

Effective Vaccine Management Initiative

Background

Version v1.7
Sep.2010

Effective Vaccine Management Initiative

EVM—setting a standard for the vaccine supply chain



World Health
Organization



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1. Background

Health care facilities and programmes rely on efficient and effective supply chain systems to store, transport and distribute health care products and commodities. This ensures that the right products are available at the right place, at the right time and in the right condition in order to provide health services to the community.

Experience shows that a high quality vaccine supply chain is one of the most crucial elements of an immunization program. Over the past decade, the world has invested enormous resources and energy into the development of new and lifesaving vaccines. Now that these new vaccines and health technologies are becoming available, the world is facing an alarming logistical challenge. Most of these new vaccines are much more expensive and are much bulkier than traditional vaccines; this means that supply chains will need to handle increased volumes and the value of these stock holdings will be very much greater than has previously been the case.

With the rising cost of vaccines and the greater storage capacity now required at every level of the cold chain, managers must be able to maintain lower stock levels, reduce wastage, accurately forecast vaccine requirements, and prevent equipment break-downs or malfunctions. Maintaining high standards of performance in these areas can only be achieved if all the links in the vaccine supply chain are effectively monitored, assessed and improved based on the latest principles of good storage and distribution practice. The new Effective Vaccine Management Initiative will help countries to do just that.

2. VMA and EVSM

In recent years, two tools have been developed to help EPI managers and logisticians assess their vaccine supply chains and to use these assessments to improve vaccine management practices and procedures.

The **Vaccine Management Assessment** (VMA) tool, produced in 2001¹ and further updated in 2005² was designed to investigate both the knowledge and practice of vaccine-management among health care staff across entire supply chain- from national to sub-national to the service-delivery level.

The **Effective Vaccine Store Management** (EVSM) tool and supporting documents were launched in 2003³ as a self-assessment process designed to encourage countries to improve vaccine storage and distribution management by focusing attention on the primary vaccine store(s).

Looking at the trends in EVSM assessments, there has been a major decline of countries conducting EVSM since 2005. The decline can be attributed to a number of reasons, chief amongst them are countries' preference to assess their immunization supply chains beyond the primary vaccine store, inadequate financial and technical know-how to address the challenges and weaknesses revealed during the assessment and lack of awareness on the importance of the tool.

¹ AFRO *Vaccine Management Project 21.03.03, 21-03*

² *Vaccine Management Assessment*. WHO/IVB/05.02.

³ *WHO-UNICEF Effective Vaccine Store Management Initiative: Modules 1-4*. WHO/IVB/04.16-20.

3. The rationale for EVM

Experience gained through using the EVSM and VMA tools has demonstrated that systematic assessment of vaccine management procedures can lead to improved performance. However, there is a clear need to address the overlap between the two approaches and to produce a unified and updated tool.

The new Effective Vaccine Management (EVM) assessment tool combines the strengths of the two earlier approaches, while addressing the identified weaknesses in each. In addition, EVM will introduce several important new features, including a web-based platform allowing for a centralized updating procedure to ensure that users have easy access to the latest version of the tool and associated guidance documents. In addition, if they wish to do so, users will be able upload assessments to a central database, via the website. This process will include an external audit service so that self-assessment results can be reviewed and verified before the data are incorporated into the database. The database will enable EVM partners to carry out cross-assessment analyses – a task that was difficult to achieve with VMA and EVSM.

4. Nine global criteria

EVM's scope and focus will be based on the nine global criteria listed below, each of which must be validated against records kept over a recent 12 month period during the assessment.

1. 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. All vaccines and diluents are stored and distributed within WHO-recommended temperature ranges.
3. Cold storage, dry storage and transport capacity is sufficient to accommodate all vaccines and supplies needed for the programme.
4. Buildings, cold chain equipment and transport systems enable the vaccine and consumables supply chain to function effectively.
5. Maintenance of buildings, cold chain equipment and vehicles is satisfactory.
6. Stock management systems and procedures are effective.
7. Distribution between each level in the supply chain is effective.
8. Appropriate vaccine management policies are adopted and implemented.
9. Information systems and supportive management functions are satisfactory.

5. EVM tool highlights

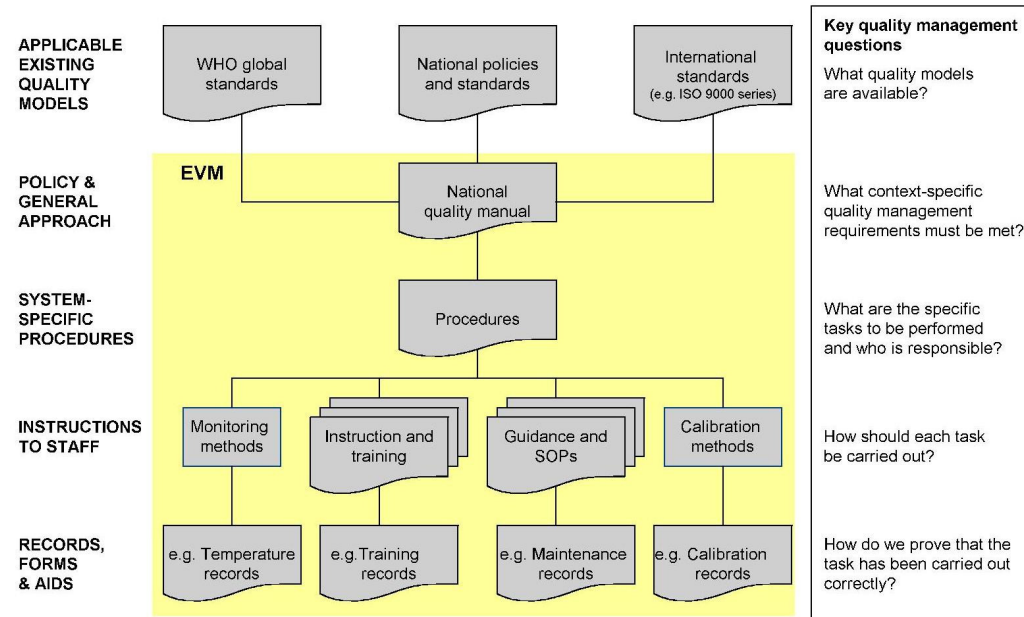
EVM is first and foremost a **quality management tool** that combines a structured assessment with supplementary guidance materials. The tool is designed to help countries to build a vaccine supply chain based on the well-established principles of quality management used throughout the industrialized world – for example the ISO 9000 series of standards.

EVSM was designed to deal in detail with central vaccine stores, whilst VMA applied a more limited range of indicators across the whole supply chain. EVM includes assessment questions and materials drawn from both the earlier tools and covers all levels of the storage and distribution system.

A common questionnaire is used at all levels of the immunization supply chain with automatic filtering so that the indicators offered to the assessor suit the level being assessed – whether a primary store, a sub-national store, a lowest delivery level store or a service delivery point (typically a health facility). In addition the user can choose to work at a very detailed level – a **full** assessment – or to further filter the questionnaire in order to carry out a rapid **review** assessment based on a subset of critical indicators.

EVM is designed to help countries to develop strength-in-depth by building a culture of quality based on a structured approach to supply chain management, monitoring and evaluation. Figure 1 illustrates the hierarchy of documentation needed to support this approach. EVM covers the yellow shaded area of the diagram.

Figure 1 – The quality management hierarchy



The EVM tool is used to assess the quality and sufficiency of the seven component elements of an effective supply chain: buildings; storage and transport capacity; cold chain equipment; vehicles; repairs and maintenance; training and the management systems needed for the effective operation and control of the system.

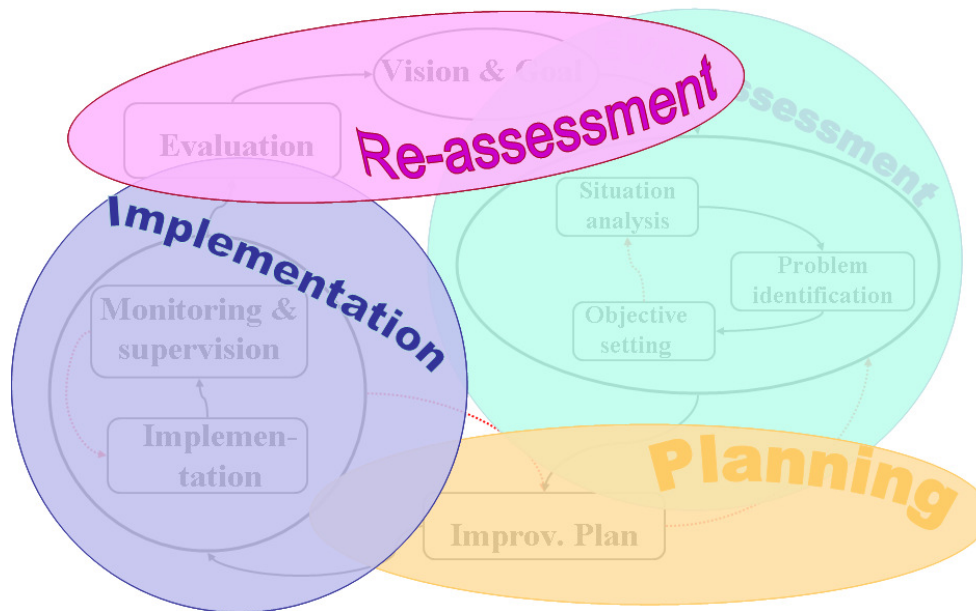
EVM is **normative** to the extent that it advocates and assesses good vaccine management practices. However it is also designed to be flexible and responsive. This is achieved in two ways:

1. Context-dependent questions allow alternative ‘routes’ through the questionnaire and countries are always assessed on their own terms. For example, a programme that uses refrigerated trucks for vaccine distribution can be assessed alongside a programme that uses passive cooling, or a programme that uses a mixed system. All three approaches are treated as equally valid.
2. The EVM software system allows for changes to be made to the questionnaire to incorporate future technologies and alternative context-dependent approaches to vaccine management. The design of the assessment tool and the EVM database allows these changes to be made whilst retaining backward compatibility with previous assessments. In this way, cross-assessment analyses can be done with minimum loss of comparability.

In keeping with established quality management principles, EVM is a **continuous process**, not an intermittent activity. Figure 2 shows how EVM will be used as part of a cyclical improvement process.

Figure 2 – EVM quality improvement process

EVM is a continuous quality improvement process !



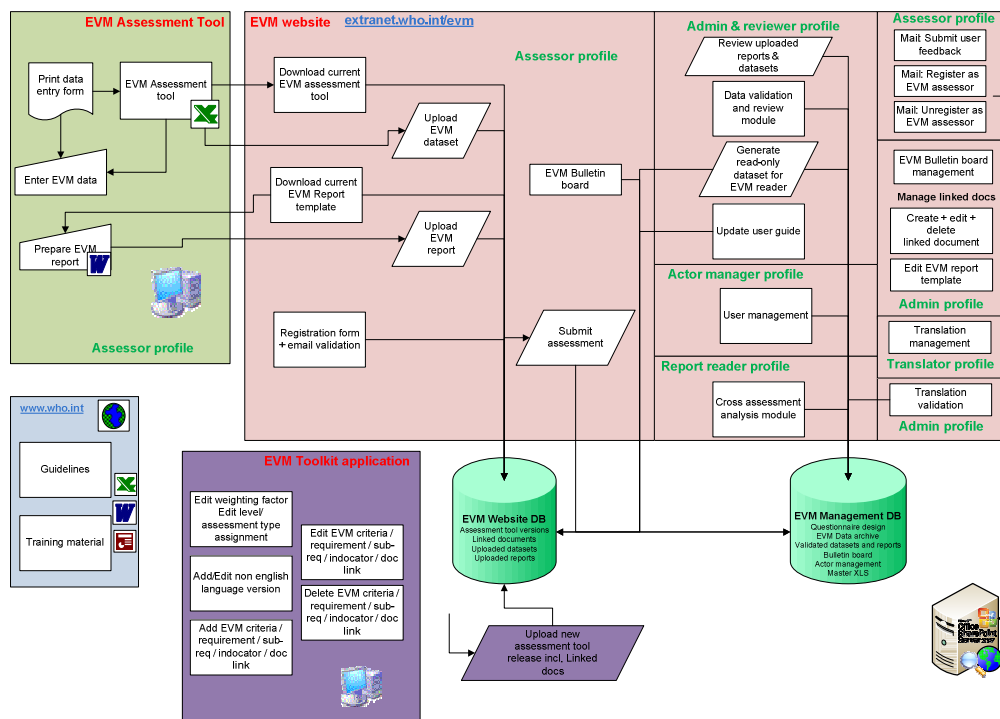
This long-term approach is one of the keys to embedding good management practices into supply chain operations so as to ensure their sustainability. Too frequently systems break down because key personnel leave and there is insufficient managerial strength to maintain operational quality. For this reason, the tool has been designed so that it can also be used as a **supervisory** aid to monitor and support the long-term progress of individual facilities.

The EVM package, comprising the EVM assessment tool and website, together with supplementary guidance, model Standard Operating Procedures (SOPs) and training materials, will provide countries with the resources needed to integrate good storage and distribution principles and practices into national vaccine supply chains. Many of these principles and practices are equally applicable to the storage and distribution of other temperature-controlled medicines.

In order to embed the EVM approach as part of routine management, it is essential that local language versions of the tool can readily be created. A problem with the various language versions of EVSM and VMA is that there was never any effective central version control. Accordingly, the EVM software system has been designed to encourage translations, whilst maintaining version control within WHO-HQ. This will ensure that countries always have access to the latest tool release in their own language via the EVM website.

Finally, EVM can be used to monitor progress in and between countries. The database function and related analytical tools will allow participating countries voluntarily to upload EVM datasets to a central database. Immunization partners, WHO HQ and regional offices will be able to access the database; performance comparisons can then be made between selected countries and within individual countries over time. This level of functionality was not possible with EVSM and VMA. Figure 3 shows the system architecture.

Figure 3 – EVM architecture



Source: Blue-

infinity

The main components of the EVM system are the **EVM Assessment tool**, the **EVM website** and the **EVM toolkit**.

The EVM assessment tool is a Windows-based application which contains the Excel assessment tool itself and a set of linked guidance documents. Once the package is downloaded from the EVM website it can be used independently by an in-country assessment team. At the start of an assessment, the principal assessor will generate a version of the Excel assessment tool for each of the sites to be assessed. These Excel workbooks can either be copied onto the assessment teams' laptops or printed out as paper forms. Once an individual workbook has been completed, it can be re-integrated into the overall assessment so that all collected data may be systematically analysed using the package's graphing and data analysis functions.

As mentioned above, a completed assessment can, optionally, be uploaded via the EVM website to the central EVM database. This will allow cross-assessment analyses to be carried out as previously described.

Finally, the EVM toolkit will be used by the EVM management team to update the EVM tool and supporting documents and to add new language versions. Once a new version has been validated, it will become the current version on the EVM website. The design of the core Excel tool and of the EVM database ensures that backward compatibility is maintained with earlier versions – this means that data uploaded to the database using earlier versions of the tool can continue to be compared with data collected using more recent versions.

6. The EVM call

EVM is a collaborative initiative of immunization partners and much of the piloting of EVM and its initial and final test phases is being undertaken as part of Optimize's demonstration project work where WHO is playing the key role in further finalizing the key technical document and tools. However, the EVM global training and the extension of EVM implementation beyond the demonstration countries will require the long-term assistance and support of the entire immunization and logistics community.

EVM provides countries with a mechanism to monitor and improve their vaccine management structures and procedures in depth, and on a continuing basis. Widespread acknowledgement of the importance of so doing, combined with adequate resources to ensure that it happens is crucial.

The adoption and long term success of EVM ultimately depends on the benefits it brings. Countries need to see for themselves that systematic identification of challenges and weaknesses followed by implementation of the good storage and distribution practices advocated by EVM leads to system-wide improvements. Partners need to provide the necessary long-term support to identify and address these challenges and weaknesses. Both countries and partners need to provide feedback so that the EVM package remains up-to-date and relevant.

Revision history

Date	Change summary	Reason for change	Approved
25.01.2010	Original		Hailu Kenea
25.02.2010	Editing and GAVI logo	Feedback	Hailu Kenea
22.03.2010	Milestones update		Hailu K.
01.06.2010	Updated		Hailu K.