# TECHNET 2008 Consultation

## 2 – 4 December 2008

## Tunis, Tunisia

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# Overview

This report summarizes the presentations and the discussions of the 10th TECHNET Consultation held from 2 to 4 December 2008 in Tunis, Tunisia. The consultation was inaugurated by H.E. the Minister of Health of Tunisia, Mr. Mondher Zenaidi. WHO Representative in Tunisia delivered the opening remarks on behalf of the Regional Director of WHO Eastern Mediterranean Regional Office.

There were a total of 94 participants in this consultation, including representatives of the industries producing vaccines and cold chain and injection equipment (31) and partners such as AMP, US Centre for Disease Control and Prevention (CDC), GAVI, Immunization Basics, IT Power India, Médecins Sans Frontières and PATH (17). Representatives from 10 Ministries of Health (12) from different regions together with field, regional and HQs staff from WHO and UNICEF (30) were among the participants. A few freelance consultants (4) also participated in the consultation. The list of the name of the participants and their organizations are in Annex 1.

The agenda of the consultation is (Annex 2) shows that there were five major plenary sessions as follows:
Session 1: Introduction and context
Session 2: Advances in cold chain and logistics
Session 3: Equipment development and management
Session 4: Vaccine management and
Session 5: Other topics
In addition, three satellite sessions were organized on:

- WHO/PATH Project Optimize
- Software demonstration on logistics and vaccine management tools
- Pharmaceutical cold chain training

The CD containing all the presentations, agenda and the list of participants with group photos of the participants is available on request from WHO.

We would like to gratefully acknowledge the assistance in the implementation of this meeting of the staff of the WHO Country Office in Tunisia, the WHO Eastern Mediterranean Regional office and the coordination of Motjaba Haghgou.

# Session 1: Introduction and context

## Objectives of the Consultation - by R. Eggers (WHO)

The agenda was presented and objectives of the consultation were outlined as follows:

- To provide current information on recent technological innovations, strategies or practices that impact logistic systems management in national immunization programmes;
- To share developing country experiences on field operations in the areas of vaccine storage and transport, vaccine management, cold chain and equipment performance, waste management, introduction of new vaccines or immunization technologies and overall systems monitoring;
- To stimulate dialogue and debate on the development and implementation of best practices.

## Report on the Technologies and Logistics Advisory Committee (TLAC) - by R. Steinglass (Immunization Basics)

WHO created the Technologies and Logistics Advisory Committee (TLAC), whose purpose, composition, and preliminary findings from its first, semi-annual meeting in September 2008 will is outlined in this session. TLAC advises the WHO Director of IVB on gaps and constraints facing immunization programs and makes recommendations concerning field operations, logistics, cold chain, and technological innovations. TLAC deliberations will help strengthen immunization programs; facilitate new vaccine introduction; gather and review evidence; and address relevant regulatory aspects related to technologies and logistics.

In September, the TLAC meeting mainly addressed the use of vaccines “out of the cold chain” (OCC) and revision of the multi-dose vial policy (MDVP). Sub-groups of TLAC have been formed around these two issues, as well as a review of VVM documentation. After hearing presentations framing the problems and potential solutions, TLAC made some preliminary recommendations, e.g. TLAC supported the concept and need for studies to justify OCC, with each vaccine type and brand requiring independent evidence. In addition, TLAC requested WHO to commission a thorough review of the complex issues surrounding MDVP, in light of the development of new vaccine formulations and presentations that potentially complicate previous understanding of MDVP.

The effort of WHO in creating TLAC was commended and the participants urged TLAC to become involved in more issues related to vaccine management, setting policies and advising WHO.

## Report on TECHNET e-forum - by M.T. Hart (IT Power India)

Over a decade, the Technet21 e-forum, has come to offer a reliable and accessible virtual space for discussion, dissemination of information, and global networking in the area of vaccine operations and management, cold chain and immunization. In addition to enabling immunization

personnel to keep apace of new technical developments, the forum enabled participants to post queries, clarify doubts, and seek suggestions.

Over the last 11 months, the forum has posted contributions on a wide range of subjects, including cold chain maintenance, medical waste disposal, vaccine freezing, school-based tetanus toxoid (TT) vaccination, need for energy policy to reflect health sector needs, the vaccine vial monitor (VVM), and polio eradication among others. The effort has been to ensure that the information that is posted is scientific and evidence-based. The forum has also kept abreast of current global concerns and posted on global climate change and its impact on health and reducing environmental impact of immunization services. In addition to posting on new subjects, an eye is also kept on keyword balance.

Though subscription and participation statistics are limited parameters to evaluate global use of the forum, the growth trends have been encouraging. Many new members have registered, especially from India. The challenge will be to widen access both geographically/spatially and in terms of percolation of information to those in the field. Suggestions are invited from participants as to how this can happen.

The TechNet21 website has been totally revamped and user statistics reveal that the change has been welcomed by users. The web site has six major pages:

- Home Page
- About Us Page
- TechNet E-forum
- Tools and Resources
- News and Events
- Links

While retaining some of the features of the old website, additional ones have been added. These include:

- Enhanced Forum System, which facilitates archive-browsing and enables quick data retrieval using the PHP BB forum link http://www.itpi.co.in/technet21/phpBB2/. Readers can access the entire archives dating back to 2001.
- Expert Database with open-access registration and search facility.
- A sophisticated site-wide Search Tool
- A searchable Events Calendar, with an added facility that allows the readers to add their own events to the list.
- Invite Your Colleagues –a link to support subscription.
- Photo submissions, whereby readers can send immunization-related images for the TechNet photo bank.
- Up-to-date News Features.
- List of Acronyms and a Dictionary of Immunization Terms.
- Researched Articles.

As for future trends, the endeavour is to equip the TechNet 21 communications initiative to support efficient delivery of immunization services even more actively. The participants expressed their view on topics that were covered by TECHNET e-forum and ask for including more information on job vacancies in the routine posting of e-forum.

# Session 2: Advances in cold chain and logistics

## Country experience of cold chain, operational and logistics issues with introduction of new vaccines: Bolivia - by P. Halkyer (MoH Bolivia)

On 1 August 2008, Bolivia introduced rotavirus vaccine into routine immunization. This was supported by the National Immunizations Committee and data from the sentinel hospital surveillance system (2005-2008) showed that rotavirus was detected in 38% of patients hospitalized for diarrhoeal diseases.

The introduced vaccine is the monovalent Rotarix® (GSK) in single dose presentations. The vaccine is administered orally in a two dose schedule. For the first year, 300,000 doses were imported. The vaccines were procured through the PAHO's Revolving Fund of Vaccines and were co-financed by government (50%) and by GAVI (50%). It is planned that after five years all the funds will be obtained from the national fund.

The Expanded Program of Immunization of Bolivia produced training materials for the health workers together with several kinds of guidelines, posters, stickers and some materials for TV and radio. On the vaccination sessions the safety boxes were provided and the proper recycling of waste materials were envisaged.

In relation to the cold chain capacity, some cold rooms were built cold rooms increase the storage capacity. Bolivia has now 13 cold rooms with a total capacity of 260 $m^3$. For the lower levels of the cold chain, additional refrigerators were provided where it was required. It was also decided to distribute vaccines in monthly or bi-monthly.

The most common vaccine carriers in Bolivia are the Geostyle®, Kingseley® and Coleman. The first two have limited space while the Coleman is bigger. However, all types vaccine carriers were sufficient for house to house vaccinations.

From the beginning of the planning for introduction of rotavirus vaccine, the existing capacity of the system was evaluated by an effective inventory of the existing cold chain equipment. Therefore, adequate storage capacity at the central level was ensured. The staff were properly trained and were motivated and they were supported by appropriate training materials. The transportation of the vaccines from the central level was contracted a to private currier service equipped with refrigerated vehicles.

In order to meet the challenges related to introduction of new vaccines the countries should plan in advance. They have to have a relatively accurate inventory of equipment and the estimation of cold chain capacity at all levels particularly at the national and intermediate levels. They have to train health workers long in advance and to have standardizes operational systems. Financial resources should be well secured. Professionally designed stock management tools should be in place. Number of staff dealing with vaccine storage and distribution should be increased. Transportation should be planned and should be adequate.

## Country experience of cold chain, operational and logistics issues with introduction of new vaccines: Turkey - H. Ozdemir (MoH Turkey)

Republic of Turkey has 70 million populations and a 1.34 million birth cohort. MOH is the responsible body for leading the vaccination and is the main supplier of vaccines and service delivery. All EPI vaccines are procured from international manufacturers. The vaccines are distributed from the primary vaccine store to the provinces by refrigerated trucks. There are 7 routes and each route is approximately 2,000 km. There are cold rooms at intermediate levels.


The Advisory Committee on Immunization recommended new vaccines to be included in the routine immunization programme. Since 2006, EPI vaccination schedule went through major changes. Measles vaccination was replaced by MMR and Haemophilus influenza type b (Hib) has been added to the programme. Since the beginning of January 2008, pentavalent combination with acellular pertussis, diphtheria, tetanus, Hib and IPV in single dose syringes started to be used. In November 2008, conjugate pneumococcal vaccines in single-dose prefilled syringes were also introduced to the programme.

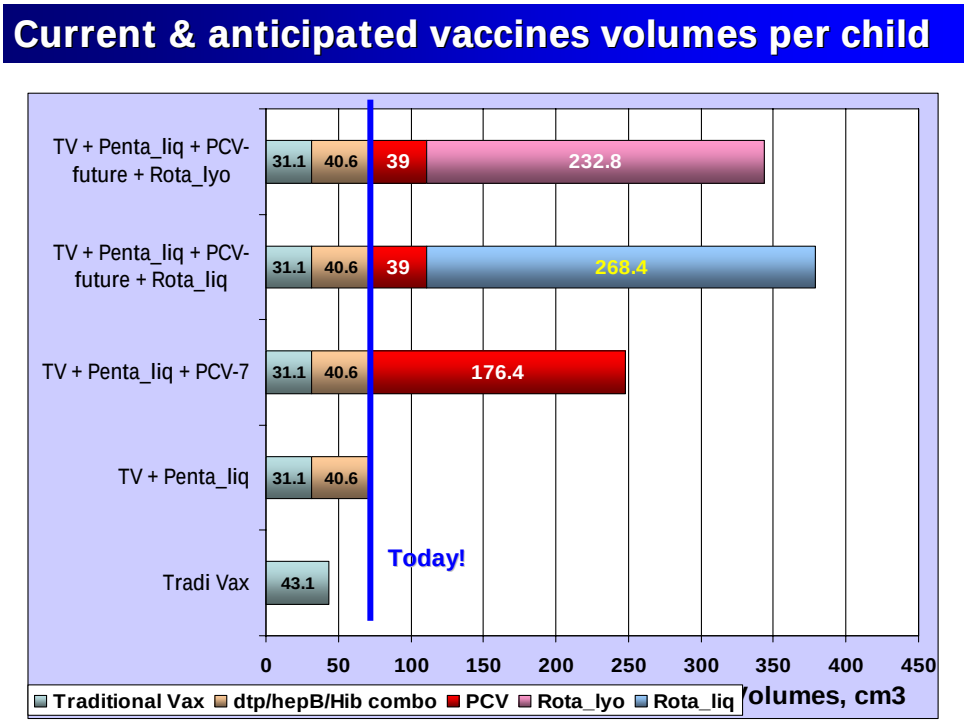
Since July 2006, there has been a five-fold increase in the net storage capacity of required for vaccines in the national vaccine store. The increase in capacity required also affected the intermediate level storage and health facilities. All the logistics issues and equipments requirements needed to be addressed. Adding a new vaccine to the schedule requires meeting the additional capacity requirements. The policy makers are generally interested only in the schedule without taking into consideration that the quality is as important as quantity.

Ensuring the adequate cold chain capacity at each level, supplementation of the equipments takes much more effort and time than addition of a new vaccine into the schedule.

## Cold Chain preparation for introduction of new vaccines -by S. Kone (WHO)

From WHO vaccines pipeline, the introduction of new vaccines will have a significant impact on child mortality reduction provided that programmatic challenges are properly managed and adequate resources are available. Among those challenges cold chain is the key issue. The introduction of the underutilized and new vaccines will have a great impact on the cold chain regarding storage, distribution and transportation of vaccines for outreach. These vaccines will likely to be presented in single, low multi-dose vials or pre-filled injection devices, with larger volume per dose compared to the traditional vaccines. However the use of single or low multi-

dose presentations and auto-disable compact pre-filled devices has a potential for improving access and reducing vaccine wastage. In many developing countries, the current design and capacity of the cold chain may not meet the requirements for the introduction of these new vaccines. Availability of comprehensive methods/tools to properly plan the cold chain and logistics are essential to optimize new vaccines introduction efforts.




*Cold-chain capacity:*
The required cold storage capacity is estimated on the basis of vaccines required per fully immunized child. This will include traditional, underutilized and new vaccines based on national immunization programme plans. The method for estimating the vaccine volume required per fully immunized child includes: i) the vaccine's packed volumes, ii) the number of doses in the national immunization schedule, iii) the expected vaccine wastage rates during service delivery and iv) the number of consignments based on annual shipment plan.

The vaccine packed volumes are taken from WHO guideline on international shipping and packaging of vaccines (WHO/IVB/05.23) or from specific manufacturer's data. Data for future vaccine presentations are based on outcomes from Vaccine Packaging and Presentation Advisory Group (VPPAG) discussions with manufacturers and SAGE recommendations on Target Product Profile (TPP).

Although WHO generic volumes exist for each vaccine for the number of doses per child and the wastage rates, each national immunization programme may use their own figures based on specific epidemiological and vaccine delivery conditions.

The available gross cold chain capacity of cold/freezer rooms of the national and sub-national stores are divided by the grossing factors to estimate the net vaccine storage capacity.

Based on these assumptions and anticipated approach, the ultimate target for establishing the optimum cold-chain storage capacity of the national vaccine store is recommended at 300 cm3 per new born per year for the introduction of pneumococcal and rotavirus vaccines. Therefore, cold chain in many countries will need to be upgraded.

*In-country vaccine distribution:*
The increased vaccine volume will affect also volumes and weights to be distributed to lower levels. In many cases it may be necessary to adjust the current vaccine distribution schedule by increasing the number of deliveries per year in order to fit in existing capacities for storage and transportation and also to reduce the risk of damaging a large amount of costly vaccines. In addition, new vaccine distribution methods and schemas, including alternative types, modes and routes of transporting vaccines will be needed. Tools for conducting such an analysis are required.

*Outreach sessions:*
The volume of vaccines to be carried for outreach may increase beyond the capacity of the current PIS/PQS vaccine carriers for large sessions. There is a need for bigger and lighter vaccine carriers to be prequalified.

*Options to reduce cold chain:*
Options exist for reducing the chain requirement of new vaccines particularly if pro-active discussions can be made with manufacturers at the early stages of vaccine production. The presentation and packaging are being discussed through the VPPAG to reduce the dead space in current packaging. There is a need for detailed analysis to defined appropriate balance between programme desired characteristics of the vaccines and production challenges.

The above three presentations depicted on the fact that preparedness, advance and detailed planning, particularly in meeting the capacity of the cold chain and securing financial resources are essential in successful introduction of new vaccines. It was repeatedly commented by participants that no more *ad-hoc approaches* and *quick fixes* are acceptable in the paradigm of introduction of new vaccines. It was argued that outsourcing of the storage and distribution of the vaccines should be only done when there is a strong and effective control system in place. Turkey's experience in introduction of new vaccines clearly showed the immenseness of the task. Several participants recommended documentation of Turkey's experience both for the wider propagating and sharing this experience with other countries which eventually will introduce new vaccine in their routine programmes and also for training purposes.

## GAVI Independent Review Committee recommendations in relation to vaccine management and logistics issues - by I. Rizzo (GAVI Secretariat)

In the last two years, the GAVI Independent Review Committee (IRC) has deliberated a number of recommendations in order to improve the documentation submitted with the country proposals for receiving GAVI support for introduction of new vaccines. Following these recommendations, in July 2007, the application form, the annual progress report form and the guidelines for country proposals have been modified to facilitate countries to document the preparedness of the cold chain capacity to store new vaccines. This has improved tremendously the quality of proposals submitted to GAVI.

Similarly, countries had been required to conduct a vaccine management assessment in the second year of vaccine support from GAVI and to report about it to the IRC through the APR. On this issue the IRC recommends further improvements of the GAVI application form and of the EVSM/VMA tool.

The IRC has also made few recommendations for countries self-procuring vaccines and injection safety supplies to document that the mechanism of procurement used is controlled by a pre-qualified National Regulatory Authority. Waste management is another issue that is recommended to be addressed more precisely in the guidelines for country proposals.

## Future vaccines: Projected impact on supply chain and logistics systems – by J. Lloyd (PATH

Based on a the PATH 'Delivery System Framework' and current assessments of the evolution of new vaccines, 'high' and 'low' scenarios have been constructed their adoption by 2015 and 2025. The scenario for 2015 suggests that countries may see demands for a 6 to 10 fold increase in the capacity of their cool-chain systems. The main drivers of this increase are the number of new vaccines and new delivery systems combined with vaccines and the greater unit volume of single dose and 'few-dose' presentations compared with traditional multi-dose vaccine presentations. On the other hand, the scenario for 2025 suggests that the advent of thermostable vaccines and several new unit-dose, integral systems for intradermal delivery will reduce cool chain storage volumes in the longer term.

In the meantime, preparations need to be made for:

- more appropriate container-based shipping and transport of vaccines internationally and in-country
- larger cold room installations at primary and intermediate storage levels
- increased use of refrigerated vehicles and refrigerated containers on vehicles
- larger capacity refrigerators at health facilities for vaccines and chilled water packs
- in-service training in the handling and administration of new vaccine products
- more outsourced logistics to minimize capital investment in expanding the cool chain
- less steps in the cool chain - less handling - less reserve stocks - faster distribution.

To assure that storage volumes are reduced in the long term and that the benefits of new, thermo-stable, single dose delivery systems are realized, a clear message needs to emerge from the public health community that these technologies are needed.

## National supply chain and logistics solutions for vaccines - by P. Lydon (Project Optimize)

The current national supply chain for vaccines in most developing countries is based on a series of uninterrupted storage and distribution points from the national level, all the way down to service delivery points. An efficient supply chain would guarantee that the right quantities of vaccines end up at the right place, in the right conditions, and at the right time.

A review of these vaccine supply chains in 20+ low and middle income countries revealed that this basic condition is not met. This is all the more important in immunization which is timely activity based on a strict schedule of vaccinations. The consequences of this are that children may not get immunized (due to vaccine stock outs and delays in deliveries to health centres) or immunized with damaged vaccines (too many storage points leading to mishandling of vaccines and exposure to inappropriate temperatures); and wasted financial resources (due to overstocking at lower levels; high rates of vaccine expiry and discarding...). As such, there is a need to find long term solutions to these enduring problems that will be increasingly challenged as new and more expensive vaccines become available. The introduction of these will put mounting pressures on the national supply chains.

With this backdrop, Project Optimize undertook a review of the experiences and best practices in supply chain management within and outside the health sector with the goal of exploring possible and promising solutions applicable to vaccines. The presentation reviewed some of these solutions centred around: (a) inter-country warehousing of vaccines; (b) more direct distribution down the supply chain; (c) moving warehouses as a sub-national distribution system for vaccines; (d) options and models of outsourcing supply chain functions.

Clearly, there is no magic bullet and no "one size fits all" solution; rather a selection of options that can help countries improve the future of vaccine supply chain and logistics systems. In moving forward, project Optimize will collaborate with interested countries to demonstrate the efficiency, flexibility, and cost-effectiveness of these system solutions and explore their replicability in different settings.

## Mapping and assessment of vaccine management software tools - by H. Kenea (WHO)

The objective of this presentation was to share the result of the mapping exercise and following next steps with the participants. Fourteen tools were identified for the mapping. These tools intended to support national immunization programmes in the following one or more areas: Immunization supply forecasting, vaccine volume estimates, cold chain capacity analysis, cold chain inventory and replacement plan, cold chain capacity evaluation, vaccine stock management and immunization data management.
The list of the tools mapped is as follows:

- Cold Chain Equipment Management Tool (CCEM), PATH;
- Cold Chain Capacity Planning Tool, WHO;
- Cold Chain Inventory and Replacement Tool, WHO;
- cMYP New Vaccine Introduction Tool, WHO;
- EPI Logistics Forecasting Tool, WHO;
- Vaccine Forecasting Tool, UNICEF;

- Vaccine Volume Calculator  WHO/V&B/01.24;
- Vaccine Volume Calculator (revised from version WHO/V&B/01.24);
- Vaccine Volume Calculator (revised as VVC), WHO;
- Vaccine Stock Management Tool, WHO,
- Stock Management Tool, WHO;
- Vaccination Supplies Stock Management (VSSM), WHO/EMRO;
- M-Supply;
- District Vaccine Data Management Tool, (DVDMT), WHO.

The following  frames of reference were identified and used for the mapping of vaccine management tools: general feature, inputs and outputs, documentation and supplementary materials, effectiveness, ease of use, audience appeal and suitability and user feedback. The following findings were made:

- **Strengths:** Excel based (11 excel based and 3 access based) tools are easy to use, can be effectively implemented, can reduce the tedious work in the subject area and are suitable to users.
- **Weakness:** lack wide target users awareness, lack formal implementation plan, user feedback records and further improvement activities, lack proper documentations and supplementary materials (publications, guideline, instruction of use, tutorials), manual updating of reference data , Lack of wide target audience awareness

The review recommended the creation of a database system for all EPI Tools (Tool Information Sheet –TIS like PIS/PQS) and posting them on a website is essential for providing accurate information to potential users. There should be a screening process to identify which tools should be field tested and improved and provide feedback to the developer for further action. In addition, establishing a life cycle for tools could be considered and this information could be used for future tool improvement and development activities. Web-based updating or sharing reference data among tools should be considered as an effective way to tackle the frequent manual based updating systems. There is a need by each country to address the issue of sustainability when a new tool(s) is introduced for implementation and further use.

## Logistics management information software – where do we go from here? –  by O. Ronveaux (WHO)

The efficient management of immunization logistics requires accurate and timely information on cold chain equipment, supply stocks, and transport. These three sets of data should be used together with coverage and target population information in order to (a) adequately forecast, plan, and distribute supplies and equipment and (b) properly maintain and timely replace cold chain and transport equipment. Currently available Logistics Management Information System (LMIS) packages often do not use database applications, are isolated -serving only one function at only one level, and rely on inaccurate target population data. As a result, information can be rapidly out of date (cold chain equipment), or does not meet real needs (inadequate vaccine supply and forecast based on incorrect denominators).

With the emergence of many new and more costly vaccines, the need for more accurate information shared by all levels of the supply chain is becoming critical. Currently available

technologies allowing for more paper-free data entry (PDAs) and electronic follow-up of supplies (bar-coding) can now be integrated into the information data flow. Open source database software urgently need to be developed and/or fixed but should come together with human resource management and IT capacity-building before dissemination. Future developments include the linkage of the applications together on the internet and with immunization registries.

Questions stakeholders should address now include the availability (probably web-based) and maintenance (with the question of sustainability) of new software tools, and technical support for their implementation and local adaptation.

## Logistics Management Information Systems: Plenary Discussion Session- facilitated by M. Zaffran (WHO)

**SUMMARY OF KEY POINTS**

**Current tools**

- There are a plethora of tools in existence, however they are of varying quality and lack the ability to be integrated.

- Need to identify gaps (areas where there is currently no adequate tool):
    - WHO to review and promote the development of appropriate solutions/tools.
    - Agreement on a recommended platform for future tool development will be key to enabling the different tools to eventually talk and interact with each other.

- Tools available today should be gathered, reviewed and placed on Technet website for ease of download. The site should also include functionality to enable user comments on the tools, and a system to allow for feedback to be provided to the tool's developer/owner.

**Future tool development**

- There is a need to develop tools that can be adapted at the local (country) level.
- It is essential to ensure that we do not coordinate to the extent that we hinder innovation.

- Platform for tool development
    - Excel versus database (Access like) tools
        - Countries already used to Excel
            - easy to use, and serve their needs
        - Balance between usefulness of the change and its drawbacks
        - 2 major options coming up are not ready yet (VSSM and CCEM tools)

- Accountability of having the tools available (access to them) and meeting an agreed-upon base standard. There may perhaps be a role for TLAC in this.

- The option to develop modular tools, similar to EPI-info, where countries can take a base program and insert customizable-modules as needed may be a way forward; however there is concern about whether it is realistic. It may also be worth considering the

development of each tool as a separate module, built with functionality that will enable it to be integrated at a later date.

- Need for quality control of the tools. Ensuring basic data and calculations are meeting the standards- perhaps develop a certification of the tools /PQS-system?

**Maintenance and support**

- Maintenance/updating of tool:
  - Ability to access and use tools updates (Technet website?)
  - RSS feeds (ability to be notified of updates as they are created, and of new tools as they are developed)

- Support will need to be provided in the following area:
  - **Tool usage**
    - Help documentation should be included with all tools
    - User groups should be set up to offer informal support to fellow users
  - **Tool adaptation (programming expertise needed)**
    - *Programming documentation*- including how to modify the tool
    - *List of resource people*- those who can be contacted to help/consult on the modification process
    - *Country capacity building*- to ensure that countries are not reliant on external consultants in order to modify and maintain their systems
    - Role of international organizations?
  - **Tool operationalization**
    - *Support in implementing the tool in country*- from system set up to training to implementation

The discussion continued to the satellite A1 in which two tools: VSSM and CCEM were presented and discussed.

## Effective Vaccine Store Management (EVSM) – Rejuvenating the effort - by P. Lydon (WHO)

The WHO and UNICEF Effective Vaccine Store Management (EVSM) initiative began in December 2001 and was officially launched in 2004 in order to improve vaccine storage and distribution in country primary vaccine stores mainly. Because the national cold store is the most critical node of an immunization system where all vaccines are received, stored and distributed, it is important for the central stores to be managed in the best possible fashion to ensure an efficient supply chain for vaccines. The focus on efficiency is all the more important now that countries are introducing new and more costly vaccines with larger presentations that will put mounting pressure on the supply and cold chain systems. The value of stocks in national cold store runs to millions of dollars and protecting this investment in life saving vaccines requires having national stores up to management par.

Unfortunately, in recent years the EVSM initiative lost traction and other vaccine management tools (namely the VMA) have emerged that assess both national stores, but sub-national stores as well. As part of supporting this unfinished agenda, the Optimize project is providing resources to:

- Raise awareness of the value of effective vaccine management and the EVSM institutive, particularly in the context of the GIVS
- Streamline the vaccine management assessment tools by merging the EVSM and VMA into a modularized edition that will be based on a web platform
- Rejuvenate the initiative by supporting training activities, developing a pool of expert consultants, and promoting the use of the self assessment tool for vaccine management
- Undertaking global analyses of vaccine management and developing online databases.

EVSM is sometimes used as a motivating instrument to improve the conditions and the performance of the National Vaccine Stores. EMRO effectively used the tool to create competition between the countries for improving the performance of national vaccine store where the bulk of vaccines are stored. It was mentioned that UNICEF and WHO country offices are not fully aware of the existence and the use of the tool. Sudan uses the EVSM as a supervisory checklist. There is a need to simplify the tool. The tool should also be adapted to assess the private sector importing, storing and distributing vaccines.

# Session 3: Equipment development and management

## Performance, Quality and Safety (PQS) Update - by D. Maire (WHO)

The PQS after having been launched at the TECHNET consultation, Antalya, Turkey, 2004 is at a stage of being nearly fully functional. The meeting applauded the introduction of a new pre-qualification scheme with three main objectives:

1. Establish norms and standards and keep these under review.
2. Develop and maintain performance specifications and verification protocols.
3. Monitor products post-market and use the results.

The PQS has now an established structure, a defined scope of work and developed standard operating procedures. Its secretariat is hosted in WHO Geneva. Led by a steering group and delegated tasks to working groups, all specifications and verification protocols are now published. Two remaining critical functions are still to be put into place. The development of the PQS database has been outsourced and is expected to become functional in April 2009. The setting of a user feedback monitoring system will be the priority activity in 2009.
All information related to the PQS work is accessible in the WHO PQS website. All related documents, including specifications, verification protocols, guidelines for manufacturers, and product summary information are downloadable.

Further development of the PQS system can be summarized in the 6 following points:

1. Increase the number of products by category to ensure fair competition between manufacturers through strategic communication to stakeholders
2. Institute a functional user-feedback system for ever improved products and ensuring proper response to countries need; this will be done through the development of an active collection of information from the field and the development and maintenance of a database.
3. Ensure the commitment of all UN partners to guarantee the functionality of the system for the benefit of the countries it serves.
4. Develop and initiate an advocacy package for the use of PQS by national regulatory authorities.
5. Seek feedback from PQS users including manufacturers, laboratories, regulators, and procurement agencies to identify areas of improvement, bring the necessary changes for ensuring a smooth functionality of the system.
6. Establish a reality check hub for needs assessments and field test of newly developed/introduced devices and equipment.

The TECHNET consultation highlighted two issues that will need to be addressed:

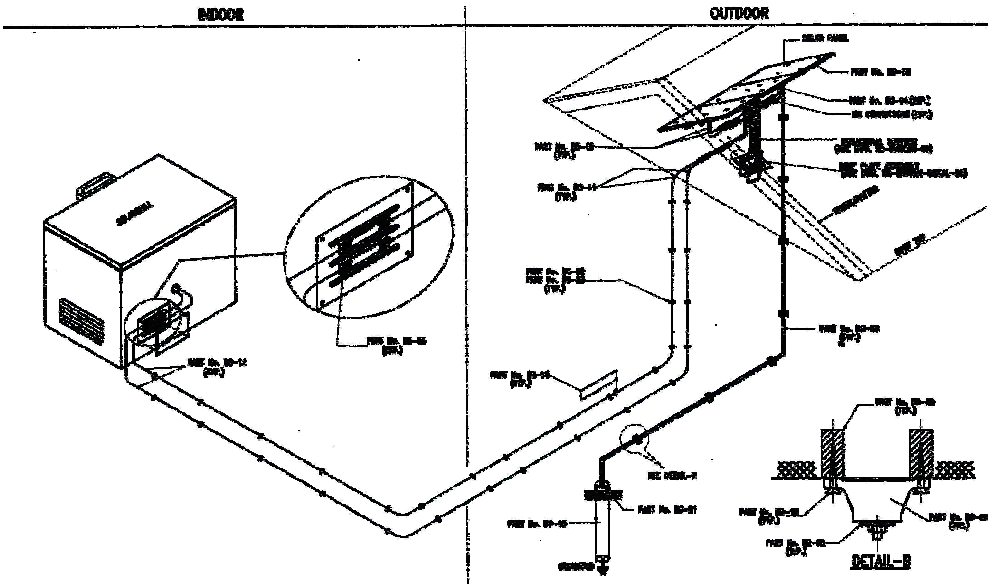
1. To ensure that the catalogue is accessible to all those who need them, including those who have poor internet connections.
2. PQS to be involved at an early stage in product innovations in order to be in a position to alleviate regulatory concerns that could arise during the development process of such products, and still ensuring that QA and QC will still be a guarantee of achieving established global standards.

On the question of the rationale to change from PIS to PQS and lack of awareness in the field, the secretariat assured the meeting that the catalogue is known and accessible to all those who need them, including those who have poor internet connections. A PQS link from the Technet21 website is planned for and regular TechNet e-forum posting will provide updates on changes in PQS list of pre-qualified devices. In respect to a print version of the PQS, the secretariat emphasized that the PQS is not a static document, but is meant to be updated in real time. All along the year, products are added to or withdrawn from the list, and that is why it is not foreseen to have a formally printed version, although at any time the existing version could be printed by the user when needed.

It was noted that there is no category in the PQS for incinerators. PQS is to be involved at an early stage in product innovations in order to be in a position to alleviate regulatory concerns that could arise during the development process of such products, and still ensuring that QA and QC will still be a guarantee of achieving established global standards. All categories of equipment should be considered for pre-qualification as long as they are endorsed by WHO. For now, WHO doesn't have a policy supporting the use of incinerators, and that is why no categories of the PQS covers these items. Participants were informed that PAHO is in the process of creating a pre-qualification system for injection equipment and reporting on post-marketing.

## Battery-less solar refrigerators: A break through - by M.T. Hart (IT Power India)

The first solar refrigerators for vaccine storage were introduced for field-testing in 1981. Over the past 25 years tens of thousands of solar refrigerators have been installed and substantial operational experience gained. Two major barriers are characterized; high capital costs compared with alternative vaccine storage technologies and poor reliability due to inadequate maintenance of batteries in the field.




25 years down the road, battery less vaccine refrigerators and hybrid refrigerators are emerging. Both offer excellent potential to reduce capital costs by 30-60% as compared to the earlier generation of solar refrigerators and both address the issue of reliability stemming from

premature battery failures resulting from poor maintenance.

The presentation reviewed the schematic configurations of battery less and hybrid options and defined what the market can expect from the emerging generation of vaccine refrigerators where electrical supply is erratic or non existent.

Future prospects are excellent. A couple of technological solutions are already commercialized. Preliminary field results indicate room for improvement, and barriers to comply with the WHO/PQS are as yet unresolved however.

With financial resources for development, little remains to be done to produce cost efficient, reliable solutions for vaccine storage at locations poorly served by the electrical grid.

Participants commended the inclusion of this topic to the TECHNET 2008 Consultation and were quite eager to know the detail of the design of the battery-less solar refrigerators. It was mentioned that battery-less solar refrigerators may be a solution to the problem of solar refrigerators. Battery has always been the bottle-neck of the solar refrigerators. If this technology proves to be reliable, then solar refrigerators not only will be suitable for areas with no electricity, they can also be used for areas with limited and unreliable power sources. Ultimately, battery-less solar refrigerators may as well be used in areas with electricity in the light of the increased cost of fossil fuel and consequently high cost of electricity.

## Freeze-free vaccine carriers for outreach - by U. Kartoglu (WHO)

Outreach represents a greater challenge to the vaccine cold chain. Health workers have to bring freeze-sensitive, freeze-dried presentations, diluents and OPV to the outreach sessions. They have to prevent freeze sensitive vaccines from being exposed to freezing temperature while providing enough cold for other vaccines. At the same time they have to maintain adequate temperature for keeping reconstituted vaccines cool. In many cases, outreach sessions are longer than a day. This presentation discussed an innovation by ColdPack® to address this challenge.

"Inflatable internal heat barrier" with its honeycomb structure is the technology used in this vaccine carrier. Vaccine carrier is designed as s soft backpack, airliner that is inflated is loaded with solid frozen icepacks and cool water packs, separated with a T-zone tray from the vaccine compartment, providing a temperature in the vaccine compartment that does not go below +2 degrees C. Airliner technology performs better than conventional insulation technologies and is close to gas filled panel insulation performance in terms of conductivity. Its greater advantage is that it comes flat so reduces the transport and storage space and costs.

Coolpack® is listed in the PIS but tested against the new PQS specifications giving 31 hours and 31 minutes of cool life (+2 to +20$^{o}$C) at 43$^{o}$C ambient testing temperatures (PIS codes E04/103-M, E04/103-M, E04.104-M). Two models of Coldpack® are tested in Sudan in 2008 and results demonstrated an extended periods of cold in the vaccine compartment that are above +2$^{o}$C with outreach activities around 24 hours.

A demonstration of the vaccine carrier was made by the representative of the manufacturer outside the consultation room. The question of whether the vaccine carrier's performance in the field was in line with the laboratory test result or not was raised. The compacted package of the

vaccine carrier was appreciated that will take much less space in transportation compared to the traditional vaccine carries was appreciated.

## Cold rooms – evolving needs and guidelines - by A. Garnett (Project Optimize consultant)

Project Optimize is investigating the impact that new and underused vaccines will have on the cold chain. These vaccines will be expensive, thus minimizing wastage will be a driving force, so most will be supplied in space-consuming single-dose and two-dose vials, or in pre-filled devices. All will be stored at +2°C to +8°C.

Landscaping work indicates that, over the next decade, countries that decide to introduce these vaccines will have to increase the capacity of their cold chains by as much as six to eight times compared with current minimum schedules. This means that new and much larger cold rooms will have to be built at national level. In addition, many intermediate stores that currently rely on refrigerators and freezers will have to be re-equipped with walk-in cold rooms. It is likely that this increase in capacity will have a short to medium-term impact. In the longer term Project Optimize is looking at alternative vaccine formulations and presentations which, ultimately, should reduce the need for cold storage.

A big increase in vaccine volumes will have multiple impacts. Large cold rooms will require large wide span buildings to accommodate them. Storing and distributing vaccine in small secondary cartons will no longer be practical – some form of tertiary bulk packaging will be needed inside the insulated shipping container. Accordingly, mechanical handling equipment is likely to be required in many stores. Very large countries may choose to build high rise cold rooms with pallet racking; this will require the use of fork lift trucks. Distributing vaccine in the current generation of cold boxes will no longer be practical – alternative approaches include a greater use of refrigerated vehicles or refrigerated containers, or the use of pallet sized active or passive insulated containers.

Project Optimize is developing guidelines to help countries implement these very significant changes. In consultation with industry, the PQS specifications will also be extended to cover large cold rooms and to include new product ranges, such as passive containers.

## Are you really monitoring temperature in the vaccine cold chain? - by U. Kartoglu (WHO)

This presentation focused on the temperature monitoring devices used at different levels of the vaccine cold chain, underlining the critical role of VVMs that they are the only tool that is available from the time of production of vaccines down to its use at the most periphery. Currently, temperature monitoring at the health centre level refrigerators are done with thermometers which is not considered as "monitoring" since it provides only with a spot check and not giving any information on the exposures for the nights, weekends and holidays.

The presentation focused on the new PQS prequalified device Fridge-tag® by Berlinger that records temperatures and shows alarms on an LCD screen. The device shows the time, current temperature and whether there has been any alarms during the last 30 days, upper (>8$^{O}$C for 10

hours) and lower alarm (<-0.5$^{O}$C for 1 hour) indicators. The history mode allows the user to evaluate the temperature exposures for the last 30 days. It shows the highest and the lowest temperatures exposed on that particular day as well as the duration if the exposure was beyond the set alarm points. This new temperature monitoring device brings a revolutionary approach to temperature monitoring at the health centre level.

The presentation also focused on the VVM use in the field underlining the importance of VVM based vaccine management. It reminded that VVM types on different vaccines should not be compared to each other and not be used as proxy. Recent events in various countries indicate that VVMs are doing what they are supposed to do, pinpointing cold chain problems.

There is always the question of extra costs and the issue of training staff when new and more sophisticated equipment are coming to the market are recommended to be used by the programmes.

## Report on Cold Chain and Logistics (CCL) Taskforce - by O. Mansoor (UNICEF)

In 2006, the Government of Japan provided UNICEF with a grant for a vaccine strategy to support countries' influenza pandemic preparedness. After consultation with WHO, it was agreed to undertake five activities, one of which was to strengthen the EPI cold chain and logistics (CCL) systems, as these systems would be used for delivery of immunization if a pandemic vaccine were to be available. From initiating this work, it became clear that there were considerable needs in most countries for CCL strengthening and that multiple partners were involved in various aspects of this support. Therefore, UNICEF convened a CCL Taskforce of immunization partners (Gates, JSI, PATH, RotaADIP, PneumoADIP, UNICEF and WHO) in New York in November 2007.

The participants agreed on the need to work together and developed a consensus on vision, goals, and outcomes for strengthening CCL systems. The vision is to strengthen the capacity of NIPs so that every individual benefits from vaccines of assured quality; delivered in the right amount at the right time through efficient logistics, proper vaccine management, and a well-functioning cold chain system. The goals of the partnership are to develop: (1) a framework for CCL strengthening; (2) indicators to monitor progress; (3) methods and database to share information; (4) country prioritization; (5) roles for each agency.

An initial dataset has been proposed that will from the basis for both the database and to generate the indicators to monitor progress. What is now needed is to formalize the process of information sharing to minimize additional burdens and to coordinate global support.

The presentation ended with a Yogi Berra quote "*In theory there is no difference between theory and practice, in practice there is*" to emphasize the need for approaches that deal with developing country realities and the need for evaluation of how CCL systems actually work in practice.

# Session 4: Vaccine Management

## Vaccine and delivery technologies: A landscape analysis - by D. Kristensen (PATH)

This presentation provided an overview of the results of a landscape analysis that was undertaken to identify trends in the availability of vaccines and novel vaccine delivery technologies that are and will be of relevance to lower and middle income countries (LMICs) between now and 2025. The key findings were:

- The number of vaccines potentially available for LMIC use will increase substantially.
- Vaccine manufacturers are conservative and the majority of existing and new vaccines will continue to be delivered by needle and syringe unless incentives and/or compelling data are generated to support alternative delivery methods.
- A wide range of novel vaccine technologies, many of which are needle-free and/or employ alternative immunization routes are being developed. Overall the goals of these technologies are to reduce needle and syringe use, reduce the dose of vaccine required, reduce wastage, and deliver the vaccine by a route that will stimulate an appropriate immune response
- Some of the approaches for new delivery technologies will require significant effort to be spent developing appropriate vaccine formulations that are compatible with the delivery technology in addition to developing the device itself. Consequently, these approaches will not be available until the medium-to-long term (after 2015).
- Short-term activities are possible based on increasing use of existing technologies that would improve vaccination safety, such as increasing use of syringes with auto-disable and anti-stick mechanisms.
- Suitable combinations of delivery technology and 'available' vaccine need to be identified for use in 'demonstration' projects to evaluate new delivery technologies.
- Ultimately, introduction of novel vaccine formulations and delivery technologies will require their incorporation early in the development path of vaccines.

There is a need to inform the programmes of the existence of the devices that may optimize the performance.

There are a number of country experiences in storing and transporting specific vaccines out of the cold chain. Viet Nam is one of the success stories and therefore the country representative was invited to TECHNET 2008 Consultation to share the experience with the participants. This session was followed by "Use of vaccines out of cold chain: Evidence and proposed way forward" in which the importance of the issue and methods of storing vaccine out of the cold chain were presented.

## Vietnam: Country experience with giving hepatitis B birth-dose out of cold chain - by N. Van Cuong (MoH Viet Nam)

Viet Nam has a population of 85 million with 54 ethnic groups (2007), 63 provinces, 642 districts and 10,999 communes. The birth cohort is about 1.5 million per year. EPI has achieved high coverage (since 1993 over 90% of infant fully immunized).

Hep B vaccination first started in 1997 in 2 cities, expanded into 39 provinces in 2000 using local produced plasma derived vaccine and nationwide introduction in 2003 with GAVI support using recombinant vaccine.

In the last 10 years, 2 studies have been conducted in Viet Nam to evaluate the effect of out of cold chain (OCC) delivery of Hep B vaccine. The first was conducted from 1998-2000; the second from 2004-2005. In both, the study group received Hep B vaccine stored OCC for the birth-dose, and vaccine stored inside the cold chain for the 2nd and 3rd doses. The control group received vaccine stored inside the cold chain for all 3 doses.

The result of the study is summarized in the table below, and showed that *Prevalence of a protective level of antibody to hepatitis B virus surface antigen after 3 doses of Hep B Vaccine, and number of days of heat exposure for dose 1.*

| | **ICC (95% CIs)** | **OCC: days of storage outside the cold chain** | |
|---|---|---|---|
| | | **1-14** | **15-31** |
| **First study** | 77.9% (72.4-82.7) (n = 271) | 83.6% (78.4-88.0) (n = 250) | 82.7% (78.9-86.1) (n = 452) |
| **Second study** | **ICC** | **OCC: More than 10 days** | |
| | 85.7% (82.6-88.3) (n = 616) | 91.7% (88.3-94.3) (n = 351) | |

The second study also evaluated the on-time delivery of the hepatitis B vaccine birth- dose. Compared to a pre-study baseline of 45.3%, on-time birth-dose coverage increased to 89.5% birth doses delivered within 72 hours, and 82.6% delivered within 24 hours of birth. There was not an increase in adverse events as a result of delivering vaccine out of the cold chain, and satisfaction of mothers and health workers was positive.

There are several challenges to the long-term adoption of OCC policy in Viet Nam:

- VVM's are not yet available on locally produced hepatitis B vaccine.
- Lack of strong/specific guidance document and advocacy from manufacturers and regulatory agencies, including WHO.
- Recent serious adverse events following hepatitis B birth dose vaccination (not OCC-related) have drastically affected the acceptance of the birth dose among mothers and the willingness to give birth dose from health workers.

## Use of vaccines out of cold chain: Evidence and proposed way forward - by J Robertson (PATH)

Out of cold chain (OCC) is defined as the possibility of transporting and storing certain heat-stable vaccines at ambient temperature, for a certain period of time. The use of OCC is meant as an option for countries, not a mandate. It can provide flexibility by allowing countries to take some vaccines out of cold storage and transport during part of the cold chain journey to help achieve program goals such as increased coverage. An example would be providing hepatitis B vaccine to

midwives to store in their homes and use for birth dose. At this time, we do not imagine elimination of the cold chain - OCC practice is compatible with the more heat-stable vaccines such as hepatitis B, tetanus, human papillomavirus (HPV). A recent literature review at PATH identified eight studies evaluating aspects of effectiveness and/or safety of OCC practice, all but one looking at hepatitis B. Though most of these studies were relatively small, the results were positive with regards to safety and effectiveness, and several pointed to better on-time delivery of hepatitis B birth dose by using OCC.

The presentation brought to the attention of the participants the reasons why it is important to keep some vaccines out of the cold chain. OCC can be an important tool for immunization programs to help achieve the following:

- To reach more children beyond the existing cold chain in hard-to-reach rural populations.
- To enable on-time birth doses where home births are common and hepatitis B is endemic.
- To reduce/eliminate the risk of freezing.
- To limit the need to increase cold storage capacity and transport volumes.
- To limit the growth in energy needs.

Project Optimize plans to sponsor a study in collaboration with industry and regulatory agencies. Including hepatitis B vaccines from multiple manufacturers, the study will demonstrate the advantages and challenges of OCC practice, measure the impact of ambient temperature storage on shelf life and antigenicity, and seek to correlate the behaviour of the vaccine with that of the VVM at high temperature.

Other steps planned include:

- Determining the pathways for national regulatory changes and global policy recommendations and guidelines that would enable OCC.
- Demonstrate out of cold chain practice in a collaborating country.

Evaluate out of cold chain practice for HPV vaccine at the early stages of the introduction of this vaccine.

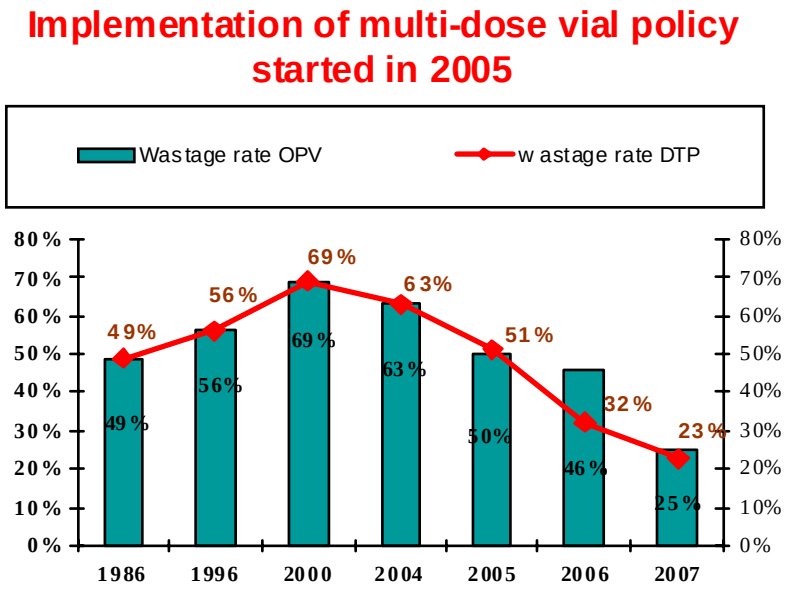
There is a great deal of experience with the use of OPV out of cold chain during National Immunization Days (NID) that should be tapped into. There is a need for a clear instruction to the field as what vaccines could be kept out of the cold chain, for how long, and in what conditions. The issue of training cannot be too strongly emphasized for vaccines OCC. The use of VVM on vaccines that are used OCC is also very important, and it is vital that the performance of VVMs in different temperature scenarios is well understood, and scientifically verified. The term “temperature controlled ambient” was suggested to be used for storage of certain vaccines. TLAC may be a body to approve OCC for certain vaccines and in certain conditions although TLAC needs to have more conclusive data and more robust studies with emphasize on AEFI. The presentation mentioned the important role of late Carib Nelson from PATH who had the courage of being one of the first to bring the issue of vaccines OCC and was the pioneer in research and field studies on this subject.

## Tunisian experience in reducing wastage by adopting Multi-Dose Vial Policy (MDVP) - by M. Ben Ghorbal (MoH Tunisia)

During the last decade the number of health centres providing vaccination services to small rural localities where number of targeted children was small has been increased in Tunisia. This strategy eliminated the gap between rural and urban areas in relation to vaccination coverage but it significantly increased the wastage rate of all vaccines.

It should be noted that between 1986 and 2002 the decrease of number of newborns and increase of the number of heath centers contributed to the increase of DPT wastage rate from 49% to 63%.

The increase of cost of vaccines and economical constrains became a concern to policy makers in 2004. In 2005 MOH Tunisia requested WHO for advice in reducing the wastage rate of vaccines. In this year, based on advice received from WHO, multi-dose vial policy (MDVP) was adopted in 12 selected provinces. Then, during the Annual Inter-provincial Meeting in 2006 the effect of the adoption of MDVP in 12 selected provinces was discussed. It was clear that there was a significant reduction of wastage for DPT, OPV and dT in these provinces in 2006 and 2007.

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Other contributing factors were decreasing the frequency of vaccination sessions in health centers with small target population. The wastage rate was reduced by approximately 10% in 2007 compared to 2004. The decrease of wastage rate was more prominent in urban areas. A moderate reduction of wastage rate was also observed in urban areas for measles vaccine and BCG that was not related to adoption of MDVP.

The monitoring of vaccination coverage and surveillance of AEFI at district levels showed that adoption of MDVP did not cause any increase of AEFI or decrease of vaccination coverage. Based on this encouraging result, the rest of the provinces adopted MDVP. It should be noted that supervision and training are the key issues in a successful adoption of MDVP in Tunisia.

## Rationale of revising the Multi-Dose Vial Policy (MDVP) - by R. Eggers (WHO)

In 2000, WHO released a statement on "The use of opened multi-dose vials of vaccine in subsequent immunization sessions", now named the Multi-Dose Vial Policy (MDVP). Its purpose

was to allow health workers to safely use opened vials in subsequent sessions under specific circumstances and with specific vaccines, thereby reducing unnecessary wastage. With the advent of new vaccines, new vaccine combinations and new levels and type of preservatives in vaccines, this policy no longer is able to meet the operational challenges. The revision was thus being prepared through the TLAC policy pathway, hopefully resulting in an effective and clear way to allow health workers to distinguish between vials that can safely be kept open, and vials that *have to* be discarded at the end of the session.

The previous MDVP was based on the vaccine formulation, allowing health workers to make an easy choice between keeping and discarding, this was being confused by the newer formulations. Two scenarios were described:

- Scenario 1 - Vaccines that are not adequately preserved may mistakenly be kept because they are liquid vaccines - making the current MDVP too unsafe; e.g
    - Multi-dose liquid vaccines containing reduced amounts of thiomersal may not meet the requirements of the MDVP
    - Multi-dose liquid vaccines containing alternative preservatives may not meet the requirements of the MDVP
    - Two-dose vials of novel vaccines (pneumococcal, human papilloma virus) in liquid formulations without containing any preservative
    - Using several fractional doses from a single dose vial eg by adoption of intradermal route (1 dose vial becomes a 5 dose vial)
- Scenario 2: Vaccines that are adequately preserved will not be kept because they are freeze dried or used to reconstitute a freeze dried component of the combination - making the current MDVP too wasteful; e.g
    - Reconstituting a lyophilized component (eg. Hib) of a combination vaccine with a liquid component containing preservative in adequate amounts (eg. DTP-Hep B)
    - Future liquid-liquid combinations where one component contains sufficient preservative

With the help of a consultant, TLAC was advising WHO how to proceed with the revision of the MDVP, taking into consideration the commercial and regulatory components, but ensuring that the operational and programmatic components are also addressed.

The question came out whether we should completely abandon MDVP and to stop training health workers on using MDVP or not at this stage. UNICEF should negotiate production of DPT in 10-dose vial presentations for most of the programmes. The possibility of production and wider use of BCG in smaller presentations is essential in reducing wastage rates. Probably use of MDVP should be continued until TLAC comes up with a solution.

## Report on the Vaccine Presentation and Packaging Advisory Group (VPPAG) - by O. Mansoor (UNICEF)

The Vaccine Presentation and Packaging Advisory Group (VPPAG) was established in 2007 by the GAVI Alliance to respond to industry request in relation to pneumococcal conjugate vaccine (PCV) and rotavirus vaccine (RV). For the former, this fed into the WHO target product profile (TPP) for the Advance Market Commitment (AMC) for PCV. VPPAG advised on a range of aspects for packaging and presentation (termed 'image' by industry), and most of its recommendations were

included in the TPP. However, VPPAG was not able to answer a key question – the optimal number of doses per vial for expensive new vaccines such as PCV.

In 2008, WHO took over the role of convening VPPAG together with the Optimize project, as the mandate of the group was extended beyond GAVI supported vaccines, with a need to address the options of Human papilloma virus (HPV) vaccine, as well as to develop a more generic approach to address presentation and packaging issues for the range of potential new vaccines. An immediate issues that emerged from consideration of HPV was the need to update WHO's multi-dose vial policy (MDVP), and VPPAG prepared a paper for WHO consideration as part of this review.

VPPAG provides a unique forum for representatives of agencies and experts involved in public sector delivery of vaccines with industry representatives – both the International Federation of Pharmaceutical Manufacturers Association (IFPMA) and DCVMN (Developing Country Manufacturer's Network).

## Shake and tell: Shake test validation - by U. Kartoglu (WHO)

The video article summarized the validation study conducted to establish specificity, sensitivity and the positive predictive value of the shake test against phase contrast microscopy as the golden test. A total of 475 vials of freeze-sensitive WHO prequalified vaccines from 10 manufacturers and eight vaccine types were included in the study. Freezing status of vaccines was confirmed by the phase-contrast microscopy. A total of 156 vials were correctly identified as frozen while 319 samples were non-frozen. Non-frozen samples showed a fine-grain structure under phase-contrast microscopy. On the contrary, frozen samples showed large conglomerates of massed precipitates. Vaccines were tested by health workers (who had no experience with vaccines nor with the shake test) trained by the principle investigator following the standard WHO shake test learning guide. Health workers correctly identified all fail and pass shakes tests. The results indicated 100% specificity, sensitivity and positive predictive value, meaning that health workers can use the test with great confidence.

The shake test for single-dose vials is not easy and may not yield correct result. Field tests in Cambodia did not have the same result as it was shown in the DVD. The shake test may not be valid for freeze-sensitive vaccines when they are exposed to only -5$^{O}$C and not to a lower temperature range. The question of how to freeze a reference vial to a -25$^{O}$C in the field was brought up. It should be noted that shake test is both costly and time consuming. Shake test cannot be used for malaria vaccines since there is no aluminium adjuvant in this vaccine. It was mentioned that the result of a study as widely as this presentation circulated may not be published in prestigious journals.

## Progress in stabilizing vaccines for both heat and freeze resistance - by D. Kristensen (PATH)

This presentation described progress that has been made to improve the thermostability of vaccines since the last TechNet meeting in Mexico City, including efforts by PATH's vaccine stabilization project as well as by other research and industry groups. The benefits, challenges and progress made with three categories of stabilization methods – lyophilization, spray-drying, and liquid formulation - were described.

Lyophilization is a well-established drying method that requires days for preparation of a single batch. It is often the best method for preparing unstable bacterial and viral vaccines. The final product is a dried cake or foam that must be reconstituted.

Substantial advancement in the field of spray-drying has occurred over the last few years by many players. PATH and collaborators have successfully stabilized hepatitis B vaccine for 24 months at 37°C. The stability of the standard liquid vaccine is one month at 37°C. Conjugate meningitis A vaccine was also successfully stabilized by spray-drying for greater than 16 weeks at 40°C. Efforts to improve the stability of spray-dried measles vaccine beyond that of the standard lyophilized products have been less successful, however, despite concerted efforts by several research groups.

Spray dried products are free-flowing powders that offer flexibility in terms of filling different numbers of doses per container and are amenable to use with new delivery technologies such as capsules/tablets for oral delivery, inhalation devices, skin patches, and single dose reconstitution devices. Theoretically it should be possible to blend different spray-dried antigens that might not be stable together as liquids. Spray-drying equipment manufacturers have made progress in development of equipment suitable for aseptic production (essential for producing injectable vaccines) and a few groups are working towards establishment of such production lines in support of clinical trials. Spray-dried oral vaccines do not require aseptic production lines, so are likely to encounter fewer hurdles for approval for clinical use.

Liquid formulation methods (e.g., the use of high throughput screening methods and stabilizing excipients) have also advanced over the past few years and offer the ability to optimize the heat stability of vaccines in the often preferable liquid format. PATH has developed a freeze-protection technology that appears be applicable to freeze-sensitive vaccines containing aluminium adjuvant (e.g. DTP, hepatitis B, and liquid Hib vaccines) and has placed the technology in the public domain to encourage broad use by vaccine producers. Two vaccine producers are currently reformulating vaccines (DTP-hepatitis B-Hib and hepatitis B) in collaboration with PATH to incorporate the freeze protection technology. The hepatitis B vaccine will also incorporate a heat stabilization technology developed by Arecor. Clinical trials for both vaccines will commence in 2009-2010. These products will ease the pathway for adoption by additional manufacturers.

In order for immunization programs to obtain maximal use of the benefits of thermostable vaccines, out of cold chain procedures, policies and appropriate equipment to ensure controlled ambient conditions must first be established. The public sector will need to work closely with industry to identify desirable product attributes, including appropriate storage temperature ranges, and to generate the data required to support regulatory approvals and out of cold chain policies. Much of this work is already being undertaken by WHO and PATH via Project Optimize, the Technology and Logistics Advisory Committee, the Vaccine Presentation and Packaging Advisory Group, and vaccine producers working the PATH vaccine stabilization project and other research groups to advance specific thermostable products.

Note: A background table entitled "*Summary of stability data for commonly used vaccines and novel formulations*" was recently prepared by PATH and is available to TechNet members as a reference document.

# Session 5: Related technical topics

## Report on Safety of Injection Global Network (SIGN) - by S. Khamassi (WHO)

There is more recognition than ever before that injection safety represents a very cost effective intervention in preventing the transmission of blood borne pathogens, mainly Hepatitis B, hepatitis C and HIV to patients through reuse of injection equipment and mishandling of multi dose vials, to health care workers through needle stick injuries and to the community at large through improper sharps waste management.

The WHO injection safety programme and the safe Injection Global Network were launched both in 1999 following major studies that documented the magnitude of unsafe injection practices worldwide and the burden of diseases transmitted by them.

The presentation reviews major achievements in terms of tools and guidelines developed by WHO to assist Member States assess injection practices, identify safety breaches, plan and implement national injection safety programmes and strategies.

The second part of the presentation reviewed the latest developments in terms of injection safety activities, innovation in safe injection technologies as well as new funding opportunities for injection safety through GAVI for immunization injections and the Global Fund for therapeutic injections and health care waste management.

The last part of the presentation discussed future collaborative activities between SIGN and WHO Regional Offices based on country needs and programme needs.

In the discussion, the need for the TechNet and the SIGN areas of work to continue to collaborate was highlighted as the areas frequently involve the same people and are to some extent overlapping. It was hoped that future TechNet and SIGN meetings would again be held back-to-back at the same venue.

## Waste management options and available technologies - by Y. Chartier (WHO)

Health-care activities produce infectious wastes which lead to adverse health effects and are a risk for patients, health care workers, waste handlers and communities. Used syringes and needles contain residual blood and blood-borne pathogens and may transmit diseases when re-used without reprocessing or through accidental needle sticks. Little attention is paid to ensure the budgeting and financing for managing infectious waste.

We should aim at developing clear guidance, policies and recommendations for safety of health workers and all levels. The guiding principles of the policy paper on safe health-care waste management are to prevent the health risk associated with exposure to HCW by promoting sound management policies and to reduce the exposure to toxic pollutants associated with the combustion process through the promotion of appropriate practices. It also acknowledges that until countries in transition and developing countries have access to health-care waste management options that are safer to the environment and health, incineration may be an acceptable response when used appropriately. Key elements of appropriate operation of

incinerators include effective waste reduction and waste segregation, placing incinerators away from populated areas, satisfactory engineered designs, construction following appropriate dimensional plans, proper operations, periodic maintenance, and staff training and management.

To support implementation of a sound health care waste management a WHO health care waste web site is available at: **http://www.healthcarewaste.org** or **http://www.who.int/water_sanitation_health** that offers technical options, costing tools, country information, contacts and 142 reference documents. This includes a pocket size document on the management of waste for injection activities which is practical and useful. There are also posters summarizing the strategies proposed for the management of waste for injection activities.

WHO is developing pre-qualification specifications on injection related equipment including needle removers aimed to assist the users when selecting equipment. There is a return value in recycling or reprocessing of plastic syringes into other utensils

Partnership is a key for a sound waste management system. The development of an official health care waste management network is under process. This network will be a platform to share information, to look at specific topics such as recycling, to brain storm on technologies, to inform partners and countries on potential sources of funding, to share and update on activities and progresses made in country programmes.

The WHO core principle recognizes that safe and sustainable management of health-care waste is a public health imperative and a responsibility of all. Improper management of health-care waste poses a significant risk to patients, health-care workers, the community and the environment. This problem can be solved, to a large extent, by the appropriate use of resources which will result in a substantive reduction of disease burden and corresponding savings in health expenditures. The WHO core principle requires that all associated with financing and supporting health-care activities should provide for the costs of managing health-care waste. Manufacturers also should share the responsibility to take waste management into account in the development and sale of their products and services. The establishment and sustained maintenance of sound systems for health-care waste management depend on the availability of resources.

This is directed to governments, donors and partners, NGOs, private sectors and all concerned institutions. Whoever signs up has to express its commitment to WHO and this will be listed on the WHO web site on health care waste management

A cost effectiveness and health impact study on health care waste is to be conducted in 2009.

Technologies, such as smelter, simple steam waste treatment system, low cost incinerators, existing or under research for being manufactured, should provide additional options in the near future. The HCWM WHO Web site proposes a number of technologies and links.

Many country level activities are taking place: for example, the 2008 objective of the health-care waste component of the Global Alliance for Vaccine and Immunization (GAVI) is that by the end of the year, 90% of countries receiving GAVI support (65 countries - half of them in Sub-Saharan Africa) have adopted national policy and developed plans for health-care waste management.

Countries such as Madagascar, Mali or Ghana in the African region have started to implement national plans. Activities to support the implementation of policies in a number of settings to demonstrate success is going on. A monitoring tool under development will be ready soon.

Three expanded Costing Assessment tools have been developed and they differentiate between low, middle and high income countries, they deal with various size categories of health centre facilities, allows several treatment options, provides centralized and/or decentralized treatment and computes potential revenues from the sale of sterilized plastic parts for re-melting.

In conclusion, there are on-going and some structured dynamics taking place in collaboration with partners at global and at country levels. This demonstrates that despite the enormous challenge that safe waste management represents, it is not a hopeless battle to ensure safety. Definitely, there is a long way to go. Progress is, unfortunately, very slow but it is moving ahead.

It was agreed that the challenge is serious and enormous. The cost of a correct disposal of medical waste is sometimes prohibitive and countries cannot be blamed for not being able to cope with the costs. Because of the difficulties and the lack of resources the quality of health care waste management has been neglected. A more active involvement of GAVI is very much recommended. The health care waste management system should be a part and parcel of the system design. Waste management should be built to the system and should start with materials used for production of syringes. Optimize Project is encouraged to be involved with the waste management and should accept it as a challenge. It was said that PATH is in the process of finalizing a report on health care waste management. The environmental impact of the waste management as a whole should not be over-looked.

## Pakistan's experience with implementing waste management plans - by F. Mansoor (MoH Pakistan)

Pakistan has a population of 160 million. It has a well laid out health infrastructure both in urban and rural areas and in public and private sectors. Close to 12,000 health care facilities in the public sector and several times more in the private sector exist that continuously produce medical waste. The hospital medical waste is estimated to be at 2 kg/bed/day which are amounted to 250,000 tones of waste annually. The situation of health care waste management is very bleak at present. A nation-wide survey was conducted under a CEHA project that shows only 28% have a Health waste Management Team and only 1% of them keep records of the waste.

More than 70% of the health providing outlets has no on-site facility to treat the waste, 60% send their waste out on the municipality vehicles and the small health care facilities have almost negligible training opportunities for waste disposal.

Another KAP study by Pakistan Medical and Research Council shows that the staff involved in disposal of health care waste has no knowledge of any health care waste management. 72% are throwing the hospital waste in public dustbins. The prevalence of HCV and HBV can be taken as proxy indicators for the safe disposal of infectious waste.

A national action plan with the support of the WHO Centre for Environmental Activities (CEHA), GAVI, Ministry of Environment, Ministry of Health, Ministry of Science and Technology, private

sector and resource persons has been prepared and submitted to the Planning Commission for implementation and allocation of resources.

As per the plans pilot projects have been started in Punjab and Sindh. The plan would empower the hospital waste management rules 2005, launching capacity building and training measures, setting up a monitoring plan, and reducing the persistent organic pollutants by adopting shredders and onsite disposal mechanisms. Improved storage and segregation facilities would also be adopted. The plan aims to generate a massive awareness in the community about the need for safe disposal of biomedical waste.

Prime Minister's Hepatitis control program has distributed 145 incinerators to all the Teaching and District Head Quarters Hospitals of the country. The EPI program now uses only AD syringes and safety boxes have been distributed for safe disposal of syringes since 2001.

The presentation depicted that an effective medical waste management system is costly and definitely not easy. It needs planning and needs enormous financial support. The presentation interestingly agued that a majority of the health workers in Pakistan, that can be the case on most of the developing countries, are not aware of a sound medical waste management. The result of the KAP survey in Pakistan showed that a big proportion of physician never heard of AD syringes.

## Capacity building for human resources for logistics, including landscape analysis on training - by J. Bahl (WHO)

The presentation covered the current status in-service and pre-service trainings in logistics, results of Training Landscape Analysis as part of project optimize and proposed next steps. A pre-service training for logisticians is being proposed by Bioforce in collaboration with AFRO. Findings from the training landscape analysis stress a need for a detailed curriculum for logistics. As next steps, WHO will work with partners in defining a curriculum for logistics training and work with training institutions on delivery of good quality training.

Immunization Basics informed the participants that an e-learning material exists and can be used. The importance of the translation of training materials was emphasized and it was said that WHO Regional Offices are responsible for translation of the materials to regional and local languages. Post training support was mentioned and emphasized. Creating motivation parallel to effective training is essential. Training materials should be tailored to the specific needs of the countries. There is a lack of cost and cost-effectiveness of the training for logisticians. Inclusion of the issues related to vaccine cold chain and vaccine management into the nursing and medical curriculum is encouraged.

## Influenza pandemic: Logistics planning for the deployment of vaccines within 7-days in pandemic situation - by P. Carrasco (WHO)

The guidelines for the deployment of a pandemic influenza vaccine describe the activities that every Member State should implement, in accordance with its deployment plan, to assure that a pandemic influenza vaccine can be delivered within seven days to designated distribution points.

Seven days is the time frame established for the deployment of a pandemic influenza vaccine. This time frame is based on the fact that an individual requires approximately 14 days to develop measurable protection (HI titers) after having been vaccinated with seasonal influenza vaccine. This seven-day time frame should be respected in order to protect individuals as quickly as possible, to reduce disease transmission and to take advantage of the power of vaccine to fight the disease. The successful eradication of smallpox and efforts to eradicate poliomyelitis in many regions of the world operated on this principle.

"Deployment" as used in this document refers to the management and organization of activities to achieve and/or support the unimpeded movement of a pandemic influenza vaccine from the point of receipt to its final point of use. The guidelines focus on the establishment of advance activities necessary to achieve a level of preparedness for the deployment of a pandemic influenza vaccine. The level of preparedness of each Member State depends on its "surge capacity" – that is, its ability to access and use the additional resources that may be required during an emergency. The guidelines are aimed at national committees and individuals – primarily managers from the public service and/or the private sector –responsible for the management and execution of the deployment of a pandemic influenza vaccine at all levels. The guidelines aim to:

- provide a framework for the development of detailed procedures to deploy a pandemic influenza vaccine and other ancillary products within seven days;
- assure that each country's vaccine delivery system plans for the surge capacity required to achieve a seven-day deployment of pandemic influenza vaccine and ancillary items;
- encourage each country to conduct exercises to test its deployment and execution capacity once it has drawn up a detailed deployment plan;
- support core-management activities that include – but are not limited to – the deployment of pandemic influenza vaccine, taking into account diverse and/or country-specific conditions and constraints;

The guidelines ***do not*** address issues related to:

- the actual task of vaccination – this subject should be addressed by the country's policy for an influenza pandemic and/or its pandemic preparedness plan;
- access to, and procurement of, a pandemic influenza vaccine;
- the decision on how to use an influenza pandemic vaccine or a novel influenza vaccine, such as H5N1.

The ability to ensure that a country can deliver a pandemic influenza vaccine in 7 days plan will depend upon how much effort and resources authorities invest into ***Pre-event Planning***. Underpinning such planning efforts includes but is not limited to the following factors:

- Develop all the objectives and activities related to logistics within the deployment plan.
- Map the current logistic capacity for delivering a vaccine within seven days and determine the gap between what *can* be done today and what will have to be done during an influenza pandemic.
- Develop the specifications for the logistic information flow with the IC and personnel in charge of information technologies (IT) and communications.
- Document estimated deployment costs and ensures that the estimates are regularly updated.

Experience working with several countries and from meetings indicates that countries vary widely in the details and scope of their PPP. Most developing countries do not include the use of a pandemic influenza vaccine in their PPP. PPP and use/availability of antiviral and a possible

pandemic influenza vaccine are very sensitive political decisions. In many countries there is no mechanisms in place for changing the decision on how to use a pandemic influenza vaccine based on epidemiology of the pandemic as it evolves, this may have profound impact on logistics as the influenza pandemic evolves and original plans for using a vaccine change.

There is a need to inform the countries and the programme managers of this plan and the guidelines. Although the plan and the guidelines are prepared by EPI, in reality EPI managers at the country level may not be responsible for pandemic control. The inclusion of this topic to the agenda was appreciated. EMRO has distributed the guidelines to the programme managers in the EMR countries. It was mentioned that the plan should also include the transportation and the waste management.

Closing session:

- **E-forum: next step**
- **Evaluation of the Consultation**
- **TechNet Consultation - future**

## Main conclusions

1. **New vaccines introduction**: With the introduction of new vaccines, countries should end any ad-hoc, reactive planning approach to vaccine management. Instead, careful planning and costing of storage and transportation space has to be done prior to the introduction of new vaccines, allowing enough time for the findings of the report to be addressed before the new vaccines are shipped. This should include the national and sub-national levels at least, but should ideally comprise the whole vaccine storage and distribution system. The review should include an examination of vaccine distribution frequency and mechanisms, and current cold chain equipment, which in many instances requires critical upgrading and maintenance.

2. **Human resource capacity in logistics & vaccine management**: There is need for official recognition of the importance and benefit of logisticians and vaccine managers as a defined cadre of workers in the health system. With this, these positions should be professionalized (eg established career path with clear training levels and a certification process). A clear need for more trained and knowledgeable logistics and operations managers at national and sub-national level is evident; to build and maintain their skills, countries and regions need ongoing, updated training preferably by training bodies within these countries and regions.

3. **Planning, management, training and public information materials**: New vaccine introduction, vaccine management and operations information, and training material should be collected and made available in a central common repository, allowing insight and means for adaptation to other countries. The Technet website would be an ideal forum for this purpose.

4. **Software tools of vaccine and equipment managemen**t: Similarly, a repository is needed for existing tools and their descriptions from the landscape analysis to be widely available (potentially the TechNet website). Through the normative roles of WHO and TLAC, the standardization of definitions, variables, key methods of calculations and data sources should be achieved. Software tools need to be more closely aligned with each other, eliminating overlap, and in each case there needs to be a mechanism for user feedback, technical support and quality control of tools. Ultimately, we should work towards more comprehensive, modular tool(s) with the flexibility of local adaptation.

5. **Anticipated policy changes (such OCC and revision of MDVP)** are welcomed and encouraged, and the authors of these new policies are urged to rapidly conclude policy discussion and communicate decisions widely. The TechNet consultation highlighted the need to consider regulatory and programmatic implications / aspects as well as the cost of changing policies. In addition, a clear statement is required in the interim (while these policies have not been finalized). To assure acceptance, stakeholders have to be consulted and field tests conducted prior to institution of new policies. It was recognized that the while the simplicity of the vaccine management and cold chain system devised in the 1970's has reached its limits, it is essential that new systems and approaches work to minimize complexity and ensure that future recommendations and guidelines are practical for field settings.

6. **Partnership for cold chain, operations and logistics:** An increasing number of interested parties, contributors and implementers are operating in the field of logistics, operations and vaccine management. To facilitate efficiency and avoid overlap, a partnership approach

between interested partners including field based staff is sought , that ties vaccine and cold chain equipment manufacturing industry should be strengthened (potentially public-private partnership).

7. **Experiences with outsourcing of vaccine logistics and management components**: As partners and countries gain experiences with outsourcing various parts of their immunization systems from logistics, to storage, transport, equipment maintenance and other components of vaccine management and logistics, both good and bad experiences need to be documented and shared widely (maybe through TechNet e-forum). Subsequently, guidelines for appropriate outsourcing need to be developed, which should include a clear definition of "outsourcing".

8. **PQS:** The progress with the PQS is welcomed and its full launch eagerly anticipated, as it creates a clear advantage of standard setting and renewable quality checks. Within PQS, the open and responsive mechanism of feedback should be made more widely known, allowing users of specific PQS items to record their experiences and challenges. PQS should be further developed to allow for the inclusion of new categories, and provide advice to quality and standards to countries purchasing equipment locally. In order to allow for feedback on products to reach both PQS and manufacturers, a mechanism for recording and sharing user experiences should be explored.

9. **Innovations in technology**: Advances in battery-free solar fridges, vaccine carriers, temperature monitoring devices and vaccine stabilization are welcomed and further encouraged. Untested technologies require further field testing and the outcomes of these field tests should be shared widely. Also, potentially thorough the TechNet e-forum and website, early adopters of new technologies should have the opportunity to provide user feedback.

10. **Management of cold chain and vaccines in temperature extremes:** More analysis and strategy development is needed in addressing cold chain needs in sub-zero and very high ambient temperature (>37 deg) settings, both in terms of equipment and management practices.

11. **EVSM / VMA /VMA**: The transition of EVSM/VMA to VMA should be finalized rapidly. Country level assessments using the new methodology should be revitalized, expanded and encouraged. In addition, the newly developed assessments methodology and quality plan should be packaged to allow their use in self-assessments and supervision.

12. **Injection safety & waste disposal:** In addition to SIGN, a coordination partnership is necessary for waste disposal and injection safety partners, especially in line with the need to coordinate with the global health initiatives. To enable monitoring, the recording and ongoing monitoring of injection safety and waste disposal practices have to be expanded, using developed M&E framework. Injection equipment supply and waste disposal need to be closer bound, potentially using the vaccine distribution systems to centralize disposal (back-loading).

13. **TechNet Continuum:** This consultation welcomed the proposal to expand and modernize the TechNet e-forum, the establishment of TLAC as the key policy pathway and the continuation of TechNet consultations in the future (18-24 months). A stronger and clearer mechanism of interaction between the TechNet Consultation and TLAC was encouraged. For future TechNet

consultations, it was proposed that more country level participation should be sought, and potentially plan for a manufacturers session prior or after the meeting.

## Satellite session A: Optimizing future logistics systems: Overview of Project Optimize – by M. Zaffran and J. Lloyd

This session provided an opportunity to present the mandate and work of Optimize, a five-year WHO-PATH collaboration, funded by the Bill & Melinda Gates Foundation to the TECHNET Consultation. Optimize has been given a unique mandate to think far into the future: to create a vaccine supply chain that is flexible and robust enough to handle an increasingly large and costly portfolio of vaccines and ultimately, create synergies with the delivery of other health commodities. Putting technological and scientific advances to work, Optimize also aims to facilitate the development of a set of ideal characteristics that will guide the development of new products, ensuring they are designed for maximum efficiency and safety in low and middle income countries. Central to this work is developing consensus amongst major partners and stakeholders around the global vision for immunization technologies and logistics.

The session began with a brief presentation on Optimize's overarching strategy by Michel Zaffran, the Project Director. He was followed by John Lloyd, Senior Technical Advisor, who shared insights into the history of the cold chain, and the ad-hoc way in which it was created. He urged those at the session to think in terms of system solutions, and not quick fixes, and to realize how much can be achieved in ten years. To capitalize on the knowledge and experience of those attending the TECHNET consultation, participants were encouraged to contribute their thoughts and experiences on Optimize's direction by joining one of four informal breakout groups on the following topics: technologies, outsourcing, Cold Chain Logistics (CCL), integration with other health delivery systems. The main ideas emerged from these sessions were as follows:

- **Technologies**: Discussion focused on the challenges and way forward in several key areas: *Solar Technologies*- equipment will remain expensive in the near future (5-10 years). There is a lot of interest in improving battery technology, and in the emerging battery-free technologies. Reliability is essential for all products, and for the reputation of the product group as a whole. Some participants expressed a need for more field-testing, as the conditions in the field are often harsher than those used for laboratory testings. *Information management (MIS)*- need to define what information we need, and what technologies are needed to gather and use it. The importance of using MIS as a management tool was discussed, along with the importance of getting good quality data in the right place at the right time- and creating the necessary process to enable data use- to support increased efficiency in the supply chain. *Out of the cold chain (OCC)*: questions were raised as to the ability to use AC rooms for storage, how long and at what temperatures can vaccines be OCC, and what happens if they go in and out of cold storage, what are the risks of going off-label?

- **Integration with other health supply chains**: Many successful examples can be found in AFRO, but are currently not documented. However, other regions shared experiences of problems in terms of stock-outs when using integrated delivery. It is also important to discuss at what point in the system we are talking about integration- during storage, procurement, delivery, etc.

- **Cold Chain Logistics (CCL):** There is a need to clarify the objectives of the task force perhaps by using SMART objectives and to develop a TOR. CCL aims to work on coordination of operational and programmatic support to national programs as a primary focus, but may also aim to facilitate work in the policy arena, which could be a possible synergy with Optimize.

There are possible synergies with the work being done on an integrated EVSM/VMA tool. CCL should not be confused with official advisory bodies, like TLAC.

- **Outsourcing**: The group discussed the pros and cons of outsourcing. One example of outsourcing the actual management of the cold chain was given. It is essential to define the term 'outsourcing' before it is widely used. There is a great deal of existing experience in this area and there is a need to document successful and unsuccessful country experiences in order to generate an accurate understanding and extract best practices for moving forward. However, it is important to note that there is not a 'one size fits all' solution in this area, and potential activities will need to be customized to the settings in which they are operating.

# Satellite session B1: Introduction of new software tools

## Vaccination Supplies Stock Management (VSSM): a new tool for store managers – by M. Haghgou

Assessment made 2004 in 18 countries of the Eastern Mediterranean Region (EMR) showed that vaccine stock management was a common most important problem. This finding was confirmed in 67 assessments made globally in 2003. The 9th TECHNET consultation in Mexico City called for a development of a professional tool for vaccine stock management. Options for computerized vaccine stock management are limited. Very little commercially made software is suitable for vaccine stock management. Excel-based, locally developed software seemed to be the best solution so far, although inadequate for large stores and large countries. Software developed by PAHO is not widely used. A number of new costly vaccines added to the routine immunization programs, and increased coverage and supplementary immunization days including NIDs and school vaccination programmes had increased the quantity of different vaccines handled by the national stores. Considering the increase in the type and the quantity of vaccines and increase in the price of almost all vaccines, most national vaccine stores now keep millions of dollars worth of vaccines and other related supplies at any given moment.

There were several attempts in EMR to develop professional tools at the country level. Most of them could not be sustained and were abandoned after a while. Building on the failure of the local experiences, EMRO pioneered to develop a tool that was based on the most common practices of vaccine store keeping and based on the training given to vaccine store staff. Vaccination Supplies Stock Management (VSSM) version 1, an open-source, MS Access base software was developed in late 2006. The aim was to replace paper-based vaccine stock management and in some extent to replace Excel-based locally used tools.


VSSM version 1 was tested and used in Sudan and later based on feedback from the field, version 2 was developed. Further testing in the real field situation resulted in completion of versions 2.4 and 2.5. The latest version is a multilingual tool (English, French, Arabic and Russian) and can easily be translated by users into other local languages. A detailed user guideline is accompanying VSSM and a training of 3 to 4 days ensures the smooth transition from paper-based and excel-based to VSSM a more professional and appropriate tool.

VSSM version 3.0 is under development that makes the toll more users friendly and adds new functions to the tool. This version is expected to be ready beginning of 2009.

The presentation described the tool, its functions and utilities to participants and it seems that the tool is promising to be the solution to most of the problems related to vaccine stock management. It was emphasized during the presentation and it should be noted here that no tool and no matter how professionally it is designed can replace an effective, committed, disciplined and motivated manager. A tool can only be useful when a good management system is in place.

The participants appreciated EMRO's for developing the tool particularly that the tool might be a solution to the longstanding problem of vaccine stock management. The participants appreciated the fact that the tool can be used in different languages at the same time. The participants recommended inclusion of the status of VVM into the tool and to explore the utility of combining the tool with a bar-code reader and bar-code developer. It was agreed that more field testing is required for the perfection of the tool. It was mentioned that there is no suitable commercial software that can meet all the needs of the vaccine stock management at the field level and this emphasizes the importance of VSSM.

## Cold Chain Equipment Management (CCEM) tool by J. Lloyd

CCEM is an open-source MS-Access based software tool to manage and analyse data from a national equipment inventory survey of health facilities that store or administer vaccines. The tool includes a forecasting function that compares existing cold chain storage capacity against requirements based on vaccine target populations for each facility. The forecast allocates new equipment according to national policies on standardization, prioritized energy availability and minimum cost. The forecast can be generated for any year in the future and the resulting equipment lists, with associated purchase and energy costs, can be incorporated into Multi-Year Plans. In addition, the forecast can be used to evaluate future scenarios of new vaccine introduction or modified systems of vaccine distribution.

Version 1.0 of CCEM was tested in Uganda in 2007 and is available from the PATH website (....) together with user and technical manuals, sample survey forms and guides in English, French and Spanish.
Version 2.0 will be released during 2009 and will feature an updating system, multi-year cyclic forecasts and an interface with PDAs/Bar-code readers for more accurate equipment identification. CCEM provides for data transfer to MS-Excel and to the WHO Excel-based inventory analysis tool.

This session went to late night discussion and all three versions of CCEM were discussed in detail. It was reiterated that the utility of CCEM depends heavily on the effectiveness and accuracy of the inventory that is an essential prerequisite for use of CCEM. It was also mentioned that an accurate inventory takes time, it might be costly and it may need training.

## Satellite session B2: Pharmaceutical cold chain management training at the heart of action – by U. Kartoglu

Members of the pharmaceutical supply chain have various global requirements to meet during storage, transportation and handling of temperature sensitive products. Changing product portfolios, requirements for good storage and distribution practices, regulatory trends, quality management, and risk assessment factors bring many challenges to pharmaceutical cold chain management. Pharmaceutical cold chain management on wheels is offered by the WHO Global training Network for Vaccine Quality and Parenteral Drug Association in association with Tip Kurumu (Medical Society - Turkey), DHL, Pfizer, Selçuk Ecza Deposu (Selçuk Warehouse Pharmaceuticals), Hacettepe University Hospitals, Turkish Pharmacists' Association and the Ministry of Health of Turkey. 2008 course took place in Turkey during 2-7 June.

Pharmaceutical cold chain management on wheels is a training course aimed at developing skills in the critical evaluation of a pharmaceutical cold chain system and improving associated supervisory skills. The course encourages participants to make direct observations at the storage and health facilities which participants will visit whilst physically travelling down the length of the cold chain. This competency based training approach is designed to offer the participants insights into the theoretical background of pharmaceutical cold chain management, combining this with real life, hands-on observation at a variety of storage and health facilities.

This video showed during the consultation summarized the course activities.

### Educational video: Shake test and discussion

This 10-minute video provides the steps of a standard validated way of performing a shake test and evaluating the results, and suggests the correct actions for different outcomes. It also discusses the effects of freezing on adsorbed vaccines and illustrates the mechanism behind the shake test.

# WORLD HEALTH ORGANIZATION

## TECHNET 2008 CONSULTATION

## 02 - 04 December 2008
## Tunis, Tunisia

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## Annex 2: Agenda of the consultation

# TECHNET Consultation
# Tunis, Tunisia, 2 - 4 December 2008

**Objectives of the Consultation**

- Provide current information on recent technological innovations, strategies or practices that impact logistic systems management in national immunization programmes
- Share developing country experiences on field operations in the areas of vaccine storage and transport, vaccine management, cold chain and equipment performance, waste management, introduction of new vaccines or immunization technologies and overall systems monitoring.
- Stimulate dialogue and debate on the development and implementation of best practices.

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**Monday, 1 December 2008**

***SATELLITE SESSION A: PROJECT OPTIMIZE***

| | | |
|---|---|---|
| 17:00 | Optimizing future logistics systems: Overview of Project Optimize | Michel Zaffran<br>John Lloyd<br>WHO/PATH |
| 18:00 | Closing | |

**Day 1: Tuesday, 2 December 2008**

08:30 Registration

***PLENARY SESSION 1: INTRODUCTION AND CONTEXT***

Chairperson: Dr. Mounira Garbouj, Representative of Ministry of Health, Tunisia

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|---|---|---|
| 09:00 | Opening remarks | Dr. Ibrahim Abdel Rahim<br>WHO Representative in Tunisia<br><br>H.E. Mr. Mondher Zenaidi<br>Minister of Health, Tunisia |
| 09:30 | Introduction and objectives of the consultation | Rudi Eggers<br>WHO |
| 09:45 | Report on the Technologies and Logistics Advisory Committee (TLAC) | Robert Steinglass<br>TLAC member |
| 10:00 | Report on TECHNET e-forum | Markku Toryalai Hart<br>IT Power India |
| 10:15 | Discussion | |

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| 10:30 | Tea/Coffee Break | |

## *PLENARY SESSION 2: ADVANCES IN VACCINES AND LOGISTICS*

Chairperson: Robert Steinglass, Immunization BASICS & TLAC member

| | | |
|---|---|---|
| 11:00 | Country experience of cold chain, operational and logistics issues with introduction of new vaccines | |
| | • Bolivia | Percy Halkyer Immunization Focal Point |
| | • Turkey | Hamza Ozdemir MOH Turkey |
| 11:40 | Cold chain preparation for introduction of new vaccines | Souleymane Kone WHO |
| 12:00 | Discussion | |
| 12:20 | GAVI Independent Review Committee recommendations in relation to vaccine management and logistics issues | Ivone Rizzo GAVI Secretariat |
| 12:40 | Discussion | |
| 13:00 | Lunch break | |
| 14:30 | Future vaccines: Projected impact on supply chain and logistics systems | John Lloyd PATH |
| 14:50 | Discussion | |
| 15:00 | National supply chain and logistics solutions for vaccines: thoughts from Project Optimize | Patrick Lydon WHO |
| 15:30 | Discussion | |
| 16:00 | Tea/Coffee break | |
| 16:30 | Mapping and assessment of vaccine management software tools | Hailu Makonnen WHO |
| 16:50 | Logistics management information software – where do we go from here? | Olivier Ronveaux WHO |
| 17:10 | Brain storming on future of software development | Michel Zaffran WHO |
| 17:45 | Closing | |

| *PARALLEL SATELLITE SESSION B1: SOFTFWARE DEMONSTRATION* | | |
|---|---|---|
| 18:00 | Vaccination Supplies Stock Management (VSSM): a new tool for store managers (30 minutes) | Mojtaba Haghgou Consultant |
| 18:30 | Cold Chain Equipment Management (CCEM) (30 minutes) | John Lloyd PATH |

| *PARALLEL SATELLITE SESSION B2: COLD CHAIN MANAGEMENT TRAINING* | | |
|---|---|---|
| 18:00 | Pharmaceutical cold chain management training at the heart of action (30 minutes) | Umit Kartoglu WHO |
| 18:30 | Educational video: Shake test and discussion (30 | Umit Kartoglu WHO |

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| 19:00 | Closing | | 19:00 | minutes)<br>Closing |

**Day 2: Wednesday, 3 December 2008**

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| 08:30 | Effective Vaccine Store Management (EVSM) – Rejuvenating this effort | Patrick Lydon<br>WHO |
| 08:50 | Discussion | |

***PLENARY SESSION 3: EQUIPMENT DEVELOPMENT AND MANAGEMENT***

Chairperson: Diana Chang-Blanc, UNICEF Bangkok

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|---|---|---|
| 09:10 | Performance, Quality and Safety (PQS) Update | Denis Maire<br>WHO |
| 09:30 | Discussion | |
| 09:50 | Battery-less solar refrigerators: A break through | Terry Hart<br>IT Power India |
| 10:05 | Freeze-free vaccine carriers for outreach | Umit Kartoglu<br>WHO |
| 10:20 | Discussion | |
| 10:30 | Tea/Coffee break | |
| 11:00 | Cold rooms – evolving needs and guidelines | Andrew Garnett<br>Consultant |
| 11:20 | Discussion | |
| 11:40 | Are you really monitoring temperature in the vaccine cold chain? | Umit Kartoglu<br>WHO |
| 12:00 | Discussion | |
| 12:20 | Report on Cold Chain and Logistics (CCL) Taskforce | Osman Mansoor<br>UNICEF |
| 12:40 | Discussion | |
| 13:00 | Lunch break<br><br>(including demonstration session on the Vaccine presentation assessment tool (VPAT) | Andrew Garnett<br>Consultant |

***PLENARY SESSION 4: VACCINE MANAGEMENT***

Chairperson: Michel Zaffran, WHO

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| 14:30 | Vaccine and delivery mechanisms: A landscape analysis | Debbie Kristensen<br>PATH |
| 14:50 | Discussion | |

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| 15:10 | Vietnam: Country experience of using vaccines out of the cold chain | Nguyen Van Cuong<br>Vu Minh Huong<br>MoH Vietnam |
| 15:30 | Use of vaccines out of cold chain: Evidence and proposed way forward | Joanie Robertson<br>PATH |
| 16:00 | Tea/Coffee break | |
| 16:30 | Discussion | |
| 16:50 | Tunisian experience in reducing wastage by adopting Multi-Dose Vial Policy (MDVP) | Dr. M. Ben Ghorbal<br>EPI Manager<br>MoH Tunisia |
| 17:10 | Rationale of revising the Multi-Dose Vial Policy (MDVP) | Rudi Eggers<br>WHO |
| 17:30 | Discussion | |
| 17:50 | Closing | |

**Day 3: Thursday, 4 December 2008**

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| 08:30 | Report on the Vaccine Presentation and Packaging Advisory Group (VPPAG) | Osman Mansoor<br>UNICEF |
| 08:50 | Discussion | |
| 09:10 | Shake and tell: Shake test validation | Umit Kartoglu<br>WHO<br>Wieslaw Kurzatkowski<br>Institute of Hygiene, Warsaw, Poland |
| 09:40 | Discussion | |
| 10:00 | Progress in stabilizing vaccines for both heat and freeze resistance | Debbie Kristensen<br>PATH |
| 10:30 | Tea/Coffee break | |
| 11:00 | Discussion | |

***PLENARY SESSION 5: RELATED TOPICS***

Chairperson: Ezzedine Mohsni, Regional Advisor, WHO EMRO

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| 11:20 | Report on Safety of Injection Global Network (SIGN) | Selma Khamassi<br>WHO |
| 11:40 | Discussion | |
| 12:00 | Waste management options and available technologies | Yves Chartier<br>WHO |
| 12:20 | Country experience with implementing waste management plans | Faisal Mansoor<br>Deputy EPI Manager Pakistan |

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| 12:40 | Discussion | |
| 13:00 | Lunch break | |
| | (including a demonstration / discussion on how to evolve the TechNet e-forum and website) | Markku Toryalai Hart<br>IT Power India |
| 14:30 | Capacity building for human resources for logistics, including landscape analysis on training | Jhimil Bahl<br>WHO |
| 14:50 | Discussion | |
| 15:10 | Influenza pandemic: Logistics planning for the deployment of vaccines within 7-days in pandemic situation | Peter Carrasco<br>WHO |
| 15:40 | Discussion | |
| 16:00 | Tea/Coffee break | |
| 16:30 | • E-forum: next step<br>• Evaluation of the Consultation<br>• TechNet Consultation - future | Rudi Eggers<br>WHO |
| | Main recommendations | |
| 17:00 | Closing | |

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