Vaccine Vial Monitor (VVM) Availability and Use in the African, Eastern Mediterranean, Southeast Asian, and Western Pacific Regions

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Dr. Julie Mistien. *Vaccine Vial Monitor (VVM) Availability and Use in the Western Pacific Region*. Ferney: PATH, World Health Organization (WHO); 2009.

Mojtaba Haghou. *Vaccine Vial Monitor (VVM) Availability and Use in the Eastern Mediterranean Region*. Ferney: PATH, WHO; 2009

Caroline Chevalier. *Vaccine Vial Monitor (VVM) Availability and Use in the Southeast Asian Region*. Ferney: PATH; WHO; 2008

Andrew Garnett. *Analysis of VMAT Indicators*. Ferney: PATH, WHO; 2008.

Vaccine Vial Monitor (VVM) Availability and Use in the African, Eastern Mediterranean, Southeast Asian, and Western Pacific Regions

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Executive summary

Commissioned by project Optimize, a collaboration of PATH and the World Health Organization (WHO), a study of vaccine vial monitor (VVM) availability and use in developing countries in four regions was undertaken. VVMs are small, circular indicators, printed directly on vial labels or adhered to the tops of vials. The inner square is chemically active and changes color irreversibly from light to dark with exposure to heat over time. By comparing the color of the inner square to the color of the outer ring (reference ring), a health worker can determine whether the vaccine has been exposed to heat. Important decisions on whether to use or discard vaccine and which vials should be used first are now clear due to the VVM. The study had three aspects: the total proportion of vaccines with VVMs in the regions with detailed information by country, in-depth information on policies and practices, and knowledge and attitudes in a selected sample of countries.

The methodology for the study was to assess the total number of doses of vaccines used in each country in the region, relying mainly on the WHO/United Nations Children's Fund (UNICEF) Joint Report Forms and similar information available on the WHO website. When possible the information was confirmed with the UNICEF Supply Division and with the country and regional offices of WHO and UNICEF. In addition, eight countries were visited in 2008 and 2009, and policies and practices were observed and discussed at the national, regional (or provincial), and lower levels in each country. Cold stores were visited, vaccine arrival reports (VARs) were reviewed, and staff were interviewed according to a standard format, except in the African (AF) region. National and WHO staff participated in these visits. In Africa the majority of the work focused on VVM availability and vaccine sources, although some policy issues were assessed by WHO staff.

Because this report is a synthesis of reports from four different regions all using differing methodologies, some of the results are not directly comparable. For example, vaccines used for supplementary immunization activities were generally not included in this study although in some cases they figure in the totals. In addition, exact data on countries which were not directly visited or for which a questionnaire was not filled out are not available, so different methods of estimating VVM availability have been used. Some of the regional reports went into great depth on vaccine financing and procurement methods which have not been included in this synthesis but can be accessed by referencing the original regional reports; the interested reader is advised to do so. Because of the variability in the methods used to assemble the data in the different regions, the results on VVM utilization practices are not directly comparable. This report has tried to indicate where methods are different (for example, the lack of focus group discussions in some countries, and a different methodology for obtaining the data in Africa compared to the other three regions where a small number of direct country visits were used to provide a picture of the situation). The fact that most of the issues in VVM use were noted across the board supports the validity of the synthesis.

Proportion of regional vaccines carrying VVMs

The proportion of vaccines with VVMs was examined using the following assumptions:

- Vaccines in industrialized countries do not carry VVMs (although industrialized countries were generally not included in this study).

- Vaccines produced domestically do not carry VVMs (except in India and Indonesia).
- Vaccines procured directly from manufacturers do not carry VVMs unless information was available to indicate that this was included in the procurement specifications.
- Vaccines received through UNICEF procurement all carry VVMs. In some cases this latter assumption was refined as information became available that not all these vaccines carried VVMs.

About 22% of the estimated 344 million doses used for routine immunization in the Western Pacific region carry VVMs. When only developing countries are considered, the percentage of vaccines with VVMs is about 30%. In the Eastern Mediterranean region the figure is about 82%, in the Southeast Asian region 56%, and in the AF region 84%. Vaccines without VVMs are primarily those that are produced in country or are directly procured from the manufacturers. To date, India and Indonesia appear to be the only countries which are ensuring VVMs are affixed to vaccines produced for domestic use. The work of the Indian Government to ensure VVMs are affixed to domestically produced vaccines is noteworthy and considered in this report. Procurement specifications and reception procedures play a major role in the lack of VVMs on vaccines in some countries.

The policies and practices in place were analyzed in depth in eight countries: Bangladesh, India, Laos, Nepal, Oman, the Philippines, Sudan, and Syria. Analyses considered the following issues:

- Presence of a written policy on the use of VVMs.
- Availability of teaching aids and staff training.
- Documentation practices of VVM status on receipt and dispatch of vaccines.
- Use or nonuse of VVMs as management tools (as part of the multidose vial policy [MDVP]) and for measurement of closed vial wastage.

In some countries, notably Nepal, Sudan, and the Philippines, VVM implementation is supported by infrastructure and documentation although each country has some weaknesses. In the remainder there is a need for better training initiatives, stronger policy implementation, and better understanding of the potential of VVMs to improve national immunization management.

Finally, the attitudes of health staff in these eight countries towards using VVMs were explored. Staff at all levels were generally enthusiastic about the use of VVMs. The major problems in VVM use were perceived difficulty in interpreting the VVMs (not supported by actual performance), failure to use the VVMs as a management tool, and widespread misunderstanding of the MDVP.

Recommendations on improving availability and use of VVMs

The following recommendations describe actions that could be taken to support or enhance VVM availability and use.

Availability

- Work with the UNICEF Supply Division and vaccine manufacturers to ensure that all vaccines, especially newer ones, are supplied with VVMs through United Nations (UN)-agency procurement.

- Ensure that all countries are specifying VVMs as part of their procurement requirements. This not only includes countries procuring vaccines directly from external manufacturers or from their domestic manufacturers but also those countries sourcing vaccines through UN agencies and those relying on procurement by other donors.
- Assemble a policy group to consider the implications of VVMs on all vaccines produced within a country for domestic use, whether or not they are prequalified, including issues of assigning of the appropriate VVM, oversight and enforcement of implementation, and financial questions if relevant.
- Attempt to extend the use of these specifications for private-sector procurement to countries where vaccine use in the private sector is significant (greater than 1,000 doses per year).
- Consider a standardized usage format for the expiry date that would be generally understandable by most health workers, especially for WHO-prequalified vaccines, but also by countries where reading the expiry date is a significant problem for all vaccines received in the country. Some countries experience difficulty in reading the expiry date because of language.
- Ensure that the guidelines on vaccine donations include the presence of VVMs as part of the vaccine specifications (for countries receiving vaccines from other sources through donations).
- Put in place stricter guidelines on the requirement that WHO-prequalified vaccines use VVMs, although use of VVMs on WHO-prequalified vaccines is implicit both by the WHO prequalification team and by UN procurement agencies.

Use

- Ensure that posters explaining the use of VVMs and the MDVP are available at all locations where vaccinations are given and in the cold stores of all countries. These should include training instructions that explain how to properly read the VVM.
- Have countries and regions consider how to best make immunization training available to health center staff whether by training at fixed sites or by supervision and on-the-job training. Although these studies have in general found that cold chain staff at all levels have received training in VVM use, this training has not systematically been made available to the health center staff actually administering the vaccination. These training gaps must be addressed.
- Make the use of VARs, particularly the section that captures the VVM stage,[i] receive more attention from national, WHO, and UNICEF staff. In cases when this section is not filled out or where it is indicated that the VVM is in a stage other than stage 1 or 2, rapid follow-up should be carried out.

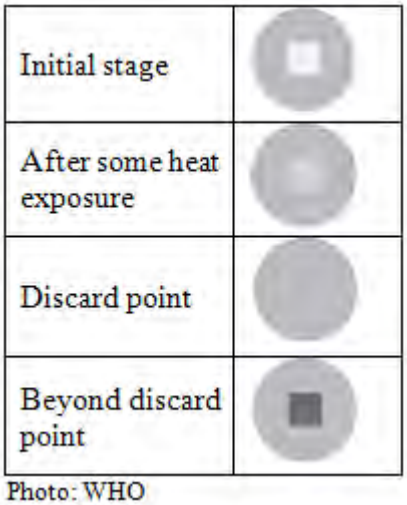

Photo: WHO

[i] For training purposes, four stages of VVMs are sometimes used—but not recommended. Stage 1 represents a VVM that is at the initial stage or start point and has received no heat exposure, stage 2 represents a VVM that has received some heat exposure but is still usable, stage 3 represents a VVM that is at a discard point, and stage 4 represents a VVM that is beyond the discard point. Vaccine vials with VVMs at stages 3 and 4 must be discarded.

- Work with manufacturers to explore an unambiguous numerical dating system (e.g., 3-10 for the end of March 2010) in order to better meet the needs in countries where the standard written language is not one of those in which labels are routinely supplied.
- Put in place enhanced supervision practices in order to ensure proper implementation of practices involving the use of VVMs including:
  - The recording of VVM stages at each level.
  - Using the MDVP.
  - Prioritizing the use of vaccines with VVMs that have started to darken.
  - Appropriate handling and disposing of vaccines with VVMs that have reached or passed the discard point.
  - Appropriate use of stock cards to record vaccine movements and VVM stages.
  - Monitoring of vaccine wastage and using it to improve vaccine management practices and vaccine needs forecasting.

Follow-up on the implementation of these recommendations can be ensured through similar studies aimed for completion in 2012. The proposed studies will take place in the same regions and countries so that progress achieved can be measured.

Introduction and terms of reference

The introduction of the vaccine vial monitor (VVM), a time-temperature indicator that accumulates information on the exposure of a given vaccine vial to heat and temperature, has allowed vaccinators to use vaccines with confidence as to their potency. In 1996, VVMs were introduced on the oral polio vaccine (OPV). Their use was then extended to all Expanded Program on Immunization (EPI) vaccines.

The World Health Organization (WHO) in partnership with PATH promotes the use of the VVM on every vaccine. In 2007, project Optimize was developed as a WHO-PATH collaboration and received funding from the Bill & Melinda Gates Foundation. This project sets the foundation for efficiency-driven immunization logistics systems by extending the use of existing technologies (i.e., VVMs) and systems and advancing new relevant technologies and systems. Critical to the achievement of project goals are several immediate initiatives including expansion of VVM implementation and use. The studies synthesized in this report are a part of that effort.

In the latest list of WHO-prequalified vaccines (January 2010) there are 31 different products most of which are produced by multiple manufacturers. Of these, four products do not carry VVMs (inactivated polio vaccine, cholera vaccine, pandemic influenza vaccine, and meningitis AC polysaccharide vaccine); fortunately those products are in general not used in national immunization programs. For all other vaccines there is at least one presentation that carries VVMs. The only commonly supplied vaccines that are not yet available with VVMs are the tetanus-containing vaccines, *Haemophilus influenzae* type b, and measles-mumps-rubella vaccines from Sanofi Pasteur.

While many of the early successful studies to design and test VVMs took place in Pan American countries, the Pan America Health Organization (PAHO) has not included VVMs in specifications for vaccine procurement via their Revolving Fund, a mechanism developed by PAHO in 1979 for the purchase of vaccines. Therefore, no country in the PAHO region is using VVMs on vaccines.

In all other WHO regions the availability of VVMs will depend on how the vaccine is procured. Countries with United Nations (UN)-based procurement systems are generally guaranteed to have VVMs on all EPI vaccines. Countries producing their own vaccines are not likely to use VVMs with few exceptions, and those using a mixed sourcing system are likely to have a mix of products. The following tasks were undertaken to develop this report.

VVM availability

- Document the proportion of national immunization program (EPI) vaccines supplied with VVMs in countries in consultation with WHO regional and country offices, national EPI managers in member states, and the United Nations Children's Fund (UNICEF).
- Review, to the extent possible, current policies and guidelines on vaccine specifications and procurement procedures for vaccines in countries that import vaccines without going through UN procurement services.

VVM utilization

- Assess the present status of VVM utilization at the different levels of the health systems in selected countries.
- Review current policy documents, plans, and training materials on the utilization of VVMs in selected countries with health workers at all levels.
- Conduct focus group discussions with national, central, and mid-level EPI managers and immunization health workers in selected countries. Assess VVM knowledge, attitudes, and practices as well as the impact of VVMs on vaccine handling and management practices.

Methodology

Regional situation: vaccines with VVMs

This information was obtained from the country-specific UNICEF-WHO Joint Reporting Forms (JRFs) and supplemented by knowledge from vaccine sources in country. UNICEF staff as well as WHO staff were important sources of data. For the Eastern Mediterranean (EM), Southeast Asian (SEA), and Western Pacific (WP) regions this information was supplemented with in-depth studies in two to three countries as described in the country studies and focus groups sections below.[1,2,3] For the African (AF) region the results of vaccine management assessments provided an important source of information.[4]

Country studies

Interviews and visits were held with staff of the ministries of health (MOHs) and national, regional, and local levels in selected countries. Observations of cold stores and of vaccine management practices, review of relevant documents, and focused discussions were held at all levels to obtain an understanding of the situation in country.

Focus groups

Focus group discussions were held at each level with as many people as possible at each level based on the guidelines, "A Brief Guide to Planning and Conducting Focus Group Discussions," and, "Vaccine Vial Monitors: Focus Group Discussion Guide," developed by Elizabeth Abu-Haydar, PATH. An indicative copy of the discussion guide used is given in Annex 1. In some cases, at the request of the commissioning officer, questions were added on storage parameters for non-EPI vaccines, such as H1N1 pandemic influenza vaccine, on the desirability of having VVMs on these vaccines, and on the monitoring of closed-vial wastage using VVMs.

Results: proportion of EPI vaccines with VVMs

Data from the Western Pacific region

Annex 4, Table 1 gives a summary of all the countries in the region with information on birth cohort, vaccine sources, and percentage of doses of vaccine supplied with VVMs. VVM dose data were obtained from WHO-UNICEF JRFs when available and from extrapolating coverage and population data obtained from the WHO immunization database for the other countries.

An analysis of the proportion of EPI vaccines with VVMs at the regional level indicates that of the approximately 344 million doses of vaccines used, 77 million or 22% are with VVMs. This

information is heavily influenced by the industrialized countries Australia, Japan, Korea, and New Zealand, with an estimated total of 87 million doses (Annex 3, Figure 1).

For the three largest developing countries (China, the Philippines, and Vietnam), China has the largest impact and does not use VVMs. The Philippines have VVMs on virtually 100% of their vaccines (private-sector vaccine use without VVMs is estimated below 5%), and Vietnam produces most of its own vaccines, sourcing only measles vaccines through UNICEF in 2008 (Annex 3, Figure 2). Japanese encephalitis SA-14-14-2 live vaccines exported from China to countries in the SEA region do contain VVMs, at the initiative of PATH promoting the use of this vaccine. However, given the current price of the VVMs, about $0.05 each,[ii] relative to the cost and volumes of vaccines used in China, it is not surprising that these are not in local use.

Annex 3, Figure 3 shows the remaining developing countries having birth cohorts over 10,000 individuals (as those with lower populations will not show up on the figures). The smaller countries have a higher proportion of VVMs, thus bringing the overall total for the developing countries to about 30% of approximately 250 million doses. To date no information is available on practices in countries such as Malaysia and Brunei Darussalam, and these might be countries where initiatives should be focused. However, it is known that Papua New Guinea procures its own vaccines, includes VVMs as part of the specifications, and that vaccines are being received with VVMs.[iii] A summary of the status of individual countries with regard to their inclusion of VVMs in vaccine specifications and other regions can be found in Annex 4, Table 8. The other countries of the region using UNICEF procurement (Cambodia, the Pacific Islands, and Mongolia) are expected to have a significant proportion, near 100%, of vaccines with VVMs, except for those Pacific Island countries using diphtheria-pertussis-acellular pertussis (DTaP)-based combination vaccines which have been excluded from the totals of vaccines with VVMs.[iv] Supplementary immunization activities are not included in these figures. However, where used and available, data on influenza vaccines have been included.

Vaccines provided through the private sector

The percentage of vaccines being supplied through the private sector is not known for most countries, and this remains an important factor to understand. However, this will be a challenge depending on whether there is a significant percentage of centralized procurement for the private sector, perhaps through private hospitals.

Data from the Eastern Mediterranean region

Annex 4, Table 2 is a summary table for 22 EM countries (including separate information for South Sudan) containing information on birth cohort and the percentage of doses with VVMs. For this region, information on each vaccine was obtained by questionnaire and precise information on doses of vaccines with VVMs per country is provided in Annex 2. Of the 22 countries, seven did not fill out a questionnaire. These seven procure vaccines either directly or through the Gulf States' pooled procurement system. For the latter countries it was assumed that,

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[ii.] Debbie Kristensen, PATH, personal communication, 2009.

[iii.] Diana Chang-Blanc, UNICEF Bangkok, personal communication, 2009.

[iv.] No validation has been made on the assumption that countries received vaccines with VVMs through UNICEF except in the case of Laos where some of the doses did not have VVMs according to the vaccine arrival report.

as for Oman, only OPV carried VVMs, i.e., about 31% of the total vaccine doses (for Tunisia and Libya it was assumed that no VVMs were supplied). Because dose data per vaccine were not available for these countries, we took the total number of doses to be 15% of the regional total, as they represent about 15% of the population, and assigned values of either 0% or 31% vaccines with VVMs as noted above. When this information was added to the information found from the questionnaires, the regional total was 82% of vaccines with VVMs. If we take into account only countries that responded to the questionnaire, the regional total will jump to 86.5%.

The approach of using a questionnaire to get extensive vaccine-specific data for many countries allows us to calculate which vaccines usually come with VVMs and which do not (see Annex 4, Table 3). For this region, a large proportion (almost all) of OPV, measles, measles-rubella (MR), and pentavalent vaccines come with VVMs. For the rest, except for tetanus toxoid (TT), tetanus and diphtheria toxoids (Td), Bacille Calmette-Guerin (BCG), and diphtheria-tetanus-pertussis-hepatitis B (DTP-hep B) (which have proportions between 60% and 90%), the proportion is far less than 50%. This observation can reveal weak points in VVM coverage and will be addressed in the recommendations.

Procurement in the Eastern Mediterranean region

Countries in the EM region procuring vaccines using funds provided by the MOHs include Egypt, Jordan, Lebanon, Libya, Morocco, Syria, and Tunisia. In Syria, the only one of these countries where an in-depth analysis of procurement was performed, it was found that although the specifications clearly called for VVMs on all vaccines VVMs were only being provided on OPV vaccines through a misunderstanding. It has been agreed that VVMs on all vaccines will be specifically requested in the tender from 2010 on.

Gulf countries procure all or a major part of their vaccines through a pooled system (Gulf Cooperation Council [GCC] Secretariat General of Health [SGH]). This includes Bahrain, Kuwait, Oman, Qatar, Saudi Arabia, and the United Arab Emirates. Only OPV vials carry VVMs in the six Gulf States. This means that only 31% of the total vaccines in these countries carry VVMs. Vaccines purchased directly by the countries also do not carry VVMs. The EPI staff in Oman were aware of the importance of VVMs but expressed their frustration in having to repeatedly bring the issue to the attention of other GCC EPI managers. It seems that the other larger GCC countries that have more influence in providing specifications for tenders, such as Saudi Arabia, are not convinced about the importance of VVM placement on vaccines other than OPV. Since SGH cannot purchase vaccines with different specifications for different countries, the tender for purchasing vaccines is identical for all GCC countries.

The issue of the lack of VVMs on all vaccines was brought to the attention of the EPI management in Oman. The question of the importance of VVMs for all vaccines was discussed during the meeting with the management. Since Oman and other GCC countries are mainly following the policies of the industrial countries, and VVMs are not used there (for instance in the United States and Europe), the importance of VVMs and their utility are always questioned. In addition, the EPI managers wonder why VVMs are not used in the PAHO region where polio and measles were both eradicated before the other regions.

Private sector

In Syria, it is estimated that 10% to 15% of total immunization is provided by private physicians, particularly by pediatricians. Vaccination by private physicians is carried out in large cities like Aleppo, Damascus, and Latakia. Private physicians purchase vaccines from MOH pharmacies. The price of vaccines purchased from these pharmacies is as high as $10 per dose. Unchecked information indicates that the private physicians charge up to $30 for each immunization. The bulk of immunization is provided by the MOH free of charge and through a series of different types of health facilities. How VVMs are perceived and used for discarding vaccines by private physicians providing vaccination services is unknown. The degree of knowledge of private physicians on VVMs is also unknown as only one private physician was interviewed. Some MOH staff believed that the majority of private physicians are aware of VVMs and how to interpret VVM stages, but they were not sure whether they should discard vaccines that have reached VVM stages 3 and 4 because of high vaccine prices.

In Oman, a small number of children are vaccinated by the private sector. In the past, private pediatricians and physicians received vaccines from the MOH free of charge, but now they have to pay the government for the actual cost.

Data from the Southeast Asian region

For the SEA region, the summary information on vaccine sources and percentage of doses with VVMs is given in Annex 4, Table 4. Because the report did not give a breakdown of information by vaccine, we have used the proportion of birth cohort covered by VVMs to analyze the information in Annex 4, Table 4. Assuming that Thailand had no vaccines with VVMs, and Sri Lanka had 30%, the overall regional VVM coverage is 56%.

Specific case of domestically produced vaccines in India

Efforts have been underway for several years to have VVMs on all domestically produced vaccines in India. Recently the government, with WHO assistance, developed the Vaccine Catalog which incorporates vaccine specifications and shipping guidelines to be implemented in all future tenders. Annex 4, Table 5 shows 2008 data on the status of VVMs for key Indian manufacturers. It was anticipated that all manufacturers would be providing vaccines with VVMs in the near future. This should give a significant increase to the percentage of vaccines with VVMs in the SEA region.

The major concerns of manufacturers in India in implementing this policy include:

- The government's scheme for reimbursing the cost of VVMs.
- The need for a fixed reimbursement price for the full cost of the label.
- The three-month lead time to obtain reimbursement from the government of India.
- The lack of multiple supplier choices for VVMs.

Procurement Southeast Asian region

Countries procuring vaccines in the SEA region include Bangladesh, Nepal, Sri Lanka, and Thailand. Bangladesh has a procurement policy with technical specifications requiring VVMs and procures using UNICEF procurement services. Nepal procures either through UNICEF or directly purchases only WHO-prequalified products, and includes specific VVM requirements in

its tender. The report does not cover procurement practices of Sri Lanka and Thailand, but it is known that Sri Lanka has considered specifications for vaccines equivalent to those supplied through UNICEF in the past.

Data from the African region

Summary information for AF countries is given in Annex 4, Table 6. Because the report did not give a breakdown of information by vaccine, we have used the proportion of birth cohort covered by VVMs to analyze the information. Using the assumptions given, the overall regional VVM coverage is 84%.

Procurement in the AF region

The majority of countries in the AF region receive vaccines through UNICEF, including all 7 countries in Eastern Africa, 4 of 11 in Southern Africa, 8 of 11 in Central Africa, and 14 of 17 in West Africa. The following countries have some sourcing through procurement: Algeria, Angola, Botswana, Cameroon, Congo, Cote d'Ivoire, Mauritius, Mozambique, Namibia, Senegal, Seychelles, South Africa, and Swaziland. Countries procuring vaccines are not specifying VVMs in general, except for Namibia. Seychelles, South Africa, and Swaziland were to introduce specifications for VVMs in 2008.

Synthesis

The highest regional proportion of vaccines with VVMs was found in the AF and EM regions because of the relatively low proportion of countries that were self-procuring vaccines (Annex 4, Table 8). Changes of policy in two large EM countries, Iran and Egypt, who are producing and procuring vaccines, could greatly increase the proportion of vaccines supplied with VVMs. In the AF region, changes in procurement specifications in South Africa and a few other countries could change the proportion of vaccines supplied with VVMs, and this may have already happened. The SEA region has more than 50% of its vaccines supplied with VVMs, and the progress made in India with domestic manufacturers will increase that proportion. Better information and/or a reinforcement of procurement specifications in Sri Lanka and Thailand could also increase the proportion. The impact of the large number of vaccines in the WP region coming from industrialized countries that are not using VVMs, plus those from large producing countries, such as China and Vietnam, lowers the positive proportion of vaccines from the WP region.

In-depth country studies

The following eight countries were selected for an in-depth review on VVM availability and utility:

- Sudan, Syria, and Oman in the EM region.
- The Philippines and Laos in the WP region.
- Bangladesh, India, and Nepal in the SEA region.

The rational for selection of these countries for in-depth review is based on the fact these countries represent all different situations in terms of vaccine procurement in the respective regions: procurement through UN agencies (UNICEF), self-procurement from WHO prequalified suppliers, and local production.

The policies and practices in place were analyzed in depth in the above-listed eight countries. The analysis considered the presence of a written policy on the use of VVMs, the availability of teaching aids and staff training, and documentation practices of VVM status on receipt and dispatch of vaccines. The use of VVMs as management tools (as part of the multidose vial policy [MDVP]) and measurement of closed-vial wastage were also considered. The findings are summarized in Annex 4, Table 7.

The Philippines

Policies pertaining to VVM use in the Philippines are covered in the Cold Chain Manual; the latest version was revised in 2005. As mentioned above, all vaccines administered by the department of health have been supplied with VVMs, this being a part of the specifications included in their procurement services contract with UNICEF. The policies are fairly simple. All staff should receive training on how to read the four stages of VVMs which are illustrated in the manual, but posters illustrating the four stages of VVMs are not normally in vaccine stores or in barangay health posts.

In an attempt to receive only vaccines with minimal or no previous heat exposure, the national cold store at the Research Institute for Tropical Medicine presently refuses to accept vaccines with VVMs that they deem to be at stage 2 (see Figure 1). However, the process of VVM color change is gradual and dependent on VVM type, and the chart with four stages is not meant to be a tool to reject or accept vaccines. This visual judgment by store managers therefore is not a reliable measurement and they might often reject vaccines that have not had any heat exposure. The important point of comparison should be the status of the inner square in comparison to the reference ring on individual vials of vaccine. Vaccines that are becoming close to the discard point received at any point with VVMs should be used in priority compared to vaccines that have incurred less heat exposure regardless of expiry date. There is a space on the stock card for recording VVM stage when the vaccines enter and leave the national store. This information is not currently captured further down the supply chain.

The VVM is also mentioned in the MDVP. In order for this policy to be applied to opened vials of OPV, diphtheria-tetanus-pertussis (DTP), TT, and hepatitis B (hep B) vaccine (which would allow them to be used for up to 28 days or until the vial was empty, whichever came first), the manual currently specifies five criteria:

1. The expiry date must not have passed.
2. The vaccine should be stored continuously in an appropriate cold chain.
3. The vials should not have been submerged in water.
4. Aseptic technique should have been followed.
5. The VVM should be in place and must not have reached the discard point.

*Recently a sixth criterion was added, that the date the vial was opened should be written on it.

Because, with few exceptions based on local initiative, there are no posters or visual aids in either the cold stores or the health posts to remind staff of the color changes, it was reiterated at every site we visited that life sized (at minimum) color posters should be provided. It was felt that if

there were a standard to compare the VVMs to in order to determine whether they were actually in stage 2 or not, it would facilitate decision-making.

Figure 1. VVM chart is currently used for training

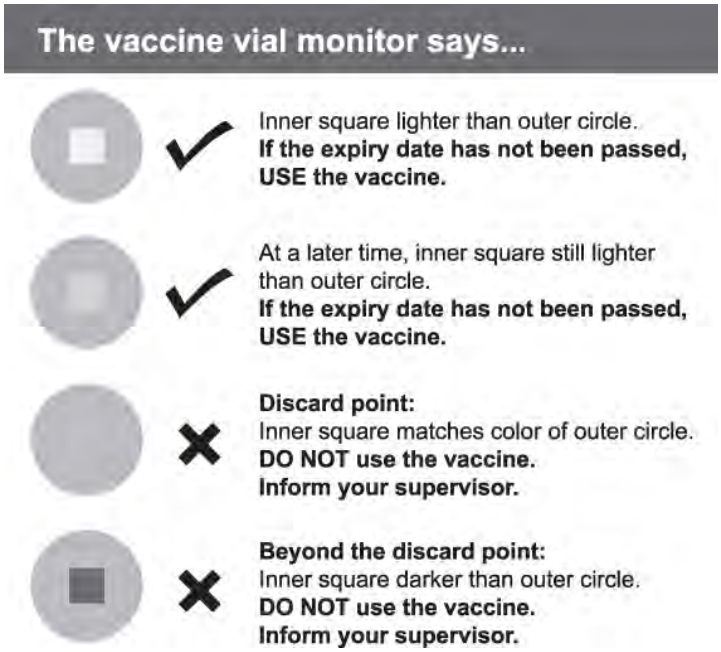

Photo: WHO

Cold chain training, which includes training in VVM use, is repeated about every two years for staff at the national, regional, provincial, and/or city levels and provides updates on new policy indications as well as provides refresher training. Training is also reinforced for staff at higher levels as they train the lower-level staff. The training is based on the Cold Chain Manual, which mentions the four VVM stages and the action to take at each stage, and on the MDVP. Some national staff also received training in vaccine management sponsored by UNICEF (courses have been held in Thailand and Mongolia, for example) which uses the Global Training Network methodology and such things as a VVM game. The staff that had participated in the training were very enthusiastic about it and reproduced it for their own site staff on their return attempting to maintain the spirit of the course as well as the basic information.

Health post staff have an orientation when they join and at intervals are updated on policy. Although staff felt the training was useful, they felt that there was not enough opportunity to practice the skills covered by the training with regard to the VVM. However, there is an active program of supervisory visits, held at minimum quarterly but normally monthly, which are designed to reinforce these skills.

In the case of hospital staff, who administer BCG and hep B at birth, training has recently been done during assessments to prepare for providing birth doses of hep B vaccines in the hospitals. It is not known whether this training will be repeated at regular intervals in the future.

Laos

The policy in Laos on VVM use is based on the assumption that all products have VVMs. Staff are trained on the use of the four stages: stage 1 is fine to use, stage 2 should be used as a priority, and stages 3 and 4 should not be used. It is understood that vaccines that have VVMs that reach stages 3 and 4 are to be reported to the central level, but this is not happening.

The MDVP mentions the existence of the VVM as one of the criterion for multidose vial use. In Laos, vaccines used in fixed centers, except for measles and BCG, are allowed to be used for up to one month after being opened assuming that the VVM is alright, the expiry date has not passed, the vaccines are stored correctly, and the vaccines have been used aseptically. However, there is reluctance to use them for this length of time because of the fear of contamination. For outreach, vaccines in opened vials are often not reused, even if the above conditions are met. There are written documents which are in all health centers on the policy for VVMs; however, the pictures of the four stages are only in two colors. The criteria for the MDVP are also outlined in this manual. The EPI is working with UNICEF to have posters for both of these issues.

When vaccines arrive, they are logged in and the vaccine arrival report (VAR) is completed including information as to whether the vaccines had VVMs on them and whether the selected number of vials showed that the VVM status was good. A crosscheck of VARs with actual vials received showed that the VVM status may not have been checked even though there were VVMs on the vaccines.

There are new forms on which the VVM stage can be monitored at each level. We saw these in use at the provincial level, even if the one form we saw had all vaccines marked as having VVMs in stage 2. Although this is supposed to be monitored and documented at all levels, we did not see this at the lower levels.

The distribution system has been a pull system. However, there are many stockout and overstock situations, so they are adding a requirement that the staff from higher levels should visit the next lower level a minimum of two to four times per year to ensure an accurate estimation of needs and sufficient budget. We saw, in two health centers in the Hin Heup District, a large volume of measles vaccines due to expire at the end of the month (140 doses in Na Som Health Center and 40 doses in Phon Kham Health Center). We also saw a similarly large number of doses of DTP-hep B vaccine due to expire in two months but which needed to be used sooner as the replacement pentavalent vaccine was already in stock (50 doses in Phon Kham Center and 150 doses in Na Som Center, plus 50 doses in the district store). The target population of Na Som is 200 children, so clearly there was too much vaccine ordered. Drs. Kongxay[v] and Feldon[vi] mentioned that staff were having problems reading expiry dates correctly, perhaps because of an inability to read English dates, even if VVMs are being read.

Cold chain staff at all levels are trained on the national policy guidelines, Vaccines and Cold Chain Management. UNICEF provides the training. All cold chain staff we met had been trained within the past 12 months. Immunization staff are trained on immunization in practice and routine

[v.] National EPI manager, Laos.
[vi.] WHO Technical Advisor, Laos.

vaccine management. District and health facility staff are trained by the provincial levels. The health center staff we met had not been uniformly trained.

The national cold chain manager had received effective vaccine store management (EVSM) training in Oman, and it is clear that he is trying to implement policies such as those covered in the training. Examples of this are the increased levels of documentation and the avoidance of the use of ice for vaccine transport.

Laos' EPI is using VVMs as a management tool at the higher levels with a system of recording VVM status on receipt of vaccines. In addition, the MDVP is in use at levels where vaccines are administered. The national policies are well described in the Vaccine and Cold Chain Management Guidelines, and there have been multiple training activities. Apparently, however, this training is not having the desired impact at the service-delivery level. Staff at this level, while able to read the VVM with ease, were not correctly applying the MDVP and were unsure of the conditions or how the policy should be applied. It was reassuring, though, that all staff knew that measles and BCG vaccines should be discarded six hours after reconstitution. Other issues in vaccine management, such as vaccine overstock conditions, improperly filled out forms, and vaccines with damaged labels, point to the need for a different approach to training at the service-delivery level, reinforced by effective supervision. Until the health center staff can master these simple principles of vaccine management, it is unlikely they will be able to effectively master more demanding concepts such as wastage monitoring. In fact, it was noted even at the higher levels that information on VVM status, although recorded, was not recorded correctly in several cases.

Monitoring of closed-vial vaccine wastage would seem to be a priority in Laos. Since the coverage in Laos is consistently under 80%, this should be taken into account in the vaccine forecasting for ordering. In 2008, 400,000 doses of DTP-hep B were ordered which is a large number for a 170,000 birth cohort with about 60% coverage. In fact, last year over 100,000 doses of this vaccine expired before they could be used,[5] and other similar overstock situations have occurred.[6]

India

India is at an early stage of VVM implementation and usage. As of March 2007, there is a VVM policy for all EPI vaccines supplied to the Indian immunization program. There is increased attention given to the cold chain, and as of 2007 EVSM assessments have been implemented in several states which will strengthen VVM use as a stock management tool. Currently, VVMs are used in hep B stock management leading to easier monitoring and discarding of spoiled vaccines. Thus, weak links in the cold chain can be identified and addressed. There have been training programs and materials for every level of the cold chain including a section on VVMs. The most recent publication, "Immunization Handbook for Health Workers," was printed in 2006. The new VVM policy was transmitted during a meeting of state immunization officers and cold chain officers, to be followed by a circular memorandum, but enforcement of the VVM policy remains a challenge without defined vaccine specifications. A barrier exists in aligning orders and supply of vaccines to minimize shortages and stockouts, particularly for urgent vaccine orders, which give manufacturers who have not fully integrated VVMs no incentives to do so.

The cold chain equipment in India is old and poorly maintained. This has been demonstrated with the implementation of VVMs on hep B vaccines where increased wastage rates have been observed.

Several training programs have taken place and training materials have been published, but the VVM technology is not mastered throughout the chain which indicates that the training is inadequate. The technology has been found difficult to interpret especially without a demonstration of all the possible stages of VVM. The high turnover of staff makes it challenging to incorporate a yearly basic training program, and the proper training for incoming staff is still needed.

Bangladesh

The cold chain has been strengthened to meet the minimum criteria for EVSM certification for the central store following the 2004 complete EVSM and Vaccine Management Assessment Tool (VMAT) assessments and the 2008 rapid evaluation. The acceptance and understanding of the VVM technology and its benefits as a stock management tool is applied at both the central and district store. A new dispatch form has been drafted with a specific column for VVM-stage recording. The form was awaiting approval in 2008.

Training programs occur regularly including those for national immunization days. Refresher training programs occur every three years. Recently published training guidelines are available including, "EPI Cold Chain and Store Management Guidelines," for central, district, and Upazilla cold chain personnel which includes a section on VVM reading and the use of VVM in stock management (earliest expiry, first out [EEFO] vs. prioritizing stages of VVM), and an EPI manual for health assistants. Communication is well established through monthly meetings where updates are given and issues are discussed, including VVMs.

However, the government of Bangladesh has no national immunization policy. Such a policy could incorporate specifications from the latest, "Guidelines on the International Shipment and Packaging of Vaccine (WHO/IVB/05.23)," and other VVM-specific documents. The national EPI team confirmed in 2008 that this document would be available within six months. Continued efforts to truly integrate VVMs as part of the VAR are crucial. Implementing a management information system (MIS) for stock management would support the use of VVMs as a stock management tool (i.e., EEFO vs. VVM stage). A local software programmer has been hired to develop a package for this task. VVMs should be seen as the vehicle to encourage reliable out of cold chain practices, particularly the MDVP, which is only practiced at fixed sites. There is the need for a formal recording system of VVMs in the vaccine stock and dispatch register at the district and Upazilla levels to be implemented through a formal circular memorandum from the central level. There is the need for the dissemination of VVM materials including training cards, posters, and waterproof stickers affixed on vaccine carriers in areas where evaluation of the VVM is most important.

Nepal

The use of VVMs on all vaccines is specified in the, "National Strategic Guidelines for Immunization Program of Nepal," which was published in 2000 with strict policy enforcement since 2006. There has been implementation of recommendations for the 2007 EVSM assessment

including VMAT training for all EPI regional and district personnel and proper record keeping including the use of the VAR and the use of the VVM as a stock management tool. There is an efficient cascade structure training program with special VVM training at every National Immunization Day (NID) for polio. Recently, the document, "WHO Immunization in Practice," has been translated into Nepali and made available to cold chain personnel. The cold chain has seen tremendous improvements since August 2007. Continued efforts to truly integrate VVMs as part of the VAR are crucial. Implementing an MIS for stock management would encourage the use of VVMs as a stock management tool (i.e., EEFO vs. VVM stage) and improve vaccine forecasting. The VVM should also be seen as the vehicle to encourage reliable out of cold chain practices. Training geared towards female community health volunteers is necessary. It should include the dissemination of VVM training cards and the concept of vaccine freezing, which has been identified as a problem in Nepal. Better support and supervision are needed from central to district to peripheral levels.

Syria

The MDVP is not in practice in Syria. There is a strong pediatric association in Syria, and the EPI team is in constant contact with the representatives of this association and seeks their opinion and approval for any policy changes or implementation of new ones. There is no poster showing the four stages of VVM. There is a topic related to VVMs in the curriculum for health worker training. The subject related to VVMs is tackled as a part of the vaccine cold chain. The manual for health workers was first published in 2004 and reviewed in 2009, and the updated version has not yet been printed. Reviewing the soft copy showed that the section on VVMs is adequately covered.

The VVM is translated into Arabic[vii] and not abbreviated; however, the abbreviation of a VVM in English is widely used and known by the majority of health workers. In the lower echelon of staff there is some confusion between the VVM and the Freeze Tag® device. During recent years a significant turnover of staff has been reported. This requires more systematic training courses with which the EPI team cannot properly cope. During on-the-job training, the VVM is sometimes neglected.

The stage at which a VVM arrives with vaccines at the national vaccine store is registered in a kind of VAR. However, the VVM stage is not recorded when vaccines are dispatched. Recently there was a failure in one of the freezer rooms in the Damascus National Vaccine Store, and 8,000 doses of OPV were discarded based on VVM color changes to stages 3 and 4. It can be inferred that the VVM is used for managerial decision-making at the central level. There is no feedback from the stores at the lower levels receiving vaccines on the stages of VVM.

Syria has a very stringent method for discarding drugs and equipment which also includes vaccines. There is a technical committee at all levels for discarding drugs and vaccines. Once a VVM changes color and reaches stage 3 or 4, the members of the committee are called to investigate the situation and discard vaccines.

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vii. مراقب اللقاح الذات

The majority of the staff interviewed had the opinion that VVMs can play a great role in achieving a more efficient supply chain and in achieving stronger decision-making power. There is no recollection of any OPV arriving in Syria with VVM in stages higher than 1.

Sudan

The national vaccine store in Sahafa, Khartoum, was certified by a WHO and UNICEF team in February 2008. The national vaccine store has EVSM. The store has been using Vaccination Supplies Stock Management (VSSM)[viii] since late 2007, and the manual system is updated regularly parallel to the computerized system. VARs are regularly completed and returned to UNICEF for all vaccines.

VVM seems to be a household name in the EPI of Sudan. In Sudan, VVM is referred to as مراقب قاروره اللقاح in Arabic, and it is abbreviated as مقل. It is known by all health staff who were interviewed and those who participated in the focus group studies.

VVMs are quite widely used as a tool for decision-making, whether to use or to discard vaccines, at all levels in Sudan. The policy, which is fairly simple, is well specified in the manual for vaccinators.[ix] A copy of this manual exists in Arabic in all health facilities and is well distributed to all health workers involved in vaccination activities. The manual was reviewed and updated in 2002.

Photo: PATH

In all of the health facilities visited, VVM-related posters were displayed in Arabic in the vaccination rooms. The posters were in black and white and on A4-sized paper. On these posters the four stages of a VVM with clear instructions as when to use or to discard a vaccine is specified. The poster is the exact Arabic translation from WHO-recommended information. Information related to the VVM is part of the curriculum for the training given regularly to health workers upon entering the vaccination program. This also applies to refresher training courses.

[viii] VSSM is a stock management computer tool designed by the WHO Regional Office for the EM Region and recommended by WHO for vaccine stores.

[ix] Manual for Vaccinators, Ministry of Health, Sudan 2002.

Sudan conducts several rounds of NIDs for polio eradication every year. All volunteers involved in NIDs are also trained in matters related to VVMs. It is estimated that every year approximately 30,000 volunteers are trained to take part in NIDs. Based on the records available in the UNICEF country office, 36,420 volunteers were trained in 2009 and learned how to employ VVMs for the use or discarding of OPV vials. It should be noted that a large number of volunteers carry on into the next year; therefore, only a small portion of them receive training for the first time every year. The four stages of VVMs are printed on the NID tally sheets of which every team carries one during campaigns. Teams of volunteers are trained to use or to discard vaccine based on the simple diagram specifying the four stages of a VVM. They are instructed to report vials that reach stages 3 and 4 during the campaign and to register these vials on the tally sheet.

States receiving vaccines are required to complete a standard form and to provide feedback to the national vaccine store. In this form the stage of VVM is recorded and it is sent back to the national vaccine store. It was said that action was taken when vaccines arrived at the state stores with VVMs at stages 3 or 4. However, actions taken are so far not documented.

In 2009, VVMs on 1,200 vials of pentavalent vaccines[x] changed color rapidly and reached stage 3. The vials were immediately discarded. This was an unprecedented incident, and therefore, it was reported to UNICEF and WHO. This, to a large extent, shook the confidence of the staff in VVMs at the national vaccine store. Investigation took place immediately. The temperatures of all cold rooms and freezer rooms in the national vaccine store are automatically recorded. Manual recording is also available. No temperature violation was noted. WHO's response[xi] was that similar complaints were received from other countries on Quinvaxem® products. In short, the response specified that VVM7 was attached to these vials whereas VVM14 would have been more appropriate. The explanation did not mean much to the staff at the country level since they were not aware that different types of VVMs were attached to different vaccines.

Oman

The National Vaccine Store in Muscat, Sultanate of Oman, was the first vaccine store certified by WHO and UNICEF. Issues related to VVMs are not treated as seriously as in other countries where the majority of vaccines carry VVMs. However, most of the staff directly involved in providing vaccination services were aware of VVMs and their utility and importance. One of the issues mentioned during discussion and interviews was that since electricity is quite reliable in Oman at all levels, VVMs may not play a great role in ensuring the potency of vaccines.

Posters printed only in English in 2006 on the four stages of the VVM were out of stock. Only one of the visited facilities[xii] displayed the poster. The use of VVMs as a managerial tool is limited in Oman. Decisions on whether to use OPV vials are made based on VVM stages. The only occasion where vaccines were discarded due to VVMs being at stage 4 was after the June 2007 cyclone. All vaccines in the Muscat area were destroyed because the cyclone caused the electricity to be cut for a relatively long period of time.

[x.] Quinvaxem® by Berna Novartis, batch number 0451152, expiry January 30, 2011.

[xi.] Personal correspondence between Dr. Umit Kartoglu, Medical Officer, Vaccines and Biologicals, WHO headquarters and WR Sudan, and WR Sudan's letter to Jamal Khalfallah, Secretary General, Family Blood Pressure Program on July 16, 2009.

[xii.] Rustaq District Vaccine Store.

In the latest edition of the EPI manual, two pages are dedicated to issues related to VVMs. This latest edition was updated in 2003. Most of the staff met and interviewed learned about VVMs through on-the-job training.

The staff at the national vaccine store in Muscat complete VARs for all vaccine shipments. This was checked and confirmed for all shipments from 2007 to 2009. However, the boxes related to VVMs were left blank on the VARs and the stages of the VVM when the shipment arrived were not documented. Staff at the national vaccine store believed that there was no need for registration of VVM stages since VVMs were in stage 1. There is no specific column for the registration of VVM stages on the forms. However, in the district visited in Rustaq the store staff registered VVMs in the "remark" column. In this store, stage 1 was referred to as "normal." All this indicates is that training on VVMs is not standardized.

Wastage is calculated at two levels in the Oman program. It was reported that wastage would be calculated based on VVMs in stages 3 and 4 for OPV.

African countries

Vaccine Management Assessments (VMAs) were conducted since 2003 in 11 AF countries. The overall results show that knowledge of the VVM appears to be strong at the national and subnational level—less so at service points. Hence, only about 60% of peripheral facilities appear to be using VVMs for outreach correctly. Looking into more details from the AF region, one finds similar discrepancies between VVM knowledge and use from central through intermediate to service level across the countries (Annex 3, Figure 4, a to c). Annex 3, Figure 4c shows a surprisingly high performance from two Central African countries (Cameroon and Congo). However, in Cameroon the service level still does not make full use of the VVM's potential for vaccine management. The conclusion from these results is that there is still a need for vigorous action to promote VVMs in the AF region. Posters on VVMs exist in 45% of central stores, 36% of intermediate stores, and 43% of health facilities.

This indicates two things:

1. Posters do not explain all of the successes as the central and intermediate stores score much higher than 45%.
2. Posters might still have a role to play at the service level but must be combined with other types of support such as supportive supervision and training.

Focus group discussions: feedback on VVM use

Philippines

In general, staff interviewed (at the national level, including the national cold store, two regional cold stores, one city health center, and three barangay health posts) were very enthusiastic about VVMs. In the words of one regional cold store manager, "I like it very much. This is one of the best gadgets or indicators that WHO has given us. It helps us."

Staff noted that the VVM was useful in a number of ways:

- To provide confidence that the vaccine being administered was potent.

- To give instant decision-making power to the vaccinator.
- To allow for a means to prioritize the use of vaccines.
- To give additional assurance for the use of the MDVP.
- To allow the tracing of problems in the delivery system.
- For use as a management tool at the national and regional cold stores.

The major problem that was mentioned was the difficulty of distinguishing between stage 1 and different levels of stage 2. This specifically involved DTP vaccines from the Serum Institute of India which were received at VVM stage 1 (although at least one staff member of the national cold store maintained it was at stage 2), but the VVMs on these vaccines appeared to have reached stage 2 by the time they arrived at the regional cold stores. This causes a problem in the Philippines as the regional staff do not want to accept a vaccine with the VVM in stage 2 as it means its use must be prioritized which can complicate logistics. So far, none of these VVMs have progressed to stage 3 in the course of being used.

Laos

Staff generally showed a high degree of confidence in VVMs. The following were given as reasons for using VVMs:

- Awareness of heat exposure and thus the quality of vaccines.
- Ability to make a decision on whether to use the vaccine.
- Ability to use the vaccines even if there is no thermometer or in case of high-temperature storage or power failure.
- Ability to use the MDVP.
- During outreach, possibility to monitor for excessive heat exposure.

The only challenges reported in using VVMs by staff interviewed in Laos were that they had not seen stages 3 and 4 in the field and were a little unsure about their ability to recognize them. Some people experienced difficulty regarding the transition from late stage 2 to stage 3. We also noted problems with the implementation of the MDVP and other vaccine management practices and problems with overstocked vaccines at the health center level. These latter issues were not directly related to the use of the VVM, but keeping vaccines so close to their expiry date is not good vaccine management practice.

India

Focus group discussions were not included in the report for India.

Bangladesh

The focus group discussions had a total of nine participants from two districts. Participants were from the national store (2), the mid-level district stores (3), and Upazilla and ward level (4). Two districts were visited including the Narsingdi and Dhaka City Corporation to represent a rural versus urban setting. In Narsingdi, the visit included the district store, one Upazilla at Shibpur, and one ward. In Dhaka City, there are ten zones; two health posts in Zone 9 Ward 21 were visited. There were a total of ten evaluative questions to assess VVM knowledge. A question about the “shake test” was added to gauge the potential importance of heat sensitivity evaluation versus the awareness of vaccine freezing. The “shake test” is a test to compare the sedimentation

rate of vaccine that is suspected as being frozen with a control vaccine that has been purposely frozen. Fifty-six percent of respondents acknowledged saving open vials. Of these respondents only one EPI medical technologist (MT) confirmed that he would save the vial only if the VVM was OK. In addition, 100% of respondents were aware of the "shake test," but only one EPI MT actually knew how to perform it.

There were 19 informative questions used to determine participants' attitudes towards VVMs. Of these, 25% of respondents affirm that they have changed the way they transported and keep the vaccines. One EPI MT confirms segregating vaccines received without VVMs. All respondents also found VVMs useful when there was a power failure. Three health assistants do not have to worry about this situation as they only bring the vaccine required for the immunization day.

There is a high level of awareness of the VVM technology among the staff. The majority were aware that all vaccines have VVM labels on them. Respondents even indicated that recently they had seen measles and DTP vaccines without VVMs. The VVMs have been well integrated as a stock management tool, and EPI staff seem to understand the concept of using vaccines with VVMs at stage 2 prior to those with VVMs at stage 1 regardless of the expiration date.

All the respondents knew that VVMs were used to detect heat exposure and were comfortable with using the technology and trusted its benefits. About half of them found the VVMs difficult to interpret and emphasized that interpretation may be subjective at times. However, the same participants perfectly interpreted the VVM pictures in the questionnaire.

The MDVP has not made any serious impact in Bangladesh as only 50% of the participants saved open vials. All of them knew the rules regarding reconstituted vaccines. They also knew that VVMs enable use of open vials for subsequent sessions but were unclear as to the length of time a vial, other than reconstituted vials, could be used after being opened. The MDVP is currently only practiced at fixed sites. Over half of the respondents knew that VVMs enable use of a vaccine out of the cold chain, but only a quarter of them had changed the way they transported vaccine, in that they had become more careful. Cold chain equipment monitoring practices have not changed since VVM introduction. EPI staff also demonstrated knowledge of vaccine freezing, though most of them were not fully trained on how to detect freezing.

Nepal

There were a total of 26 participants from nine districts. They included individuals from the national store (3), the mid-level district stores (15), and the health posts (8). Two districts in the central region were visited, Bhaktapur and Kabhre; the visits included one district store and one health post at each district. The questionnaire contained eight evaluative questions to assess VVM knowledge. Only 38% of respondents knew which vaccines had been given with VVMs, but every respondent checked off OPV. The incorrect responses represented a range of EPI personnel including primary health workers. Respondents stated that they had faced the following problems: lack of adhesion of VVM labels on BCG/measles caps, lack of VVM reaction after long exposure to sunlight and heat, and the potential increase of heat conduction if a vial is wet. Studies have refuted these problems, and better training will resolve these issues.

This questionnaire was useful in assessing the knowledge and impact of VVMs in the country. Information confirmed familiarity with VVMs and their use for better vaccine quality and stock

management (i.e., which vaccine to use first). The VVM technology is trusted, and benefits such as the MDVP and longer use of vaccine out of the cold chain is recognized. It is also clear that VVMs help by allowing people to know that the vaccine is still useful at the end of the immunization day. Vaccine handling is more careful since the VVM. VVMs are recognized as a good indicator during adverse events such as power failure. Visual aids such as VVM posters would sustain awareness. Good MDVP practice was observed at one health post where the vials were labeled with the date of opening and the date of discard (i.e., four weeks later).

Syria

There was a consensus that using VVMs on all vaccines will help to run the program more efficiently. They mentioned that since electricity is not reliable in Syria, and not all refrigerators have a reliable thermometer, VVMs can play a great role in ensuring that the vaccines used are potent. Some had doubts on the relation of VVM color change with the potency of vaccines. It was said with surprise and disbelief that if one keeps a vial of vaccine in one's pocket the VVM color will not change for more than a week. All those who participated in these discussions mentioned that they had seen vials of OPV with VVMs at stage 4. The long process of discarding vaccines either due to VVM color change or expiry date was cited. There was a consensus on the lack of difficulty in training new health workers in the reading and interpreting of VVM stages.

The most interesting issue which came up in Syria during discussions was the option of printing VVM stages on children's vaccination cards. This would bring to the parents' attention to check the VVM before allowing their children to be vaccinated. This came up in the discussion since the private sector charges heavily for the same vaccines which are provided by the MOH free of charge. Later this view was totally rejected by the staff at higher levels since they thought it would put parents at unnecessary odds with physicians and consequently destroy their established trust. It was also mentioned that the pediatric association would not allow the printing of VVM stages on vaccination cards.

Sudan

Since VVMs have for a long time been widely used in Sudan, there is no recollection of the exact year when VVMs first came to the country. However, there was a consensus that VVMs were first used during NIDs in the late 1990s. Most of the participants in the discussions, particularly the staff in the higher echelon, mentioned that VVMs increase the degree of control of the vaccine cold chain. The majority of health workers did not know the exact mechanism by which VVM colors change. Some health workers thought that VVMs ease their consciences since they can easily use or discard vials, and they are confident that the vaccines being used are effective.

Most believed that the introduction of VVMs has contributed to an increase in vaccination coverage in Sudan. The simplicity of the policy to use or discard vials was an important factor in the widespread usage of VVMs in Sudan. There was no consensus on whether VVMs would increase or decrease vaccine wastage.

The health staff who participated in discussions at the state level mentioned that they never noted any VVMs at stages 3 and 4 in the routine cold chain although they have discarded vaccines due to VVM stages during campaigns. They were all aware that vaccines with VVMs at stages 3 and

4 should be discarded. They all thought that VVMs were an important tool particularly due to the hot climate of Sudan and Sudan's unreliable electrical power supply.

There was no consensus on whether VVMs were more useful during the campaigns or for routine activities. Some thought that VVMs are more useful for routine activities since vaccines are stored and kept for a longer period of time, while others thought them to be more useful during campaigns since there is less control of the cold chain.

Those who participated in the discussions were all aware of the reason why VVMs are sometimes attached to the upper or the lower parts of the vial. The reason is that if a VVM is on the lower part of the vial it's because it's a vaccine that can be used for more than one day once opened. If it's on the upper part of the vial (that is on the cap or neck of the ampoule) it is because the vaccine must be discarded shortly after the vial is opened; therefore, the VVM is removed upon being opened and can no longer be referred to. This indicates the effectiveness of training on the issues related to VVMs.

On the question of possibilities to change the design, shape, and function of VVMs, the majority thought that it would be helpful to design and produce new VVMs in which the color differences between stages 1 and 2 are more pronounced. Some thought that something similar to VVMs should also be designed and used for freeze-sensitive vaccines, or the current VVMs should also somehow indicate when vials have been exposed to freezing temperatures. Most of the health workers who participated in the discussions mentioned that they learned about VVMs during the training courses and that they were confident in training volunteers. They mentioned that as a part of volunteer training they bring empty vials with VVM color changes to the sessions.

Oman

It was suggested that WHO should specify that vaccines must carry VVMs and particularly that VVMs should be on vials of vaccines against target diseases for eradication, elimination, and control. Except for the staff at the national level, the rest of the staff were not aware that there are different types of VVMs for different types of vaccines. Staff at the national level believed that VVMs must be part and parcel of all vaccines. They believed that serious actions should be taken to convince the GCC SGH to make VVMs a requirement for all vaccines when placing tenders. They expressed that one of the GCC EPI managers should always participate in the meeting where vaccine tenders are specified.

At the vaccination service-delivery level, staff said that they always checked for VVMs on OPV vials before use. They all believed that all vaccines must carry VVMs. Some OPV vials were noted in one of the districts with VVMs at stages 3 and 4 and were discarded accordingly. It was said that the reason for this incident was that staff at the health center did not follow the EEFO rule. Therefore, some OPV vials stayed for a longer period of time than they were supposed to at 2^{o} to 8^{o}C. They expressed that VVMs on all vaccines would grant them confidence and ensure the efficiency of the system and efficacy of the vaccines.

African countries

This section is based on the results of the surveys conducted among national EPI Managers and their counterparts from development agencies (UNICEF, WHO, etc.) during the Annual EPI

Managers' Meetings held in Dar Es Salaam, Tanzania, and Ouagadougou, Burkina Faso, both in March 2008. The box below provides a summary of the answers collected.

Pertinence of the project: 2 negative answers (4%):

- Human resource shortage is not addressed.
- Not all logistics items are taken into account.

Needed support:

- EVSM assessments were requested by 30 repliers (60%).
- Support for VVM availability on vaccines was requested by 15 repliers (30%).
- Support for VVM use was requested by only 8 repliers (16%).

Demonstration projects:

- Thirty-four repliers (68%) volunteered their countries to host.

The above box indicates that VVM availability and use were mentioned as a concern by almost half of participants (respectively 30% and 16%) to the surveys. The type of support requested included mainly training and provision of training materials/job aids (posters, etc.) as shown in Table 1.

Table 1. Type of support requested

Areas	Expectations	
	Number	Percent
Vaccine management	34	68
Support for VVM availability	15	30
Support for VVM utilization	8	16

Several things that can be noticed from the table are:

- Improving vaccine management came as the first concern.
- Support was requested for both VVM availability and utilization.
- Support for utilization: training, training materials, and job aids.

Further, at a roundtable discussion in Leysin (June 19, 2008–not only African participants were present), to ignite discussions on VVM use, the following box was used to present the status of VVM use, the problem that VVMs as a vaccine management tool are facing, and a question regarding potential strategies that could be implemented to improve VVM use to be answered by participants.

Status:

Both EVSM and VMA reports show insufficiencies in VVM use as a vaccine management tool particularly at the service delivery level. VVMs have been available for a long time, and training was provided particularly during the preparation of polio NIDs for several years.

Problem:

Despite its long presence and numerous trainings, VVM utilization as a vaccine management tool is still inadequate.

Question:

What strategies can we implement in order to improve VVM use in the countries?

The outcome of the discussions can be summarized as follows.

VVM policy:

- In order to speed up the implementation of the use of VVMs, the VVM policy must be revised for adoption in country.
- Such policy should explain the out of cold chain requirements and emphasize the preeminence of the expiry date over the VVM reading.

Reporting and stock management:

- Reporting forms should be revised to include a column for reporting VVM status.
- Vaccine stock management forms should also be adapted.

Training and supervision:

- Health workers from central, through district, to periphery levels should be trained in the use of VVMs as vaccine management tools.
- Cascade training is not effective in transmitting information to lower levels; therefore, it should be avoided.
- Training on VVMs should go beyond the knowledge of the famous “four stages”of VVMs and should include the use of VVMs for vaccine management.
- Supportive supervision should include VVMs in the checklists and in the content of onsite training documents.

In a parallel discussion it was decided to maintain a column in the AF Regional Office Stock Management Tool for recording closed vials discarded because of VVM change.

General discussion

VVM Availability

Any study that looks at the availability and utilization of a tool such as the VVM must cover a wide range of study areas. In the areas studied there is large variability among countries in

population size, income, and methods for sourcing vaccines. There are large vaccine-producing countries that may supply vaccines for export with VVMs but that do not use them domestically. There are also many countries that use a variety of means to source their vaccines, from production or bulk filling, to direct procurement, to supply through UNICEF, or some combination.

Because this report is a synthesis of reports from four different regions, all using differing methodologies, some of the results are not directly comparable. For example, vaccines used for supplementary immunization activities have generally not been included in this study, although in some cases they figure in the totals. In addition, exact data on countries which were not directly visited or for which a questionnaire was not filled out are not available, so different methods of estimating VVM availability have been used. Some of the regional reports went into great depth on vaccine financing and procurement methods that have not been included in this synthesis but can be accessed by referencing the original regional reports; the interested reader is advised to do so.

In the countries procuring vaccines directly from manufacturers, not enough is known of their methods and the specifications they use. These countries should be a priority for activities based on increasing the use of VVMs.

Even among those countries receiving vaccines through UNICEF, many may occasionally receive vaccines by other mechanisms, such as Laos, which in 2008 received a donation to procure directly one shipment of OPV. In addition, there is a variation in the proportion of vaccines from UNICEF that are actually supplied with VVMs. Thus a second priority to increase the use of VVMs would be to work with UNICEF and manufacturers of prequalified products to ensure that all these prequalified products have VVMs.

A third area where policy and implementation are needed deals with those countries producing vaccines for domestic use. Although it would seem at first glance to be important that these vaccines are provided with VVMs, it is not clear how the determination of which VVMs to use and how the oversight of that determination is done correctly can be managed for vaccines that are not prequalified (for prequalified vaccines it is WHO that makes this determination, although even in this case there may be issues some of which are referred to in the report).

In areas where private-sector acquisition and use of vaccines is significant, approaches to cover these areas with VVMs and to use them effectively should be considered.

VVM Use

Once the vaccines with VVMs are in country, they must be used effectively. This involves several activities:

- Training cold store staff and health workers to read the VVMs. This is not difficult but requires practice and could be aided by color posters depicting the VVM stages along with the national policy on VVM use.
- Training cold store staff and health workers to consider both the expiry date and the VVM in prioritizing the use of vaccines. This may be more difficult in countries where the national

language is not covered by the available label languages as the health staff may not be able to read the expiry date.
- Ensuring the understanding and correct application of the MDVP. The use of this policy has been linked with VVMs because the VVM on the vial is one of the criteria for its use. However, the visits described in this study have indicated deviations from national policy in practice and a lack of familiarity with the criteria for its application.
- Using the VVM as a springboard to improve vaccine management practices including appropriate documentation of VVM stages at each level; attention to proper completion of vaccine management forms; attention to the condition of the vial label during outreach; use and collection of wastage information for both opened and closed vials; and attention to forecasting of needs to avoid stockouts and loss of vaccines because of limits on usability, either because the expiry date is reached and/or the VVM expires before the stocks are exhausted. All of these practices will need strong supervision at all levels to ensure they are being meticulously carried out.

Again, because of the variability in the methods used to assemble the data in the different regions, the results are not directly comparable. This synthesis has tried to indicate where methods are different (for example, the lack of focus group discussions in some countries, and a different methodology for obtaining the data in Africa compared to the other three regions where a small number of direct country visits were used to provide a picture of the situation). The fact that most of the issues in VVM use were noted across the board supports the validity of the synthesis.

Conclusions and recommendations

This study has shown first that almost 15 years after their introduction, VVMs are still not being used as effectively as possible as a management tool in the areas studied. The following recommendations describe actions that can be taken to enhance VVM availability and use.

Availability

- Work with UNICEF Supply Division and vaccine manufacturers to ensure that all vaccines, especially newer ones, are supplied with VVMs through UN agency procurement.
- Ensure that all countries are specifying VVMs as part of their procurement requirements. This includes not only countries procuring vaccines directly from external manufacturers or from their domestic manufacturers, but also those countries sourcing vaccines through UN agencies and those relying on procurement by other donors.
- Assemble a policy group to consider the implications of VVMs on all vaccines produced within a country for domestic use, whether or not they are prequalified, including issues of assigning the appropriate VVM, oversight and enforcement of implementation, as well as financial questions if relevant.
- Attempt to extend use of these specifications for private-sector procurement to countries where vaccine use in the private sector is significant (greater than 1000 doses per year).
- Because of difficulty in some countries in reading the expiry date due to language, consider a standardized usage format for the expiry date that would be generally understandable by most health workers, especially for WHO prequalified vaccines, but also in countries where this is a significant problem for all vaccines received in the country.

- For countries receiving vaccines from other sources through donations, ensure that guidelines on vaccine donations include the presence of VVMs as part of the vaccine specifications.
- Although the use of VVMs on WHO-prequalified vaccines is implicit, put in place stricter implementation of this requirement, both by the WHO prequalification team and by UN procurement agencies.

Use

- Ensure that posters explaining the use of the VVMs and the MDVP are available at all places where vaccinations are given and in cold stores in all countries. These should include guides to reading the VVM.
- Although these studies have found that in general cold chain staff at all levels have received training in VVM use, this training has not systematically been made available to the health center staff actually administering the vaccination, and these training gaps must be addressed. Countries and regions should consider how immunization training can best be made to health center staff, whether by training at fixed sites or by supervision and on-the-job training.
- Use of the VAR, particularly the section that captures the VVM stage, should receive more attention from national, WHO, and UNICEF staff. In cases when this section is not filled out or where it is indicated that the VVM is in a stage other than stage 1 or 2, rapid follow-up should be ensured.
- To better meet the needs in countries where the standard written language is not one of those in which labels are routinely supplied, work with manufacturers to explore an unambiguous numerical dating system (e.g., 3-10 for end of March 2010).
- Enhanced supervision should be put in place to ensure proper implementation of practices involving the use of VVMs:
  - Recording of VVM stages at each level.
  - Using the MDVP.
  - Prioritizing the use of vaccines with VVMs at stage 2.
  - Appropriate handling and disposal of vaccines with VVMs at stages 3 and 4.
  - Appropriate use of stock cards to record vaccine movements and VVM stages.
  - Monitoring of vaccine wastage and using it to improve vaccine management practices and vaccine needs forecasting.

Follow-up of the implementation of these recommendations could be ensured through similar studies aimed for completion in 2012.

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Annex 1. Focus group discussion format

Categories	National/regional	District	Health center
Knowledge and information	Written instructions on use of VVMs, e.g., posters, available to health worker?		
	Do you think VVMs improve quality control? Examples?		
	What is the impact of VVMs on effective vaccination coverage?		
	What training have you received on VVMs?		
	How effective was the training? What would you change?		
	Are you confident at reading the different stages of VVM?		
	Are VVMs difficult to interpret?		
	Can VVMs detect vaccines damaged by heat?		
	Do you know that VVMs are available on all EPI vaccines?		
		What vaccines have you given with VVMs?	
Practice	Do storekeepers/health workers know how to read VVMs?		
	Are VVMs used correctly (no stage 3-4 vaccines, MDVP correctly applied, etc.)?		
	Are you confident that VVMs are accurate?		
	Do you have any challenges in using the VVMs?		
	What do you think are the advantages of using VVMs?		
	How often do you encounter vaccine vials with VVMs at stage 3? Stage 4? What action do you take?		
		Do you save open vials of vaccines?	
	Does a VVM help you to keep an open vial longer?		
			For at least three vials, verify that the VVMs have not passed stage 2.
	Are all vaccines contained in the refrigerator within their date of expiry and with a valid (stage 1 to 2) VVM?		
	Describe how you and your colleagues currently use VVMs.		
	See picture (stage 4). Do you discard vaccine?		
	See picture (stage 1). Do you discard vaccine?		
	See picture (stage 3). Do you discard vaccine?		

Categories	National/regional	District	Health center
Management	Do vaccine managers/health workers use VVM status of vaccine for management purposes?		
	Describe how VVMs have changed the way you manage your vaccine stocks.		
	With VVMs, do you know which vials to use first?		
	What could be done to improve the use of VVMs as a vaccine management tool?		
	With VVMs have you changed the way you keep and transport vaccines?		
	With VVMs have you changed the way you manage the cold chain?		
	With VVMs do you monitor the EPI refrigerators as frequently?		
	With VVMs do you not need to keep vaccine vials on ice packs once out of the vaccine carrier/refrigerator?		
	With VVMs do you still use vaccines even when ice packs melt during outreach?		
	With VVMs can you still use vaccines when power failure occurs?		
	Are VVMs helpful to prevent you from discarding open vials at the end of an immunization day?		
		How have your vaccination practices changed because of VVMs?	

Annex 2. Information on availability of VVMs for each vaccine and for each country 2007 and 2008 (14 EM countries[xiii])

Table 1. Afghanistan, Djibouti, Egypt, and Iran*

Vaccines		Afghanistan		Djibouti		Egypt		Iran	
BCG	Total	9,502,600		70,000		8,700,000		9,000,000	
	With VVM	9,502,600	100%	70,000	100%	0	0%	0	0%
DTP	Total			130,000		11,052,000		14,000,000	
	With VVM			130,000	100%	0	0%	5,400,000	39%
DTP-Hep B	Total	6,790,500				7,200,000			
	With VVM	6,790,500	100%			0	0%		
DTP-Hep B-Hib	Total	6,790,500		44,400					
	With VVM	6,790,500	100%	44,400	100%				
DTP-Hib	Total								
	With VVM								
DT	Total					9,200,000		400,000	
	With VVM					0	0%	0	0%
Td	Total					6,500		12,500,000	
	With VVM					0	0%	8,900,000	71%
TT	Total	17,220,800		850,000		5,600,000			
	With VVM	17,220,800	100%	850,000	100%	0	0%		
Hep B	Total					5,150,000		27,500,000	
	With VVM					0	0%	0	0%
OPV	Total	125,301,500		227,000		58,000,000		33,500,000	
	With VVM	125,301,500	100%	227,000	100%	58,000,000	100%	3,400,000	10%
IPV	Total							2,000	
	With VVM							0	0%
Measles	Total	8,428,370		110,000		2,500,000			
	With VVM	8,428,370	100%	110,000	100%	0	0%		

[xiii] Sudan and South Sudan appear separately in these tables, but South Sudan is not a separate country from Sudan.

Vaccines		Afghanistan		Djibouti		Egypt		Iran	
MR	Total								
	With VVM								
MMR	Total					11,300,000		12,000,000	
	With VVM					0	0%	6,000,000	50%
	Total	174,034,270		1,431,400		118,708,500		108,902,000	
	With VVM	174,034,270	100%	1,431,400	100%	58,000,000	49%	23,700,000	22%

Acronyms/abbreviations used: BCG: Bacille Calmette-Guerin; DT: diphtheria toxoid (high-dose); DTP: diphtheria-tetanus-toxoid; DTP-Hep B: diphtheria-tetanus-pertussis-hepatitis B; DTP-Hep B-Hib: diphtheria-tetanus-pertussis-hepatitis B-*Haemophilus influenzae* type b; DTP-Hib: diphtheria-tetanus-pertussis-*Haemophilus influenzae* type b; Hep B: hepatitis B; IPV: inactivated polio vaccine; MMR: measles, mumps, rubella; MR: measles and rubella; OPV: oral polio vaccine; Td: diphtheria toxoid (low-dose); TT: tetanus toxoid; VVM: vaccine vial monitor.

* Based on the 13 countries that responded to the questionnaire.

Table 2. Jordan, Lebanon, Morocco, and Oman*

Vaccines		Jordan		Lebanon		Morocco		Oman**	
BCG	Total	1,026,800				3,100,000		450,000	
	With VVM	0	0%			3,100,000	100%	0	0%
DTP	Total	400,500		67,000		1,400,000		100,000	
	With VVM	0	0%	67,000	100%	1,000,000	71%	0	0%
DTP-Hep B	Total			240,000					
	With VVM			240,000	100%				
DTP-Hep B-Hib	Total	724,400						330,000	
	With VVM	0	0%					0	0%
DTP-Hib	Total	100,550		136,000		3,562,400			
	With VVM	0		0	0%	0	0%		
DT	Total	11,000		4,000					
	With VVM	0	0%	4,000	100%				
Td	Total	470,300		25,000					
	With VVM	0	0%	25,000	100%				
TT	Total	50,300				1,300,000		405,500	
	With VVM	0	0%			300,000	23%	0	0%
Hep B	Total	84,780		123,350		3,600,000		132,500	
	With VVM	0	0%	123,350	100%	3,600,000	100%	0	0%
OPV	Total	1,600,330		949,000		5,900,000		750,000	
	With VVM	1,600,330	100%	949,000	100%	5,900,000	100%	750,000	100%
IPV	Total	751,800						55,500	
	With VVM	0	0%					0	0%
Measles	Total	276,750		65,670		1,850,000			
	With VVM	276,750	100%	65,670	100%	1,850,000	100%		
MR	Total			1,000,000					
	With VVM			1,000,000	100%				

Vaccines		Jordan		Lebanon		Morocco		Oman**	
MMR	Total	758,500		205,085				210,000	
	With VVM	0	0%	205,085	100%			0	0%
	Total	6,256,010		2,815,105		20,712,400		2,433,500	
	With VVM	1,877,080	30%	2,679,105	95%	15,750,000	76%	750,000	31%

Acronyms/abbreviations used: BCG: Bacille Calmette-Guerin; DT: diphtheria toxoid (high-dose); DTP: diphtheria-tetanus-toxoid; DTP-Hep B: diphtheria-tetanus-pertussis-hepatitis B; DTP-Hep B-Hib: diphtheria-tetanus-pertussis-hepatitis B-*Haemophilus influenzae* type b; DTP-Hib: diphtheria-tetanus-pertussis-*Haemophilus influenzae* type b; Hep B: hepatitis B; IPV: inactivated polio vaccine; MMR: measles, mumps, rubella; MR: measles and rubella; OPV: oral polio vaccine; Td: diphtheria toxoid (low-dose); TT: tetanus toxoid; VVM: vaccine vial monitor.

* Based on the 13 countries that responded to the questionnaire.
** Verified data from the in-depth study.

Table 3. Pakistan, Palestine, Somalia, and Sudan*

Vaccines		Pakistan		Palestine		Somalia		Sudan**	
BCG	Total	12,108,000		458,000		1,858,000		2,671,000	
	With VVM	12,108,000	100%	458,000	100%	1,858,000	100%	2,671,000	100%
DTP	Total			254,400		1,753,000		2,212,000	
	With VVM			254,400	100%	1,753,000	100%	2,212,000	100%
DTP-Hep B	Total	12,108,000							
	With VVM	12,108,000	100%						
DTP-Hep B-Hib	Total	12,108,000						4,251,000	
	With VVM	12,108,000	100%					4,251,000	100%
DTP-Hib	Total			1,145,000					
	With VVM			0	0%				
DT	Total			214,000					
	With VVM			214,000	100%				
Td	Total			347,000					
	With VVM			347,000	100%				
TT	Total	31,236,970		280,000		3,900,000		7,222,000	
	With VVM	30,772,231	99%	280,000	100%	3,900,000	100%	7,222,000	100%
Hep B	Total			4,273,300				3,762,900	
	With VVM			4,273,300	100%			3,762,900	100%
OPV	Total	538,030,700		1,431,250		15,886,600		81,535,400	
	With VVM	538,030,700	100%	1,431,250	100%	15,886,600	100%	81,535,400	100%
IPV	Total			763,300					
	With VVM			0	0%				
Measles	Total	111,834,240		381,600		1,835,500		7,129,740	
	With VVM	111,834,240	100%	381,600	100%	1,835,500	100%	7,129,740	100%
MR	Total								
	With VVM								

Vaccines		Pakistan		Palestine		Somalia		Sudan**	
MMR	Total			381,600					
	With VVM			0	0%				
	Total	717,425,910		9,929,450		25,233,100		108,784,040	
	With VVM	716,961,171	100%	7,639,550	77%	25,233,100	100%	108,784,040	100%

Acronyms/abbreviations used: BCG: Bacille Calmette-Guerin; DT: diphtheria toxoid (high-dose); DTP: diphtheria-tetanus-toxoid; DTP-Hep B: diphtheria-tetanus-pertussis-hepatitis B; DTP-Hep B-Hib: diphtheria-tetanus-pertussis-hepatitis B-*Haemophilus influenzae* type b; DTP-Hib: diphtheria-tetanus-pertussis-*Haemophilus influenzae* type b; Hep B: hepatitis B; IPV: inactivated polio vaccine; MMR: measles, mumps, rubella; MR: measles and rubella; OPV: oral polio vaccine; Td: diphtheria toxoid (low-dose); TT: tetanus toxoid; VVM: vaccine vial monitor.

* Based on the 13 countries that responded to the questionnaire.
** Verified data from the in-depth study.

Table 4. South Sudan, Syria, Yemen, and total from previous tables*

Vaccines		South Sudan		Syria**		Yemen		Total	%
BCG	Total	1,077,860		1,699,500		2,141,100		53,862,860	
	With VVM	1,077,860	100%	0	0%	2,141,100	100%	32,986,568	61%
DTP	Total	1,116,856		515,000				33,000,756	
	With VVM	1,116,856	100%	0	0%			11,933,263	36%
DTP-Hep B	Total			5,300,000				31,638,500	
	With VVM			2,000,000	38%			21,138,503	67%
DTP-Hep B-Hib	Total			700,000		3,755,100		28,703,400	
	With VVM			0	0%	3,755,100	100%	26,949,004	94%
DTP-Hib	Total							4,943,950	
	With VVM							0	0%
DT	Total			1,440,600				11,269,600	
	With VVM			0	0%			218,002	2%
Td	Total			412,000				13,760,800	
	With VVM			0	0%			9,272,003	67%
TT	Total	1,254,450		1,763,400		4,397,780		75,481,200	
	With VVM	1,254,450	100%	0	0%	4,397,780	100%	66,197,268	88%
Hep B	Total			4,600,000				49,226,830	
	With VVM			0				11,759,554	24%
OPV	Total	6,705,400		9,870,500		5,991,790		885,679,470	
	With VVM	6,705,400	100%	9,870,500	100%	5,991,790	100%	855,579,483	97%
IPV	Total			1,200,000				2,772,600	
	With VVM			0	0%			0	0%
Measles	Total	1,893,380		1,200,000		1,786,830		139,292,080	
	With VVM	1,893,380	100%	0	0%	1,786,830	100%	135,592,090	97%
MR	Total							1,000,000	
	With VVM							1,000,001	100%

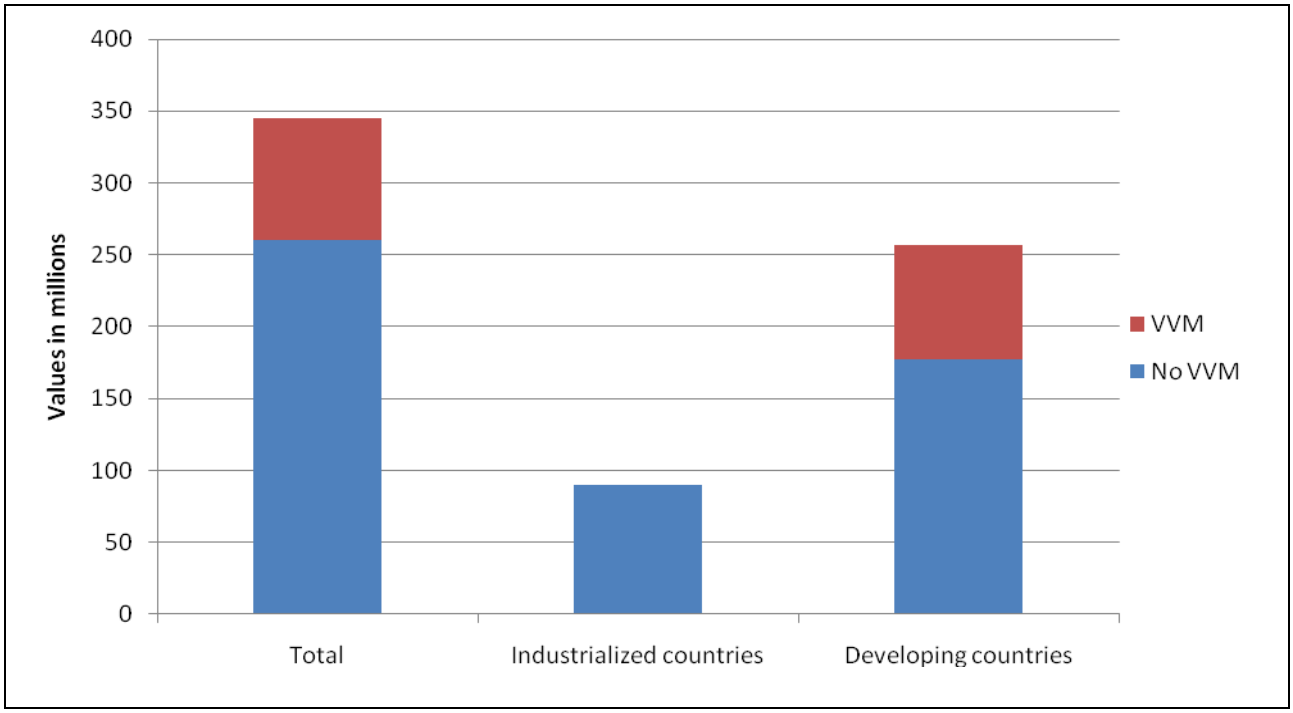
Vaccines		South Sudan		Syria**		Yemen		Total	%
MMR	Total			7,269,000				32,124,185	
	With VVM			0	0%			6,205,087	19%
	Total	12,047,946		35,970,000		18,072,600		1,362,756,231	87%
	With VVM	12,047,946	100%	11,870,500	33%	18,072,600	100%	1,178,830,826	

Acronyms/abbreviations used: BCG: Bacille Calmette-Guerin; DT: diphtheria toxoid (high-dose); DTP: diphtheria-tetanus-toxoid; DTP-Hep B: diphtheria-tetanus-pertussis-hepatitis B; DTP-Hep B-Hib: diphtheria-tetanus-pertussis-hepatitis B-*Haemophilus influenzae* type b; DTP-Hib: diphtheria-tetanus-pertussis-*Haemophilus influenzae* type b; Hep B: hepatitis B; IPV: inactivated polio vaccine; MMR: measles, mumps, rubella; MR: measles and rubella; OPV: oral polio vaccine; Td: diphtheria toxoid (low-dose); TT: tetanus toxoid; VVM: vaccine vial monitor.

* Based on the 13 countries that responded to the questionnaire.
** Verified data from the in-depth study.

Annex 3: Figures

Figure 1. Proportion of vaccines with VVMs in the WP region, 2008 data



Note: Developing countries are those with a birth cohort of over 10,000.

Figure 2. Proportion of vaccines with VVMs in the three largest developing countries in the WP region, 2008 data

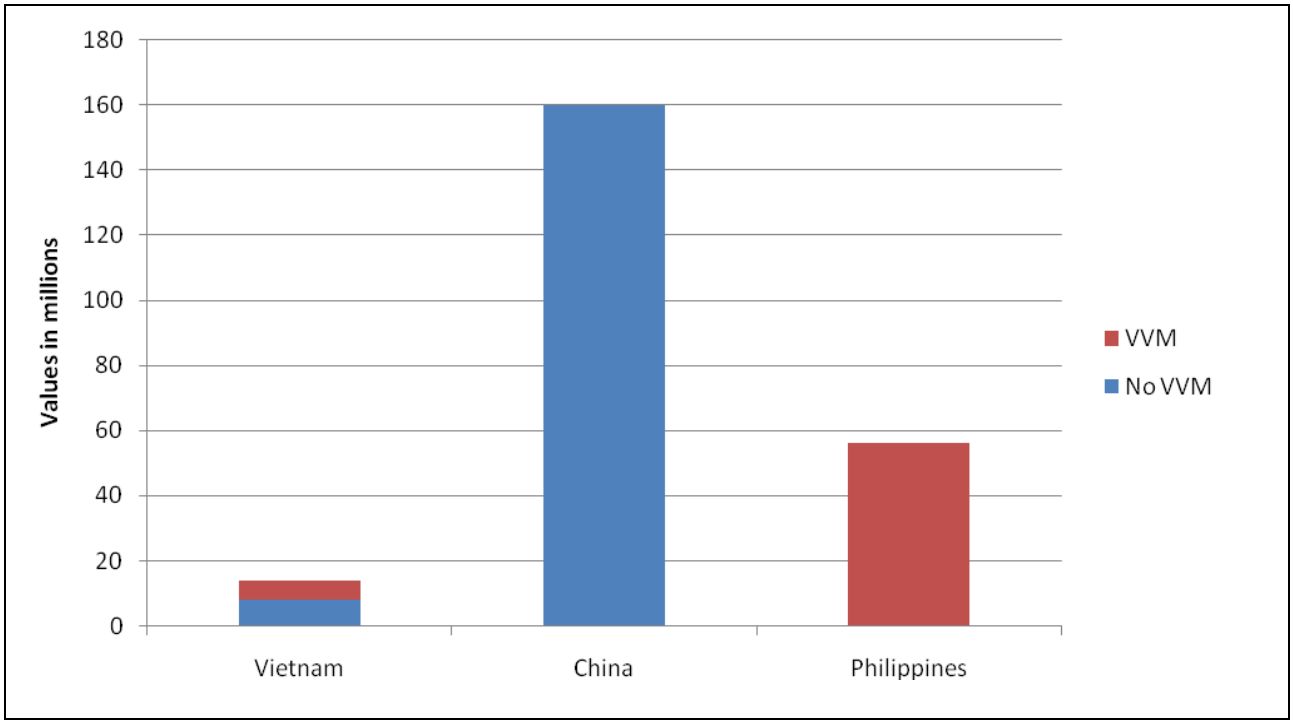
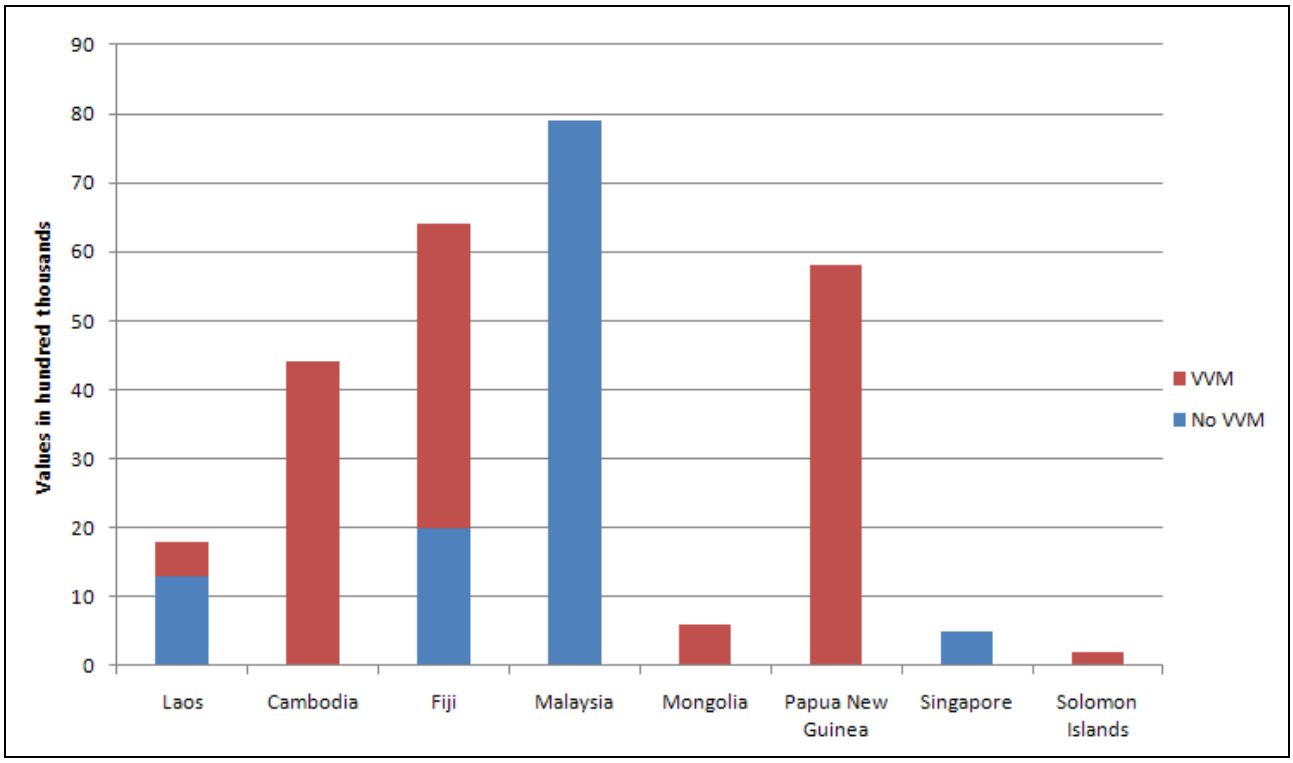
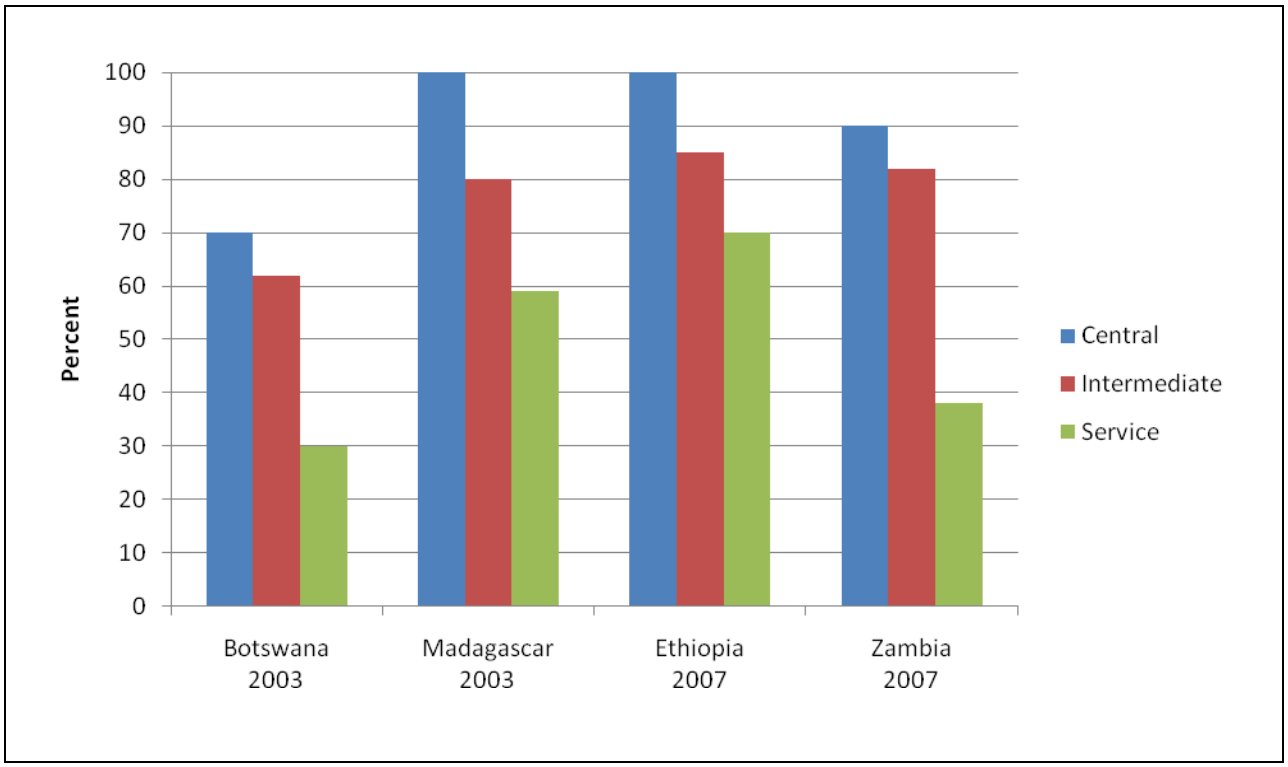


Figure 3. Proportion of vaccines with VVMs in the rest of the developing countries in the WP region, 2008 data

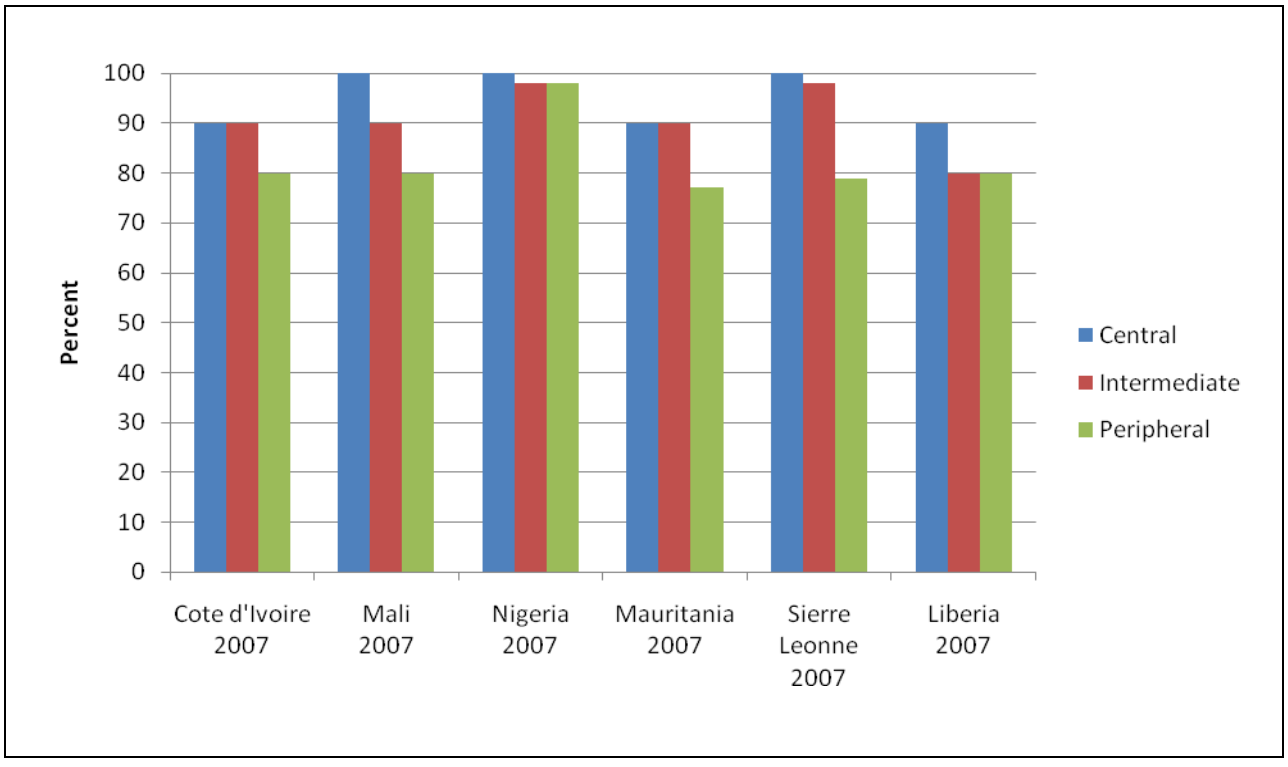


Note: (countries with birth cohorts less than 10,000 not included on graph).

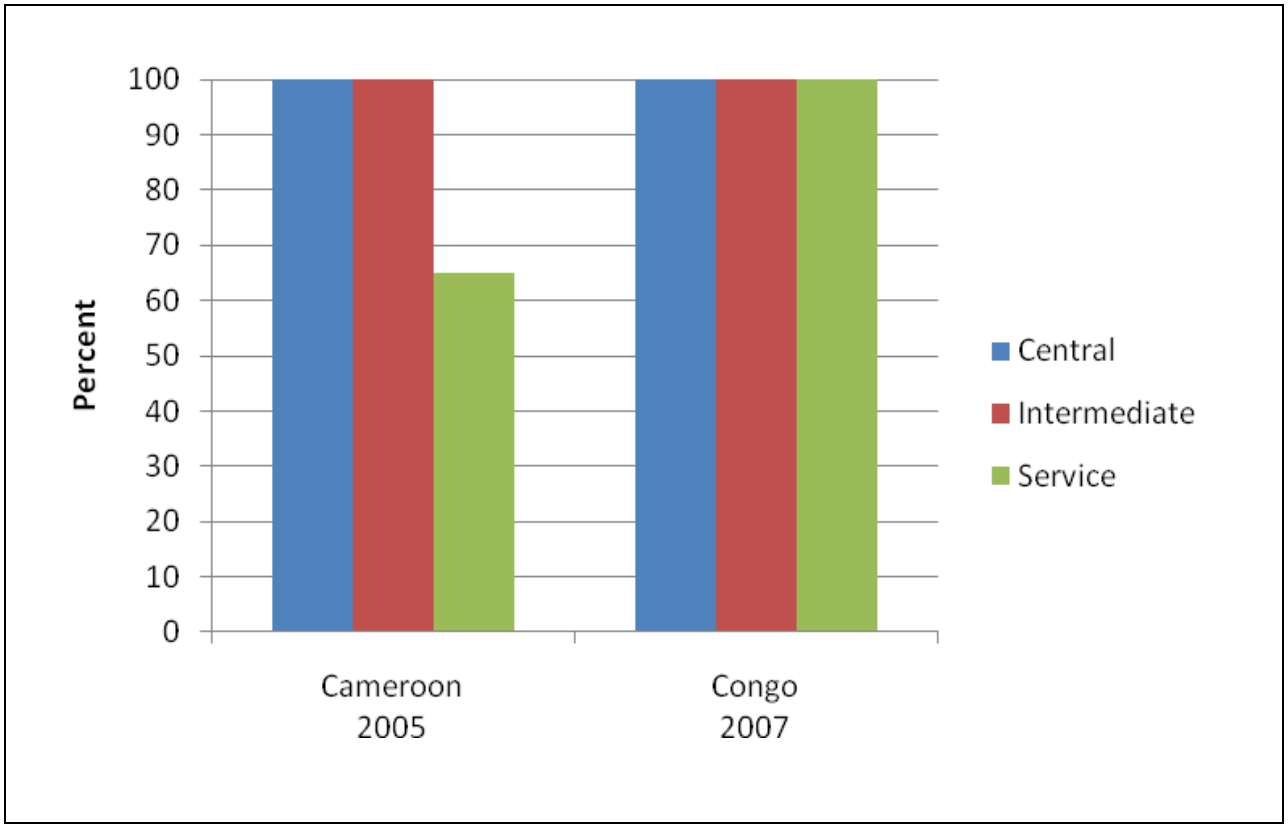
Figure 4. Overall VVM Scores from selected countries in the AF region: (a) Eastern and Southern Africa, (b) Western Africa, and (c) Central Africa



(a)



(b)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50
40
30
20
10
0
Percent
Cameroon
2005
Congo
2007
Central
Intermediate
Service

(c)

Annex 4: Tables

Table 1. Total birth cohort, vaccine sources, and percent of doses with VVMs for WP countries

Country	Birth cohort	Vaccine sources	% doses with VVMs
American Samoa			
Australia	266,000	Procure, Produce	0
Brunei Darussalam	8000	Procure	0
Cambodia	381,000	UNICEF, UNICEF PS	100
China	17,724,000	Produce	0
Cook Islands			0
Fiji	17,000	UNICEF, UNICEF PS	22
French Polynesia			
Guam			
Hong Kong (China)			
Japan	1,034,000	Produce	0
Kiribati	2,000	UNICEF	100
Korea, Republic of	450,000	Produce	0
Laos	162,000	UNICEF	24
Macao (China)			
Malaysia	546,000	Procure	0
Marshall Islands	2,000	Procure	75
Micronesia, Federated States of	3,000	Procure	77
Mongolia	50,000	UNICEF, UNICEF PS	100
Nauru			
New Caledonia			
New Zealand	58,000	Procure	0
Niue			
Northern Mariana Islands			
Palau			

Country	Birth cohort	Vaccine sources	% doses with VVMs
Papua New Guinea	207,000	UNICEF, UNICEF PS	23
Philippines	2,186,000	UNICEF PS	100
Pitcairn Islands			
Samoa	4,000	UNICEF	100
Singapore	37,000	Procure	0
Solomon Islands	16,000	UNICEF, UNICEF PS	100
Tokelau			
Tonga	3,000	UNICEF, UNICEF PS	100
Tuvalu			
Vanuatu	7,000	UNICEF	23
Vietnam	1,465,000	Produce, UNICEF	16
Wallis and Futuna			

Acronyms/abbreviations used: PS: procurement services; UNICEF: United Nations Children's Fund; VVM: vaccine vial monitor.

Table 2. Total birth cohort, vaccine sources, and percentage of doses with VVMs for EM countries

Country	Birth cohort	Vaccine sources	% doses with VVMs
Afghanistan	1,269,000	UNICEF	100
Bahrain	14,000	Procure	31
Djibouti	24,000	UNICEF	100
Egypt	2,015,000	Procure	49
Iran (Islamic Republic of)	1,388,000	Produce, Procure	22
Jordan	157,000	Procure	30
Kuwait	52,000	Procure	31
Lebanon	66,000	Procure	95
Libyan Arab Jamayahira	147,000	Procure	0
Morocco	646,000	Procure	76
Oman	61,000	Procure, UNICEF PS	31
Pakistan	5,337,000	UNICEF, procure	100
Palestine		UNICEF	77
Qatar	15,000	Procure	31
Saudi Arabia	591,000	Procure	31
Somalia	395,000	UNICEF	100
South Sudan	1,296,000	UNICEF	100
Sudan	1,296,000	UNICEF	100
Syrian Arab Republic	590,000	Procure	33
Tunisia	164,000	Procure	0
United Arab Emirates	63,000	Procure	31
Yemen	846,000	UNICEF	100

Acronyms/abbreviations used: PS: procurement services; UNICEF: United Nations Children's Fund; VVM: vaccine vial monitor.

Table 3. Availability of VVMs on different vaccines in EM countries

Vaccines	Total 2007 and 2008 (in doses)	Percentage with VVM
BCG	53,862,900	61%
DTP	33,000,800	36%
DTP-Hep B	31,638,500	67%
DTP-Hep B-Hib	28,703,400	94%
DTP-Hib	4,944,000	0%
DT	11,269,000	2%
Td	13,760,800	67%
TT	75,481,200	88%
Hep B	49,226,800	24%
OPV	885,679,500	97%
IPV	2,717,600	0%
Measles	139,292,100	97%
MR	1,000,000	100%
MMR	32,124,200	19%
Total (doses)	1,362,756,500	87%

Acronyms/abbreviations used: BCG: Bacille Calmette-Guerin; DT: diphtheria toxoid (high-dose); DTP: diphtheria-tetanus-toxoid; DTP-Hep B: diphtheria-tetanus-pertussis-hepatitis B; DTP-Hep B-Hib: diphtheria-tetanus-pertussis-hepatitis B-*Haemophilus influenzae* type b; DTP-Hib: diphtheria-tetanus-pertussis-*Haemophilus influenzae* type b; Hep B: hepatitis B; IPV: inactivated polio vaccine; MMR: measles, mumps, rubella; MR: measles and rubella; OPV: oral polio vaccine; Td: diphtheria toxoid (low-dose); TT: tetanus toxoid; VVM: vaccine vial monitor.

Note: All data in Table 3 were extracted from questionnaires sent to the countries of the region, and the data has been verified. The data show the trend of availability of VVMs on different vaccines. The grey shaded areas represent the four highest percentages with VVMs.

Table 4. Total birth cohort, vaccine sources, and percent of doses with VVMs for SEA countries

Country	Birth cohort	Vaccine sources	% doses with VVMs
Bangladesh	3,430,000	UNICEF	91
Bhutan	15,000	UNICEF	100
DPR Korea	327,000	UNICEF	100
India	26,913,000	Produce, UNICEF	For 2008, 100% of OPV, about 20% of other vaccines.*
Indonesia	4,220,000	Produce	100
Maldives	6,000	UNICEF	>95
Myanmar	1,020,000	UNICEF	100
Nepal	732,000	Procure	91
Sri Lanka	365,000	Procure	Unknown
Thailand	977,000	Produce (filling bulks), procure	Unknown
Timor Leste	44,000	UNICEF	Not on some measles vaccines in 2007.

Acronyms/abbreviations used: DPR: Democratic People's Republic (of Korea); OPV= oral polio vaccine; PS= procurement services; UNICEF: United Nations Children's Fund; VVM: vaccine vial monitor.

*More than 50% DTP; 50% DT, TT; and 100% measles, Japanese encephalitis, and hep B.

Table 5. Current status of VVMs for Indian manufacturers

Manufacturer	Vaccine	Order awarded 2008–2009 (doses)	Previous VVM experience	Validation status	VVM implementation status
Biological E Limited	DT	37.5 M	Less than 1 year	Available (partially)	Pending
	TT	136 M			
	DTP	285 M			
Indian Immun.	Hep B	1.52 M	1 year	Available (partially)	Achieved
	DTP	6.3 M			
	Measles	9 M			
Shanta Biotec	DTP	25.2 M	10 years	Available	Established
Serum	DTP	30 M	Greater than 5 years	Available	Established
	Measles	36 M			
	BCG	Unknown.			
Bharat Biotech	tOPV	382 M	Greater than 2 years	Available	Established
	Hep B	5.7 M			

Acronyms/abbreviations used: BCG: Bacille Calmette-Guerin; DT: diphtheria toxoid (high-dose); DTP: diphtheria-tetanus-toxoid; Hep B: hepatitis B; Indian Immun: Indian Immunological Limited; M= million; tOPV: trivalent oral polio vaccine; TT: tetanus toxoid; VVM: vaccine vial monitor.

Table 6. Total birth cohort, vaccine sources and % doses with VVMs for AF countries (2007 data)

Country	Birth cohort	Vaccine sources	% doses with VVMs
Algeria	714,000	Procure	Assumed 0
Angola	774,000	Procure, UNICEF	100%
Benin	342,000	UNICEF	100%
Botswana	47,000	Procure	Only OPV, assumed 30%
Burkina Faso	721,000	UNICEF	100%
Burundi	278,000	UNICEF	100%
Cameroon	704,000	Procure, UNICEF	100%
Cape Verde	12,000	UNICEF	100%
Central African Republic	154,000	UNICEF	100%
Chad	498,000	UNICEF	100%
Comoros	21,000	UNICEF	100%
Côte d'Ivoire	722,000	Procure, UNICEF for YF and hep B	YF and hep B*, assumed 20%
Democratic Republic of Congo	2,886,000	UNICEF	All but measles, assumed 95%
Equatorial Guinea	25,000	UNICEF	100%
Eritrea	182,000	UNICEF	100%
Ethiopia	3,093,000	UNICEF	100%
Gabon	40,000	UNICEF	100%
Gambia	61,000	UNICEF	100%
Ghana	757,000	UNICEF	100%
Guinea	392,000	UNICEF	100%
Guinea-Bissau	65,000	UNICEF	100%
Kenya	1,506,000	UNICEF	100%
Lesotho	59,000	UNICEF	100%
Liberia	145,000	UNICEF	100%
Madagascar	687,000	UNICEF	100%
Malawi	599,000	UNICEF	All but measles, assumed 90%

Country	Birth cohort	Vaccine sources	% doses with VVMs
Mali	542,000	UNICEF	100%
Mauritania	108,000	UNICEF	100%
Mauritius	18,000	Procure	On OPV and hep B, assumed 40%
Mozambique	876,000	Procure, UNICEF	On OPV and DTP-Hep B only, assumed 40%
Namibia	59,000	UNICEF, procure	All but hep B, assumed 90%
Niger	791,000	UNICEF	100%
Nigeria	6,028,000	UNICEF	100%
Republic of the Congo	125,000	Procure, UNICEF	100%
Rwanda	403,000	Procure, UNICEF	100%
Sao Tome & Principe	5,000	UNICEF	100%
Senegal	470,000	UNICEF, procure	Procures hep B, assumed 90%
Seychelles		Procure	On OPV, DTP, TT*
Sierra Leone	223,000	UNICEF	100%
South Africa	1,091,000	Procure	Only OPV*, assumed 31%
Swaziland	35,000	Procure	OPV and TT**, assumed 40%
Togo	213,000	UNICEF	100%
Uganda	1,466,000	UNICEF	100%
United Republic of Tanzania	1,771,000	UNICEF	All but measles and tetanus for Zanzibar, assumed 95%
Zambia	542,000	UNICEF	100%
Zimbabwe	378,000	UNICEF	100%

Acronyms/abbreviations used: DTP-Hep B: diphtheria-tetanus-pertussis-hepatitis B; Hep B: hepatitis B; OPV: oral polio vaccine; UNICEF: United Nations Children's Fund; VVM: vaccine vial monitor; TT: tetanus toxoid; YF: yellow fever.

*VVMs on BCG and measles to be introduced in 2008.
**Expect VVMs on all vaccines in 2008.

Table 7. Summary information from in-depth country studies on VVMs in EM, SEA, and WP regions

	Bangladesh	India	Laos	Nepal	Oman	Philippines	Sudan	Syria
Policy	None.	VVMs on all vaccines in immunization handbook.	In staff manual.	VVMs on all vaccines, enforced since 2006.	Manual.	Cold chain manual.	Vaccinator manual.	Vaccinator manual.
Posters, teaching aids	Not documented.	Not clear.	Only in manual; requested.	Not clear.	Out of stock.	No; requested.	Black and white A4 posters.	No posters.
Training	Every 3 years.	Every level of cold chain, not mastered.	Cold chain staff yearly but not vaccinators.	VMAT training for EPI regional and district staff; NID training needed.	Not standard, nor taken seriously.	Yes, not systematic for vaccinators.	NID training several times/year.	In health worker training, not systematic.
Documentation	Part of VAR, only at central level.	Poor and inconsistent.	Yes, new forms in use to regional level.	Yes, use VARs.	No.	VAR at central level, not at lower levels.	On tally sheets for NIDs; to state level for routine.	On VAR but not for dispatch.
Management tool use	Yes.	For hepatitis B.	Yes, inconsistent at health centers.	Yes.	No.	At higher levels only.	Not clear.	At all levels.
MDVP use	Only fixed sites, uneven.	Unclear.	Yes, policy but no practice.	Yes.	Yes, but not with VVMs.	Yes.	Not clear.	No MDVP.
Wastage use	Unclear.	Unclear.	No.	Not clear.	Feel no role for VVMs here.	No.	Not clear.	Not given.
Comments	Difficulties in interpretation.	VVMs on domestically produced vaccines.			Small private-sector vaccines. VVMs only on OPV, difficulty with pooled procurement specs.	Included in specs.	No private-sector imports; no special procurement specs.	10 to 15% private sector; VVMs only on OPV to date.

Acronyms/abbreviations used: EPI: Expanded Program on Immunization; MDVP: multidose vial policy; NID: national immunization days; OPV: oral polio vaccine; specs: specifications; VAR: vaccine arrival reports; VVM: vaccine vial monitor; VMAT: Vaccine Management Assessment Tool.

Table 8. VVMs in vaccine specifications, April 2010

Region	Country	Vaccine sourcing	VVMs in specs	Comments
AF	Namibia	Procurement	Yes	
	South Africa	Procurement	Yes	BCG and measles from mid-2008
	Swaziland	Procurement	Yes	In tender 2008 to 2009
	Angola	Procurement	Yes	
	Cameroon	Procurement	Yes	VVMs on all vaccines
	Botswana	Procurement	Yes	OPV only
	Cote d'Ivoire	Procurement	Yes	Starting 2008
	Rwanda	Procurement	Yes	
	Mauritius	Procurement	Yes	Only OPV and Hep B
	Mozambique	Procurement and UNICEF	No	VVMs only on DTP-Hep B and OPV
	Congo	Procurement and UNICEF	Yes	VVMs on all vaccines
	Seychelles	Procurement	Yes	VVMs on all vaccines but Hep B
EM	Morocco	Procurement through UNICEF	All OPV, BCG, Hep B, MCV, and some DTP	
	Syria	Self-procurement	All OPV and some DTP-Hep B	
	Oman	Pooled procurement	Only on OPV	
	UAE			
	Qatar			
	Saudi Arabia			
	Bahrain			
	Kuwait			
	Sudan	UNICEF	Yes	
	Pakistan	Self-procurement and UNICEF	Yes	
	Afghanistan	UNICEF	Yes	
	Djibouti	UNICEF	Yes	
	Somalia	UNICEF	Yes	
	Yemen	UNICEF	Yes	
	Jordan	Self-procurement	All OPV and all MCV	
	Lebanon	Public-sector UNICEF, private-sector self-procurement	All vaccines except DTP/Hib	
	Palestine		All vaccines except DTP-Hib and IPV	

Region	Country	Vaccine sourcing	VVMs in specs	Comments
EM	Iran	Produce, procure from local and internationally	Some of DTP, Td, MMR, and OPV	
	Egypt	Self-procurement	Only OPV	
	Tunis	Self-procurement	No	
	Libya	Self-procurement	No	
	Iraq	Self-procurement	No	
SEA	India	Produce, procure from local and internationally	Yes, required for domestic producers	
	Bangladesh	Procurement services	Yes	
	Nepal	Procure	Yes	
	Sri Lanka	Procure	Yes	Check
WP	Cambodia	UNICEF revolving fund	Yes	Changing to procurement services
	China	Production	No	
	Cook Islands	UNICEF revolving fund	Yes	
	Fiji			
	Kiribati			
	Laos	UNICEF	Expects VVMs	Not always received
	Malaysia	Procure	No	
	Marshall Islands	US affiliated	No	
	Micronesia			
	Mongolia	UNICEF procurement services	Yes	
	Nauru	UNICEF revolving fund	Yes	
	Niue			
	Palau	US affiliated	No	
	Papua New Guinea	UNICEF procurement services	Yes	
	Philippines	UNICEF procurement services	Yes	Private: no VVM
	Samoa	UNICEF revolving fund	Yes	
	Solomon Islands			
	Tonga			

Region	Country	Vaccine sourcing	VVMs in specs	Comments
WP	Tuvalu			
	Vanuatu			
	Vietnam	Procure UNICEF procurement services	No	Only on GAVI-funded vaccines

Acronyms/abbreviations used: AF: African; BCG: Bacille Calmette-Guerin; DTP: diphtheria-tetanus-pertussis; DTP-Hep B: diphtheria-tetanus-pertussis-hepatitis B; DTP-Hib: diphtheria-tetanus-pertussis-*Haemophilus influenzae* type b; EM: Eastern Mediterranean; Hep B: hepatitis B; Hib: *Haemophilus influenzae* type b; IPV: inactivated polio vaccine; MCV: Meningococcal conjugate vaccine; MMR: measles, mumps, rubella; OPV: oral polio vaccine; SEA: Southeast Asian; specs: specifications; Td: diphtheria toxoid (low-dose); UAE: United Arab Emirates; UNICEF: United Nations Children's Fund; VVM: vaccine vial monitor; WP: Western Pacific.