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VACCINE INSIGHTS

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Raw materials & supply chains

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VACCINEINSIGHTS

RAW MATERIALS & SUPPLY CHAIN

SPOTLIGHT

COMMENTARY

Vaccine supply chains: priority areas of action emerging from the COVID-19 pandemic

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Vaccine supply chains – from raw material sourcing and production to getting vaccines into people's arms – have been widely acknowledged as a key constraint to achieving high coverage for COVID-19 vaccines globally. While there has been extensive discussion on vaccine production and access, equally important are the complexities of sourcing critical components and raw materials; installing and maintaining cold chain infrastructure; vaccine supply chain information systems; and well-trained and motivated staff to run and manage the logistics of vaccine distribution. There is an urgent need for a blueprint (and accompanying governance structure) that lays out specific technical activities, public and private investments, and coordination tasks needed for the overall vaccine supply chain to be ready to handle large demand surges such as during pandemics and large outbreaks.

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Producing vaccines and getting them into people's arms requires a carefully orchestrated global supply chain that starts with vaccine raw materials and ends with trained healthcare workers administering the vaccine to willing recipients [1,2]. Successful planning and execution of logistics can be the difference between the success and failure of vaccination campaigns. To be ready for infectious disease outbreaks and to improve coverage of routine childhood vaccination, we must make vaccine supply chains across all countries as robust as possible. While supply chains for all health products are complex [3], vaccines have the added complexity of more geographically concentrated manufacturing; many inputs/

raw materials needed for vaccine manufacturing; the need for cold chain infrastructure; guaranteeing synchronous availability of auxiliary material/immunization supplies such as vaccine-specific syringes; special immunization-related information systems; and the coordination of local, national and international vaccine shipments [4]. When vaccine supply chains don't work well, it can lead to stockouts of vaccine vials and immunization-related supplies, which can reduce vaccine coverage [5] and increase vaccination program costs due to wastage or expedited deliveries. Considerable investments and efforts have been made to improve supply chains for routine childhood immunization across countries. However, the immunization supply chain is not ready to cope with significant demand surges such as those observed in the first wave of population-wide COVID-19 vaccination. To provide a comparison, the number of COVID-19 vaccine doses distributed in the 92 low- to middle-income countries (LMICs) was two to three times UNICEF's annual supply of vaccines to LMICs. In addition, the routine immunization supply chain is largely geared towards childhood vaccination and does not have an apparatus designed for large-scale adult vaccination. Vaccine supply chains face numerous challenges, and their importance has been recognized in recent literature [4,6–8]. Similarly, the benefits of expanded regional manufacturing to improve access, and the need for greater investment in building such capabilities, have also been covered in recent literature [9,10].

To ensure vaccine supply chains worldwide are better prepared for large demand surges arising from pandemics, disease eradication efforts, or large disease outbreaks, we highlight five specific areas for concrete action (in addition to expanded regional manufacturing).

ADEQUATE CONSIDERATION OF SUPPLY CHAIN & LOGISTICS DURING VACCINE DEVELOPMENT

Global logistical constraints around cold chain infrastructure, dosing schedule, and type of syringe/delivery device are important factors that must be taken into account when developing vaccines.

Pfizer/BioNTech's mRNA vaccine, for instance, had a 0.3 mL dose in contrast with the more commonly used vaccine dosing of 0.5 mL, which required procuring specialized non-standard syringes in countries where injection safety mandates the use of auto-disable syringes [1]. As a result, 0.3 mL auto-disable syringes were in extremely short supply and presented procurement challenges for many countries. Admittedly, the tradeoff between speed of vaccine development, vaccine efficacy, and ease of supply chain/delivery is extremely complex. However, considerations such as thermostability, dose volume, number of doses, and type of syringe/device for administration should be given prominence in pre-pandemic R&D programs. Research into platform approaches to increase vaccine thermostability should be encouraged through large grant programs from R&D funding agencies globally. The development of varied vaccine delivery methods, including needle-free administration, which may be preferred by some vaccine recipients, may also create a more diversified supplier base and more diversity in terms of the syringe market's raw material needs.

At the same time, agencies responsible for decisions regarding vaccine suitability for LMICs should view thermostability in a dynamic decision-making framework and acknowledge that as more information becomes available, thermostability capabilities may improve. Hence, access to some vaccines for LMIC populations should not be completely ruled out on the basis of initial thermostability and cold-chain distribution infrastructure considerations alone.

STABLE & DIVERSIFIED SUPPLY OF RAW MATERIALS & COMPONENTS

It takes more than developing the right biological construct, plant, and equipment to produce vaccines on an industrial scale.

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Modern vaccines typically require about 9000 different materials obtained from approximately 300 suppliers in some 30 different countries [1,11]. Additionally, vaccine manufacturers need to procure more than 100 different critical components, including glass vials, culture media, filters of all kinds, tubing, stabilizing agents, resins, and disposable bags [12]. Supply problems with any one of these components or input materials can halt production of a vaccine entirely [2]. While this is a challenge for all vaccine manufacturers, it becomes particularly pronounced for new manufacturers who do not have existing long-term relationships with suppliers of such materials. COVAX and its partners led by CEPI have developed a marketplace to match suppliers of critical inputs with vaccine manufacturers who urgently need them [13]. However, some manufacturers have expressed their dissatisfaction with the ability of this marketplace to solve their sourcing problems [14]. The governance structure, technical capabilities, and partnership modalities of such a marketplace need to be carefully configured [15] and adequately resourced to solve the material sourcing problem for new and existing manufacturers, especially during a period of high demand and constrained supply. Careful consideration should be given to ensuring that such a marketplace can be maintained during inter-pandemic periods and that trade barriers do not stymie its usefulness during pandemics and large health emergencies.

COLD-CHAIN INVESTMENTS AS A LONG-TERM HEALTH SYSTEM INVESTMENT

Limitations in existing cold chain infrastructure were one of the biggest challenges for COVID-19 vaccine access and distribution. Limited cold chain capacity has long been recognized as a bottleneck in the vaccine supply chain [2]. The Cold Chain Equipment Optimization Platform (CCEOP) was set up by GAVI in 2015 to upgrade/install high-performance cold chain equipment (CCE) across LMICs, and to shape the CCE market for LMICs [16]. It financed solar direct drive and off-electrical-grid refrigerators and freezers in several GAVI-eligible countries. CCEOP explicitly took into account the fact that cold chain capacity building in LMICs is not merely about installing fridges, and freezers. It also requires building an eco-system for preventive maintenance and repair of such equipment. However, CCEOP was geared mostly towards CCE for 2–8°C – the most used temperature range across vaccines in LMICs. mRNA vaccines for COVID-19 required ultra-cold chain storage for which much of this infrastructure was not suitable. COVAX was initially focused on expanding the normal 2–8°C cold chain capacity with the assumption that much of the early supply of vaccines to COVAX countries would be 2–8°C (based on the portfolio of vaccines that COVAX had contracted). With the large-scale donations of Pfizer/BioNTech vaccines to COVAX, much of the cold chain capacity at the national and regional level had to be readied for ultra-cold chain. While some such ultra-cold chain freezers are now in place as a result of these efforts, there is a need to redesign CCEOP and its market-shaping effort around two scenarios: a) future vaccines will have better thermostability, or b) future vaccines (and other medical countermeasures) will require ultra-cold chain capacity. The redesign of CCEOP should explicitly account for the fact that cold chain investments can help in preparing the health system not just for vaccines, but for other health products such as insulin, oxytocin, and new human immunodeficiency virus treatments.

The cold chain storage capacity required in a country also depends on the configuration of the in-country vaccine supply chain. Typically, vaccines are first transported from the airport of entry to the main national distribution center from where they go to regional and district distribution centers, and eventually to immunization service delivery points. Changing this configuration e.g., distributing more directly from national distribution centers to district or health clinics, or delivering more frequently

between each stage, changes the total requirement of cold chain capacity and its location [17] and may be more cost-effective and efficient. The lack of ultra-cold chain equipment at the subnational levels led to a more direct distribution system for some COVID vaccines. This more direct distribution model should be explored as a permanent option for routine vaccines. Besides improving efficiency and reducing cold chain requirements [17], this would enhance operational readiness for fast response distribution during disease outbreaks or pandemics.

COVID-19 vaccine distribution in many countries also relied on special arrangements for shipment preclearance, airspace clearance, advance documentation sharing, and sharing assets across public and private agencies. There should be an assessment of whether the ad-hoc measures for the distribution of COVID-19 vaccine can be made more systematic. Overall, there is a need for a Project-Optimize [18]-type technical task force to focus on in-country vaccine supply chain redesign in light of many new developments and provide high-level inputs to the evolving global architecture for pandemic preparedness.

IMMUNIZATION SUPPLY CHAIN DATA SYSTEMS, DEMAND FORECASTING & TRACKING VACCINE WASTAGE

A robust system that provides real-time information about vaccine stock and temperature/conditions of storage throughout the supply chain is essential to the effective and efficient distribution of vaccines, both for routine immunization [20] and particularly during a pandemic. Such visibility not only improves supply chain performance but also has the potential to help identify locations with low vaccine uptake rates and dynamically allocate stock in ways that are best suited for the public health response when supplies are scarce [19]. In many instances, the core information system that was in place for vaccine stock, flow, consumption, and temperature monitoring was expanded to include vaccination registration and scheduling. A prominent example is India's COVID-19 Vaccine Intelligence Network (Co-WIN), which was developed as an extension of the existing electronic Vaccine supply chain Intelligence Network (eVIN) [26].

Systematic collection of immunization supply chain data in real-time also facilitates better demand forecasting [20]. Analytics around uptake at sufficiently high levels of granularity, allow an understanding of drivers of vaccine hesitancy, supply availability, and other health system factor that affect demand.

COVID-19 vaccine wastage rates of up to 30% have been reported in low-income, middle-income, and high-income countries [21]. Mature supply chain stock tracking systems can also provide granular data on COVID-19 vaccine wastage, which can help identify key drivers of wastage and help develop specific interventions to minimize such wastage [21]. These interventions could include assessing the stock of vaccines globally and distributing unused vaccines to areas in need.

INVESTING IN THE PEOPLE WHO MANUFACTURE & DELIVER

In order to manufacture vaccines at scale, new vaccine plants need highly skilled staff in the areas of Chemistry, Manufacturing, and Controls (CMC), lab chemistry and analytical methods, regulatory processes, sourcing, and market dynamics [22–24]. In the period of a pandemic, the shortage of trained biomanufacturing staff can constrain vaccine production not only in new vaccine manufacturing regions, but even in established biomanufacturing clusters [12,23].

Aside from the biomanufacturing workforce, vaccine distribution requires logisticians, supply chain managers, data system managers, warehouse, and transport staff at the national, district, and health facility levels [25]. While these staff cadres exist, in many instances weak organizational systems, processes, and working environments result in staff positions not being filled. Such positions require not only technical skills but also 'social-creative' skills to solve unique problems when they arise.

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Some of the supply chain skill sets that are in short supply in public sector vaccine supply chains exist in private companies with significant supply chain footprints in the countries concerned. Platforms such as the Africa Resource Center (ARC) for supply chain management can be utilized to bring supply chain human resource capacity in the private sector to meet short-term staffing gaps in the vaccine supply chain.

In both the manufacturing and distribution areas of vaccine supply chains, it is necessary to bring together university curricula with practical internships and professional development opportunities for in-service staff. A number of initiatives are underway to address this issue, but the most important need is to establish a global network of different types of training and capability-building providers who have, or are willing to establish, an on-the-ground presence across LMICs.

CONCLUSION

The lessons learned from the COVID-19 pandemic provide a very clear set of priority actions to improve vaccine supply chains:

- The importance of considering logistics and supply chain early in the vaccine development process;
- Creating a better system for sourcing critical input materials;
- Investing in cold chain and data systems;
- Building human capital for biomanufacturing and supply chain.

The implementation of these actions will require national and global leadership, clear collaboration and coordination structures, and investment of financial resources according to needs that will vary in different settings. The new financial intermediary fund for pandemic prevention, preparedness, and response hosted by the World Bank, with technical leadership from WHO, should prioritize these action items in its financing to LMICs. Besides providing domestic financing for strengthening the vaccine supply chain, LMIC country governments should provide much-needed high-level ministerial attention to strengthening in-country vaccine supply chains.

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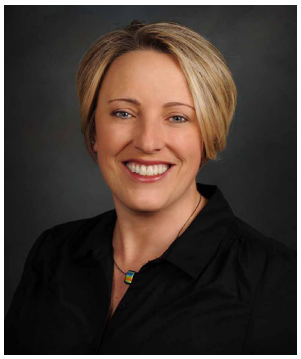
INTERVIEW

Cold chain management: a perspective from the US Defense Logistics Agency

Charlotte Barker, Editor, *Vaccine Insights*, speaks to **Dana Dallas,** Cold chain program manager, Defense Logistics Agency, United States Department of Defense



DANA DALLAS began serving her country as a United States Air Force Academy graduate, using her Biology/Pre-Medicine degree as a Healthcare Administrator and Medical Logistician with the United States Air Force, recently retiring as a Lieutenant Colonel with the 914th Aeromedical Evacuation Squadron. Joining the Defense Logistics Agency in 2000, Dana worked with vendors and beneficiaries alike in support of the National Mail Order Pharmacy program. Joining the Pharmaceutical Technical/Quality branch in 2003, Dana quickly took over program management for DLA's Cold Chain Management Program. Taking on such initiatives as the Department of Defense Seasonal and Pandemic Influenza programs, technical representative for the Pharmaceutical and Medical-Surgical Prime Vendor programs, as well as DoD COVID-19 Vaccine Operations packaging/distribution for overseas and US Navy Fleet assets has established DLA Troop Support Medical as an industry benchmark for Cold Chain, and Miss Dallas as a Department of Defense subject matter expert in Cold Chain Management.

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Q How did you get involved in medical logistics and cold chain management?

DD: I originally got into medical logistics with the Air Force. I was a Medical Service Core hospital administrator, and during one of my first duty assignments, I was placed in medical logistics. When I completed active duty and transitioned into the reserves, an opportunity with the Defense Logistics Agency (DLA) as a civil servant also presented itself. When a coworker managing the Department of Defense (DoD) flu vaccine program needed some help, I was happy to get involved. Eventually, I took over as program manager, and what started out as flu vaccine is now a wide range of vaccines and other medical supplies that we manage for the DoD.

Q What does your current role at the DLA involve?

DD: I am the cold chain program manager for the DLA, as part of Troop Support Medical where we support the entire medical supply chain for DoD. I work with and monitor our contractors and distributors to ensure supplies get to where they are needed and arrive in good condition. Plus, I work with the manufacturers to determine product viability, and with leadership teams for all the end-destination facilities to make sure they have the information they need for storage and administration.

It is never boring and always challenging. I have a degree in biology with an emphasis on microbiology, and this job allowed me to combine that degree with my medical logistics training from the Air Force. I never counted on COVID making it quite as exciting as it has been for the last 3 years though!

Q What unique challenges does the DoD face in cold chain management?

DD: Most civilian counterparts in the industry do not ship overseas. Their basic distribution lanes are in the United States, at most they may ship raw components or bulk material overseas, and they generally time deliveries for cooler months. They often times also have funding to be able to use so-called 'white glove' carriers to carefully escort the product.

We ship year-round, worldwide, no matter the season. We could be shipping one vial or whole pallets, so we need packaging and transportation solutions to accommodate the full spectrum. We also have a lot of last-mile challenges, with the warfighter having to carry coolers from one tactical environment to another. Furthermore, as a US Military organization, we often face challenges in terms of customs.

Much of our purchasing and contracting is regulated by Federal Acquisition legislation, so there are a lot of rules to follow. Trying to work within these rules and making sure that the product is kept in good condition when it reaches the end destination can be difficult. Most manufacturers will only stage the material at domestic locations in the United States for us

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after the initial purchase, and from there the packaging, distribution, and transportation are our responsibility.

Q What were some of the unique challenges posed by the COVID vaccines?

DD: In December 2019, I watched reports of a new respiratory virus on the TV news and remember thinking that we might soon be very busy! I had some experience preparing for a potential pandemic with the H1N1 flu variant back in 2009, but that was nowhere near the scale of COVID. We pulled out our influenza pandemic plans and tried to work out how to adapt them to COVID, but at that stage, we had no idea what the storage requirements would be for any vaccine that was developed.

The vaccines came out so much faster than any of us were expecting. I was asked by the Counter Measures Acceleration Group, as part of the White House COVID-19 Response Team (formerly referred to as Operation Warp Speed), to be present when the first Pfizer-BioNTech COVID-19 Vaccine doses rolled off the line on December 12th and 13th, which was an unforgettable experience. Shortly afterward, we started moving our COVID vaccine doses.

Unlike the flu vaccines, which are purchased via a DLA contract, our COVID vaccines are covered by a federal contract through Health and Human Services (HHS), the Centers for Disease Control (CDC), and the Biomedical Advanced Research and Development Authority (BARDA). This involved a lot of planning to fit their agency processes into our established processes.

The vaccine manufacturers and their distributors are able to carry out domestic shipping, but overseas shipping was not part of their scope in supporting us. In particular, it is extremely difficult for them to deliver to naval ships because they do not have access to the secure systems we use to find out where the ships are at a given time. We decided to partner with FedEx Custom Critical/Air Expedite for overseas and naval fleet deliveries – they provide the packaging components and protocols, we pack it, and they move and monitor it.

We had all kinds of customs challenges at the beginning. Some countries were apprehensive to let the shipments in, and some required paperwork we had never seen before!

Furthermore, the US Food and Drug Administration generally uses pre-defined temperature ranges, and none of the initial COVID vaccines fit into any of those ranges. We did not have a qualified packaging protocol that would guarantee that the mRNA vaccines would be delivered within their precise temperature requirements: the Pfizer-BioNTech vaccine at -90 to -60°C and Moderna at -25 to -15°C.

Our initial DLA mission was small in scope, and we initially planned to ship only Johnson & Johnson's vaccine, which could be maintained at 2–8°C, but it did not hit the market soon enough. We then shifted our focus to Moderna, which we could manage but at lower quantities. Once Pfizer was able to obtain a refrigerated allowance for its vaccine with a shorter shelf life, we added that to the mission. Now we do it all – Novavax, Pfizer, and Moderna.

"We're constantly looking at opportunities to improve as we move forward, possibly integrating more 'green' solutions. I would love to do more bulk shipping of cold chain material, but this comes with challenges such as more coolant and increased weight."

Q How do you see cold chain management for vaccines evolving in future? Any new innovations you would like to see?

DD: I envision a lot of change in the coming years, as DoD establishes requirements based on World Health Organization and CDC guidance. Many would like to align with our flu vaccine program eventually, which runs July to January.

As the vaccines become more established and further studies are carried out, there is more flexibility in storage requirements. I would love to see all the COVID vaccines become refrigerated and get out of the frozen vaccine shipping business altogether!

As a result of COVID, most countries' customs offices are now much more aware of the cold chain and are paying more attention to the refrigerated medical items coming in and out of their countries, which has also generated a lot of change. As we move forward, we will continue to work with those countries to ensure the smooth transit of vaccines.

The standard refrigerated packaging we use right now is good but could be better. We're constantly looking at opportunities to improve as we move forward, possibly integrating more 'green' solutions. I would love to do more bulk shipping of cold chain material, but this comes with challenges such as more coolant and increased weight.

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INTERVIEW

Collaborating for stronger supply chains

Charlotte Barker, Editor, *Vaccine Insights,* speaks to **Rebecca Logan,** Senior Vice President, Supply Chain Management Division, Chemonics to find out why partnerships are the key to success in global vaccine supply chains.

REBECCA LOGAN is an experienced senior executive and certified Project Management Professional with 23 years of professional experience, including 20 years in the humanitarian and international development fields with expertise in strategic planning and project implementation, risk mitigation, crisis management, and personnel management. As senior vice president, Rebecca oversees Chemonics' portfolio of supply chain programs, including the procurement and delivery of health commodities to 34 countries/regional offices on the USAID Global Health Supply Chain Program-Procurement and Supply Management (GHSC-PSM) project and several projects funded by The Global Fund to Fight AIDS, Tuberculosis and Malaria. She is responsible for overseeing overall project implementation and strategy and building and managing relationships with clients, in-country stakeholders, and government partners. Previously, she held several management roles in Chemonics' headquarters as well as in Cairo, Egypt, Ramallah, West Bank, and Mongolia. Rebecca holds a Bachelor of Arts in political science from the College of New Jersey and a Master of Arts in international development from The American University, and has completed a Mini-Masters in global supply chain management from Arizona State University.

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Q How did you get involved in supply chain management?

RL: I feel in many ways my life has come full circle. My stepfather managed a warehouse and as a child, I used to have fun riding the forklifts and trucks.

My career took me into different areas of international development, but ultimately, I found myself back in the world of trucks and warehouses! I found that supply chain was a very rewarding area for someone with a Type A personality – you always have a task at hand, work with a range of stakeholders, and see concrete results on the ground. Every single day brings unique challenges so it's always dynamic and never boring.

My current role is Senior Vice President for the Supply Chain Management Division. I also play a key role in the Global Health Supply Chain Program-Procurement and Supply Management (GHSC-PSM) project.

Q What is the mission of Chemonics?

RL: Chemonics is an international development company operating in more than 80 countries, with a global workforce of about 5000 specialists. Our mission is to help people live healthier, more productive, and more independent lives around the world.

The size and scale of Chemonics allow us to consistently achieve results even in complex environments and crisis situations, to scale up and down, and build and leverage our strong partnerships with governments and civil society organizations (CSOs) to reach patients and beneficiaries. For example, Chemonics was the first organization to deliver life-saving antiretroviral drugs for HIV into Ukraine after the war broke out. Our broad network meant we already had people on the ground in the region and were able to tap into our global supply chain.

Q What are some of the key factors for successful partnerships between governments, NGOs, and the private sector?

RL: First and foremost, you have to listen carefully to all the stakeholders involved, and really understand where you can find common objectives. Listening will allow you to build trust, align expectations, and establish clear roles and responsibilities.

Thinking of our work in supply chain, we have also found that partnerships succeed when they have a stable environment or plain field – no surprises for anyone, an established source of truth for all stakeholders (for quantitative and qualitative data), and regular communications with transparency.

For example, our GHSC-PSM's project in Ghana had built a strong relationship with the Ghana Ministry of Health and Ghana Health Services early in the project, which allowed them to plan and coordinate a prompt and swift response to support Ghana's COVID-19 response. GHSC-PSM helped transport vaccines from Accra to regional cold rooms across the country; installed temperature monitoring devices to monitor and help maintain the integrity

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"So much of what we do in the supply chain is driven by forecasting – who needs the product, how many, and where do we need to move it to? "

of vaccines; and developed capacity in vaccine logistics management for relevant health staff as part of efforts to ensure consistent availability and access at the last mile. The US Government has donated 12 million vaccine doses which have contributed to the vaccination of 22.5 million Ghanaians (as of January 2023).

Q How was the company involved in the response to COVID-19?

RL: Our USAID-funded GHSC-PSM project is an enormous integrated program that purchases and delivers health commodities globally, particularly in the areas of HIV, malaria, family planning, and infant health. We also work to strengthen national supply chain systems and provide global supply chain leadership to ensure those drugs get to where they are needed.

When the pandemic hit, our priority was to make sure that our current supply chains would remain intact. We worked closely with our country offices, US government, and partner governments to put plans and mitigation measures in place.

The vaccine rollout was fast and furious, with the added complication of very specific cold-chain requirements. One day we would have no vaccines, the next day we would have many vaccines that needed to go to numerous countries' central and subnational levels.

So much of what we do in the supply chain is driven by forecasting – who needs the product, how many, and where do we need to move it to? With the COVID-19 vaccine, we didn't have any of that information. We worked with governments to understand where the largest concentrations of populations were and try to ensure vaccine equity, but the information vacuum was very difficult.

However, our size and scale again gave us a great advantage. We already had networks in place for delivery of various health commodities, and strong relationships with health clinics and central warehouses. Our country offices were able to work with governments and local CSOs to get vaccines delivered quickly.

Early on in the pandemic we had conversations with the UN, global pharma, and governments, and found that no one had clear visibility into cold chain capacity around the world. So one of the first things we did was to reach out to our country officers to better understand more about each country's cold chain capacity and provide feedback to other organizations. One positive outcome of the pandemic is the strengthening of cold chain capacity around the

world, which is likely to be key in future pandemics, as well as ongoing health priorities such as routine vaccinations and oxytocin for use in childbirth.

Q What lessons have we learned from the pandemic?

RL: We learned how fragile supply chains are and the level of dependency we as a community have on each other to get medicines out efficiently.

Prior to the pandemic, Chemonics-implemented GHSC-Technical Assistance Francophone Task Order developed the Emergency Supply Chain Preparedness Framework [1]. We rolled it out in several countries such as Liberia, Mozambique, and Cameroon as part of our global health supply chain security efforts. The framework worked well, but we are in the process of assessing its effectiveness to produce additional lessons learned from the COVID-19 experience.

In response to COVID-19, our GHSC-PSM project developed the Recovery Strategies for Public Health Supply Chains Post Black Swan Event [2] guide to help field program managers define and manage disruptions to both supply and demand, and to think through recovery strategies for public health supply chains. It is the intent that this guide will assist stakeholders as they plan and strategize for the future – ultimately building more resilient supply chains that can recover quickly after a black swan event (an unpredictable catastrophic event).

Q Any thoughts for vaccine developers and manufacturers?

RL: There is a lot of discussion about regionalization versus globalization of vaccine manufacture. Do we need to bring manufacturing capacity into the countries where vaccines are most needed? Or do we need to improve supply chains so that vaccines can move more freely around the world? Or maybe both? Other key considerations are the business-enabling environment readiness in Africa, quality assurance procedures, and health regulatory constraints. It will be interesting to see how that conversation develops in the wake of the pandemic.

I would encourage companies to have an open dialogue with the global community, particularly African representatives, so that health supply chain actors proactively work together to smooth the production and movement of vaccines. For example, creating mechanisms to fast-track authorization for use in different countries, which is required to allow imports and was a real roadblock for COVID-19 vaccines.

The pace with which pharmaceutical companies got the COVID-19 vaccines out was absolutely amazing. This shows that challenging context and constraints also pushes the industry to innovate and scale quickly. This gets us excited about what we can achieve next and motivates us to keep working hard and smart to achieve better health outcomes for all.

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VACCINEINSIGHTS

RAW MATERIALS & SUPPLY CHAIN

SPOTLIGHT

Lessons learned in the transportation of healthcare products by drones

Archimède Makaya, Drone Program Manager **& Louis Tshituka,** Team Lead, Monitoring and Evaluation at VillageReach

VIEWPOINT

"If cost-effectiveness can be increased, this healthcare transport method could prove vital for vaccine delivery to hard-to-reach locations."

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On January 16, 2023, Charlotte Barker, Editor, *Vaccine Insights*, spoke to Archimède Makaya, Drone Program Manager, and Louis Tshituka, Team Lead, Monitoring and Evaluation, VillageReach. This article has been written based on that interview.

Drones offer a means to transport healthcare supplies, including vaccines, to/from regions not easily accessed by road or plane. Here, we explore the benefits and limitations of drone transport, and how best to leverage this technology to achieve vaccine equity.

VillageReach is an global health organization working with governments and drone transport service providers to identify priority locations, design drone supply and collection systems of health products by drones – and ensure transportation of health products by drone in three core countries, the Democratic Republic of Congo (DRC), Malawi, and Mozambique. This coordinated effort of all stakeholders including drone transport service providers, governments, and local communities, creates an enabling environment for the business development of drone solutions in these countries.

Drones for Health (D4H) is one such collaborative program. In DRC, D4H is located in the Equateur Province and is one of the largest bi-directional (delivering and picking up) drone networks in the world, serving 40 health facilities via 24 landing sites, across an area of 37445 km^2.

DRONES FOR MORE EQUITABLE VACCINE DELIVERY

One of the primary problems for the healthcare supply chain in Africa, and especially in DRC, is the low availability of products in hard-to-reach locations. Traveling between locations in DRC is often challenging, due to an abundance of rivers, forested areas, and poor road infrastructure. This also creates challenges in transporting samples to laboratories for diagnostics.

By introducing a two-way drone network, the D4H program has increased access to vaccines and other medications for hard-to-reach health facilities and allowed rapid transport of biological samples to provincial labs, despite natural barriers like the Congo River, Lake Tumba, and the Pacific Equatorial Forest. According to the Kinshasa School of Public Health's performance research on the use of drones in the delivery of health commodities, the availability of vaccines has increased from 65 to 98% in health facilities supplied by drones [1]. Similarly, the number of health facilities shipping samples in less than 3 days has increased from 10 to 69%.

Drones contribute to the goal of universal health coverage, and ensure the quality of the product transported, due to their speed, which is especially important for sensitive products such as vaccines and biological samples. Last year, D4H succeeded in transporting an Ebola lab sample 220 km in 1.5 h. Drones are also responsive and resilient, suiting them to emergency situations.

UNDERSTANDING & OVERCOMING THE LIMITATIONS OF DRONE DELIVERY

Drones are powered by rechargeable batteries and have a limited range. To allow drone transport over longer distances, battery charging sites have been established between the main hub and outlying drone sites in the D4H network.

According to a study by supply chain consultancy OPS MEND LLC, conducted by Noel Watson, doses transported by drone cost more than those transported by other modes, meaning that integration of drones into public health supply chains is not fit for every purpose [2]. Finding the most cost-effective and beneficial way to integrate drones requires planning, collaboration, and staged implementation.

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To increase cost-effectiveness, transportation can be optimized in two ways. First, ensuring drones are used at maximum capacity is essential. In addition, the cost needs to be shared between more network end-users. Currently, only the vaccine program is supporting the drone's operations. If the network and products can be diversified, resources from many donors and end-users can be acquired.

The overall supply chain can be optimized by only transporting products by drone that are best suited to this mode of transport, such as vaccines, laboratory samples, and test kits for the management of diseases such as malaria, tuberculosis, and HIV/AIDS. Less time-sensitive and bulkier health products continue to be delivered by other means, such as by road or river.

FUTURE PLANS FOR D4H

In the latest phase of the D4H program, one of the objectives was to generate evidence for the use of drones in the supply chain and to create an enabling environment for drone use. The results of these performance and cost-effectiveness studies were shared with all stakeholders. This includes, for example, the establishment of the drone health commission at the national level and the drone working group at the provincial level. D4H is also organizing media reporting such as television segments and billboards.

D4H aims to continue studying the benefits of drones in terms of quality and equity. D4H will also continue exploring the product and customer diversification approach to achieve better cost-effectiveness. If cost-effectiveness can be increased, this healthcare transport method could prove vital for vaccine delivery to hard-to-reach locations.

BIOGRAPHIES

ARCHIMÈDE B MAKAYA is Drone Program Manager for VillageReach in the Democratic Republic of Congo (DRC). He is a medical doctor at the University of Lubumbashi in the DRC, and has more than 15 years of experience in public health. He is experienced in primary health care, the treatment of infectious diseases, the supply chain of health products, Drone health products supply chain system design, collaborating with Government officers and Drone providers, and the Implementing Drone Supply Chain program in hard-to-each & remote areas.

LOUIS K TSHITUKA is Team Lead, Monitoring and Evaluation at VillageReach in the DRC. He is currently a doctoral student in health and social protection economics after having obtained a specialization in quantitative and econometric methods for health research from the Public Health Master of Aix-Marseille University in France. He has more than 10 years of experience in the field of monitoring and evaluation of public health projects and programs. His current work focuses on monitoring and evaluation, quality, demand and use of evidence for decision-making, quality of services, capacity building and research on health inequalities.

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RAW MATERIALS & SUPPLY CHAIN

SPOTLIGHT

Barcode technology: a game changer for public health supply chains

Edward Wilson,
Director, Center for Health Logistics and the Partnership for Supply Chain Management, JSI

"Now we see a concerted effort across the value chain and across product categories to incorporate and implement barcodes based on data standards – the benefits of which will be felt around the world."

VIEWPOINT

Vaccine Insights 2023; 2(2), 55–58

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Barcodes are a key tool to ensure the traceability and safety of vaccines, particularly for lower- or middle-income countries, and now is the time to employ them.

On February 2, 2023, Charlotte Barker, Editor, *Vaccine Insights*, spoke to Edward Wilson about barcode technology for vaccines in low and middle-income countries. This article has been written based on that interview.

BARCODES FOR VACCINE SAFETY

Barcodes are labels on the primary or secondary packaging of a pharmaceutical or vaccine that contain information about the item, such as lot or batch information, the expiration date, and serialized information about the unit. Barcodes are typically encoded according to a global standard and applied at the point of manufacture.

Barcodes can help ensure the safety of vaccines, especially in lower-income countries (LIC) or lower-middle-income countries (LMIC), by ensuring that they are delivered to the intended recipients and are used before they expire. Barcodes can help trace a particular batch or lot of a vaccine, should there be a quality issue or an adverse event that requires batch recall or investigation. This can be key in providing public information to help fight vaccine hesitancy and dispel the type of false rumors that have been rife during the COVID pandemic.

Barcodes can also be used to verify that a particular vaccine is authentic and not a counterfeit. With certain pharmaceutical barcodes, a consumer can scan a barcode on the product to verify its authenticity using a nationally available service. Finally, barcodes can be used at the point of service delivery to ensure that medicines or vaccines are dispensed properly to patients. This helps improve the quality of care and mitigates the risk of incorrect dispensing of medicines, i.e., patients receiving the wrong medicine or dose.

HISTORIC CHALLENGES TO INTRODUCING BARCODING FOR HEALTH PRODUCTS IN LICS & LMICS

There have been many efforts over the years to introduce the use of barcodes in LICs and LMICs, especially where there are existing digital supply chain information systems. In the public sector, this has been limited to higher levels in the supply chain. In the private sector, barcode use is seen in national or subnational distribution centers for large and medium-scale operators and pharmacy chains but is typically limited to pharmacies that cater to higher-income level patients or consumers in urban areas. The efforts to introduce barcodes have often encountered system limitations and a historic lack of global standardization and regulatory harmonization.

First, there is a lack of standardization at the global and regulatory levels to ensure that common information is present on barcodes and that barcodes are presented on packaging in a standard way. Without that, it can be a challenge to build a system that can incorporate barcode information.

Second, there are often limitations in human resources and process management. There is a lack of staff with the right skills to effectively manage the technology required to operate a barcode-driven warehouse and delivery system. There may also be limitations in processes and procedures that are not mature enough to enforce the process discipline

BOX 1

Definition of Global Standard 1 for public health supply chains.

Global Standard 1 (GS1) is a standard format that outlines the specific data fields being collected, how this information is going to be used, and the way it is encoded on a barcode. The standard provides a reference to use when systems are being implemented, to understand the expected information and formatting. GS1 has played a key role in providing data standardization to enable suppliers, in-country supply chains, and operators to exchange data in a smoother and more seamless way. Having a standard that articulates data format enables a global exchange of data among trading partners.

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needed to use barcodes. Typically, using barcodes requires that staff use specific and replicable processes for the management of commodities. If these aren't followed, then data or commodities can be lost and the advantages of barcoding are significantly diminished.

Third, there have also been limitations in technology, such as the inability to integrate barcode capture and usage into existing digital systems, and limitations in connectivity, especially at lower levels in the supply chain, making it difficult to share data to make a barcoding system work efficiently. A lack of barcode standardization, design, and implementation, further exacerbates these technological issues.

The COVID pandemic highlighted issues related to knowing where vaccines were, how much was being used, and what the remaining shelf life was. Barcodes could have been used as tools to help with those challenges, although they would not have solved any of those problems alone. Without the people, the processes, the supporting technology, and the policy and governance infrastructure in place, barcodes will fail to be helpful. Barcodes can make up part of an overall system for effective use. With COVID, it was clear that the overall systems were not as effective as they should have been.

VACCINE BARCODES: THE TIME IS NOW

In past decades, barcode implementation was ad hoc and opportunistic. Now, due to a confluence of policy, technical, political, and public health factors coupled with consumer demand, the time is now for barcode technology to be a game changer for public health supply chains in limited resource contexts. And, as countries increasingly adopt national digitization strategies, incorporating barcoding into those strategies can smooth their implementation.

Across the value chain, standards are gradually being adopted to make it easier for all players in the global supply chain and value chain to be able to exchange data with each other. In the case of vaccines for LIC and LMIC countries, Gavi and UNICEF have mandated barcodes on all products they procure, to encourage countries to start using barcodes for tracking and authentication. Now, for large purchasers in the public sector, particularly for LMIC, there will be standard barcodes available to use.

In addition, major collaborative initiatives such as the Vaccine Innovation Prioritization Strategy are identifying priority barcoding use cases, looking at the process of implementation for those cases, and developing implementation guidelines. Not only do we have the standards and barcodes available on the packaging, but we have better information about the priorities for the use of barcodes, in addition to cost and implementation. Initially, using the GS1 standard data from COVID vaccine manufacturers, the Trust Repository is creating a centralized database of supplies linked to national country databases and providing tools for individuals to verify that the vaccine they receive is authentic. National public health supply chains are increasing in sophistication and capacity and there are improved tools for barcode capture and use available. Gavi, The Global Fund, and United States Agency for International Development (USAID) are all supporting supply chain technology investments to assist barcoding implementation.

As seen with COVID, there is increasing demand and awareness from the public about information related to vaccine and medicine authenticity. There is increased public pressure for governments to be able to provide this information, and the local demand will drive political will for implementing these systems.

All stages of the value chain are coming together, and I am optimistic that we will soon see adoption at a much faster pace. In past decades, barcode implementation was ad hoc and opportunistic. Now, we see a concerted effort across the value chain and across product categories to incorporate and implement barcodes based on data standards

– the benefits of which will be felt around the world.

BIOGRAPHY

EDWARD WILSON has over 30 years of experience in pharmaceutical supply chain management, including managing complex multi-country public health projects, creating and leading project teams, and building and maintaining positive and productive client relationships with governments and international organizations. As Director of JSI's Center for Health Logistics, Edward oversees 30 projects across Asia, Africa, and Latin America that improve access to medicines and medical supplies for a range of clients, including foundations, bilateral and multi-lateral donors, and private companies. As Director of the Partnership for Supply Chain Management (PFSCM), Edward oversees a supply chain services organization that sourced, procured, and delivered US $561 million worth of health commodities to 96 countries for a range of public, private, and non-profit clients in 2021.

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