

Improving Global Health Supply Chains through Traceability

Michael Pisa and Denise McCurdy

Abstract

In many low- and lower-middle-income countries (LMICs) where disease burdens are highest, health supply chains function poorly, resulting in frequent stockouts and a high prevalence of substandard and even falsified medications. In response to these concerns, the global health initiatives have stepped up their efforts to improve supply chain management. At the same time, a growing number of rich country pharmaceutical companies are investing in digital technologies that help them “track and trace” the movement of medicines through the supply chain at the package-level. Drawing from interviews with over thirty experts, we find that traceability offers a realistic solution to some of the problems found in LMIC health supply chains but that implementing the approach is a huge logistical endeavor that requires a strong political commitment. We close by discussing how donors can support committed governments, by taking an evidence-based approach to determine what traceability methods work best.

We are grateful to the following people who took the time to review earlier drafts and provide their insights: Kalipso Chalkidou, Amanda Glassman, Janeen Madan Keller, Eric Marshall, Daniel Rosen, Rachel Silverman, Jessica Vernon, and Tom Woods. Any errors are solely our responsibility.

Michael Pisa and Denise McCurdy. 2019. “Improving Global Health Supply Chains through Traceability” CGD Policy Paper. Washington, DC: Center for Global Development. <https://www.cgdev.org/publication/improving-global-health-supply-chains-through-traceability>

CGD is grateful for contributions from the Bill & Melinda Gates Foundation in support of this work.

Center for Global Development
2055 L Street NW
Fifth Floor
Washington DC 20036
202-416-4000
www.cgdev.org

This work is made available under
the terms of the Creative Commons
Attribution-NonCommercial 4.0
license.

Contents

Introduction	1
The State of LMIC Health Supply Chains	2
Digital Supply Chains and Traceability	7
Two Traceability Models.....	9
Making Serialization Work for Health Supply Chains.....	10
Identifying Products.....	10
Capturing Data.....	11
Sharing Data.....	11
Making Use of Data	13
Traceability Initiatives.....	14
Making Traceability Work in Low-Income Countries: Ongoing Initiatives	18
Hurdles to Implementation in LMICs	19
The Limits of Traceability.....	20
The Next Frontier? Using Distributed Ledger Technology for Traceability.....	20
DLT’s Potential Benefits.....	23
DLT in Reality: Challenges and Limitations	23
A Potentially Worthy but Distant Goal	24
Recommendations.....	24
Conclusion.....	26
Appendix. Expert Interviews	27

Introduction

Providing patients with high-quality medicines in a timely and cost-effective manner requires effective supply chains. However, in many low- and lower-middle-income countries (LMICs) where disease burdens are highest, health supply chains function poorly, resulting in frequent stockouts and a high prevalence of substandard and even falsified medications. For this reason, there is growing interest in the global health community about whether LMICs can use digital technologies to help improve their supply chains and procurement processes.

Now is a good time to examine the issue for three reasons:

- First, over the next two decades LMICs will need to play a much larger role in procuring health products. To date, these countries have been able to rely on global health initiatives like GAVI, the Global Fund, and PEPFAR to procure many essential medicines and health products on their behalf. However, over the next two decades many of these countries will graduate from aid eligibility, which means they will need to procure these commodities for themselves.¹ This transition represents both a challenge and an opportunity: a challenge because LMIC governments will have to take on greater responsibility, and an opportunity because the expectation of this change will force governments to act.
- Second, rich country pharmaceutical companies are investing heavily in digital technologies in response to new regulations—including the US Drug Supply Chain Security Act (DSCA) and the EU’s Falsified Medicines Directive—that require producers and distributors to “track and trace” the movement of medicines through the supply chain. With traceability now a reality in some supply chains in high-income countries, the question is whether LMICs can make use of the approach as well.
- Third, over the last several years the global health community has become increasingly concerned about how dysfunctional supply chains can threaten the goal of providing affordable and high-quality essential medicines to the neediest populations. The high frequency of stockouts and widespread use of substandard medicines undermine effective treatment and raise the risk of antimicrobial resistance. In response, donors have begun to direct more resources towards strengthening supply chain management.

With these trends as backdrop, we explore the potential of digital technologies—focusing on serialization and, to a lesser degree, blockchain—to improve how LMICs manage their health supply chains and procurement processes. Drawing from interviews with over 30 experts, we aim to show the potential of traceability to improve the integrity of health supply chains, as well as highlight the work already underway by the global health community to make traceability in LMICs a reality.

While the use of traceability in health supply chains holds great promise, there are also significant challenges to implementation. Because many of these barriers are political rather

¹ Silverman, Rachel. *Projected Health Financing Transitions: Timeline and Magnitude- Working Paper 488*. Center for Global Development. July 10, 2018.

than technical in nature, governments that have a strong commitment should be able to overcome them. At the end of the paper, we discuss how donors can further support these governments, by taking an evidence-based approach to determine what traceability methods work best.

The State of LMIC Health Supply Chains

A supply chain is a system of organizations, people, and activities that support the movement of a product or service from supplier to customer by facilitating the flow of material, information, and financial resources.² The core functions of a supply chain are carried out in three phases: manufacturing, procurement, and distribution.³ This paper focuses on the latter two, and particularly on how digital technology can improve the flow of information between and within them.⁴

Unlike in rich countries, where health supply chains are managed almost entirely by the private sector, in LMICs “public, private, and nongovernmental organizations (NGOs) coexist as channels of distribution for medicines, with various interconnected flows between the three channels.”⁵ Of the three, the public sector—which here refers to domestic governments working in coordination with health initiatives like GAVI, the Global Fund, and PEPFAR—plays the dominant role.⁶ However, the private sector is playing an increasingly important role in LMICs and this trend will continue as incomes rise.⁷

While each LMIC government manages its health supply chains differently, the most common model involves a central medical store (CMS), which oversees the storage and distribution of medicines once they arrive in country, a transport fleet, and a tiered network of regional and district medical stores.⁸ In addition to the CMS-managed system, in many countries, donors have established their own vertical supply chains to handle product

² This definition draws from:

Yadav, Prashant. *Health Product Supply Chains in Developing Countries: Diagnosis of the Root Causes of Underperformance and an Agenda for Reform*. Health Systems and Reform. April 28, 2015 and Sullivan E, Goentzel J, Weintraub R. *Concept Note: The Global Health Supply Chain*. Harvard Business Publishing. 2012.

³ Sullivan E, Goentzel J, Weintraub R. *Concept Note: The Global Health Supply Chain*. Harvard Business Publishing. 2012.

⁴ The description of LMIC health supply chains below draws heavily from Yadav, Prashant. *Health Product Supply Chains in Developing Countries: Diagnosis of the Root Causes of Underperformance and an Agenda for Reform*. Health Systems and Reform. April 28, 2015.

⁵ Babaley, Magali, Helen Lega Tata, and Prashant Yadav. *The World Medicines Situation 2011: Storage and Supply Chain Management*. World Health Organization. 2011.

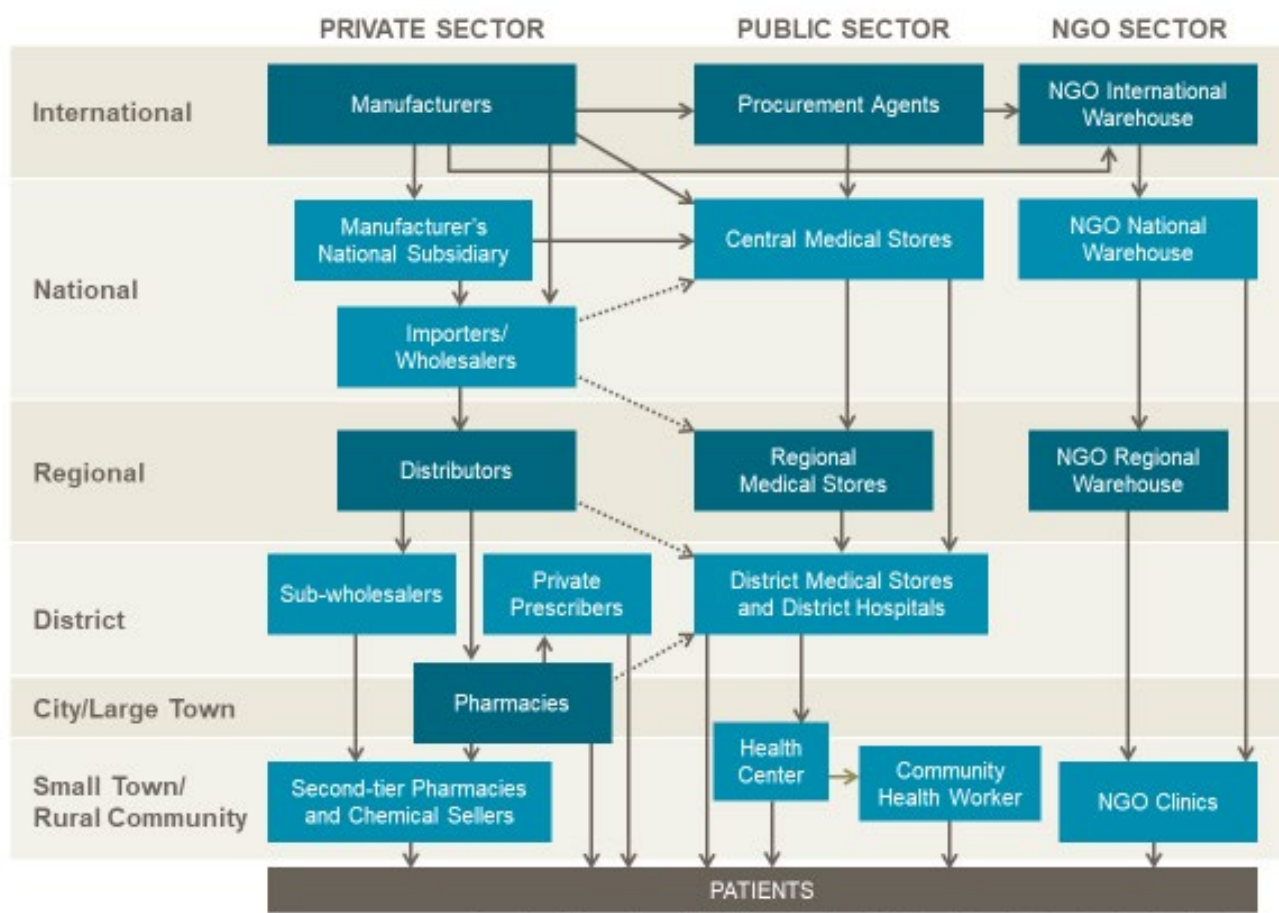
⁶ Chalkidou, Kalipso, Janeen Madan Keller, and Daniel Rosen. *An Initial Estimation of the Size of Health Commodity Markets in Low- and Middle-Income Countries*. Center for Global Development. December 13, 2017.

⁷ For more on the role of start-ups in LMIC health supply chains, see: Chalkidou, Kalipso, Cassandra Nemzoff, and Daniel Rosen. *Entrepreneurship on the Rise in the Medical Supply Chain in Africa: A Tale of Four Pharmacy Disruptors*. Center for Global Development. November 7, 2018 and Impact for Health. *Landscaping Innovations in Health Product Distribution in Sub-Saharan Africa*. October 2018.

⁸ Babaley, Magali, Helen Lega Tata, and Prashant Yadav. *The World Medicines Situation 2011: Storage and Supply Chain Management*. World Health Organization. 2011.

distribution (see figure 1). These independent and often disease- or program-specific chains at times overlap with one another (e.g., when they use the same warehouse facilities) but more frequently run “in parallel with other disease-specific programs and the national essential drugs system.”⁹

Figure 1. Structure of the health supply chain in developing countries



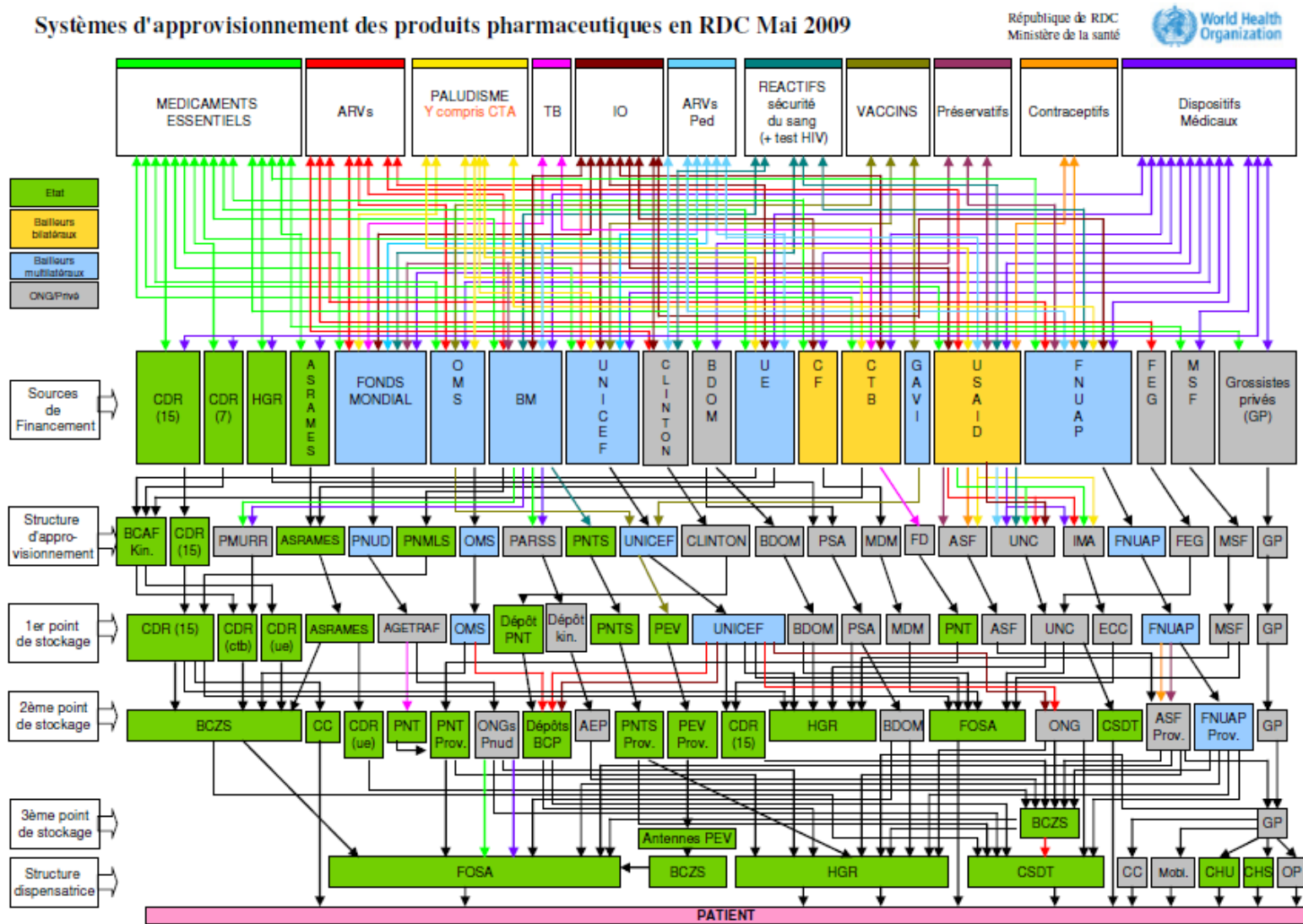
Reproduced from a figure in Health Product Supply Chains in Developing Countries by Prashant Yadav

This arrangement reflects earlier decisions made by the global health initiatives. Early on in their existence, some of these initiatives decided to create their own parallel supply chains, or work with external agents, rather than integrate them into poorly-functioning domestic systems in order to get high-quality essential medicines to as many people as quickly as possible. The result is a convoluted tangle of relationships that national authorities struggle to manage. Figure 2, which maps the medical supply system in the Democratic Republic of Congo, illustrates just how complex these arrangements can be.¹⁰

⁹ Sullivan E, Goentzel J, Weintraub R. *Concept Note: The Global Health Supply Chain*. Harvard Business Publishing, 2012.

¹⁰ Ministry of Health, Democratic Republic of Congo. *Cartographie des systèmes d'approvisionnement et de distribution des médicaments et autres produits de santé en RDC*, January 2010.

Figure 2. Medical supply system in the Democratic Republic of Congo



The complexity and opacity of LMIC health supply systems creates inefficiencies and makes them vulnerable to corruption and product diversion. Without effective monitoring, each handoff on a supply chain represents an opportunity for diversion, and there are often many intermediaries on the path between a CMS and a local health center. For example, in Kenya medicines can change hands “five to seven times” before reaching local clinics.¹¹ There is also a strong incentive for theft since medicines are often expensive and willingness to pay is high.¹² A recent report on product diversion in Malawi highlights this difficulty. The problem is exacerbated by a lack of accountability, as government responsibility over supervising supply chain practices is often fragmented across different ministries and administrative units, making it easier for the authorities to look the other way or reassign blame when fraud takes place.¹³

Product diversion is a key driver of the high frequency of stock-outs in LMICs, along with poor demand forecasting. In a recent WHO survey, 36 percent of surveyed antiretroviral therapy (ARV) clinics in 35 countries reported at least one ARV stock-out in a 12-month reporting period.¹⁴ The problem is even worse in Africa. For example, a recent survey in South Africa found that one-fourth of facilities had at least one ARV/TB stock-out within a three-month period and a similar survey in Tanzania found that 29 percent of participating facilities were out of stock of ACT for the *entire* 15-month period under study.¹⁵ These stock-outs can be deadly because they force patients to interrupt treatment (or prevent them from beginning treatment in the first place), raising the likelihood of illness and the antimicrobial resistance.

Product diversion also raises the risk that substandard medicines will enter the health system, as wrongdoers try to cover their trail by substituting in substandard or (more rarely) falsified medicines in their place. The WHO estimates that 1 in 10 medical products in low- and middle-income countries is substandard or falsified.¹⁶ Again, the problem is most acute in sub-Saharan Africa, where a meta-analysis by Webb (2014) found that roughly 39 percent of anti-malarials in nine countries were found to be “sub-therapeutic” after chemical analysis.¹⁷

¹¹ This point was made to us by Jessica Vernon, Co-Founder/CEO of MaishaMeds

¹² For an overview of some of the tactics used in product diversion see: Chirwa W.C., Mwalyambwire T., and Mwaungulu E.E., 2017, A Rapid Assessment Study of Formal and Informal Networks Facilitating Leakage of Health Commodities in Malawi, DFID

¹³ Yadav, Prashant. *Health Product Supply Chains in Developing Countries: Diagnosis of the Root Causes of Underperformance and an Agenda for Reform*. Health Systems and Reform. April 28, 2015.

¹⁴ World Health Organization. *Global Report on Early Warning Indicators of HIV Drug Resistance*. July 2016.

¹⁵ Stop Stockouts Project. *2014 Stock Outs Survey*. 2014.

Barrington, Jim, Don deSavigny, Inez Mikkelsen-Lopez, Winna Shango, Tom Smith, Rene Ziegler. *The Challenge to Avoid Anti-Malarial Medicine Stock-Outs in an Era of Funding Partners: The Case of Tanzania*.

¹⁶ World Health Organization. Substandard and Falsified Medical Products. January 31, 2018.

<http://www.who.int/news-room/fact-sheets/detail/substandard-and-falsified-medical-products>

¹⁷ Webb, Silas. A Bitter Pill to Swallow: The Problem of, and Solutions to, Sub-Saharan Africa’s Counterfeit Pharmaceutical Trade. *Journal of Global Health*. November 1, 2014. <https://www.ghjournal.org/a-bitter-pill-to-swallow-the-problem-of-and-solutions-to-sub-saharan-africas-counterfeit-pharmaceutical-trade/> Breman, Joel, James Herrington, Gaurvika Nayyar, and Paul Newton. Poor-Quality Antimalarial Drugs in Southeast Asia and Sub-Saharan Africa. *Lancet of Infectious Diseases*. June 2012.

<https://www.thelancet.com/journals/laninf/article/PIIS1473-3099%2812%2970064-6/abstract> found a similar

Because substandard medications may not be strong enough to effectively treat patients or protect them from illness, their use increases the risk of mortality and antimicrobial resistance.

The risks presented by dysfunctional supply chains have become more apparent as the amount of medicines flowing through LMICs has increased: between 2000 and 2015, global antibiotic consumption grew by 65 percent, driven largely by rising consumption in LMICs.¹⁸ Much of this consumption was funded by the global health initiatives.

These initiatives have historically taken different approaches to working with in-country supply chains. For example, PEPFAR has worked closely with local staff to strengthen national supply chains since its inception. Contrarily, the Global Fund took a largely hands-off approach through its first ten years of existence until it changed course in 2013 following the publication of an internal report that flagged the procurement, storage, and distribution of medicines as “significant vulnerabilities” that posed “larger risks to the Global Fund’s finances, operations, and reputation than any other activity in its business model.”¹⁹

The Global Fund responded by focusing more on improving in-country supply chains, which included spending \$130 million from 2014–16 to support the storage and distribution of medicines to the last mile. Similarly, GAVI has made improving immunization supply chains one of its six strategic focus areas for the period 2016–2020 and is providing guidance and technical assistance to recipient countries.²⁰

The importance donors place on the issue was highlighted by the \$9.5 billion contract that USAID awarded to a consortium led by Chemonics International in 2015 to carry out a Global Health Supply Chain Procurement and Supply Management (GHSC-PSM) project—the largest single contract that the agency has ever awarded. The project drew sharp criticism in its first year of implementation as the number of health commodity shipments that USAID delivered “on time and in full” dropped from 67 percent in the fourth quarter of 2016 to 7 percent half a year later.²¹ While the program’s performance has since improved, its struggles illustrate the difficulty of getting global health supply chains “right.”

result: 35 percent of tested antimalarials from 21 countries in SSA and seven countries in southeast Asia failed chemical analysis.

¹⁸ Original number from CDCC. Also: Cogan, Deirdre, Karrar Karrar, and Jayasree Iyer. Shortages, Stockouts, and Scarcity. Access to Medicine Foundation. May 31, 2018.

https://accessmedicinefoundation.org/media/uploads/downloads/5bf6bd722dea3_Antibiotic-Shortages-Stockouts-and-Scarcity_Access-to-Medicine-Foundation_31-May-2018.pdf

¹⁹ Global Fund. Audit Report: The Global Fund’s In-Country Supply Chain Processes. April 28, 2017.

https://www.theglobalfund.org/media/6363/oig_gf-oig-17-008_report_en.pdf?u=636784021770000000

²⁰ Gavi. Strategic Focus Areas. <https://www.gavi.org/support/pef/strategic-focus-areas/>

²¹ Igoe, Michael. Exclusive: Documents Reveal Largest USAID Health Project in Trouble. Devex. August 25, 2017. <https://www.devex.com/news/exclusive-documents-reveal-largest-usaid-health-project-in-trouble-90933>

Digital Supply Chains and Traceability

Throughout most of history, major advances in the reach of supply chains were driven by inventions that made it easier to move goods over long distances (e.g., steam power, the internal combustion engine, containerization). More recent advances, however, have been due to innovations that have made it easier to collect, store, and, most importantly, share information. The information and communications technology (ICT) revolution that took hold in the 1980s made it easier to coordinate complexity at long distances, enabling firms to take advantage of cross-country wage differentials by outsourcing production. At the same time, digitizing records made it easier to share data across the supply chain, automate recurrent tasks, and use analytics to improve business processes.

Computer networking and digitization not only allowed firms to manage their own internal supply chains more efficiently, it also made it easier for them to share data with their supply chain partners. As early as 1992, Wal-Mart was transmitting sale and inventory data from their retail stores directly to vendors on an hourly basis through their *Retail Link* system.²²

Today, the state of the art in supply chain management is the concept of “track and trace” or traceability. As the name suggests, track and trace initiatives allow actors on a supply chain to determine where a product is at any given time (tracking) and where it came from (tracing).

The approach starts with the process of serialization, in which a manufacturer assigns a unique identifier to each product that it ships using a two-dimensional (2-D) barcode that other supply chain actors can scan to obtain information about the product and record when it changes hands. The result is a digital trail of information tied to each package that records its origin, path through the supply chain, and other attributes. Track and trace is already common in many sectors in advanced economies. For example, any time you go to a retail or shipping company’s website to check on the status of a delivery, you are using a proprietary version of the approach (the key difference between this example and those discussed below is that in this case shipping companies use their own unique identifier and their own IT system).

Two examples help to illustrate how traceability systems can improve the way supply chains are managed:

- *Verifying the origin of goods:* Traceability can help vendors and customers verify the origin of the products they use, which is valuable in industries where concerns about sourcing practices or counterfeiting are common. For instance, the diamond industry has long sought ways to verify that traded gems have not been sourced in conflict zones and now faces the added challenge of preventing synthetic diamonds from entering the market. In response, several start-ups have developed platforms (in the proof-of-concept phase) intended to trace the provenance of gems from the mine to the jewelry store.²³ Similarly, in the fishing industry “boat to plate”

²² Wailgum, Thomas. 45 Years of Wal-Mart History: A Technology Time Line. CIO. October 17, 2017. <https://www.cio.com/article/2437873/infrastructure/45-years-of-wal-mart-history--a-technology-time-line.html>

²³ Kelley, Jason. Global Diamond and Jewelry Market Tracks Authenticity with IBM Blockchain. IBM. April 26, 2018. <https://www.ibm.com/blogs/think/2018/04/global-jewelry-ibm-blockchain/>

initiatives provide consumers with information about whether fish has been caught using sustainable methods.²⁴

- *Improving product safety and facilitating recalls:* Tracing a product's chain of custody back to its origin makes it easier and quicker to conduct recalls. This is particularly important for goods that can be contaminated. For example, it took the FDA two weeks to locate the source of an E. coli outbreak in spinach in 2006, during which time 199 people were hospitalized and three died in the United States.²⁵ More recently, it took the FDA four months to find the source of an E. coli outbreak in romaine lettuce in 2018.²⁶ As we discuss in more detail below, Walmart and IBM collaborated on a blockchain-based proof of concept that reduced the time it took to trace mangoes back to their origin from one week to several seconds.²⁷

The case for using traceability in health supply chains rests mainly on its ability to improve supply chain security. As noted above, counterfeiting and product diversion are significant risks in LMIC health systems. The ability to trace a product back to its origin can help retailers (and potentially even customers) verify that a product is what its label claims. And the ability to track the movement of individual products through a chain of custody can make it easier to detect when a product is diverted away from its intended destination.

Traceability could also improve the efficiency of health supply chain and procurement processes in a variety of ways, including:

- *Facilitating recalls:* As with the food safety example above, having the ability to quickly identify the source manufacturer of a contaminated medicine could make it easier to halt production and process recalls, reducing both costs and the risk of illness.
- *Improving supply and demand forecasts for procurement:* Aggregated and anonymized traceability data could provide greater visibility over supply and demand patterns for a given product and improve demand forecasting. Procurement agencies could use this information to forecast their commodity needs, anticipate stockouts, and strengthen their negotiating power (since they could more confidently guarantee volumes). In addition, the results of this quantification process “can be used to help maximize the use of available resources for procurement; advocate for mobilization of additional resources, when needed; and inform manufacturer production cycles and supplier shipment schedules.”²⁸
- *Managing inventory:* Improved visibility could also help actors on the supply chain better manage stocks within their own facilities by reducing waste and streamlining

²⁴ See Provenance.Org <https://www.provenance.org/>

²⁵ Yiannas, Frank. Genius of Things: Blockchain and Food Safety with IBM and Walmart. February 16, 2017. https://www.youtube.com/watch?v=MMOF0G_2H0A

²⁶ The FDA knew within weeks that the lettuce came from the Yuma, Arizona region, but was unable to pinpoint the exact source for four months. Belluz, Julia. The Romaine Lettuce E. coli Outbreak is Finally Over. Vox. July 1, 2018. <https://www.vox.com/science-and-health/2018/6/29/17517906/romaine-lettuce-e-coli-outbreak-over>

²⁷ Yiannas, Frank. A New Era of Food Transparency Powered by Blockchain. MIT Innovations. July 10, 2018. https://www.mitpressjournals.org/doi/pdf/10.1162/inov_a_00266

²⁸ USAID, Quantification of Health Commodities: A Guide to Forecasting and Supply Planning for Procurement June 2014.

inventory. For example, including unit-level product data in advanced shipping notices could allow managers to know a product's attributes, like its expiry date, before it arrives. Greater visibility could also facilitate "just in time" delivery, allowing managers to reduce the stock they hold in their warehouses.

It is worth noting that some of these benefits may be attainable using lot-level data in combination with better inventory management and communications without incurring the cost and complexity of unit-level serialization. More research is needed to determine when the benefits of more granular data outweigh the costs of producing it.

Two Traceability Models

Governments that want to establish a traceability system can choose between two basic approaches: point-of-dispense verification and full traceability.²⁹

In its simplest form, a point-of-dispense verification model involves two stages – one at the top of the supply chain and one at the bottom. In the first stage, manufacturers affix a serialized ID in barcode form to each of their outgoing packages and record information about the event in their databases. In the second, pharmacy and local clinic staff scan the product and send a query to the manufacturer (or to a centralized hub where manufacturers have uploaded data about their unique identifiers) to verify its authenticity before dispensing it.³⁰

While this approach reduces the likelihood that counterfeit products will be provided to consumers, it does not allow actors to track or trace the movement of products through the supply chain. As a result, it does not offer some of the benefits that full supply chain visibility can provide, such as easier product recall and the ability to pinpoint where certain products enter or exit the supply chain.

A full traceability model can provide these benefits but only at the cost of greater complexity. This model requires parties throughout the supply chain (including central medical stores, distributors, and warehouses) to scan, record, and share data each time a product changes hands. This forces more companies to collect and manage data and requires a more complex data architecture to enable sharing. It also produces significantly more data. For these reasons, the industry group RxGPS has argued that the verification model is the most cost-effective approach to improving supply chain security and that the added "minimal benefit of a [full traceability] system is realized only at significant cost."³¹ (See figure 3.)

Determining whether the benefit of shifting from a verification to a full traceability model is indeed "minimal" will require more evidence and experimentation. It will also depend largely on country context. While governments should implement the model that best aligns with

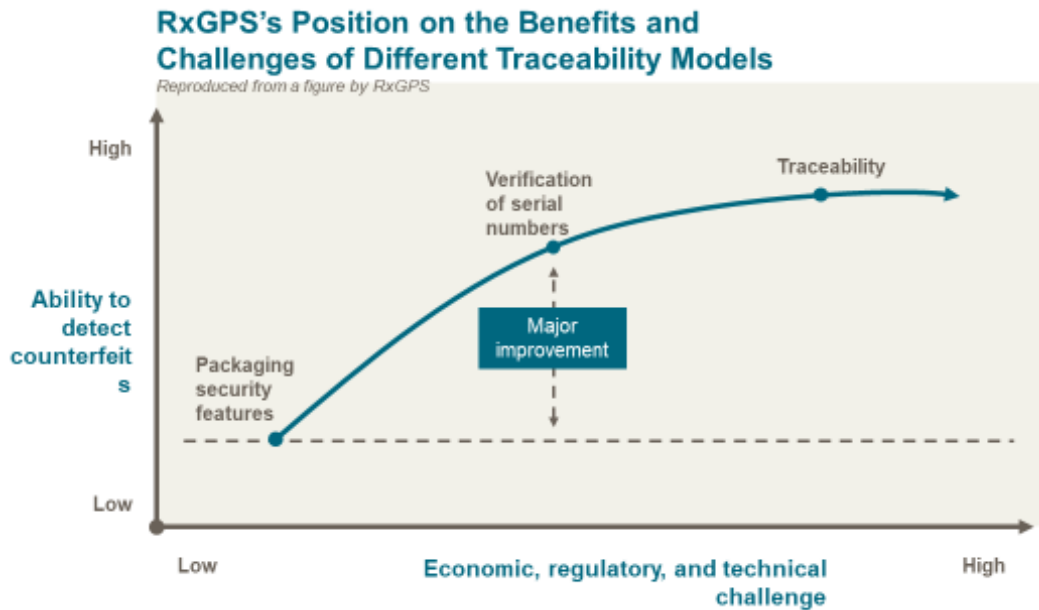
²⁹ This section draws heavily from the industry group's RxGPS's "[Position Statement: Benefits and Complexity of Common Serialization Models](#)"

³⁰ For an example of a central hub approach, see the European Hub that is part of the [European Medicines Verification System \(EMVS\)](#).

³¹ RxGPS "[Position Statement: Benefits and Complexity of Common Serialization Models](#)"

their aims and capabilities, taking a phased approach that establishes point-of-dispense verification first before considering using full traceability seems sensible.

Figure 3.



Source: [RxGPS Position Statement: Benefits and Complexity of Common Serialization Models](#)

Making Serialization Work for Health Supply Chains

An effective traceability system must carry out four functions: *identify* products down to the unit level, *capture* data, *share* that data with supply chain partners, and *use* it to improve outcomes.³² We consider each of these activities in turn, noting some of the challenges that LMICs may face.

Identifying Products

The first step towards establishing traceability is developing a system that assigns a unique ID to every product moving through a supply chain. This requires a classification scheme, often referred to as a Product Master, that matches standard identifiers to products based on their attributes.³³

Because the healthcare industry is global in nature, having different countries use a common standard for identifying products is important to ensure interoperability. Today, the biggest actors in global health, including large manufacturers, distributors, governments, and the global health initiatives, are converging behind traceability standards issued by the not-for-

³² GS1. *Standards*.

³³ GS1. *How Traceability Standards Work*.

profit organization GS1, which develops and maintains global standards for barcodes in global business (see figure 4).

The GS1 standard assigns a unique ID called a Global Trade Item Number (GTIN) to each good, which, when combined with a serial number, allows entities to uniquely identify each individual unit of a product line.³⁴ The resulting unique ID number is then incorporated into a barcode along with information about other important attributes such as batch number, expiry data, and the identity of a manufacturer.

For most pharmaceutical manufacturers, the one-time cost of upgrading labelling systems to produce barcodes that conform to GS1 standards is manageable. In fact, while large manufacturers initially resisted regulatory efforts to require serialization, many now view it as a valuable tool for the efficiency-enhancing reasons cited above. However, the cost could be more burdensome for small and niche manufacturers, particularly domestic LMIC manufacturers. Given the risk that these producers could be priced out of the market if GS1 standards become mandatory, the donor community may need to consider ways to subsidize this transition.

Capturing Data

Once a system to assign unique IDs is in place, the next step is to ensure that supply chain actors can capture the data linked to each product, usually by scanning a barcode. The rapid uptake of smartphones, which can be equipped with apps that enable them to scan barcodes, has drastically reduced the price of data capture. Evidence from pilot projects, however, suggests that single-purpose handheld scanners are still more effective.³⁵

Data capture will pose a greater challenge at lower levels of the supply chain in LMICs, where many records are paper-based and local staff are often underpaid and overworked. Unless local health workers believe there is a clear benefit to scanning products, data capture and entry will be inconsistent in the last mile, undermining the benefit of traceability. This is a challenge for both point-of-dispense verification and full traceability solutions. Several experts we spoke to cited a variety of mhealth initiatives that failed not because the technology was ineffective but because health workers did not have an incentive to use it.

Sharing Data

The information captured at each stage in the supply chain is useful only to the extent that it can be used and shared. For that reason, low levels of internet penetration in some LMICs could constrain their ability to implement a traceability approach. While connectivity is rapidly improving in sub-Saharan Africa and other low-income regions, it remains a barrier in rural and remote areas.

³⁴ GS1. *Global Trade Item Number (GTIN)*.

³⁵ Guirguis, Ramy, Liuchi Hara, Keith Hummel, and Monica Villanueva. *More Than Bar Codes: Integrating Global Standards-Based Bar Code Technology Into National Health Information Systems in Ethiopia and Pakistan to Increase End-to-End Supply Chain Visibility*. Global Health: Science and Practice. December 2017.

Sharing traceability data requires a “data architecture” that defines the rules, policies, and standards that govern how data is collected, used, stored, and shared between organizations.³⁶ In a centralized architecture, trading partners provide data to a repository that a single actor (usually a government agency) controls access to. In a distributed model, trading partners either keep data in their own databases and share it with one another by sending queries across a communication hub, or upload data to a shared ledger.

Unsurprisingly, industry actors generally prefer a decentralized system that gives them more control over how data is shared, while policymakers tend to favor a centralized one that gives government agencies a larger role. For countries with lower levels of technical capacity, however, creating and managing such a centralized system could be difficult. Thus, some governments may be better off relying on the private sector to manage the data-sharing network, while retaining the capacity to play an oversight role on the network.

Regardless of the model chosen, the sheer scale of data generated by traceability systems presents a challenge. Shifting from a system that tracks products at the batch level to one that does so at the unit level will generate orders of magnitude more data. For instance, while a pallet carrying five thousand units of a medicine from a single batch could be represented by one data point in a batch system (i.e., “there are five thousand units from Batch X on pallet X in this warehouse”), in a unit-level system the same pallet of goods would create 5,000 data points.³⁷

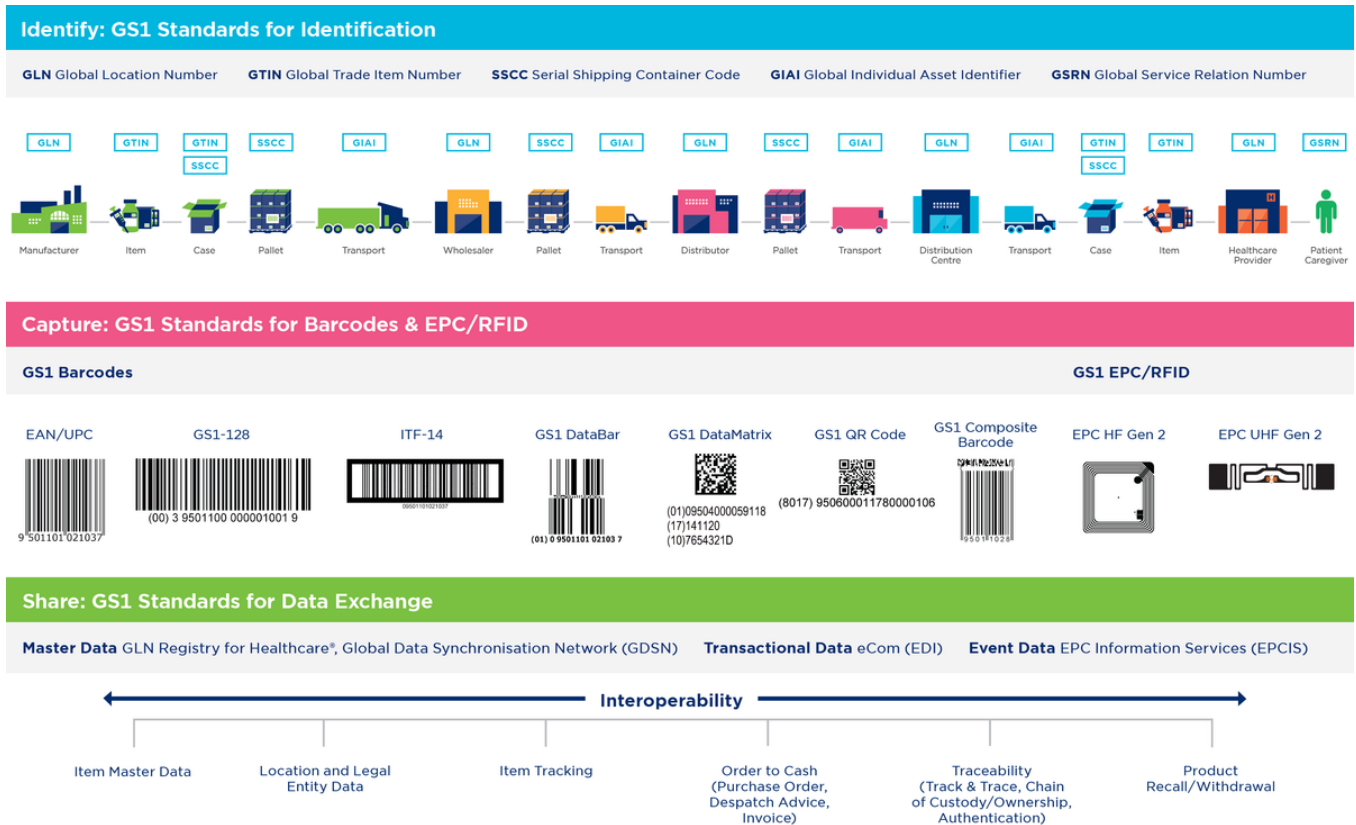
System designers must also ensure that data remains secure. Data security and privacy will be especially critical in cases where traceability systems extend down to the patient level or any time patient health records are involved.

³⁶ Food and Drug Administration. Drug Supply Chain Security Act (DSCSA) Public Meeting Series: Enhanced Drug Distribution Security. December 5-6, 2017. GS1 makes a more granular distinction between five different models of sharing data, including “one step up, one step down,” centralized, networked, cumulative, and decentralized.

GS1. GS1 Global Traceability Standard. August 2017.

³⁷ This point was made to us by Clinton D’Souza, Director of Public Health at Imperial Health Sciences.

Figure 4. The GS1 System of Standards



Source: https://www.gs1.org/sites/default/files/docs/traceability/GS1_Global_Traceability_Standard_i2.pdf

Making Use of Data

Once traceability data has been captured and shared, the final task is using it to achieve better outcomes. In a point-of-dispense verification model, data is used solely to verify the authenticity of medicine. In a full traceability model, data can be used for multiple purposes: it could be used by supervisors to improve monitoring; by procurement agents to enable better forecasting; and by distributors to facilitate inventory management. Since it will be difficult for a single system to meet all these needs, governments will need to clearly define the objectives they want to achieve.³⁸ They will also need to consider how much data sharing they will allow or mandate, as achieving the benefits described will depend on whether companies can access data from other supply chain actors.

Putting data to use requires the technical capacity to use digital tools and the ability to interpret the information provided. For example, local health workers must know what to do when a product scan reveals that the information on a given label is incorrect, or when the provenance of an item cannot be established. For that reason, training local health workers will be an important component of any serialization effort.

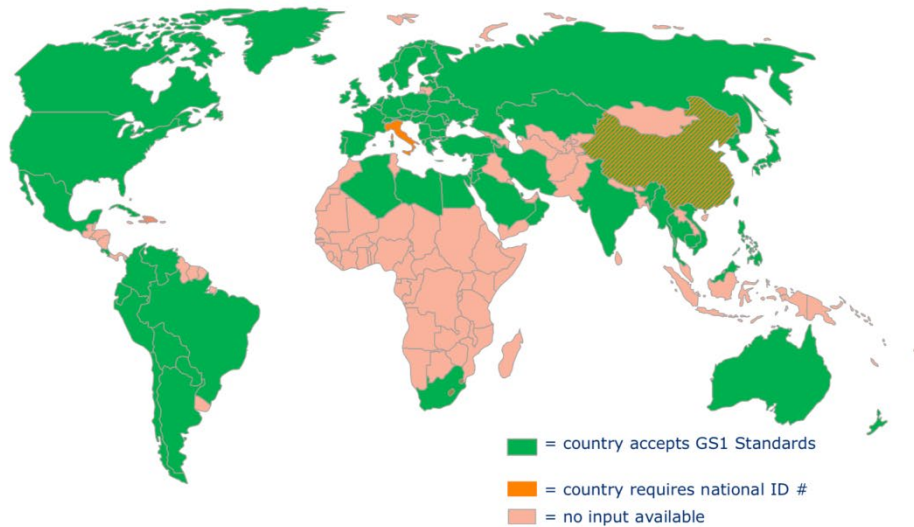
³⁸ Kreysa, Ulrike. *Traceability- The Basics*. African GS1 Healthcare Conference 2018. May 9, 2018.

Traceability Initiatives

More than 45 countries have already signed some form of a traceability approach into law, though few have reached an implementation stage.³⁹ Early movers include Argentina, China, India, Russia, Saudi Arabia, South Korea, and Turkey, whose long-standing system we discuss in box 1. The European Union and United States also merit special attention because of the size of their markets. We examine their regulations in box 2.

Figure 5.

Identification of pharmaceuticals using GS1



The Global Language of Business

© GS1 2018

³⁹ Infosys. *Pharmaceutical Serialization Track and Trace: Easy Guide to Country-Wise Mandates*.

Box 1. The Case of Turkey

Turkey was the first country in the world to pass comprehensive legislation requiring full traceability of all medicines sold in its territory. The country implemented the approach mainly to limit widespread reimbursement fraud, which was seen as a major (and costly) political problem, but used the same tools to improve other aspects of its supply chain, including drug quality.⁴⁰ A recent study on the Turkish system by Koray Parmaksiz noted that it has resulted in “a clean regulated supply chain, minimization of reimbursement fraud, facilitation of fast market recalls, and timely prevention of medicine shortages.”⁴¹

Due to its success, Turkey’s approach may be considered a model for governments that want to introduce track and trace into their own supply chains. But the country has several factors in its favor that will be difficult for most LMICs to recreate. This includes having a universal healthcare system in which the government acts as a single buyer for 95 percent of the medicines in the market, which gives it negotiating power.⁴² Pharmaceutical manufacturers have complied with the country’s traceability requirements, often at significant cost, because they are unwilling to forego doing business in its large market.

Having a single-payer system also removes the incentive for Turkish citizens to make purchases outside the regulated supply chain. This led to a positive feedback loop between the single-payer system and traceability. As Elizabeth Pisani notes, “well-managed stocks and an adequate benefits package reduce the likelihood that patients will step outside of the regular supply chain in Turkey, and falsified products are now rare in the nation’s regulated supply chain.”⁴³

Parmaksiz emphasizes the importance of aligning stakeholders in support of the project, noting that “although manufacturers, wholesalers and pharmacists expressed skepticism initially...both the size of the domestic market and the political determination to prevent fraud provided the state the power to align all stakeholders to implement [track and trace].”⁴⁴

Most countries with traceability laws either require or allow the use of GS1 standards.⁴⁵ Beyond that, however, governments have varied in their approach. Some key differences include:

- *Degree of visibility:* Some countries, like Brazil and United States, will ultimately require end-to-end visibility, in which every movement of a product through the supply chain must be recorded but most others mandate only point-of-dispense verification. The European Union’s “book end” approach requires supply chain actors to verify a medicine’s authenticity at the point of origin and the point of

⁴⁰ Pisani, Elizabeth. “The political economy of substandard and falsified medicines: an evidence-informed risk-assessment framework based on a multi-country study.” September 2018. Research Gate.

⁴¹ Parmaksiz, Koray. “Political and Economic Drivers of Medicine Quality: Main Drivers of Success of the Pharmaceutical Track and Trace System in Turkey.” July 2018. Thesis, Vrije Universiteit Amsterdam.

⁴² *ibid*

⁴³ Pisani, Elizabeth. “The political economy of substandard and falsified medicines: an evidence-informed risk-assessment framework based on a multi-country study.” September 2018. Research Gate.

⁴⁴ Parmaksiz, Koray. “Political and Economic Drivers of Medicine Quality: Main Drivers of Success of the Pharmaceutical Track and Trace System in Turkey.” July 2018. Thesis, Vrije Universiteit Amsterdam.

⁴⁵ GS1. Recommendations on a Harmonized Implementation of Traceability System Using GS1 Standards in China. February 2017.

dispensation but allows Member State health regulators to decide the degree of traceability required throughout the supply chain.

- *Product scope:* Many countries require all prescription drugs to be serialized, but others require it only for certain classes or types of drugs. For example, at present India only requires unique IDs on pharmaceuticals exported from the country.⁴⁶ Some countries, such as Egypt, have included over-the-counter products, which significantly expands the scope, cost, and complexity of the approach.⁴⁷ Many countries, including Argentina, China, Russia, and South Korea, have phased in a wider set of classes and types of drugs overtime.⁴⁸
- *Packaging level:* The European Union requires serialization at the unit level only while some countries, like India, require primary, secondary, and tertiary packages to each have a unique ID.⁴⁹

Each of these choices affects the cost, complexity, and effectiveness of the traceability approach taken, and how governments make them reflects both the aims they want to achieve and their capacity.

At present, deriving lessons for using track and trace in low income countries is difficult for several reasons. First, most of the countries that have enacted traceability regulations are high- or high-middle income economies. Not only do these countries have more human and technical capacity to draw on, their health systems are also less complex since they do not rely on global health initiatives to provide medicines. Second, even among countries with laws in place, most have only partially phased in their serialization requirements, which means that a significant share of medicines remain out of scope.

⁴⁶ Infosys. *Pharmaceutical Serialization Track and Trace: Easy Guide to Country-Wise Mandates.*

⁴⁷ Industry interviews

⁴⁸ *ibid*

⁴⁹ Infosys. *Pharmaceutical Serialization Track and Trace: Easy Guide to Country-Wise Mandates.*

Box 2. Comparing the US and EU Approaches to Traceability

The US Digital Supply Chain Security Act (DSCSA)

The DSCSA, which was signed into law in 2013, calls on the health industry to create an electronic, interoperable system to identify and trace the movement of prescription drugs distributed in the United States by 2023. The act is intended to increase supply chain traceability and “protect consumers from exposure to drugs that may be counterfeit, stolen, contaminated, or otherwise harmful.”⁵⁰

The regulation requires companies to record information about each product hand-off in an electronic “transaction history” and to provide this information to the FDA at request. It also requires supply chain actors to verify that each product is legitimate and unaltered in certain circumstances, and to quarantine drugs identified as suspect (i.e., counterfeit, unapproved, or potentially dangerous) and inform the FDA within 24 hours.

Notably, the DSCSA does not mandate how information exchange should take place and instead leaves this up to the healthcare industry to decide. The US health industry has yet to converge around a single solution that will provide an electronic, interoperable system to trace products at the package level by 2023.

The EU Falsified Medicines Directive (FMD)

The FMD was passed in 2011 and comes fully into force in February 2019. An EU-wide regulation, the FMD is intended to prevent counterfeit prescription drugs from entering the pharmaceutical supply chain. The regulation requires manufacturers to imprint a unique identifier on each pack of medicine and send data about identifiers to the European Medicines Verification System (EMVS) and member state verification systems, which dispensing agents must use to verify the authenticity of medicines.⁵¹

The FMD also requires some form of an anti-tamper device, such as an imprinted seal. If the seal is compromised, the medicine cannot be sold. The specifications of the anti-tampering devices are at the discretion of the manufacturers. These safety features are intended to identify and verify the authenticity of individual packs of medicine.

Comparing the approaches

Both the DSCA and the FMD allow for the use of GS1 standards, but do not mandate them. Both systems also require manufacturers and re-packagers to label each lot (and eventually each package) with a unique serial number in a barcoded format for event recording, verification, and recordkeeping. In addition, both regulations leave most over-the-counter (OTC) drugs out of scope.

Beyond that, the regulations take different approaches. In the United States, the DSCSA requires full traceability, with supply chain actors responsible for collecting data on each change of ownership. Conversely, the EU FMD implements a point-of-dispense verification model that requires supply chain actors to verify a medicine’s authenticity only at the point of origin and point of dispensation. It leaves the decision whether to require traceability in other parts of the supply chain up to Member State health regulators.

⁵⁰ See: [Drug Supply Chain Security Act](#)

⁵¹ European Medicines Verification Systems. [Introduction to the European Medicines Verification System \(EMVS\)](#).

Making Traceability Work in Low-Income Countries: Ongoing Initiatives

The global health community has worked to expand the use of traceability in LMIC health systems by encouraging the use of GS1 standards by their suppliers and working with LMIC governments to establish the foundation required for adopting serialization.

In 2017, the Interagency Supply Chain Group (ISG)—which includes among its members the Bill and Melinda Gates Foundation, DFID, the Global Fund, Gavi, World Bank, World Food Programme (WFP), World Health Organization (WHO), and several UN agencies—endorsed GS1 standards. The same year, USAID notified its suppliers that they would have to identify and label products using GS1 standards by end-2018.⁵²

USAID has also played a lead role in developing a master product list for global health commodities. Using the GS1's Global Data Synchronization Network (GDSN), which allows manufacturers to share product master data in near-real-time, the project aims to provide a “single source of truth” for product attributes that is accessible to all supply chain actors.⁵³ Other organizations, including the Global Fund and the United Nations Population Fund (UNFPA) have already agreed to work off this list and USAID is encouraging its partner countries to use the list as the basis for their own product directories. South Africa announced in 2017 that it would require its vendors to use global data standards aligned with USAID's requirements.⁵⁴

Finally, USAID is also taking the lead working with governments to improve in-country supply chains. Through the GHSC-PSM project, the organization is currently working with Ethiopia, Ghana, Lesotho, Malawi, Pakistan, Uganda, and Tanzania.⁵⁵

Other organizations working to encourage the use of traceability in LMICs include the Global Steering Committee (GSC) for Quality Assurance of Health Products, a voluntary coalition of global health initiatives, national governments, NGOs, and drug companies focused on improving supply chain integrity, and the industry group RxGPS, which works with national regulators to promote traceability.⁵⁶

These advocacy efforts have made a difference. The growing interest of LMIC governments in traceability was on display at the first African GS1 Healthcare conference held in Addis Ababa, Ethiopia in May 2018, which was attended by representatives from 38 countries, 45

⁵² USAID Global Health Supply Chain Program. *Barcode Registration to GDSN Synchronization*.

⁵³ USAID Global Health Supply Chain Program. *The GDSN Opportunity for Global Health*.

⁵⁴ Calvaresi Barr, Ann. *Memorandum for the Acting Administrator: OIG Advisory Memorandums and Global Health Advisory on Internal Control Concerns*. USAID Office of the Inspector General. June 7, 2017.

⁵⁵ USAID Global Health Supply Chain Program. *Implementation of GS1 Global Standards for Product Identification*. February 21-23, 2017.

⁵⁶ Cinnamond, Martin and Tom Woods. *The Joint Interagency Task Force and the Global Steering Committee for the Quality Assurance of Health Products: Two New and Proactive Approaches Promoting Access to Safe and Effective Medicines*. American Journal of Tropical Medicine and Hygiene. June 2015.

RxGPS Website: <http://www.rxgpsalliance.org/>

regulatory bodies and 23 humanitarian organizations.⁵⁷ The next African GS1 Healthcare conference will take place in Nigeria in September 2019.

Hurdles to Implementation in LMICs

Although the concepts behind traceability are relatively simple and the hardware requirements not prohibitively expensive for most supply chain actors, developing the systems needed to use traceability is a huge endeavor that requires significant upfront investment.

These start-up costs include the need by manufacturers to install new machinery and software to label products according to agreed standards, develop databases to retain the data, put systems in place to share data, and integrate the serialization process into their existing systems. Downstream actors also face start-up costs, as they need to purchase scanning equipment and train employees how to access and use serialization data.

In addition, all parties must also have the necessary IT tools in place to allow data sharing over the network. While connectivity may be a limiting factor in remote areas, from a purely technical perspective, most of these requirements appear manageable. The specific IT requirements will differ depending on the data-sharing model used. For example, it is feasible that countries with Logistics Management and Information Systems (LMIS) in place could use them as a backbone for a data-sharing network.

Achieving scale is another hurdle since, for a traceability system to be effective, participation must be widespread. If too many of a country's supply chain actors remain outside the network, the visibility provided by a traceability approach and its contribution to supply chain integrity will both be undermined.

Political leadership is crucial to overcoming the challenge of coordination, particularly as some companies may be reluctant to participate because of the start-up costs involved. Government officials can foster participation by convincing supply chain actors of the benefits of traceability or mandate participation by law. Government commitment is also critical: in many instances implementation dates for laws have been delayed due to a government's inability to meet their own deadline.

There is also a need to build political consensus around the use of traceability within governments. Several experts we spoke to noted instances in which senior health agency officials had blocked efforts to improve supply chain visibility because they benefitted from corrupt practices, like parallel importation.

Even with strong political leadership, laying the groundwork for traceability will take time. The industry group RxGPS suggests that governments give companies at least four years to comply with serialization requirements. It is worthwhile to note that the United States and European Union have both given their industries ten years to meet full traceability requirements.⁵⁸

⁵⁷ GS1. [Healthcare Conference Ethiopia 2018](#). 2018.

⁵⁸ RxGPS. *Serialization Primer*.

The complexity of the undertaking will depend largely on how well the approach taken aligns with the country's human capacity and existing legal framework and market structure. Of course, some countries are better positioned than others.

For example, Ethiopia has several conditions in its favor compared to other countries in sub-Saharan Africa including its progress towards achieving universal health care by 2035 and the large role played by the government in its pharmaceutical market, where it buys an estimated 80 percent of all medicines.⁵⁹ Conversely, in Kenya, where 50 percent of medicines in value terms are distributed through the private sector, with many passing through the informal gray market, and where the country has made only limited progress towards achieving universal health coverage, the path to establishing traceability will likely be more difficult.

The Limits of Traceability

While establishing serialization-based systems in LMICs is an important goal, they cannot address concerns about drug quality on their own. For that reason, it is appropriate to consider traceability as just one element of a broader, holistic effort to enhance supply chain integrity.

For instance, while traceability can make it easier to trace substandard products back to their source, quality assurance testing is needed to determine what medicines are substandard in the first place. Post-market surveillance is also needed to ensure that consumers are receiving high-quality products. To date, quality assurance testing has not spread widely enough in LMICs. For example, Kenya has only three quality testing labs in the entire country and it costs the equivalent of \$300 to test a single medicine packet.

An effective traceability system also requires a clear legal framework supported by a culture of compliance and enforcement. If dispensing agents who identify substandard medicines do not know how to report their findings, or have little confidence that those findings will be acted on, the traceability system will not work. More broadly, it is a mistake to expect technology to solve for political and social problems, such as lack of leadership, limited accountability, and inadequate human and financial resources.

The Next Frontier? Using Distributed Ledger Technology for Traceability

Although efforts to introduce serialization into health supply chains are still at an early stage, some in the global health community are already exploring how a more recent innovation, distributed ledger technology (DLT), may help to further improve supply chain visibility.

⁵⁹ This point and the next were made to us by Dan Rosen, Founder of AFRX Consulting.

At its core, DLT is a database structure in which records are shared and synchronized across different computers (often referred to as nodes) in a peer-to-peer network.⁶⁰ Unlike most databases, where a single entity has the authority to amend records and approve updates, changes to a distributed ledger must be validated by a predetermined set of network participants, each of which maintains an up-to-date copy of the ledger. Once an update to the ledger is approved, it is synchronized across the entire network and protected against tampering by cryptography.

DLT is a fast-evolving technology with a wide variety of models under its banner. One key difference across these models is whether participation is open or restricted. In *permissionless* systems, like Bitcoin and Ethereum, anyone can maintain a copy of the ledger and participate in the consensus process without being pre-approved. This means that no single actor or group of actors can independently approve or block updates.⁶¹ But this “censorship resistance” comes at a cost, as it requires the use of a computationally difficult (and therefore energy-intensive) consensus protocol that makes cheating nearly impossible.

Permissioned ledgers function quite differently. In these systems, membership is restricted to a pre-selected group of participants and the authority to approve updates may be limited to an even smaller set of actors, sometimes referred to as “trust anchors.” Because these systems have pre-vetted membership, they can rely on less computationally intensive consensus mechanisms to validate transactions.

Permissioned systems therefore forego the benefit of censorship resistance in exchange for greater efficiency. Although this is at odds with the original decentralizing ethos that gave rise to DLT, it appeals to organizations that want to take advantage of the efficiency and visibility gains that the technology offers while maintaining greater control over outcomes. For that reason, most enterprise solutions - and all the supply chain proposals discussed below - use a permissioned approach.

Despite the excitement around DLT’s potential to tackle a broad variety of societal problems, the number of its real-world applications remains small and many of the technology’s proposed uses are unlikely to take hold in the foreseeable future.⁶² But supply chain management could be an exception and there is considerable momentum in the logistics industry on exploring its use, particularly in the food sector (see Box 3 for more details on DLT initiatives underway in the food and health sectors).

⁶⁰ Although the terms “blockchain” and DLT are often used synonymously, the former is a particular kind of distributed ledger in which data are stored in “blocks” cryptographically linked to one another in a “chain.”

⁶¹ An important caveat is the possibility of a “51 percent attack,” in which “a party controlling the majority of the hash power [on a permissionless ledger] can double-spend, reverse or censor transactions.”

B, Matt. *Bitcoin’s Attack Vectors: 51% Attacks*. Medium. November 27, 2018.

⁶² For example, in another paper, one of us argues that the hopes that DLT can serve as a basis for digital ID: Pisa, Michael. *Reassessing Expectations for Blockchain and Development*. Center for Global Development. May 17, 2018.

Box 3. Ongoing DLT Initiatives in the Food and Health Sectors

Many of the challenges found in health supply chains also exist in the food industry, including the need to verify the safety and freshness of products, ensure best production (or horticulture) practices, and prevent the entry of fraudulent goods. In addition, supply chains in both sectors often have many intermediaries and product handoffs.

Although actors in both sectors have expressed interest in using DLT for supply chains, the food industry has advanced further in its experiments with the technology. This may reflect the health industry's stricter data security standards, which can slow innovation. Another notable difference between the industries is that the food sector's traceability initiatives have been conducted at the batch level, while the health sector has increasingly focused on item-level traceability (which produces more data and is costlier to implement).

Food Sector

Walmart has been a leader in the use of DLT for supply chains since 2016 when it conducted a proof of concept in collaboration with IBM that tracked the movement of mangoes from farmers in Mexico to Walmart stores in the United States. The company reported that using DLT allowed them to reduce the time it took to trace mangoes back to their origin from one week to several seconds.⁶³ The two companies then conducted a separate pilot using DLT to track pork from farms in China to stores in the United States with similar positive results.

Since that time, IBM has established a DLT-based food supply chain network, IBM Food Trust, which comprises some of the largest food retailers in the world, including Walmart, Carrefour, Kroger, Wegmans, Tyson, Driscolls, Nestle, Unilever, Danone, McCormick, and Dole.⁶⁴ In September 2018, Walmart announced that it would require all its leafy greens suppliers "to capture digital, end-to-end traceability event information using the IBM Food Trust network" by September 2019.⁶⁵

Health Sector

The US pharmaceutical industry is exploring DLT's potential in response to the US Drug Supply Chain Security Act (DSCA), which calls on the industry to develop an electronic and interoperable system to trace the movement of prescription drugs in the country by 2023.

Over the last two years, several initiatives that aim to use DLT to meet DSCA requirements have been announced, including The MediLedger Project run by the company Chronicled, and a collaboration between DHL and Accenture.⁶⁶ Industry organizations like the Center for Supply Chain Studies are also exploring how distributed ledger solutions might help meet DSCA requirements.⁶⁷ Because these projects are not nearly as advanced as those conducted in the food sector, data on their effectiveness has not yet been published.

⁶³ Yiannas, Frank. *A New Era of Food Transparency Powered by Blockchain*. MIT Innovations. July 10, 2018.

⁶⁴ IBM. *IBM Food Trust: Trust and Transparency in Our Food*.

⁶⁵ Mounce, Russell, Martin Mundo, Charles Redfield, and Frank Yiannas. *Food Traceability Initiative Fresh Leafy Greens*. Walmart. September 24, 2018.

⁶⁶ Accenture. *DHL and Accenture Unlock the Power of Blockchain in Logistics*. March 12, 2018.

⁶⁷ Center for Supply Chain Studies. <https://www.c4scs.org/>

DLT's Potential Benefits

Many of the challenges facing supply chains across industries stem from a lack of information flow. The biggest barrier to sharing information across the supply chain is the need for data security, which is particularly acute in the pharmaceutical industry. For good reason, companies are unwilling to share data that may be commercially valuable with their supply chain partners. As a result, data that could be used to improve logistics remains siloed within individual organizations.

DLT provides a potential solution to this problem by providing a single, tamper-resistant ledger that uses cryptography to ensure that only authorized parties can access certain records. For instance, a distributed ledger could be designed to allow regulators full visibility of a supply chain, while limiting others to a “one-up, one-down” view that only provides information about a good’s movement one step upstream and one step downstream in the supply chain.

By allowing companies to share control over a ledger rather than send their data to a third party that maintains a separate database, DLT could help overcome the “trust gap” that prevents them from sharing information. Having parties upload transaction data to the same ledger could also reduce the time companies spend reconciling records by making it easier to detect errors and inconsistencies. And the near-real-time visibility that DLT provides could make it easier to track product movement, conduct recalls, manage inventory, and monitor regulatory compliance.

Another potential advantage of using DLT is the ability to use smart contracts—i.e., computer programs that execute automatically when certain conditions are met—to automate processes that were formerly done manually. This includes the possibility of automating the steps involved with obtaining trade financing, a time-consuming and often paper-intensive process that can be a bottleneck in LMIC health supply chains.

DLT in Reality: Challenges and Limitations

Although DLT holds some promise, the health industry would need to overcome several obstacles before the technology can provide a viable framework for health supply chains.

As with serialization, the biggest challenges to using DLT are political rather than technical. Indeed, the technical necessities required by DLT are similar to other traceability systems. Beyond the need for a network connection and a mobile device, uploading data should not be a hurdle, if workers are well-trained and incentivized and the user interface is well-designed.

The bigger hurdles are achieving scale and regulatory uncertainty. As with any traceability system, a DLT approach must achieve enough scale (sometimes referred to as creating a “minimally viable network”) to function effectively. This requires having a business model that gives actors at every level of the supply chain an incentive to participate and a path to onboarding.

The willingness of companies to join a DLT-based system will depend in part on how it is managed. Almost by definition, distributed solutions are more difficult to govern than centralized approaches that give administrative authority to a single actor. Some of the

governance issues that a DLT approach must address include who controls network membership, who can access what pieces of information, and who owns data on the ledger.

Regulatory uncertainty makes answering these questions more difficult. Experts in the highly regulated health sector are just beginning to consider how decentralized models fit with existing legal frameworks for data security and what reforms might be needed to enable a DLT approach. At the same time, national standards for data privacy and security are evolving quickly, with governments taking a variety of approaches that may raise compatibility issues for cross-border DLT solutions.

Until companies have confidence that a DLT system can comply with these regulations, they are unlikely to invest enough to create one. At the same time, policymakers will only pursue reforms once they have developed expertise around decentralized models. The risk is that both groups will take a “wait and see” approach that stunts the development of the technology.

A Potentially Worthy but Distant Goal

While most of the experts we spoke to believe that DLT-based supply chain solutions are a distant goal in lower income countries (and, some would argue, in rich countries as well), the good news is that having unique product IDs is an important prerequisite for any DLT solution. Therefore, any steps that the global health community takes to further the use of serialization today will also lay the groundwork for a DLT-based approach.

Recommendations

The global health community has made impressive strides in recent years raising awareness of the benefits of traceability and working with LMIC governments to lay the groundwork. The recommendations below are intended to support those efforts going forward.

Identify the problem to be solved

The approach to traceability a government should take depends entirely on the objective it wants to achieve. Countries whose primary aim is to improve supply chain visibility should take different measures than those focused on limiting reimbursement fraud or facilitating recall management. While a traceability system may be able to meet multiple aims in the long-run, over the short-run governments should focus only on their primary goal, given the high level of political willingness and coordination that implementing traceability requires.

Develop an evidence base

Despite growing interest in traceability solutions, there is still a lack of information about which approaches work best and in what context. While it seems likely that a less resource-intensive approach like point-of-dispense verification will be the best fit for many LMICs, determining the added cost and benefit of shifting to a full traceability approach is ultimately an empirical question. The donor community can help fill this gap by funding pilot projects that use different traceability models to measure their impact.

For example, USAID/PEPFAR and the Global Fund could design a series of pilot projects to assess the impact of introducing a specific traceability system on leakage, savings, the share of products delivered on-time-in-full (OTIF), and inventory management, as well as the operational and capacity requirements for implementation. An evaluation team would measure a baseline of metrics ahead of implementation and assess progress on those metrics on a monthly basis.

The findings of such an evaluation would help USAID and the Global Fund assess the costs and impact of introducing traceability and better understand the operational requirements needed for its introduction. Donors could also use this information to estimate the return on investment (ROI) that governments face over the medium-term (when limited elements of the system are in place) and long-term (after a full traceability system is established) to make a business case for investment.

Build technical capacity

Traceability systems generate a massive amount of data and their effectiveness depends on the ability of supply chain actors to put that data to use and on the integrity of the data collected and entered. For that reason, harnessing the full benefits of traceability will require workers to have a high level of data literacy. Donors should work with LMIC governments to develop capacity building programs that emphasize training in digital skills, including basic digital literacy as well as more advanced analytics and data science skills.

Shift resources

With many LMICs set to graduate from aid eligibility over the next two decades, more should be done now to improve their procurement and in-country supply chain processes. While the global health initiatives are taking supply chain integrity more seriously than in the past, the amount of resources they direct towards strengthening supply chains is a small fraction of their overall spending. Donors should shift more of their resources towards activities that help LMICs lay the groundwork for serialization, including building capacity and investing in data infrastructure.

Incentivize adoption and harmonization

The best way to encourage LMIC adoption of traceability is to provide evidence of its benefit, including through the evaluation process described above, but donors might also consider ways to reward LMICs that take concrete steps to implement the approach or harmonize their national medicines list with USAID's Product Master, including by offering more aid or technical assistance. This could include having donors provide cash on delivery for achieving measurable, verifiable outcomes tied to adoption and harmonization.⁶⁸

Protect small manufacturers

Although the upfront investment required to use serialization is not prohibitive for most supply chain actors, it may be for small manufacturers and those that produce for niche

⁶⁸ [Cash on Delivery](#). Center for Global Development.

markets. For that reason, the donor community should consider subsidizing manufacturers that are unable to afford the one-time cost and providing them with the necessary training.

Make room for the private sector

Private sector start-ups are playing an increasingly important role in LMIC health system, including many that are focused on improving medicine distribution in areas where supply chains are dysfunctional. Conversations about implementing traceability tend to be dominated by big actors like governments, global health organizations, and large manufacturers. But it is important to take the needs of these start-ups (and the lessons they have learned) into account and to design a traceability system that promotes further innovation. To that end, these companies should have a voice in policy discussions, and it would be useful to have private sector actors participate in some of pilot evaluations.

Conclusion

Traceability holds great promise for improving LMIC health supply chains. While the challenges to implementation are real, they are also surmountable by governments who have a strong political commitment. The donor community has helped to create momentum in support of using traceability for health supply chains worldwide but these efforts are still in the early stages. Today, donors can sustain the momentum they have helped to create by building evidence about what approaches work best and working with LMIC governments committed to improving supply chain integrity to translate that knowledge into action.

Appendix. Expert Interviews

- Anup Akkihal. Logistimo, CEO
- Azhee Akinrin, Global Health and Development Consultant
- John Bass. Hashed Health, Founder and CEO
- Agustina Calatayud, Inter-American Development Bank. Supply Chain and Logistics Specialist
- Bob Celeste, Center for Supply Chain Studies. Founder
- Iulian Circo, Proof of Impact. Co-Founder
- Stuart Corby. Track.one for Pharma solutions. Co-Founder
- Clinton De Souza, Imperial Health Sciences, Director of Public HealthHealth
- Lindabeth Doby. USAID. Senior MIS Advisor
- Ramy Guirguis. USAID, Senior IT Advisor
- Ramesh Gopinath. IBM, Blockchain Solutions
- Aradhana Gurung. Nepal Innovation Lab, Lead Manager
- April Harding, Global Health advisor
- Hitesh Hurkchand, UNICEF, Principal Consultant
- Ulrike Kreysa .GS1 Healthcare, VP
- Jerry La Forgia. Aceso Global, CTO
- Eric Marshall. Senior Director, Leavitt Partners
- Koray Parmaksiz. Researcher at Erasmus School of Health Policy & Management
- Elizabeth Pisani. Ternyata Ltd, Public Health Consultant
- Gregory Rockson. mPharma, Co-Founder and CEO
- Kaitlyn Roche, IBM. Global Standards Consultant for USAID
- Daniel Rosen. AFRX Consulting. Founder
- Bright Simons. mPedigree, President and Founder
- Natalie Smolenski. The Learning Machine, SVP Business Development
- Anne Snowdon. World Health Innovation Network. Chair and Professor
- Susanne Somerville, Chronicled. CEO
- Jessica Vernon, Maisha Meds. Co-Founder/CEO
- Tom Woods, Woods International. ChairChair of the Global Steering Committee (GSC) for Quality Assurance of Medical Products
- Prashant Yadav, Bill and Melinda Gates Foundation. Strategy Leader, Supply Chain
- Raul Zambrano, International Development in ICT