

Review

The imperative for stronger vaccine supply and logistics systems

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ABSTRACT

With the introduction of new vaccines, developing countries are facing serious challenges in their vaccine supply and logistics systems. Storage capacity bottlenecks occur at national, regional, and district levels and system inefficiencies threaten vaccine access, availability, and quality. As countries adopt newer and more expensive vaccines and attempt to reach people at different ages and in new settings, their logistics systems must be strengthened and optimized.

As a first step, national governments, donors, and international agencies have crafted a global vision for 2020 vaccine supply and logistics systems with detailed plans of action to achieve five priority objectives. Vaccine products and packaging are designed to meet the needs of developing countries.

Immunization supply systems support efficient and effective vaccine delivery.

The environmental impact of energy, materials, and processes used in immunization systems is minimized.

Immunization information systems enable better and more timely decision-making.

Competent and motivated personnel are empowered to handle immunization supply chain issues.

Over the next decade, vaccine supply and logistics systems in nearly all developing countries will require significant investments of time and resources from global and national partners, donors, and governments. These investments are critical if we are to reach more people with current and newer vaccines.

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1. Current issues facing vaccine supply chain and logistics systems

Since 2000, national-level Expanded Programmes on Immunization (EPIs) have seen their vaccine portfolios grow from 6 basic antigens to the 12 now recommended by the World Health Organization (WHO) for all countries [1]. Additional vaccines are recommended for specific population groups and regions, and more are in the product development pipeline [1,2]. These vaccines have great potential to reduce morbidity and mortality associated with pneumonia, diarrhea, cancers, and other diseases. However, access to all vaccines hinges on the ability of supply and logistics systems to receive, store, and transport vaccines at proper temperatures and get them to the right places in a timely manner [3].

With few exceptions, vaccine supply and logistics systems around the world are unable to keep pace with growing immunization programs [4–10].

1.1. Impact of vaccine schedules and presentations on cold chain volume requirements

The most visible impact of new vaccines is an increase in the volume of products that need to be stored, tracked, and transported. Fig. 1 shows per-dose volume requirements for various immunization schedules. For countries introducing both rotavirus and 10-valent pneumococcal conjugate vaccines (moving from schedule C* to schedule E in Fig. 1 below), the total volume increases by as much as 143% per dose, assuming wastage rates remain constant [11]. This figure does not reflect the fact that closed vial wastage rates are substantially higher for vaccines in multi-dose vials than in single dose presentations. This means that more doses must be ordered, stored, and managed than implied by the figure [12,13].

In a recent analysis of 20 countries planning to introduce pneumococcal and/or rotavirus vaccine in 2011 and 2013, researchers from WHO and PATH compared vaccine volume requirements with available capacity [14]. Fig. 2 shows how planned vaccine introduction impacts capacity utilization at the national store between 2011 and 2015, assuming no new equipment is purchased beyond already planned expansions and no changes are made to current delivery strategies.

Figs. 3 and 4 show how the introduction of new vaccines impacts capacity at regional and district levels. Because only a portion of regional and district-level facilities were assessed, these graphs show the proportion of assessed facilities for which the required capacity exceeds available capacity by at least 25%. When compared to Fig. 2, one can see how capacity constraints at one level can sometimes be overcome by moving products to another level. Nonetheless, Figs. 3 and 4 show that regional and district stores in some countries are and will continue to face severe capacity constraints requiring new equipment or new delivery strategies.

1.2. Choices for cold chain equipment

Choosing the right cold chain equipment is strategically important, as such choices can facilitate changes in delivery routes and frequencies, which in turn could have an impact on vaccination schedules and strategies. For example, the availability of cold boxes with long hold-over times for stationary storage may enable

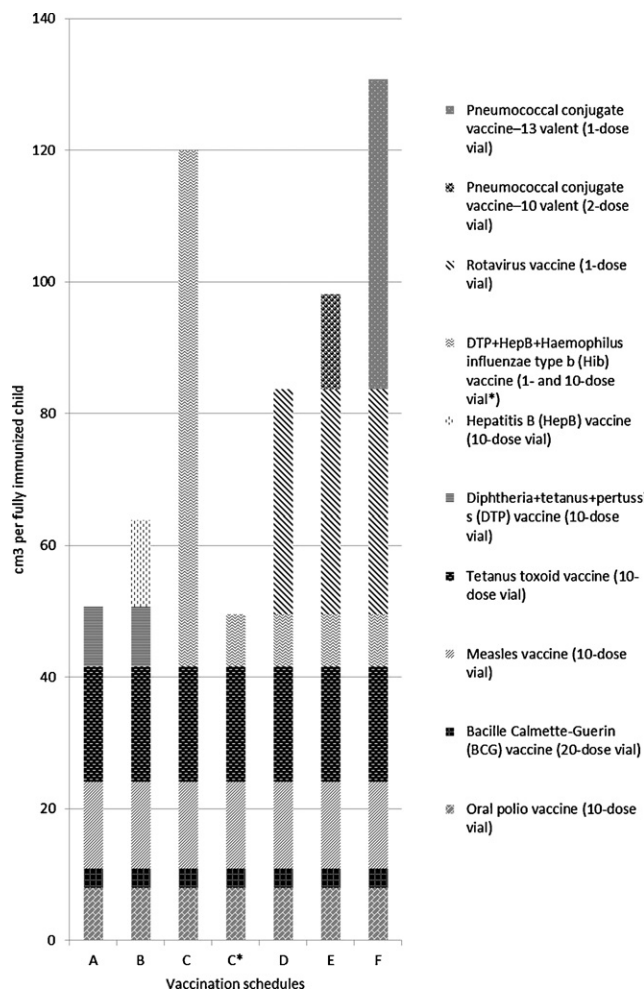


Fig. 1. Vaccine volume requirements for various immunization schedules. *Notes:* Volumes shown in the graph are for full immunization (e.g., all recommended doses). Schedule A: traditional EPI vaccines: 4 doses oral polio, 1 dose BCG, 2 doses measles, 3 doses DTP, and 4 doses TT vaccine. Schedule B: traditional EPI vaccines, plus 3 doses HepB vaccine. Schedule C and C*: traditional EPI vaccines, replacing DTP with 3 doses pentavalent (DTP + HepB + Hib) vaccine. Schedule D: Schedule C* plus 2 doses rotavirus vaccine. Schedule E: Schedule D plus 3 doses pneumococcal conjugate vaccine-10 valent. Schedule F: Schedule D plus 3 doses pneumococcal conjugate vaccine-13 valent.

countries to provide the birth dose of hepatitis B vaccine in remote areas with no access to electricity [15]. New direct-drive solar refrigerators without batteries are a reliable choice for areas with only intermittent access to electricity, but they require adequate sunlight. Domestic refrigerators may be an attractive and low-cost choice but do not often meet minimum WHO Performance, Quality, and Safety (PQS) specifications and can damage vaccines through unreliable temperature control [16–19]. To navigate equipment choices, countries need more information and tools that allow them to assess trade-offs and select equipment that best fits their needs and programmatic goals. Budgets need to be made available. Equipment manufacturers, in turn, need adequate demand to spur new

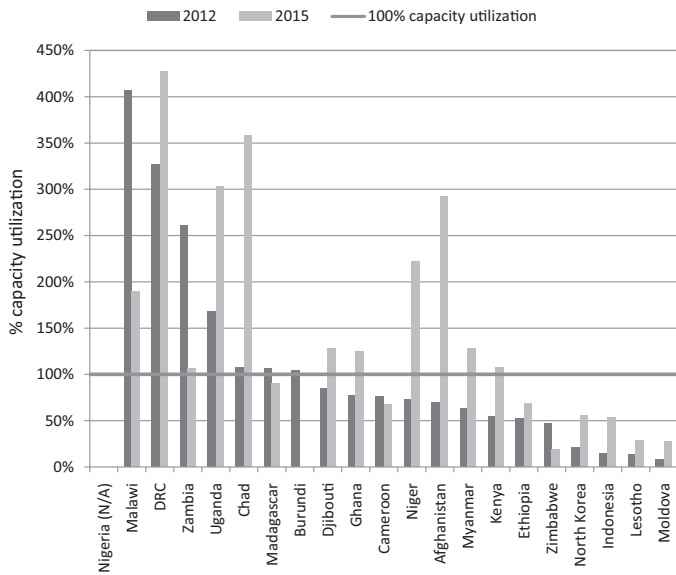


Fig. 2. Percent of national store occupied by vaccine in 20 GAVI-eligible countries (actual and planned). *Notes:* For most countries, the data source is either an effective vaccine management (EVM) assessment or a cold chain equipment manager (CCEM) comprehensive inventory. Data show the percentage of the national store occupied by current and planned vaccines based on New and Underused Vaccine Initiative group internal tracking tools. Reductions in capacity utilization from 2011 to 2015 are explained by planned equipment upgrades or by a switch from mono-dose to multi-dose presentations of pentavalent vaccine. The order of countries in the x-axis reflects highest to lowest capacity utilization in 2011. In some countries, reliable data was not available (N/A).

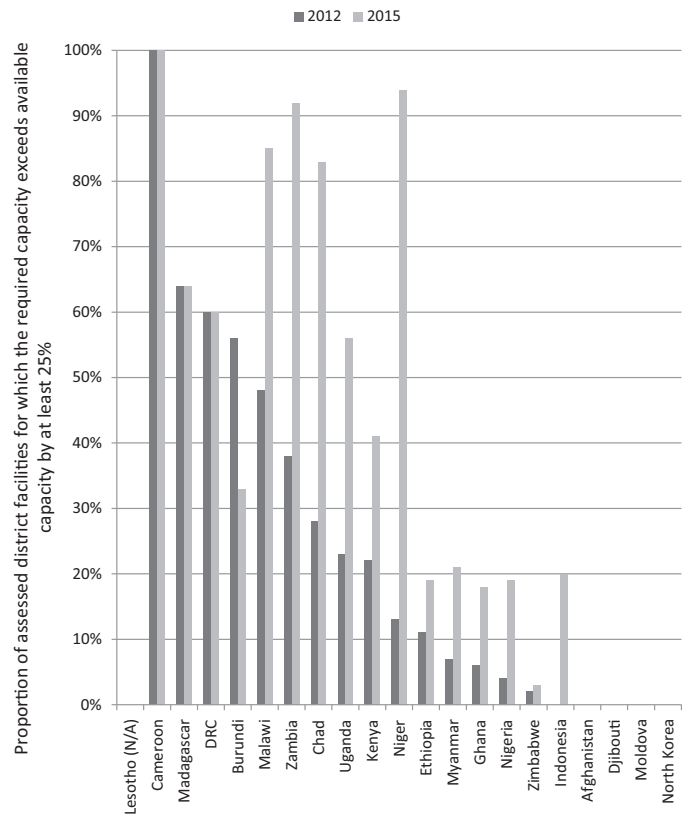


Fig. 4. Proportion of assessed district facilities for which the required capacity exceeds available capacity by at least 25%. *Figs. 3 and 4 notes:* For most countries, the data source is either an EVM assessment or a CCEM comprehensive inventory. The order of countries in the x-axis reflects highest to lowest capacity utilization in 2011. In some countries, reliable data was not available (N/A). In other countries (those on the right side of the graph), required capacity exceeded available capacity by at least 25% in none of the facilities sampled.

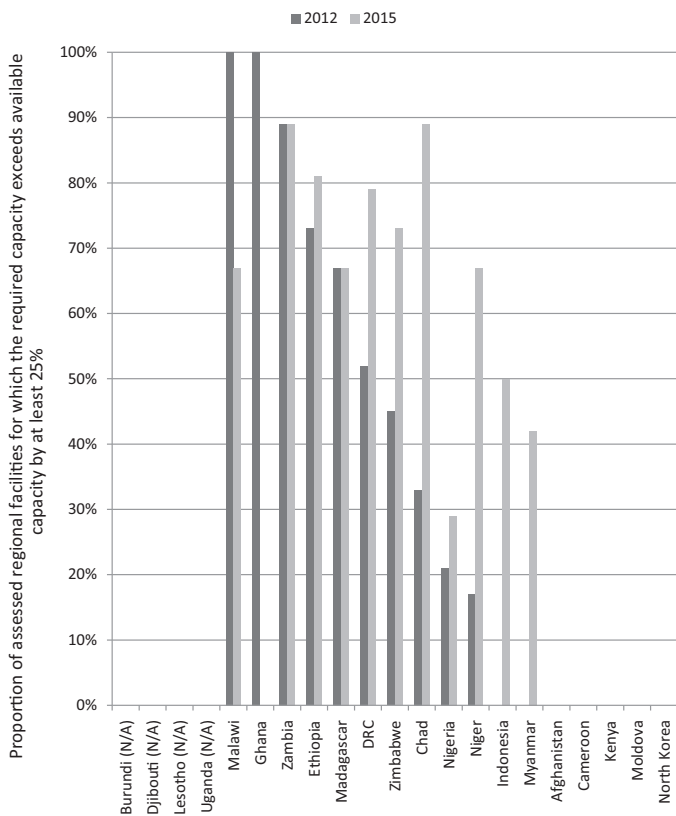


Fig. 3. Proportion of assessed regional facilities for which the required capacity exceeds available capacity by at least 25%.

innovations, and national governments need options for bulk procurement or other methods of stimulating price reductions.

1.3. Cold chain maintenance and temperature control

New equipment requires installation and maintenance, which necessitates the availability of properly trained technicians, replacement parts, a system to monitor equipment performance, and the capability to rapidly respond to breakdowns and failures. Although existing supply chains should already have maintenance plans in place, recent cold chain assessments reveal consistent deficiencies in this area [12]. With the introduction of new vaccines, however, common equipment failures—a broken refrigerator, a leaky ice pack, lack of fuel—can easily damage thousands of dollars of vaccines, which makes proper installation and maintenance critically important [13]. It is also increasingly important that health staff have updated tools and knowledge to monitor equipment performance and maintain safe temperatures in cold rooms, cold boxes, and refrigerators [20,21].

1.4. Immunization-related information systems

Supply chain assessments over the last five years suggest that managerial oversight has been largely neglected and underestimated [12]. Larger and more valuable inventories put increased pressure on managers to make accurate forecasts for product needs, allocate stock more efficiently, make the right investment decisions, and optimize distribution channels. To handle these responsibilities, managers need accurate and timely information

that allows them to verify product and equipment needs, validate coverage rates, monitor temperature in the cold chain, and identify weak links in the supply chain. This may require implementation of more advanced information systems, installation of computers, tailored software systems, monitoring equipment, accountability indicators, and mobile phone or Internet access.

1.5. Human resources for the vaccine supply chain

As new vaccines enter the system with different handling requirements and different schedules, targeting different populations at different times of their life, staff members may need to be reallocated. Health workers also require training to handle new vaccine products, use and monitor new cooling equipment, or operate software systems. Maintenance teams require training, funding, and transportation to install, maintain, and repair refrigerators, or the function may need to be outsourced. Managers must learn how to use information to forecast needs, allocate stock, manage staff and resources, modify delivery routes and frequencies, act rapidly where equipment becomes dysfunctional, and recommend policy changes.

1.6. Vaccine cost and wastage

Many newer vaccines are very complicated to make and are considerably more costly than traditional vaccines. For example, diphtheria–tetanus–pertussis vaccine in a 20-dose vial was only US\$0.14 per dose through UNICEF in 2012 [22]. In comparison, pneumococcal conjugate vaccines were 50 times more costly at US\$7.00 per dose in a one- or two-dose vial through UNICEF in 2012 [23].

The expense associated with newer vaccines makes supply chain issues extremely important. WHO estimates that in some countries, 50% of all vaccine doses are wasted either before or after a vial is opened [20]. Most closed-vial vaccine wastage can be attributed to supply chain issues including accidental freezing, expiry, vaccine vial monitor indication, breakage, theft, and loss [20,24]. Unless these supply chain issues are solved, closed-vial vaccine wastage will continue to consume much-needed vaccine and unnecessarily inflate the cost of vaccination programs.

1.7. Coping mechanisms

As immunization programs grow, supply systems have coped with increased volume and complexity in several ways. However, short-term coping strategies can cause more problems than they solve. Overstocking cold rooms is unavoidable when vaccine stock exceeds storage capacity, but the practice can compromise first-in, first-out stock management practices, impair air circulation and temperature maintenance, and/or result in expired vaccines [14]. Increasing the frequency of deliveries to lower-level facilities can mitigate central storage capacity issues. However, stocking more vaccines at lower levels can also lead to simultaneous stockouts and overstock situations in different parts of the country because vaccines are stored where there is space, rather than where vaccines are needed [8,9]. Reducing buffer stock levels is somewhat desirable, but in the absence of reliable stock management strategies, this can lead to stockouts as well.

As we stand at the beginning of what is now called “the Decade of Vaccines,” countries have wrung every drop of value from short-term solutions. Purchasing new refrigerators and increasing delivery frequencies will alleviate immediate pressures, but these strategies will not solve perennial problems that have been highlighted for years in vaccine supply chain assessments and other studies [4,6,12,13,16,24]. Coping strategies will not make supply systems more efficient, nor will they accelerate access. In the

absence of systematic improvements in vaccine supply and logistics systems, new vaccines cannot easily reach target populations and may even compromise the availability of traditional vaccines [4,8,9].

2. A global plan of action for vaccine supply and logistics systems

Over the past 15 years, the field of supply chain and logistics management has steadily evolved in the private sector. Capitalizing on advances in information technology, all manner of consumer products, including perishable and temperature-sensitive products, now routinely travel to even the most remote villages on predictable and reliable schedules [25]. Today, an Internet connection is sometimes all that is required to track shipments, check inventories, estimate the date and time of delivery, and request changes or new products.

Applying lessons from the commercial sector and from recent demonstrations in low- and middle-income countries, it has finally become feasible to build state-of-the-art supply and logistics systems that can handle a growing and more costly portfolio of vaccine products.

In 2011, national governments, donors, and international agencies developed a global vision for vaccine supply and logistics systems:

By 2020, state-of-the-art supply systems meet the changing needs of a changing world; they enable the right vaccines to be in the right place, at the right time, in the right quantities, in the right condition, at the right cost [26].

The vision stands on five key pillars that are considered indispensable for optimal immunization supply systems. To determine how to strengthen these pillars, cross-organizational working groups were formed in 2011 to analyze the landscape of ongoing activities and technologies and develop “vision action plans” that propose activities to help achieve the vision. Each pillar is described below with examples of progress made and the way forward. Complete landscape analysis summaries and action plans can be downloaded online [26,27].

Vaccine products and packaging are designed to meet the needs of developing countries

Concept: Not only do vaccines need to meet internationally recognized standards of quality and safety, but manufacturers and immunization programs must agree on attributes and product specifications that facilitate use in developing-country environments, including their supply chains.

Major progress: Over the last five years, several mechanisms have been created and supported to improve public/private-sector collaboration and help ensure that vaccine products meet low- and middle-income country needs. The Vaccine Presentation and Packaging Advisory Group (VPPAG) was launched to bring vaccine manufacturers, public health policy experts, and developing-country representatives together to reach consensus on vaccine product attributes that are both feasible for industry and address immunization program opportunities and constraints. Within the VPPAG, discussions are currently under way to minimize and potentially standardize packaging sizes to make for a more efficient fit inside cold boxes during storage and transport. Manufacturers are also discussing the utility of placing barcodes on vaccine vials, which would allow for better stock management and lot tracking.

In addition, WHO has established a set of prequalification requirements for vaccines to address developing-country program needs in its Programmatic Suitability for Prequalification (PSPQ)

requirements. Many of the PSPQ requirements were derived from VPPAG recommendations. The VPPAG and the PSPQ process help ensure that careful consideration is given to vaccine product features and packaging so that the resulting products will be better suited for their intended contexts of use.

Way forward: As new vaccine products become available, national authorities need better data and tools to support decision-making around vaccine product selection. One such tool is being developed under WHO's Vaccine Price, Product, and Procurement (V3P) project [28]. Both national and global vaccine procurement bodies need to change the mindset from *cost per dose procured* to *cost per dose delivered*, as the latter better reflects the true costs of introducing a new vaccine. For example, it may make sense to purchase a more expensive presentation of a vaccine if doing so reduces vaccine wastage and/or reduces risk of human error and/or improves timely delivery of vaccines and increases coverage among vulnerable and currently unreached populations. Such analyses will require that countries have adequate data on the performance and costs of their immunization programs and supply chains. In addition, better dissemination of information on the features of available vaccine products will be needed to inform product selection [28,29].

3. Immunization supply systems support efficient and effective vaccine delivery

Concept: In most health systems, there are multiple supply and logistics systems that perform essentially the same functions (e.g., sourcing, procurement, storage, and distribution) and travel the same routes to reach the same populations. Delivery routes often follow administrative levels rather than the shortest distance, and expensive or cumbersome tasks that could be accomplished more efficiently by private-sector operators (e.g., vehicle or equipment maintenance, transport, vaccine storage and requisition) generally remain the purview of government staff [4,5].

Redesigning such systems to be as streamlined as possible may require outsourcing certain functions to private or parastatal agencies or require integrating certain functions with other supply chain systems [30,31]. Even in countries where integration and outsourcing are not options, opportunities exist to adopt best management practices and continuous quality improvement systems [32].

Truly effective, agile supply systems also make use of supply chain equipment—vehicles, refrigerators, cold rooms, and cold boxes—that can handle increasing volumes of vaccine within stringent temperature limits and apply heuristics to maintain and replace them when necessary.

Major progress: New evidence is being generated and collected to describe how various system design changes have worked in different settings. South Africa and Thailand have outsourced various supply chain functions to parastatal agencies/private companies, and their experience has been documented in detail [33,34]. Other efforts to streamline delivery routes and integrate vaccine supply chain systems with pharmaceutical and other delivery systems are being demonstrated in Senegal and Tunisia in collaboration with project Optimize [35]. Evidence describing the cost and impact of these efforts on immunization supply, wastage, and political processes will be available early in 2013.

The growth in commercial cold chain capacity in some countries—even in remote rural areas—is creating higher availability of repair staff, mechanics, spare-part sites, etc., which can be leveraged to ensure better maintenance of equipment without investments in dedicated staff and infrastructure [36].

The development of direct-drive (i.e., battery-free) solar refrigerators has spurred the creation of two new PQS categories and generated momentum among manufacturers to improve products for health centers with solar potential [18,37].

Way forward: Preliminary results from project Optimize collaborations with the Ministries of Health of Senegal and Tunisia show that system redesign can be highly political, as it often involves increases and decreases in responsibility, budget, and authority of various departments, agencies, and personnel. This highlights the importance of continuing to monitor and learn from countries that have redesigned their supply and logistics systems, perhaps developing public-private partnership models that other countries can apply and build upon. It also underscores the need for leadership from high-level political offices to be involved in discussions on improving the efficiency and effectiveness of vaccine supply chains.

4. The environmental impact of energy, materials, and processes used in immunization systems is minimized

Concept: Environmental impact can be minimized both in terms of energy and resource efficiency and waste reduction and management. The rising cost of fuel and electricity combined with their environmental impact makes energy efficiency an important focus for supply chains [38]. Impacts can be reduced by making better use of solar power and other forms of alternative energy, replacing inefficient gas and kerosene refrigerators with energy-efficient cooling equipment, allowing certain thermostable vaccines to travel in controlled temperature chains without the need for ice packs, and reducing transport distances or choosing more energy- and environment-friendly transport options such as sea freight or electric vehicles [39–44].

The environmental impact of waste from vaccination programs can also be reduced by implementing safe and environmentally sound sharps-disposal procedures, minimizing the size of packaging materials, and reusing and recycling non-sharps waste and packaging materials [45–47].

Major progress: By leveraging small amounts of funding and providing incentives for innovation in equipment manufacturing, WHO and PATH have enticed several new and existing cooling equipment manufacturers to improve or create new products that take advantage of solar and passive solar cooling technologies [48]. Simultaneously, WHO has created several new PQS standards for categories of products that had not previously existed, namely the direct-drive solar refrigerator, extra-large cold box, and stationary passive cooling container [18]. Grand Challenges Explorations grants from the Bill & Melinda Gates Foundation are promoting efforts to reduce the environmental impacts of vaccine and packaging waste.

Way forward: Manufacturers of cooling equipment need ongoing incentives to invest the necessary time and energy into research and development for new technologies that minimize environmental impact and operate in areas with minimal energy infrastructure [43]. They also need a mechanism for increased dialog and feedback between countries and procurement agencies to better understand user needs, financial realities, and the political landscape. Without such dialog, it is likely that manufacturers will return their focus to more profitable and predictable markets.

In waste management, partners need to include financial and technical support and other incentives that reward and encourage innovative waste-management strategies, particularly for mass vaccination campaigns with target populations in the millions. For example, it might be possible to add a “disposal tax” to syringes that can be used to build incinerators or develop a recycling program for plastic waste.

5. Immunization information systems enable better and more timely decision-making

Concept: Information technology has long been a core feature of modern supply chains [49]. When deployed successfully,

computerized information systems can facilitate information sharing, speed order processing, and improve decision-making, thus enabling smooth and efficient supply chains [50]. Some developing countries have begun to create their own computerized logistics management information systems to manage vaccine supplies and in some cases link to immunization registries, but these efforts are disparate and lessons learned in software development are not being shared or built upon to improve immunization information systems [51]. As more countries move toward computerized information systems, they can prioritize information systems with ideal characteristics.

Ideal information systems are:

- Integrated and interoperable with other health information systems.
- Built on reliable data collected at the place where the events occur and aggregated or disaggregated as needed.
- Flexible, adaptable, and compatible with different contexts, programs, and changes over time as needs evolve.
- Driven by the needs of end-users, managers, planners, recipients of health services, and other stakeholders.
- Affordable and sustainable so decision-makers can evaluate the wider cost implications of adopting an information system across the health system.
- Reliable and secure from unauthorized use.
- Built upon a consistent design framework with standards, common data, common software applications, and technologies that are properly supported by clear design and user documentation.
- Designed and used for evidence-based decision-making.

Major progress: Countries have high interest in software-driven solutions, and a few logistics management information systems based on Microsoft Excel or Access have been successfully scaled and sustained [52]. These tools represent improvements over paper-based systems, even if they do not meet all the requirements of a successful information system. OpenLMS, a project recently launched by VillageReach, is trying to build on early successes by documenting best practices for selecting and designing logistics software systems and by sharing open-source systems or components along with information and instructions on how to modify and continue to share improvements [53]. The Rockefeller Foundation, PATH, and Public Health Informatics Institute released a Collaborative Requirements Development Methodology (CRDM) for logistics management in 2010 [54]. CRDM is a systematic method of identifying user requirements and system specifications. Its use greatly improves the likelihood that a new system will be effective, sustained, and compatible with the health system it supports.

Way forward: Global partners need to develop a unifying vision or agreed-upon standards for integrated logistics information systems and promote flexible, affordable software components—whether open source, commercial off the shelf, or custom built—that can meet the needs of multiple countries. This will enable countries to build upon (rather than reinvent) functional systems and to share tools, components, and knowledge more readily.

Creating or choosing information systems that meet the ideal characteristics (above) should also be a top priority for global and national immunization program decision-makers who are keen to use electronic data for decision-making.

6. Competent and motivated personnel are empowered to handle immunization supply chain issues

Concept: Human resources across national health programs can be inconsistent and loosely defined. Because people working along

immunization supply chains wear many hats, there is a need to strengthen human resources in general with standard procedures for recruiting, training, retaining, and motivating workers. Key personnel working on logistics or supply chain functions should be aware of and held to competency frameworks that describe the key skills and knowledge they are expected to maintain [55]. Levels of supervision must exist to ensure that health personnel have the resources, training, and tools needed to meet minimum standards of performance. And, adequate staff need to be hired, trained, and supported to perform the functions required [56].

Major progress: Global and national partners through the People that Deliver Initiative are building consensus around a competency framework for supply chain managers that defines the specific skills a supply chain manager should have [57]. In addition, several training initiatives as well as professional-level degrees are now offered in the field of supply chain management [26].

Way forward: Developing-country governments that do not outsource the entire supply chain function to an external agency need to start attracting, hiring, and recognizing professionally trained supply chain managers for their vaccination programs and shift their view of supply chain management from a marginal function to a core driver of immunization performance. Such professionals must be able to contemplate a career path in the public sector in order for them not to be lost to the private sector [56]. Also, programs that offer professional training in supply chain management should be made available in additional regions and supported with seed funding from donors interested in immunization program performance.

Launching supply chain revitalization efforts

As global partners work to address upstream challenges related to vaccine attributes, cooling equipment, and software system standards, national partners are working out ways to gain efficiencies in the design of their supply chains, make wise procurement decisions for both vaccine products and cooling equipment, and make use of existing information to drive decisions. Gaining political support for supply chain investments is a key step in making progressive and real changes in the vaccine supply system rather than pursuing a “business as usual” approach.

Countries that use the EVM assessment—and the ensuing management improvement effort—to launch higher-level discussions within their Inter-Agency Coordinating Committee or National Immunization Technical Advisory Group and in relevant government departments will likely progress faster. These more strategic discussions raise awareness of anticipated supply chain bottlenecks and propose meaningful *system-wide* solutions that may come with varying levels of cost and complexity. Embarking on this process will require countries to carefully reconsider their current system design—which often involves taking political or financial risk—in order to get more from their supply chain systems [58]. Global donors and agencies must help subsidize these efforts and provide support to countries to move beyond incremental solutions to supply chain problems. Technical agencies must set standards, share knowledge, provide on-the-ground support, and coordinate efforts so that countries are able to learn from and build upon each other’s experiences and successes. Finally, the private sector has an increasingly large role to play as it continues to innovate and fine-tune vaccines and cold chain equipment to better meet the needs of low- and middle-income countries.

7. Conclusion

For the last 30 years, the role of vaccine supply chains in protecting and managing the movement of vaccine products and

immunization supplies has been largely taken for granted. The introduction of a number of newer and more expensive vaccines has placed significant pressure on vaccine supply chain systems to perform at a level for which they were not designed. Compared to the investments made in vaccine products themselves, the investments needed in supply and logistics systems are marginal but absolutely critical if we are to see the health gains promised by newer vaccines.

Fortunately, global and national partners have agreed on a vision for future supply chain systems and identified gaps and action plans for five key areas of vaccine supply chains. Investing time and resources in these areas will enable immunization supply chains to meet the needs of 21st century immunization programs [26].

All this work will make it easier for countries to select solutions that not only address short-term needs but meet longer-term demands of immunization programs. The progress made so far will also make it easier for global partners to maintain the ongoing momentum for innovation and policy adaptation.

In this Decade of Vaccines there is a tangible opportunity to build supply systems that are efficient and as effective as the vaccines they handle.

Conflict of interest

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