



EVM - setting a standard for the vaccine supply chain

WHO & UNICEF Joint Statement **DRAFT VERSION**

Effective Vaccine Management



World Health
Organization

unicef 

The Context

In the early days of EPI since its launch 40 years ago at the World Health Assembly (in May 1974), vaccines were the only essential commodity that required their own specific supply chain system – with vaccines needing to be kept in a 2-8°C cold chain unlike any other essential medicines at the time. Subsequently, the Universal Childhood Immunization (UCI) launched by UNICEF in the 1980s, and the abundance of external funding that flowed for this initiative, saw the rise of in-country immunization supply chain systems as the backbone of routine immunization. Both EPI and UCI were significant forces from both WHO and UNICEF that drew attention and resources to the global immunization push of the 1980s and early 1990s.

When the UCI goals were reached and the world claimed success of achieved global immunization coverage rates of 80% or more, donor priorities shifted away from routine immunization towards support the next priority – eradicating Polio. After UCI, few national governments were able to continue funding the upkeep and improvements of the supply chain infrastructure upon which the success of UCI was built. Although some elements of in-country immunization supply chain system were sustained and improved with support of the Polio Eradication Initiative (PEI), little attention and funding has been provided since the mid-90s. This has led to its gradual downfall.

Today, and many decades later, in-country immunization supply chains continue to be government-run and severely underfunded. In 2010 and 2011 WHO and UNICEF have supported 65 countries in the implementation of Effective Vaccine Management (EVM) assessments. Key findings from these assessments highlighted to what extent countries are failing to reach the minimum WHO recommended target level of 80% for each of the nine criteria that is measured under the EVM. As a consequence, countries have not been able to adapt, innovate and change to meet the demands of today's immunization programme needs.

Figure 1: Supply chain performance in 65 low and lower-middle income countries (2010-2013)



Source: WHO analysis based on 65 EVM assessments

Key findings highlight that in 65 low and lower-middle income countries:

- Adequate temperature control for vaccines is achieved in 26% of countries,
- Sufficient storage capacity for vaccines and supplies is available in 38% of countries,
- Functional vaccine stock management is attained in 20% of countries,
- Effective distribution of vaccines is compliant in 20% of countries, and
- Adherence to vaccine management policies and practices are reached in 28% of countries

“Of the 65 low and lower-middle income countries assessed on effective vaccine management, none has met the recommended WHO standard.”

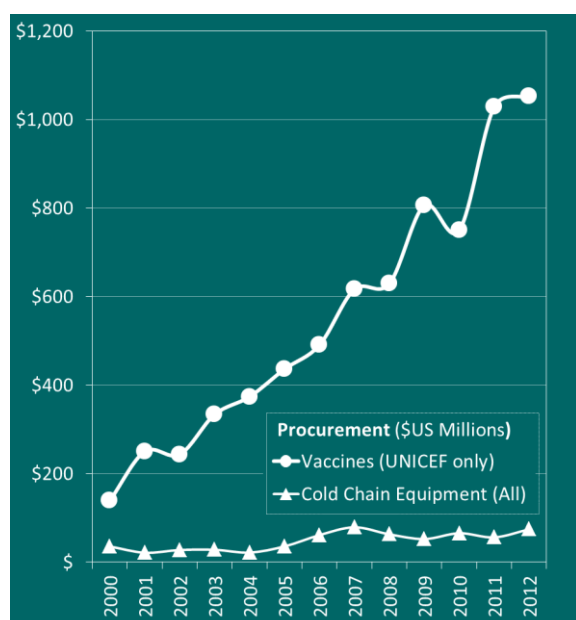
In addition to the persistent challenges in the storage, distribution, handling, management and stock control of vaccines and supplies, new challenges are putting additional pressure on currently fragile and strained systems that have,

up to now, shown extreme resilience by resorting to coping mechanisms. However, these coping mechanisms are ad-hoc and unsustainable approaches to dealing with the growing challenges. There is growing evidence that these immunization supply chain systems developed over 35 years ago have outgrown their ability to manage the priorities of introducing new vaccines, vaccinating age groups beyond infancy, and addressing the equity gaps in access to all vaccines at the last mile.

“Global procurement of vaccines has risen tenfold in the last 10 years, while procurement for cold chain equipment to protect the potency of vaccines has remained relatively constant”

Ignoring these challenges is no longer possible given the significant growth in the volume and financial investment in vaccines – respectively a four and ten-fold increase from the year 2000. In contrast, investments in protecting vaccines in the cold chain have remained relatively constant. This gap in funding for cold chain equipment is indicative of the inattention given to in-country immunization supply chains systems.

Figure 2: Vaccine and cold chain procurement (2000-2012)



Without fundamental and transformational changes in the way the immunization supply chains are designed and managed, the aspirations delineated in the *Global Vaccine Action Plan* (GVAP)

will not be achieved and the ability for this decade to become a successful *Decade of Vaccines* will be compromised.

Box 1: Key context messages

1. Today, immunization supply chains in developing countries are fragile, strained to keep up with the demands for today's immunization priorities, and continue to suffer from enduring problems of vaccine storage, transport and stock management.
2. Without a better alignment between the investments in vaccines and those to protect them in the cold chain, in-country supply chains will soon become a bottleneck to achieving future immunization goals and the aspiration delineated in the Global Vaccine Action Plan will not be achieved.
3. Estimates suggest that investing up-to 10% of the value of vaccines being procured will ensure that in-country immunization supply chain systems facilitate the equitable access and availability of effective vaccines at service delivery over the next decades; and ultimately support immunization programmes to reach the estimated 22 million children in developing countries each year.

“Better supply and logistics systems, international cooperation and funding are essential to reach the estimated 22 million children annually in developing countries.”

The EVM Initiative

In 2010, WHO and UNICEF launched the EVM initiative to help low and lower-middle income countries upgrade their immunization supply chains, and in doing so, strengthen their ability to manage today's, tomorrow's and future priorities. This includes introducing new vaccines, vaccinating age groups beyond infancy, and addressing the equity gaps in access to all vaccines at the last mile. The EVM initiative began by establishing a process to help countries evaluate the current performance of their immunization supply chain, and benchmark this performance against best-practice standards. For this exercise, an EVM assessment tool was developed by WHO and UNICEF that is used to thoroughly review their immunization supply chain at all relevant levels of the system – from national to service levels.

The EVM assessment tool sets standards in nine areas (criteria) of vaccine management based on well-established principles and standards for quality management that are applied throughout the industrialized world (for example the ISO 9000 series of standards). The EVM criteria are described as follows.

1. **Vaccine arrival:** to assess that pre-shipment and arrival procedures ensure that every shipment from the vaccine manufacturer reaches the receiving store in satisfactory condition and with correct paperwork
2. **Temperature control:** to assess that vaccines and diluents are stored within the WHO recommended temperature ranges in the cold chain system.
3. **Storage capacity:** to assess that cold storage, dry storage and transport capacity is sufficient to accommodate all vaccines and supplies needed for the programme.
4. **Infrastructure:** to assess whether the state of the storage buildings, the cold chain equipment and the fleet of vehicles for distributing vaccines and supplies is acceptable.
5. **Maintenance:** to assess that the maintenance systems for the storage buildings, the cold chain equipment and vehicles is satisfactory.
6. **Stock management:** to assess that effective stock management systems and procedures are in place.
7. **Distribution:** to assess that vaccines are distributed between each level in the supply chain in an effective manner.
8. **Vaccine management:** to assess that appropriate vaccine management policies are adopted and implemented at all levels of the immunization supply chain.
9. **Information systems:** to assess that relevant information systems and supportive management functions are satisfactory.

Once completed with the necessary information, the EVM assessment tool generates an overall score in percent, for each criterion at each level of the supply chain assessed. The minimum recommended standard score for each criterion at each level of the supply chain is set at 80%.

“WHO and UNICEF recommend that countries should strive to reach and exceed the minimum requirement for EVM. The minimum EVM score for each of the nine criteria and for each level of

the national supply chain system should be 80% or higher”.

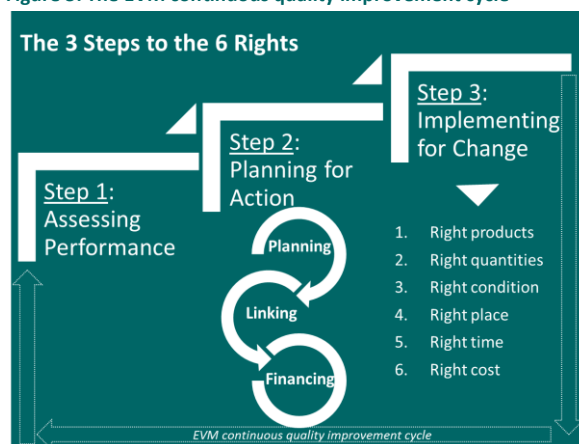
The Improvement Process

The EVM is first and foremost a continuous quality improvement process. The ultimate objectives are for countries to have immunization supply chains that ensure the **availability** of the needed vaccines and supplies up to service delivery levels; with vaccines that have not lost their **potency** from temperature damage in the cold chain; and with increased supply chain **efficiency** achievable within the reach of each country specific setting.

These three objectives are captured within the six rights of an effective immunization supply chain system to ensure that the right vaccines are delivered in the right quantities, in the right condition, at the right place, in the right time at the right cost.

Reaching these objectives cannot rely on conducting an EVM assessment alone. It will rest on putting in motion a comprehensive continuous quality improvement process at country level coined the **3 steps to achieving the 6 rights** of an effective supply chain. The cyclical nature of the process is aimed to help countries define an achievable target for each iteration; within what is achievable in a cycle; and to benchmark that targets have been met or exceeded this during the next cycle.

Figure 3: The EVM continuous quality improvement cycle



Source: WHO and UNICEF

Step 1: Assessing Performance

The objective of this first step is to assess the current performance of the immunization supply chain using the EVM assessment tool in order to identify key strengths, weaknesses and bottlenecks. Given that an EVM assessment is conducted in a representative sample of storage facilities in the country, it is worth collecting additional data during this process to complement certain aspects of the immunization supply chain not covered in the EVM assessment tool. This is particularly encouraged for countries wanting to conduct a cold chain inventory or a supply chain network optimization modelling exercise and gain a deeper understanding of certain aspects related to human resources for logistics or their logistics management information systems (LMIS).

Step 2: Planning for Action

The objective of this second step is to use the findings and recommendations from the assessment results from step 1 and translate these into a comprehensive plan of action, identifying interventions and activities to address both current and future challenges. The planning for action step is a critical one in the EVM improvement process and is best described through three inter-related sub-steps as follows:

2.1 – Comprehensive Improvement Planning

A comprehensive improvement plan should include all prioritized strategies, tactics, and implementable activities to address each of the identified deficiencies from the EVM assessment in a successful and sustainable way. It is strongly encouraged that the improvement planning process be taken as an opportunity to plan for supply chain strengthening beyond the nine vaccine management criteria covered in the EVM assessment tool. Many relevant assessment tools and methods exist for activities such as vaccine forecasting or cold chain equipment planning for the future. As such, the comprehensive improvement planning process should try to include recommendations, activities and strategies from other relevant assessments to:

- Address both current and future anticipated supply chain challenges, especially those linked with new vaccine introduction, and

- Explore the adoption of innovative solutions and promising approaches around immunization supply chain optimization (see box 2).

Box 2: Immunization supply chain optimization – key attribution for comprehensive improvement planning

- Immunization supply chain networks should be designed to maximize efficiency, effectiveness, agility and responsiveness to the needs of the immunization programme.
- Immunization supply chain systems should continually improve by monitoring performance with key indicators that are track through a strong logistics management information systems based on point of service data.
- Immunization supply chain systems for heat tolerant products should be optimized at all levels, including through the adoption of a controlled temperature chain (CTC) strategy.
- Human resources for immunization logistics should be in sufficient numbers, competent, motivated, and empowered by professionalizing supply chain management.
- Immunization supply chain systems should introduce innovative technologies in the field of cold chain equipment, temperature monitoring, and more efficient, reliable, and durable equipment choices for storing and transporting vaccines.
- Immunization supply chain systems should be integrated with wider health commodity supply systems when appropriate and leverage synergies with the private sector where feasible.

2.2– Linking for Visibility and Ownership

While it is important to develop a comprehensive improvement plan, government ownership and commitments is critical from the onset. No matter how strong the improvement plan is, it will have little chance of implementation if there is no national buy-in from all stakeholders in the Ministry of Health; no strong ownership within the national immunization programme; and limited visibility within the broader strategic immunization or the health sector planning processes. Given that the comprehensive multi-year plan (cMYP) is the basis for formulating the national immunization budget, the improvement plan for strengthening the in-country immunization supply chain should be linked to an existing cMYP and/or be an integral piece during the elaboration of a new one. This will ensure that activities, strategies and resource requirements are included in the broader strategic plan for immunization and contribute to linking for visibility and national ownership.

Box 3: Guiding principles for developing a comprehensive improvement plan

1. Government ownership and commitment
2. Review and endorsed by the national inter-agency coordinating committee (ICC)
3. Improvement plan addresses:
 - *EVM Assessment recommendations*
 - *Recommendations of other related assessments*
 - *Future new vaccine introduction needs*
4. Improvement plan outlines steps towards immunization supply chain optimization
5. Improvement plan includes realistic activities, responsibilities, budget, and timeline
6. Improvement plan includes a system to monitor implementation

2.3– Financing for Improvements

The last sub-step is to ensure that opportunities to mobilize resources and financing are leveraged. Linking the comprehensive improvement plan to the broader strategic plan for immunization and reflecting activities and resource requirements in the cMYP will help raise the visibility for needed resources – particularly from national domestic sources. However, this is no guarantee that funds will be made available. Financing for Improvement will first require increased awareness-raising efforts of the issues at stake and the consequences of not investing the immunization supply chain. Advocacy efforts should be targeted at decision makers within the Ministry of Health, the interagency coordinating committee (ICC) and, if present in country, the national immunization technical advisory committee (NITAC) or any other forum and in-country mechanism for planning, budgeting and financing. Secondly, every funding opportunity needs to be leveraged. For instance, in countries eligible for Global Alliance for Vaccines and Immunization (GAVI), Health Systems Strengthening (HSS) funding is potentially an important source of financing for the improvement plan. If a country is planning to submit an HSS application or discuss the reprogramming of existing HSS funds, this is an ideal opportunity to ensure that elements of the improvement plan are featured in the HSS application or reprogramming discussions.

Step 3: Implementing for Change

The objective of this third step is to implement the comprehensive plan of action developed in step 2

and put in place a mechanism for reviewing progress against planned activities on an annual basis, and monitor implementation using defined process indicators.

The ending of an implementation cycle for the improvement plan will mark the end of an iteration in the three steps. The results of this iteration are used as the starting point for the next. The process begins again with step 1 and each iteration aims to further approach a desired goal and performance targets on the nine EVM criteria for an effective vaccine supply chain management system.

The Resources

For this EVM initiative, WHO and UNICEF have developed several tools, guidance materials and e-learning courses to assist countries and many produced in several languages.

- The EVM assessment package and guidance materials are available on the [WHO website for EVM](#)
- The EVM technical assistance and training course is available on the [EVM e-learning site](#)
- The EVM assessments conducted and the reports are available on the [EVM database site](#) (registration is required)

The Recommendations

The adoption and long-term success of the EVM initiative ultimately depends on the benefits it brings. Countries need to embrace the EVM process for system-wide improvements of their immunization supply chain systems. In addition, WHO, UNICEF and global partners recognize the importance of providing necessary long-term support to strengthen country supply chain systems for immunization.

In order to achieve these aims, **the EVM initiative embodies key recommendations as follows:**

WHO-UNICEF recommends that countries:

- Adopt the 3 step approach of assessing, planning and implementing change and within the national immunization programme budgeting, planning and financing cycle.
- Ensure that the 3 step approach to EVM addresses today's, tomorrows' and future anticipated supply chain challenges, especially those linked with new vaccine introduction.
- Make every effort towards achieving an effective vaccine management system that meets the minimum recommended standard for each criteria and each level of the in-country supply chain.
- Implement steps towards immunization supply chain optimization
- Continually adapt to the changing context with innovative approaches and technologies.
- Continuously monitor the performance of their in-country immunization supply chain with defined metrics and key performance indicators measuring the objective of availability, potency and efficiency.
- Commit the necessary human and financial resources to address existing and anticipated challenges of immunization supply chain and logistics systems.

WHO-UNICEF commits to:

- Support countries with the EVM initiative and adopting the 3 step approach of assessing, planning and implementing change for in-country immunization supply chain strengthening.
- Ensure that guidance and policies on immunization supply systems keep pace with country needs and that tools, methods and training materials are continually updated.
- Provide training and local capacity building opportunities as it relates to the EVM initiative.
- Provide enhanced technical assistance and strategic support to countries by training WHO and UNICEF staff, in addition to a cadre of consultants that can be deployed to support countries on any, or all recommended steps in the EVM process.
- Continue to generate knowledge and evidence on supply chain performance and experiences

in countries to support fund-raising efforts for national immunization supply systems.

WHO-UNICEF signatories

TBD

World Health Organization (WHO)



TBD

Programme Division
UNICEF



TBD

Supply Division
UNICEF





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Photo credit: Cover (GAVI Alliance): Two health workers covering the last mile logistics in Zanzibar to reach every child.

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