with Gavi and the Coalition for Epidemic Preparedness Innovations (CEPI). Nonetheless, as shown in Figure 2, country vaccination rates varied significantly by income tiers.⁸

Figure 2. January 2022 country vaccination rates by income



Source: World Bank (2021), Our World in Data (February 2022); bubble size corresponds to size of country population.



Growing acknowledgement of need for global standards to secure supply chain

Given the number of manufacturers and different vaccines available, tracking and tracing shipping, delivery, and administration of vaccines was bound to be complex. Many stakeholders now recognize the need for globally standardized product identification to track the location and use of vaccines to gauge vaccination rates, identify adverse events, better match demand with supply, and stop fake vaccines from reaching patients. Accomplishing these goals also would build trust in the vaccines.

GS1 (www.gs1.org), an international nonprofit standards development organization, developed a unique, global standard to identify products more than 40 years ago: the Global Trade Item Number (GTIN®). In health care, it gained significant traction among manufacturers, health care systems or organizations, and logistics providers. The GTIN is the preferred method by WHO for vaccine identification and packaging. While the GTIN is recommended to be used with lot number and expiry date, tender requirements for forthcoming tenders of UNICEF and GAVI request a serial number to more effectively link one vaccine to one patient and to secure the supply chain.

The adoption of the GS1 identifiers allowed for quick shipment of vast volumes of vaccines. One example: Global logistics firm DHL found that the GTIN and Serial Shipping Container Code (SSCC) standards helped efficiently track vaccine shipments to hundreds of thousands of distribution points. “It is precisely by working with standards as much as possible that we succeeded in providing timely, high-quality service,” stated Peter Korte, vice president, life sciences and health care, Benelux, and Denmark, at DHL.⁹The company did not have to develop its own system, saving time and expense in distributing promised vaccines.

The advances in using global standards improved the traceability and integrity of vaccine shipments from manufacturers to destination countries or health agencies. Yet challenges remain in achieving last-mile traceability from country destination to patient administration.

Using traditional and creative tactics to deliver safe and efficacious vaccines

Effectively navigating the last mile to get vaccinations to citizens requires exceptional logistical planning, secure health care facilities, and reliable transportation as well as community engagement and communication. Multiple activities and resources need to exist and align for vaccines to move from a manufacturing facility to a patient.

Throughout early 2021, most vaccines were delivered in urban areas in high income countries. Governmental leaders and health care providers stood up temporary sites capable of administering doses of vaccines to thousands of people a day. Similarly, networks of pharmacies, clinics and community centers were used to administer vaccines and capture citizen vaccination data. Even as some citizens experienced frustrations in scheduling or delays in registering for uptakes, these sites proved efficient and cost-effective ways to boost vaccination rates in more densely populated areas.

Some health care agencies and communities are more creative in closing the last mile to reach eligible citizens. Instead of asking citizens to undertake inconvenient travel to

“It is precisely by working with standards as much as possible that we succeeded in providing timely, high-quality service,”

Peter Korte,
vice president, life sciences and health care, Benelux, and Denmark, at DHL.¹⁰



unfamiliar places, authorities have established alternative administration sites in area schools, grocery stores and even banks staffed by recognizable community leaders who support the vaccine initiative.

Similarly, some large employers have hosted vaccination days at company sites. In many developed countries, mobile medical vehicles were deployed to reach citizens both at alternative sites and in their homes. The Last Mile Vaccine Delivery program in Boston used EMTs, ambulance teams and firefighters to reach in-home shut-ins and students at high schools.¹¹ India has had great success targeting citizens in rural states through its Sanjeevani Pariyojana initiative, a supervised in-home care and vaccine program that makes use of local resources (see Sidebar). In Kenya, AMREF Health Africa dispatched helicoptering Flying Doctors¹² to bring vaccines to remote villages. Overall, this shift in strategy, about who and where vaccines are administered, can increase trust in the vaccines and the supply chain that delivered them.

Clear, transparent communications increased confidence in vaccines

Clear, coordinated, and continuous communication from leaders in government, health care, and local communities also builds trust in vaccines and increases vaccination rates. Transparency about progress in developing vaccines, and their delivery, was effective in early 2021.

Our earlier report identified the necessary components of an effective, comprehensive communication strategy to build trust in vaccines:

- Engagement and support of community leaders, and targeted interaction with populations with a history of vaccine hesitancy;
- Mass media campaigns to build vaccine confidence, highlighting the role of independent non-commercial organizations in vaccine development or administration; and
- Training and tools for health care professionals,¹³ including the ability to share product information and quickly report adverse events.

Many of these principles and related tactics were used, particularly broadcast public service announcements and periodic (weekly or daily) updates provided by political or health leaders. Prior to vaccines being shipped, a survey by the World Economic Forum and Ipsos across 27 countries found that 74% of people were willing to get a COVID-19 vaccine when available.¹⁴ That was good news, as scientists believed that a vaccination rate of around 70% could confer herd immunity. Yet, as of January 31, 2022, the global vaccination rate stood at just 61.9%.¹⁵

A Deloitte survey¹⁶ found that many of the unvaccinated are still persuadable, although it may take a shift in communication and outreach strategy to reach them. However, there are sizable populations—up to 22% of South Africans, and 18% of Americans—who are not just hesitant or waiting for access to vaccines but who are refusing or resisting getting vaccines.¹⁷

Key to building trust in a new therapy like COVID-19 vaccines is having the right, persuasive message delivered through the right channel and messenger. These will need to be tailored differently for those who are hesitant or resistant to getting the vaccine and could involve local health care professionals more than national figures. A 2021 Deloitte survey in four large countries¹⁸ found that for the general population, doctors and physician groups remain the most trusted sources of information. (Figure 3).



Figure 3. Trusted sources of information for health conditions and treatments

Doctors’ office and physical groups are the most trusted sources of information for health conditions and treatments

Q. If you wanted information about the most effective and safe treatment(s) for a certain health condition, which of the following sources do you feel provide(s) the most reliable information? Select the top three (N=228 participants)

Poll options	All	United States	United Kingdom	India	South Africa
Doctor’s offices/physician groups	72%	82%	76%	64%	65%
Medical association	52%	40%	50%	62%	55%
Government health agencies	48%	40%	72%	55%	25%
Pharmacies	41%	26%	45%	34%	60%
Independent health websites	35%	51%	31%	26%	33%
Nongovernment organisations	23%	28%	28%	9%	27%
Pharmaceutical companies	18%	5%	12%	31%	25%
Health insurance companies	16%	19%	10%	24%	11%

>70%
 50%-70%
 40%-50%
 30%-40%
 20%-30%

Source: Deloitte Analysis (May 2021).

This finding was not unexpected; individuals trust guidance from experts who know them and can coach them directly—a labor-intensive effort in the best of times and more difficult when a pandemic prevents face-to-face counselling. Regarding information about COVID-19 vaccines specifically, reliance on physicians was high across demographics while information from drug manufacturers or insurance providers scored far lower on the trust scale.

Interestingly, new data from a Deloitte survey of US consumers¹⁹ shows that for those resisting vaccination, friends and family are the most influential sources of vaccine information, even more than physicians. More “refusers” of the vaccines relied upon friends (30%) versus doctors (25%).

To motivate the hesitant, personal relationships and information also mattered more than incentives, which had limited appeal and impact; only 5% said incentives played a role in their decision. However well-intentioned, offers of cash bonuses, gift cards or lottery tickets had little impact in increasing vaccination rates. Finally, vaccine mandates were adopted in countries like Austria and China that demonstrated government’s trust in the vaccines and ensured high compliance and vaccination rates. Mandates are rare, however, and vaccine hesitancy and outright resistance remain significant barriers in some locations and populations.



Challenges and lessons learned

Despite the success in developing vaccines in record time, major challenges remain to convert the growing supply and availability of vaccines into high vaccination rates and equitable distribution and verified administration.

Follow-on vaccine collaboration meets market realities

Ironically, the large number of vaccines and perceived differences between them may have added to general confusion about what the vaccines could do, and whether consumers should wait for the “best” one. Comparing results of clinical trials across so many therapies proved to be challenging for experts, much less consumers, and it is human nature to want the “best” vaccine, or prefer a vaccine made in a citizen’s own country or by a company with operations in country.

In addition, while the collaboration and data-sharing to bring vaccines to market was laudable and successful, it was also unusual and unprecedented. One unanswered question for manufacturers (and regulatory bodies) is: How can we ensure ongoing collaboration while ensuring a return on investment and avoiding antitrust problems? After all, manufacturers still operate under the general laws of the marketplace, and stakeholders will expect executives to seek returns on their investment and to protect valuable intellectual property.

Multi-lateral protocols such as the World Trade Organization (WTO)’s TRIPS (Trade-Related Aspects of Intellectual Property Rights) agreement are helpful in facilitating global information sharing, yet their focus is mostly on supporting initial collaborations and relieving bottlenecks to vaccine distribution,²⁰ not allocating property or legal rights for the long term. New vaccine formulations are being introduced to respond to variants that are based upon but different from the initial vaccines. Issues about who owns the intellectual property for next-generation variant-specific COVID-19 vaccines and who can extract value from licensing it are just now being addressed.

If viruses become more common, so too will global collaboration on therapies. Accordingly, new protocols may be needed. Manufacturers and authorities should assess whether updating existing multi-lateral agreements, alliances, and laws would support faster, ongoing collaboration and flexibility to address global health emergencies.

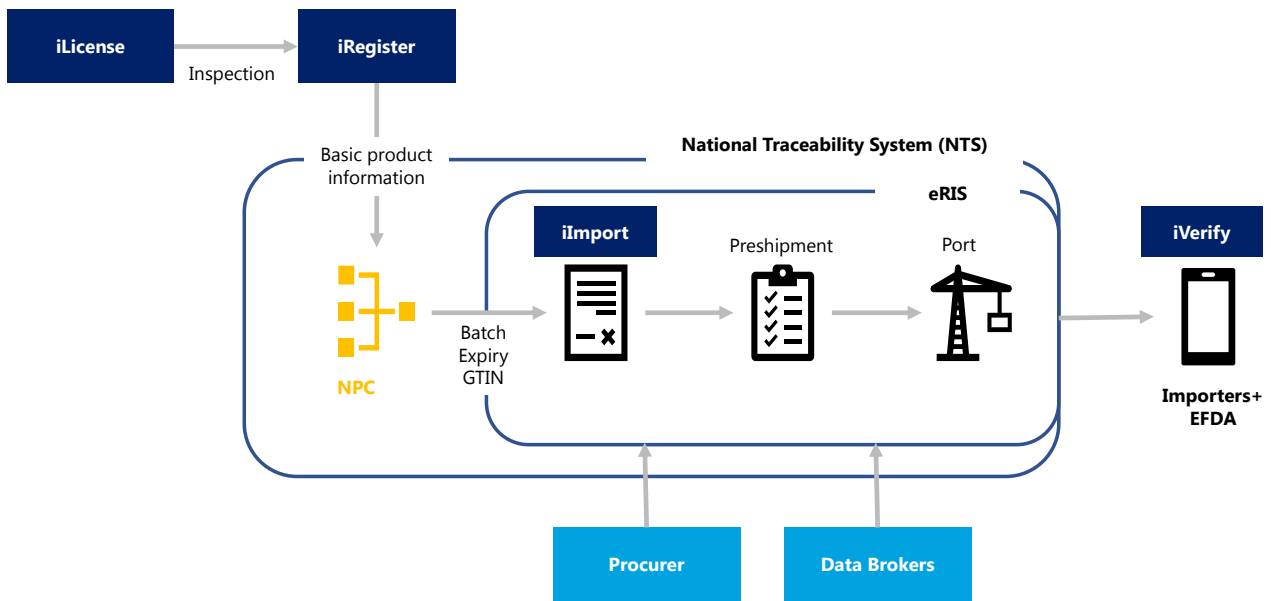
Use of global standards for product identification remains ad hoc

Product integrity is a concern with any medication, and especially with COVID-19 vaccines given the speed at which they came to market, the number of vaccines, the prevalence of fake vaccinations (and fake vaccination certificates), and knowledge that vaccines have an expiration date. Ideally, global standards for product identification and traceability would have been used to allow verified track and trace to and from manufacturers and individuals. Interoperable systems that could generate a transparent, end-to-end chain of custody could alleviate some of these concerns and would create trust with the general public.

We’re not quite there yet. When vaccines were developed in 2020, neither manufacturers nor governments required unique product identification through serialization; instead, manufacturers received appropriate exemptions from national governments that typically required those to expedite vaccine development. However well intentioned, in retrospect the lack of focus on identification and serialization was short-sighted. For pharmaceuticals, except COVID-19 vaccines, there is growing demand from national health agencies and global organizations for serialization.²¹ Many tenders require it as part of pre-qualification processes for drug importers. Further, national health agencies such as Ethiopia’s are investing in traceability systems that assume serialization. Figure 4 illustrates Ethiopia’s current approach to track and trace.

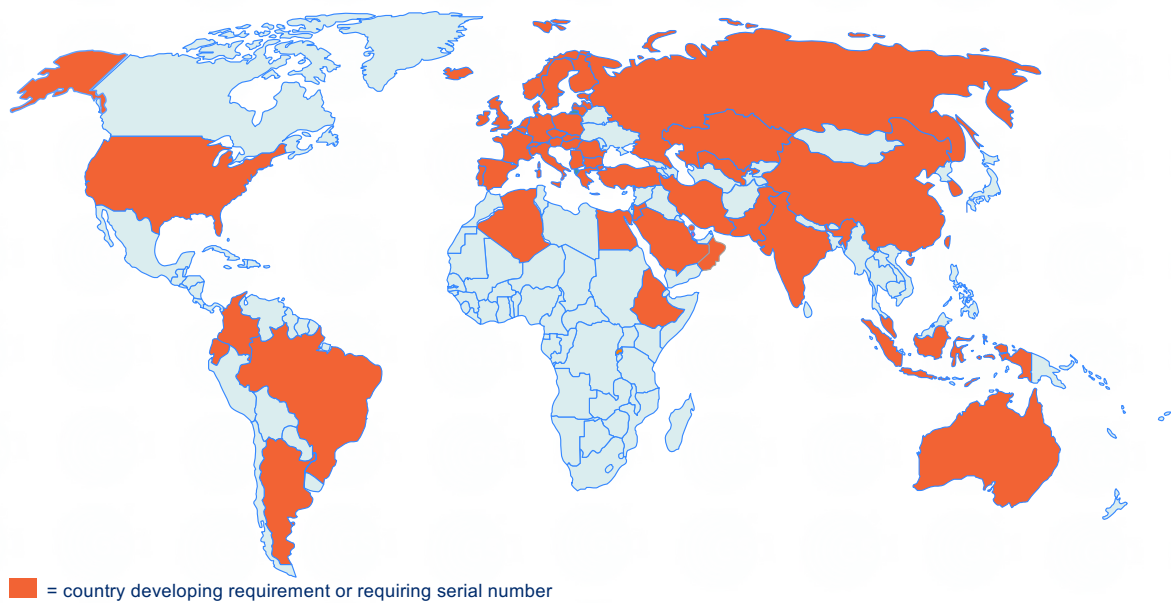


Figure 4. National Regulatory and Traceability Information System overview



Source: © GS1 2012-2022

Adopting a harmonized global standard for identification and traceability is more efficient than proceeding with multiple nation-specific traceability systems. While the norm in many countries, for COVID-19 vaccines this not the initial focus of governments or manufacturers. Figure 5 shows serialization requirements; the gaps and discrepancies are problematic for healthcare providers, manufacturers, and regulators, and could undercut trust in un-serialized vaccines and therapies. In hindsight, requiring serialization of the initial vaccines would have allowed for more efficient and accurate traceability of vaccine administration from the beginning and may have thwarted the prevalence of fake and counterfeit vaccines. In addition, serialization would make it easier to calculate vaccination rates, identify bottlenecks, and identify where vaccines were wasted.

Figure 5. Country progress on serialization of pharmaceuticals

Source: © GS1 2012-2022

More infrastructure development needed to deliver safe, effective, genuine vaccines

Even as more countries secure vaccines, the vaccination effort remains hampered by a lack of personnel and reliable infrastructure (transport, supplies, accessible administration locations, even electricity) in many locations. Delivery tactics such as mobile medical units used in high-income countries were not always replicable in developing countries, or at least not at the scale required. Like the issue with product serialization—infrastructure requirements were given secondary consideration, after vaccine development and testing. Finally, delivery is also complicated by criminals offering fake or substandard vaccines.

Infrastructure gaps and fragmented health care services frustrated the ability to turn available vaccines into actual vaccinations and highlighted the general inequities between developed nations and the rest of the world in terms of vaccine access. Manufacturers' heroic effort to produce vaccines has at times resulted in oversupply; vaccines were sometimes received in countries without allowing enough time for distribution and administration before reaching expiration. In Africa, this led to destruction of expired vaccines²² or the cancellation or delay of vaccine orders.²³ Similarly, by mid-2021 some developed countries such as the United Kingdom found that supply outpaced demand, forcing cancellation of shipments.

Central to improving infrastructure is identifying and supporting stakeholders in the position to actually build it. Some manufacturers delivering vaccines to developing nations were put in a difficult position as local health care teams looked to them to help solve the last mile problem and get vaccines to citizens. Yet, the ability to build delivery networks and vet and hire local resources that could reach dispersed rural populations is best addressed by country and community leaders familiar with the people and locations with help from experienced nonprofits.



Infrastructure deficits have led to a gap between vaccination rates in rural and urban areas across the globe.

- In the United States, there was a 14% difference between urban fully vaccinated residents (59.8%) and rural (45.8%), and rates decline with increasing rurality.²⁴
- Similarly, in New Zealand rates in remote areas were 19% less than major metropolitan centers.²⁵

In Deloitte's survey of consumers in the United States, which has more than enough vaccine supply for eligible citizens, convenient access to a shot remained a barrier for many, with transportation, wait times, and inconvenient hours all impacting vaccinations. Lack of transportation or the cost of travel, however, emerged as a significant challenge across the globe, identified in countries as diverse as Bangladesh and Ghana,²⁶ New Zealand and India, as well as the United States. Many eligible citizens are challenged to travel even a few miles to reach a vaccination site.

Beyond the challenge of physically getting vaccines and people to the same place at the right time, poor linkage of data exchanges makes it near impossible to trace the chain of custody for vaccines once they are delivered to some countries or jurisdictions. Some authorities still use pen and paper to track and trace vaccine receipts and administration, leading to incomplete or at best delayed upload of this information to centralized data repositories. Organizations like UNICEF facilitate the identification and qualification of local carriers, but frequently there is no airtight way to determine what happens to an allocation of vaccines once a carrier takes possession.

Unreliable infrastructure and delayed administration created a situation where some citizens eager to get vaccinated fell prey to criminals who built a robust black market for fake vaccines. The addressable market for vaccines is more than five billion people, making it an attractive target for fraud. Some people are willing to spend substantial sums to buy "vaccines" from unauthorized or uncertified sources. Beginning in early 2021, Israeli cybersecurity firm Check Point identified advertisements on the darknet for several unverified vaccines asking US\$500 to US\$1,000 a dose,²⁷ with such ads increasing in number monthly.

In 2021, counterfeit or fake vaccines were identified in Sudan, South Africa, Uganda, Germany, and Brazil. While some of the material was harmless, such as water or saline, other materials were contaminated. More importantly, fake vaccines deprive the recipient of the protection desired and believe they acquired, which puts them, and their friends and family at greater risk of the virus. This further erodes trust among those consumers not yet willing to be vaccinated.

While the challenges of delivering safe and efficacious vaccines were anticipated, resolving them will not be simple or quick. The lack of infrastructure and governance processes to ensure timely administration of vaccines shipped to rural areas and countries with less developed health care systems remains a major hurdle to increasing vaccination rates. Yet, as discussed below, the strategies and actions from health care leaders in Ethiopia and Nigeria demonstrate that progress is not only possible but assured with commitment and a patient-focused, long-term vision.

"The liquid gold in 2021 is the vaccine, and already we are seeing that vaccine supply chains are targeted more and more."²⁸

Jurgen Stock,
general secretary of Interpol



Disconnects in global and local communication networks undermine vaccine confidence

Increasing confidence and trust in pandemic mitigations in general, and the vaccines specifically, requires more transparency of messages from governments, national health organizations, and global nonprofits. Initial efforts to describe and clarify the origin of the virus were often contradictory and hard to understand. This focus also set a precedent in which skepticism about mitigations such as social distancing, masking, and vaccines took hold in late 2020 and early 2021.

The number of vaccines may have resulted in data overload. No unified explanation was given for why so many vaccines came to market, or clarity about the differences between them. In retrospect, more effective messaging about the variety of vaccines was needed with a recommendation by trusted authorities for people to take the first vaccine available since all provided proven protection.

Trust is built by the government setting clear expectations and enforcing them for all societal stakeholders. Yet, an additional messaging challenge was the use and debate over “vaccine mandates”—a term which did not sit well with many citizens. Mandates worked in Austria and China, but more leaders found that a more palatable approach was to not require or mandate vaccinations, but rather restrict what unvaccinated citizens could do and where they could go. This approach, coupled with a requirement to provide proof of vaccination and a personal ID, is used by Germany, France and in various states in the United States. It effectively puts the decision about vaccination in the hands of individuals, who must weigh the costs and benefits of vaccines versus attending entertainment events, shopping, or eating out at restaurants. In this way, government policy rewards vaccinations, without mandating them.

Beyond the messages, a lack of diversity among messengers and chief spokespeople was a missed opportunity given that a major known cause of vaccine hesitancy among marginalized groups is their lack of inclusion in clinical trials. In many countries, including the United States, the most frequent messengers were officials with national health agencies or political leaders—not messengers that could participate in dialogues that can change minds or target the causes of an individual’s hesitancy or concern. Broadcast, public service communications, while valuable for building a foundation of knowledge, are usually not compelling enough to convert the deeply resistant or fearful. Although our initial report suggested enlisting athletes, celebrities, and other influencers to support the vaccine rollout, this tactic was rarely deployed.

In general, the need to quickly educate the public about the virus, promote progress in vaccine development, and identify vaccine eligibility and administration timelines were given precedence over emotional, personal appeals. The campaigns executed revealed significant gaps and some overlaps in many country and state communication architectures. Most could have benefited from having a more structured protocol for managing health crisis communications to avoid delayed or mixed messages. Deputizing more people to educate citizens face-to-face also works because it reflects a more human-centered approach than mass communications. For example, Boston’s Get Out the Vaccine initiative²⁹ is modeled on Get Out the Vote efforts and involves teams knocking on doors and staffing pop-up clinics in areas where vaccination rates lagged.



Solutions: Increasing trust across the value chain

These challenges are significant but not insurmountable. In fact, many short-term and long-term solutions could address them and leave the world better prepared for future health crises.

Facilitating future collaboration in vaccine development

As difficult as it is to acknowledge, global health emergencies in the future could require the same level of collaboration seen with COVID-19 vaccines. To make information sharing and collaboration possible, national and regional governmental bodies need legal and commercial protocols that carve out exceptions to laws prohibiting anticompetitive activity and guaranteeing health care privacy during crises. Further, manufacturers may need specific indemnity agreements to protect them from legal actions when governments request accelerated development and trials.

An agreement could take the form of a treaty or accord facilitated by the United Nations (UN) and WHO with input from nation members or unions of states. Among other topics, it should address issues such as market allocation, data sharing, and shared intellectual property rights. Such an agreement should cover first-line therapies, as well as derivative therapies. Manufacturers of the vaccines will revert to standard competitive behavior once the COVID-19 pandemic has peaked. Without an agreement, there may be conflicts over intellectual property rights, or at least debates over manufacturers' contributions and investments—neither of which promote vaccine confidence.

These actions could complement more efforts funded by governments, individually or collectively, as well as subsidizing public/private efforts such as the Operation Warp Speed effort in the United States. Patent-free vaccines in the public domain avoid intellectual property disputes of course. Recently, a team at the Texas Children's Hospital³⁰ working with a commercialization team at Baylor University shared its vaccine formulation freely with manufacturing sites in India, Bangladesh, and Botswana to boost vaccination rates in those locations.

Governments that put virology research efforts on hold could reactivate these initiatives and ensure adequate communication staffing at agencies to be better prepared for future global health crises.

Requiring global standards and serialization for current and future vaccine supplies

Disparate approaches to adopting global product identification standards, as well as the high variability in traceability processes and the lack of interoperability, can undermine vaccination efforts by slowing distribution. Today, there is no credible, transparent way to verify where vaccines are in many countries, and whether supply is meeting demand. This not only affects confidence in the vaccine supply chain, it can exacerbate health care inequities and undermine patient safety.

One solution is for international health care organizations to spearhead campaigns to promote global standards for product identification across medical supply chains. A pan-association effort that encourages and helps create foundational, backbone interfaces would allow each in-country system to feed traceability data into a global repository, making it easier to align supply with demand and improve supply chain security both of which play a role in increasing transparency, and with it, trust.

Current initiatives demonstrate how this can work. More countries could follow the lead of Gavi and UNICEF, which require serialization to participate in tenders. Chinese manufacturers embed serialization based on global standards for all COVID-19 vaccines distributed or supported by UNICEF, and Gavi has recommended identification and barcoding for all vaccines. Some countries have already adopted this approach for a portion of medicines exported by local manufacturers and more countries in Europe and Africa are requiring it by regulation. Nigeria undertook post-receipt in-country serialization of millions of doses of both the Moderna and Pfizer-BioNTech vaccines with the knowledge of those manufacturers to strengthen the integrity of its vaccination program.



The drug management strategies of countries like Nigeria and Ethiopia include investments in technology that requires serialization of drugs entering the country to enhance traceability, and we believe this approach would provide a common, reliable foundation that would benefit all stakeholders. Enabling serialization requires that each saleable unit of a product carries:

- A Global Trade Item Number (GTIN)
- A Serial Number (S/N)
- A Batch/Lot number (LOT)
- Expiry Date (EXP)

More than 75 countries are requiring or accepting the GS1 DataMatrix and many donor organizations are requiring the GS1 DataMatrix on pharmaceutical products they purchase. This can be leveraged in countries with such requirements for identification and traceability of medical products such as COVID-19 vaccines. This is also an incentive for countries with no requirements yet to move forward. An example of the GS1 DataMatrix is shown in Figure 6.

Figure 6. Sample of serialization data print



(Illustration only)

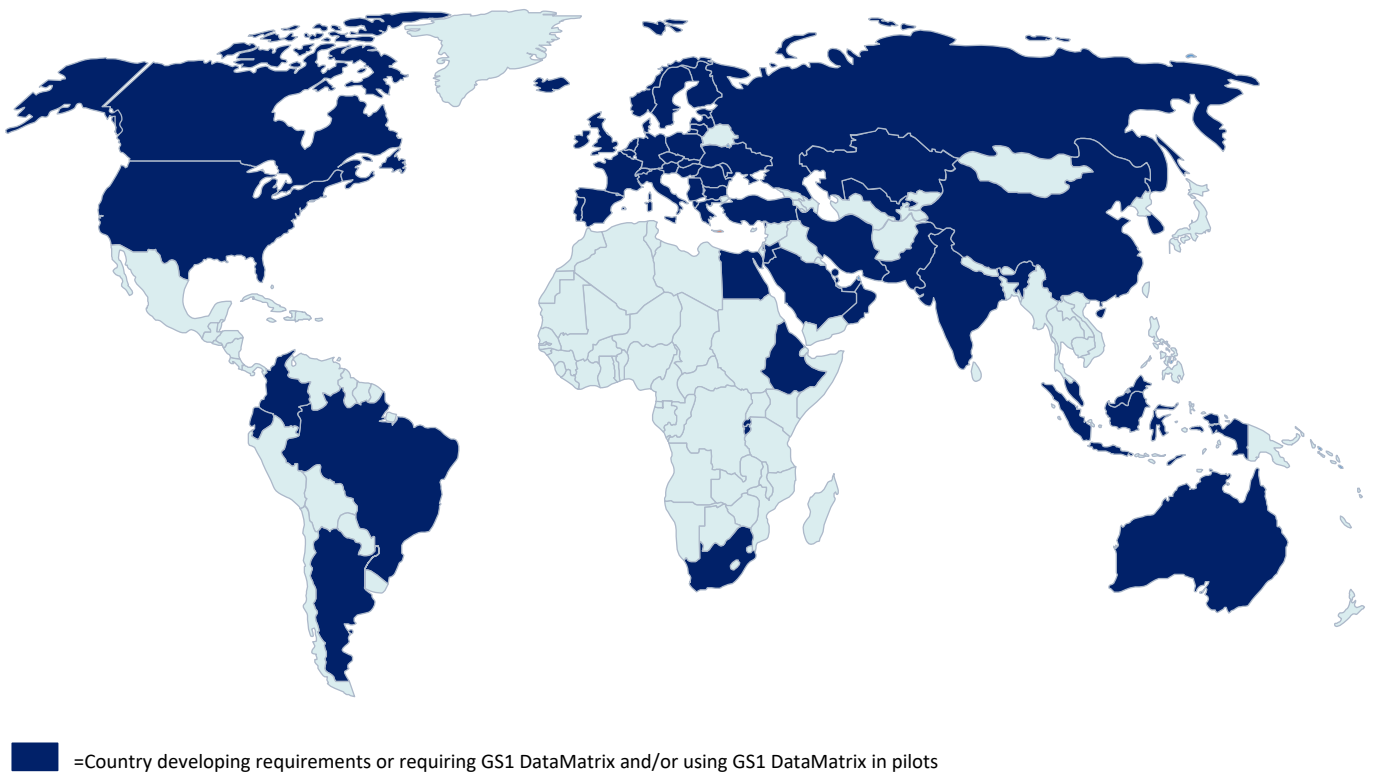
Source: GS1 March, 2022

The GS1 DataMatrix is the barcode recommended by the health care stakeholders and requested by governments for identification and traceability of health care products. While the GS1 DataMatrix is still evolving (e.g., to become mobile device readable and friendly), it has advantages over standard barcodes including:

- Captures the largest amount of identification data in the smallest amount of space on packaging;
- Allows printing directly on the products;
- Embeds sophisticated error detection and correction algorithms allowing the GS1 DataMatrix barcode to be scanned even if damaged, torn or printed poorly.



Figure 7. The breadth of adoption of the GS1 DataMatrix

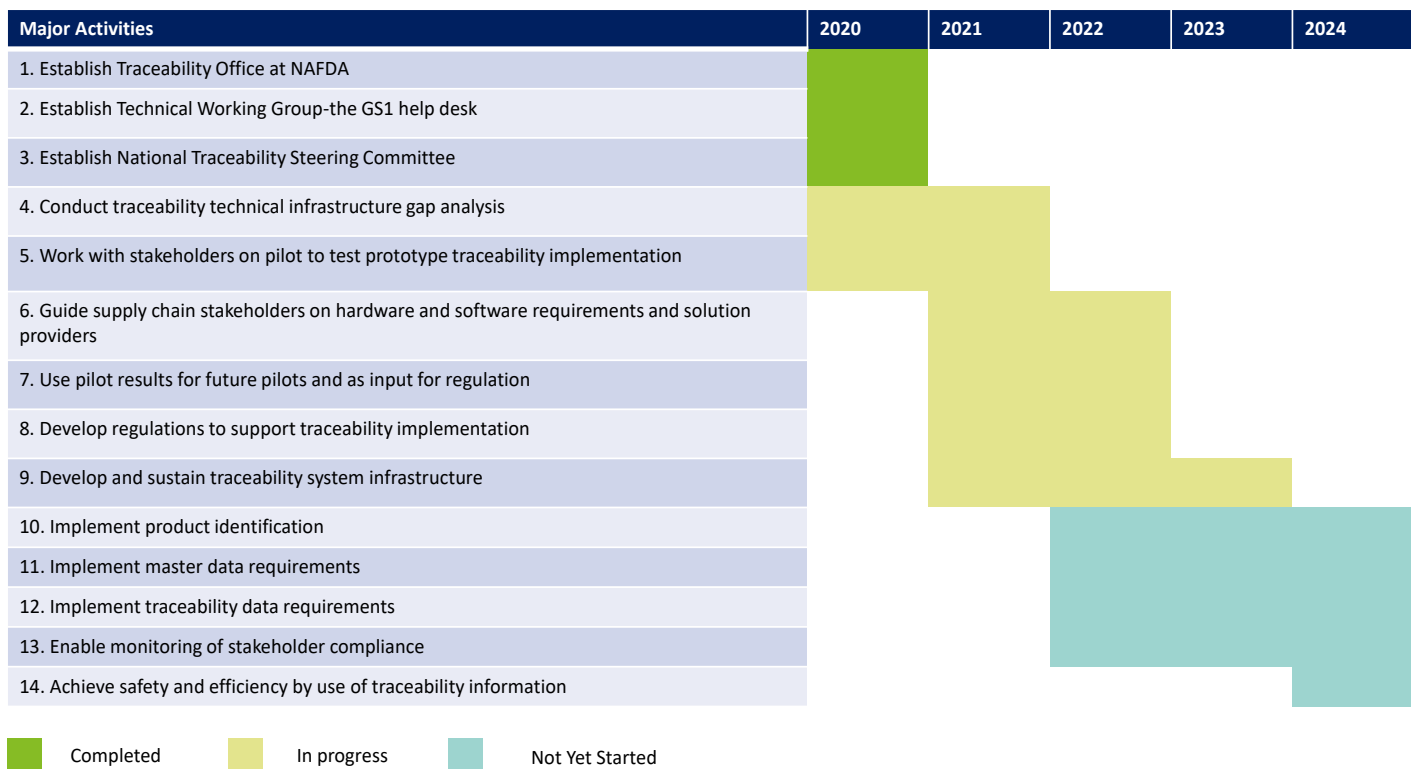


Source: © GS1 2012-2022

Achieving harmonized implementation of global standards for product identification and traceability requirements using global standards throughout the supply chain is a complex undertaking but ultimately will benefit all stakeholders. Nigeria provides a promising example. The country is in the middle of a five-year plan launched in 2019 to make traceability a reality for all drugs. It has convened numerous pan-African conferences, and 26 African countries have resolved to develop an African strategy that accurately reflects the state of current infrastructure and resources, and probable future investments to make end-to-end traceability a reality. Figure 8 shows Nigeria's progress to date³¹ in this initiative.



Figure 8. National Agency for Food & Drug Administration & Control (NAFDAC)'s Traceability Implementation: Five-Year Plan



Source: Making Traceability a Reality (NAFDAC presentation) October 2021

Nigeria's traceability initiative and progress are impressive and could serve as a blueprint for other nations to guide investment in traceability systems. With more countries and organizations requiring serialization and extensive product information, the time is now to scale up this effort and achieve universal use.

Making last mile delivery easier today and in the future

Navigating the last mile to get vaccines to citizens continues to be the most vexing issue depressing vaccination rates, particularly in rural areas and developing countries. Delivery requires coordinated action to address infrastructure and transportation barriers to administering COVID-19 vaccines. Yet, this reality raises geopolitical concerns, including where responsibility lies for achieving greater vaccine equity for developing countries while respecting national sovereignty during a global health crisis centered on a highly transmissible virus.

Nonetheless, several actions can be taken now to support delivery networks, ensure more effective operations, and increase transparency and human engagement—all of which would drive greater trust in the overall system and higher vaccination rates.

“These are huge steps in the implementation of traceability, but we can do it, I tell our staff ‘If you don’t see a challenge, if you don’t face a challenge, you may not know the potential that you have’. We are going to do it.”³²

Dr Christianah Mojisola Adeyeye
Director-General of National Agency for Food and Drug Administration and Control (NAFDAC), Nigeria



- Invest in or redeploy mobile medical units. Mobile units of local professionals can be trained and dispatched to meet people where they live, literally.
- Think outside the clinic and beyond the doctors. Many remote or rural areas do not have health facilities, or medical doctors. Neither, however, is required for vaccine administration. Nigeria and Kenya have set up administration sites in banks, car washes, social clubs, and shopping and entertainment arcades,³³ which are far more convenient locations to reach people cost effectively. In many countries, pharmacists play a leading role in administering shots, while in others military personnel have been deployed to help.
- Assess the viability of adjusting (extending) expiration dates. This would allow quantities already shipped to be retained longer while longer expiry dates on future shipments would reduce the number of shipments overall and allow countries to retain vaccine stocks until opportunities for administration arise. Both would improve the environmental and sustainability impact of vaccines.
- Produce fewer vaccines that require cold chain storage and uninterrupted refrigeration. Vaccines that require only standard refrigeration should be prioritized if possible. Being unconnected to an electrical grid is not always a barrier. Several African health agencies, including those in Sierra Leone, use solar-powered mini-refrigerators³⁴ to maintain vaccines in transit to rural areas. Manufacturers should continue to assess and publicize the thermostability of their vaccines to determine whether short gaps in refrigeration actually erode safety and efficacy.
- Provide vaccines with identification and barcoding on the vial. Some administrators are reluctant to open a five-dose vial of vaccine and trigger expiration windows if most doses cannot be administered quickly.
- Develop a unified perspective on the risk/benefit analysis of mixing of vaccines for second or booster shots. Some country health agencies have issued guidance already that allows mixing, but it would help to have an agreed-upon global perspective to increase the administration of vaccines already in-market.
- Clarify the roles manufacturers and in-country resources can and should play in local delivery and administration of vaccinations and protecting the vaccine chain of custody.

How Sanjeevani Extended the Hospital Ward in India ³⁵

In spring 2021, as COVID-19's delta variant surged in India, Deloitte and leaders in India's Haryana Karnal district launched a collaborative effort to reduce the strain on hospitals and "extend the hospital ward" by developing a supervised, virtual, in-home care program for people in rural areas with mild or moderate COVID-19 symptoms. Sanjeevani Pariyojana (in Hindi, this translates to The Life Project) mobilized local health care practitioners to help provide early detection (through home test kits), and essential care for home-isolated COVID-19 patients. The program took advantage of Haryana's existing technology infrastructure by adding or enhancing command-center capabilities, and augmenting the availability of telemedicine, virtual triage, and advanced life-support transportation services when patients required higher acuity care.

Ireland is a good example of managing last mile delivery well and clarifying roles and expectations. A centralized, dedicated team has national oversight for requisitioning vaccines, documenting shipments received, and managing distribution of vaccines and related supplies. Team leaders work with a network of local pharmacies, general practitioners, and vaccine centers to schedule and administer shots. The team uses a single data repository to roll up information on vaccine distribution, administration, disposal, and adverse events daily, allowing for quick reallocation or mitigation if necessary.

The results speak for themselves. The Health Service Executive (HSE) achieved visibility of COVID-19 vaccine usage and traceability to the point of administration across all vaccination centers by co-designing a standards-based solution with GS1 ensuring an efficient and effective way of receiving, administering, tracking, and reporting of vaccinations. The combination of centralized data-recording and community-based administration has resulted in 85% of eligible Irish citizens being fully vaccinated by 20 March, 2022.³⁶

Ireland also used a standards-based approach in its pandemic Test & Trace Program, using GS1 identifiers for sample traceability within its SamplePath diagnostics management solution, enabling visibility throughout the testing pathway and supporting the management of results within a 24-hour target.



Build global and local crisis communication networks

Vaccine development and delivery presented complex communication challenges that evolved as vaccines were tested, manufactured, and released. Global consistency and harmonization of messages in each phase was key to increasing confidence in the vaccine, as was finding the right messengers and targeted messages. The overall takeaway is that a shift, or at least an expansion, of communication tactics may be needed. Mixing broadcast communications from national leaders with more targeted, community-based tactics led by local, culturally diverse teams could increase confidence in vaccines and with-it vaccination rates.

Leaders should consider employing the following proven communication tactics to increase vaccine confidence.

- Focus messages on core, personal benefits of vaccines. The main selling point of the vaccines could not be more compelling: Vaccines reduce death rates and severity of illness. However, early messages about vaccines focused on clinical data, particularly the varied efficacy rates, and availability logistics. The result: the emotional underpinning and personal benefits were lost at times. Illinois is executing an effective “man on the street” video campaign built around testimonials by real citizens who overcame their hesitancy to get vaccinated.

Enlist influential community-based communicators. Congolese health authorities deputize social mobilizers³⁷ (members of community animation cell) to visit families and share information, including preregistering them for SMS alerts when vaccination sites closest to their homes open. In some areas the faith-based community can be a key influencer. In the rural south of the United States, a collaboration between the United Way and the Choose Healthy Life Black Clergy Council³⁸ has gained significant traction. Pope Francis recently released a message to Catholic churches³⁹ urging the faithful to get vaccinated as an act of love for community and mankind.

- Celebrate milestones. India successfully empaneled multi-disciplinary teams to participate in and sponsor its Sanjeevani A Shot of Life initiative, launched on World Health Day 2021. Nationwide progress was celebrated in an end-of-year telethon that summarized the efforts and impact by the Sanjeevani teams and encouraged adoption by highlighting how multiple Indian states overcame vaccine hesitancy.⁴⁰
- Prioritize and tailor communications to address root causes of vaccine hesitancy. The leading causes of vaccine hesitancy were well known, as were the demographics of probable vaccine hesitant. Often vaccine-hesitant people just need to be heard, not persuaded. Gavi reports that some organizations are taking a page from therapeutic approaches used for traumatized combat veterans and deploying chatbots.⁴¹

To help the vaccine hesitant explore their feelings about the vaccine without judgement or debate.

- Coordinate a strategy to counter misinformation about alternative therapies. COVID-19 inspired significant numbers of conspiracy theorists and fake vaccine suppliers. Governmental, law enforcement and social media executives should assess the possibility of identifying and countering mis- and disinformation more forcefully, including weighing the risks and benefits of taking legal action.

Governments, health care agencies and community groups have all refined their communication approaches over the course of two years to make messages more direct, clear, and personal. In the future, much like delivery infrastructure, communication infrastructure will need to be expanded and diversified to reach and motivate more people more quickly.



Conclusion

The release of numerous COVID-19 vaccines within a year of virus identification represents a significant achievement for manufacturers, governments, and health care professionals in a variety of roles. More importantly, it has benefited billions of citizens across the globe, and reduced the incidence of severe disease and death. Manufacturers and global health care organizations rose to the challenge, and trust in the COVID-19 supply chain has increased. Due to intense public education efforts and media coverage, the primary concern for most people moved past questions about efficacy and local availability to finding new ways to ensure global uptake. That movement is a victory. Further, GS1 global product identification standards will continue to play a role in establishing trust in the global supply chain for innovative products such as new vaccines, enable a better overview of supply versus need, and optimize planning and availability of vaccines.

Now stakeholders need to act on the lessons learned to strengthen the collective ability to respond to or—better yet—proactively address other global health issues. The critical success factors identified in 2020 remain paramount. Stakeholders should find ways to ensure future collaboration, expand adoption of global product identification standards, fund and develop reliable health care delivery infrastructure, and establish credible communication networks. We believe that the insights gleaned from our shared pandemic journey are applicable not only to vaccine delivery. Manufacturers, health agencies, and researchers can translate the learnings from the COVID-19 vaccination effort to other areas such as ensuring more equitable access to general health care, and increasing health education about disease transmission.

The COVID-19 pandemic will fade, but the need to deepen and broaden trust in medicine, health research, governments and NGOs remains. The momentum and insights gained over the past two years can be used to benefit citizens, countries, and for-profit and nonprofit organizations alike.



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