TechNet 21
Antalya Consultation Report

Antalya, Turkey
23–25 March 2004

Table of content

Abbreviations and acronyms

AD	auto-disable (syringe)
AEFI	adverse events following immunization
AFP	acute flaccid paralysis
AFRO WHO	Regional Office for Africa
AMRO WHO	Regional Office for the Americas
ATT	Access to Technologies (WHO)
BASICS	Basic Support for Institutionalizing Child Survival
BCG	bacille Calmette-Guérin (vaccine)
CCCCM	Collaborative Centre for Cold Chain Management (South Africa)
CCISD	Centre de coopération internationale en santé et développement
CDC	Centers for Disease Control and Prevention (USA)
CEE/CIS	Central and Eastern Europe/Commonwealth of Independent States
CSCI	WHO/UNICEF Cold Store Certification Initiative
CVI	Children's Vaccine Initiative
CVP	Children's Vaccine Programme
DFID	Department for International Development (UK)
DHMT	District Health Management Team
DMO	District Medical Officer
DQA	Data Quality Audit
DT	diphtheria–tetanus toxoid (vaccine)
DTP	diphtheria–tetanus–pertussis (vaccine) (sometimes called DPT)
DTaP	diphtheria–tetanus–acellular pertussis
DTwP	diphtheria–tetanus–whole cell pertussis
EAPRO	UNICEF Regional Office for East Asia and the Pacific
EPI	Expanded Programme on Immunization
ESARO	UNICEF Regional Office for East and Southern Africa
EURO WHO	Regional Office for Europe
EVSM	Effective Vaccine Store Management
GAVI	Global Alliance for Vaccines and Immunization
GMP	Good Manufacturing Practices
GPV	Global Programme for Vaccines and Immunizations (former V&B)
GTN	Global Training Network
GTZ	Gesellshaft für Technische Zusammenarbeit (German Aid Agency)
HBV	hepatitis B virus
HepB	hepatitis B vaccine

Hib	*Haemophilus influenzae* b
HPV	Human Papilloma Virus
IAVM	International Academy for Vehicle Management
ICC	interagency coordination committee
IEC	information–education–communication
ILR	ice-lined refrigerator
ISO	International Standards Organization
IMCI	Integrated Management of Childhood Illnesses
ISS	Immunization Service Support
IVB	Immunization, Vaccines and Biologicals
JE	Japanese Encephalitis
MDVP	multi-dose vial policy
MENA	UNICEF Regional Office for the Middle East and North Africa
MMR	mumps–measles–rubella (vaccine)
MNT	maternal and neonatal tetanus
MNTE	maternal and neonatal tetanus elimination
MR	measles–rubella (vaccine)
NATO	North Atlantic Treaty Organization
NID	national immunization day
NT	neonatal tetanus
NRA	National Regulatory Authority
OECD	Organization for Economic Cooperation and Development
OPV	oral polio vaccine
PAHO	Pan American Health Organization
PATH	Program for Appropriate Technology in Health
PIS	Product Information Sheets
PQS	Performance Quality and Safety
RED	Reach Every District
ROSA	UNICEF Regional Office for Latin America and the Carribean
SEARO	WHO Regional Office for South-East Asia
SIGN	Safe Injection Global Network
SNID	subnational immunization day
TBA	Traditional Birth Attendant
Technet	Technical Network for Logistics in Health
TechNet21	Technical network for strengthening immunization services
TT	tetanus toxoid
UCI	Universal Childhood Immunization

UN	United Nations
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNICEF	United Nations Children's Fund
USAID	United States Agency for International Development
VAR	vaccine arrival report
VF	The Vaccine Fund
VVM	vaccine vial monitor
WCARO	UNICEF Regional Office for West and Central Africa
WHO	World Health Organization
WPRO	WHO Regional Office for the Western Pacific

P r e f a c e

The Technical Network for Logistics in Health, or Technet, was established in 1989 as a loose link between experts and partner-supporting organizations working in logistics for health. Much of its focus has been on the management and operational logistics of national immunization programmes and the integration of other logistics elements into primary health service delivery in developing countries.

The Technet e-Forum began on 1 February 1998 as a communications initiative by the Technet secretariat, based in GPV WHO and BASICS. Following the 2001 conference, the e-forum has also changed its name to Technet21 and has moved its base of operations to Centre de coopération internationale en santé et développement in Quebec, Canada, its Listserv hosted at Laval University.

At the time of writing (mid-2004) the e-forum had a membership of nearly 950 subscribers to the English list. Discussions have started in French in June 2003 and contributions are translated from one to the other language. The French list has a present membership of 78.

In the period since the 1999 Technet Consultation in Harare, much has changed in the immunization world. The Vaccines and Biologicals (V&B) Department has been reorganized. The Safe Injection Global Network (SIGN) has been developed to consider some of the issues formerly considered by Technet and now holds its separate meeting. The Global Alliance for Vaccines and Immunization has been formed, including many of the same partners represented in Technet and SIGN.

In 2001,Technet was relaunched at its conference in Delhi as Technet21. The challenge still lies in the strengthening of immunization management, both programme management and operations management, and in involving immunization managers in developing, and testing strategies and policies to achieve this. Technet21 aims to reach more developing country managers, including those at subnational and district levels, WHO and UNICEF country staff, plus the traditional Technet logistics members. New challenges have also emerged such as the introduction of new vaccines. The focus is also increasingly on challenges facing us for some time, reaching populations having inadequate access to services (the « hard-to-reach ») in order to reach every child in every district by implementing the RED strategy to improve coverage.

The Antalya 2004 consultation, organized back-to-back with the Technology and Operations Panel meeting, welcomed a total of 105 participants including 15 participants representing

national immunization programmes from all continents. The Technet consultation started with a half-day satellite session, "Training Works", organized jointly with JHPIEGO an affiliate to the Johns Hopkins University, followed by the three-day TechNet meeting proper, which ran from 23 to 25 March 2004. The TOP meeting was held on 26 March.

In conclusion, we would like to express our thanks to the Minister of Health of the Republic of Turkey, to the WHO Regional Office for Europe (EURO) and to Akdeniz University Department of Public Health for their support in organizing and hosting the meeting, and finally to all others who participated in the organization of the TechNet meeting itself and satellite sessions.

TechNet21 Secretariat

Note from the editors

This report contains the proceedings of the TechNet21 Consultation held in Antalya, Turkey from 23 until 25 March 2004. It uses the same format as the previous consultation report held in Delhi, India.

Objectives and expected outcomes were set for each session and although they were not much referred to during the meeting itself, they served as framework to produce summaries of each session as they appear at the beginning of sessions reports.

Presentations are reproduced whether from narrative papers submitted by presenters or in a few cases wholly extracted from PowerPoint presentations that were used. In many cases it is a blend of both especially when images or graphs complement narratives. It is hoped that justice was done to the remarkable work of all presenters and we apologize in advance for any shortcoming of this editorial task.

Discussions are generally not just transcripts. It was decided at the beginning not to use names and only report on content. Not all interventions from the floor are reported but most of them. It is obviously arbitrary and although all contributions are valuable, there were some repetitions. Sometimes interventions have been shortened if judged too lenghty or displaced for better consistency if its topic had been discussed earlier. In this we tried to exercise our best judgment. We again apologize if some participants feel that reporting is not up to their expectations.

All editorial decisions concerning the report format were taken in close consultation with Secretariat.

Finally, the report is available on CDRom and print-out copies for those who would find these media more convenient. Please address your detailed requests to Paul Mallins.

Claude Letarte
TechNet21 Forum Moderator

Paul Mallins
Technical Officer
ATT/IVB

OPENING REMARKS and INTRODUCTORY SESSION

1.1 Welcome to delegates

Tahir Soydal, Deputy Director of Primary Health Care of the Ministry of Health of Turkey welcomed the participants of behalf of the Minister of Health. Necati Dedeo□lu Director of the Public Health Department from Akdeniz University, partner to the meeting also welcomed the delegates. Nedret Emiro□lu, Immunization Regional Advisor at WHO EURO co-sponsor of the consultation commented on the importance and usefulness of the TechNet forum to share experience and knowledge to improve and strengthen immunization services.

Finally Michel Zaffran, Coordinator of the Access to Technonlogy Team made the final welcoming remarks to participants on behalf of WHO Headquarters. He also paid tribute to John Lloyd presently with PATH, who could not attend the meeting, but always played such a critical role in the TechNet forum.

1.2 Acknowledgements

WHO wishes to thank all organizations and partners whose contributions made possible the organization of the present meeting in particular the Ministry of Health of Turkey and Akdeniz University. A special thank is also addressed to partners form industry for their financial contributions : AOV International, Berlinger, BioFarma, Chiron Vaccines, Dometic, Panacea Biotec Ltd, the Serum Institute of India and Temptimes Corporation.

FOLLOW-UP ON THE DELHI CONSULTATION RECOMMENDATIONS :

Ümit Karto□lu, WHO/HQ

Progress made since the last TechNet consultation in New Delhi, India in implementing recommendations were reviewed, starting with comments on the report of the previous consultation. The report was envisioned as a detailed reference manual for TechNet members. Only a minority of presenters submitted an executive summary of their presentation forcing editors to review and interpret full presentations. Hence the final document was delayed by almost two years.

The presentation is divided in five parts.

1. Revitalization of Working Groups :

The New Delhi Consultation meeting had targeted the revitalization of the following working groups :

- Prevention of vaccine freezing
- Vaccine wastage
- Time temperature monitoring
- Immunization waste disposal
- Best practices for the cold chain (certification)
- Management and supervision tools
- Introduction of new vaccines

Of this list of working groups, only one is now functional "Best practice for cold chain" which is now named "Effective Cold Store Management Initiative" on which there is a full presentation further below in this report. It must be remembered that this initiative had no financial resources. However forum discussions led to an individual effort and an informal group of 35 people has been set up on Vaccine Wastage.

2. Evolving the TechNet21 e-forum in a more productive format

Forum postings now follow the single-topic format. There is an active search for contributions by both secretariat and the moderator, not always very productive though. The forum also initiated postings in French on 19 June 2003 and finally the TechNet21 website was launched in October 2002. Redesigned in August 2003, the site is attracting a steadily increasing number of visitors.

3. Convening regular global meetings every 18 months

The convention of this meeting has been delayed by some organizational problems and especially the lack of financial resources. It was also felt inappropriate to convey another consultation while the report of the previous one had not yet been published. However the rule stands.

4. Establishment of expert database

So far around 40 people submitted their expertise to the database. Dr. Karto□lu reminded the audience that everybody should be included in the database which is multi-purpose. Information is not only used for filling positions or finding potential consultants but has a much broader scope.

5. New mechanisms to work closely with GAVI

We admit that nothing has been achieved on this front. Both groups are moral bodies but not legal entities. Thus it proved very difficult to set up formal groups to work on this issue.

2003 MEMBERS' SURVEY RESULTS : Claude Letarte, TechNet21 Forum Moderator

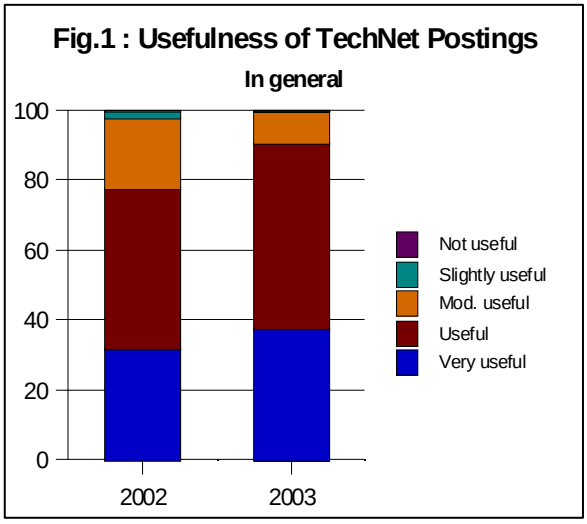
The results and analysis of the 6th annual members' survey conducted during December 2003 and January 2004 were presented. The final analysis was completed by Celal Kose, an independent consultant.

One of the main features of the survey is the low level of participation which did not reach 5% of membership. Such participation greatly reduces the level of significance and makes interpretation aleatory. Trying to explain would only lead to numerous and unverifiable hypotheses. However it is not considered a sign of decreasing interest in the forum.

This borne in mind, the overall level of satisfaction in terms of usefulness of postings has increased during 2003 compared to the previous year. A total of 91% of respondents rated them useful (53%) or very useful (38%), up from 78% in 2002 (see Figure 1. Below).

Technical information postings receive the highest rating and it also the type of posting that members wish to receive more, in a proportion of 59%.

The majority of respondents (80%) also find that the balance between links and attachments is satisfactory.



Only 13% of respondents think that the moderator should present editorial overviews or conclusions to discussions. Others identify an authoritative body, 44% think it is WHO's role.

Almost three quarters of respondents declared having visited the TechNet21 website prior to the survey. This is 19 percentage points more than last year. Increased utilization of the website is also confirmed by server's statistics.

The rating improved compared with last year, 87% of respondents find the homepage good or very good. And all other pages/corners receive a rating of combined "good" and "very good" above 60%. However the response rate for these ratings is even lower than for other questions.

The full document prepared by the analyst and the moderator's presentation can be consulted on the website at http://www.technet21.org/TechNetdocs.html

SESSION 1 : IMPROVING IMMUNIZATION COVERAGE

Chair: Ahmed Magan , UNICEF HQ

SESSION'S ACHIEVEMENTS

The objective and outcome of the session were the following :

Session objective: Discuss challenges and solutions in reaching hard to reach populations

Expected outcome: Agree on operational components of RED and its further implementation to overcome barriers to reaching every child.

Presentations highlighted challenges for Reaching Every District with immunization services. Particularly, the first presentation identified five specific challenges, follow up, documenting results, financial sustainability, system barriers, and the fifth is precisely reaching the hard-to-reach.

Some of the solutions were outlined such as national commitment for strategies and resources to reach hard-to-reach populations. This includes clear strategies to integrate other interventions for under-served communities and simple management tools for improving district capacity.

A presentation on one of the five operational components of RED, supportive supervision was also made. A few countries facing difficult circumstances, Tajikistan, VietNam, Afghanistan and Nepal, shared their experience with logistical planning for hard-to-reach populations and solutions that they implemented.

Finally participants were also informed of the results of an experimental study using a new technology the TT-Uniject to improve access for less accessible populations.
The RED strategy has been widely adopted by many countries with the collaboration of various partners. And the TechNet assembly did not question the strategy or its operational components. However some concerns were expressed about wastage rates in relation to improving coverage in hard-to-reach populations. Although the idea of supportive supervision was generally accepted, its sustainability as presented was questioned.

The TT-Uniject experiment raised more questions as it was not clear whether it had really made an impact on coverage. The acceptability of needlestick injury rates was also a concern. Consequently many aspects need to be further documented, in particular the real impact on immunization coverage, storage space, wastage rates, etc. and preferably in routine and outreach situations.

Opening the session, the Chairman remarked that there was no better theme than "Improving Immunization Coverage" to open the consultation meeting. Indeed after impressive progress in increasing coverage in the 70s and 80s culminating in the UCI achievements, coverage has since levelled off, even decreasing in a number of countries. The same proportion of children are left unimmunized as ten years ago.

It is now important that we review our thinking in order to meet the challenge of improving coverage by reaching every child in every district.

All discussions for this session took place at the end of the session.

REACHING EVERY DISTRICT (RED) : Julian Bilous, EPI Coordinator, WHO HQ

Presentation Highlights : Prepared by the presenter

BACKGROUND

« Reaching Every District » (RED) is the new name for a strategy of district capacity building to address common obstacles to increasing immunization coverage, with a district focus on planning and monitoring. There are five operational components at district level:

1. Re-establishment of outreach services : *regular outreach for communities with poor access.*
2. Supportive supervision : *on site training by supervisors.*
3. Community links with service delivery : *regular meetings between community and health staff.*
4. Monitoring and use of data for action : *chart doses, map population in each health facility.*
5. Planning and management of resources : *better management of human and financial resources.*

THE GOALS OF RED

The goals are consistent with the Millennium Development Goals set by the UN General Assembly Special Session on Children May 2002:

Ensure full immunization of children under one year of age at 90% nationally, with at least 80% coverage in every district or equivalent administrative unit by 2010; reduce deaths due to measles by half by 2005; eliminate maternal and neonatal tetanus by 2005, and extend the benefits of new and improved vaccines and other preventive health measures to children in all countries.

THE OBJECTIVES OF RED

Overiding Objective: Build national capacity from district level upward to maximize access to all vaccines, old and new, within national immunization schedules.

1 To fully immunize every infant in every district, building on the experiences of accelerated disease control initiatives.
2 To plan regular immunization sessions to reach all infants in every district with at least 4 contact per year.

3 To use immunization strategies to reach all the population with a special emphasis on under-served groups.
4 To monitor progress in implementing district plans regularly, and to take corrective action based upon the results.
5 To seek opportunities to add other interventions to immunization services, where feasible.
6 To make better use of existing resources.

MANAGEMENT PROCESS FOR RED

RED has a simple management process aimed at using district data to improve district immunization services. The planning cycle includes taking regular corrective action based upon regular problem solving discussions at local level.

The planning process is as follows:

< Regular, at least quarterly, compiling and ***analyzing*** district data to identify ***problems***.

< Deciding what ***corrective action*** is needed to solve the problems by using existing resources as far as possible, but including extra resources if needed.

< Adding the corrective ***activities*** to the workplan according to their ***priority*****.**

PUTTING RED INTO ACTION

At district and health facility level a series of steps are needed to put RED into action, by making an assessment, solving problems and making a new plan, (a coverage improvement plan). Some countries find that the best way to do this is to hold a series of workshops for district health staff where they can go through the steps using their own district data. The district staff can then repeat this with health facility staff during meetings and follow up supervisory visits.

Simple tools are required. The following list gives examples. (All these tools are described in the latest version of WHO's *Immunization in Practice,* see References).

< **Analysing** district/health facility data to assess current status and identify problems and solutions.

< Making a simple **map** showing population, communities, roads etc.

< Making **a session plan** showing how every community will be reached regularly.

< Making a quarterly **workplan** showing activities according to priority, with persons responsible and timetable, and including a supervisory visits schedule.

< Using a **monitoring chart** for regular review of progress.

< Establishing a system for **tracking defaulters.**

< Using a simple system for **stock/supply** recording and monitoring.

PROGRESS WITH RED

The strategy has been widely adopted by many countries with the collaboration of many partners. Guidelines have been distributed (see AFRO guidelines), intercountry and country workshops have been held.

District microplans are being implemented and funded in many countries. Coverage results are expected to become available during 2004. The list of countries who have been implementing RED

strategies is too long for this paper, however it includes countries in all African blocks, Eastern Mediterranean, South-East Asian, Western Pacific and European regions.

CHALLENGES FOR RED :

Follow up : Although many countries are implementing RED strategies in a variety of different ways, there is often insufficient follow up with technical support and supervision at district level.

Documenting results : Since RED is a strategy not an initiative or project, documentation of results is carried out at national level. However documentation needs to be more systematic to track progress towards national and regional coverage goals, and to facilitate sharing of experiences between countries and regions.

Financial sustainability : At present funding is often from GAVI/ISS finances, but these will not be sustainable in the long-term, and it is not always clear whether countries have included adequate financing for district level activitiesin their plans.

System Barriers : Progress in coverage is likely to be slow since it is largely dependent upon district development which is influenced by system barriers (staff, salaries, infrastructure etc.) which RED strategies cannot overcome.

Reaching the hard-to-reach : RED needs national commitment, for strategies, and resources to reach hard to reach populations. This includes clear strategies to integrate other interventions for under-served communities.

CONCLUSIONS

RED provides strategies and simple management tools for improving district capacity. The RED strategy has been developed particularly from polio experiences, and provides a method for improving routine immunization. Many immunization partners (UNICEF, CVP, USAID etc) have been closely involved in the development and implementation of the strategy. Since the RED strategy has a district focus, it is an opportunity for routine immunization and accelerated disease control initiatives to be incorporated into a single plan. The district focus also provides an opportunity for making practical links with other interventions (malaria nutrition etc.). The emphasis is on better use of existing resources (GAVI, polio, measles, MNT etc), rather than establishing a new project or initiative. Experience has shown that it is easy to do the initial orientation, but much harder to carry out the regular follow up needed. Further progress will depend upon systematically following and documenting results at district level.

REFERENCES:

WHO/HQ: Immunization in Practice 2004: WHO/IVB/04.06
WHO/HQ: Increasing Coverage at Health Facility Level: WHO/V&B/02.27
World Health Organization, Regional Office for Africa B AFRO: Implementing Red Approach, A Guide for District Health Management Teams

PUTTING SUPPORTIVE SUPERVISION INTO PRACTICE: REGIONAL PERSPECTIVE :

Modibo Dicko, WHO AFRO, presented in his absence by Suleymane Koné, WHO/Côte d'Ivoire. Prepared by Evariste Mutabaruka, Capacity Building Officer, WHO/AFRO

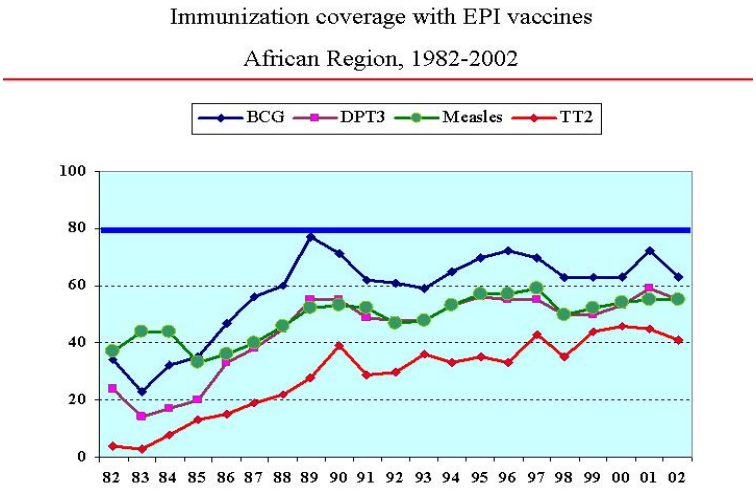
Presentation Highlights : Extracted from both the presenter's paper and presentation

BACKGROUND : WHY INTEGRATED SUPPORTIVE SUPERVISION?

Despite recognition of the importance of supervision in providing critical support for quality health services delivery and in managing human resources for health, all regional and country EPI reviews conducted during the past decade show that supervision is still weak and often not achieved in the majority of African countries.

While many factors are contributing to this poor situation, the main four merit to be highlighted

- Poor human resources management
- Lack of funding
- Supervision still tends to emphasize inspection and control by external supervisors
- Supervisors lack the requisite technical and managerial skills.



Evidence therefore favors a different approach to supervision in order to make it more conductive to improvement in health worker performance through **supportive supervision** which is one of the key components of AReaching Every District (RED)A strategy.

Since decentralization and integration of services are the major strategies of the health reforms and constitutional reforms have strengthen the role and the independence of sub-national levels, especially the district level, it is therefore recommended to implement integrated supportive supervision at this level.

WHAT IS INTEGRATED SUPPORTIVE SUPERVISION?

Integrated supportive supervision is a process guiding, supporting and assisting service providers to carry out their duties and assigned tasks in various components of the minimum package of priority health interventions at district level. It involves on-the-job transfer of knowledge, attitudes and skills between the supervisor and supervisee. This is a process of two-way communication, interaction, learning by doing and other interactive processes. It is implemented by many parties, including officially designated supervisors, informal supervisors, peers and health workers themselves. The external supervisor acts, as facilitator, trainer, coach and he/she had to be well skilled and experienced.

Integrated supportive supervision promotes quality outcomes by strengthening communication, focus on problem solving, facilitating teamwork and providing leadership and support to empower health providers to monitor and improve their own performance. Its objectives are: to make sure the health facility=s objectives are appropriate, to find out what is being done well, to help staff to identify and solve problems, to motive the staff and to improve skills of the staff. Conducted on regular basis, integrated supportive supervision builds partnerships with health workers to maximize quality of services as opposed to the traditional top-down approach of supervision. It increases accountability and helps health workers to see the progress in their work and to identify areas for improvement. It improves skills of health workers and provides on-site training on selected priority topics(mapping, micro-planning,using monitoring chart, vaccine stock ordering, monitoring of adverse events following immunization, safe disposal of waste equipmentY)

Furthermore, integrated supportive supervision involves communities in supervision process increasing demand for health interventions (e.g. immunization, IMCI, etcY). It opens opportunities for a Apeer supervision@ when other health facilities in the district meet to discuss progress and share lessons learned. It stimulates advocacy at province or central levels for supervised district or health center to get needed support for better performance.

PROBLEMATICS OF SUPERVISION: SITUATION OBSERVED IN THE FIELD

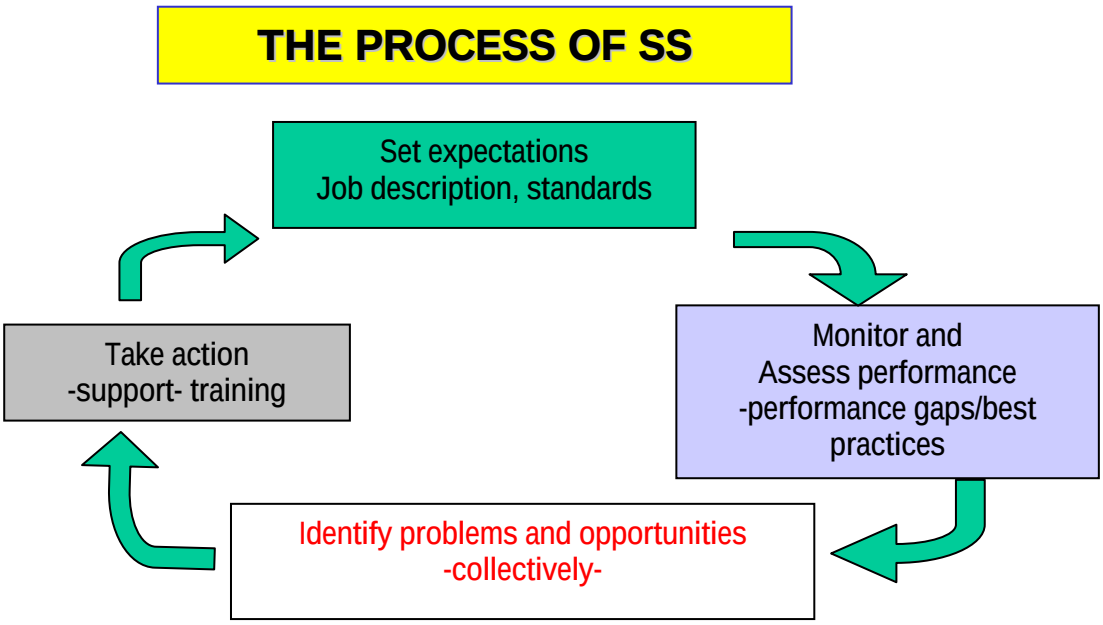
Reports from reviews, field visits, studies show many problems in the field; some of them shown below:

1. Service delivery and surveillance: Problems in monitoring and quality of data

2. Problems in injection techniques

3. Logistics: Problems in vaccine handling, refrigerator maintenance, inadequate supplies, waste management, etc.

4. Communication: Problems in inter-personal communication with care takers.



CHARACTERISTICS OF SS :

- Focus on problem solving to assure quality and meet client needs
- Collective responsibility of entire team (supervisor-supervisees) to ensure quality.
- Empowers health providers to monitor and improve their performance
- Supervisor facilitates, trains and coaches
- Supervisees participate in supervising themselves and each other
- Decision-making is participatory.

IMPLEMENTING SUPPORTIVE SUPERVISION IN TOGO

One visit per month is made per health centre by one DHMT member or a team of two, the DMO with either surveillance officer, the EPI officer or the midwife. The team uses the DHMT vehicle and motos and receives full perdiem while half-perdiem is paid to supervisees.

TOOLS FOR SUPPORTIVE SUPERVISION IN TOGO

Districts prepare and implement integrated supervision plans. Different guidelines and tools are in use in districts and supervision reports include observed strengths and weaknesses, and the supervisor's recommendations. Reports are kept in books at Health Facility level.

The training component is the weakest link because most supervisors are untrained.The training material is scarce and outdated: a few 1991 EPI Guide can be found in some USPs. Most supervisors have been in service for a long time and in-service training activities were interrupted a long time ago.

THREATS TO SUPPORTIVE SUPERVISION

District Health Management Teams are too small and overloaded, only one person carries for several responsibilities. The supervising staff is untrained, but there are no training or updating plans. Resource management is bad. Motos are under lease-sale contracts, but there are no renewal plans at the end of contracts. Finally one can ask the question: when payment of perdiem to super-visors and supervisees stops, will supervision stop?

OPPORTUNITIES FOR SUPPORTIVE SUPERVISION

A guide called “Procedures & Norms of Integrated Supervision” is being published by central level. GAVI funds and those generated by cost recovery may be partly used to fund supportive supervision. Many partners are extending their support GTZ, Plan Int’l, Red Cross, UNICEF, WHO, etc.

WAY FORWARD: PREREQUISITE FOR SS

- Have a common understanding (all stakeholders)
- Mobilize resources as needed: common basket (all health programs)
- Update norms/standards/job descriptions
- Adapt integrated SS check-lists and job-aids
- Refresh supervisors (polyvalence!)
- Put in place all pre-requisite conditions (functional health care delivery system with appropriate logistics and competent human resources)
- Build on success
- Ensure regular monitoring-evaluation and follow-up.

LOGISTICAL PLANNING FOR HARD TO REACH POPULATIONS: CHALLENGES AND SOLUTIONS

Shamsiddin Jabirov, MOH Tajikistan presented by Sergeï Deshevoï
Nguyen van Cuong, MOH Vietnam
Shyam Mishra, MOH Nepal (not presented)
Alejo Bejemino, UNICEF Afghanistan

Presentation Highlights :

Tajikistan : Planning for hard to reach populations: challenges and solutions.

Extracted both from the presenter’s paper and presentation

BACKGROUND

There were major achievements by the National Immunization Programme : diphteria has been brought under control and measles outbreaks occur with lower incidences however at same intervals.

The polio-free status was achieved in June 2002 and Hepatitis B vaccination was introduced in maternities in 2002 and for all newborns in 2004. However coverage surveys have indicated a significantly lower coverage than routine administrative data[1] and there is evidence of low-coverage areas from :

- Measles surveillance data.
- Reports from NGOs pointing to under-estimation of the target population.
- Polio NIDs vs. routine immunization data.

MAJOR CHALLENGES IN IMMUNIZATION PROGRAMME :

Sustainability of the programme (human and financial resources) is the main challenge in the context of competing health priorities and reforms and a changing socio economic environment. Besides a home delivery rates varying from 6.2% to 63.2% is considered a threat.

VACCINE DELIVERY STRATEGIES

A recent initiative through the National Immunization Programme 2003-2010, is at a very initial phase.The Programme defines three basic models for immunization service delivery:

- Fixed health facilities : Daily basis or scheduled
- Outreach services
- Mobile teams

There is a pilot project in collaboration with the World Bank and since 2003, Tajikistan is a “RED” pilot country

MAJOR STEPS FOR MICROPLANNING :

The district immunization plans are the result of four main activities :

First the design of district maps

Second the compilation and analysis of data to assess situation using administrative coverage reports at all levels, results of surveys, programme reviews, DQAs, etc.

Third the decision of the delivery strategy for each village

And finally the preparation of an immunization workplan for every health center.

The delivery strategy depends upon certain characteristics of the population or community, as seen in the following table :

DELIVERY STRATEGIES FOR "HARD-TO-REACH" POPULATIONS	
Remote or nomadic populations	Outreach or mobile teams
Inadequate services or facilities	Outreach
Inadequate community participation	Outreach or home-based
Seasonal or permanent geographical obstacles	Mobile teams

[1] The status of women and children: Tajikistan, 2000. Multiple Indicator Cluster Survey. UNICEF, 2001

Meanwhile, training at 1st admin level was implemented using tailored to EURO and country needs EPI Mid-Level Management, Immunization in Practice, and Safety of immunization training materials. Six pilot districts defined to develop the microplans

Implementation of the strategies faces many challenges. Identification of “hard-to-reach” population is one. Supplementary immunization activities for polio and measles provides useful data. Information also comes from various organizations and stakeholders (State agencies, WHO, UNICEF, NGOs, Aga Khan Foundation, National Red Crescent Society, etc.). The problem is compounded by the fact that many people do not declare births to avoid “birth registration fee” and reduce out-of-pocket payments. Health education for the public helps counter this problem.

Ensuring safety of immunization is another challenge. Training, monitoring and supervision are key elements to ensure safety. Health staff in Tajikistan is under pressure to increase immunization coverage while reducing wastage rates. So they keep vaccine vials for as long as possible. This has lead to a number of serious AEFI including deaths, as in neighbouring countries. So reaching a better balance between multi- and single-dose vials is a small cost for ensuring higher coverage and maximum safety. Advocacy for staff conscientiousness and encouraging them to discard vials at appropriate time also plays an important role.

A third challenge is supportive supervision and monitoring. 6 sub-national immunization centers were created along with immunization centers in every district. Their staff is responsible for monitoring and supervision. Integration of other interventions such as malaria control increases attractiveness of services. The terns of reference for surveillance mobile teams have been revised to stress supportive supervision. Incentives (e.g. per diem and recognition of training) have been also designed to support supervision.

And the fourth major challenge is unreliable logistics & maintenance systems. Tajikistan is committed to keeping a centralized procurement system. But more responsibility and accountability is delegated to local health authorities (e.g. chief medical doctor) along with training and involvement of local staff in cold chain/logistics.

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Viet Nam : Implement EPI in Remote Areas

Extracted from both the presenter’s paper and presentation

BACKGROUND

EPI was introduced in Viet Nam in 1981 with the cooperation of WHO and UNICEF. After a trial period and gradual expansion since early 1986, the EPI was extended to the whole country and the goal of Universal Childhood Immunization (UCI) was achieved in 1989.

Challenges faced by Viet Nam is reaching hard-to-reach populations. These are defined by those criterias, all or in part :

- Low population density
- Most of people there are ethnic minorities and without ethnic writing
- Low education level
- Limited roads
- Different kind of transportations, even walking
- Poor
- Fishing (boat living)
- Migration

Out of 10,768 communes, 95% are performing regular monthly immunizations, 5% are performing periodic 2 – 3 months per year include campaign immunizations in some commune. The last “white” commune, i.e. commune where immunization services have not been conducted was in 1995. These are located mostly in remote mountainous and difficult-to-reach areas.

For these communes, a number of solutions are being implemented :

- Village health workers are posted (nurses training 3 - 9 months)
- Increased number of trained health workers on EPI
- Health workers come from district levels during immunization session
- Cooperation with health workers in the army
- Other: leader of village, Red Cross, women union,... are involved
- Conduction immunization session by different types
- Increase number of immunization days
- Outreach immunization sessions
- Mobile teams (house to house, boat to boat)

LOGISTIC FOR HARD-TO- REACH POPULATIONS

Increased budget is one of the main solutions. With the limited fund from local government, the fund from central government for remote areas is at least two times more compared with other areas. Higher wastage rates (vaccine, safe injection equipment) are acceptable. In some mountainous provinces they were very high (BCG: 88%; DPT: 66%; measles: 71.4%). Cold boxes are set up for a group of CHCs : one of the ways to store vaccine at commune health centers for routine immunization was in a cold box at one commune health center usied for a group of communes. Vaccines stored in this cold box will cover requirements of EPI vaccines for some communes for some days.

With support from Luxembourg government 2000 refrigerators were distributed for 2000 difficult communes in 2003. In the plan 2000 refrigerators from Luxembourg government will be distributed in 2004. The number of vaccine carriers was increased.

There were special communication efforts. Specific audio and visual materials for ethnic minority groups should be designed and used for social mobilization of these population groups.

Finally, pilot districts have been designated in 13 mountainous provinces. Through these pilot districts, EPI is gaining experience and learning useful lessons. A workshop on improving immunization quality for these 13 most difficult districts in 13 mountainous provinces was conducted in 2003. These districts will become a model for other in future. One of the priorities for improving routine immunization is increase the rate of commune with immunization session monthly. This will be the basis for collaboration with health in the army as only by collaboration with army health workers can the number of villages conducting immunization sessions every 2 – 3 months or 3 months per year be reduced.

Nepal : Logistics Management in Rural Areas ; Challenges and Solutions

BACKGROUND

Nepal is a land-locked country. It is divided into three ecological regions, Mountain (16), Hill (39) and Tarai (20), most of the population resides in Tarai. Nepal has many hard-to-reach areas with many remote districts dominated by traditional cultural taboos where marginalized and deprived people reside.

Nepal being a developing country is facing great challenges for poverty, illiteracy, cultural taboos and insurgency for more than 10 years. All these factors have not only affected the development of the country but also the responses for core health activities.

In spite of challenges and geographical constrain Nepal is having very good coverage for routine immunization. There are certain challenges, which have negative impact on RI coverage. The conflict district and the problem of retaining health personnel have affected supplies and implementing the vaccination program. For better coverage of the program Nepal has developed certain tools, which are being implemented in low coverage and conflict districts.

PRIORITIZATION OF DISTRICTS ACCORDING TO CONFLICT, COVERAGE AND DROP OUT RATES

- Additional activities in conflict and lower performing districts (micro-planning, review meeting of health workers, VDC's data, training of all EPI supervisors, orientation for community health volunteers)
- Quarterly meeting of EPI related staff
- Strengthening supervision and monitoring from region and center

Nepal has very well established infrastructure for health (from top to bottom) and Human Management Information System (HMIS). This has helped in flow of information for planning and implementation.

Nepal has identified major cause of infant mortality "the six killer diseases". Vaccines can prevent these diseases, being main cause for high IMR in Nepal. BCG, DPT, Polio, Measles and newly introduced Hep.B vaccine are the vaccines given to < 1-year infant.

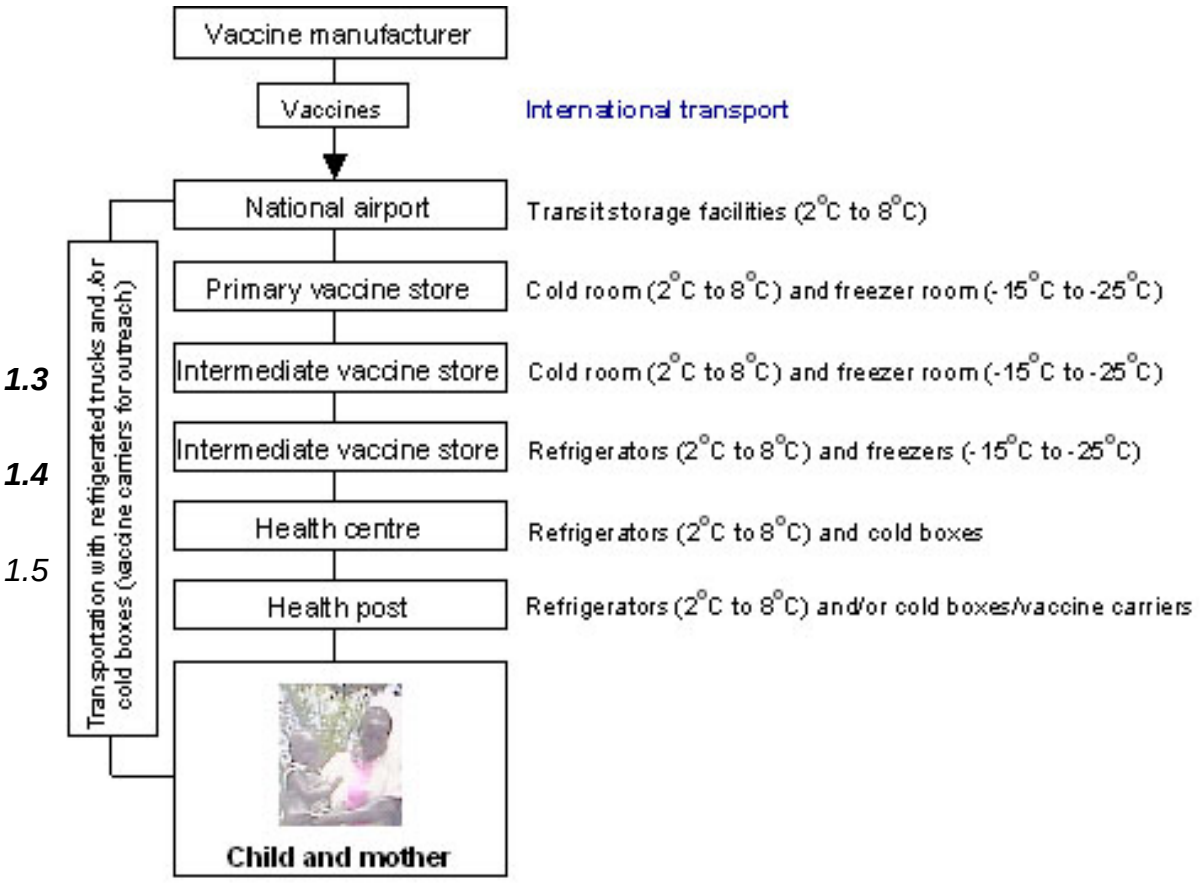
BCG	0 – 1 Month
DPT	6, 10, 14 Weeks
Polio	6, 10, 14 Weeks

Hep.B	6, 10, 14 Weeks
Measles	9 Month

Very soon Nepal is conducting a mass campaign for measles vaccine for second opportunity in Routine Immunization.

Target population for vaccinating <1 year infants are set by HMIS, and they are near about 750,000. Vaccine calculations are done accordingly and sent from central to region and, district store. The supply of vaccine needs very good vaccine and cold chain management system, because vaccine has to be sent to all over Nepal and maintain its temperature. Each antigen is calculated according to target group for each district for supply of vaccines, diluent, AD and disposable syringes, safety boxes and other accessories. EDP's through UNICEF supplies the vaccines, we collect it in custom and store it in central store maintaining its cold chain. In the same way vaccine are sent to five regional stores where they supply to each of the districts and district sends it to PHC, HP, Sub centers, SHP.

The vaccine supply is for Routine Immunization and for National Immunization Day (Polio Eradication). The supply of vaccine is same for RI and NID's. Because of geographical constrain, conflict district and hard to reach areas different strategy are made for different districts during supply of vaccine. In mountain, hard to reach areas and conflict district vaccine is send first where there is very little or no access. There is no problem in tarai because of access but some time has to face rain and flood. Generally the vaccine and other accessories are supplied by airplane, helicopters, vechiles, animals back, man as a carrier and some time curare (?).



The one working in remote areas are having very good relation with airport staffs and have no problem for supply by air or helicopter. But some times during banda and conflict situation the plane does not fly and vaccine are left in airport and the health staffs are very alert for the CCM. In that situation some times difficulty is there to send the vaccine in time and you have to hire an animal to carry the vaccine and some times even you have to hire a man.

It is seen even in conflict areas the person involved in conflict situation come and help to vaccinate the infants. They are very much motivated and they know that if vaccination is given in time and immunize their infants they can save their infants from unwanted death.

CONCLUSION

Being a developing country there are many challenges which a health personnel has to face for better achievement of the Routine Immunization coverage and Nation has to suffer from high IMR/MMR.
Due to insurgency at present days the health personnel do not want to stay in their health institution. Many infants are deprived of getting vaccine. Community people are not aware of complete immunization and thus there are more drops out rates and big challenges are for the wastage rate as well. To achieve the global goal for 90% routine immunization coverage certain tools has been developed and certain polices has been indorsed by the Government. Microplanning is one of the most suitable tools for improving the RI coverage and reducing the drop out rate. Multi Vial Policy, Safe injection practices and disposal of sharps.

Policy for Adverse Event Following Immunization (AEFI) in fact has played a vital role for better implementation and awareness of community people for the acceptance of vaccinating their infants.

Afghanistan : Logistical Planning for Hard to Reach Populations : Challenges & Solutions

BACKGROUND

This presentation will discuss issues related to the measles campaign. For several years Afghanistan has been implementing immunization services and for most antigens the EPI coverage for the last four years has remained low in the 35-45 % range. With this low coverage WHO Geneva estimates that out of 986,568 surviving infants in Afghanistan in 2001 about 690,000 children will get measles. With low estimate of case fatality of 5% one would expect approximately 35,000 measles deaths in 2001. With the poor nutritional status of children and lack of basic services in Afghanistan it is expected that the measles deaths are higher.

Overall goal: To contribute towards reduction of child mortality and morbidity through reduction of measles mortality by 95 %.

Objectives: To give one dose of measles vaccine to at least 90% of children aged 6 months to 12 years regardless of immunisation status and previous history of measles.

To reach children and families previously unreached by routine immunisation services.

To improve surveillance for measles cases and deaths.

STRATEGIES FOR ACHIEVING SUSTAINABLE REDUCTION OF MEASLES MORTALITY:

Achieving and sustaining high population immunity through :

- Routine Immunization
- Second opportunity through SIA
- Measles surveillance

STRATEGIES FOR SECOND OPPORTUNITY THROUGH SIA, MEASLES CAMPAIGN:

- EPI micro planning
- Staff training
- Social mobilization
- Logistics
- Timing and phasing

LOGISTICAL PLANNING FOR HARD TO REACH POPULATION

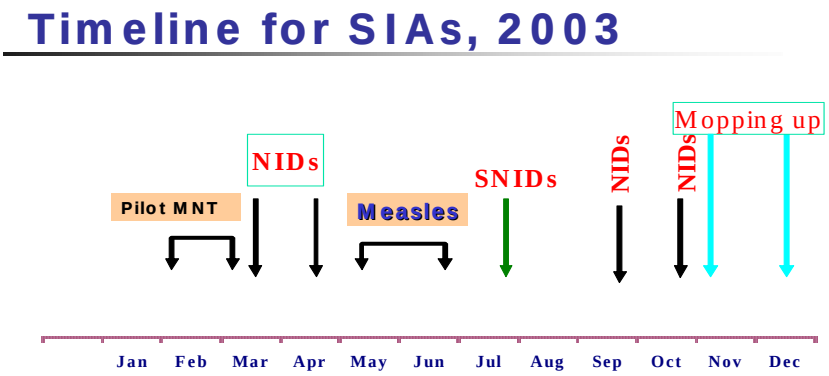
Vaccination supplies, cold chain equipment & social mobilization materials were the major concern of logistics for hard to reach populations. All of these were determined by field staff during the process of micro planning at cluster level.

Vaccines are delivered directly to Kabul, but other vaccination supplies such as syringes go through Pakistan and are transported by road. From Kabul, everything is transported to the regional level and then to the provinces and finally the districts by use of any convenient and available means of transport.

Distribution Plan of Supplies

Sn	Supplies	National level	Regional level	Provincial level	District level	Campaign week
		Week #				
		1	2	3	4	
1	Cold chain equipment					
2	Social mobilization matls					
3	Vaccination supplies					
4	Vaccines/Diluents					

The figure below shows the timeline used in the planning process. Throughout the year, there are many activities, MNTE activities, measles campaign and SIAs. So the timeline is used not to interrupt other activities.



MAJOR STRENGHTS OF THE SYSTEM :

The system benefits from strong support and commitment from the Ministry of Public Health. Campaigns are better planned and timed. Partnership between NGOs, government, WHO and UNICEF is strong. The role of REMTs and PEMTs has been critical. Required logistic and funds have been supplied in a timely manner. School teachers were massively involved as volunteers**.**

PROBLEMS ENCOUNTERED DURING IMPLEMENTATION :

Generally, the high mobility of the population, especially the continuous migration of the nomadic population is a major constraint to reaching the target population. Another problem is frequent shortages of vaccinators, together with the limited number of health workers in some districts. Climatic conditions is the third limiting factor with specially cold weather and road blocking at the beginning of MMRC.

LESSONS LEARNED :

Campaigns with an extended age range is possible and there is a window of opportunity between NIDs. Actually, there was no perceived negative impact on NIDs. Even NID greatly assisted measles micro-planning with validation of population figures. The result is that measles transmission appears to have been reduced.

MAJOR CHALLENGES :

Access to mobile population and refugees, and covering districts which are inaccessible during the winter season remain the major challenges. Older girls may also be harder to access for cultural reasons and this may require specific social mobilization messages. Screening of children during

redoing phase proves difficult. On the managerial side, injection safety, waste disposal and computerised inventory are the main problematic areas.

IMPACT OF DELIVERY TECHNOLOGIES ON INCREASED ACCESS: UNIJECT REPORT FROM MALI

Robert Steinglass, BASICS, USA, prepared by Lydia A. D'Alois, Operations & Evaluation, BASICS

Presentation Highlights : Extracted from the presentation and the study report

The goal of the experiment was to assess the impact of using a TT-Uniject as an adjunct to regular program in areas with populations that are less accessible. The experiment used prefilled TT-Uniject single-use devices that combines an AD syringe and a fine, small needle individually packaged with heat-sensitive indicator (VVM).

STUDY PURPOSE :

The purpose of this study was to determine whether TBAs as community-based volunteers (CBVs) were capable of using TT-Uniject, and whether clients would be satisfied with having CBVs, who are non-health persons, administer vaccine. Three indicators were employed:

1. percentage of CBVs who correctly used Uniject device;
2. percentage of CBVs' clients who were satisfied with having a non-health volunteer administer the TT-Uniject; and
3. as additional evidence of community acceptance, no difference in either T1 coverage or in drop out rate (DOR) between the two study districts and the four non-study districts, everything being equal.

PROGRAM METHOD

1. Approach for incorporating volunteers into administering TT injections :

   - Vaccinators would be volunteers who are TBAs.
   - They would be selected by their respective community, that is they would be community-based volunteers (CBVs).
   - CBVs' capacity would be tested during MNTE campaign held in 6 districts, using TT-Uniject in 2 districts accessible for supervision and with typical coverage, and AD syringes with multi-dose vaccine vials in the 4 other districts.

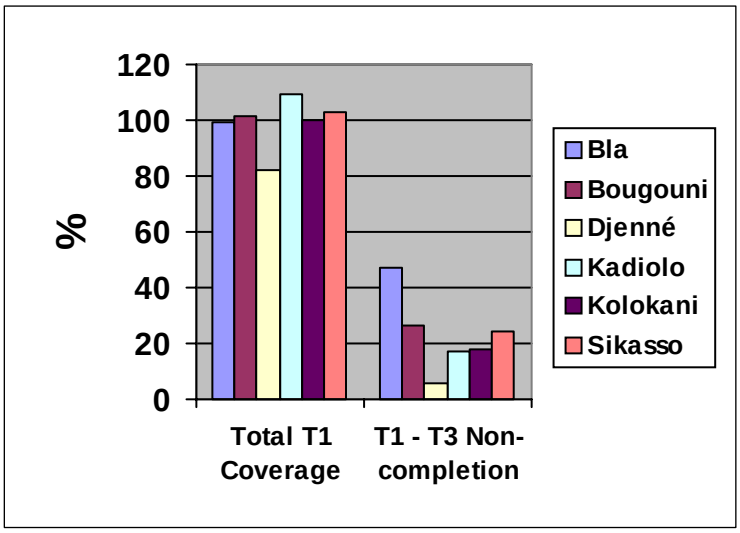
2. Selection of CBVs: District health officer (DHO) requested Area Health Officers (AHO) to talk to town chiefs to select local CBV to be trained to vaccinate reproductive-aged women with TT-Uniject:

   - One CBV per town
   - Selection based on 3 criteria:

- acceptability by the majority of townspeople
- physical capacity to use UNIJECT
- interest in participating in the activity

3. Training of CBVs :

- TOT fashion: 2 national trainers - each trained a DHO and the AHOs of a single district. In turn, AHOs trained their own CBVs.
- First training was for 2 days (before 1st MNTE round, June 2002).
- Nominated CBVs who were unable to perform during 1st training were deselected.
- 1 day refresher session preceded 3rd round (2/03).



EVALUATION METHOD

While T1 coverage and DOR were assessed as a routine activity of the campaign, additional data were collected for the first two indicators, namely, CBV performance and acceptance of them by the community. These data were collected by a combination of observations and of interviews, both individual and group. Observations were conducted during the campaign and focused on CBV performance and the environment of the vaccination site. Interviews were with key informants, CBVs and their clients, and with health staff.

The figure above shows the total % of women with T1 after the 3rd Round and T1 – T3 non-completed vaccination, by district (TT-Uniject districts, Bla and Bougouni, are first 2 on left).

1. Summary of Data Collected in TT-Uniject districts

Data Collection by	Method	Data Collected from	Date
Interviews	Individual	Key informants: DHO and other persons involved with MNTE	October, 2002
	Individual	CBVs	February, 2003

	Individual	Clients of CBVs	February, 2003
	Group	CBVs	February, 2003
	Group	Health staff	February, 2003
Observations	Individual	CBVs	February, 2003
Coverage and drop-out	Campaign monitoring tools	Data reported by district to MOH immunization office	June, 2002; July 2002; February, 2003

2. Performance indicator (PI) to measure % of CBVs who correctly used TT-Uniject, based on 8 tasks:
   1. Correctly determines vaccine vial monitor (VVM)
   2. Easily opens package
   3. Correctly activates device
   4. Uses sterile technique
   5. Injects in correct body location
   6. Completely empties reservoir
   7. Does not recap needle
   8. Places device directly into sharps container

1.6 RESULTS (Some key elements only)

1. Perception of the community's view : Townspeople agree to having CBV vaccinate. A third of Area Health Officers in Bla, and almost all of Bougouni's thought this. Yet the survey showed 9 out of 10 clients would return if CBV were vaccinating and/or if UNIJECT were used. CBVs thought that their participation helped reduce rumors, but AHOs thought that it didn't.

2. Stated advantages of having CBVs : Both AHOs and CBVs thought it increased coverage because CBVs mobilize the population and they know who's missing. AHO's said it reduces their (immunization) work load, allowing them to do other things (that CBVs can't do).

3. Performance Indicators:
   - 4 out of 10 successfully executed all 8 tasks
   - 9 out of 10 : - Used sterile technique
     - Injected at correct arm site
     - Didn't recap needle
     - Correctly disposed of the device
   - The task that posed the most difficulty was emptying the reservoir – 1 out of 4 did not completely empty the reservoir.
   - 8 out of 10: - easily opened the package
     - easily activated the device
     - correctly made a decision using the VVM

- Mean performance indicator (MPI) was 7.1 out of possible 8.0 (SD=1.1).

4. Injection Safety : 99% of the CBVs disposed of the Uniject in a safety box but 5% admitted to having stuck herself (but not someone else) at some time with the Uniject needle.

5. Client Satisfaction:
   - 4% said this was her first injection
   - 3 out of 4 had previously received injections and said the injection that day was less painful
   - 8 out of 10 thought it was good to have the CBV do the injection (6% didn't think so)
   - Virtually 100% said she would come back for a vaccination given by the CBV, for a vaccination with Uniject or both.

CONCLUSIONS

Several major findings were provided by the Mali TT-Uniject study:

1. Injection with TT-Uniject was correctly administered by female volunteers selected by their communities to participate in the campaign. Most of these volunteers were TBAs or apprentice TBAs.
2. Correct administration of TT-Uniject occurred despite the fact that at least half of the volunteers could not read.
3. CBVs administering TT-Uniject applied safe injection practices. This conclusion was supported by data from diverse sources, including observation and interview, which consistently showed that the community volunteers applied safe injection practices.
4. CBVs administering TT-Uniject were socially accepted.
5. Significant performance differences in administering TT-Uniject existed among study districts, much or most of which seemed associated with the amount and approach to training.
6. Having administered injection with Uniject had no association with volunteers giving other injections afterward.
7. TT-Uniject was accepted by women in Mali.
8. Health staff thought that having CBVs give the vaccination could reduce their work burden, allowing them to do other activities, which cannot be done by lay people.
9. Both health staff and CBVs believed that the involvement of CBVs would improve TT coverage.
10. Both health staff and CBVs thought that the CBVs could administer TT-Uniject in the context of routine vaccination.
11. The suggested structure for incorporating CBVs into the routine vaccination system was to have the AHO serve as her supervisor and have the community health worker serve as the liaison between the AHO and the CBV for the purposes of restocking the CBV with TT-Uniject and transmitting data to the MOH.

NEXT STEPS

The major next step is to create a strategy and implementation plan for incorporating into routine vaccination the TT-Uniject administered by CBVs who are community volunteers. Such a plan needs to take into consideration differing scenarios, including which health areas and villages will use this approach and which will not, and which health areas have all deliveries in a MOH facility. Creation of a decision algorithm based on current coverage rates, drop out rates, accessibility, and social factors may facilitate decision-making by region and by district. Many other facets need to be considered as well, including, for example, the logistics of delivering Uniject to the district health offices[1], changing roles of CBVs, distribution of Uniject to community volunteers, restocking volunteers with TT-Uniject, data management, and supervision of the community volunteers.

The Mali Uniject study showed that the door is open for the MOH to safely extend vaccination services into a population that accepts the volunteered services of CBVs to vaccinate using TT-Uniject.

The full report is available on the BASICS II website

DISCUSSION AND CONCLUSION

Comment : In relation with the RED strategy, concerns were expressed about wastage rates. There seems to be antagonistic strategies as health workers are trained to reduce wastage. But better planning will likely result in less immunization sessions also to reduce wastage further with the consequent risk of a negative impact on coverage.
Response : Vaccine wastage should not be considered in a vacuum and always be assessed in relation with coverage rates. The WHO document "Monitoring Vaccine Wastage at Country Level" (WHO/V&B/03.18) offers guidance on how such relation should be interpreted.

Comment : Reaching the hard-to-reach is only one aspect of the goal as they have to be reached in a timely manner. Poor access was just as likely to be a feature of large urban areas as rural areas, innovative strategies for reaching the hard-to-reach in large cities are needed.

Comment : We hear much about how health systems can better reach the population but little about how the population will use services. We should make more efforts to understand what are the fears and reservations that people have in order to develop an active process for seeking services.

Comments : Several participants expressed concerns about the sustainability of the method of supportive supervision presented. The extension of a half-perdiem to supervisees casts doubts about the sustainability of such a system. Supervision is often poorly resourced, and

[1] Our experience with the first round showed that one needs to keep in mind that the heat of the desert environment of Mali may necessitate logistic management that is not required in more moderate

efforts should be directed more at managing supervision better with existing resources. However the ideas of supportive supervision, though providing training on site are generally accepted. More country experiences will be needed to understand the best practices with supportive supervision.

Most questions were directed at the UNIJECT experience.

Comment :There are concerns that the impact measurements were not demonstrated by the study, because coverage does not seem to have been affected.

Question :It was not clear that the technology had made a difference to routine TT immunization since it was carried out during a supplementary immunization campaign. Can this be indeed carried up with routine services?
Response : It had been the wish to test the hypothesis in a situation of routine activities but it proved premature. The ICC offered much resistance, concerned with the use of CBVs to deliver vaccination services.

Question : While it seems that UNIJECT was well received by the community there are still some handling problems for the community-based volunteers. 25% of the volunteers could not completely empty the reservoir.
Response : Manufacturers overfill by design to compensate.

Question : Needle stick injuries were estimated at 5% but this was over a relatively short period. This may be higher if it were on a longer period or when ordinary syringes are handled ?
Response : There should be a debate and guidance from TechNet21 and WHO to reach a consensus on what should be an acceptable rate. On balance the study had achieved its goal of demonstrating the acceptability of community-based volunteers as vaccinators.

Question : There is also a need to field-test monodose presentations in outreach services but the impact on storage space and costs must be carefully evaluated.
Response : There is no generic answer to this question as it will vary from country to country depending on local conditions. It is clear that there are implications on cold chain, vaccine storage, wastage, etc. PATH has published a cost study in Indonesia in an issue of the WHO Bulletin in 2003. The trial in Indonesia will continue and a trial of HepB UNIJECT is in progress in China where the device will be kept in TBAs' homes to be administered to newborns. These will yield further information on coverage impact and other aspects.

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climates.

SESSION 2 : INJECTION SAFETY

Chair: Paul Mallins, WHO HQ on behalf of Modibo Dicko, WHO AFRO

SESSION'S ACHIEVEMENTS

The objective and outcome of the session were the following :

Session objectives: Review update on progress and activities in injection safety and waste management.

Expected outcome: Agree on concrete actions to implement best practices for small scale incinerators.
Agree on next steps for possible adoption of needle removers.

The session objective was met through all three presentations. First participants were given an overview of global efforts for the safe and appropriate use of injections worldwide. Progress achieved by the Safe Injection Global Network in recent years was reviewed as well as tools developed to assist managers with policy and practices for the safe and appropriate use of injections.

Options and directions for waste management were also presented. Even if there are no perfect options, technical options are not the problem. Tools exist but are under used, and implementation is the real issue. Recommendations on small-scale incineration / emission of pollutants such as dioxins and furans were not presented at the meeting but added to this report.

Finally the needle-remover technology was presented with the knowledge that no well-controlled data documents the system level cost, or safety of needle removal devices nor the impact on waste management in developing country settings. Field trials are necessary and next steps/action points were identified.

Regarding outcomes, the meeting couldn't agree clearly though on concrete actions to implement best practices for small scale incineration. Further resources may have to be devoted to waste management and staff training was identified as a concrete need. It may have to wait until WHO presents assessments and positive experiences which are in the process of being summarized, so clearer avenues will be traced.

Further field assessments of needle-removers are needed and will be carried out following WHO specifications. There were some concerns that needle-removers are to be studied only during measles campaigns but generally the next steps as presented were not challenged.

Discussions for this session followed each presentation.

FEEDBACK FROM SIGN : Sophie Logez, WHO HQ

Presentation Highlights : Prepared by the presenter

Global efforts for the safe and appropriate use of injections worldwide

WHO safe and appropriate use of injection strategy and the SIGN alliance

WHO developed a strategy to ensure that special attention is paid for the safe administration of all types of injections in health care services. WHO build national capacities to manage injection safety policies through generating data for decision making and developing technical tools.The Safe Injection Global Network (SIGN) is an international coalition of stakeholders who consider that poor injection practices waste precious health care resources, expose patients, health workers and communities to unnecessary risks, transmit pathogens on a large scale, reduce productivity through an unacceptably heavy burden of disease and can easily be avoided. Participants in the SIGN alliance include nongovernmental organizations, United Nations organizations, associations, governments and the Industry. A secretariat based at the World Health Organization facilitates the work of the SIGN alliance.

Ensuring quality and safety of injection devices

WHO developed technical tools, including a quality assurance guide to assist procurement officers, project managers, regulatory authorities to ensure quality and safety of injection devices. The International Organization for Standardization (ISO) agreed to work with WHO on a new standard for hypodermic syringes with a reuse prevention feature for general purpose (projected ISO standard 7886-4), while the committee is finalizing the draft standard for auto-disable (AD) syringes for immunization that is labeled ISO 7886-3, “Sterile hypodermic syringes for single use – part 3: Auto-disable syringes for fixed dose immunization.” Before the ISO standards become available, WHO will continue providing procurement specifications and laboratory test procedures. When the ISO standards become available, WHO will refer to them.

Proposed WHO pre-qualification procedure for the procurement of injection devices by United Nations agencies[1]

WHO and other United Nations (UN) agencies may have a role to procure single use injection devices as potential supply agencies for developing countries. The purpose of the quality assessment for single use injection devices is to verify that injection devices meet the specifications of the relevant UN agencies and are produced and controlled in accordance with product standards or WHO procurement specifications and quality system standards recommended by WHO. The assessment will determine reliable sources of procurement of single use injection devices to ensure quality and to guide other UN

[1] Procedure for the assessment, in principle, of the injection devices for procurement by United Nations Agencies. Geneva: World Health Organization, 2003; WHO document WHO/BCT/03.09.

agencies in sourcing of such devices. The quality assessment procedure is based upon three main principles,

(1) conformity with the UN agencies specifications and ISO product standards and/or WHO template specifications;

(2) documentation of the quality system in place for production of medical devices

and (3) a pledge to collaborate with WHO on complaints from the field and/or from UN agencies.

At present, the proposed procedure relies mostly on the regulations formulated by the five founding members of the Global Harmonization Task Force (GHTF), as most developing countries do not have national regulations for medical devices. WHO will assess all manufacturers who wish to have their products pre-qualified for procurement of single use injection devices by UN procurement agencies. WHO accredited laboratories will continue testing auto-disable syringes according to WHO procurement specifications until the ISO standard is finalized and approved.

Ensuring equitable access to injection devices

- *Guiding principles to ensure injection device security in health care settings*[1]

Ensuring sufficient and continuous access to single use injection devices is a key element of any strategy to achieve the safe and appropriate use of injections. WHO recommends that injection device security is ensured in all health care facilities, including therapeutic services, so that injectable medicines, appropriate diluents, single use injection devices for injection and reconstitution and safety boxes are supplied in timely manner in adequate quantities. In curative and preventive services, ensuring injection device security implies appropriate forecasting, financing, procurement and supply management so that the mentioned items are available in adequate quantities. This procurement policy does not imply that items mentioned above must be physically packaged together, but ultimately these items should be available in timely manner in health care facilities. WHO requests all donors and lenders who finance injectable products (i.e., vaccines, contraceptives and medications) also to finance appropriate quantities of single use injection devices, single dose diluents, safety boxes and the cost of sharps waste management. Ministries of health, donors, lenders and partners who are active in the health sector, including in essential medicines programmes, are invited to endorse these recommendations.

- *Procurement guide for injection devices*[2]

The objective of this guide is to assist pharmacists, physicians, procurement staff and programme managers through the process of procuring single use injection devices and safety boxes of assured quality, on a national or international market, at reasonable prices. This guide describes how

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[1] Guiding principles to ensureiInjection device security. Geneva: World Health Organization, 2003. WHO document WHO/BCT/03.12.

[2] Procuring injection equipment and safety boxes. Geneva: World Health Organization, 2003; WHO document WHO/BCT/03.04. http://www.who.int/injection_safety/toolbox/docs/en/Procurement.pdf

standardized procurement procedures for medicines and medical devices can be used to ensure the procurement of injection devices and safety boxes.

- *CD-Rom toolkit, including a behaviour change strategy*

The WHO CD-Rom toolkit on injection safety contains all the tools needed at the global, regional and national levels to benchmark, assess, implement and evaluate a national policy for the safe and appropriate use of injections. The user is guided through the toolbox according to his primary interest (physicians and injection prescribers, nurses and injection providers, public health specialists and communities). The CD-Rom also contains a pictogramme bank, an image bank and a search tool.

Recent initiatives for scaling up injection safety plans

A number of initiatives have emerged in the last months to support scaled up efforts for the safe and appropriate use of injections. First, the United States presidential initiative for HIV AIDS in 14 countries of Africa will include an injection safety component funded with US$ 29 annually for five years. Second, India completed a national assessment of injection practices in 2003. Publication of the results at the end of 2003 lead to major policy decision to switch to auto-disable syringes in the country.

Maintaining leadership for the future

Today, the evidence base of the WHO injection safety project has been consolidated. The tools for policy management were developed and the level of international awareness is high. However, little implementation of national plan has happened. Thus, there is a need to identify the steps and processes to scaling up national initiatives.

More information on injection safety is accessible on the WHO Injection Safety internet site (http://www.injectionsafety.org) which includes a toolbox of resources to assist in the management of national safe and appropriate use of injection policies.

DISCUSSION

The discusion opened with a statement by WHO to congratulate all people involved with SIGN for their tremendous achievements in the last four years. Actually Technet members should also be proud as it gave birth to SIGN from the Consultation held in Copenhagen. Injection Safety is now reaching beyond immunization to encompass all services using injections.

Question : Have efforts been made to integrate "SIGN" principles and practices into the curriculum of professional schools such as medical or pharmacy schools ?
Response : Indeed work has started but with professional associations, and also with a number of ministries of health to integrate these aspects into National Plans of Action.

Comment : Given the scale of the problem and the proportion of injections given outside of EPI, it was suggested that a concerted effort be made to promote universal use of AD syringes.
Response : SIGN is actually trying to link with MOHs and not only promotes the use of AD syringes but works on the rational use of injections as it is well-documented that there is an abuse of injections in health services.

Comment : There was no mention of technology transfer with makers of syringes.
Response : Plans have actually been drafted and shared with partners but they have not been finalized yet. It is recognized as a weakness highlighted at the last SIGN meeting. It is assumed that technology transfer increases accessibility, affordability and sustainability, but this assumption needs to be tested.

Comment : As part of the GAVI process, countries have to submit their National Plans including injection safety and report on implementation. Countries are followed-up indeed as some receive Vaccine Funds grants for injection safety.

Question : Are safety boxes effective because often they do not work ?
Response : It is indeed a weakness in the curative sector but well-implemented in immunization services. Not so much emphasis has been put on safety boxes as it is easier, less technical and WHO encourages local production.

Comment : It was suggested that we undertake an evaluation on dissemination of documents inside countries as it is unkown how far they reach.

WASTE MANAGEMENT: OPTIONS AND DIRECTIONS : Yves Chartier, WHO HQ

Presentation Highlights : Prepared by the presenter

Immunization services have high visibility and constitute a good support to develop sound health care waste management. But it must be remembered that vaccination produces only 10% of all injection-related waste.

1. **Why is health care waste management often a failure in a lot of countries throughout the world?**

Sharps are among the top priority of hazardous waste. Produced by mass or routine injections activities they belong to the global family of heath care waste and should be considered as such.

Based on facts, on recent visits, on principles which do not match, on guidelines versus field reality… the question is: why these concepts do not work for health care waste management. This evidence is

met in a lot of countries whether they are called developing, transitional or precarious situations in industrial contexts.

Basically, I would stratify this in 3 levels which stratify the environment of health care waste.

1. What do we have in hand?

   What we have in hand reflects what is existing and is often not used at the level it should be,or is information which is simply not known. There are a lot.

   - Tools to help in the development of situation assessment, to manage project, to guide through policy paper, to help in training, to monitor and produce recommendations. More of these documents are currently produced while the existing one are not used properly or simply not known. Their promoting is needed.
   - In hand are also a lot of multiple technical options for a safe management of health care waste. Autoclave, incineration, needle remover, shredding, landfill, solar system, chemical, encapsulation are some of them and can respond to most situations according to context or resources.

2. What do we have to do (global environment around health care waste)?

   What we have to do defines the frame in which health care waste management activities must be developed. National strategies, global protocols and legislations as well as environmental rules are the lines which define this frame. Within this frame sound options for a safe management of health care waste need to be developed accordingly.

   A lot of countries have not yet developed such frame and this is our responsibility to guide them into that direction.

3. What is or is not implemented and WHY?

   The alchemy for health care waste is not that obvious, Why? The failure in implementation is not fully linked to the above mentioned two first steps but rather to political contexts and willingness to invest. But also to national policies on health care waste management that do not exist. To economical poverty which restrict investment into the health system and has an impact on the development of health care waste strategies. Also to culture, attitude and habits in regards to waste that do not favours concerns about a proper and safe management of waste.

ON SITE AND IN PRACTICE

In practice a number and combination of criteria are behind health care waste options failures. Non respect of good and safe practices such as a proper segregation of waste at the source is among them. This is most probably linked to motivation, no recognition of health care waste workers as key players or poor or no training.

It can be also in relation to non permanently appointed staff turning the system weak, this also reinforced by limited resources, insufficient equipment or no facilities to accommodate the health workers on site.

CONCLUSION

To conclude, tools exist and are under used. Technical options are not the problem even if there are no perfect options. Resources and awareness can be issues but could be improved. Implementation remains the major factor leading to failure. WHY?

TENTATIVE RECOMMENDATIONS

- To globally improve the situation around health care waste management it is of a crucial importance to raise awareness and concerns at all levels.
- To develop national frame. This aspect must be regarded as a key issue to prevent from the transmission of diseases.
- The existing tools and the coming ones should be user friendly and straight forward to understand and implement.
- Health care waste management has often been perceived as the last priority in the health sector. Especially when funds are restricted. Resources at a reasonable and well defined level should be allocated from the health budget to health care waste management.
- Training at all levels and the appointment of permanent and well considered health care workers are necessary to reinforce motivation and successes in implementation.

Recommendations from the 15 December meeting on small-scale incineration / emission of pollutants such as dioxins and furans.

STRATEGY

To better understand the problem of health-care waste management, WHO recommends that countries conduct assessments prior to any decision as to which health care management methods be chosen. Tools are available to assist with the assessment and decision-making process so that appropriate policies lead to the choice of adapted technologies. Following assessment, options available include:

SHORT-TERM

- Production of all syringes components made of the same plastic to facilitate recycling;
- Selection of PVC-free medical devices;
- Identification and development of recycling options wherever possible (e.g.: for plastic, glass, etc.);
- Research and promotion on new technology or alternative to small-scale incineration;

Until transitional and developing countries have access to health care waste management options that are safer to the environment, incineration is an acceptable response when used appropriately. Key elements of appropriate operation of small scale incinerators include effective waste reduction and waste segregation, placing incinerators away from populated areas, satisfactory engineered design, construction following appropriate dimensional plans, proper operation, periodic maintenance, staff training and management.

MEDIUM-TERM

- Further efforts to reduce the number of unnecessary injections hence decreasing the amount of hazardous health-care waste that needs to be treated;
- Research into the health effects of chronic exposure to lower level of dioxin and furan ;
- Risk assessment to compare health risks associated with (1) incineration and (2) exposure to health care waste.

LONG-TERM

Effective, scaled-up promotion of non-burn technologies for the final disposal of health-care wastes to prevent the disease burden from (a) unsafe health-care waste management and (b) exposure to dioxins and furans.

DISCUSSION

Comment : From field observations, there are also excellent practices in some countries even though massive improvements are needed. Many governments are hesitant as they lack a clear policy.

Question : In practice is there any safe and sound technology?
Response : It is true that many technologies have a bad reputation because their application hasn't been good. But these applications can provide answers to problems having caused their bad reputation.

Further response : Small scale incineration has indeed a bad reputation because it produces pollutants. In most cases this is because they are poorly used, poorly operated by under-trained staff and not well constructed. However it does work well in some countries so the need is to work at national level to make sure that steps are respected.

Comment : One participant remarked that it costs roughly the same to destroy than to produce.
Response : This statement was later challenged by another participant advising caution. Equivalent resources should be devoted to waste management as to procurement. What strategies could be developed to get countries and partners to put this sort of money into the system? Most equipment is quite expensive and staff need clear strategies. As a matter of fact, there are resources flowing and the most expensive is not always the necessary, simpler technologies are often appropriate.

Comment : Attention should be brought on having sound guidelines for rural areas where a substantial amount of waste is generated.

Response : Such guidelines do exist but they often need to be adapted to specific conditions of each country. In some countries like South Africa, the problem of rural areas is already acknowledged, and small scale incineration is not the necessary evil.

Question : Are there plans for WHO to summarize assessments and present positive experiences with safe and appropriate practices?
Response : Indeed WHO would like to do so and is actually in the process of collecting all the necessary information.

NEEDLE REMOVERS: NEXT STEPS : Mary Catlin, Freelance Consultant, USA
On Behalf of the WHO Needle Removers Working Group

Presentation Highlights : Extracted from the presentation

BACKGROUND

WHO recommends that used medical devices with sharps be placed into safety boxes immediately after use: the collection of used syringes and needles into disposal containers without disassembly or manual handling at the point of use, reduces needlesticks and sharps related injuries that can transmit bloodborne pathogens in health care facilities. Unfortunately, health care facilities lack resources to destroy the enormous volume of sharps infectious waste that is generated. In areas where waste is scavenged and discarded devices may be re-used or sold, there is also concern about health risks of syringes in waste dumps. Devices that remove needles at the point of use are being reconsidered as an aid to decreasing the volume of sharps-related waste that needs special handling. Devices that destroy the syringe and or needle may aid in the prevention of re-use. However, before facilities can decide whether to return to using these devices, if is necessary to know if the use of needle-removal devices would:

- Decrease the volume of infectious sharps waste?
- Increase the rate of needlesticks?
- Have a cost- effective impact on the waste management?

The WHO Needle Removers Working Group met in January to discuss how to gather information necessary to make an informed decision about the use of devices that remove needles from syringes, and which types of devices should be included in evaluations. The following points and action items were discussed.

AVAILABLE DEVICES INCLUDE:

- Electric needle destroyers that burn the needle to a stump, and which may or may not destroy the syringe.
- Non-powered needle removers. Different models are available to remove only slip tip needle, luer lock needles or pull attached needles. Different models may or may not destroy the syringe.

DEVICES PROPOSED BY PROGRAM FOR APPROPRIATE TECHNOLOGY IN HEALTH (PATH) FOR FIELD TESTING

	Balcan Mini Destructor ®	Nomoresharps ®	BD Hub Cutter ("yellow box")
Require power source?	No	No	No
Hub+ needle cut?	YES	YES	YES
Cost of Device	$44 - 82	$17.50 - 19	Under $2 (Single use)
Needle box intended for single use only?	Yes	Yes	Yes
Cost of Needle box	$1.56	$2.00	NA
Blade life	200,000 cuts	200,000 cuts	NA

FIELD EXPERIENCE TO DATE:

Devices are in use in Africa, India, China and Europe. However, in the United States, documentation of an increase in needlesticks associated with needle removal, emptying waste containers and increased manual handling led to their discontinued use. Currently a device for individual home use of diabetics is approved in the U.S. No well-controlled data documents the system level cost, their safety of needle removal devices nor the impact on waste management in developing country settings. This information is considered necessary before health programs or regulatory agency to decide whether to approve the use of these devices.

How safe is safe ? While sharps injuy surveillance is problematic, data suggests that the rates of needlesticks in developing countries may be up to fifty times greater than rates in developed countries. Is it acceptable to use needle removal devices if they do not increase an existing high rate? Or should program managers work to achieve the lowest rate of needlesticks achievable with a defined level of resources ? If so what is that level? In the United States, in settings that have many invasive procedures, but during an era before the widespread use of needleless IV systems or safety-engineered devices, rates of needlesticks were often in the range of 3 to 6 per 100 full-time equivalent workers.[1] In contrast, WHO reports rates of needlesticks overseas may be as high as 100 to 200 per full time equivalent worker per year. If a medical device doesn't increase the rates of needlesticks, but the rate of needlesticks that occurs after use and before or during disposal remains high, is it's use ethical? How can one weigh the benefits of waste management and assumed community protection, against the costs of worker injuries?

[1] Sohn S, Eagan, J, Sepkowitz K, Zucontti G. Effect of Implementing Safety-Engineered Devices on Percutaneous Injury Epidemiology. Infection Control and Hospital Epdiemiology. 2004 :24 ;536-6. (In press at the time of TechNet.)

Needle removal adds a separate waste stream. Thus facilities will need to manage an infectious waste stream of syringes that is not burnable, and an infectious sharps waste stream. However separating the needles from the syringes may decrease the total costs of waste management. Needle removal allows syringes and needles to be disposed of separately, may require fewer sharps boxes, may facilitate alternatives to incineration BUT requires policy, procedures and supervision for safe use, especially for the process of emptying the needle box.

Comparison of Needle-remover and Safety Box for some negative events

	Needle-remover	Syringe and needle in safety box
REUSE OF SYRINGES AND NEEDLES	Could decrease reuse if both needle and syringe are damaged. If the damage to the syringe creates shards, the syringe will have to be disposed of as a sharp.	Reuse depends on control and destruction of filled safety boxes
NEEDLE-STICKS TO STAFF, JANITORS AND PATIENTS	Manual handling and disassembly increases risk of injury and exposure to potentially infectious materials. Could increase if syringes are batched, left at bed side, or discarded in general waste; or if boxes are re-used, overfilled or unavailable	Can occur if boxes are overfilled, unavailable or emptied and reused.
CONTAMINATION OF CLEAN WORK AREA	Devices with blood and body fluids can not be in clean work areas unless they are disinfected to removal blood and body fluids	Lower risk: boxes are removed when filled, do not need cleaning after use.

TERMS OF REFERENCES FOR POTENTIAL TRIALS

- ***Primary end points***

– Rates of needle-stick injuries in healthcare workers including janitors
– Volume of sharps wastes generated

- ***Secondary end points***

– Cost of needle removal and two streams of waste disposal compared to cost of safety box use and disposal alone

DEVICES TO ASSESS

- Non-powered hub cutters in immunization (Campaigns)
    - Fewer types of sharps
    - Impact on volume of waste may be significant
    - Lower rates of needle-stick injuries
    - Risk/ benefit favour needle removal

- Non-powered hub cutters and needle removers in curative settings (Hospitals)
    - More invasive procedures with many diverse sharps
    - Higher rates of needle-stick injuries
    - Impact on total sharps waste volume may be negligible
    - Risk/ benefits may favour immediate disposal of syringe and needle.

NEXT STEPS

The rates of needlesticks and sharps injuries is influenced by a number of factors including, the number of different devices that a health worker uses, the number and type of different invasive procedures done, whether the patient is confused or combative, the type of devices, the amount of manipulation of the device necessary during use, disassembly, decontamination and disposal, ergonomic considerations including lighting, angle of work, carrying equipment to different settings, and height of working field. The rate of needlesticks in immunization campaigns is expected to be lower than in health care settings providing primary care. The imminent measles campaigns however provide the opportunity to gather information about the use of needlesticks in this setting. and was felt to be an opportunity to gather information about the cost effectiveness of needle removers in "a best case scenario". Is it acknowledged that the results of these trials may not be sufficient to determine if needle removers can be safely used in hospital or clinic settings. The next steps to be undertaken were:

- Field assessment of needle removing devices
- WHO will finalize guidance on the surveillance and management of needle-stick injuries
- WHO will prepare a standardized protocol to evaluate needle removers during measles campaigns
- Partners will be encouraged to implement protocol during measles campaigns

ACTION POINTS

- WHO will develop draft specifications for needle removers to be evaluated in the field
- The need for standardized assessment of blood splatter produced by needle removers was discussed but will not be quantified in the proposed trials.
- WHO will attempt to recover experience regarding the rates of needle-stick injuries in industrialized countries (e.g., Germany) where they remain in use

For information about the needlestick protocol please contact Sophie Logez

DISCUSSION AND CONCLUSION

Comment : There is a challenge that the product be available for mass production if technology were definitely shown to be effective. No response to this comment came from the floor.

Comment : When saying that the volume of waste would decrease, it was meant volume of sharps.

Question : One participant later added that needle-removers alone are not a solution to the waste problem. There are two other components: the contained cut syringes and cut needles. The syringes could be an infectious waste, should they be treated before burning?
Response : Opinions are divided as whether syringes represent an infectious waste, but there are other options for syringes. One has also to refer to national legislation. In India for example, it is required that syringes be decontaminated.

Question : More precision was requested about what the next steps are, more general field studies or during measles campaigns in a study mode?
Response : More studies will be carried out during m easles campaigns. Countries have been contacted and other countries or partners interested should contact WHO.

Question : If needle-removers are studied during measles campaigns, then what happens after the campaigns if the devices remain at health centers? Would needlestick injury risks increase beyond acceptable levels in the longer term?
Response : There is no answer yet to this question and no funding is available after campaigns.

Question : What is the situation now on the implementation of the WHO/UNICEF joint policy on AD syringes? How many AD syringes are used compared to other syringes?
Response : No answer could be provided at this point but efforts have been made to document implementation. A survey was done and data are likely available at least partially at WHO. There are concerns however that AD syringes are used by health workers for many other purposes than what they were designed for, that is for injections.

Question : Is there any data on health workers' satisfaction with needle-removers and the implication on the time needed for vaccination?
Response : PATH has studied this issue of acceptability in India particularly. It has concluded that it is well accepted and concerns are not about staff performance but safety, costs and efficacy.

Comment : It was remarked that a major trade-off is rendering syringes totally unusable as many devices also cut the syringe.

Comment : There is also a real point in removing needles before burning syringes. By burning only plastic, it produces clean ashes and concerns are not with gas emissions.

SESSION 3 : NEW VACCINE INTRODUCTION

Chair: Mary Catlin, Freelance Consultant, USA

SESSION'S ACHIEVEMENTS :

Session' objective and outcomes were as follows :

Session objective: Review the impact of new vaccine introduction on management and logistics

Expected outcomes: Agree on work plan to collect evidence on vaccine wastage and management actions
Agree on further implementation of VAR

Sessions objectives were met through all three presentations and discussions. Challenges for new vaccine introduction were clearly presented highlighting key programmatic issues. Lessons learned from introducing HepatitisB vaccine were reviewed with an example from Ethiopia about impact on cold storage.

The issue of vaccine wastage was already raised during the discussion of the first presentation, so the second presentation on establishing sentinel reporting sites for vaccine wastage surveillance was timely. Monitoring wastage is essential for managerial decisions that must be taken considering all factors such as vaccine storage volume, transport cost and operations without compromising coverage.

The third presentation provided feedback on the introduction of the Vaccine Arrival Report globally. The operation has been rather successful worldwide with a 74.3% return in 2003. The VAR return rate is increasing, while the rate of incomplete and late inspections is decreasing significantly. The challenge remains for EPI Officers in every country receiving vaccine shipments to ensure strict compliance in filling and returning the VAR.

As for expected outcomes, there was indeed a general agreement that VAR should be further implemented. The discussion also helped clarify some confusion about temperature monitors for which data is collected on the VAR but analysis has yet to be completed. A specific workplan to collect evidence on vaccine wastage and management actions would not be realistic at this time. However the need for monitoring wastage at country level and information gathered has been recognized. Funds are available and a call for volunteer countries to carry out vaccine wastage studies is expected to be made officially.

PROGRAMMATIC ISSUES FOR NEW VACCINE INTRODUCTION : Steven Wiersma, WHO

Presentation Highlights : Extracted from the presentation and a paper prepared by Patrick Zuber, WHO HQ

BACKGROUND

Since 1974, the Expanded Programme on Immunization (EPI) has developed tools and strategies to provide 6 important vaccines to the largest number of infants in the world. This process has provided considerable gains for global health as it is estimated that EPI prevents 610000 annual deaths that would be attributable to measles and 474000 annual deaths each attributable to neonatal tetanus and pertussis. In 2002, 75% of the world's infants received three doses of diphtheria, tetanus and pertussis vaccines, and most of them also received one dose of BCG, 3 doses of poliomyelitis, and one dose of measles vaccine. It is estimated that 33 million infants are not adequately vaccinated, with approximately one third in Sub-Saharan Africa and another third in the Indian subcontinent [1].

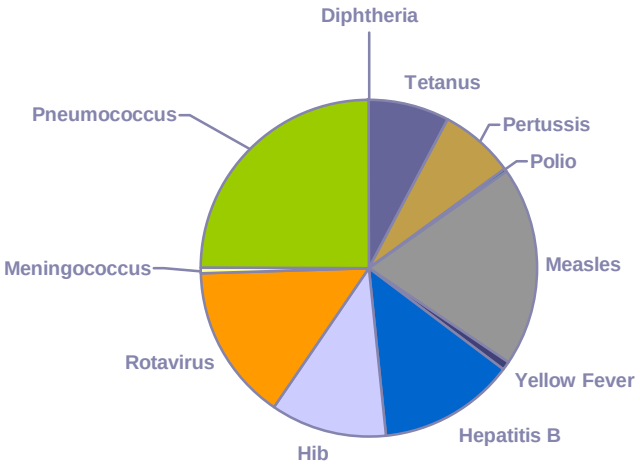
Expanding the success of EPI for additional public health gains can be accomplished through two strategies. First, strengthening immunization services and implementing accelerated disease control strategies in order to further the impact of the original 6 vaccines used in the programme. Second, adding new vaccines to the infant immunization schedule. WHO estimates that 2.7 million deaths annually result worldwide from hepatitis B (HepB), Haemophilus influenzae type b (Hib), yellow fever (YF), rotavirus (RV), pneumococcus (PC), meningococcus (MC) and Japanese encephalitis virus (JE) infections [WHO unpublished data]. Although effective vaccines have been developed against all these diseases, none has yet reached infant immunization coverage similar to that accomplished with traditional vaccines. The barriers to the introduction and utilization of vaccines in immunization programs are multiple. WHO has therefore developed a series of strategic activities that address each of these specific barriers and are illustrated through the following examples.

HepB vaccine has been available since 1982. It has an excellent record of safety and efficacy. By 2003, however, only half of the world infants benefited from a full immunization series consisting of 3 vaccine doses during their first year of life. Although WHO recommends its use in all countries, only 144 of 192 WHO member states had introduced hepatitis B vaccination in their infant immunization schedule by 2003 and at least 30 of the countries that have introduced it reported coverage below 80% with a full immunization series. Increasing the impact of hepatitis B vaccine is limited by the performance of vaccination systems, the availability of combination vaccines that could easily substitute for traditional vaccines without requiring additional injections, manipulations and storage capacity, as well as by the additional cost incurred for vaccines procurement. Providing countries with tools for decision-making, assisting with rational vaccine introduction while strengthening the immunization delivery services and assisting countries that cannot ensure the provision of regulatory

[1] http://www.who.int/vaccines-surveillance/StatsAndGraphs.htm "Progress towards Global Immunization Goals", slide set (October 2003). Last accessed 12 May 2004.

mechanisms to ensure product quality are all integral functions of WHO's Department of Immunization, Vaccines and Biologicals. Developing tools to assess the impact of immunization on the incidence of hepatitis B infection is also an integral part of the program.

2 Deaths from Vaccine-Preventable Diseases - 2000



CURRENT STATUS OF NEW VACCINES

Hepatitis B	The first vaccine against a cancer, this vaccine could prevent over 500,000 deaths per year from acute and chronic liver disease
Haemophilus influenzae type b	This vaccine, available since 1990, prevents a major cause of severe meningitis and pneumonia in young children; global introduction could save another 400,000 annual deaths
Yellow Fever	This effective vaccine can prevent 30,000 deaths annually and can stop severe outbreaks of haemorrhagic fever observed in Africa and South America
Rotavirus	Promising vaccines, available by 2006, could prevent over 600,000 deaths per year against the most common cause of severe diarrhoeal disease in children
Pneumococcus	Effective vaccines against a leading cause of severe respiratory infections, estimated to be responsible for around 1 million childhood deaths annually, could be available by 2006
Meningococcus	Deadly meningitis outbreaks in sub-Saharan African killing 50,000 persons annually could be prevented with a new affordable vaccine possibly available by 2008
Japanese Encephalitis	New and improved vaccines against this major killer of children and adults in Asia, should be available by 2005

GAVI MILESTONE 6

A new initiative, the Global Alliance for Vaccines and Immunization (GAVI) has provided several mechanisms that facilitate the implementation of under-utilized vaccines and the development of needed new products. In terms of programmatic implementation, important progresses were accomplished over the past 3 years regarding hepB, Hib and YF vaccines. This alliance involves WHO and UNICEF, major donor agencies, governments from developed and developing countries as well as vaccine manufacturers. GAVI provides support to 75 of the poorest countries in the world for new vaccines introduction during 5 years. The GAVI partnership has allowed countries that could not have afforded it to introduce costly vaccines in their immunization schedules while increasing global demand for those products, thereby stimulating global vaccine production capacity. This increased capacity should help reduce vaccine price and therefore could guarantee more sustainable vaccine supply in the future.

In addition, GAVI and major donors are sponsoring vaccine development and introduction projects that should help facilitate access to RV, PC, JE and MC vaccines to low and middle income countries. Current efforts are focused on increasing the availability of reliable disease burden data, as well as on expanding the development and clinical assessment of adequate products that could benefit countries that would have the greatest need for these vaccines. The GAVI partnership therefore facilitates the achievement of an important WHO objective of expanded and more equitable access to new technologies for all infants in the world.

By 2007, all developing countries with adequate delivery systems will have introduced hepatitis B vaccine and achieved HepB3 coverage comparable* to DTP3 levels

Status	01/2003	12/2003
Developing countries (n=149)		
HepB in schedule:	78 %	84% (n=125)
with comparable coverage*	33%	42% (n=62)
VF eligible countries (n=61)		
HepB in schedule:	70%	79% (n=48)
with comparable coverage*	12%	30% (n=18)

* comparable: coverage +/- 5%

KEY PROGRAMMATIC ISSUES

• Management decisions : One of the first management decisions is the selection of products, monovalent or combination, liquid or lyophylized, and vial size(s) depending on which vaccine. A specific challenge faced in the procurement of vaccines for the poorest countries is related to the increasing discrepancies in types of vaccine products and presentations used in various parts of the world. For example, as most low income countries use measles vaccines alone, countries with stronger economies prefer products that combine antigens against mumps and rubella. An acellular,

more expensive, pertussis component of the classic diphtheria-tetanus-pertussis vaccine is currently preferred in most developed economies despite a slightly lower efficacy but because it induces a lower proportion of short-term minor side-effects. Although the oral poliovirus vaccine remains the only vaccine capable to complete the global project of polio eradication, many industrialized countries that have not faced poliomyelitis for decades prefer using the injectable inactivated vaccine, usually combined with DTP and other antigens in combination products. As a result, vaccine manufacturers are faced with developing different products for different markets which adversely affects the availability of affordable vaccines for the poorest countries that are frequently also the most affected by the burden of those diseases [1].

- Further issues : In the case of HepB vaccine introduction, a decision must be made whether proceed by phases or to a nationwide introduction. Schedule issues (birth dose) must be resolved. Policies and strategies have to be developed for catch-up and special populations.

PREPARATION FOR INTRODUCTION OF HepB VACCINE

In the preparation phase the following points must be carefully considered and all issues resolved:

- Financing
- Health care worker training
- Forms revision
- Workload management
- Monitoring/surveillance issues
- National communication and social mobilization efforts
- Injection safety issues
- Waste disposal issues

LESSONS LEARNED FROM HepB INTRODUCTION:

…be careful what you ask for…

Monitor global vaccine availability closely prior to making decision. GAVI approved applications for combos that later proved not to be available due to global shortage. Consequently, many countries were not able to get the vaccine of choice. It caused delays for countries that had to create new plans for alternate vaccines. Introductions were also delayed in some cases due to lack of availability of vaccines

Plan and seek support…

Allow adequate time for training and developing materials and plan additional session time due to additional vaccinations. Ensure adequate supervision. Support from the private sector is critical especially from professional groups for effective social mobilization and political support.

Start strong…

- India introduced HepB in slum areas of 15 metropolitan cities, the weakest health delivery points. Coverage after one year was 32% and drop out 20-40%.

[1] Milstien, J, Munira SL, McKinney SL. Issues in selection of DTwP-based combination vaccines. Vaccines 21: 1658-64 (2003).

- Sri Lanka introduced HepB in best performing provinces. Coverage exceeded 95% with drop out was less than 20%.

EXAMPLE FROM THE FIELD : ETHIOPIA

The Introduction of new vaccines had a substantial impact on cold storage. Data analysis shows that starting with a factor of 3 for storing DTP in 10-dose vials, it increases to 19.21 when adding Hib and HepB monodose (the full graphic could not be displayed)

CONCLUSION : INTRODUCTION CHALLENGES

- Strengthen immunization systems
- Create financial sustainability : - Post-GAVI issues
  - Maintain national priority
- Strengthen cold chain and logistics : - Expand cold chain and replace ageing equipment
- Reducing vaccine wastage : - MDV policy
- Maintain political and public support : - Safety and communications
- Prepare for new vaccines of the future

DISCUSSION

Comment : It is hard to understand why GAVI assessment teams sent to countries did not include enough field operational experts so cold chain readiness for new vaccine introduction was overlooked. The agency missed the opportunity to engage TechNet in the process. Countries were actually mislead by being encouraged to apply for vaccines which were known to be in short supply and manipulated for the purpose of stimulating demand.

Comment : Products are not available because everybody focused on one product, that is the tetravalent DTPHepB vaccine. There was much pressure on countries to use this product so that they didn't consider other options. It is not too late to look at implications of other products and look at them in a constructive way so to relieve the availablility problems.

Response : We deal in fact with the whole menu of available products. The issue of national selection had already been raised when considering the time these products would no longer be free. A full product menu with advantages and disadvantages was to be completed by this Spring of 2004 and should be available. There is more than one answer given contry situations and what each wants to achieve.

Question : At what point of the pre-introduction phase should storage area design and lay-out, and transport issues be looked at?
Response : Judging from Ethiopia's experience, these should be addessed as early as possible, before the final application is made. Another participant commented that cold chain

planning is indeed part of the introduction planning and shall not be only quantitative as there are qualitative aspects. EPI reviews had identified instances of vaccine freezing but were not mentioned by introduction reports. It should ring a bell that it is a risk factor to the introduction of a new freeze-sensitive vaccine.

Comment : It is time that we take a stand on the issue of vaccine wastage so that GAVI gives as much leeway as possible. In some countries, a high wastage rate is necessary so not to miss opportunities and see a drop in coverage.
Response : In theory, this is correct. GAVI has already changed its wastage allowable rates to take into account some of the field realities. If a country can demonstrate that higher coverage could only be achieved at the expense of a higher wastage rate, GAVI allows this. The Chair commented that it highlights a point made earlier in the meeting that wastage should always be analyzed in relation with coverage.

Question : As 84% of developing countries have now introduced HepB vaccine only 42% have a coverage rate comparable to that of DTP3. Is it too early to make a judgement, some countries may have introduced the vaccine only during the last year?
Response : It is indeed too early especially that some large countries are phasing in the introduction. It is not pulling down DTP3 coverage and comparability is only delayed.

ESTABLISHING SENTINEL REPORTING SITES FOR VACCINE WASTAGE SURVEILLANCE IN MALAWI : Serge Ganivet, WHO AFRO

Presentation Highlights : Prepared by the presenter (abriged version)

BACKGROUND

The Malawi Expanded Program on Immunization (MEPI), which was launched in 1976, has been regarded as one of the better performing programs in the Africa Region. The program maintained high DTP3 coverage (above 90%) in the 1990s. However, DTP3 coverage declined to 75% in the year 2000. The final data for the year 2003 is not yet available.

ADMINISTRATIVE DATA

Malawi is divided into three administrative regions (north, central and south), which are sub-divided into 26 districts.
The population of Malawi is estimated at 10,893,265.
It is said that government directly provides about 60% of health services in Malawi and the Christian Health Association of Malawi provides services of about 37%.

EPI STRUCTURE

At the central level, the programme is managed by the EPI Manager and assisted by Logistics Officer, Data Officer and Vaccine Stores Officer/Cold Chain Officer. The Regional EPI Officers in the North and South are responsible for coordinating EPI activities in their respective regions. These are assisted by the Regional Cold Chain Technicians.

At district level, there are two EPI Coordinators assisted by Cold Chain Technicians who are responsible for control and allocation of supplies to health facilities within the districts. At health centre level, all health workers participate in EPI activities.

SUPERVISION

Supervisory visits are done every month using a designed checklist. The checklist includes routine, disease surveillance, monitoring and evaluation activities.

DATA MANAGEMENT

At clinic level, immunization information is collected on tally sheets. The health facility staff compiles immunization information from static and outreach clinics on "Maternal and Child Health" (MCH) form. The report is sent to the district not later than 5th day of the following month. At district level, the MCH Coordinator scrutinizes and consolidates all health facility reports on immunization and disease surveillance. The report is sent to the EPI Unit not later than 14th day of the following month with a copy to the Regional EPI Offices.

MONITORING - EVALUATION

Immunization services are monitored monthly at health centre and district levels. Immunization coverage, wastage and drop-out rates are calculated using catchment population. The central level provides feedback to all districts and partners through a quarterly EPI newsletter.

STRATEGIES TO REDUCE VACCINE WASTAGE AND DROP OUT

- Implementation of the Multi Dose Vial Policy (MDVP)
- Vaccine Vial Monitor (VVM) on Oral Polio Vaccine
- Opening of more outreach clinics

COLD CHAIN EQUIPMENT

Cold chain equipment for the EPI programme include deep freezers, refrigerators, cold boxes and vaccine carriers. Deep freezers and refrigerators are used for storage of vaccines at all levels whereas cold boxes and vaccine carriers are used for transportation of vaccines. One hundred percent (100%) of deep freezers use electricity as a source of energy while refrigerators use kerosene, gas, electricity and solar energy as a source of power.

INTRODUCTION OF NEW VACCINE

In June 2000, Malawi submitted a request to the Global Alliance for Vaccines and Immunization (GAVI) for support for the introduction of new vaccines (pentavalent, DPT-HepB+Hib). The request was accepted and approved by GAVI secretariat in September 2000. Arrival of the new vaccines commenced in the last quarter of 2001.

VACCINE WASTAGE MONITORING

The introduction of new vaccines has presented a challenge in immunization services, but also brought a great deal of opportunity for better demand calculations, and monitoring of immunization coverage and vaccine wastage. Countries receiving GAVI support are requested to reduce their wastage rates within three years down to 15% for 10 and 20 dose presentations.

No matter how successful it is, vaccine wastage is expected in all programmes. There are many factors affecting vaccine wastage. Improved vaccine management practices are the key in addressing vaccine wastage as a whole.

Vaccine wastage can be classified as in "unopened" and "opened" vials. Wastage in unopened vials are the result of incorrect/inappropriate vaccine storage and transport practices and mainly occurs at or between primary and intermediate vaccine storage facilities. Vaccine wastage at service level occurs in combination of many factors and mainly involves opened vials.

The vaccine wastage rate reported by MEPI is indicated below:

- BCG (20 doses) = ? %
- OPV (? doses) = ? %
- Penta (2 doses) = 16 %
- Measles (10 doses) = ? %
- TT (? doses) = ? %

The EPI manager agreed on the methodology recommended by WHO and is committed to monitor the vaccine wastage for all antigens.

- **Monitor vaccine wastage regularly**

1. All immunization points should monitor their vaccine usage and wastage on a monthly basis. This has to be done as a self-audit and not for the sake of submitting data to upper levels.
2. Similarly, vaccine stores should also monitor their wastage rates on a monthly basis.
3. The minimum data that need to be collected at service level are:
    - Start balance
    - Doses received
    - Doses discarded unopened
    - Doses opened for use
    - Number of children immunized

4. Calculating vaccine usage at service level should always be encouraged as the first step.
5. Vaccine wastage can easily be calculated from vaccine usage rate:

   Vaccine wastage (rate) = 100 - vaccine usage rate
6. Vaccine stores should focus on handling performance which can be expressed as proportional vaccine wastage in unopened vials.
7. Since vaccine wastage is calculated at two different settings, both figures from these calculations should be incorporated in demand forecast calculations. Wastage factor for the country is the multiplication of wastage factors calculated from these two different wastage rates:

   Wastage factor = { Wastage factor of **"proportional vaccine wastage rate"** calculated from stores } x { Wastage factor of **"vaccine wastage rate"** calculated from sentinel points }
8. Vaccine wastage rate at service level should be monitored against the immunization coverage for the same time period. Any changes in both trends must be carefully analyzed.

- **Consider all factors when making a decision**

9. Naturally, use of smaller vaccine presentations results in less vaccine wastage. However, changing vial size to reduce vaccine wastage must be carefully studied since there might be negative implications regarding vaccine storage volume, transport cost and operations.

- **Do not compromise immunization coverage**

10. Whatever measures are taken to reduce the vaccine wastage, they should not compromise immunization coverage. If selected approach to reduce vaccine wastage results also in reducing immunization coverage, consider other approaches.

- **Reporting through sentinel sites**

Sentinel sites should report directly to the director of the national immunization programme or to a unit designated to compile the reports.

DISCUSSION

Comment : WHO Headquarters supports this type of study. There is funding for other countries from GAVI funds and this is a call for volunteers.

Question :Why has the study been extended over twelve months and not six ?
Response : The budget is for six months but there is the issue of seasonality that needs to be taken into account.

Comment : In East Africa, wastage surveillance is being developed. It cannot be called a study and although no tools are provided to encourage countries to put it in place, it is nevertheless a system. On a study basis, a desk review over a short period provides the same results. Early results are encouraging.

Comment : The methodology can be found in the book "Monitoring Wastage at Country Level". Indeed it is not a study but establishing a sentinel-site system for vaccine wastage surveillance. Once established, it can serve continuously and for all antigens. Countries, especially those using the pentavalent vaccine, are encouraged to stand as volunteers.

Comment : In West Africa, a training program is in place for DMOs and some research papers are concerned with vaccine wastage. Results will be made available later but it proves a good tool to implement routine vaccine wastage surveillance.

Comment : In Bangladesh, as a change from session-based to population-based calculations of vaccine needs may result in a syringe shortage, a retrospective study will be conducted. 80% of vaccinations are administered through outreach with a good registration system. The intervention that will result is likely to be a rationalization of the number of sessions. Prospectively the surveillance methodology shall be applied as scientific evidence is needed.

FEEDBACK – "VACCINE ARRIVAL REPORT" INTRODUCTION :

Samuel Sawa, UNICEF SD

Presentation Highlights : Prepared by the presenter

BACKGROUND

The Vaccine Arrival Report (VAR) is a report whose purpose is to monitor cold chain conditions during transport, compliance deviations with shipping instructions and ensure adequate record keeping of information related to vaccines. It can also serve as the basis for documenting claims or initiating corrective action if problems occur.

Recipient Governments, UNICEF Country Offices and UNICEF Supply Division are responsible for the implementation of the Vaccine Arrival Report, and for taking corrective action if necessary.

The VAR is completed by consignee upon arrival of a shipment. Its' part of the documents that accompany any shipment enclosed in box labelled number 1. While it ensures shipments are checked and vaccine quality monitored, it also reports on:

- Receipt of shipping documents prior to shipment
- Flight arrival details

- Details of vaccine shipment
- Documents accompanying shipment
- Status of shipping indicators
- General conditions of shipment

Once completed, the VAR should be forwarded to UNICEF Supply Division within 3 days of vaccine arrival. It enables UNICEF to monitor supplier, forwarder and carrier performance.

VAR PERFORMANCE – 2003

In 2003, VAR was introduced for all GAVI shipments and in East and Southern Africa Region (ESARO) between 1st January and 30th April 03. Of the 108, shipments during this period, 69.6% VAR's were returned. It was then rolled out to cover all shipments to the rest of the world from May 1st 2003. Of the 931 shipments during this period, 73.5% VAR's were returned.

In 2003, UNICEF Supply Division shipped vaccines to 87 countries. Their VAR return was as follows:

- 15 countries had a 0% return
- 27 countries had 100% return
- 45 countries oscillated above 50% return

There was an average time of 29 days to receive VAR.

Region	CEE/CIS	EAPRO	ESARO	ROSA	WCARO	MENA	TACRO	Total
% VAR received	71%	86%	80%	76%	63%	73%	27%	74.3%
Average no. of days to receive VARs	18	13	39	40	23	25	35	29

COMMON ISSUES

Some of the issues encountered while examining the VAR are:

- Incomplete VARs: Arrival dates/flight information missing
- Dates regarding shipping documents not accurate
- Incomplete inspections:
  - Out of 810 VAR's received, 129 (15.9%) indicated incomplete inspections.
  - Non-vaccine boxes (droppers/diluents) often not inspected

Other issues that the VAR is able to highlight are whether there was an early or late arrival of shipments, short shipments and damaged shipments. This forms part of the supplier, forwarder and carrier evaluation carried out by UNICEF Supply Division.

EARLY AND LATE ARRIVALS :

In 2003, out of 1,400 shipments, 810 VARs were received; out of which 53 VARs indicated shipments arrived late due to a variety of reasons, which were:

Reasons	Number of delayed shipments	Average delay (days)
Shipment off-loaded	**31**	**4.0**
Flight delayed / cancelled	**14**	**2.2**
Missed flight	**8**	**1.6**

VAR also indicated 9 shipments arriving early without notice. Below is a summary table by UNICEF region indicating early or late arrivals:

Region	CEE/CIS	EAPRO	ESARO	MENA	ROSA	WCARO
Late Arrivals	7	8	15	5	9	9
Early Arrivals	1	0	4	0	2	2
ELA per Region (%)	11.4	7	8	3.6	8.3	8.3

SHORT SHIPMENTS

In 2003, of the 1,400 shipments, 5 countries experienced short shipments of the quantity expected. UNICEF SD, was able to take remedial measures immediately by following up with the suppliers to ship the balance of the expected quantity of vaccines.

DAMAGED SHIPMENTS

Only 4 consignments of the 1,400 shipments were damaged due to airline mishandling. UNICEF SD was able to replace all the damaged shipments.

CONCLUSIONS

There has been a successful introduction of VAR worldwide with a 74.3% return in 2003. The rate of receiving VARs is increasing, while the rate of incomplete and late inspections is decreasing significantly.

Through the usage of VAR there has been a clear demonstration that by manufacturers, forwarders and carriers adhering to the WHO International shipping standards of vaccines, the integrity and safety of vaccines is maintained.

There is a need though of EPI Officers in every country receiving vaccine shipments to ensure strict compliance in filling and returning the VAR, so as any deviation to the standards is immediately addressed. This will ensure a world safe and free of the communicable diseases the vaccines are intended to eradicate.

DISCUSSION

Question : Has early or late shipment had any impact on vaccines?
Response : As said, only four shipments out of 1400 were damaged and this was shown to be from airport mishandling.

Comment : There is confusion about the release certificate between the lot certificate provided by the manufacturer and the export certificate by the exporting country government. This cause misleading information being transmitted to UNICEF Supply Division.

Question : In UNICEF shipments what is done to ensure that there are temperature monitors in every shipment? What proportion complained that there wasn't?
Response : It is stipulated in the contract that there will be monitors for every 50th box and that VVMs will also be included.

Question : OPV shipments have VVMs and some boxes with CCMs. There is also confusion because on reception, the "A" is often blue meaning that OPV must be used within 3 months while the VVM cards are all white. Why not remove the CCMs?
Response : VVM is not a transit and shipping monitor. It monitors heat exposure from the moment the vaccine is labelled up to the use point. In VVM's time, the duration of transport is very minimal so it is almost impossible to notice a change with the naked eye unless shipment has been unduly long.

Further response : Other devices will assist in deciding whether the rules of contract as defined by WHO and UNICEF are respected. CCM can measure those violations. But no matter what the CCM says, it is only on VVMs that one can depend when using the vaccine is concerned.

Question : There is space for cold chain monitor reading on the VAR, is there any data on this?
Response : There is but cannot be provided now. It will be made available on the website as soon as possible.

Comment : It is hoped that the JRF and Annual Report to GAVI would provide scope for reporting on vaccine shipments.

Comment : There is a positive experience in East Africa with VARs and it is not only for keeping a file with all the shipments' documentation but above all to identify weak points during reception. When a correct temperature is recorded upon arrival but a much too high

one at a delayed departure from the airport, authorities tend to react differently and bring improvements in the country.

What about late inspection? Sometimes we have to go to the airport in the middle of the night for vaccine arrival and wait for the flight because we want to be present. We inspect briefly and fill just what is necessary, leaving the rest until the next day. Why a three-day deadline? For huge shipments it is indeed important to inspect a few boxes but the whole shipment thoroughly the next day because waiting longer is problematic if anything went wrong. If there was a break in the cold chain, responsibilities must be ascertained for any insurance claim.

SESSION 4 : OVERCOMING FREEZING IN THE COLD CHAIN

Chair: Steve Landry, The Vaccine Fund

SESSION ACHIEVEMENTS :

Session's objective and outcome were as follows :

Session objective: Review update on tools to overcome freezing in the cold chain

Expected outcome: Agree on work plan to develop policy statement on two temperature cold chain approaches

The importance of knowing freezing risks at various levels of the cold chain in order to effectively prevent actual freezing has been stressed. The introduction of new freeze-sensitive vaccines has even increased the emphasis placed on this issue. The first presentation shared the results of such a freezing risks assessment in Ukraine. Some of the issues raised in the study have also some characteristics specific and shared by countries of the former Soviet Union.

As TechNet members are aware a study had been conducted to evaluate the use of chilled waterpacks instead of icepacks during vaccine transportation. The second presentation reviewed the final very conclusive results that freezing of sensitive vaccines can be prevented by the use of waterpacks with no risk of heat damage to vaccines. This does not apply to OPV vaccine except for the fast chain during campaigns. This will lead to policy changes after the study findings have been presented to SAGE for endorsement.

In the third presentation results of a trial experiment taking freeze-sensitive vaccines out of the cold chain under specific conditions were presented. It concluded that removing vaccines from freeze-susceptible parts of the cold chain prevents freezing and does not result in excessive heat exposure. However VVMs are needed when taking vaccines out of the cold chain.

Two other presentations discussed the issue of taking vaccines out of the cold chain. First data for HepatitisB vaccine, existing research and manufacturers' data, were reviewed. It provides support for using HepB vaccine after storage out of the cold chain but field data is still weak. The presentation discussed the issue of protective efficacy and concluded by encouraging countries to go ahead but whith close monitoring and evaluation.

A fifth and final presentation discussed WHO plans for HepB policy development. It concluded that vaccines with VVMs can be taken out of the cold chain only if health workers and others handling the vaccines have been trained to interpret VVM readings correctly and

if any vial bearing a VVM that has reached its end-point is discarded. There is an urgent need to review the evidence that has accumulated over the past few years, to identify the remaining gaps in knowledge and to develop clear guidance on this issue. WHO will provide leadership over the next 2 years to reviewing the literature, identifying and filling gaps in the knowledge base, and in developing and promulgating policy options.

The objective of the session was clearly met through the five presentations. However heated plenary discussions couldn't produce an agreement on a two-temperature cold chain, even the name to be used. A working group convened during the evening and produced a short strategy paper on the issue that is presented at the end of this session instead of the proceedings of an inconclusive discussion.

ASSESSMENT OF FREEZING RISK IN THE COLD CHAIN

Ludmila Mukharskaya, MOH Ukraine

Presentation Highlights : Prepared by the presenter (abriged version)

BACKGROUND

The presence of an adequate cold-chain system to assure appropriate continuous refrigeration of temperature-sensitive vaccines is an essential component of every national immunization system. Countries of the former Soviet Union inherited cold-chain infrastructure from what had been established in the 1960's and 70's during the growth of the USSR's national immunization program. Since independence funding to upgrade and/or replace aging equipment was limited and came mostly from external donors. There is a concern that much of the existing cold-chain equipment in the region is old, inefficient, ineffective, or inoperable and in need of repair or replacement.

The Ministry of Health of Ukraine (MoH), in collaboration with the Program for Appropriate Technology in Health (PATH), undertook a cold-chain assessment as part of the government's multi-year plan to strengthen the national immunization program through capital investment to repair or replace aging equipment and provision of training to mid-level managers and service providers. This assessment included inventory of cold chain at some 30,000 delivery points and focussed research study on the performance of the existing equipment at two oblasts.

RESULTS

The inventory of cold chain revealed that 12% of refrigerators are broken, most of equipment is of domestic type and is in use for 10 and more years.

In two study oblasts 18 percent of the facilities monitored showed some color changes on the CCM cards, although less than 5 percent had CCM changes of B+, and none had changes of C+ or higher. As Table 1 indicates, there was statistically significant variation ($p < .001$) between the two study oblasts, with most of the CCM changes recorded in Ternopilska.

Table 1 – CCM Indicator			
CCM Windows	**Ternopilska**	**Zhitomirska**	**Total**
No Change	62 (70.5%)	97 (91.5%)	159 (82%)
A+	18 (20.5%)	8 (7.5%)	26 (13.4%)
B+	8 (9.1%)	1 (.9%)	9 (4.6%)
Total	88 (100%)	106 (100%)	194 (100%)

By contrast, as table 2 indicates, 25 percent of all facilities monitored showed evidence of possible freezing. However, in contrast to the CCM results, the differences between oblasts in the FreezeWatch indicators were modest and not statistically significant. In fact, this lack of association between Freeze Watch results and system characteristics was consistent and contrasts with strong associations found for the CCM data and some of those same system factors. Nor was it statistically associated with storage time (Table 4).

There is evidence from other countries that the Freeze Watch™ may be unusually sensitive and may produce a considerable percentage of false positives (see TechNet forum). Unfortunately, there is not enough TTM data from the present study to confirm this. However, where TTM data is available, in only one of the seven TTM graphs recorded in facilities with a positive Freeze Watch Indicator was there corresponding TTM evidence suggesting a problem with freezing. In two other graphs there were very short negative spikes indicating possible brief temperature drops below 0° (on the order of less than an hour) in otherwise remarkably stable temperature patterns. In the remaining four graphs there was no evidence to support the FW results. On the contrary, the TTM graphs indicate stable temperatures never varying more than 2-3 degrees from 4°C.

The standard shake test was performed at the facilities that had evidence of freezing. It appeared to be positive only in one facility.

Roughly twice the proportion of peripheral facilities (21.5 percent) compared to polyclinics and hospitals (10.9 percent) had CCM changes of A+ or greater (Table 3), while the Freeze Watch results were almost identical (26 percent versus 25 percent) between the two facility groups (Table 4). While neither CCM nor FW indicators showed statistically significant associations with storage time, there was stronger evidence supporting an association for CCM results (Table 5) than for FW (Table 6).

Table 2 – FreezeWatch Indicator			
FW Indicator	**Ternopilska**	**Zhitomirska**	**TOTAL**
No Change	55 (67.9%)	83 (79.8%)	138 (79%)
Freeze	26 (32.1%)	21 (20.2%)	47 (25.4%)
TOTAL	81 (100%)	104 (100%)	185 (100%)

Both indicators were significantly associated with season, with a greater proportion indicating changes in the winter (Tables 7 and 8). This latter association may not be as strong as the tables imply, however, because almost all indicators were installed during the summer of 2001, and some were not

read until late Winter or early Spring. It is possible that the modest association noted between the indicator results and storage time may be confounding these results.

Table 3 – Cold Chain Monitor and Type of Facility			
CCM Indicator	**FAP/Ambulatory**	**Polyclinic/Hospital**	**Total**
No Change	102 (78.5%)	57 (89.1%)	159 (82%)
A+	20 (15.4%)	6 (9.4%)	26 (13.4%)
B+	8 (6.2%)	1 (1.6%)	9 (4.6%)
Total	130 (100%)	64 (100%)	194 (100%)

Table 4 – Freeze Watch Indicator and Type of Facility			
FW Indicator	**FAP/Ambulatory**	**Polyclinic/Hospital**	**TOTAL**
No Change	92 (74.2%)	46 (75.4%)	138 (74.6%)
Freeze	32 (25.8%)	15 (24.6%)	47 (25.4%)
Total	124 (100%)	61 (100%)	185 (100%)

Table 5 – Cold Chain Monitor and Time in Storage			
CCM Indicator	**< 3 Months**	**3+ Months**	**Total**
No Change	60 (89.6%)	99 (78%)	159 (82%)
A+	6 (9%)	20 (15.7%)	14 (13.4%)
B+	1 (1.5%)	8 (6.3%)	9 (4.6%)
Total	67 (100%)	127 (100%)	194 (100%)

Table 6 – Freeze Watch Indicator and Time in Storage			
FW Indicator	**< 3 Months**	**3+ Months**	**Total**
No Change	53 (79.1%)	85 (72%)	138 (74.6%)
Freeze	14 (20.9%)	33 (28%)	47 (25.4%)
Total	67 (100%)	118 (100%)	185 (100%)

Table 7 – Cold Chain Monitor and Seasonality			
CCM Indicator	**Summer**	**Winter**	**Total**
No Change	100 (91.7%)	59 (69.4%)	159 (82%)
A+	8 (7.3%)	18 (21.2%)	14 (13.4%)
B+	1 (.9%)	8 (9.4%)	9 (4.6%)
Total	109 (100%)	85 (100%)	194 (100%)

Table 8 – Freeze Watch Indicator and Seasonality			
FW Indicator	**Summer**	**Winter**	**Total**
No Change	87 (82.1%)	51 (64.6%)	138 (74.6%)
Freeze	19 (17.9%)	28 (35.4%)	47 (25.4%)
Total	106 (100%)	79 (100%)	185 (100%)

CONCLUSIONS

Freezing is a significant problem in Ukraine. 25% of all refrigerators tested showed evidence of freezing and it is a more common in winter. It may even affect the expansion of hepatitis B universal newborn immunization programme.

High temperature is less of a problem. 18% of all refrigerators tested showed evidence of temperatures above 8°C for extended periods. Inconsistencies across oblasts indicated a local rather than a systemic problem. It is also more common in winter and at peripheral units.

The lack of corroborating evidence from the TTM data loggers and the consistency with which the Freeze Watch Indicators gave positive results, unassociated with system factors that were strongly associated with the CCM results, argues in favor of there being a possible problem with the device itself, rather than with the cold chain equipment it is testing. As noted above, there is anecdotal evidence from other countries that the Freeze Watch indicator may be prone to false positive results. That is also confirmed by the fact that shake test was positive in only one facility out of those where FWI were positive. More research is necessary to determine the extent of this potential problem.

ACTIONS TAKEN

- Inventory of cold chain with follow-up repair or replacement is conducted every year.
- Number of immunization delivery points (mostly FAPs) with < 10 infants/year is decreased.
- Outreach services are provided for immunization at rural settlements.
- Training of medical professionals involved into immunization to correct use of cold chain equipment is conducted regularly.

DISCUSSION

Question : Knowing that the Freeze-Watch indicator is very sensitive, has there been any confirmation tests such as the Shake Test conducted to confirm that vaccines had indeed frozen or not?

Response : This study was conducted 3 years ago and there are no records of any shake test done. But now things have changed and it would be different.

Question : How did you interpret the fact that there were more CCM changes in winter months?
Response : It was guessed that refrigerators did not work properly. Another participant remarked that this is consistent with other WHO studies in that region. CCMs are more exposed to higher temperatures in winter months because many buildings are heated with hot-water systems (often over-heated) resulting in high room temperatures while refrigerators do not work regularly due to frequent power shortages.

Question : Once having found that domestic refrigerators were inappropriate, what type of equipment was identified to replace them? Response : They could not be replaced as a matter of fact because in too large numbers and average temperatures inside refrigerators were adjusted to 4°C instead of 2°C.

Question : This presentation highlights the importance of knowing about freezing risks before introducing new freeze-sensitive vaccines. Did the study include assessing the cold chain during transport of vaccines, or should it now be assessed?
Response : Only facilities were assessed as they were rather sure about transport.

Question : Freezing during transport might be a problem or not and one cannot know until it has been studied and documented. It is surprising for most of us to see a high percentage of vaccines exposed to very low temperatures where ambient temperatures are high like in Indonesia. So what about in Ukraine?
Response : The next presentation will discuss ways to address certain causes of freezing during transport of vaccines.

Comment : We have known about vaccine freezing for many years and one major concern is the impact on population. Events of vaccine freezing usually triggers a number of public health actions such as recalls, revaccination efforts, etc. In the present case, there doesn't seem to be any such actions taken.
Response : Indeed no specific public health action has been taken. Freezing occured in smaller facilities and the number of such facilities involved with vaccination has been reduced. The situation has improved since and there are less concerns about freezing now. The study was done before the introduction of HepB vaccine. A supply of DTP had been received from GAVI and samples were sent to WHO HQ for testing and it proved that vaccines were fine.

USE OF CHILLED WATER PACKS : Ümit Karto□lu, WHO HQ

Presentation Highlights : Extracted from the presentation

BACKGROUND

Current policy recommends ice packs to be conditioned. WHO international shipping guidelines do NOT require the use of ice packs for freeze-sensitive vaccines. All vaccine manufacturers are using 2^{o}C to 8^{o}C chilled or room temperature water packs.

If packed together, there is NO technology available to provide enough cold for OPV while preventing freezing freeze-sensitive vaccines.

THE STUDY

STUDY HYPOTHESIS : Using chilled water packs during vaccine transportation can safely replace use of ice packs to prevent freezing of cold sensitive vaccines.

STUDY OBJECTIVES :
- Recommend to distinguish shipment of OPV from all other vaccines at country level.
- Recommend the use of chilled water packs (2°C to 8°C) for transportation of vaccines other than OPV.

STUDY SITES AND MATERIAL :

SITE	MATERIAL
CSIR (South Africa)	**RCW25/CF, RCW2/CF**
Blow Kings (India)	**BK-VC 1.6CF, CB20-5U-CF**
Bio Farma (Indonesia)	**Insulated shipping box**
Nepal, Turkey, Zimbabwe	**Various**
Dummy load of vaccines, ambient and inside the transport box multi-channel electronic temperature monitoring, VVM **Testing at 43^{o}C, 32^{o}C and without ice packs**	

RESULTS

RCW25/CF : at 43^{o}C ambient 48 hours, 8^{o}C chilled water packs
Minimum 8.4^{o}C, Maximum 23.8^{o}C, Average 16.5^{o}C
Reading from the hottest recording thermocouple

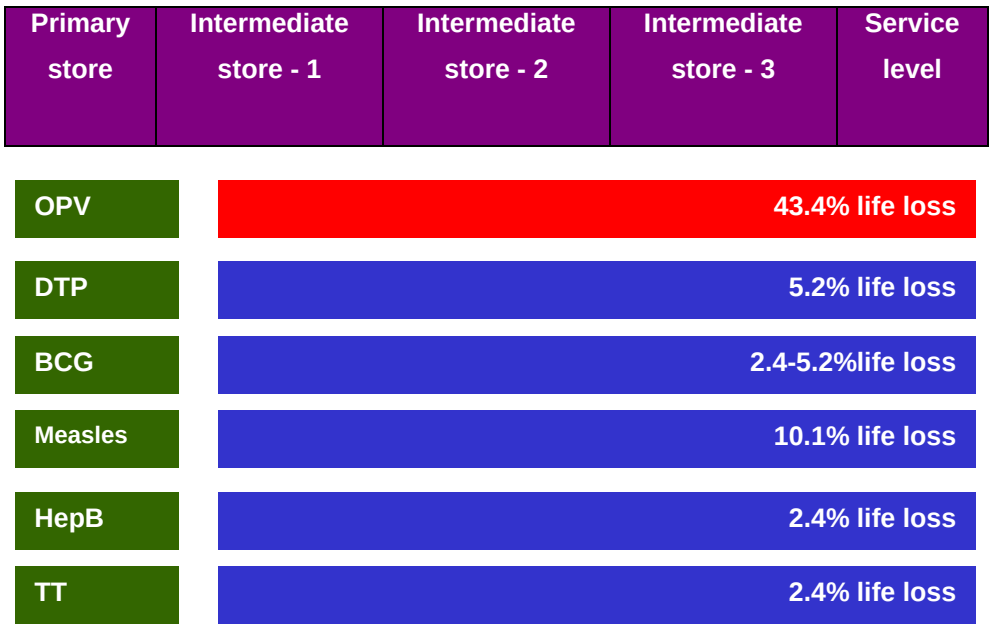
If kept at 37°C

VVM2	1.75 days > 1.61
VVM7	6.12 days > 6.01
VVM14	12.25 days > 12.14
VVM30	26.25 days > 26.14

International shipping box at 43°C ambient 48 hours, 2°C chilled water packs
Minimum 11.58°C, Maximum 25.37°C, Average 18.91°C
Reading from the hottest recording thermocouple

If kept at 37°C

VVM2	1.75 days > 1.56
VVM7	6.12 days > 5.97
VVM14	12.25 days > 12.09
VVM30	26.25 days > 26.09



RCW25/CF at 43°C ambient 48 hours, NO WATER PACKS
Minimum 9.5°C, Maximum 41.2°C, Average 33.1°C
Reading from the hottest recording thermocouple

If kept at 37°C

VVM2	**1.75 days > 0.06**
VVM7	**6.12 days > 4.42**
VVM14	**12.25 days > 10.55**
VVM30	**26.25 days > 24.55**

PLAN FOR POLICY CHANGE

- OPV is to remain in the cold chain except for fast chain during NIDs
- All other vaccines can be safely transported with 2°C to 8°C chilled water packs for a maximum of 4 times not exceeding 48-hour transport time each.
- Present findings and recommendations on how to switch to TWO-TEMPERATURE cold chain at country level will be submitted to SAGE to obtain endorsement.
- Recommend countries to study freezing risks and document and analyze temperature exposures for extreme conditions.
- Study and analyze chilling volume requirements.
- Introduce necessary changes.
- Document success

DISCUSSION

Question : As both RCW2 and RCW2 were tested what was found with the smaller vaccine carriers?
Response : Studied transportation levels do not use small vaccine carriers most of the time. Study results were lower with the smaller carrier and it confirms that it is not an option for OPV but other vaccines are kept within a safe temperature range.

Question : There is no indicator on the packs so will there be one or how does one recognize that they are at the correct temperature?
Response : There will not be any indicator but the recommendation is to chill them between 2° and 8°C in normal refrigerators. It raises the issue of chilling volume requirements that has been raised before.

Comment : There would be problems if large numbers of waterpacks need to be chilled in a hurry.
Response : It is indeed a concern that needs to be looked at.

Comment : It is high spikes of temperature that is damaging for the vaccines, at least this was the impression but this issue was not addressed. In many countries, drivers are on

extended delivery schedules, vehicles are sometimes in very hot temperatures especially inside vehicles.
Response : This was actually tested in Zimbabwe for example, with four full days at very high temperatures. Details are available and the mathematical model shows less vaccine life loss than laboratory studies, having the cold box in the trunk of a vehicle for four days in the sun.

Comment : When storing waterpacks in a refrigerator to chill them the temperature will rise very much. It has been recommended for many years to store water bottles in vaccine refrigerators, so this is the same. We are not concerned with 100 waterpacks in a refrigerator, there will actually be less freezing events. But ideally it is advisable to use separate refrigerators for chilling waterpacks. In the case of absorption refrigerators, it is even necessary.

Question : How should transport for outreach sessions be managed as it is not included in this study? There are additional issues at peripheral level.
Response : True, only four levels were studied and it stopped at Health Center level. Outreach was not taken into consideration in the study but results are also applicable at that level. We cannot recommend -20°C icepacks because of freezing risks so in fact it needs 2 boxes, one with icepacks and one with chilled waterpacks. Another participant also supported the point of considering transport during outreach advising caution about logistics, i.e. requiring staff to transport more equipment than they usually do.

Question : Why not just use less icepacks, for example six frozen and six chilled?
Response : It is done in the field and programme managers have experimented with many variations. One manufacturer also uses a combination of 2°C and room-temperature waterpacks for DTP shipments, and it works. But it has not been fully studied. Once validated and shown to be safe, such combinations could be used.

Question : We know that a RCW25 with icepacks can stay 8 days if unopened. What about cold life with chilled waterpacks?
Response : This needs a redefinition of cold life presently defined at the temperature range of -3° -+10°C. It is ackward as we know that -3°C is not a temperature we should keep vaccines. RCW25 and RCW2 were tested but other boxes could possibly yield different results. These two were tested indeed in a laboratory in South Africa but international shipping standard boxes without seal were also used. Country studies also used locally-produced boxes. The list and results are available.

Comment : What has just been presented will require a complete change in mentality. For 20 years or more, we were conditioned that vaccines had to be kept cold. Now with our present knowledge of vaccines and the availability of VVMs on the one hand, and the serious risks

and problems of vaccine freezing in the context of new and quite expensive vaccines being gradually introduced on the other hand, it requires all of us to support this process and achieve what has been proposed. We have to let go of our feeling that vaccines have to be kept cold.

Comment : We also have to find ways to convince the international community and call on national programme managers and staff for support. Finally we have to find ways to communicate when talking to regulators or manufacturers. There are all sorts of liabilities and vaccines were licenced under certain criteria, and they should not be frightened.

TWO TEMPERATURE COLD CHAIN: CASE STUDY, INDONESIA : Carib Nelson, PATH

Presentation Highlights : Prepared by the presenter and Jane Soepardi, Indonesian MOH

BACKGROUND : Problem Definition

In 2002 a temperature monitoring study was conducted in two of Indonesia's provinces. Electronic data loggers were sent with 16 hepatitis B vaccine shipments from the manufacturer, BioFarma, to the point of use. Freezing temperatures were found in several legs of the cold chain. The most freezing occurred in shipment from province to district (50% of shipments) and during district storage in ice-lined refrigerators (ILRs) (43%). Overall, freezing temperatures occurred in 75% of the vaccine shipments. Since the data loggers measured complete temperature history, we were able to calculate the amount of the VVM life that had been used during these shipments. On average, 29% of the VVM life was expended (29% VVM color change from starting color to discard point color). This amount of heat exposure included an average of 32 days out of the cold chain since midwives in Indonesia routinely store HB-Uniject vaccine in their homes prior to at-birth home immunization.

In 2003, four additional vaccine shipments were monitored during shipment to two new provinces. This time, freezing temperatures were found during provincial storage (50% of shipments), district ILR storage (50% of shipments), and health center refrigeration (50%). Overall 100% of shipments were exposed to freezing temperatures. Temperature analysis showed that the heat exposure for DPT and TT to be 13% and 7% of VVM life expended. HB-Uniject heat exposure consumed 50% of VVM life, including 43 days out of the cold chain.

ANALYZING THE PROBLEM

Meetings were held between the Indonesian MOH, PATH, UNICEF, and WHO to analyze the vaccine freezing problem and lay out plans to overcome it. It was noted that the vaccines fall into two distinct groups: those that are freeze sensitive and those that are heat sensitive. The freeze sensitive vaccines – DPT, HB, and TT -- are also reasonably heat stable and therefore were considered candidates for taking out of the cold chain.

The analysis concluded that:

- Freezing occurs at all levels – interventions must target all levels

- Biggest problems: ILRs, district transport, HC refrigerators, province cold rooms
- HB, TT, DPT experience low heat exposure in cold chain
- Freeze damage probably exceeds heat damage (for freeze-sensitive vaccines)

Several constraints to fixing the cold chain were also identified:

- Indonesia cannot immediately replace all cold chain equipment
- The complexity of the cold chain must not be increased
- Ice pack conditioning is not practiced despite training to do so
- There is a very low recognition of the problem of vaccine freezing at all levels
- Practices and policies put emphasis on heat protection, not freeze prevention

A number of Indonesia-specific opportunities to improve the cold chain were identified:

- VVMs would be put on all freeze-sensitive vaccines in 2004
- BioFarma started using chilled water packs for all international shipments of freeze-sensitive vaccines in 2003
- Indonesia had experienced very positive results with taking HB-Uniject vaccine out of the cold chain since 1995.

EXPLORING SOLUTIONS TO THE PROBLEM

To explore options for reducing freezing and to test the feasibility of taking vaccines out of the cold chain, several interventions were monitored during shipments of HB-Uniject:

1. Out-of-cold-chain transport. Vaccines were transported in cold boxes and vaccine carriers but with no ice packs or water packs. This reduced freezing to 63% of shipments (from 75% in the baseline).
2. Out-of-cold-chain transport + AC district storage. In addition to out of cold chain transport, the vaccines were stored in air-conditioned rooms instead of ILRs at the districts. This reduced freezing to 30% of shipments.
3. Out-of-cold-chain transport + AC at district + room temp HC. In addition to out of cold chain transport and district air-conditioned storage, HB-Uniject vaccines were stored at room temperature at the health centers. This reduced freezing to 0%.

While this proved that taking HB vaccine almost completely out of the cold chain was an effective way of eliminating inadvertent freezing, it was not clear whether this approach would be appropriate for the more heat-sensitive DPT vaccine. Therefore a second round of interventions were monitored using shipments of DPT, TT, and HB-Uniject. The interventions in this round consisted of out-of-cold-chain transport + district and health center retraining. Vaccines were transported without ice packs and district and health center staff were retrained on refrigerator operating procedures. Proper thermostat settings and vaccine loading were emphasized (see attached posters). This reduced freezing to 25% (from 100% of shipments during the baseline for these 2 districts). Freezing still occurred in one province cold room.

Currently, the Indonesian MOH and PATH are conducting an additional round of trial interventions to fine-tune a national approach to reducing cold chain freezing and simplifying the cold chain. In addition

to out of cold chain transport and the district/health center retraining mentioned above, the problematic province has conducted WHO's EVSM cold stores assessment. Freeze-sensitive vaccines are also being stored at room temperature in the health center. Results are expected in May 2004.

Although it is not finalized yet, Indonesia's proposed solution is being called the "Two-Temp Cold Chain" since it handles the freeze-sensitive and heat-sensitive vaccines somewhat differently. The procedures are summarized in figure 1. For the most part, all vaccines are stored together in 2-8 degree cold rooms and refrigerators. The two groups are separated during transport, with freeze-sensitive vaccines transported without ice packs. Heat-sensitive vaccines are transported with ice packs without ice pack conditioning. Chilled water packs are being considered as an option to transport heat and freeze sensitive vaccines together. (OPV is handled separately at the province and during district transport).

Figure 1. Indonesia's 2-temp cold chain approach

<table>
<tr><th></th><th>Transport to Province</th><th>Province Cold Room Storage</th><th>Transport to District</th><th>District Storage</th><th>Transport to Health Center</th><th>Health Center Storage</th><th>Out of Cold Chain Outreach</th></tr>
<tr><td>Freeze sensitive</td><td>Water packs</td><td rowspan="2">2° to 8°C cold room: conduct EVSM, repair, reset thermostat (OPV: -20°C cold room)</td><td>No packs (alt: water packs)</td><td rowspan="2">ILR with retraining: loading, reset thermostat</td><td>No packs (alt: water packs)</td><td rowspan="2">RCW refrigerator with retraining: loading, setting thermostat</td><td>No packs</td></tr>
<tr><td>Heat sensitive</td><td>Ice packs
(OPV: dry ice)</td><td>Ice packs (alt: water packs)</td><td>Ice packs (alt: water packs)</td><td>Ice packs (alt: water packs)</td></tr>
</table>

OVERVIEW OF INDONESIA'S COLD CHAIN REVIEW PROCESS AND FINDINGS

Timeline of Indonesia's cold chain improvement process

1. Conduct temperature monitoring studies: '02-'03
2. Implement and evaluate interventions: '03-'04
3. Review options and finalize improvements: '04
4. Validate revised procedures: '04
5. National implementation: '05

Transport Considerations

Approach	**Issue**
Ice packs	Vaccines freeze
Conditioned ice packs	People don't do it
Chilled water packs	Effective, easy, need dedicated fridges, heat exposure minimal
Out-of-cold-chain transport	Effective, easy, more vaccines per carrier, no refrigerators needed, heat exposure minimal

Cold Room Options

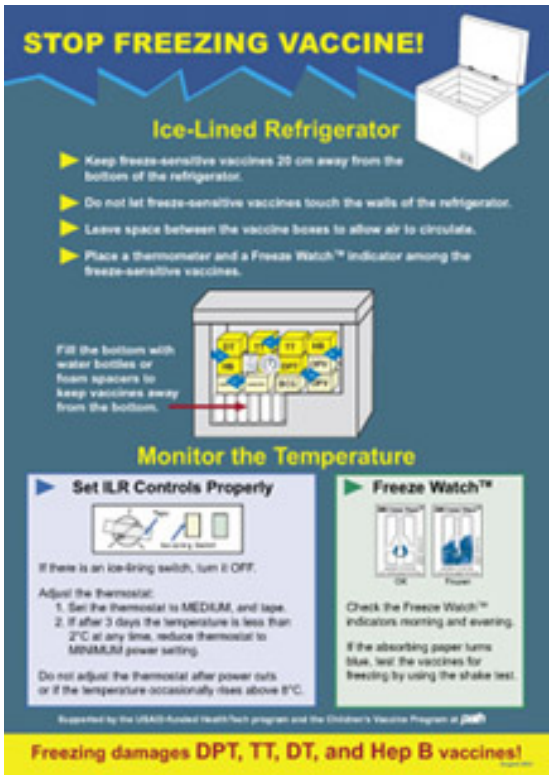
- Raise awareness of freezing
- Conduct EVSM audit
- Fix equipment
- Install computerized temperature monitoring system

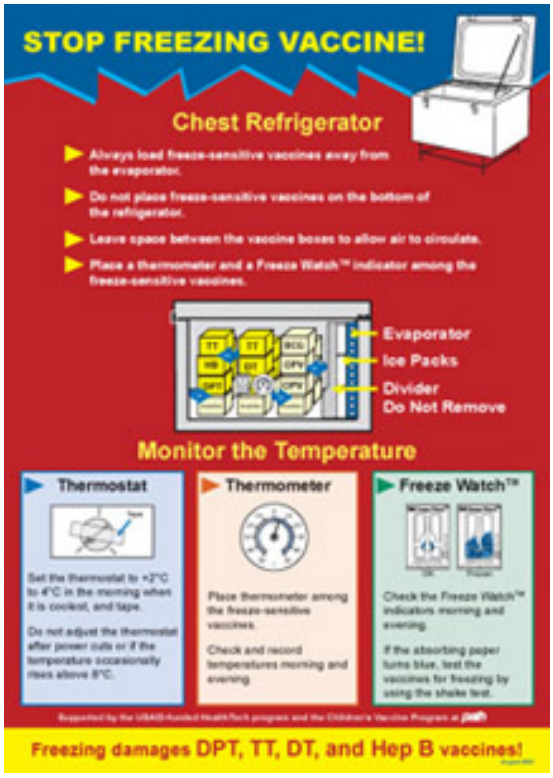
ILR retraining points

A training poster was developed to teach and remind users of ILRs about proper temperature control and loading procedures (below).

The key points are:

- Raise awareness of inadvertent vaccine freezing
- Set control to minimum power – this converts the ILR into a water-lined refrigerator
- Load freeze-sensitive vaccines on top
- Strengthen supervision





Health Center refrigerator retraining points : A training poster was developed to teach and remind users of health center refrigerators about proper temperature control and loading procedures (see above). The key points are:

- Raise awareness of inadvertent vaccine freezing
- Load properly – keep freeze-sensitive vaccines away from evaporator and allow circulation
- Reset thermostat to warmer temperature -- Do not readjust thermostat
- Strengthen supervision

Awareness of Freezing is Crucial

- Conduct a temperature monitoring study
- TTMs required -- $1000
- Protocol is available from PATH

CONCLUSIONS

Freezing probably causes more vaccine damage than heat. Removing vaccines from freeze-susceptible parts of the cold chain prevents freezing and does not result in excessive heat exposure. However VVMs are needed when taking vaccines out of the cold chain. High-level commitment to increasing awareness, policy change, and retraining are necessary to overcome freezing,

Please contact Carib Nelson (cnelson@path.org) for more information or for electronic versions of the freeze-prevention training posters or the temperature monitoring protocol.

The study is published in the following issue of the WHO Bulletin :

Bulletin of the World Health Organization ; February 2004, 82 (2) pp. 99-105

DISCUSSION

A few comments were made first to the effect that this study provoked a shift in health workers' minds and raised awareness about freezing instead of heat exposure. In places like the State of Andra Pradesh in India and Afghanistan, actions were taken as a result.

Question : It is convincing that vaccines have a potential of being exposed to freezing but not that they actually froze. Indeed only sub-zero temperatures were recorded but what was done to determine that vaccines actually froze ?
Response : Two cases of Diphteria outbreaks occured in Indonesia and storage management was not too good in these areas. But vaccine efficacy was still fine as cases occured in older age groups. In other provinces, storage was good and it was determined that freezing did occur in cold romms in affected provinces.

Comment : We have to follow recommendations of manufacturers and often transport of cold-sensitive vaccines can even be done without icepacks.

Comment : Shipping trials should be given more general value for use globally by accompanying them with potency testing. Follow-up of children with seroprotection rates for up to 10-20 years would be very useful. Seroanalysis was indeed conducted, and there is a publication that can be found on the meeting CD.

Question : It is confusing to have cold boxes that don't work any more. Before we had to maintain a temperature above -3°C but it is now higher at -0.5°C. And we are still left with

having to keep vacines in refrigerators equipment. Can we think of having a freeze-sensitive VVM in the future?

Response : It is a good idea and PATH is looking for the technology yet to be found. Another participant stated that the technology for a freeze indicator exists but it is quite complex. Freezing is not cumulative, an indicator can show exposure to freezing temperature over a certain period of time but not that the vaccine actually froze. A second technology is needed at that point. Manufacturers didn't show interest fore that technology.

Question : What support can countries count on to really assess if vaccines can be used or if there is a need for another dose?

Response : Temperature data loggers can show that vacines were exposed to too low or too high temperatures but there is a question of interpretation and decision-making. It can eventually have a major impact on epidemiology. This question is left for the end-of-session discussion. It could go in quite many details and it may be the case that we complicate matters or going in the wrong direction.

VACCINES OUT OF THE COLD CHAIN: REVIEW OF EXISTING DATA FOR HepB

David Hipgrave, Australian International Health Institute, University of Melbourne

Presentation Highlights : Extracted both from the presenter's paper and presentation

BACKGROUND

Vaccines against the hepatitis B virus (HBV) have been available for over 20 years, but are usually distributed within the cold chain, along with other vaccines used in national immunisation programs. Recognition of the heat stability of the main component of hepatitis B vaccine (HepB vaccine), the HBV surface antigen, stimulated research into its use after storage in or exposure to ambient or high temperatures. Storage at ambient temperature would facilitate the timely administration of a birth dose of the vaccine to newborns delivered at home or at health posts lacking refrigeration. This presentation reviews the current evidence for use of vaccines against HBV outside the cold chain. Whilst concluding that existing HepB vaccines shipped with a vaccine vial monitor and used appropriately are almost certainly safe and effective for use outside the cold chain, it discusses the need for further research into both the immunogenicity and protective efficacy of the vaccine amongst newborns, to assist policy- and country-level decision-makers.

SUMMARY OF EXISTING RESEARCH

- Search methodology:
  - Medline database accessed through PubMed and again through the New England Journal of Medicine
  - Embase search
  - Entry point 1980
- Reviews of vaccine thermostability and HepB vaccines in clinical practice

- Personal contacts with experts

RESEARCH PAPERS

- Four papers identified : - Two field studies (plasma-derived vaccine)
  - Two controlled studies (rDNA vaccine)

Table 1: Summary of human studies of the immunogenicity and protective efficacy of hepatitis B vaccine stored outside the cold chain (OCC)

Report and type of vaccine used	Group	How doses stored	Number followed up	Anti-HBs >1/ ≥10 mIU/ml in percent	GMT	Protective efficacy (percent)
Otto et al. (1999)	1	At 2 - 8°C, in 10-dose vials	55	98.2 / 94.7	376	NA
5µg plasma-derived	2	At 2 - 8°C, in Uniject	75	95.2 / 92.8	312	NA
	3	Dose-1 OCC in Uniject, for up to one month, doses 2 & 3 at 2 - 8°C	87	97.8 / 88.2	288	NA
Anonymous (1993)	1	At 4 – 8°C	232	81.9 / NA	NA	77.8
10µg plasma-derived	2	Dose-1 OCC (15-30°C) for up to 3 months, doses 2 & 3 at 4 - 8°C	358	81.6 / NA	NA	84.5
Just and Berger (1988)	1	At 4 °C	31	100 / 100	2054	NA
20µg recombinant	2	All 3 doses exposed to 37°C for one week	27	97 / 97	3392	NA
Van Damme et al. (1992)	1	At 4 °C	33	100 / 100	10,359	NA
20µg recombinant	2	All 3 doses exposed to 45°C for one month	39	95 / 95	6,813	NA
	3	All 3 doses exposed to 37°C for one month	37	100 / 100	5,937	NA

MANUFACTURERS' DATA

The final source of information about the heat stability of HepB vaccine comes from the manufacturers of the vaccines themselves. Although pharmaceutical companies are traditionally cautious in recommending use of their products outside standard conditions, these sources also offer encouragement.

WHAT CAN BE CONCLUDED?

The existing data

These four studies and manufacturer data offer encouraging support for use of HepB vaccine after storage OCC, and are in keeping with the known heat stability of the HBsAg, the immunogenic component of all HepB vaccines. The results of each study suggest no difference in the frequency or strength of the antibody response between infants or adults immunised with vaccine stored cold, OCC, or exposed to fixed high temperatures. In particular, studies three and four offer important information on the immunogenicity of HepB vaccine exposed to heat, as all three doses of vaccine in the "treatment" groups were exposed, as opposed to only the first dose in the two field studies, yet there were normal rates of seroconversion and titres of antibody amongst recipients.

The attachment of VVMs to vials of HepB vaccine by manufacturers adds a new dimension to this issue. To the extent that vaccine safety and effectiveness exactly mirrors changes in the VVM, storage OCC should be completely safe and effective if the VVM is used strictly as intended. However, it may also result in high rates of vaccine wastage if spoilage of the VVM is common. This parameter should also be included in future field studies of HepB vaccine OCC.

Table 2: Stability of several types of hepatitis B vaccine according to immunogenicity tests on animals

Vaccine type	Parameter used to assess vaccine	Storage temperature (°C)			
		2 – 8	**20 – 26**	**36 – 40**	**45**
Plasma	Longest storage without significant loss of potency	24m.	12m.	3m.	ND
Plasma	Remaining % potency after specified time	100% at 24 m.	70% at 24m.	70% at 24m	ND
Plasma	Longest storage with relative potency upper confidence interval >1[1]	44m.	ND	ND	ND
Plasma	Half-life [2]	>3y.	4m.	7d.	ND
Recombinant	Longest storage with relative potency upper confidence interval >1	53m.	12m.	7m.	1m.
	Half-life	ND	9m.	1m.	3d.

adapted from Galazka et al., 1998: ND = no data available / y. = years / m. = months / d. = days

[1] Refers to potency in comparison to vaccine stored for shorter periods of time or at +2- 8°C for the same period of time.

[2] half-life: time at which 50% of original vaccine potency lost

Each study supports the safety and effectiveness (immunogenicity) of HepB vaccine after storage OCC. However only the Chinese study addressed the issue of protective efficacy (PE) amongst infants delivered by infectious mothers. The research and manufacturer data presented above refer only to the immunogenicity of HepB vaccines exposed to heat, but in most south east Asian tropical nations, the objective of birth dosing is to prevent perinatal transmission. This is measured by the protective efficacy of the vaccine amongst infants delivered by carrier mothers (essentially the vaccine's post-exposure efficacy), and is far more difficult to assess because of the need to screen mothers and the relatively smaller number of infants in this group.

WHAT ABOUT PE?

- Protective efficacy is the main reason for bothering with birth dosing.
- If heat-exposure has any effect on PE, might birth dosing not be worth the cost, risk and effort?
- Countries reluctant to implement an OCC strategy worry about wastage due to vaccine spoilage
- They also worry that health staff will take other vaccines OCC in error.

SHOULD COUNTRIES WAIT OR GO AHEAD?

- GO AHEAD!
- The issue of ↓ PE after storage OCC is hypothetical.
- The benefit of birth dosing is not in doubt. We believe that with appropriate support, nations should proceed with an OCC strategy for the birth dose as the risks are low and the public health gains potentially large, particularly in increasing the likelihood of infants receiving 3 doses of HepB vaccine.
- However such programs should be monitored and evaluated carefully.
- *Primum non nocere?* (Is it dangerous?) In the era of the VVM, and with the available data, storage of HepB vaccine OCC the cold chain must be considered safe.
- Wastage / spoilage can be minimised with VVM, and other risks minimised with good HW education.

GO AHEAD! BUT MONITOR AND EVALUATE

- Evaluation of OCC strategies in the context of program evaluation is recommended
- Both immunogenicity and HBsAg rates should be included.
- If can't formally test for PE prospectively, post-hoc HBsAg rates should be compared with pre-hoc rates and with those amongst infants receiving vaccine stored cold
- Possible role of quicktest?
- Also monitor quantitative / qualitative benefits relating to timeliness and acceptability to HW and community

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DISCUSSION

Comment : When saying that "storage of vaccines out-of-the-cold-chain (OCC) is safe" we should be very careful about how the message is received by health workers who have to interpret. It has to be clear that this applies to HepB vaccines in specific conditions with clear parameters as conditions vary from country to country. Alongside with policy changes there must be a high level of commitment to training and re-training.

Comment : EPI Managers have lost control over drivers in many countries as they became integrated in wider Health logistics. Often drivers do not know about vaccines and the need they be kept cold. It would be incorrect to say that vaccines no longer need to be in the cold chain. It applies only to HepB vaccines indeed.

Comment : One other advantage observed in Indonesia is that it permitted to tag on other health interventions such as umbilical cord care, breast-feeding education, etc.

Comment : The age of vaccines used was not stated. Knowing that vaccines remain on average for two years in the cold chain, if fresh-from-the-manufacturer vaccines were used, it would not be representative.

Response : It is true that two studies conducted in Belgium used just-produced vaccines and yielded good serological results.

Question : Were sero-conversion rates lower in recipients of OCC vaccines ?
Response : There is a need for further research but Van Damme' study and those in China showed similar conversion rates. In Indonesia rates were lower but there are other confounding variables. More data are needed.

Comment : Data from Galaska's papers on potency were for fresh vaccines. When looking at potency loss until it reaches a sub-potent level, vaccines cannot be kept at 37°C for more than 1-2 weeks without affecting shelf life of the product. MDVP depends upon which climatic conditions and some vaccines may not go up through usage point.

Question : Is there a potential implication for combined vaccines?
Response : Research was conducted only with monovalent vaccine and it would be different with combined ones. However the benefit is for the birth dose and other vaccines are not used for this dose.

Question : Vaccines out-of-the-cold-chain can also be exposed to freezing in some countries in winter, there would be a need for a "warm chain". Are there any studies on this?
Response : Nobody seems aware of any such studies.

VACCINES OUT OF THE COLD CHAIN: WHO PLANS FOR HepB POLICY DEVELOPMENT

Steven Wiersma, WHO HQ

Presentation Highlights : Extracted from the presentation with additions from the presenter's paper.

BACKGROUND

There has been much work on looking at the issue of allowing the use of hepatitis B vaccine outside of the cold chain. This information has led to the widespread use of the VVM30 marker with this vaccine. One WHO document calls for further research be conducted to “evaluate cost, cost-effectiveness, logistics (e.g. storage, transport, administration, waste disposal), vaccine coverage and safety issues”[1] A more recent WHO document goes further towards providing guidance for a policy change but stresses that this is a country responsibility .

[1] “Introduction of hepatitis B vaccine into childhood immunization services” (WHO/V&B/01.31)

WHAT IS OCC?

- OCC is an operational tool to increase the access to vaccines with VVMs safely and effectively
- OCC is intended to be applied in circumstances where benefits exceed risks
- OCC does not change current routine storage guidelines
- OCC does not change the need for close monitoring of vaccines
- OCC: A Bad Name?
    - Fast Chain
    - Dual Cold Chain
    - Two Temperature Cold Chain
    - Modified Cold Chain
    - VVM-Guided Vaccine Management
    - Others?

CONCLUSIONS

Vaccines with VVMs can be taken out of the cold chain only if health workers and others handling the vaccines have been trained to interpret VVM readings correctly and if any vial bearing a VVM that has reached its end-point is discarded. Managerially, however, it is wise to maintain vaccine in the cold chain for as long as possible during distribution. This ensures the maximum viable life in the field. A policy permitting the use of vaccine outside the cold chain can be implemented either generally for all routine immunization activities or on a limited basis in certain areas or under special circumstances, such as:

- national immunization days;
- hard-to-reach geographical areas;
- immunizations provided in the home;
- cool seasons;
- storage and transportation of freeze-sensitive vaccines (DTP, TT, DT, Td, hepatitis B and Hib vaccines) where the risk of freezing is greater than the risk of heat exposure.[5]

So far only one country, Indonesia, has implemented the use of birth dose hepatitis B outside of the cold chain. This country uses locally produced Hepatitis B vaccine in Uniject™ devices.

NEXT STEPS

There is an urgent need to review the evidence that has accumulated over the past few years, to identify the remaining gaps in knowledge and to develop clear guidance on this issue:

1. In areas where many births take place outside of health facilities, the use of hepatitis B outside the cold chain can facilitate access to the critical birth dose.

ccccccccccccccccc

5 "Getting started with vaccine vial monitors" (WHO/V&B/02.35)

2. Storage and transport of Hepatitis B vaccine outside of the cold chain will help reduce the risks of freezing which for Hepatitis B vaccine are a greater threat to potency that exposure to heat.

3. The cost saving implications can be substantial: reducing the need for specialized cold chain equipment and reducing the number of appliances required.
4. Programmatic information gained could be applied to other vaccines to improve effectiveness and decrease costs.

WHO will provide leadership over the next 2 years to reviewing the literature, identifying and filling gaps in the knowledge base, and in developing and promulgating policy options.

CONCLUSIONS

Instead of the plenary discussion, the conclusions of the Working Group are presented here below.

A STRATEGY FOR CREATING A VACCINE SAFE CHAIN: INCREASING ACCESS AND REDUCING TEMPERATURE DAMAGE : VACCINE SAFE CHAIN

- Technet has identified temperature damage to vaccines as a major issue.
- Recent data show that vaccine exposure to sub-zero temperatures poses a significant public health risk.
- This risk is especially concerning due to the increase in expensive freeze-sensitive vaccines being introduced in many countries.
- *Technet recommends that WHO convenes a group to outline a strategy and plan of action to ensure a vaccine safe chain that prevents damage to all vaccines.*

- The implementation of this strategy will depend on the provision of all vaccines with VVMs.
- The work group will provide the opportunity for multiple partner inputs, including those from the private and public sectors.
- This strategy and work plan should be presented to the next SAGE.
- Technet wishes to recognize the important efforts of the Governments of Indonesia and Ukraine in advancing our understanding of these issues.

3 A STRATEGY OUTLINE…

- Create awareness regarding the global problem of vaccine freezing
  - Publish an educational document on the problem of vaccine freezing
  - Facilitate the publication of peer-reviewed studies on freezing as well as solutions
  - Develop research agenda
- Document freezing problems where they exist
  - Develop guidelines for country-level comprehensive freezing assessments (using Indonesia blueprint)
  - Increase use of temperature/time monitors
- Promote solutions for addressing freezing issues
  - Use case studies to develop a menu of proven options for reducing temperature damage
  - Make available a menu of solutions
    - International transport and acceptance issues (eg chilled water packs, vaccine arrival reports)
    - Central, provincial, district storage issues
    - In-country transport issues
    - End-use storage issues (eg VVM-guided cold chain)
- Evaluate and document results

SESSION 5 : VACCINE MANAGEMENT

Chair: Diana Chang-Blanc, PATH, Thailand

SESSION ACHIEVEMENT

Session objective: Review update on progress in EVSM initiative and vaccine management assessments

Expected outcome: Agree on target countries for self-assessments and adoption of the initiative

Four presentations contributed to fully achieve the session's objective. First a thorough review of the initiative was presented which has just come to maturity the very same month of the meeting with the release of the EVSM package. It was followed by an update on EVSM activities so far.

An example of best practices in the Sultanate of Oman was presented. Oman achievements in vaccine store menagement is impressive indeed and it became the first and so far only country to have its primary cold store awarded the EVSM certification. A brief ceremony followed the presentation during which Dr. Salah al-Awaidi from Oman received from WHO and UNICEF representatives, a plaque awarded in recognition of Oman's achievements in vaccine store management.

Finally, a regional perspective from the South-east Asian region was presented. Following EVSM and the VM assessments, EPI and central store managers from the region participated in the GTN course on EVSM and VM. The region is now moving ahead in developing its own training capacities in some countries. In Nepal, National Health Training Center (NHTC) in Katmandu is to conduct in-country vaccine management courses for district level EPI managers and for PHC workers.

The Initiative was praised and widely accepted without discussion. Target countries were not questioned and were also accepted. There were a few suggestions for addition but although some additional countries may be considered, it is unclear if more can be included in actual plans.

WHO-UNICEF EFFECTIVE VACCINE STORE MANAGEMENT INITIATIVE : Ümit Karto□lu, WHO HQ

Presentation Highlights : Prepared by the presenter

BACKGROUND :

The WHO-UNICEF Effective Vaccine Store Management (EVSM) initiative grew from a working group of experts meeting that convened in December 2001. The working group aimed at defining measurable minimum standards for Primary Vaccine stores. The standards would form objective performance criteria that would be applicable globally. Experience showed that critical management and equipment failures that occur at primary and intermediate vaccine stores place whole immunization services at risk.

During 2002 the package of documents and materials, known as the Cold Store Certification Initiative (CSCI) was developed and field tested in Albania and Oman. Following the field testing the material were revised and updated.

In early 2003 the initiative changed its name and evolved into the EVSM. The partners in the initiative, WHO-UNICEF in collaboration with their regional and country offices agreed on a list of priority countries. The first EVSM assessment took place in Moldova in July 2003. Oman was the first country to meet the standards in October 2003. The EVSM package was released in the March 2004.

EVSM GOAL

The goal of the EVSM is to encourage countries to procure and maintain equipment and to adopt management and training practices that fully protect vaccines in primary and intermediate vaccine stores. The highest priority lies at the primary store because this affects the quality of the vaccine delivered nation-wide. The intention of the EVSM is to assist programmes, in a systematic manner, to identify and correct weaknesses in store management where these exist. Equally, the EVSM aims to strengthen existing practices where these are of a high standard.

As a package the EVSM initiative provides a tool to national managers to improve their vaccine storage and distribution systems. It provides a framework, in a systematic manner to assist national programmes.

EVSM STRATEGY

The EVSM defines ten global criteria for effective vaccine store management. The initiative provides self-assessments tools, guidelines and model standards, focussed primarily on primary vaccine stores. Countries will use the tools to assess their performance against the 10 global criteria in the areas of equipment, operating procedures, training and funding arrangements, highlighting the areas that require improvements. Subsequently if a country wishes it can be internationally assessed and recognized.

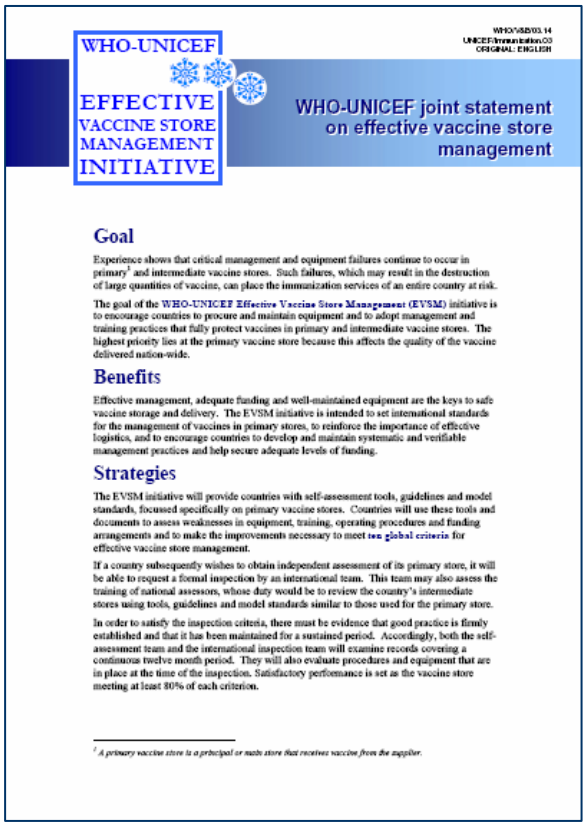
EVSM assessments should be presented to the ICC and endorsement gained to support the changes required, both management and resources. It is key that all the partners recognize the significance of the primary store and support the EVSM.

THE EVSM PACKAGE

The EVSM package consists of a joint statement and four modules.

THE JOINT STATEMENT

The initiative is underpinned by a joint statement that specifies the goals, benefits, strategies, and global criteria endorsed by the Director of the department of Immunization, Vaccines and Biologicals at WHO HQ, the Director of UNICEF Supply Division and the Director Programme Division UNICEF New York.



WHO/V&B/03.14
UNICEF/Immunization/03
ORIGINAL: ENGLISH

WHO-UNICEF

EFFECTIVE VACCINE STORE MANAGEMENT INITIATIVE

WHO-UNICEF joint statement on effective vaccine store management

Goal

Experience shows that critical management and equipment failures continue to occur in primary[1] and intermediate vaccine stores. Such failures, which may result in the destruction of large quantities of vaccine, can place the immunization services of an entire country at risk.

The goal of the WHO-UNICEF Effective Vaccine Store Management (EVSM) initiative is to encourage countries to procure and maintain equipment and to adopt management and training practices that fully protect vaccines in primary and intermediate vaccine stores. The highest priority lies at the primary vaccine store because this affects the quality of the vaccine delivered nation-wide.

Benefits

Effective management, adequate funding and well-maintained equipment are the keys to safe vaccine storage and delivery. The EVSM initiative is intended to set international standards for the management of vaccines in primary stores, to reinforce the importance of effective logistics, and to encourage countries to develop and maintain systematic and verifiable management practices and help secure adequate levels of funding.

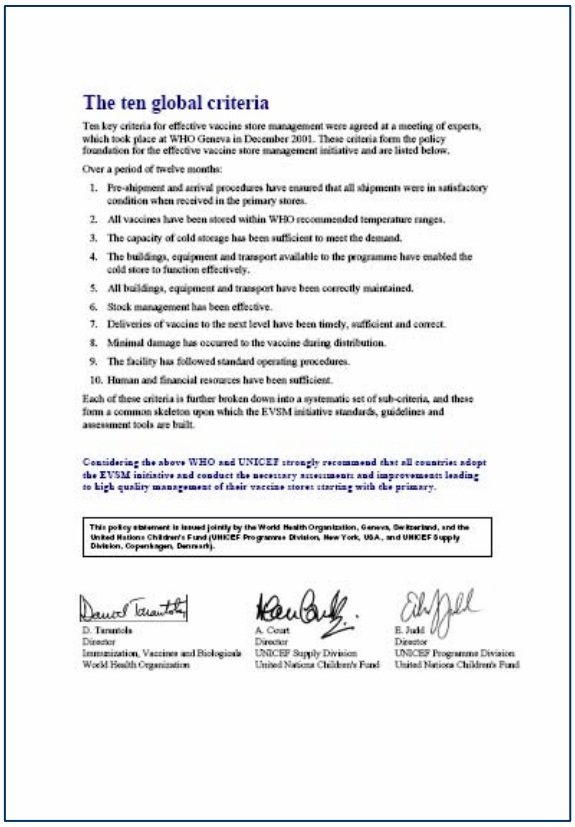
Strategies

The EVSM initiative will provide countries with self-assessment tools, guidelines and model standards, focussed specifically on primary vaccine stores. Countries will use these tools and documents to assess weaknesses in equipment, training, operating procedures and funding arrangements and to make the improvements necessary to meet ten global criteria for effective vaccine store management.

If a country subsequently wishes to obtain independent assessment of its primary store, it will be able to request a formal inspection by an international team. This team may also assess the training of national assessors, whose duty would be to review the country's intermediate stores using tools, guidelines and model standards similar to those used for the primary store.

In order to satisfy the inspection criteria, there must be evidence that good practice is firmly established and that it has been maintained for a sustained period. Accordingly, both the self-assessment team and the international inspection team will examine records covering a continuous twelve month period. They will also evaluate procedures and equipment that are in place at the time of the inspection. Satisfactory performance is set as the vaccine store meeting at least 80% of each criterion.

[1] *A primary vaccine store is a principal or main store that receives vaccine from the supplier.*



The ten global criteria

Ten key criteria for effective vaccine store management were agreed at a meeting of experts, which took place at WHO Geneva in December 2001. These criteria form the policy foundation for the effective vaccine store management initiative and are listed below.

Over a period of twelve months:

1. Pre-shipment and arrival procedures have ensured that all shipments were in satisfactory condition when received in the primary stores.
2. All vaccines have been stored within WHO recommended temperature ranges.
3. The capacity of cold storage has been sufficient to meet the demand.
4. The buildings, equipment and transport available to the programme have enabled the cold store to function effectively.
5. All buildings, equipment and transport have been correctly maintained.
6. Stock management has been effective.
7. Deliveries of vaccine to the next level have been timely, sufficient and correct.
8. Minimal damage has occurred to the vaccine during distribution.
9. The facility has followed standard operating procedures.
10. Human and financial resources have been sufficient.

Each of these criteria is further broken down into a systematic set of sub-criteria, and these form a common skeleton upon which the EVSM initiative standards, guidelines and assessment tools are built.

Considering the above WHO and UNICEF strongly recommend that all countries adopt the EVSM initiative and conduct the necessary assessments and improvements leading to high quality management of their vaccine stores starting with the primary.

This policy statement is issued jointly by the World Health Organization, Geneva, Switzerland, and the United Nations Children's Fund (UNICEF Programme Division, New York, USA, and UNICEF Supply Division, Copenhagen, Denmark).

D. Tarantola
Director
Immunization, Vaccines and Biologicals
World Health Organization

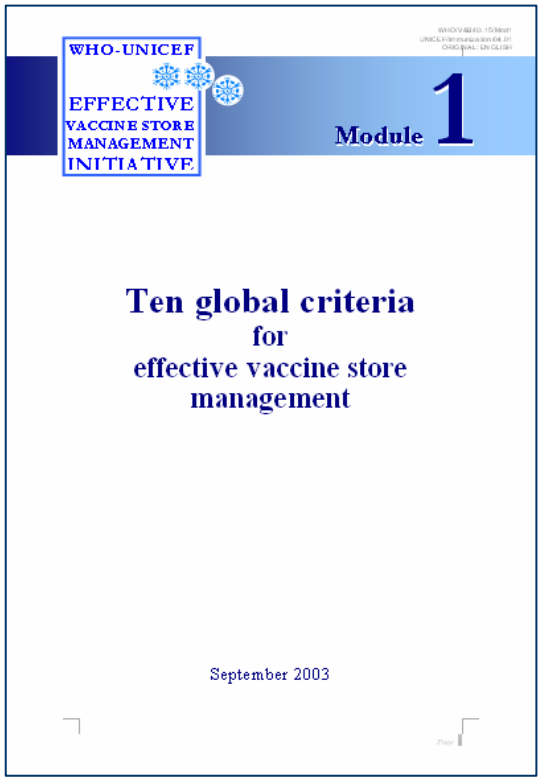
A. Court
Director
UNICEF Supply Division
United Nations Children's Fund

E. Judd
Director
UNICEF Programme Division
United Nations Children's Fund

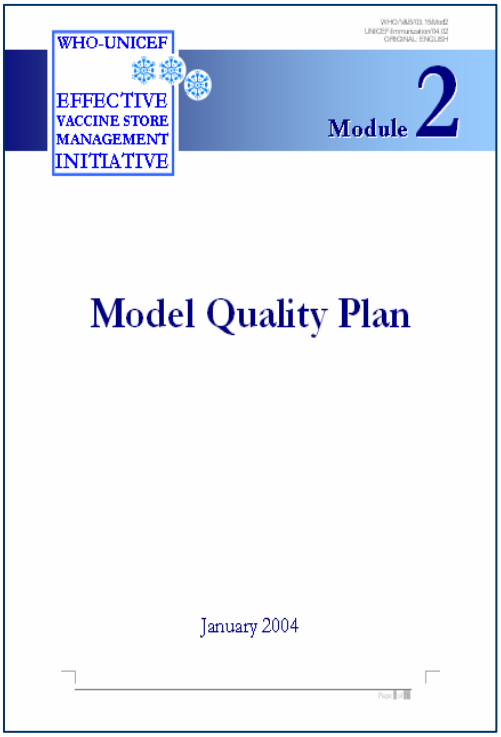
MODULE 1. TEN GLOBAL CRITERIA FOR EFFECTIVE STORE MANAGEMENT

This document details the ten global criteria:

1. all shipments were in satisfactory condition when received in primary stores
2. all vaccines have been stored within WHO recommended temperature ranges
3. the capacity of cold storage has been sufficient to meet demand
4. the buildings, equipment and transport available to the programme have enabled the cold store to function effectively
5. all buildings, equipment and transport have been correctly maintained
6. stock management has been effective
7. deliveries of vaccine to the next level have been timely, sufficient and correct
8. minimal damage has occurred during distribution
9. the facility has followed standard operating procedures
10. human and financial resources have been sufficient



MODULE 2. MODEL QUALITY



This document is a reference source. It takes the ten global criteria listed in Module 1 and breaks them down into sub-headings, critical indicators, and supplements these sub-headings with supporting material. Much of the material in the Model Quality Plan has been extracted and edited (and referenced) from other sources such as WHO documents and UNICEF standard forms

The Model Quality Plan is a source document. Programme managers are encouraged to adapt the material to meet national needs. The intention is that the document should be used as a basis for a National Quality Plan. It may also be used as a source for developing the Standard Operating Procedures and training materials referred to in the Model Quality Plan.

MODULE 3. ASSESSMENT QUESTIONNAIRE

The assessment questionnaire is a standardized form that is used to collect data so that it can be analyzed in a consistent manner. It is an easy to use tool that guides the assessor in detailed logical data collection that objectively measure the performance of the cold store against the ten global criteria for effective vaccine store management.

The tool itself is an excel workbook made up of 14 worksheets. The worksheets include three types of question.

First there are those highlighted as ***Critical indicators***. These questions are intended to test the most fundamental aspects of vaccine store management, and for this reason each one attracts a high score. A low score against a critical indicator provides strong evidence that an aspect of store management is dangerously weak and that significant improvements need to be made.

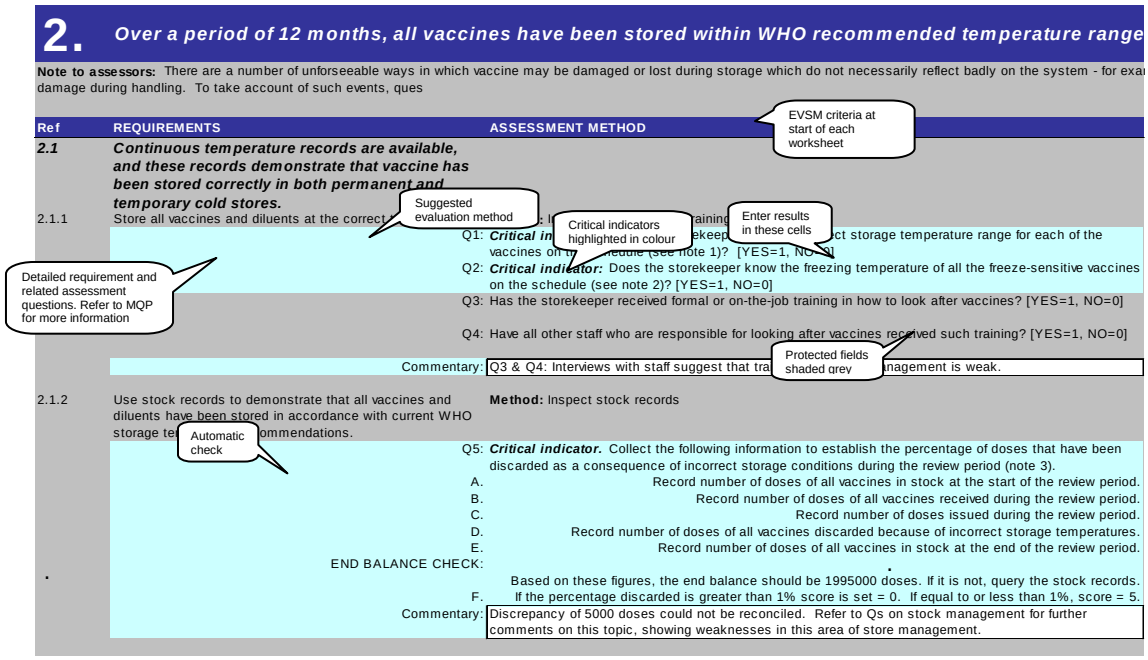
The second group of questions evaluates aspects of store management, which although less critical than the first group, nevertheless provide evidence of good management practice. These questions are also scored numerically.

The third group of questions requires a written commentary. Most of these questions deal with broader issues, such as financial management and resources. As noted above, the majority of the questions of this type are listed under criteria 9 and 10.

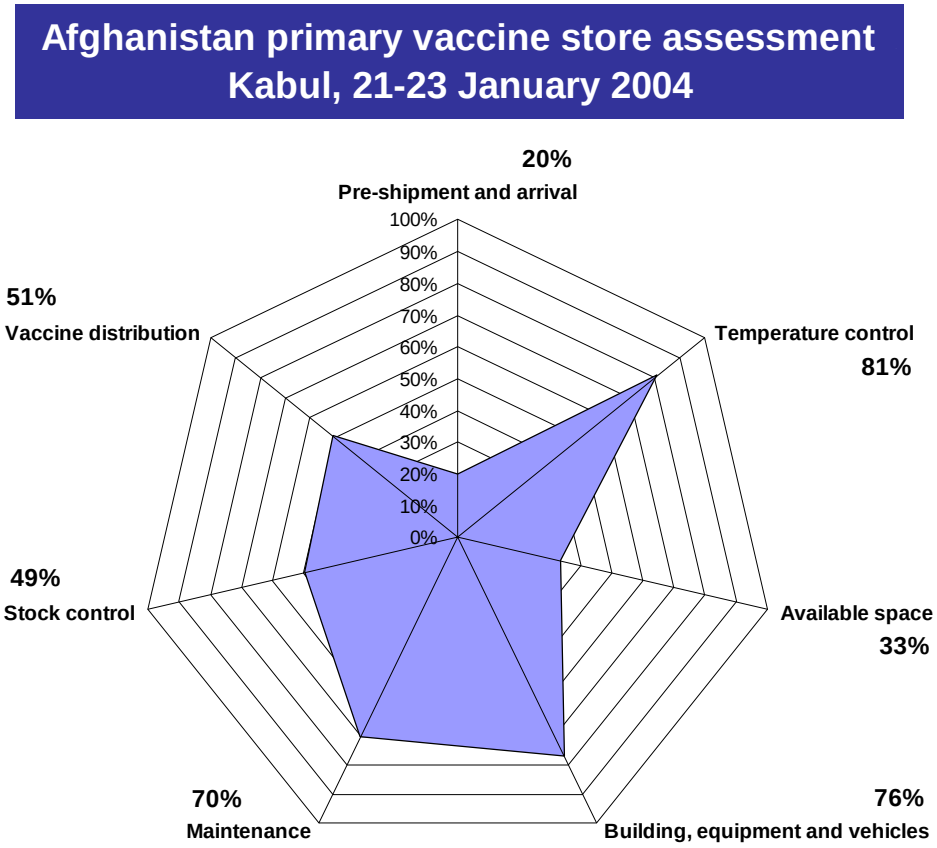
Note that numerical scoring is only part of the evaluation exercise. It is essential that assessors also record their observations in written form. For this reason every question, or group of questions, is followed by a *Commentary* box in which assessors can amplify and qualify their findings. These commentaries are intended to form part of the content of the assessment report which will accompany every EVSM evaluation.

Satisfactory performance level for each criteria is set as 80%.

The Figure below shows an annotated extract from the questionnaire.



EVSM assessment overall results are displayed automatically by the tool as below



MODULE 4. GUIDELINES FOR SELF-ASSESSMENT

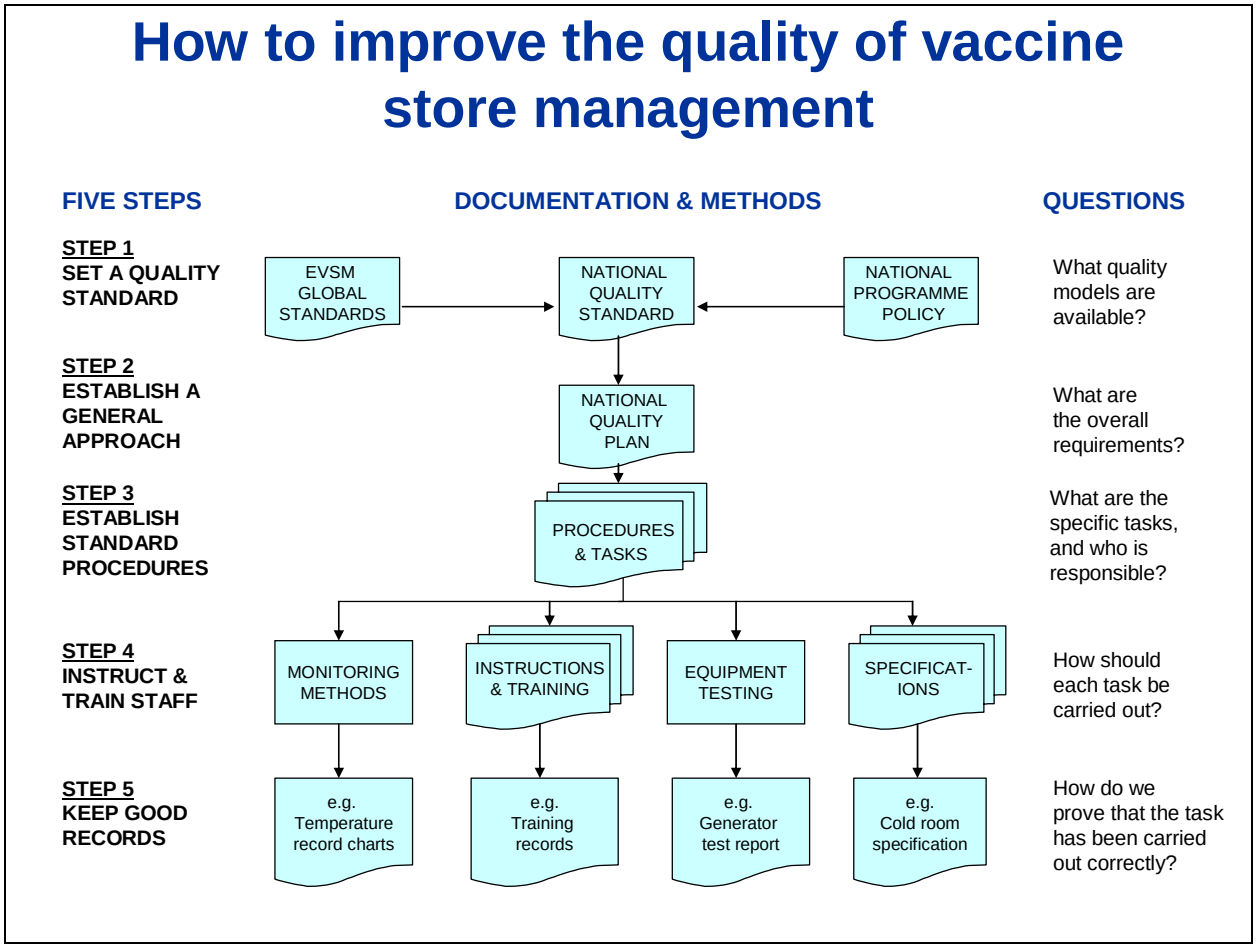
The guidelines are designed to assist national managers to assess their own vaccine stores using the Assessment Questionnaire. It describes, in detail the process of implementing the EVSM.

The guidelines show how national teams can use the Model Quality Plan and the Assessment Questionnaire to analyze and rectify defects in the management of the primary store and then carry out a self-assessment exercise.

IMPLEMENTING THE EVSM

Implementing the EVSM requires a significant management effort over a period of months. However the cost of a major loss of vaccine at a primary level vaccine store is high and is likely to far outweigh the cost of introducing the sound management methods and effective monitoring procedures advocated by the Effective Vaccine Store Management initiative.

The suggested approach is illustrated below :



The process of implementing EVSM:

- Countries use the assessment tool and the Model quality Plan to carry out a rapid review of existing procedures, financial resources, staffing levels, training, buildings, equipment and transport. Identify any major weaknesses, especially in areas identified as ***critical indicators*** in the assessment tool. This preliminary assessment will become the ***benchmark*** against which future assessments can be compared.

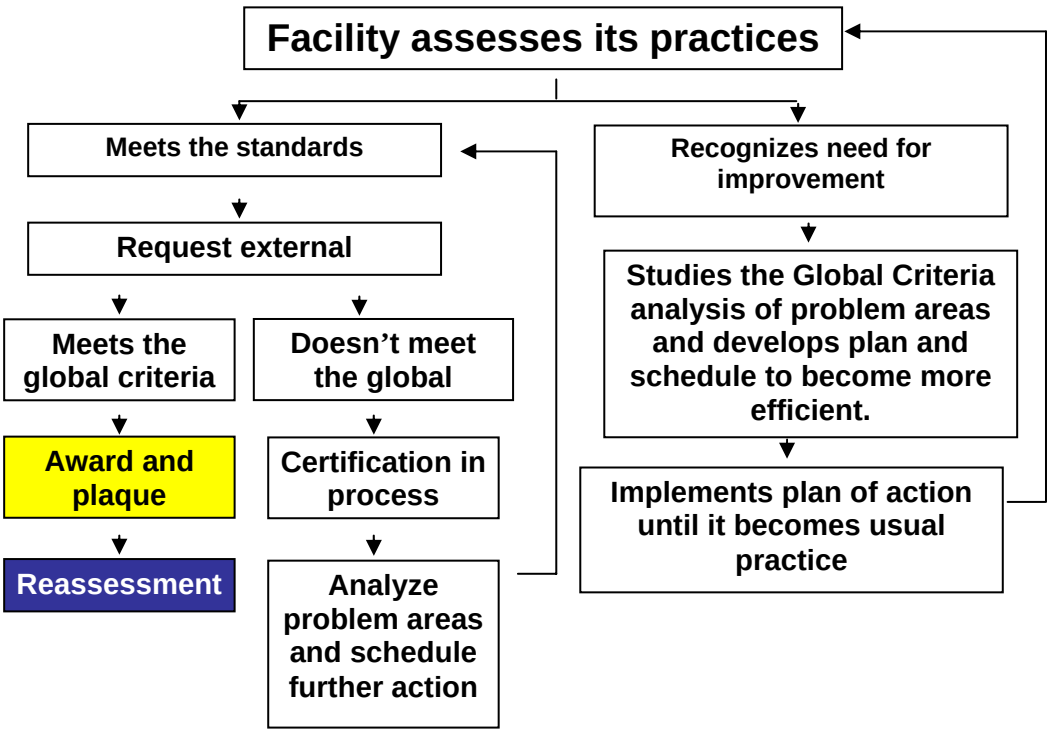
- Make time to prepare a ***National Quality Plan*** and draw up a programme of improvements.

- Implement the improvement programme. Start with improvements to procedures, as these can often be improved quite rapidly, and at low cost. Move on to improvements in other areas as resources become available.

- When performance levels have reached an acceptable level, carry out a more formal self-assessment exercise using the assessment tool.

- Assuming that the self-assessment is satisfactory, invite an international assessment team to evaluate the store. Make sure that a full set of records exists for the twelve month period leading up to the assessment. It is essential that these records are collected together and made available to the team so that they can carry out their work effectively.

The below flow chart illustrates the process:



Reassessments, that ideally should be scheduled to take place every two years, aim to ensure that national teams are continuing to question and to develop their quality procedures. As well as measuring the same indicators a change report should be requested to record the changes that have taken place since the last report.

The whole purpose of the quality management philosophy is that it should become culturally embedded in the organization and should become second nature to stores staff.

The EVSM will be formally available as a WHO document in the last quarter of 2004 details of which will be published through TechNet21.

Any countries or partners wishing to obtain the tool should contact Dr. Umit Karto□lu

DISCUSSION

The discussion started with a number of praises of the initiative, rightly deserved.

Question : Do assessments finding stores with weaknesses such as inefficient stock management or insufficient human resources include qualitative aspects like the ability of the person responsible to do accurate vaccine forecasting, as opposed to just somebody being there?
Response : Actually vaccine forecasting is not a responsibility of primary vaccine store management. However in the assessment process as explained in the presentation, there is a debriefing session the last day to discuss issue. The team leaves comments before leaving. But the process confines itself pretty much to within the store and other tools also exist.

Question : The assessment brings out critical issues and as a result develops action points that are the stepping stones towards accreditation. In situations where there is a favorable environment and immediate support, it is straightforward. But if there isn't such an environment, is there a follow-up process?
Response : As will be described in the next presentation, the management training cluster developed courses to improve managerial performance. Countries that did the assessment have a model quality plan. WHO and UNICEF are dedicated and the mentorship system is in place.

Some more questions will also find answers in following presentations.

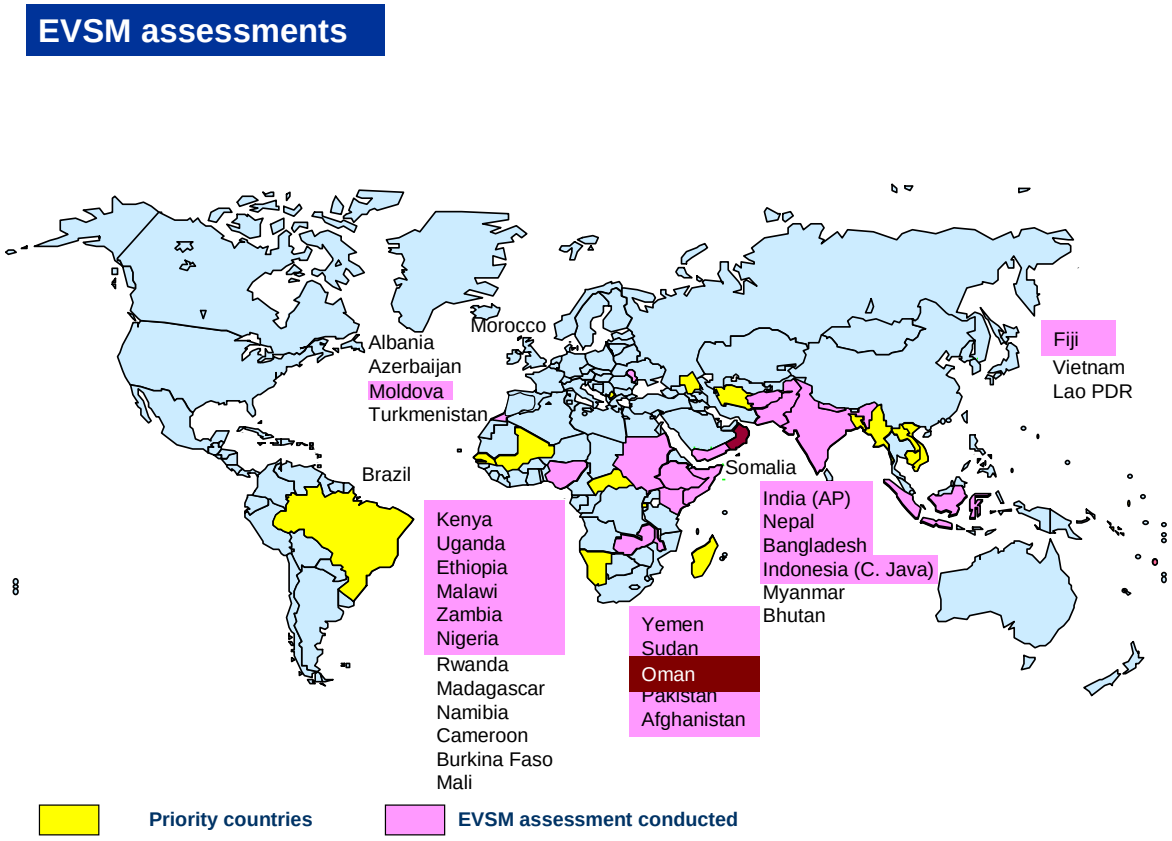
EVSM UPDATE : Paul Mallins, WHO HQ

Presentation Highlights : Prepared by the presenter

EVSM PRIORITY COUNTRIES

A wide consultation was undertaken to determine which countries should be the priority for the EVSM. The consultation included WHO regional and country offices, UNICEF global, regional and country offices and with key partners such as PATH. 33 countries were identified as priorities. At of the time of the Antalya consultation16 countries had undertaken the EVSM assessment.

The below illustration shows the priority countries and those that have implemented an EVSM assessment:

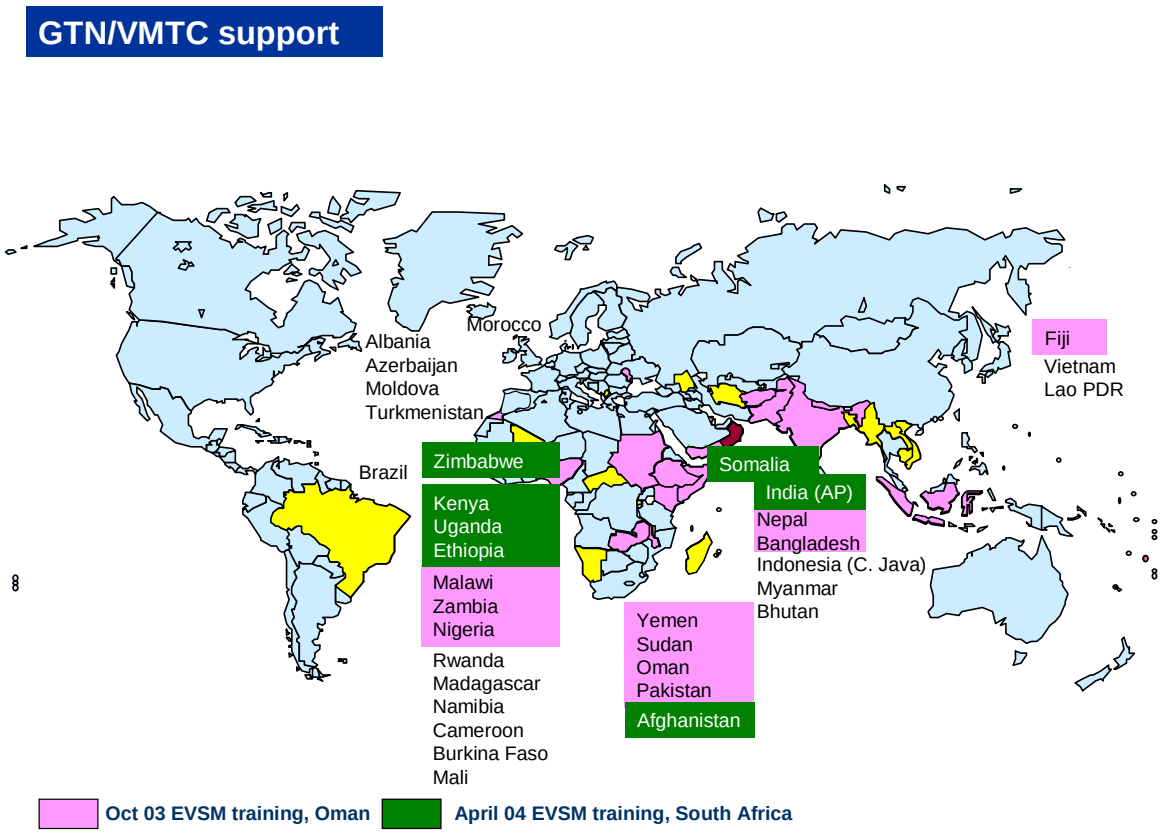


These initial pioneering EVSM assessments were implemented as assisted self assessments. National colleagues were assisted by WHO or UNICEF colleagues or consultants hired by these agencies. The agency colleagues and consultants worked along side the national colleagues to implement the assessments.

The original EVSM "workforce" was Umit Kartoglu, Stephane Guichard, Ticky Raubenheimer, Ahmet Afsar, Mojtaba Haghgou, Andrew Garnett, Emmanuel Taylor, Soren Spanner, Mikko Lainejoki and Denis Maire. The second line of individuals was Diana Chang-Blanc, Oleg Benes, Youris Perevoscikovs, Fabian Cenko, Kshem Prasad, Andrew Etsano, Bassey Bassey Okposen, Mohammed Braikat, Richard Duncan, Terry Hart, John Pott and Alejo Bejemino.

Another role of the assessors assisting countries to implement the EVSM assessment was to identify national participants to Global Training Network (GTN) Vaccine Management Training Cluster (VMTC) training programmes. The EVSM initiative is a complemented by a training programme based on the 10 global criteria. Countries that implement the EVSM assessment are eligible to send candidates to the Effective Vaccine Store Management training courses offered by the WHO. (see session on training for more details.)

The below illustration shows which countries attended GTN/VMTC training at the time of the Antalya consultation



For details of the of GTN/VMTC training courses please see the following link: http://www.who.int/vaccines-access/vacman/VMTC/VMTCmain.htm

DISCUSSION

Comment : One aspect should be highlighted and it is capacity-building through the assessment. The process could also be potentially useful for other health comodities.

Question : How was it determined to have a period of two years for the certificate to last? Is it realistic to have all countries go through the process?

Response : The answer is not easy as only one country has been certified so far. The assessment looks at the past twelve months and after the second twelve months international assessors are sent again maybe for a shorter stay in order to reassess. We will learn by doing it and it may have to be revised.

BEST PRACTICES: OMAN PRIMARY VACCINE STORE : Salah Al Awaidy, MOH Sultanate of Oman

Presentation Highlights : Prepared by the presenter

BACKGROUND

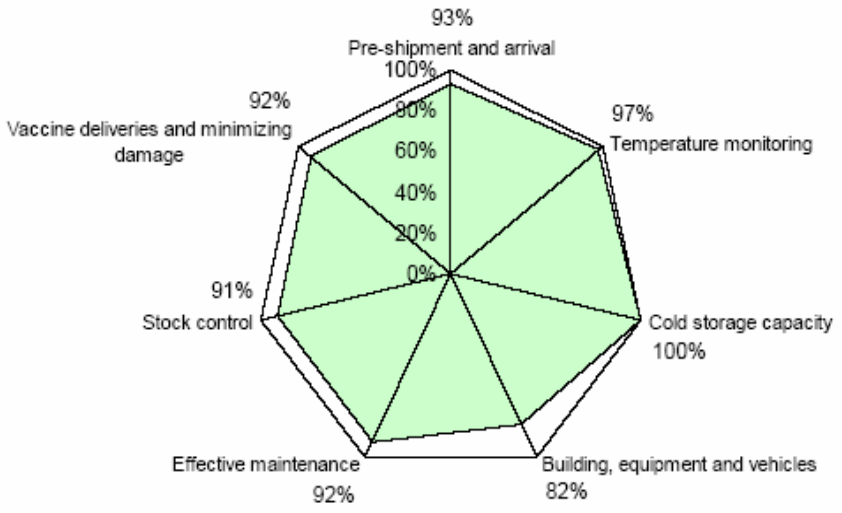
Over the last three decades of Oman's renaissance great achievements have been made in the control of communicable diseases especially the common childhood illnesses. The major share of the success was due to the impact of the Expanded Programme of Immunization (EPI) on the incidence of vaccine preventable diseases (VPD). The Ministry of Health has given top priority to the Expanded Programme on Immunization (EPI) since its inception in the early eighties.

Poliomyelitis and neonatal tetanus have been eradicated. Measles and rubella have been practically eliminated. Last case of Diphtheria was reported in 1992. All other VPD are on the decline.

ASSESSMENT OF OMAN'S PRIMARY VACCINE STORE

The Oman primary vaccine store became the first to meet the new WHO/UNICEF criteria or Effective Vaccine Store Management (EVSM). The announcement was made at the closing session of the recent GTN/VMTC vaccine store management training course in Muscat. The vaccine store was assessed by an external international team during 16 to 22 October 2003. Oman's Primary Vaccine Store exceeded the required 80% score in all areas of vaccine cold store management.

OMAN'S WINNING EVSM SCORE



Factors Contributing to the Success Story:

- The strong political commitment to the EPI within Ministry of Health.
- Single administrative control for EPI and cold chain management.
- Specially assigned, highly dedicated and professional staff for cold store management.
- Encouragement to the cold store staff through monetary incentives such as bonus, overtime etc. along with complete freedom of working and respect for their views and opinions.
- Built-in efficient internal supervisory and monitoring system.
- Regular external review (WHO/UNICEF) requested by MoH.

THE EVSM CRITERIA

The primary cold store currently in use in Oman was commissioned by the end of 1990. Two cold rooms and two freezer rooms were built in the premises of the EPI headquarters. The stores scored above 80% in all the ten EVSM criteria.

1. Pre-shipment & Arrival (Score 93%)

Memorandum of Understanding (MoU) exists between MoH, supplier and the customs authority hence there is no delay in the clearance of vaccine consignments. Clearing and transport of vaccine is the sole responsibility of the supplier. Usually a one week's notice of vaccine arrival is received by the store manager. There is a personal relation and communication between supplier and the cold store manager leading to a good understanding.

Vaccine consignments are accepted any day and anytime including weekends and holidays. VAR are filled for each shipment and faxed to the EPI program manager immediately for approval.

2. Temperature Monitoring (Score 97%)

The temperature stability and monitoring system of the newly installed cold rooms as well as the freezers was tested for one year (1990) before their utilization for storing vaccines.

Similarly the alarm system was installed after considering various options. Finally the system involving the 'Security & Fire Prevention Services (SFPS)' under the Royal Oman Police was judged to be the most reliable 24 hours alarm system for the vaccine stores. Eight points for monitoring were identified viz. high/low temp for 2 chillers, high temp for 2 freezers, fire in store & building, generator failure and general power failure. Any of these events would trigger the alarm. The police would inform the store manager by phone with problem location. The response time would be within 5 to 10 minutes. It is important to note that the cold store manager stays in the vicinity of the stores. On average such calls are received 2-3 times a month including the dry runs to test the alarm system that evoke an appropriate response.

3. Cold Storage Capacity (Score 100%)

It was the vision of the policy makers and the EPI manager while the new primary vaccine stores was being built in 1990 that was responsible for deciding the present ample capacity of the stores. It was decided to build a store that would suffice for the country for its future needs for the next 20 to 25

years considering the estimated population growth and the introduction of new vaccines in EPI. The new store was built with 3 times the capacity of the old store.
WHO/UNICEF was consulted for the design and capacity of cold store.

4. Building, Equipment & Vehicle (Score 82%)

The building used for the primary stores is appropriate and well maintained structure. Here is enough space to allow the vehicle to arrive with the vaccine and for loading and unloading. Within the building there is adequate packing area with space for ice pack conditioning, packing material, unfrozen ice packs, cold boxes and other consumables. Hand washing facilities are available. The entire area is protected against direct sunlight.

Cold rooms & freezers have been built with WHO specifications. There are dual refrigeration units with constant temperature monitoring devices. Within the cold store there are adequate shelves for storage. Standby Generator set is auto-start type. It is provided with a large fuel tank and located in a secure place. The store has good and working telecommunication system. Computerized stock control system is complemented with manual records.

5. Effective Maintenance (Score 92%)

Initially the store was maintained by the company who supplied (*Balley* of UK) until 1996. Afterwards *ONEC* was awarded the annual service contract.

No major failures were observed in the cold store necessitating transfer of the entire stock of vaccines elsewhere since 1991. Permanent service and temperature records are available since beginning along with the log book of maintenance. Temperature of cold room and freezers are recorded manually twice daily. Back-up Generator is checked every month. Run for 30 to 40 minutes. Automatic switchover after power failure is also tested. In the Oman's vaccine store "NO" vaccine was damaged due to the failure of the cold rooms and/or freezers since it was commissioned into the country's EPI.

6. Stock Control (Score 91%)

Adequate stock recording system is in place with a requisition system. Periodic physical inventory of vaccines is conducted. Expired vaccines are clearly marked and kept in a secure place. Adherence to EEFO principle is a standard practice. All delivery/arrival forms from the intermediate stores are preserved. There are adequate safety stock levels. No stock-outs have ever been experienced in the past.

Good warehouse practices are meticulously followed. Good general cleanliness is maintained in and around the vaccine store. The access and the data are secure. Adequate supervision is conducted by the EPI staff.

7 & 8. Vaccine Deliveries & Minimizing Damage (Score 92%)

Consistently reliable vaccine deliveries to the intermediate stores were conducted. There is adequate reporting system in place to monitor deliveries. No short shipments were received by the intermediate stores in the past. Similarly no vaccine was damaged or lost during the delivery.

Freeze indicators are placed in every shipment and the VVM status is recorded on all delivery/arrival forms returned from the intermediate stores.

9 & 10. SOP and Finance

EPI manual (SOP) updated regularly (3 editions). Available at all vaccine stores and EPI units. External review of cold chain was requested by MoH. All praised the primary stores (no further recommendations). Adequate finances available for vaccines and all other consumables

SELF ASSESSED SCORE

- **Module 4.3.8**: One vaccine freezer (small) enlisted without alarm system belonged to the Muscat's intermediate vaccine store (lost 0.2 point).
- **Module 5.3.1**: The issue of *'adequate stock of spares & maintenance consumables'* doesn't apply due to service contract in place (lost 1 point).
- **Module 6.3.2**: Physical inventory of other consumables (syringes/safety boxes etc.) was not carried out in the primary stores since these stocks were held at the main medical stores (lost 2 points).
- **Module 7.1.1.Q4**: Reliability of transport is only applicable to *'scheduled deliveries by primary vaccine store to intermediate stores'* hence not applicable for the Oman's primary stores (lost 1 point).

OBSERVED DEFICIENCIES IN THE PRIMARY STORES

1. **M4.3.5**: All refrigeration equipment uses 'CFC'.
2. **M1.2.2**: **'Lot release protocol'** not followed for the non-UN vaccines
3. **M2.2.1**: Temperature **'accuracy testing'** of all recording appliances in the primary stores was not carried out on annual basis.
4. **M6.1.3**: Formal **'pre-delivery notification'** system was not in place.

PROPOSED ACTIONS TO RECTIFY THE DEFICIENCIES

The CFC based refrigeration equipment would be phased out. However it is felt that the present situation although not ideal, it would not damage the vaccines. MoH is training its personnel in the *'Lot Release Protocol'*. Temperature accuracy testing of all the recording devices in the primary store is required to be done every year once. However it's not clear as to how to make these testing and compared to which standards. The pre-delivery notification system is being established.

FUTURE PLANS

It is planned to conduct similar assessment exercises at the intermediate vaccine stores (provincial) in 2004.

Similarly it is being planned to conduct training programmes in vaccine store management for the managers of the intermediate stores in conceptual tune with the VMTC framework

We strive to continue to improve all aspects of Vaccine Management in Oman

DISCUSSION

Question : What do you do with expired vaccines?
Response : It has happened as a result of our own mistakes and they are discarded. However suppliers are requested to provide vaccines with long enough shelf-life.

Question : Over a ten-year perspective, what would be the critical factor that will determine the system's sustainability?
Response : The key factor is political commitment to EPI by the Ministry of Health.

Question : Can countries with low budgets meet criteria without external funds? And if these are needed isn't there a risk that it would take so much time that countries will feel lassitude?
Response : Maybe some criteria would be hard to meet for some countries but the tool has a lot of advantages. It tells that achievements are in the right direction. And maybe some criteria should be lowered. It was added that it is not a question of budget.

AWARD CEREMONY

After the discussion, a short award ceremony took place. Michel Zaffran and Ahmed Magan representing WHO and UNICEF respectively handed Dr. Al Awaidy a plaque in recognition of Oman achievements being the first country to have its primary cold store certified under the EVSM initiative.

REGIONAL PERSPECTIVE: SEARO EXPERIENCE IN NEPAL AND BANGLADESH :

Stéphane Guichard, WHO SEARO

Presentation Highlights : Prepared by the presenter

BACKGROUND

A well performing immunization program relies on an effective vaccine management system. Since the launch of Universal Child Immunization (UCI), vaccine management activities at country level have included the strengthening of vaccine forecasts to enable advanced planning of vaccine needs and the setting up of logistic systems for the distribution of vaccine to a network of storage facilities at national, regional, district levels to health facilities level from where the vaccine is administered. Nowadays, immunization is recognized as the most successful public health intervention throughout the world. Consequently, vaccine preventable diseases have decreased to such low incidence that most people do not remember the disease and they are less willing to accept the risks associated with vaccination,

despite very rare cases of vaccine associated Adverse Events Following Immunization (AEFI). In addition, in the last decade anti-vaccination lobbies have become more effective in the circulation of false allegations about vaccination, notably through internet. To maintain public confidence in national immunization program the quality control of vaccine use in program became an integral part of vaccine management.

To assure and document the quality of vaccine, WHO and UNICEF have developed the pre-qualification scheme and established in 1996 the Global Training Network (GTN). The GTN offers to National Regulatory Authority (NRA) staff a set of training courses to enhance each of the functions that NRA must implement according to their system of procuring vaccines i.e.: through UN, direct procurement or procurement from local producers.

The methodology developed to assess NRA capacity is based on the following 4 steps:

1. Benchmarking an ideal system
2. Assessment against established indicators
3. Development of institutional development plan including training through GTN
4. NRA assessment follow-up

EXPANSION OF GNT ACTIVITIES

This methodology has been successful in assisting countries to identify priority interventions and in planning activities to address weaknesses. In 2000, based on this four-step approach, WHO developed the Effective Vaccine Store Management (EVSM) and Vaccine Management (VM) initiatives and, recently initiated a review of vaccine procurement mechanisms in several countries including Sri-Lanka and Maldives in the SEA region. EVSM was conducted in Indonesia and both EVSM/VM were conducted in Myanmar, Nepal and Bangladesh.

In 2004, WHO HQ integrated all training activities including NRA, EVSM, VM under the GTN umbrella. Centers were established in Oman and South Africa for EVSM and VM. Additional centers are being established by WHO HQ as global centers to address training needs on vaccine procurement.

A SINGLE APPROACH BUT DIFFERENT STRATEGIES TO IDENTIFY AND TO ADDRESS TRAINING NEEDS

The four core activities NRA, EVSM, VM and vaccine procurement are articulated around the same four-step methodology and are inter-related. EVSM and VM are probably the most inter-related activities. Both assessments are developed to evaluate storage conditions and distribution practices but EVSM is more detailed in reviewing vaccine arrival procedures (review of vaccine documentation, vaccine lot release and clearing procedures) while VM gives an insight of vaccine storage and logistics at each level of the health infrastructure. The NRA has been assessed in all SEA countries and it was felt that EVSM was more suitable to provide detailed information on how NRA was interacting with EPI to control vaccine quality and to implement procedures for vaccine lot release especially, in Nepal which purchases vaccine directly on the international market. Both EVSM and VM were integrated into a single assessment in Nepal and Bangladesh. In the VM questionnaire the part related to central level storage assessment was replaced by EVSM assessment tool. This strategy allows reduction in

assessment costs without adding significant burden on the country. It created stronger momentum among decision makers, provided the rational for better cooperation between NRA and EPI, raised awareness on a wider range of issues from the point of entry of vaccine to the immunization service delivery that allowed the development of a comprehensive institutional development plan.

Following the assessments, EPI and central store managers participated in the GTN course on EVSM and VM. Back to their country central store managers are able to introduce new management practices in a short period of time. However, to improve vaccine management practices requires more resources and careful planning because of the large number of health workers to be trained.

To reach out to this large number of health professionals SEAR has set plan to develop regional capacity for training.

NATIONAL TRAINING INSTITUTES CAPACITY BUILDING

In Nepal, SEARO in cooperation with the Child Health Division (CHD) in Nepal identified the National Health Training Center (NHTC) in Katmandu to conduct in-country vaccine management courses for district level EPI managers and for PHC workers. NHTC has training facilities at regional level as well as in several districts. Two focal persons currently working in the NHTC were identified to prepare and conduct courses. They will attend a skills training course in Greece before initiating Vaccine Management courses in the country. As a priority they will train regional and district EPI managers and then will train PHC workers. WHO will provide technical assistance to the NHTC to prepare the training course for PHC workers. The course will include relevant part of the VM programme and additional topics on vaccine handling, injection safety, AEFI and waste management. It is expected that by 2005 NHTC will have completed the training of EPI managers at regional and district level and finalize the training package for PHC workers.

In the next program biennium, WHO/SEARO will support the establishment of GTN centers in the region for EVSM/Vaccine management and vaccine procurement. In addition, national training institutes will be identified in selected countries to carry on in-country training for AEFI and vaccine management as these courses have a large target audience.

DISCUSSION

Question : Some countries are resisting efforts to train large numbers of health workers and let staff out of health centers as it disrupts service activities. Sometimes training does take place with the staff away from health centers but it has no connection with staff day-to-day activities. How are these addressed in the programme presented? How are you going to make sure that what they do, first will not harm immunization activities, and second, is going to be linked to immunization activities and related to job situations?

Response : This issue was raised in Bangladesh when talking to EPI managers at district level. They are the only person in charge of the district and if we take them out the

programme stops entirely. It was suggested to train a nurse to act as back-up, not only for training periods but also in case of sickness or supervision trips.
As for the second concern, one person will be selected to carry a comprehensive review of existing courses in order to add those issues of management, injection safety and AEFI. It has been dicided to focus on these three areas but micro-planning may be added.

Comment : If long term sustainability is considered, it is difficult to achieve once people start working and become absorbed in daily activities. It would be preferable in a pre-service setting; vaccine management must find its way into nursing schools and universities.

SESSION 6 : PERFORMANCE, QUALITY and SAFETY PROJECT

Chair: Nedret Emiro□lu in replacement of John Lloyd, PATH, France

SESSION ACHIEVEMENTS

The objective and outcomes of the session were as follow:

Session objective: Inform participants on development and progress of the PQS project.
Expected outcomes: For information
Receive feedback from participants

As clear from above, this session was only intended for communicating information and receiving feedback. It consisted of only two presentations. The first explained in details to participants what means the evolution from PIS to PQS and components of PQS. It was followed by a report of a meeting with representatives of industry which had taken place on 22 March.

At this meeting, there was a broad agreement that PQS is a positive step. However some general concerns were expressed and further comments and suggestions were made. The final discussion brought further comments and feedback, and the opportunity will be given to all TechNet members to express opinions through the forum.

FROM PIS TO PQS : Michel Zaffran, WHO HQ

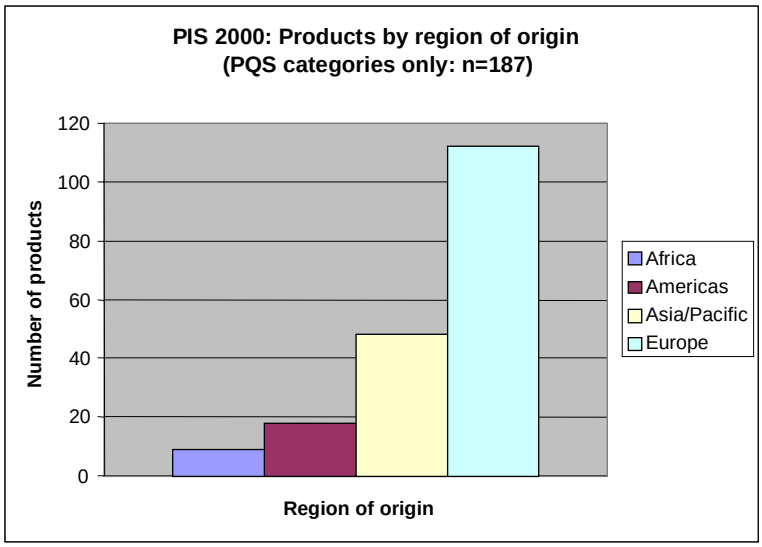
Presentation Highlights : Prepared by Andrew Garnett

THE PIS SYSTEM

- **Purpose:** Identify/develop equipment meeting EPI needs.
- **Method:** Product selection, development and testing in partnership with industry.
- **Standards:** WHO performance specifications and test procedures.
- **Product verification:** Testing in accredited laboratories.
- **Dissemination:** A purchasing guide, used around the world - 12 editions of PIS produced since 1979 – now available on-line.
- **Users:** UN procurement agencies; NGOs; governments; manufacturer's wanting their products to be included.

WHAT'S WRONG WITH PIS?

- Irregular re-testing – test reports for products in PIS 2000, 10+ years old.
- Euro-centric bias as seen in the figure below.

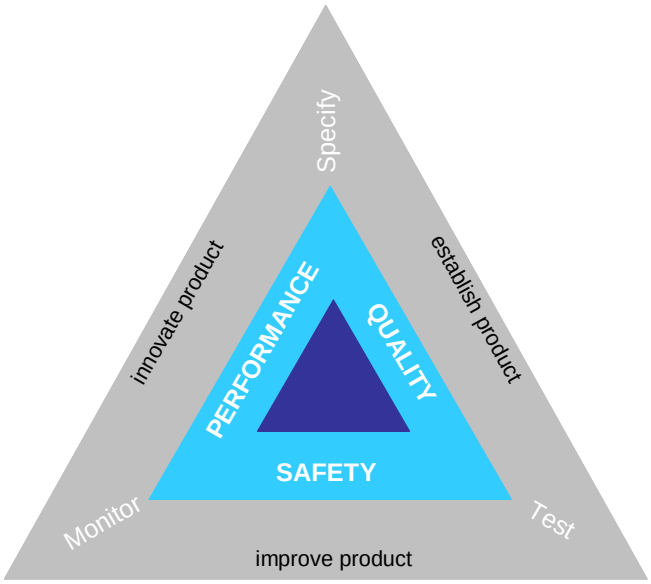


- Criteria for product acceptance need clarification.
- Key specifications are too manufacturer-specific.
- Absence of formal procedures (specification revision, product withdrawal, etc).
- Inconsistencies between specifications and test procedures.
- No systematic mechanism to collect and respond to user feedback.

The PIS process is incomplete: there are specifications and testing but…no monitoring. **It needs to be overhauled.**

WHAT IS PQS?

- **Performance:** sufficient to meet defined specification standards.
- **Quality:** quality and reliability sufficient to meet field conditions.
- **Safety:** cause no harm to users, patients, or to the environment over the course of the product's life cycle, from cradle-to-grave.



THE GOAL OF PQS : Three main goals have been set for PQS. They are :

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.

PQS SECRETARIAT : PQS systems will be managed by its Secretariat which will carry the following functions :

- Set up PQS systems.
- Liaise with the PQS-SG and the working groups.
- Liaise within WHO and UNICEF-SD.
- Commission specifications and verification protocols.
- Pre-qualify test laboratories.
- Commission and supervise contract work.
- Pre-qualify products.
- Manage the PQS website and other publication activities.
- Co-ordinate product feedback reports.
- Review and circulate results of field monitoring.
- Follow-ups with pre-qualified manufacturers.

PQS STEERING GROUP : Will provide strategic guidance and oversight and have the following tasks:

- Review programme and policy changes and direct action.
- Monitor and guide the working groups.
- Direct new or revised specifications and verification protocols.
- Direct withdrawal of out-dated documents.
- Oversee development of specifications & verification protocols.
- Oversee peer-review process.
- Direct addition or omission of PQS product categories.

Core membership drawn from relevant departments within WHO and UNICEF-SD.

SPECIFICATION WORKING GROUPS : Activities within the group's area of competence:

- Identify need for new performance specifications and product verification protocols.
- Identify need for revisions to existing documents.
- Draw up design criteria to guide the Technical Specialists.
- Work with the Technical Specialists.
- Consult with the FMWG to agree field testing and/or field monitoring techniques.

Each group is to have a lead investigator responsible for the group's tasks and for liaison with the Secretariat.

FIELD-MONITORING WORKING GROUP : Will identify field monitoring techniques and review monitoring activities by :

- Initiating methods for obtaining user feedback in association with Ministries of Health and other users of PQS products.
- Developing field monitoring methods to suit specific product types, working in consultation with the SWGs.
- Working with Technical Specialists on field monitoring test protocols.

TECHNICAL SPECIALISTS :

Will provide specialized skills to write and revise performance specifications, product verification protocols and field testing protocols. Technical Specialists will be appointed and managed by the Secretariat in consultation with the relevant SWG and/or the FMWG.

PQS CATEGORIES

PQS cat.	Description
PQS - E01	Cold rooms and related equipment
PQS - E02	Transport (buyer's guides only).
PQS - E03	Refrigerators and freezers for storing vaccines and freezing icepacks.
PQS - E04	Cold boxes and vaccine carriers.
PQS - E05	Icepacks.
PQS - E06	Temperature monitoring devices
PQS - E07	Cold chain accessories and spare parts.
PQS - E08	Equipment for administration of vaccine.
PQS - E09	Steam sterilizers (to be phased out over a period to be agreed).
PQS - E10	Waste management.
PQS - E11	Specimen collection equipment.
PQS - E12	Software (buyer's guides only)

Discontinue:

Injection accessories (E10), ARI (A1, A2), Blood storage (B4) , Emergency Campaigns (EC), syringes and accessories for PHC (P7, P8).

STANDARD OPERATING PROCEDURES

- Build on existing ISO and other international standards to the greatest extent possible
- Performance specifications and Product verification
  - How to develop a procedure
  - How to review and revise a procedure
  - How to withdraw a procedure
- Product Prequalification
  - How to prequalify
  - How to re-evaluate
  - How to remove

- Laboratories (ISO 17025)
  - How to assess
  - How to re-evaluate
- Field testing
- User feedback

PRODUCT VERIFICATION- QUALITY ASSURANCE

THREE VERIFICATION METHODS:

1. *Type-examination:* Sample inspection.
   Checklist inspection, primarily for technologically simple items.
2. *Independent type-testing:* Sample testing, in an accredited laboratory, against a test protocol.
   Primarily for complex high value off-the-shelf products.
3. *Full Quality Assurance:* Site inspection by an independent inspecting organization.
   For complex high value products involving site-specific design and on-site work.

PRODUCT PRE-QUALIFICATION

Prequalification will be a necessary condition for products to be purchased by UN procurement agencies …But not be a guarantee nor sufficient for an award to be granted.

USER FEEDBACK :

Data will be collected from:

- PQS on-line reporting system.
- National management reporting.
- Manufacturers' product defect reports.
- WHO/UNICEF field staff and inspections.

And distributed annually (or more frequently) to:

- Product manufacturers.
- The Specification Working Groups
- Included in annual *Product Re-evaluation Report*
- Moderated and published on the PQS website.
- *Product Alerts* posted on PQS website.

REPORT FROM THE PQS SESSION WITH INDUSTRY ON 22 MARCH 2004 : Andrew Garnett, WHO Consultant

There was a broad agreement that PQS is a positive step, particularly the emphasis on monitoring and testing which has not been addressed by PIS. However some general concerns were expressed and were well taken.

1. PQS should not be too bureaucratic.

2. The system should not impose excessive costs on industry.
3. There is a need for agreement with industry on their feedback on product defects reporting obligation.
4. The transition from PIS to PQS needs to be clear. For example, there should be a clearly defined programme for re-evaluating products that were performing satisfactorily under PIS.

Some further comments and suggestions were made:

- PQS should at all cost avoid procedures that duplicate existing industry standards.
- The PQS website should be available in several languages. That was discussed briefly and it was felt that it would not be a problem to have the product information element in several languages. However it could be more difficult for the guidelines.
- PQS should be open to satisfying local needs.

SPECIFICATION WORKING GROUPS :

There will be seven specifications working groups as the number of product categories. These are :

1. Refrigeration and related items
2. Transport guidelines
3. Passive cooling
4. Temperature monitoring
5. Injection equipment
6. Waste management
7. Softwares, a new category

Provisional members have been identified and volunteers are welcomed as well as comments on Standard Operations Procedures (SOPs).

PRODUCTS :

From exisiting product categories under PQS heading, a list of products that should be considered for inclusion follows.

1. Refrigeration and related items : design of cool rooms to keep vaccines out of the cold chain, generators and concentrators, refrigerator toolkits and spare-parts kits.
2. Transport guidelines : no product will be listed anymore but guides and links to other UN agencies' catalogues.
3. Passive cooling : icepacks and coolers. It was suggested to add refrigerators with freeze-prevention devices and hybrid refrigerators. Need to test boxes withchilled waterpacks.
4. Temperature monitoring : need for specifications and verification protocols for temperature and event loggers for cold rooms, and digital recorders and printers. Updated specifications for recorders, temperature alarms and data loggers.

5. Injection equipment : dealt with by procedures developed by EHT. When new specifications for AD syringes come into force, there will be a need for new specifications to be written directly related to safer standards. There is also a need to consider if jet injectors should be included.

   There is a strong feeling that steam sterilizers should not be dropped from the list yet. It would be helpful if this point were further discussed.
6. Waste management : incinerators, syringe melters, needle destroyers and autoclaves. Guidelines for syringe burial kits. It was suggested that measles laboratory testing equipment be included in the specimen collection equipment sub-category.
7. Software : this is an issue. There is a significant need for a guide to suitable stock control software and programme evaluation software. A large number of software is available but they are not properly structured and there is a need for reliable, user-friendly softwares that can be widely circulated with a proper updating system.

We look forward for any further suggestion to include anything else.

IMPLEMENTATION TASK

For the moment, PQS reached stage one, a general endorsement by WHO and UNICEF. The next stage will imply :

- Start setting-up the administrative structure
- Establish Secretariat
- Design the database and all other systems, and implement them
- Pre-qualify all accrediting and testing laboratories
- Prepare specifications and field-test protocols
- Pre-qualify all products
- Maintain the whole system on an ongoing basis once it is operational

The completion date is the end of 2004 or beginning of 2005.

DISCUSSION

Meeting with Industry session (actually took place before the above report)

Question : Concerning feedback TechNet 21 has a form on its website (only one response received). Would the proposed PQS feedback system come in duplication?
Response : Use of the feedback form will rely on good motivation amongst respondents and this will require that people see the results of their comments in the form of action.

Comment : PQS should be flexible enough to meet local needs. For example a specific syringe requirement from Andhra Pradesh not satisfied by PIS.

Response :A country is free to make its own purchasing arrangements to satisfy specific local requirements.

Comment : PQS product verification needs to discriminate more finely between simple and complex products and level of risk.

Comment : PQS may be reinventing the wheel – specifically with regard to syringe pre-qualification.
Response : The PQS system has simply adopted the syringe pre-qualification procedures developed by EHT in consultation with industry.

Comment : The 'developmental' route may be a barrier to manufacturers. Actually the 'non-developmental' route was the preferred method unless no other option was available.

Question : What are the respective roles of the PQS Steering Group and the Technical Specialists?
Response : PQS-SG provides guidance and policy; Technical Specialists are responsible for writing technical specifications and verification procedures.

Comment : PQS looks complex and overly bureaucratic. The transition between PIS and PQS needs to be clarified. The term 'pre-qualification' should not be used in relation to laboratories – a new term is needed. PQS also needs to ensure that manufacturers maintain a consistent ability to meet specifications. Another participant also worried about PQS being over-bureaucratic. Field testing is essential, but expensive and it is asked how PQS would deal with field tests that had already been carried out by the manufacturer.

Comment : PQS is a positive step and could be of benefit to industry. It is suggested that pre-qualified products should be able to display a 'PQS seal of approval'.

Comment : The term 'accreditation' is suggested for testing laboratories.

Question : It is still unclear about the transition from PIS to PQS, can it be further clarified?
Response : PIS products will be put on the PQS database, which will be updated as products achieve PQS pre-qualification status.

Comment : A good system for reporting product defects is needed.

Comment : The feedback issue needs to be fully resolved to ensure that there is a precise agreement with industry on their responsibilities.

Comment : The steam sterilizer category should be maintained and the transport section should include links to the UNDP catalogue. It is also proposed to add a category for cool rooms and freeze-prevention refrigerators should be added. The cool room proposal is supported by another participant and it is suggested that measles lab testing equipment be added to the category list.

Comment : A proposal to include a software category in PQS is strongly endorsed. It is hard for the agencies to give good advice on software at present. The meeting should consider what languages software should be made available in. One participant suggested that French, Russian and Spanish be selected.

Other proposals for inclusion were :

- The category for VVMs should incorporate a freeze indicator.
- A category for waste treatment autoclaves.
- Hybrid refrigeration to be added.

Comment : Specifications for syringe disposal pits need to be developed.

Question : Should curative syringes be included?
Response : Curative syringes will be dealt with by EHT.

24th March Q&A session

Question : PQS will be expensive to develop. Does WHO have the necessary funds?
Response : The start up process will not be a permanent expense. After the transition phase has been completed, funding will be from industry cost-recovery.

Comment : It is a positive initiative – needs to be progressed.

Question : What happens if there are no international standards for a product? How will industry be involved in specification development?
Response : Reference will be made to international standards where they exist. The intention is to produce neutral performance specifications which are internationally relevant and acceptable. Industry will be involved to the extent necessary to achieve this.

Comment : It is suggested to add chemicals for disinfection and shredders to the list of new waste management categories.

Comment : The testing process for PQS pre-qualification will be expensive – especially for small manufacturers.

Response : The type-examination route to pre-qualification will not necessarily be expensive, and this route is likely to be applicable to quite a variety of products in PQS.

Comment : A weakness of PIS is that recommended spare parts lists do not necessarily relate to the actual rate of consumption.
Response : This is why PQS is placing much greater emphasis on feedback from users.

Comment : PQS will be a good system and organizers should be thanked for inviting industry to discuss the initiative. Manufacturer's in-house quality management systems and testing facilities/test results should be taken into account as part of the pre-qualification process.
Response : The pre-qualification process will certainly look at in-house quality systems and PQS team will certainly consider the validity of in-house testing.

Question : The PIS catalogue is a great reference resource for countries and other users - will PQS database be available in hard copy format?
Response : The intention is that it will. However PQS will be more dynamic than PIS so we will have to come up with a system which allows the hard copy version to be updated by print-outs from the website.

SESSION 7 : TRAINING

Chair: Robert Steinglass, BASICS, USA

SESSION'S ACHIEVEMENTS :

Session objective: Review update on training initiatives on vaccine management

Expected outcomes: Agree on plans to broaden use of adult learning techniques in competency based training beyond vaccine management

Agree on next priority countries for vaccine management training

The first presentation reviewed activities of the Vaccine Management Training Cluster. In particular, it explained to participants what is the Global Training Network, its set of available courses and what is unique about it. The training methodology was presented insisting on its participatory and interactive character. Finally the programmed training support for 2004 was announced and courses in French and Russian are also planned.

Kemal Gökhan Gürses, from Shop of Miracles, Turkey, made an enlightening presentation with some of the images from his complete illustration of the Vaccine Management Training Course. Entitled "The Storyboard: Illustrating for VMTC", his presentation was greeted with an ovation. His work is available in full on CDRom by request to Christine Husser (husserc@who.int).

A third presentation provided feedback from a Vaccine Management Training Course graduate from VietNam. His highly appreciative account of the training course also highligthed the issue of the trainees' role once they return to their respective countries. Although the course is neither designed nor intended to be a first step to cascade training within countries, it was clear from the presentation that a great deal of that is actually happening because of countries needs and expectations generated by their participation in the course.

A fourth presentation reviewed progress in the upgrading/updating of Mid-Level Management and in-country training to strengthen and maintain managerial and technical skills in African EPI programmes. Activities of the past two years and those planned for 2004 were presented with a brief evaluation of activities so far.

A final and fifth presentation completed the review of training initiatives. It presented the experience of Mali in the development of training plans. The assessment, curriculum development and monitoring of impact were reviewed and the conclusion highligthed the real

potential in developing this training program into a node in the GTN, serving Africa, primarily in French.

Questions were asked presenters but the VMTC training methodology was received with enthusiasm. However no discussion took place on expanding it beyond. VMTC is complementary to EVSM and as such the training programme presented was not questioned. Thus the objective of the session were fully met but outcomes didn't fully materialize.

GTN/VACCINE MANAGEMENT TRAINING CLUSTER ACTIVITIES : Ümit Karto□lu, WHO HQ and Hande Harmancı, WHO Consultant

Presentation Highlights : Extracted from the presentation

BACKGROUND : WHAT IS GTN?

Global Training Network :

Specific objectives
Perform the necessary skills and functions
Fully protect vaccines in countries

- Vaccine quality :
- Lot Release and Laboratory Access, BREC, Canada
- Adverse Events Following Immunization, UCT, South Africa and National Pharmacovigilance Centre, Tunisia and Epidemiological Unit, Ministry of Health, Sri Lanka
- Quality Control of DTP Vaccines, RIVM, The Netherlands
- Laboratory Animal Science and Husbandry for Vaccine Quality Control, RIVM, The Netherlands
- Laboratory Animal Husbandry, CECAL/Fiocruz, Brazil
- DTP Production for National Regulatory Staff, RIVM, The Netherlands
- Laboratory Quality Systems, NIBSC, UK
- Regulation of Vaccines (formerly Licensing), TGA, Australia
- Vaccine Quality Control Technology, Biken, Japan
- Quality Assurance of Live Attenuated Polio and Measles Vaccines, Bio Farma, Indonesia

COURSES :

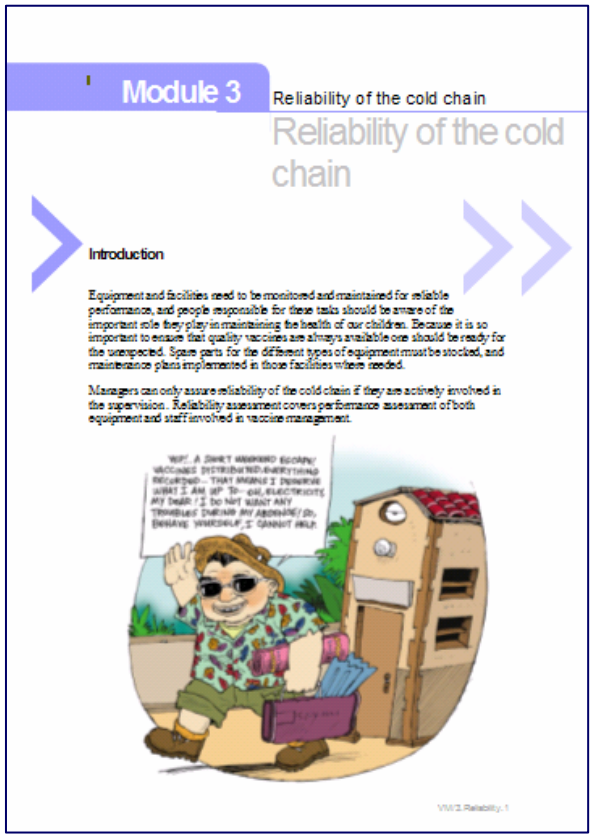
- Vaccine Management (VMTC) :
- Training of Trainers : a MUST to teach in VMTC training centres
- Vaccine management : For EPI managers

Based on vaccine management assessment

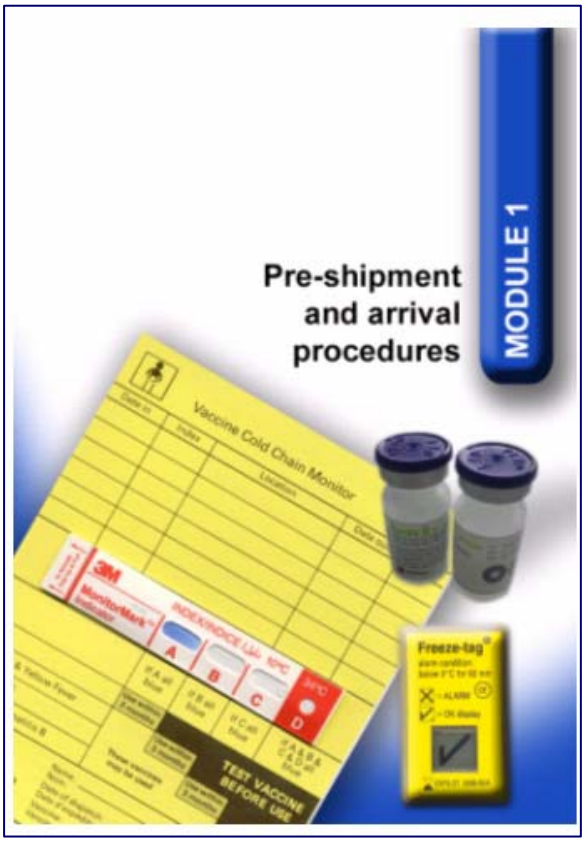
- Vaccine Store Management : For vaccine store managers, cold chain managers and national logisticians
  Based on Effective Vaccine Store Management (EVSM initiative) assessment
- Vaccine Management on Wheels : 5 days in the field for the graduates of vaccine management and vaccine store management training courses
- Financing and procurement :

WHAT IS UNIQUE ABOUT IT?

➞ Up-to-date standardized training materials



Vaccine Management



Vaccine Store Management

➞ Detailed qualification processes for training centres, trainers, trainees

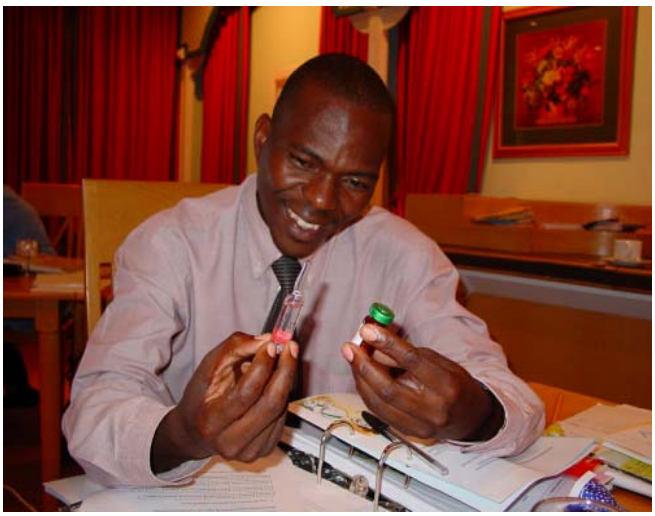
- Training Centers : - Initial assessment, detailed review of history of the centre, its publications and previously developed courses
  - candidate status for minimum 2 training courses
  - full accreditation for 2 years

- Trainers : Training of trainers, coaching for 2 training courses, random checks
- Trainees : Application form, letter of intention, CV, language proof, telephone interviews, endorsement by WHO country and regional offices

➞ Competency based training – built upon adult learning theories

➞ Training is not an end activity – linked with VM and EVSM initiatives

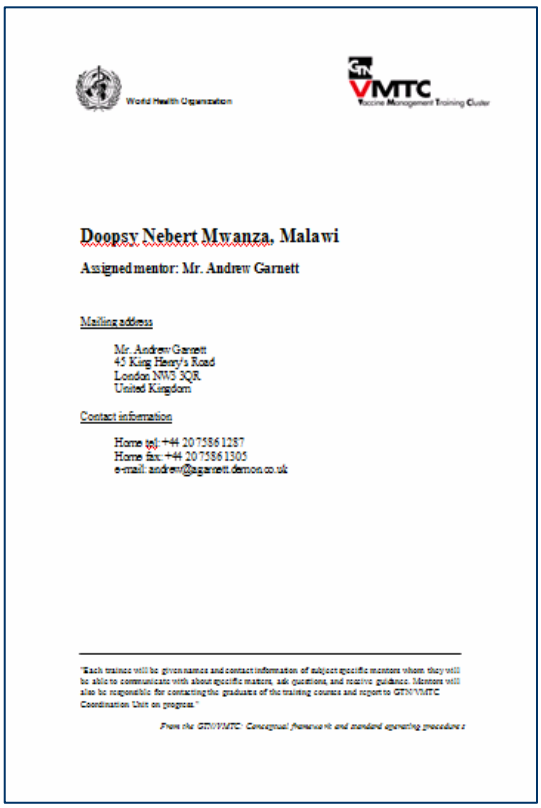
- Before training : Conduct VM and/or EVSM assessment
- After training : - Develop VM project / Adopt EVSM
  - Present activity plan to ICC
  - Introduce changes
  - Implement and evaluate plan



➞ Four-level evaluation methodology to follow-up and measure impact

	Method of evaluation
During training	
Views of trainees	Daily feedback Daily trainers meetings Trainer evaluation form Course evaluation form
Trainee proficiency	Pre and post course questionnaires Vaccine management board game
After training	
Occupational performance	Early post-course feedback VMTC portfolios Monthly mentor reports
Effects of training - Impact	Before and after VM and/or EVSM assessments

➔ Mentoring for VMTC



World Health Organization

GTN VMTC Vaccine Management Training Cluster

Doopsy Nebert Mwanza, Malawi

Assigned mentor: Mr. Andrew Garnett

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"Each trainee will be given names and contact information of subject specific mentors whom they will be able to communicate with about specific matters, ask questions, and receive guidance. Mentors will also be responsible for contacting the graduates of the training courses and report to GTN/VMTC Coordination Unit on progress."

From the GTN/VMTC Conceptual framework and standard operating procedures

Participated in
Vaccine store management training course, 14-23 October 2003, Muscat, Oman

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TRAINING METHODOLOGY

- Participatory : *warm up activities, daily reviews, group work, presentations, group discussions*
- Interactive :
- Instructional
- Contractual
- Competency based
- Safe

TRAINING SUPPORT 2004

- Vaccine store management, 26-30 April Durban, South Africa
- Vaccine management on wheels, 23-28 May – Turkey
- Training skills, 21-25 June – Greece
- Vaccine management, 6-10 September – South Africa
- Vaccine store management, 9-13 October – Muscat, Oman
- 2nd SAC meeting, 9 December – Venue

French and Russian courses depend on assessments

DISCUSSION

Question : What are mentors' activities and is there any feedback from mentors and trainees?
Response : There are two styles of mentorship. There is the passive one where the trainee contacts his/her mentor if they have a question. It is a private approach and the trainee shouldn't hesitate to ask any kind of question. The mentor may not know the answer but will research and get back to the trainee. There is also the active type where mentors are initiators. From assessments, gaps are identified and starting by the more critical ones, the mentor initiates talks with trainees whether by e-mail or phone. It is a human relationship that provides good support and helps motivation.

Comment : The State of Andra Pradesh is going through this process at present. It would be a good idea to have another training center in Asia.
Response : An evaluation of another English-speaking training in Thailand is in progress.

Question : Is there a follow-up exercise on proper arrangements of vaccines in the refrigerator at health center level?
Response : There is no particular exercise although central store managers should know. Emphasis is on cold rooms and freezer rooms-related issues.

Question : Are there any plans for the Americas?
Response : Yes there are plans for a Spanish-speaking training center, the e-mail exchange has started but dates cannot be determined with any certainty.

Question : This is an enormously attractive approach and it is very nice to see it in practice. However is there any flexibility if for example it is found as a result of an assessment that a particular need in one country or part of a country could be addressed in a learning process that may need 2 days instead of 4-5? Can it be adapted to be country-specific or group-specific?
Response : This is a global training course and it is not the intention to change. It is not budgeted and there is no room to manage other courses. So it cannot serve particular needs. Of course some participants may not need as much from one session but more from another one. All assessments are reviewed and performance of the group is analyzed during the pre-test to see what particular topics have problems. This is put into a performance matrix shared with participants. Gaps are identified and there is flexibility in the schedule depending on performance.
Further response : The aim is to get everybody to a certain standardized level from which mentors and regional offices take over. It is standardized but flexible. The course is very practical. Trainers get profiles of participants and assessment results. They are in a position

to spend more time with particular people during practical sessions. Because of the methodology, plans can be developed the night before to spend more or less time in one session the next day. It is participant-oriented.

Question : One difficulty in regional offices is selection of the right person. Is there a similar difficulty within VMTC?
Response : There is an assessment as the first requirement. EVSM is an assisted process and all consultants in one country are involved in identifying best participants. It is in their terms of reference. Results are presented to MOH/WHO/UNICEF during debriefing. VMTC did get these people but the system is not completely fool-proof.

Question : Civil servants are often subject to transfers. Is there any coordination with countries and WHO to make sure that there are opportunities to disseminate the information acquired during training and that there is in-country-training?
Response : These courses are not training of trainers which imply different skills to disseminate. The goal of the course is to have participants perform their own job correctly. We cannot prevent them from teaching afterwards but it is not the intention of the course.

Question : In Indonesia, there was a request that EVSM be conducted in a number of other cold stores in provinces. In Andra Pradesh also the assessment is carried out further to other cold stores. How can we deal with a fairly substantial number of store managers who would need to go through such a course.
Response : Indonesia is a particular situation because there is more than one primary store. One participant from Andra Pradesh is scheduled for the next session and one from Indonesia later on. There is only 15 seats per session, 30 in a year. We are confronted with the situation and EPI is working at mid-level and health facility levels. Good links with mid-level management and Immunization in Practice should be established to build on what is being achieved at national level. We have not yet figured out how this should be done but definitely not by cascade training.

Question : Precautions are taken to select appropriate candidates and they need endorsement from WHO country and regional offices. What then is the role of these offices afterwards? What would happen if candidates are selected by other organizations or moved to other posts?
Response : The document “Vaccine Management Training Cluster Conceptual Framework” describes roles and responsibilities of all parties. It is shared with Regional Offices and expected to move down to country offices. A series of Standard Operations Procedures are being developed, for selection of participants, identification of training centers and so on.

People also move on and it cannot be prevented. We were in such positions ourselves and we moved on.

Comment : Zambia had a similar experience. People were eager to have our report which was senn as training material, especially people who handle vaccines at stores level. There was a need to organize in-country training at district and provinces levels. The training package was developed from material we got.

THE STORYBOARD: ILLUSTRATING FOR VMTC : Kemal Gökhan Gürses, Shop of Miracles

Presentation Highlights : Extracted from the presentation

Merhaba...

I guess you have had a chance to get to know me by now from the brochures that you have. And those of you who are very careful must have noticed that I drew myself a role in the 'vaccine store management training' manual as a health worker named Kemal.

During the last 3 years that I worked for the VMTC I had a chance to understand what type of work you perform, and under what circumstances...

Everything I learned about you not only made me respect all of you deeply…

All your efforts for sending vaccine in a timely and correct manner, to some corner of the world to an unknown child…

And your professional dedication where you risk yourselves trying to deliver "health" to children…

Knowing all this put me in a position to make me want to live up to your standards while using my drawings for this project...

This drawing for instance... I merely redrew a photograph taken by a photographer... I mean this is not even a product of my imagination... It is a drawing created by your incredible professional courage and devotion.

My drawing might just have softened the dangers and toughness of that moment...

But I certainly did not just use photographs to make drawings...

The infrastructure created by many experts whose names I don't even know helped me learn the reality in this field. Someone I know very well, Dr.Umit Kartoglu, and I got together using every means of communication. This included meeting in person, working for days and nights and this is how we decided to create a hero. A birth needed to take place so that the universal language of cartoons would make our message more deliverable. That's how WRONG AHMED was born...

While WRONG AHMED keeps trying hard with all his good intentions, each mistake that he makes probably represents most of our habits and common mistakes.
Since we showed so many mistakes through WRONG AHMED, we also had to show the best practices through CORRECT AYSHA. There had to be a woman to stand beside Wrong Ahmed to show him the right way to do things (as always happens in real life) with all her calmness and expertise.

Maybe she is not as much fun as Wrong Ahmed but if we come to think of it, we don't have the luxury of making mistakes. So CORRECT AYSHA had to be there.

And then the adventure begins...

When all the work was finished and this entertaining but very useful training manual was complete, you could imagine the joy that we felt...

The games you play, I try to animate with my drawings...

Well, all my work into this project and all yours as health workers in all corners of the globe, is to reach a common goal.

DISCUSSION

The discussion-question period opened on a remark by the Chair to thank Kemal for his brilliant illustration of how to spice up training.

Then Ticky Raubenheimer from South Africa speaking on behalf of himself and his two colleagues involved in developing the content of the first course, thanked Kemal for putting so much fun in information and transfer of information. When the first storyboard came out he

added, they knew they had a winner and that they were part of a winning team. Kemal has put life in what they are trying to tell the world.
Michel Zaffran from WHO also paid tribute to Ümit Kartoglu for what participants have seen today and the day before, not only for the professional quality of the work but the level of innovation and creativity not seen for a long time in this area of immunization.

The only question raised was to ask if any of these beautiful images were publicly available in an image bank for countries to use in their own presentations.

The CDROM of VMTC illustrations is currently available from Ms. Christine Husser at WHO/HQ husserc@who.int

FEEDBACK FROM COURSE GRADUATES : Nguyen van Cuong, MOH Vietnam

Presentation Highlights : Prepared by the presenter

BACKGROUND

In Viet Nam, there are six diseases currently targeted by EPI. Routine immunizations consist of BCG, diphtheria, tetanus, pertussis, polio and measles. Hepatitis B vaccination has been recently introduced. Additionally, vaccination Japanese encephalitis, typhoid fever, and cholera are provided through EPI according to need. There are also accelerated programs for neonatal tetanus with vaccination of women of childbearing age in high-risk districts, as well as plans to introduce a second dose of measles vaccine during childhood.

The cold chain system in Vietnam is based on active refrigeration at national, regional, provincial, and district levels. Vaccine carriers are used to transport vaccines to communes and outreach in all areas in the past, but recently there has been a trend towards installing refrigerators in some communes. Most communes collect vaccine from the district in vaccine carriers using icepacks or wet ice the day before the monthly session and do not store vaccines between sessions. Cold boxes and vaccines carriers are used for vaccine collection and for periodic outreach work in more remote areas of some communes.

Training for national, regional, provincial and district EPI staff on EPI management base on information from MLM (The cold chain management module). Training for commune health workers on EPI skills used immunization in practice (IIP). And for storekeeper is guideline come from EPI staff at the same level. We have training plan for storekeeper at different levels in 2004. I feel that the materials available are not enough information necessary for training on cold chain and vaccine management. But where and how I can get material for this?

PARTICIPATION IN THE COURSE

I am very lucky to have the chance to go to Geneva for presentation on “Strengthening of the AEFI monitoring and management sys tem in Viet Nam” in the 4th Meeting of the Steering Committee on Immunization Safety, Geneva, 16 - 18 June, 2003. In that meeting, the first time I know that GTN will have training course on vaccine and cold chain management through one presentation. Even this is first time I have chance to participate in the important meeting, I asked: “how I can have the materials for that training course”. Coming back from the meeting I had contact with local WHO officer to help become a participant in the course. With fellowship from UNICEF I have chance to participate in the first vaccine management training course in South Africa from 10 to 14 November 2003 conducted by WHO. My expectation to learn how to manage vaccine EPI in good condition include get material use for training courses on cold chain and vaccine management from this course.

The course was designed for 5 working days include the following topics:

- Adequacy of the cold chain relates to the type of cold chain equipment, availability of vaccine storage space and the knowledge of managers in adjusting supply periods when capacity seems to be limited. This also includes the optimal planning and utilization of the cold chain space.
- Availability of adequate quantities of vaccines indicates the capacity of the vaccine management to provide sufficient quantities of vaccine and other immunization supplies for immunization services at each level, and to forecast requirements.
- A good stock recording system gives an insight into vaccines and diluent stock movements. It appreciates the traceability of all vaccines/diluents and other immunization supplies at each level.
- Efficiency of vaccine distribution system gives an insight into the ability to provide the right service at the right time, to the right place.
- Reliability of the cold chain relates to the quality of the cold chain. It indicates how vaccine storage temperatures have been maintained within recommended limits. It also takes into account measures put in place to deal with accidental failures of the cold chain. This criterion also addresses both infrastructure requirements and knowledge of managers needed for a reliable cold chain.
- Correct use of diluent indicates the correct handling and use of diluent. It also includes the availability and use of the proper diluent for each freeze-dried vaccine at the correct temperature for immunization.
- Effective use of VVMs measures the knowledge, attitude and practices of the health workers and managers with regard to the use of VVMs as a managerial tool. It also indicates the impact of such a use on the service delivery.
- Effective use of MDVP indicates if the MDVP has been adopted in the national EPI at all, and the safety and effectiveness of vaccine use for immunization sessions.
- Monitoring of vaccine wastage aims at showing if wastage rates are determined and an effective monitoring system is in place and managed.

RESULTS AND FEEDBACK

It seems that all of problem for cold chain and vaccine management in Vietnam will be resolved if follow what has been introduction in the course. It is very clear for me when I know how to calculate vaccine wastage rate and monthly report by different levels. Do not to worry about high wastage rate for vaccine in remote area. Need to record necessary information in register book about vaccine stock at different levels. Reliability of the cold chain. How to introduce Multi dose vial policy with local vaccine.

The first time I have chance to see the chill icepack. The first time I become guider on how to use cold chain monitoring card in the international course in 5 minute. Working in small group only 2- 3 people. I can't remember how many winner received presents during the course. And we can play Vaccine management Board Game during the course.

The course content was relevant for me (National EPI staff). I felt content at the end of the course because all my expectancies were met. The trainers did a good job maintaining a positive learning and made me feel comfortable in asking questions. That is why in the feedback session of the course I said: "I want to sleep because of the 6 hours jetlag, but the course is so interesting and I can not sleep".

The course finish but not stop, at the end of the course each participant received one notebook. It will be used for writing all activities related with learning from the course. In my notebook now we can read:

15 Nov. 2003: Working with Dr. Diana, PATH-BKK on how to improve cold chain and vaccine management in Viet Nam

30 Nov. 2003: Discuss with Dr. Rikke, WHO Hanoi about learning from the course and how to improve cold chain and vaccine management in Viet Nam

4 Dec. 2003: Working with Dr Len, UNICEF Hanoi to prepare POA for EPI in 2004 include cold chain and vaccine management activities

Jan. 2004: Discuss with Dr. Umit on EVSM assessment in Viet Nam

Jan. 2004: Discuss with Dr. Hitoshi, WHO Hanoi on activities for cold chain and vaccine management

Materials for storekeeper and for EPI staff will be available in the first week of April 2004

A plan of action for 2004 to improve of cold chain and vaccine management was repeated after the course. Base on job description of cold storekeeper and EPI staff two kinds of materials on cold chain and vaccine management for EPI staff and for store keepers were developed base on material from the course and other EPI materials (Immunization In Practice, MLM). We can conduct one workshop on cold chain and vaccine management for up date cold chain and vaccine management skills for national and regional EPI key staff will be conducted in early April. Four training courses on cold chain and vaccine management for store keeper at national, regional and provincial levels will be conducted in April and May 2004. This will be the first time storekeeper have chance to participate the training course on cold chain and vaccine management. All of these activities will be supported by UNICEF. Twenty training courses on cold chain and vaccine management for district storekeeper will be

conducted in 4th quarter 2004 with support from WHO. Training for EPI staff on vaccine management at different levels will be combine with training course on EPI management in 2004 and 2005. Commune health workers will be received the information on cold chain and vaccine management practices through monthly meeting and training course on immunization in practice in district health center.

Vaccine register book and monthly reporting form will be add some more columns: manufactory, state of VVM... Wastage rate of EPI vaccines will be report monthly and separate by level. Monitoring checklist for all levels will be repaired cold chain and vaccine management information part. Monitoring and surveillance on cold chain and vaccine management will be more often.

Training on cold chain and vaccine management become one of the most priorities in Vietnam in 2004 and 2005. We hope WHO, UNICEF and other donor to continue support for EPI in Vietnam in future.
Cold chain and Vaccine management assessment will be conducted in April 2004 with support from UNICEF and WHO. Same assessment will be conducted in 2005 following the project implementation to review the impact.

ACKNOWLEDGEMENTS

I would like to thank WHO and UNICEF for supporting me to participate the vaccine management training course. I believe that all of you will continue to support for me to improve management skills on EPI and hope that other country EPI staff have lucky chance to participate the same course in near future.

DISCUSSION

Question : What kind of ongoing support are you receiving for developing your own training after having taken that course?
Response : The main support is from documents brought back from the course. This is new and useful. It also permitted the review of older documents such as “Mid-level Management Training” and “Immunization in Practice”. We could organize training workshops with key EPI staff from national and regional level to look through this material and extract useful parts and decide what to do in the field. If we wait for the outside, it will be too late.

Comment : The presentation is a good example of whether it is intended to disseminate or not, it is going to happen. It suggests that the design should be looking at how participants can use the material to disseminate further in their country.
Response : It was indeed envisaged by VMTC that this could happen and there are plans to produce training packages for participants to bring back home to use for training their own staff. It will not be general training packages but specific, targeted and competency-based packages, for example “Shake Test” training package.

Question : Is there any emchanism to cross-check whether the information disseminated from national level down to the field is not transformed? One way is to spot-check at the end level (HC). How can we also make sure that trainers do not introduce themselves information that might be wrong?
Response : Cascading is not in VMTC's training course plans, so it is not in its mission to check if countries want to initiate their own training. If countries ask for help, ways will be found to provide although it is not in VMTC's workplan. Regional and country offices should be in the picture.

Question : Are there any mechanism to call back on participants to update information when needed?
Response : It has been a problem faced ever since, also in other areas of public health. That's why WHO tries to revise EPI guidelines as often as possible. It highlights the need to bridge efforts made at national level by MLM and Immunization in Practice.

Question : An EVSM assessment was not carried out prior to participating in the course. Do you have a mentor and how do you use him/her?
Response : EVSM was conducted earlier this year but it was not necessary to find out all the problems before going to the course. There is still the need to train all our people. I wanted to attend the course not to become a trainer but because of what needs to be done in my country. Attending the course was much more useful.

THE CHALLENGE: MLM AND COUNTRY LEVEL TRAINING : Evariste Mutabaruka, WHO AFRO, presented by Serge Ganivet

Presentation Highlights : Extracted from both the presenter's paper and presentation

BACKGROUND : EPI CAPACITY BUILDING(CB): SITUATION IN AFRICA

Ensuring the quality of immunization, education and training is the cornerstone of building capacity of individuals and communities involved in immunization services. Between 2001 and 2003 in the African Region, the institutional training capability of EPI has improved substantially through significant investment in human and material resources. The big challenge is to put in place a training system that anticipates and responds to immunization systems in evolving health systems.

OBJECTIVES OF EPI TRAINING

To build / strengthen / maintain technical and managerial skills of students/EPI personnel in all EPI operations and supportive components at regional, intecountry and country levels.
NB: Both pre- & in-service training!

REVISITING EPI TRAINING PROCESS

The on-going EPI training system addresses both pre-and in-service training. It consists of the following operational functions: training needs assessment, training materials and tools development, training of trainers/teachers, curriculum development/revision, workshops/courses organization, monitoring, supervision, evaluation, follow-up and operational research. The main target audience of EPI training is community health workers, EPI staff (epidemiologists, logisticians, communicators, other managers and support staff including secretaries, laboratory technicians, drivers), students and trainers/teachers.

The main partners in the upgrading of the EPI training process in Africa are the UN Foundation with the Management Strengthening Project in 8 African Nations, USAID, CDC, UNICEF, CVP / PATH, NESI and other partners: BASICS, GAVI, etc.

RELAUNCHING MLM TRAINING

- Updating of MLM Modules and other training materials and tools
- Reorganisation of MLM and other EPI courses scenarios
- MLM Courses implementation
- MLM Training , Monitoring & Evaluation and follow-up.

REORGANIZED MLM MODULES IN 8 BLOCKS

BLOCK	**Module / Reference**
I. Introd.+ common mod.	3 mod. + 2 Ref.
II. Planning & Organisat.	3 mod. + 1 Ref.
III. Logistics	8 mod. + 2 Ref.
IV. New vaccines	2 mod. + 1 Ref.
V. Suppl. immunisation.	2 mod. + 2 Ref.
VI. Disease surveillance.	2 mod. + 2 Ref.
VII. Monit.& Evaluation	3 mod. + 2 Ref.
VIII. Training kit	1 mod. + Tools

FINALIZED MLM MODULES

As of the time of this meeting, 12 out of 24 modules had been revised and finalized. “Communication Handbook for Polio and Routine EPI” and the revised “EPI Planning Guide” are to serve as referential manuals. Training tools and guides are : - EPI training kit

- Facilitator’s guide
- Course Director’s guide .

PEDAGOGICAL SCENARIOS

To get more positive effects and sustainability from this MLM training, efforts are now concentrated on peripheral level and on pre-service training institutions. For this, the new pedagogical scenario proposed is to offer short seminars (2-5 days) at provincial and district levels, especially during the monthly monitoring meetings. It is also planned to update teachers and professors on EPI content to enable them to effect needed changes in their lessons and curricula.

COURSE	SCENARIO	DURATION
Inter-country	**Seminar**	**6 - 10 days**
National	**Seminar**	**6 days**
Provincial	**Seminar/short courses/monitoring**	**3 - 6 days**
District	**Short courses /monitoring**	**2 - 3 days**
Health facility	**On –the-job training**	**½ day**

2001-2003 MLM ACTIVITIES

During the past three years (2001-2003), 6 intercountry MLM courses were conducted for Anglophone and Francophone countries and 316 EPI managers and 61 WHO/UNICEF EPI focal points were trained. Since 2002, MLM courses have been conducted within 14 countries at national and provincial levels. Available evidence shows that this MLM in-service training contributed to the improvement of the performance of EPI since the immunization coverage is now increasing within the majority of African countries and in the Region (Regional DPT3 coverage moved from 55% in 2001 to 61% in 2003.

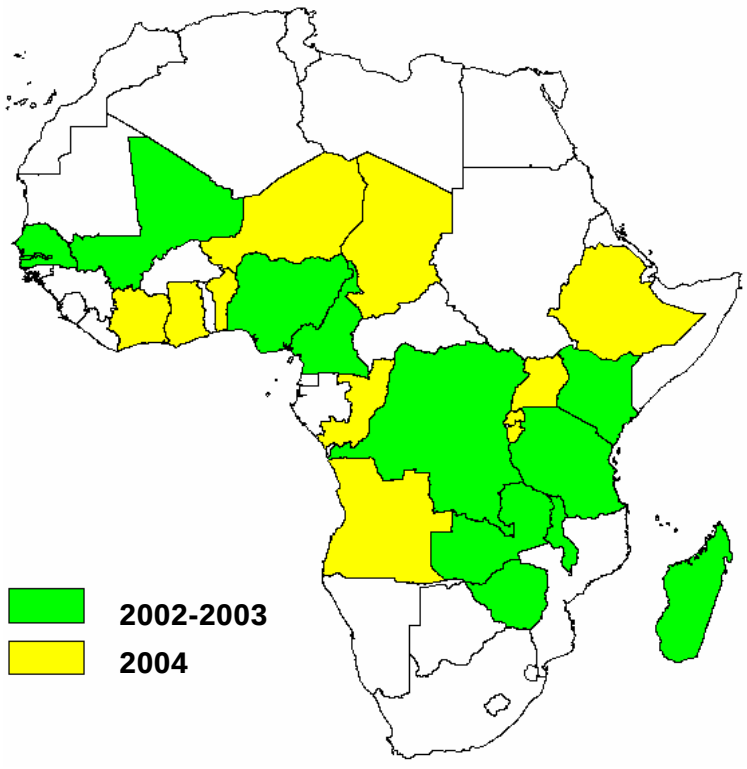
- 23 MLM training country plans available
- High committment of partners:
    - WHO: AFRO, HQ, Country Offices
    - UNICEF: Regional & Country Offices
    - CVP/PATH
- High involvement and motivation of participants and facilitators
- National & intercountry workshops on:
    - Logistics
    - New Vaccine Introduction
    - Data management
    - Micro-planning
    - Integrated disease surveillance

EXAMPLE OF ESTIMATED COSTS AND SOURCE OF FUNDS OF 2001 MLM INTERCOUNTRY COURSES

Location	Nb of participants	Estimated budget (USD)	Sources of funding
Abuja (3weeks)	**74**	**150,000**	**HQ + AFRO +UNICEF+ USAID+UNF**
Douala (3weeks)	**58**	**108,000**	**HQ +AFRO +UNICEF+ USAID+UNF**

TNAs CONDUCTED IN 2002-2003 AND PLANNED IN 2004

Assessments conducted recently within countries indicate that the major barriers to reaching every child in every district with immunization services are related to management of human, material and financial resources at the level of services delivery. These barriers include high staff turnover, managerial weakness and failure to communicate with the community, as well as the physical distance from the service. Capacity building is required to improve managerial skills, to integrate the immunization service within the local, social and health infrastructure and to stimulate the participation of the community.



OTHER RESULTS OF 2002 -2003 EPI TNAs

- Priority target audience: Logisticians, health workers, communicators, epidemiologists, EPI focal persons/partners and students and teachers
- Priority topics at all levels: Logistics: cold chain & vaccine management, injection safety, new vaccines introduction and data management
- Central/provincial/ district levels : MLM including IDSR, SIAs management
- Operational level (health facility) : Immunisation in practice including AFP surveillance at health facility

OTHER INITIATIVES & OPPORTUNITIES FOR EPI TRAINING

- Training on GAVI Process in collaboration with CVP–AMP & UNICEF
- EPIVAC Project: a 5-year training initiative for Francophone African countries (AMP).
- NESI project (University of Antwerp)
- Merck Vaccine Network for Africa
- GTN
- Senior level managers training: CVP/PATH
- Global collaboration with HQ, UNF, USAID, UNICEF, CVP/PATH, etc.
- Reorientation of surveillance officers.

CHALLENGE : Integration! In the context of Health Sector Reforms:

Since decentralization and integration of services are the major strategies of health reforms and constitutional reforms have strengthen the role and the independence of sub-national levels, especially the district level. In many African countries, immunization services are currently delivered as part of integrated mother and child health care interventions at district level. With decentralized and integrated immunization services, health sector reforms provide opportunities for improving the quality of immunization services to ensure full immunization of children under one year of age at 90% nationally, with at least 80% coverage in every district by 2010 (UNGASS/GAVI goals). It is therefore recommended to implement **integrated MLM training** at district level.

- Decentralization : Integrated planning at district level and integrated supervision plan and checklist
- Efficiency : Shared Logistics/Transport and Allowances
- Polyvalent service provider & supervisor : Shift towards community health provider, integrated checklist and cost-effective human resource utilization

RECOMMENDATIONS FOR EPI TRAINING

- More collaboration, partnership and coordination.
- Networking of national & regional training institutions
- Inclusion of explicit cb objectives & activities in Government plans.

ACKNOWLEDGEMENT

Thanks to all partners for their technical and financial support: UN Foundation, USAID, CDC, UNICEF, CVP / PATH, NESI and other partners: BASICS, GAVI, etc.

THE DISCUSSION/QUESTION PERIOD FOR THIS PRESENTATION WAS POSTPONED AFTER THE NEXT AND LAST PRESENTATION OF THIS SESSION

DEVELOPMENT OF TRAINING PLANS: MALI EXPERIENCE : Julie Milstien, University of Maryland, USA; prepared by Julie Milstien[1], Samba Sow[2], Milagritos Tapia[1], Lassana Keita[3], and Karen Kotloff[1]

This study/initiative was supported by an unrestricted educational grant from The Merck Company Foundation, the philanthropic arm of Merck & Co., Inc., Whitehouse Station, New Jersey, USA.

INTRODUCTION

The Centre pour les Vaccins en Développement (CVD Mali) has been established in Mali in partnership with the Center for Vaccine Development of the University of Maryland School of Medicine (CVD Maryland) and the Ministry of Health in Mali. Situated administratively within the Centre National pour l'Appui contre les Maladies (CNAM), CVD Mali has among its goals to become a center in Mali for epidemiology and for training in infections diseases and vaccinology. In collaboration with CVD Maryland, CVD Mali has undertaken a number of activities in disease and laboratory surveillance, vaccine clinical trials, and support to immunization.

In 2003, the Merck Foundation awarded to CVD a 4-year African Program Training Grant (Merck Vaccine Network - Africa, or MVN-A) starting with $200,000 for the first year. The Principal Investigator is Dr Karen Kotloff of CVD Maryland, the Coordinator is Dr Samba Sow, of CVD Mali, and Dr Lassana Keita, CNI Mali, has been named coordinator of the training intervention. The aims of the project are five:

- To perform immunization services assessments at selected sites;
- To delineate goals for EPI performance in line with national priorities;
- To develop an interactive educational curriculum for mid- and high- level EPI managers that addresses gaps in key operational areas;
- To establish a system whereby similar training programs can be conducted for peripheral health care workers;
- To assess the impact of the educational intervention.

A Technical Advisory Group (TAG) has been named, and includes high level officials in the Malian Ministry of Health, the National Department of Public Health (which oversees EPI), faculty from the schools of medicine and nursing, representatives of women's groups, officials from the national health

[1] Center for Vaccine Development (CVD Maryland), University of Maryland School of Medicine, Baltimore, MD USA

[2] Centre pour les Vaccins en Développement (CVD Mali), Bamako, Mali
[3] Centre National d'Immunisation (CNI), Bamako, Mali

surveillance laboratory, and community advocates. It is hoped to include representatives from WHO/AFRO and donor organizations as well on the TAG.

ACTIVITIES TO ESTABLISH THE TRAINING INTERVENTION

The activities to establish this center include or will include:

- Involvement with Malian health officials
- Coordination with WHO
- Preliminary assessment
- In-depth assessments of
    - Vaccine management
    - Immunization safety
    - Surveillance
    - Immunization coverage
- Curriculum development
- Training interventions
- Impact monitoring.

As part of the involvement with Malian health officials, discussions were held with the Vice Minister for Health, the National Director of Public Health, the National Surveillance and Disease Control Office, the EPI manager and staff. In addition, contacts were made with WHO at global, regional and national levels, with UNICEF, and with other partners in Mali.

A preliminary assessment was done in two regions, Koulikoro and Sikasso, not far from Bamako. Three district health centers (Kangaba, Bougouni, and Sikasso) were visited, as well as four CSCOMs (peripheral health centers). Issues of concern relative to vaccine management found in these preliminary assessment visits included:

- Inaccurate understanding of storage temperatures
- Limited or inappropriate use of the multidose vial policy
- Improper handling of diluents
- Nonstandard refrigerators, which raised problems with replacement parts
- Impure kerosene, resulting in nonfunctional refrigerators
- Vaccine stock ruptures
- Broken autodisable syringes, mainly a result of lack of training in their use
- Unsafe disposal and incinerator practices
- Uncertain denominators, making calculation of coverage unreliable.

ASSESSMENTS

In order to better define the needs and provide a basis against which to measure the impact of the proposed training, more formal assessments were planned at the central level, in the capital city of Bamako, where 10% of the population resides, as well as sites representative of the three major

climatic areas in Mali: savannah, central sudano-sahelian (steppe), and Saharan. The map below shows where the assessments were done. In each region a representative district was selected, in collaboration with the EPI manager, and assessments were done at the regional and district levels, as well as at two community health centers (CSCOMs) in each district, representing the best and weakest peripheral units in terms of coverage in the district

In total, 17 sites were selected for assessment, as listed below:

1. Bamako
   - National
   - Regional
   - District - Commune IV
   - CSCOMs – ASACOSEK (Sekénikouro), ASACOLA 1 (Lafiabougou)
2. Saharan – Mopti Region
   - District - Mopti
   - CSCOMs - Soufouroulaye, Diambakourou
3. Sudano-sahalian (steppe) – Ségou Region
   - District - Macina
   - CSCOMS – Kokry, Oulan
4. Savannah – Kayes Region
   - District - Nioro
   - CSCOMS –Diamwelicounda, Tintiba

Figure 1. Map showing the four assessment sites: Bamako, Kayes (savannah), Ségou (sudano-sahelian), and Mopti (Saharan). [Map used by courtesy of The General Libraries, The University of Texas at Austin, at http://www.utexas.edu/maps/mali.html

Most assessments were completed in February, 2004. The final round of assessments, in Kayes, took place in April, 2004

The assessments covered the following areas: vaccine management, immunization safety, surveillance of vaccine-preventable diseases, and an exhaustive coverage survey in the community served by the lowest performing health center. This coverage survey was particularly useful in pinpointing how policies and practices impacted coverage. For example, one of Mali's priorities has been to reduce unnecessary vaccine wastage, with the recommendation that session sizes be optimized as much as possible, especially for administration of lyophilized vaccines. Accordingly, measles and yellow fever

vaccines are administered only on specific days per week. In areas where few children are served by fixed sites, if a critical number of children do not show up on a measles-yellow fever vaccination day, the session could be postponed, and this appears to have resulted in a sizeable DTP3-measles dropout rate.

The WHO vaccine management assessment tool, found at http://www.who.int/vaccines-access/vacman/VTMC/vacman, version D5, May 2003, was translated into French and used for the vaccine management assessments. WHO's injection safety assessment tool, WHO/V&B/01.30, Annex 2, available in French, was modified for this project. A surveillance assessment tool was developed based on surveillance documents published by WHO's Department of Immunization, Vaccines and Biologicals, and the coverage survey used similar data gathering instruments as in standard Lot Quality Assessment and 30-cluster coverage survey documents. Both tools were developed in French and tested before use. The assessment teams comprised the authors, as well as staff from the EPI and logistics units at the central and regional levels, with additional staff from Bamako and the relevant regions assisting with the coverage surveys.

The results summarized below are primarily those from the vaccine management assessment. At the central level, it was evident that the staff were well-trained and resourceful in solving problems. Major issues that were also evident further down the line included tracking of diluents, lack of a comprehensive transport system, and problems with equipment donated from abroad (service, availability of spare parts). A new computerized vaccine management tool was just being put into practice; however, data management and quality assurance for this were weak.

At the service level, many of the problems seen in the preassessments in the Koulikoro and Sikasso regions were reinforced in the other regions. The most evident area of concern was the weakness of channels for communication and supervision to the periphery, and a real challenge in this training intervention will be to address this issue. In contrast to the situation seen in the central area of the country, where adulterated petrol was a major cause of cold chain failure, refrigerators in Mopti were powered by electricity or solar power. Where electricity was used, it appeared to be reliable, but lack of batteries for the solar refrigerators became an issue. Several important technical issues were identified that adversely impact the quality of immunization services, including:

- Risk of vaccine freeze damage
- Weak planning for preventive maintenance, parts replacement
- Vaccine and syringe stockouts
- Lack of tracking of diluents, resulting in mismatching diluents to vaccines
- Wastage monitoring in place but little understanding of its utility at peripheral level
- Insufficient storage capacity, especially for tetanus campaigns, when volume of Uniject became an issue.

CURRICULUM DEVELOPMENT

On completion of the assessments, a comprehensive report will be developed and presented to the TAG for their formulation of educational priorities. It is anticipated that training will be at three levels,

with likely different curricular needs for each: the central and regional levels, which will be focused on major problems, both technical and supervisory/communications-oriented; the peripheral levels, where training may be better done through supportive supervision and task monitoring; and as part of the Global Training Network (GTN) in the future. Targeted curricula will be developed and training will start in selected sites soon thereafter, possibly by the end of 2004

MONITORING OF IMPACT

Targets and indicators to be monitored have been developed in coordination with Mali's EPI staff. Several impact indicators, such as coverage and drop-out rates, will be used, along with process indicators which will be based on reassessment using the same tools as used prior to training. Indicators mentioned in the Merck grant application include the following:

- Number of children <1 year of age receiving DTP3
- Proportion of sub-national units by coverage level for DTP3
- DTP1-DTP3 drop-out rate
- Inventory tracking
- Stores of high quality vaccine, diluent, and administration supplies
- Viability and monitoring of cold chain
- Vaccine wastage
- Stock-outs
- Use of vaccine vial monitors (VVMs)
- Standard procedures for incineration.

CONCLUSIONS

The training intervention described here is primarily a means to build immunization delivery capacity in Mali. It is being developed using approaches pioneered by WHO, in collaboration with the Department of Health of Mali, which has the largest stake in the outcome and thus the largest impact on the priorities. All educational interventions will be coordinated with other activities ongoing in Mali, for example, the EPIVAC initiative. In addition, the program seeks to accelerate the development of CNAM, through its work with CVD, to a financially and programmatically sustainable training capability. Finally, all those involved see real potential in developing this training program into a node in the GTN, serving Africa, primarily in French.

DISCUSSION

Question : AFRO is revising MLM modules while the same is deing done at headquarters, is there collaboration between both?

Response : In the absence of the author, it was understood that there has been some problems at the beginning but collaboration is good now.

Comment : It seems quite sure that HQ and AFRO are not coordinating on the matter of MLM modules revision so we are going to end up with two different sets of modules. So there is room for better coordination between the two groups.

Response : WHO HQ acknowledges that the two initiatives have been started on parallel tracks because not only people were not talking to each other but also the speed at which things could develop at HQ didn't meet the needs of the African region. So the region wanted to go ahead and there was a fair amount of miscommunication and lack of coordination. It was realized and since then there were attempts to merge the effort acknowledging that needs are different. It is recognized that there was a certain waste of resources. Although the coordination may not have been optimal, the effort put into conceiving and updating material will eventually lead to a very strong and sound package.

Question : It is welcomed that West Africa would receive more support in capacity-building. Will the content of courses to be developed be for short or long-duration courses? And there is a large training facility in Bénin supported by WHO. It is not presently used very much by EPI training so would it be possible that it becomes more involved in training for the region?
Response : The first course will be for national and regional staff and the Technical Advisory Group will determine the training priorities based on the assessments. Results for Immunization Safety and Surveillance assessments were not presented but only the Vaccine Management assessment. As a first course it is intended to develop a Vaccine Management course that will emphasize the areas where real problems have been identified and it will probably be a 5-day course using a similar curriculum to the one you heard about this morning. Training is not the only option to improve performance and we have to look at other ways so that the project can an educational intervention that is not necessarily a training course, and how that will eventually get down to the service delivery level. It is not known yet where it will go after this first 5-day course.

In a meeting with AFRO colleagues recently to discuss the establishment of a French training center, the one in Bénin was considered together with one other in Sénégal. Unfortunately with many other initiatives in West Africa such as polio eradication and so on, it has not been possible for our colleagues to devote enough time to this activity. But it is our intention to assess capibilities of these two centers and select one of them to become the training center for vaccine management.

Question : Integrated training and the challenge it presents has become a reality, and EPI has to face the issue. In certain health sector reforms it can be too broad and stagnate. On the other hand one can select a few priority interventions, for example vitamine A or malaria/bednets and you try to integrate these issues into your training programme. You are not only getting integrated training but you are not overloading your EPI training so it is effective and you are adressing some of the other issues. So how is this challenge being met? Are you selecting interventions you can integrate or it is becoming unmanageable?

Response : The Chair commented that these multiple-intervention training is often asking for the same or largely the same people to come out for training and we do need to think creatively. The term drip-training has been heard in refernce to coffee machines that just drip. There are opportunities to provide exposures to mini-modules, for example drop-outs and how to reduce drop-outs, when people congregate for other reasons like coming to collect their pay checks. We have to be very adaptable to take advantage of such situations as they develop and not always assume that there will always be opportunities to have first of all huge amounts of money to conduct crash training for everybody that takes them away from their jobs for long periods of time. We need to have multiple approaches in our pockets.

Question : Refferring to the incineration experience, Mali has been a focal point for training on small-scale incinerator training less than two years ago. Entrepreneurs from West Africa were trained in Bamako. Was there any evidence of good incineration practices, especially outside the city particularly small-scale incineration?
Response : Apart from the example shown in the presentation, there was evidence of bad practices everywhere, incinerators were not well-maintained, or non-functioning, there was a kind of haphazard allocation of staff to actually run the incinerator. They mentioned that they had been trained but they had really no standard operating procedures for how they were working. There were incinerators with no restricted access so one could find needles, syringes or ash full of needles all around them. In one center the incinerator was run by an EPI staff but also used by the curative sector. The incinerator was broken so the immunization services sent their safety boxes kept under quarantine to the upper level for incineration but the curative sector kept throwing their waste on the incinerator even though nothing happened and the pile was getting bigger everyday. However hard we looked for an incinerator operated properly, none was found.

Question : Does this means that this would be part of your training initiative to address this incineration training need?
Response : It can be expected that it would be but it is for the TAG to determine the priorities. It seems that this is something that really does need to be emphasized. The simple procedures that CNAM put in place, designating the staff, giving them uniforms and training, doing incineration at a set time every day, doing preventive maintenance don’t cost a lot of money. But it’s putting an infrastructure to the activity and giving some recognition for the activity well-done and it makes it happen.

Comment from the Chair : Many African countries have put some of their own training plans on the backburner with the expectation that the MLM modules will come along and this is a

common danger of putting all the eggs in the same basket waiting for a big course to be developed. It slows down training and kills many indigenous ideas.

Question : Should it be advocated that all countries that undertake MLM training conduct pre-hoc assessments to know on what focus training or should it be left to countries to decide given that assesments are time-consuming and expensive?
Response : Prior assessments gives a better idea of the scope of problems but even more importantly, it gives a basis on which from judge the impact of training. We've had lots of training without much of an idea of how it made an impact on performance. So assessments need to be conducted.

Comment : As we need to be careful about the language such as "out-of-the-cold-chain" so we need to be careful about how we talk about training because the message after these excellent courses at the national level is not that participants shoud go and start cascade training but rather start applying those skills, identify gaps in performance and find the best ways to fill those gaps, only one of which is classroom training. Many other things could change on the job performance including changing the forms, passing information through meetings and doing all sorts of other things in addition. One training should not automatically beget other training.

Question : How is it that Mali be chosen for this initiative? Is it a clinical study that is planned to be implemented in Mali and building capacity is a first step? There are targeted countries (8). If it is a clinical study, are these countries well-informed and knowledgeable about what it will be or this training is a gift?
Response : Work started in Mali a number of years ago by looking at clinical trial sites and there is a such a site that is developed with the University of Mali in Bandiagara, doing a malaria vaccine trial in collaboration with the Center for Vaccine Development in Maryland and the National Institutes of Health of the United States. In looking at expanding the field sites for cholera vaccine trials, collaboration was sought with CNAM. This was the basis for development of CVD-Mali. When the Merck programme came along the basis is that it is a joint collaboration between a US site and an African site. Because this collaboration already existed and the intent was to develop CVD-Mali into more than just a clinical trial site, it seemed a natural site to work from.

Question : What we heard from Mali is an excellent illustration of the need to respond flexibly and quickly when faced with dangerous or unsafe practices, and recognize problems and therefore training needs not only at country level but within countries. So global training of a limited number of people has got a place but a lot more needs to be done at all levels using

what we can learn from these excellent assessments tools. Following on that and linking with global VMTC courses, what are the possibilities of taking best practices from that course in terms of participatory, competency-based approach to training? We all know that the conventional lecture-style approach that still characterizes MLM training and other similar courses presents many problems. Let us remind ourselves words said previously that “we are good at training but poor at supplying support”.
Response : During the assessments in Mali, opportunities were systematically used to provide on the job coaching. For example, 15 minutes were used to explain to a Health Center manager how to enter coverage data into the chart because he didn’t know how to do it and what it was for. This is one simple thing to do with budget and transport, that sort of supervision that can get a lot of information across in a short period of time and judge the impact by going back for follow-up.

Question : To ensure sustainability, what are the plans to maintain those training centers once external assistance is finished?
Response : This is a good question and it is not known whether this has been included in the worplan or not. Trying to involve other partners at country level in developing a sustainable training activity is clearly part of the plan. Mali has funds for training and they have done training down to the health center level. If those funds were diverted into more effective pratices, it could probably make an impact without costing more. We will be using these four years to see what has the best impact and how this can be sustained.

Question : Training modules are being developed and it is an excellent way to fill the gap between standards and the field reality. These modules are self-learning packages but how this learning can be monitored and certified?
Response : This is the challenge for the years to come, to monitor training and how participants get the knowledge. It cannot be said at this point how this will be done.

Comment : There may be a problem with the term “Mid-Level Management” that is not really well-defined. What was seen from the presentation, it seems clearly used for senior-level managers and in-country-level managers. It seems heavily focused on technical skills specific to immunization but lacking the general skills that managers need to be able to think straight, to be analytical, to identify priorities and rank them, to find solutions and think outside the box. We need more of that than technical skills. The challenge for developing modules for capacity-building in EPI is enormous. What was done was to develop individual specific tasks, vaccine management, surveillance, how to increase coverage, but the challenge is how to put all this together to give a global view to the manager so he can carry safe immunizations. This is the challenge.

Response : These are interesting comments as it highlights the question whether we are training technicians or managers.

Comment : We have to be extremely careful as outsiders coming into a system of being prescriptive about what we see. Something life-threatening or likely to be is the only case that needs intervention. In all probability management of that system is going to be undermined by outsiders showing them up as incompetent.
Response : It is not only the case of outsiders versus nationals. Most of these activities are made as teams and it is the team's responsibility to correct wrong practices. It would also be unethical to leave a place without making necessary interventions.

Question : When using the assessment tool was it possible to identify whether similar assessment had been done before was there an opportunity to compare results to see if there was deterioration or improvements and how would that affect the project in the future?
Response : It seems that similar assessments had been carried out before but there wasn't enough institutional memory to remember that it had happened and it was very diifcult to find any evidence that it had taken place. The one assessment that they remember was the data quality audit. It is quite sure that there was vaccine management and injection safety assessments before but copies could never be found.

Comment : A need assessment was carried out from EPI reviews done in West African countries and it showed that a lot of training had been done and many health workers had attended courses but were incapable to implement the correct technical procedures to improve performance. It was also noted that district medical officers had not been trained on management. Some of them were just coming out of university without any training in public health or management while it is their main task to manage health activities. That's why a programme was implemented to train them on topics such as human and financial resources management, institutional relations, etc. to have this global view of what such officer should have. MLM is for technical officers not for district medical officers.

SESSION 8 : VACCINE SUPPLY and PROCUREMENT

Chair: Salah Al Awaidy, Sultanate of Oman

The objective and outmes of the session were as follows :

Session objective: Review update on work assisting countries to improve procurement practices

Expected outcomes: For information
Feedback from participants

This session was only intended to provide participants with information and receiving their feedback.

During this session, five presentations broadly reviewed the assistance provided to countries for improving their procurement practices. The first presentation examines different aspects of vaccine supply and procurement in developing countries. Some realities of vaccine supply and particularities of the vaccine market are highlighted. WHO's analysis of different types of situation at global, regional and country level are also presented.

The three following presentations illustrate the policies and strategies implemented in two regions (SEARO and EURO) and in one transition country (Latvia). The success of immunization services are influenced by the quality of existing vaccine procurement system, and especially by country capacity to set its priorities, analyze the vaccine market and manage its procurement system in order to get the needed and quality vaccines at the best prices.

The final presentation reviewed global production and availability of vaccines, current work in WHO on vaccine supply and production capacity and major factors affecting supply. Vaccine production of more needed vaccines, it concluded, should be considered as a strategic public health priority and not just based on financial and market factors. This presentation completed the update on Vaccine Supply and Procurement thus meeting the objective.

OVERVIEW : Miloud Kaddar, WHO HQ

Presentation Highlights : Extracted from both the presentation and the narrative prepared by the presenter

BACKGROUND :

Vaccine procurement aims at delivering sure, efficient and reasonable-priced products to countries, in order to implement planned vaccination activities. This procurement has to happen in due time, in sufficient quantities, and with assured quality.

This presentation wants to briefly answer three essential questions:

- Why vaccine procurement is important?
- Which framework can be used for situation analysis?
- What are our priorities?

WHY VACCINE PROCUREMENT IS IMPORTANT ?

Vaccine procurement is important for at least three reasons:

- The first one being the fact that a number of countries are importers, and hence entirely dependant of external sources to fulfill their national demand. This raises issues of international trade, public procurement rules, use of currency payment means, suppliers' selection, and also issues of product registration, market licensing, quality control and regulation.

- World vaccine market is specific and atypical. Supply is relatively limited, with very few producers, and monopoly situations are not exceptional, especially for new and combined vaccines.

- Vaccine procurement implies taking into consideration several factors together, implying expertise and capacities barely gathered within a single team or institution at national level.

PROCUREMENT SYSTEM :

Four factors must be considered together to build and manage a good vaccine procurement system..

- The first group of factors is linked to the immunization program itself to determine vaccines to consider, preferred presentations, quantities needed on a multi-year period.
- The second group is linked to financing: determination of needs and of demand must be based on timely and adequate funding. An assured multi-year financing plan is a condition of demand credibility and of acute attention of suppliers and producers.
- The third group of factors is linked to the procurement system itself. One should find out, for example, what is the analysis capacity of vaccine market and its opportunities, what is the room for negotiating prices, payment and delivery terms. Other aspects are related to quality control procedures, storage management and distribution capacity and performance.
- The last important group of factors is linked to National Regulation Authorities, and the functions they take on depending whether the country is just importer or producer and whether it uses the UN system for vaccine procurement.

A CHANGING CONTEXT

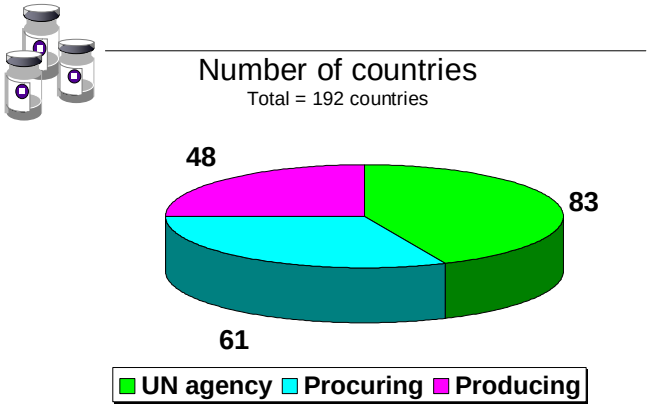
- Vaccine market is a concentrated one : 4 "big pharma" represent 75 % of the global sales, competition is limited.

- Geographical segmentation and diverging markets in terms of products and presentations used in OECD/middle income/poor countries.
- Surplus capacity of assured quality vaccines no longer exists for all basic products
- Vaccine industry ability to rapidly change capacity is limited due to conflicting priorities, regulatory requirements and production constraints
- Developing country vaccine manufacturers are an increasingly important source (70% for UNICEF in terms of volume)
- Availability of funding for vaccine purchases is a key driver to manufacturer response
- With new vaccine introduction: vaccine component is becoming the first cost driver in poor countries
- Predictability of demand is a key factor for both producers and suppliers
- Vaccine prices are slightly increasing in recent years
- Epidemics, emerging diseases and threats put vaccine in the up front of the health scene

SITUATION ANALYSIS : FRAMEWORK

- How to classify the various situations and vaccine procurement in place ?

Based on global estimations, we note that more than 80 countries use the UN channel for their vaccine procurement (UNICEF SD and PAHO-RF). This system can be the only source of supply (most poor countries are using UNICEF-SD), or only one among others (for basic vaccines for example). More than 40 countries are vaccine producers, in most of the cases to fulfill their internal demand. More than 60 countries are direct importers of vaccines, mainly transition and middle-income countries.



Reality is a little more complex, many countries being in a mixed situation. Some of them produce few vaccines and import the rest. Other countries import themselves some vaccines and use UNICEF for

their remaining needs. And others are both producers and UNICEF's or PAHO 's purchase system users.

This complexity of situation may have several explanations, linked to the history of vaccine industry in the country, to the vaccine type being considered (traditional or new, monovalent or not, single or multi dose), to limited production capacities for other than basic vaccines, to the evolution of the immunization schedule, to products quality issues, to price level, to economic adjustments and reforms or countries' health and trade policies. Production and marketing international regulations for vaccines and global immunization policies have most likely affected procurement practices and systems for vaccines in a number of countries. Numerous examples can be cited from these situations and evolutions. Some countries have even experienced fast evolutions.

- How to set up priorities and needed actions ?

To better assist countries to get the best vaccine procurement, we tried to classify the various types of situations to identify which are the countries who need priority assistance. We assume that the following factors can be considered as non-satisfactory functioning signals of their procurement systems and hence of potential support need:

- repeated stock shortages at central level
- too high prices relative to regional averages, or to the ones from comparable countries
- repeated quality problems for imported vaccines

On the opposite, we estimate that countries which get the following results need much less support in terms of their system reinforcement:

- no vaccine stock shortages during the last 12 months
- competitive price level to the regional ones or comparable countries' ones
- a functional and operational national regulation authority

Thus, countries getting the following situations are priorities:

- importers and/or producers countries facing persistent problems in terms of price, procurement quality and regularity
- importing countries moving from UNICEF system to their own direct procurement
- countries wishing to implement bulk procurement mechanisms.

TYPE OF ACTIVITIES : What kind of support are we offering to countries?

- Assessment of the vaccine procurement systems, at the request of countries and design of an institutional development plan (IDP)
- Technical assistance on vaccines procurement strategies and policies as well as on procurement mechanisms and procedures
- Information on best practices, pre-qualified vaccines,..
- Training on Vaccine procurement principles, procedures and tools.

Assessments	TA	Information	Training
TOOL	**Strategies and policies**	**Pre-qualified vaccines, prices,**	**Manual, modules,..**
IDP	**Operations and tools**	**Country experiences**	**Courses with centres of excellence**

QUESTIONS TO BE DISCUSSED

- What is a sound vaccine procurement system ?
- Should we encourage self procurement mechanisms ?
- Are group mechanisms viable options ?
- Should UN agencies define a common strategy and action plan for vaccine procurement ?
- Should we work with middle income countries or focus only on poor countries ?
- What type of WHO-UNICEF coordination should be promoted and implemented ?
- Is there a role for GAVI in vaccine procurement ?
- How should we link vaccine procurement, NRA strengthening, vaccine management and immunization financing activities ?

SELECTED RECENT REFERENCES :

Sabin Vaccine Institute, 2003, "Global Vaccine Shortage: The Threat To Children and What To Do About It", Exploring Lessons from the Sabin Vaccine Institute's Ninth Annual Vaccine Colloquium http://www.who.int/vaccines-access/financing/references.html

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Glennerster, R., Kremer, M., 2001, "A vaccine purchase commitment: Preliminary Cost-effectiveness Estimates and Pricing guidelines" http://www.who.int/vaccines-access/financing/references.html

Theta Reports: Vaccines 2003: World Markets and Developments

Milstien, J., **Candries, B.**, 2002, "Economics of Vaccine Development and Implementation: Changes Over the Past 20 Years", *The Jordan Report,* 2002

Mercer Management Consulting, June 2002, "Lessons learned: New Procurement Strategies for Vaccines" Final Report to the GAVI board http://www.who.int/vaccines-access/financing/references.html

DISCUSSION (Limited in view of a general discussion at the end of the session)

Question : Forecasting is one of the building blocks and very critical for the procurement side. On the management side it is also a critical element so is there an answer to this impossible question or a magic suggestion for refining forecasting methods, as we all know that it is difficult in government systems?
Response : It is an important question as it is at the crossroad between vaccine procurement and vaccine management. There should be links between vaccine procurement, management, financing, and forecasting is a key factor. For the moment we have different tools for forecasting, the UNICEF method, the GAVI one and some countries have developped their own. There is a need to consolidate and to learn from all experiences, and come up with something that is really strong and powerful and could be used by most countries. We are working on this and it is hoped that links between vaccine procurement and management will help make progress on this issue of forecasting in a way acceptable for all countries.

Question : What are the problems with current methodologies of forecasting and why it is not good now?
Response : If we want to have good vaccine procurement, we need to link programme, supply and financing. Sometimes, EPI managers do the forecasting alone without discussions with others to make sure that what is estimated is what is needed according to the budget available. Sometimes forecasting is done at central level without taking into account the field reality. It involves many factors.

REGIONAL PERSPECTIVE: EASTERN EUROPE EXPERIENCE : Denis Maire, WHO EURO

Presentation Highlights : Extracted from both the presentation and the narrative prepared by the presenter

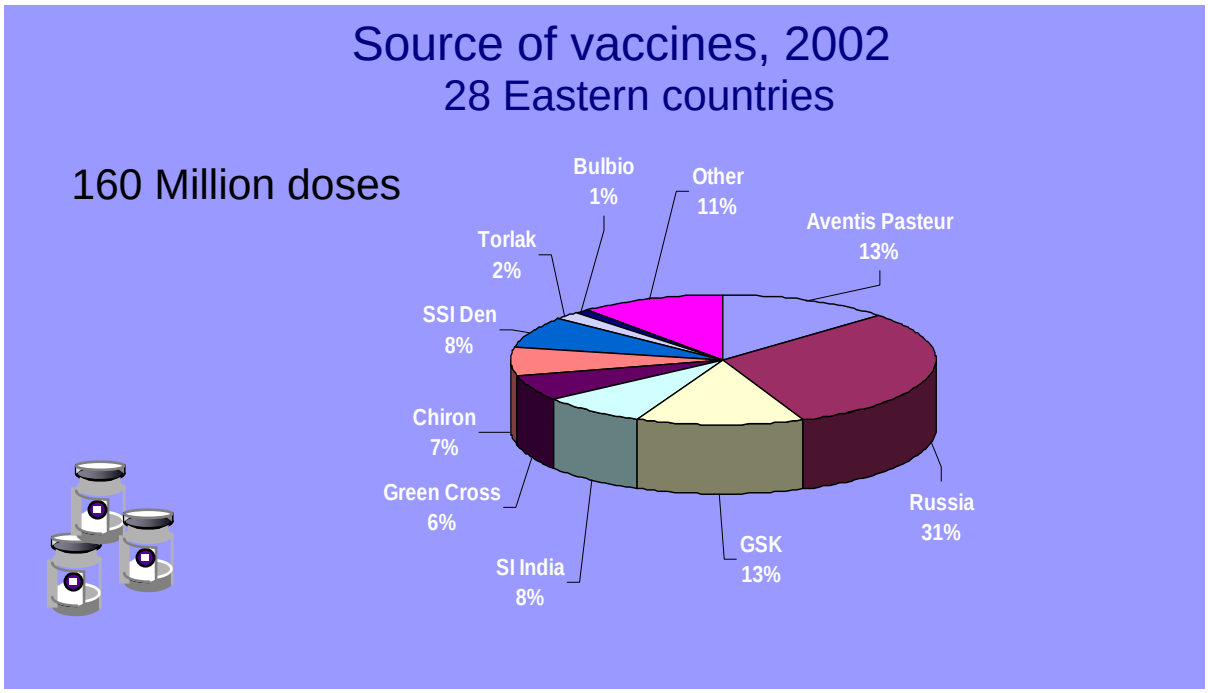
BACKGROUND :

Most European countries have achieved considerable success with their immunization programs, including coverage rates that are mostly above 90% for childhood vaccines and the introduction of several newer vaccines, such as hepatitis B, and MMR. This success is in part due to the progress made these past years in ensuring a sufficient provision of vaccines to national programmes. The majority of Eastern countries have instituted their own vaccine procurement system, while few others are dependant partially or entirely to the Unicef procurement services. While major steps have been taken towards countries vaccine procurement autonomy through the UNICEF Vaccine Independence initiative, self-procuring countries are facing new challenges due to the changes of the vaccine market.

VACCINE PROCUREMENT

The European region still counts 20 countries producing vaccines. While including some major international players (Aventis Pasteur France, Glaxo-Smithkline Belgium, Chiron Italy, SSI Denmark, etc.), other countries have recently stopped their production. Another category of countries have a low production capacity and often do not access the international market. In those countries, internal market is still strong and as a consequence influences the vaccine procurement process by allowing very limited competition.

Based on information given through the WHO/UNICEF Joint Reporting Form, about 160 million doses of EPI vaccines have been provided to routine immunization programmes from the 28 Eastern countries (CEE, NIS and Turkey). Among these, 80% were procured directly by Governments while 20% were provided through UNICEF services. UNICEF procurement decreased to 8.5% in 2003. Looking at the share of these vaccines by manufacturer, we can note that the largest quantity of vaccine consumed is from the Russian Federation (31%). Two major producers (Aventis Pasteur, GSK) account for 26% of the market, while Chiron, SSI Denmark, S I India, and the Green Cross are between 5 and 10%. Other Manufactures play a lesser or no role in the international market. They mainly produce traditional vaccines (BCG; DTP; DT; TT). If few of them have been privatized, still many are semi-private or state-owned companies with legal preference to supply their own national programme, reducing the chances of competition.



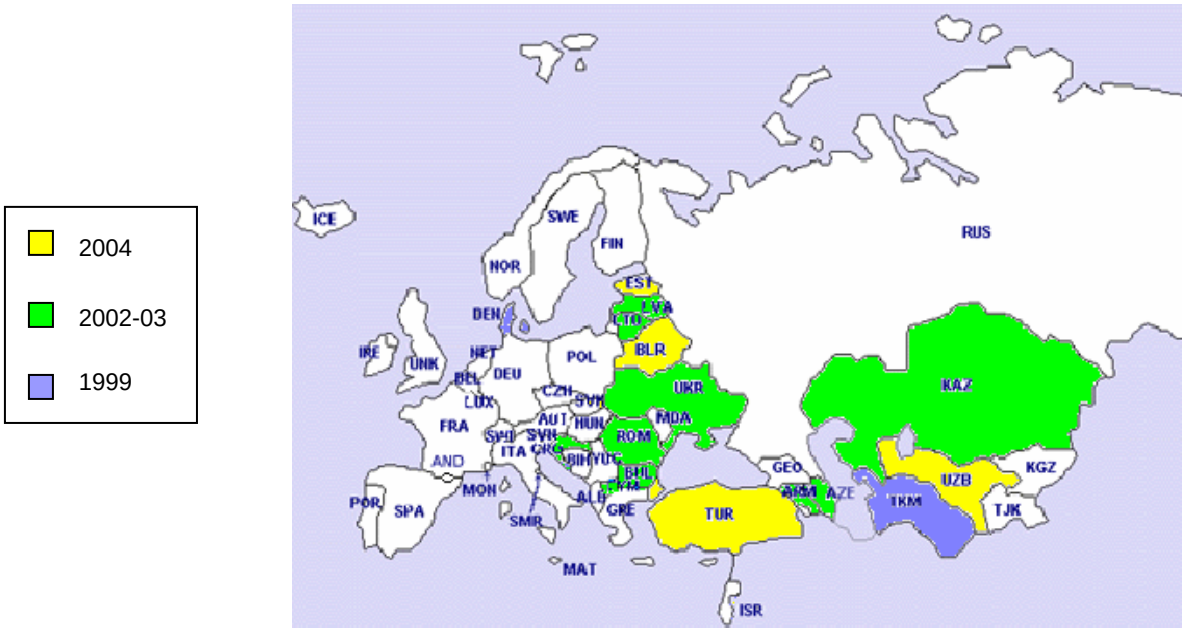
Our regional programme on vaccine procurement started in 2002 at the request of EPI managers from self-procuring countries concerned about the difficulties they encounter in having vaccines delivered on time, and surprised about the prices paid for (Hep B; MMR; other new vaccines) when comparing with CDC or UNICEF prices. A meeting was held at the end 2002 involving 15 “middle income and

self-procuring" countries, and representatives from PATH and UNICEF SD. The objectives were to review good procurement practices and present and discuss other mechanisms including the UNICEF procurement services, the PAHO revolving fund, and the Gulf Cooperation Council.

PROCUREMENT ASSESSMENTS

At the occasion of the workshop, an e-mail survey was implemented and 15 self-procuring countries responded to a standard questionnaire, Bulgaria, Croatia, Czech republic, Estonia, Hungary, Kazakhstan, Latvia Lithuania, Macedonia, Romania, Serbia Montenegro, Slovakia, Slovenia, Turkey, Ukraine.

Following the workshop, technical support has been provided to selected countries through assessments and recommendations based on findings using an assessment tool jointly developed with WHO HQ. Countries assessed include Kazakhstan, Ukraine, Bulgaria, Romania, Croatia, the FYR of Macedonia, Lithuania, Latvia, Armenia and Azerbaijan. An earlier assessment had been carried out in Turkmenistan and two other assessments are planned these following months in Estonia and Belarus.



ASSESSMENTS FINDINGS

The assessment questionnaire covers the following 7 areas: (1) Legal basis and infrastructure, (2) Organisation, (3) budgeting and finance, (4) Forecasting, (5) Procurement process, (6) Delivery, distribution and cold chain, (7) Ensuring quality. Findings by category are summarized as follows:

1. Legal basis and Infrastructure

In all countries assessed public procurement is subject to legislation. In still too many countries, there is no specific legal provision for vaccines or even pharmaceuticals. Access to international commerce, international communication and hard currency is generally not a problem. One component commonly overlooked is contract management. Countries do not have up-to-date information on suppliers, follow up on their contracts, and conduct audits for further reference.

2. Organisation

Vaccine procurement systems involve various departments usually from the ministry of health and ministry of finance. Each country has its proper organisation and generally the bureau or agency in charge of the process is the same than for pharmaceuticals. The main problem encountered in the organisation is the lack of communication between the various entities. In addition, responsibilities are not always clearly stated.

Commonly, the Ministry of Health nominates a Public Procurement Commission for Vaccines. It is responsible for preparing the bidding documents, including the evaluation criteria; announcing and issuing the tenders; and making recommendations or deciding the awards. Members are selected among different medical specialties as well as law and finance.

3. Budgeting and finance

Vaccination is by and large free of charge and there is commonly a budget allocated to immunization. It can be from the budget of MOH or other sources such as health insurance, etc. The e-mail survey revealed that 1/3 had no specific budget line for vaccines and the same number considered the level of funding inadequate. However, immunization is still given high priority in most middle-income countries and sustainability is not perceived as a problem as long as there is no major cost increase. The introduction of new vaccines is often the results of long negotiations between the immunization programme, the immunization committee and the ministry of finance and requires clear and strong justifications.

4. Forecasting requirements

- The e-mail survey revealed that 1/3 of countries were facing shortages of vaccines the previous year and 2 countries recognized that stock management was a real issue in their country
- Forecasting vaccine and other supplies requirements is generally performed by the EPI programme (in one country forecasting was found to be performed by the immunization committee) and in most cases on a basis of at least three years (e-mail 11/15). In some instance the frequency is one year due to the yearly planning and budgetary cycle.
- Besides Latvia, countries do not have a long-term view of the evolution of their schedule.
- Monitoring wastage at all levels is still not a generalized practice. It is either a pre-established rate, or an estimate from previous year consumption.
- Maintaining a 25% reserve stock has been seen as an issue in several countries either because consumption is under-estimated or delays of deliveries. In at least one country, the quantity of vaccines delivered was found to be systematically decreased due to governmental budget cuts.

5. Procurement Process

Bidding and awards: Written policies and procedures related to the purchase of goods are present in all countries. As mentioned above, a vaccine commission is usually formed to prepare the bidding documents including the evaluation criteria, issue tenders and decide on awards. The majority of

countries systematically perform procurement through competition (between several prospective suppliers). Criteria are pre-established and varies from one country to another. It might be based only on price or include additional specifications such as delivery schedule, manner of payment, operating costs, efficiency, quality, and functional characteristics, technical qualities, and provision of post-sale services. Most countries assessed use a merit point system attributing values to each criterion. However, these systems do not always serve the purpose of fair competition, and sometimes discourage suppliers.

Contracts: contracts include a written description of purchaser's expectations and conditions of the purchase about the product including:

- packaging and labelling terms

Contracts also include terms for quality assurance such as inspection and testing:

- certification for the release of vaccine lot by NRA of producing country
- summary Lot Protocol, including Certificate of Analysis

More often the release certificate originating by the manufacturer is received instead of the one from the NRA of country of origin.

Terms on documents to be included related to normal and customary international shipping are found in all contracts.

6. Delivery, distribution and cold chain

There are two scenarios for the receipt of vaccines among the countries assessed. Either the airport has a cold room where vaccines can be stored during custom procedures, or there is no cold room and a decree stipulates that vaccines can be transported to the national store upon arrival at the airport.

A visual inspection of goods is usually performed, but mostly concerns the verification of the name of products and quantities. Checking and more specifically documenting the quality and conformity with specifications remains an area to be improved. Significant progress is being made, however, as more and more, countries are adopting either the VAR or a similar document for inspection at receipt.

Another aspect that needs some advocacy on our part is the involvement of the procurement office in the receipt of the goods. Reports upon receipt of supplies should be checked against the terms of contracts and filed by the procurement office.

7. Ensuring quality

Ensuring quality refers primarily to the NRA performance of the 6 WHO defined functions, licensing, post-marketing surveillance, lot release, laboratory access, GMP and clinical trial.

The NRA needs to play an important role in overseeing the purchase of vaccines, ensuring that the process is implemented according to regulations. Although price of vaccines becomes more and more a concern as it increases, quality of vaccines remains at the forefront of programme manager’s

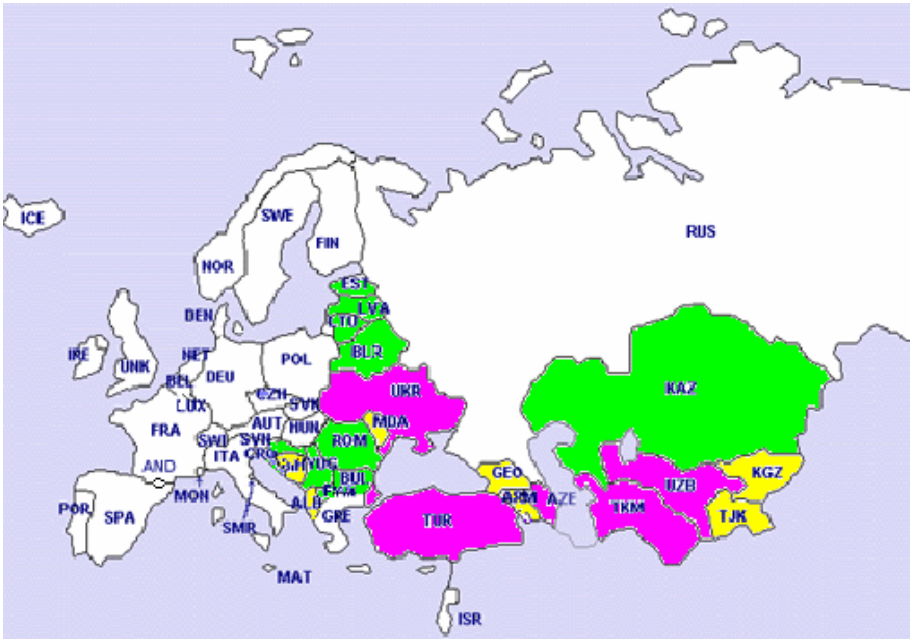
interest. The vaccine WHO pre-qualified list is now known across the region as a result of advocacy activities done these past years.

Systems for the surveillance of AEFI exists in the vast majority of countries, but these systems need to be revised to become more effective.

COUNTRY SUPPORT

In order to be more effective and appropriately prioritize WHO support, countries are classified into 4 categories as follows:

1. Countries with well functioning procurement services
2. Countries still very much dependant on UNICEF services
3. Countries recently partially or entirely out of UNICEF services
4. Self-procuring countries with issues on financing and/or regulations



WHO support to countries, from categories (2) and (3), considers the strengthening of countries procurement systems through capacity building in conducting assessments and providing recommendations, developing institutional plans and implementing training activities.

For a limited number of countries from the 4th category, feasibility studies for the institution of an inter-country bulk-procurement system are taking place.

BULK PROCUREMENT : KEY ISSUES

Bulk procurement is an option that is considered for countries with:

- A well functioning NRA
- A vaccine procurement system with no major unresolved issues, and
- A strong commitment to work with other countries in building a common system

When examining similar systems that are already existing, it is expected that it will be advantageous in countries where

- Budget for health and vaccines is limited
- Combo and costly vaccines might be required
    - to improve coverage and
    - respond to specific needs
- Relative higher price for most vaccines is paid
- There is limited competition, too few vaccines registered
- The size of the population represents a too small market for manufacturers

BULK PROCUREMENT : WHY ?

It is anticipated that through bulk procurement countries would benefit in:

- Acquiring the vaccines at a lower purchasing prices
- Obtaining better quality assurance
- Having more choices through more competition,
- Gaining by reducing the transaction costs and staff time
- Achieving better access to up to date information through improved communication

BULK PROCUREMENT : SYSTEM DESIGN

At this early stage of the system design, discussions between interested countries are taking place to determine some critical elements such as the structure that will manage this group mechanism, its functions, financial terms, and management mechanisms.

CONCLUSION

Most Eastern countries of the European region are performing their own vaccine procurement. Systems are in place but require strengthening to ensure the provision of sufficient quantities and assuring quality of vaccines. This can be achieved by assisting countries in bringing the necessary changes including the revision of legislations, the empowerment of NRAs, the building up of effective procurement structures, the allocation of appropriate resources specific for vaccines, and the development of effective procedures. National programmes are facing new challenges caused by a changing market. If the success of immunization programmes is to be sustained, innovative mechanisms such as bulk procurement need to be explored.

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DISCUSSION

Question : What is bulk procurement?

Response : This is when a number of countries organize themselves so they would do a group procurement or one procurement for several countries. More details will be provided later.

COUNTRY PERSPECTIVE: LATVIA : Yurijs Perevoscikovs, State « Public Health Agency », Latvia

Presentation Highlights : Prepared by the presenter

BACKGROUND

The Republic of Latvia is located on the eastern coast of the Baltic sea, bordering Estonia on the north, the Russian Federation on the east, Lithuania on the south and Belarus on the southwest. Latvia reestablished its independence in 1991 following the breakup of the Soviet Union. Latvia continues to revamp its economy for eventual integration into various Western European political and economic institutions. Latvia will be joining the EU in May 2004.

Latvia covers 64 589 square km and has a population of 2 331 480 (2003). About 2/3 of population live in urban areas. GDP per capita is $ 3 594.

NATIONAL IMMUNIZATION PROGRAMME

Since 1997 Latvian vaccination schedule includes 10 antigens, including the new ones *Heamophilus influenzae* type b introduced in 1994 and hepatitis B introduced in 1997. In 2003 11 different types of vaccines were purchased and used for the State Immunization Programme (HepB, BCG, DTP-IPV, Hib, DTP-IPV+Hib, DTaP-IPV+Hib, DTaP, OPV, MMR, DT, Td).

New vaccines (Hib, hepatitis B, IPV, DTP-IPV, DTaP, DTP-IPV-Hib, DTaP-IPV-Hib) have been introduced during past years and are intended to phase out traditional EPI vaccines in favor of combined and less reactogenic ones. Government finances 100% of country's vaccine needs for public health use including new vaccines. Small amount of vaccines is purchased through the private sector. Following the health care reforms, responsibility for immunization was shifted to general practitioners based in primary health care facilities.

PERFORMANCE

The National Immunization Programme has succeeded in maintaining high immunization coverage this past decade. Despite this high level of achievement, it should be highlighted that vaccination timeliness is an issue of two reasons. On the one side, providers are more lenient in postponing immunization even for mild illness. On the other side, mothers and even providers do not accept several vaccine administrations during immunization session. Immunizations are provided free of charge and payment is made through a system of contract of medical institution with the Health Compulsory Insurance State Agency/Sickness Insurance Fonds on the basis of services rendered.

Implementation of the Immunization programme had a significant impact on vaccine preventable diseases incidence in Latvia. It's should be noted that diphtheria among adult population is still a concern in Latvia, although morbidity is decreasing.

LEGAL BASIS

Immunization including vaccine public procurement is subject to recent legislation. At least 10 legislative acts regulate different aspects of immunization in Latvia. Legislative system on immunization is based on the Epidemiological Safety Law (1997) and the Order of the Cabinet of Ministers on Vaccination (2000). A set of Orders of the Ministry of Welfare (since 2003, Ministry of Health) regulates different aspects of immunization including immunization policies, coordination and management, financing, monitoring of immunization coverage, immunization safety. Regarding to the procurement of vaccines Latvia must follow EU tender directives starting May 2004.

INFRASTRUCTURE AND ORGANIZATION OF VACCINE PROCUREMENT

All functions of vaccine procurement are shared between different agencies. The Public Health Agency (PHA) is the state institution that is supervised by MoH. The PHA is consists of State centre and ten local branches. The PHA has the responsibility of infectious diseases surveillance and response, as well as diseases prevention, including the management of the National Immunization Programme. The PHA is responsible for monitoring of coverage, forecasting and planning of annual vaccine requirements, keeping of national and intermediate vaccine stores and distribution of vaccines on the basis of monthly vaccine supply requests received from the vaccination centres and local PHA branches.

The State Agency of Compulsory Health Insurance (SACHI) is under jurisdiction of MoH. It receives tax-financed budget allocations and distributes to the regional funds that make allocations to primary and secondary care. A certain proportion of primary health care budget is earmarked for purchase of vaccines for the National Immunization Programme.

The State Immunization Council (ICC) has been established in Latvia in 1999 and meets usually 3-4 times a year. One meeting is held in order to assess the annual vaccine demand prepared by PHA.
The procurement of vaccines is based on a yearly national forecast done each May and produced by the PHA. Evaluation of the forecast takes place each June and is done by the State Immunization Council. Subsequently the forecast is confirmed in June/August by the MoH.

The vaccine procurement is centralized and implemented by an office at the SACHI. Procurement of vaccines is performed through competition. Vaccines are paid for directly by the Treasury.

All EPI vaccines come from sources of assured quality. Mandatory licensing and registration process is in place for all vaccines procured for the public proposes. The State Agency of Medicine implements the NRA functions.

DELIVERY, DISTRIBUTION AND COLD CHAIN

Transport of vaccines to the national cold store in PHA is the responsibility of the local wholesalers. On the basis of monthly vaccine supply requests from primary healthcare centres vaccines are

transported in cold boxes to the PHA branches. Each immunization centre collects their ordered vaccines directly from the local PHA usually on the monthly basis providing standard reporting form about performed vaccinations.

WHO MISSION VACCINE PROCUREMENT SYSTEM ASSESSMENT IN LATVIA

Latvian MoH expressed interest to have its vaccine procurement system reviewed and to discuss the feasibility of a group procurement mechanism in the context of the association to the EU. Several problems and gaps in procurement system were identified during the WHO assessment mission in November 2003. There is a 5-year immunization plan 2001-2005 but this plan states the main directions of the programme but stays very generic in its formulations. There were difficulties in maintaining a reserve stock of 25%. Budget for vaccine is restricted and concerns have been expressed while comparing prices paid by other countries in the region. The general trend in the prices is in increase. It is could be reasonable to develop and maintain database to follow un evolution of market (new vaccines, technology, source of vaccine, etc.). Long term contract with supplier have not been considered yet. Few prospective local suppliers (wholesalers) are participating in the bid. Real competition is very limited.

As the result of the mission the following recommendations have been received:

1. Maintain current performance and ensure human resource development (training).
2. Promote more competition in registering more vaccines and suppliers.
3. Improve transparency through improved communications and documentation exchange as well as institute a selection process on the basis of multi-criteria (price/quality/performance).
4. Improve planning through development an EPI multi-year plan including budget requirements.
5. Conduct internal meetings to discuss different issues concerning the group procurement and suggest proposals for the necessary changes that are required for join procurement mechanism.
6. Evaluate possibility to organize regional training course on vaccine procurement using the PHA facilities.

Due to the relatively small market size with limited competition and a limited budget for health and for vaccines added to the need of using high price combination vaccines, Latvia could consider other procurement options to respond more efficiently to the requirements of the Immunization programme. A joint procurement with several other countries from the region could be beneficial in allowing better prices through more competition and more choices, reducing the transaction and staff cost and time.
The MoH started to conduct internal meetings to discuss the issues related to the group procurement introduction. National and regional workshops are planned to discuss group procurement practical implications and steps.

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DISCUSSION

Question : Can AEFI surveillance be clarified because it was said that there are lots of contraindications affecting timeliness of vaccination. Was there any attempt to decrease contraindications?
Response : Yes many guidelines were produced explaining true and false contraindications and they were widely distributed. Last year an investigation study was conducted about missed opportunities and real coverage and it showed that physicians still consider false contraindications and postpone vaccination. It is felt that it is better to introduce new vaccines than try an extensive education campaign with physicians that would be very difficult and costly.

Question : Some countries in Eastern Europe are decentralizing procurement so that it becomes the responsibility of individual oblasts and some countries receive their entire annual vaccine supply in one single shipment, can the last speaker comment on these two practices and is this something happening in Latvia ?
Response : No, this is not happening in Latvia where there is only one procurement source. It is still a centralized system considered cost-saving.
Further response : There was only one country, Armenia, that was receiving only one shipment per year three years ago. Things have changed especially last year and now that Latvian system can be considered quite representative of the whole region. Quite an extensive work has been done to convince countries that decentralization of vaccine procurement is not a good solution. This is an issue that was encountered, like in Ukraine and Serbia-Montenegro which were convinced to recentralize, but less and less often.

REGIONAL PERSPECTIVE: SEARO : Stephane Guichard, WHO SEARO

Presentation Highlights : Extracted from both the presentation and the narrative prepared by the presenter

I. Context

WHO South East Asia Region (SEAR) includes 11 countries. It is estimated that approximately one quarter of world population live in this region. The three major producing countries are Indonesia, Thailand and India. While Thailand is producing vaccine mainly for domestic use, Indonesia and in particular India have become major suppliers of traditional EPI vaccine to UN agencies. Four vaccines manufacturers in India are producing 11 pre-qualified vaccines and one in Indonesia which is producing 7 pre-qualified vaccines including TT in UNIJECT™.

The other 8 countries either rely on UN agencies or procure directly their vaccine from the international market. Table 1 provides a summary of vaccine procurement mechanisms with funding sources.

Table 1

Through UN agencies		From local producer		Direct procurement	
country	Source of funds	country	Source of funds	country	Source of funds
Bangladesh	Domestic	India	Domestic	Nepal	Domestic
Bhutan	External	Indonesia	Domestic	Sri-Lanka	Domestic
DPRK	External	Thailand	Domestic		
Myanmar	External				
Maldives	Domestic				
Timor Leste	External				

II. WHO SEARO activities

II..1 Vaccine Quality

Guided by the experts committee on Standardization of biologicals WHO defines vaccines of assured quality when the three following criteria are met:

1. NRA independent from vaccine manufacturer
2. NRA fully functional (system in place with 6 functions)
3. No unresolved reported problem with vaccine

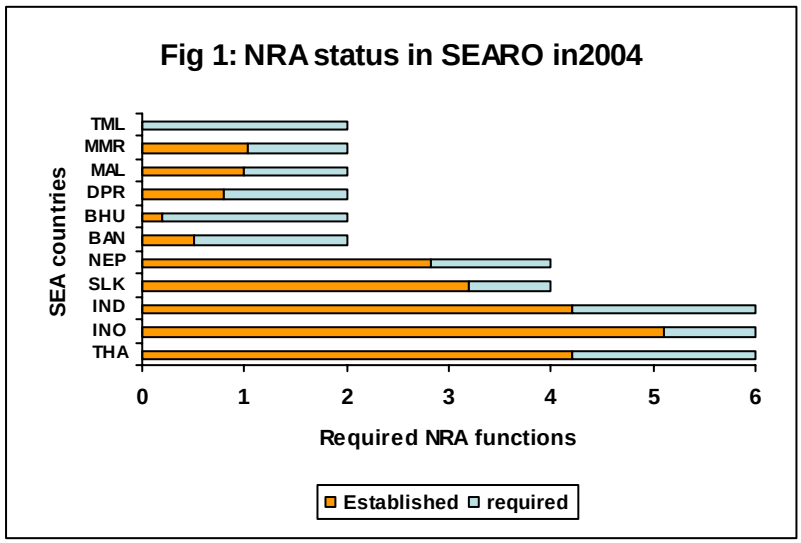
WHO in collaboration with NRA experts from developed and developing countries has defined the functions that NRA must carry out to regulate vaccine depending on the procurement procedures. Table 2 displays the required functions according to procurement methods.

Table 2

Procurement Mechanism	1. Licensing	2.Post-marketing surveillance (AEFI)	3.Lot release	4.Lab access	5.GMP compliance	6.Clinical Evaluation
UN						
Direct Proc.						
Producing						

In 1996, The Global Training Network (GTN) was launched to provide training to NRA experts throughout the world and, in 1998, a tool to assess NRA was developed. In 2003, 52 NRA had been assessed worldwide and 816 national staff including regulatory experts had been trained.

Since 1997, 207 technicians from SEA countries NRA, National Control Laboratory, vaccine manufacturers (public sector) and EPI managers participated in GTN trainings. In 2000, the first NRA assessment was conducted and in 2003 all SEA countries NRA were assessed. Figure 1 shows assessment findings for each country.



The priority is the establishment of fully functioning NRA in the producing countries. In 2003-2004 GTN activities were followed up with in-country GMP workshops in India and Thailand. In 2004 a workshop on clinical trial was conducted in Thailand with producing countries participation. Two workshops on AEFI are planned in 2004 in India and to respond to increasing demand for AEFI courses in all SEA countries, a GTN center on AEFI was established in Sri Lanka in 2003. In 2004, it is planned to establish in SEA two additional GTN center for Good Manufacturer Practices (GMP) and for vaccine lot release.

II.2 Vaccine Procurement assessment

In 2002, an assessment of vaccine procurement was conducted in Sri-Lanka. This country procures vaccine directly from the international market since 1995 using domestic funds. Over the year, the Government has acquired a strong expertise on vaccine procurement and they obtain affordable prices for their EPI vaccines that are all procured from pre-qualified sources. In 2003, procurement procedures were assessed in Nepal which also procures vaccine directly from international market. This assessment identified a lack of cooperation between NRA and EPI and lack of expertise for lot release procedures. For some vaccine the government does not receive offers from manufacturers and in 2003 some BCG had to be procured through UNICEF.

In 2004, assessment was conducted in Maldives. Although, Maldives procure vaccine through UNICEF using domestic founds, the Government requested WHO assistance to identify suitable procurement procedures for non-EPI vaccines. In addition to EPI vaccine all countries need to produce or import specific vaccine such as Rubella for CRS, Meningitis to vaccinate pilgrims who go the Mecca and JE vaccine for specific areas. Maldives with a very small population does not obtain good offers from manufacturers through a traditional tender process. Maldives has to rely on procurement agents who charge high fee.

II.3 Bulk procurement for vaccine supply

An alternative to obtain more competitive prices is to group vaccine requirement from several countries in order to issue tender for greater quantity of vaccines. Several countries in the region are procuring non-EPI vaccine. For example Sri Lanka is buying Rubella vaccine for CRS program, meningitis and JE vaccine which in 2003 was procured from Thailand. Meetings were held in Sri Lanka to discuss the possibility of grouping their vaccine requirement with Maldives. A pilot project will be initiated in 2004 for the procurement of Meningitis vaccine.

The principal of this bulk procurement is that Maldives and Sri Lanka would enter into a group contracting agreement. In this agreement both countries would jointly negotiate and select suppliers. They would agree to purchase from selected suppliers but will initiate procurement individually. The vaccine will be airfreight by the manufacturer directly to each country. Upon receipt each Government will make payment. Bulk procurement has several advantages aside from providing to countries stronger leverage to negotiate better price. It sets the justifications to establish cooperation among NRA and EPI to harmonize quality control procedures and rationalize the use of National Control Laboratory.

In addition to this pilot project WHO has initiated with the Government of Sri-Lanka the establishment of a GTN training center for vaccine procurement. The first course is planned to be conducted in October with the participation of Nepal, Bhutan, Maldives and Bangladesh.

WHAT IS BULK PROCUREMENT ?

- **Informed buying**
  Member countries share information about suppliers
  Countries conduct procurement individually

- **Coordinated informed buying**
  Member countries undertake joint market survey, share suppliers performance, information and monitor prices
  Countries conduct procurement individually

- **Group contracting**
  Member countries jointly negotiate prices and select suppliers
  Countries agree to purchase from selected suppliers
  Countries conduct procurement individually

- **Central contracting**
  Member countries jointly conduct tenders and award contract through an organized acting on their behalf
  The central buying unit manages the purchase on behalf of countries

DISCUSSION

Question : There are some good aspects in self-procurement of vaccines by countries such as an increased responsibility for ensuring suppliers, but there are some issues and problems. One such problem is the government's ability to provide the required funds on time. This problem causes programmes to increase buffer stocks to avoid shortages. How can they manage to run the programme in Latvia without a 35% buffer stock as it seems very risky?

Response : It is indeed a problem and recently the Ministry of Health had to decide to use reserve budgets for immediate procurement of vaccines because of delays in the tendering process.

Question : Is there a possibility when a group of countries purchasing together, for swaping stocks to respond to potential overstocking in some countries and understocking in others ?

Response : In group procurement, each individual country places an order after having tendered and selected the manufacturer together. Vaccines are delivered directly to individual countries. There is no central delivery point where it would be further dispatched to each country. It then depends on each country to make accurate forecasting. An exchange of vaccines between two countries is always possible but it would have to be discussed on a bilateral basis. However few countries would be keen on such practices because one never knows how vaccines were kept. Another lot release would be necessary and it becomes very complicated.

Comment : The 25% buffer stock is not a blanket recommendation and it depends how accurate is forecasting and how reliably government releases funds. If funds are released quarterly but incurs over-two-months delays, then buffer may have to be increased.

Comment : The table presented above on bulk procurement are not alternative options but can be sequential. Also, within a few weeks a document on PAHO and the GCC (Gulf Cooperation Council) revolving funds will be published, explaining experiences and lessons learned from group procurement systems.

GLOBAL PRODUCTION AND AVAILABILITY OF VACCINES : Alejandro Costa, WHO HQ

Presentation Highlights : Extracted from both the presentation and the narrative prepared by the presenter

BACKGROUND - BRIEF HISTORY ON VACCINE PRODUCTION

Since Louis Pasteur discovered that micro-organisms cause diseases and later on the discovery of vaccines, the tradition was that Public Research Institutes, Public Hospitals or Universities were

responsible for vaccine production in many countries. Often these research institutions were under government administration like the National Institute of Health, in USA. In other cases they were private-public non-profit foundations such as Institute Pasteur or Merieux Biological Institute.

In the past when something was discovered, the discovery suddenly became the public domain to fight against the disease. As examples, microorganism, viral and bacterial vaccines were shared among Research Institutions and Universities without patent protection. There was close worldwide collaboration between scintists, as for example Sabin in the United-States and Chumakov in Russia developing the OPV in the 50's.

HOW IT WAS

- In the 60's, 70's and 80's EPI vaccines were produced by local manufacturers in many countries
- Vaccine producers were public institutions or foundations
- Vaccine production was manual production and relatively simple
- R&D was under government administrations such as NIH in USA, Sclavo in Italy, CSL in Australia, SBL in Sweden, SSI in Switzerland

WHAT HAPPENED IN THE 90'S?

- Producing countries decline from 61 in 1990 to 27 in 2003
- Inability to upgrade facilities for compliance with cGMP
- Privatisation era; government delegated vaccine production to the private sector
  - Lack of financing for new technology in poor countries
  - Privatisation tendency in rich and poor countries
- Many vaccine companies merged into few big groups: Berna Biotech, Chiron, GSK, AVP, Merck

HOW IT IS... Current vaccine market and Development

In terms of vaccine security the vaccine market does not look very healthy.

- There is a potential risk of vaccine shortages for EPI and new combination vaccine (polio, YF, meningo, DTwP/DT) and new combination vaccine based on DTwP
- There is a monopoly situation for new vaccines, DTwP-HepB and DTwP-HepB + Hib, currently produced by one manufacturer (GSK).
- There is a quasi-monopoly for old vaccines. In the case of EPI vaccine emerging suppliers from developing countries supply 70% of the total UNICEF demand for traditional vaccines. Supply of EPI vaccines are mainly by two manufacturers.

In terms of development, there are no incentives to develop new vaccines for developing countries. This market is not attractive enough for companies as much as it is for the pharmaceutical market. As a result, they will rather invest on new or therapeutic vaccines and pharmaceutical products which will give them higher returns. E.g HPV, Chlamydia, Cytomegalovirus, Herpes simplex, Streptococcus A and B, new flu or intranasal, Varicella, pneumococcal 9 and 11-valent or meningococcal ACWY conjugate vaccine, new combos with DTaP, HepC, HepA.

CURRENT WORK IN WHO ON VACCINE SUPPLY AND PRODUCTION CAPACITY

Since 2001 WHO/ATT has been working on developing a world-wide vaccine production capacity and supply database for all critical vaccines. The main objective of the database is to monitor and to give updated information on vaccine supply and production any time upon request. This information serves to anticipate critical levels or shortages of vaccines and also analyze vaccine market trends.
The data contained in the data base is reliable, accurate and updated on regular basis.

- During the period 2001-2003, ATT/WHO identified and incorporated data from 98 producers
  - **66** we have regular updated production capacity information
  - **43** were visited to double check the data.
  - **28** we have their plans about future, planned production and development for the next 5 years
- The information contained in the database is about 36 different types of vaccines, with manufacturer details sorted out in maximum capacity, current production, planned production and storage capacity.

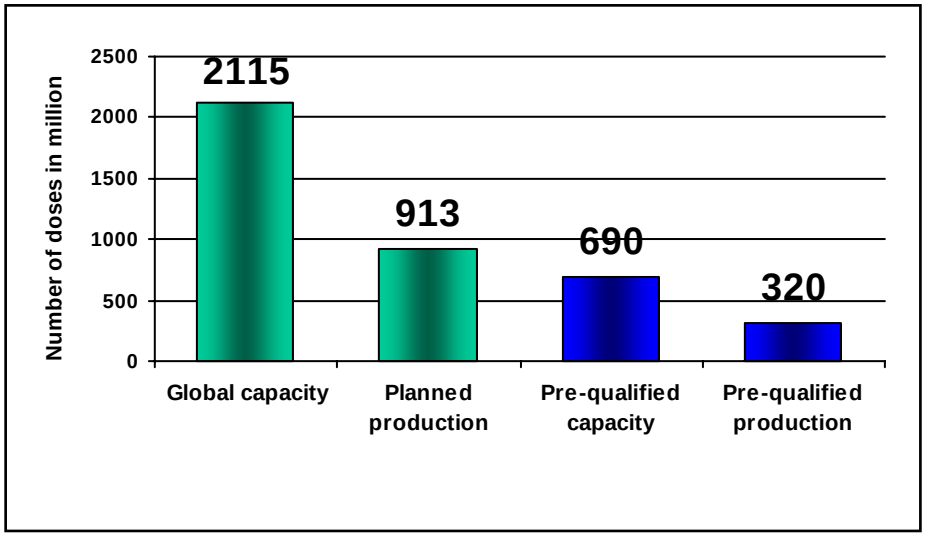
BCG PRODUCTION 2003

- 18 manufacturers producing BCG world wide
- 4 of them have WHO pre-qualified vaccine
- 44 % is of the assured quality.

BCG is very old technology; the production process does not require very sophisticated equipment. There is still greater capacity in big countries such as India, China, Indonesia and Brazil. It results in small international demand with low price, low proportion of assured quality and low interest to produce this vaccine for the international market.

DTwP/DT/TT GLOBAL CAPACITY AND PRODUCTION

- 31 manufacturers producing DTwP/DT worldwide
  - 9 of them have WHO pre-qualified vaccines
  - 35 % of DTwP and 16% of TT is of assured quality



- DTwP is also a bacterial vaccine produced with an old technology, relatively easy to produce resulting in very low price and low interest for production
  - Large local production capacity; India, Indonesia, China, Brazil
  - High proportion of pre-qualified vaccine produced is diverted for production of combination vaccines with HepB and Hib.
  - Production capacity is underused in many countries like India, Russia and China

OPV PRODUCTION 2003

OPV supply is adequate

- 20 manufacturers with 4 pre-qualified vaccines supply 78.5 % of the total demand.
- Although OPV is an old vaccine, very low prices/profits are compensated by large market, which is around 2.5 billion doses. This large market is attractive for vaccine companies even with low profit. As a result large vaccine producers such as GSK, Chiron and AVP are still in the market.
- Furthermore manufacturers have very accurate and secure demand. UNICEF signed long-term agreements with them; it allowed manufacturers after 2000 to invest and increase their production capacity to meet the demand with an adequate guarantee of sales.

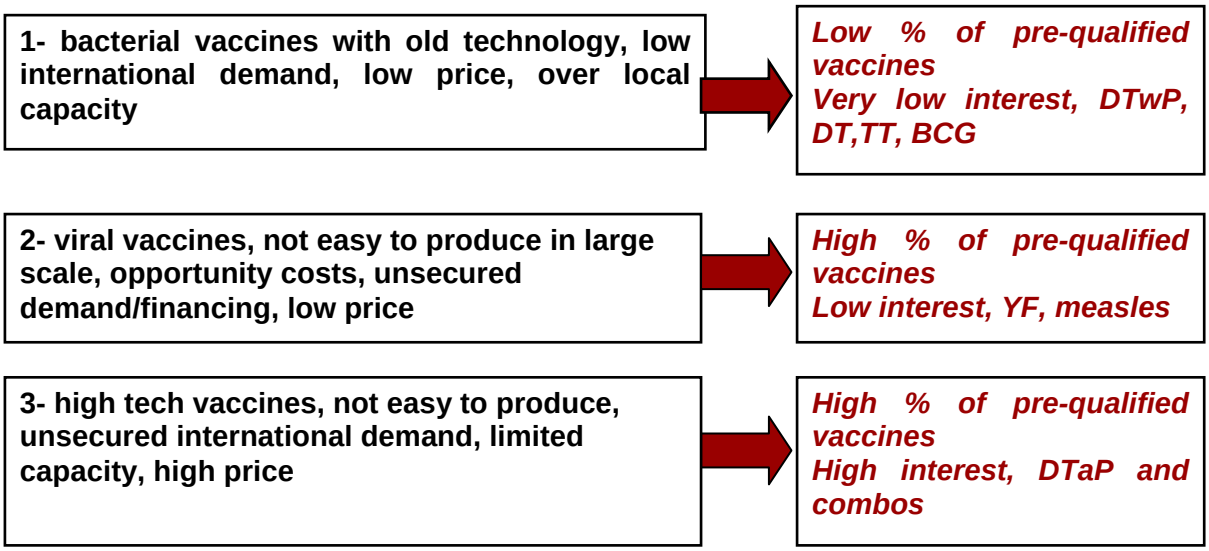
DTwP COMBINATION VACCINES

The supply situation is not expected to show a considerable improvement for the next couple of years (2004-2006)

- DTwP global limited pre-qualified production and low interest for increasing production.
- One pre-qualified DTwP-HepB+Hib vaccine, limited production capacity for freeze-drying Hib.
- No developing country manufacturers currently produce DTwP combination vaccines.
- No new pre-qualified vaccine expected before 2005-2006.
- Increasing demand for DTaP in middle income countries like Korea and private market in China, Indonesia, which impacts on DTwP production.

- Expected at least one DCVM get license for DTwP-HepB in 2004 and 2005. Cuba, Brazil, India.
- Expected at least one DCVM get license for DTwP-HepB-Hib in 2005 and 2006. Cuba, Brazil.
- China, Korea, Indonesia working on DTaP/DTwP-HepB
- Current vaccine manufacturer is increasing freeze drying capacity for Hib, more vaccine available in 2004/2005
- More DTwP for combination will be available during 2004 by increasing capacity in current manufacturers

TECHNOLOGY, CAPACITY AND IMPLICATIONS



MAJOR FACTORS AFFECTING SUPPLY

Patents : Vaccine producers holding a patent have a guaranteed 20-year monopoly of the market. This is a way to give incentives to companies to invest in R&D. Since there is a monopoly, the concern here is how to ensure equal access to the vaccine and how to establish a fair price when there is limited availability and competition.

Liability : the high risk associated with vaccine adverse events discourages manufacturers to produce cheaper vaccines. Current low prices could be compensated by producing high quantities (eg OPV), but there is also a proportional increase in the risk of having AEFIs

R&D investments : are proportional to the potential market, companies spend much more money in drugs rather in vaccines. The vaccine market is just 2% of the total pharmaceutical market.

Licensing : currently to get the license of vaccine is very expensive, especially clinical trials have very high costs. This discourages manufacturers to get a license for products which will have low prices, like traditional vaccines. There is also an issue of timeline. If it takes 10 years to get a license, the 20 years patent-protected market for such a product is reduced to 10 years.

cGMP : current *GMP* costs are extremely high and sometimes manufactures can not cover production cost of cheaper vaccines. In other cases companies have to stop production and make the required changes to comply with GMP requirement given by NRAs' audits; it usually takes time and money, and often results in shortages.

Market size : For basic vaccines whose prices are in cents, the production scale should be more than one hundred million doses (DTP, BCG, OPV) in order to generate profit. UNICEF forecasted

demand for 2004 is 108 million doses for BCG and 145 million doses for DTP, which can be produced and supplied by one company.

Biological production : Biological processes are more complicated than drug production methods. It is more expensive and also very risky in terms of potential contaminations. The yield is sometimes unpredictable and companies have to throw away several lots. Each batch has different characteristics and quality control tests must be very rigorous and strict.

ISSUES: WHAT IS CLEAR

- Vaccine production should not be based just on financial analysis.
- It should be considered as a strategic public health priority
- As a good experience, the long term agreement between public and private sector. E.g. OPV
- Increase prices get more interest

ISSUES: WHAT IS NOT CLEAR

- Can market forces solve vaccine shortages or market failure?
- Public-Private sector roles? (Incentives, subsidies, rewards)
- Who will produce non-profitable products?. Who will invest in R&D or improve production technology for current vaccines?
- Why not consider vaccine as a public good?
  - When development or production of vaccines could not be profitable or feasible

TOPICS FOR DISCUSSION

There is a need to define at country and international level the grade of responsibility for production and supply of vaccines.

At national level, governments could provide incentives to the industry to develop a new product such as taxes reductions, compensations, rewards, subsides, etc.

At international level, there is a need to better coordinate efforts; think of what the best way is to finance the introduction of new vaccines, how to support the production of non-profitable products (clinical trials, production, joint projects) or whether to support local production without influencing the market.

How to give incentives or make attractive the R&D of new products when the disease does not exist in developed countries.

Finally, how to be accurate as much as possible in forecasting demand, secure funding to purchase vaccine and sign long term agreements with manufacturers to make them secure about the vaccine demand for the next 5 years.

DO MARKET FORCES WORK TO ENSURE ADEQUATE VACCINE SUPPLY?

What is clear is that vaccines do not have the same profit margin than drug products, they are more difficult to produce and develop, have higher liability risks and production costs; and there is no

guaranteed compensation with intellectual property rights. Therefore, it seems the market itself cannot solve this current vaccine supply issue.

In 2004 UNICEF prices for measles, DTwP and TT have had a significant increments and UNICEF has received from manufacturers more interest, some of them re-entering the market for supplying these vaccines.

Even though there would be an increase in price, as happened with CDC prices in USA, there is no guarantee that the availability of vaccines will improve.

To make sustainable supply for non-profitable or very low profitable vaccines, long term financing to support R&D and production should be ensured, by governments, international organizations and donors.

Vaccine production of more needed vaccines should be considered as a strategic public health priority and not just based on financial and market factors.

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DISCUSSION

Comments UNICEF : In 1999 there was a scarce availability of almost all EPI vaccines. In 2001 in order to improve the situation the concept of vaccine security was developed. It is based on the concepts of accurate and long-term forecasting, timely and reliable funding and a new concept of contracting based on a set of procurement principles. Among them is the belief in the need for a healthy market with multiple suppliers for each antigen, and prices not only affordable for governments but acceptable for manufacturers. In terms of forecasting UNICEF has worked closely with countries and donors for the past three years, and is happy

to report that forecasting accuracy is now 90% over the board for all EPI vaccines. Moreover for the tender last year that covers the period 2004-06 we are very positive with the results. There was a moderate and in some instances considerable price increases altogether with a more accurate forecasting. The market situation looks better and we see new manufacturers pursuing WHO pre-qualification.

Last but not least, apart from procuring vaccines, UNICEF is spending considerable time to conduct vaccine security missions to middle-income countries which have been facing problems with obtaining the required quantity of vaccines and on time, and also with paying acceptable prices. We are now reviewing our involvement in providing assistance to middle-income countries to go from providing assistance to putting procurement mechanisms in place specifically for these countries while at the same time respecting the market situation.

Comment : This attention on vaccine forecasting and procurement is very welcome and there is a new focus on having good forecasting at the global level. This is very important. But we haven't finished the business of improving forecasts at the national and sub-national levels. The idea of a buffer or reserve stock is an essential part of good management even if funds can be released in a timely basis at the national level. A buffer stock is needed at the national level in order to have one at the peripheral level where the problems are. There is an annual forecast of vaccines given to UNICEF often in October. During the following year as vaccines are about to be ordered, it is very useful to link finance, procurement, supplies, policies, practices, to have all of the partners (WHO, UNICEF and the national Government) to review the forecast made months before to make sure that the next scheduled supply of vaccines still makes sense.

Question : Given measles accelerated control, a number of countries are doing campaigns and some regions targetting elimination, how is the availability of measles and measles-containing vaccines for supplementary immunization activities ?
Response : The current capacity for measles is enough to meet the demand. The issue with measles is the price paid to manufacturers so some prefer to produced combined MMR or MR, especially in Europe. One manufacturer in India has the capacity to meet the full demand but there is the risk of depending on a single manufacturer.

Question : There are some aspects of this broad subject where we could make contributions. One of those is the requirement for the AEFI surveillance be a condition that a country has to comply with. Among SEARO or EURO countries is there one that could be pointed out as a good example for their practices and if so what are they doing that others should be doing ?

Response : In the SEARO region, Sri Lanka has a very good system, followed by Indonesia and Thailand. Sri Lanka implemented AEFI surveillance gradually starting with a sentinel system that was later expanded nationally.

Question : How ready is the ATT database and how can a country access it ?
Response : It is available on our website under « vaccine supply ». The only information that cannot be public is each manufacturer’s capacity per company as it considered confidential. All other information is available.

WRAP-UP SESSION : Michel Zaffran, Coordinator, Access to Technologies, WHO HQ

This wrap-up session will review some of the main points that emerged at least in the mind of some of the participants. There will be many gaps but the final report should fill most of those. This consultation has not been structured in a way that is leading to specific recommandations or action plan. So the points will be reviewed session by session.

Session 1. Improving Coverage

- Uniject and monodose vials: It is an area not yet fully explored and more studies are needed on impact in routine settings? Are some countries volunteers or are some studies already being conducted that can be analyzed?
- RED : There must be a role for TechNet in the logistics of RED and it could be further discussed in the forum.

Session 2. Injection Safety:

- Needle removers in measles campaigns : should they be introduced as a component of best practices? We need to show more evidence on the risks associated with their use. We need countries and partners to volunteer to carry out studies.
- Syringe melting : ***Satellite session outcome***
- Jet Injectors : ***Satellite session outcome***
- Publication of waste management assessments
- Waste Management clear policy directions
- Technology transfer : TORs for WHO role

Session 3. New vaccine introduction

- Vaccine Arrival Reports: They are operational now. Does more work need to be done? Efforts are being made so that a few non-compliant countries do use them. Should there be further analysis of their content ?

- Vaccine wastage studies; WHO offers funding for those countries and partners who are available to conduct studies on vaccine wastage. Initially studies should focus on those countries introducing new more expensive vaccines. In the context of RED, there may also be the need to look at vaccine wastage more carefully in countries implementing more aggressively strategies to increase coverage. WHO is offering funding to volunteers for conducting such studies.

Session 4. Overcoming Freezing

- VVMs : Now that they are here, an action point for everybody is to use every opportunity to demand them for all vaccines. VVMs for measles are available and countries, regional offices should stress the need to have them. Donors, partners and countries who procure their vaccines directly should also be informed.
- Safe vaccine chain : A group discussion took place and came up with a statement. The question is framed better if we talk about a strategy for a vaccine safe chain, addressing specifically the issues of access and temperature damage.

The text of the statement can be found at the end of the Session 4 report, page 73.

Session 5. Vaccine Management

- Priority countries: Should we add more countries to the list of priorities? Which partner will be willing to support the assessments, the training that follows and the follow up assessments? PATH/CVP and UNICEF have already been very active? Can we ask them to do more and will others join?
- Should we seriously consider the possibility of combining the assessements for Vaccine Mnaagement and Effective Vaccine Store Management as is being done in the South East Asian region?
- The tools need to be translated into French, Spanish and Portuguese. UNICEF (Paolo Freis) offered to take care of the Spanish translation.

Session 6. PQS

- We will be establishing Specification Working Groups for each one of the equipment categories that we have listed and agreed upon. We are seeking volunteers to participate in these working groups. We are also expecting comments on the PQS documentation which is contained in the CD roms.
- Deadlines April 16 for volunteers, April 23 for comments on docs
- ***Outcome of HFC and HC satellite session:*** **The satellite session made a strong recommendation for the WHO specifications for refrigerators to be revised to allow the use of Hydrocarbon gases and gradually move away from HFCs which while they do not contribute to the depletion of the ozone layer, do have a non negligible contribution to the greenhouse effect. It was agreed that this recommendation would be made part of the documentation that the PQS Specification Working Group would review when they meet to propose new specifications.**

Session 7. Training

- The VMTC is a very successful initiative; however it only touches staff at the central level. It is therefore critical that efforts be made to collaborate with the staff in WHO/EPI and the Regional offices to support in-country training activities and ensure that the materials developed for this purpose (IIP-Immunization in Practice series and MLM-Mid level management series) be entirely consistent with the VMTC materials.
- The very nice cartoons developed for the VMTC materials should be made available on CD roms for broader use and adaptation.
- Training centers should be identified and established to hold courses in French and Russian and the training curriculum should be translated.
- A recommendation was made that the refrigerator management should be the topics of exercises in the VM course.
- An appeal was made to ensure that the MLM series be finalised and made available rapidly.

Session 8. Vaccine supply and Procurement

- This session was for the information of the Technet Group. Any need for a more active role of TechNet in this area will be the topic of further discussion

DISCUSSION

Comment : It was suggested that for "Reaching Every District" the role of TechNet could be to encourage members to disseminate successful experiences and lessons learned by posting them on the forum to be shared by other people. It also useful to remind ourselves that within RED the issue of creating a sustainable outreach and the logistics support needed for that is critical and by no means a solved problem yet.

Comment : Wastage need to be interpreted not only against vaccination coverage but also adherence to the vaccination schedule.

Comment : It may be helpful to carry a survey to collect information on VVM availability and use by asking countries simple questions.
Response : Asking countries to demand VVMs is being done but there is very little impact.

Comment : We have to be very careful with changing the name "vaccine cold chain". The appellation "vaccine safe chain" is far too ambiguous to be readily understood to be requiring a climatic control as well as other safe controls.

CONCLUSIONS :

It was a short meeting but it has to be taken into account that SIGN now covers the majority of the safe injection issues . The PQS session with Industry brought very positive comments and suggestions. In the future, should we try to have an industry specific session at each meeting?

Existing mechanisms of communications must be used to their full capacity. These include the forum, website , feedback on equipment forms, etc. TechNet is not only a meeting, it must live before and after ….through all the above and more.

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Chairs : Ahmed, Paul, Mary, Steve, Diana, Nedret, Robert and Salah

Rapporteurs: Claude, Julian, Yves, Serge, Andrew, Hande, Alejandro, Steve and Stephane

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- Dr Soydal & the Ministry of Health of Turkey
- Nedret, Denis and the WHO/EURO office
- Kemal Gökhan Gürses
- Umit Kartoglu

Sponsors from Industry :

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And finally : Jackie Christensen , Paul Mallins, the Microphone holders : Souleymane, Alejandro, Hakan, Yves, Umit, Eric and many others…
…. and all participants for their contributions to the debates.

ANNEX 1 : TRAINING WORKS!

What makes one training experience better than another? Effective training can help providers of family planning/reproductive health (FP/RH) services to improve their performance. This handbook summarizes the tasks that should be completed at each stage of training to ensure an effective training course. If you carry out these tasks, you will have a high-quality training course. Think of these tasks as standards to be achieved or guidelines to be followed.

This handbook will be useful to anyone who has a role in the management, design, delivery, or evaluation of group-based training for healthcare professionals who are currently providing services such as inservice training. You may be a project manager, an instructional designer, a clinical trainer, an evaluation specialist, or a trainer who "does it all." Or, you simply may be interested in knowing more about training to help you make program decisions or participate in stakeholder meetings. There is something in this handbook for each of you. Also, you will recognize that many of these standards apply to other types of training, such as on-the-job training, distance learning courses, and computer-assisted learning.

How to use this handbook

There are many ways you can use *Training Works!* In general, take your time learning about how to make training effective. Reading the entire handbook all at once may not be the best way to use the information. Here are a few suggestions:

- Read about why conducting a performance needs assessment is an important first step.
- Look at the tasks within the four stages of training.
- Determine where you want to start. What is your role in the training process? If you are a training manager, you may simply want to read that section first. Where are you in the training process? Is one stage more important to you at this point than the others? Is there a specific task within a stage that you need to know about right now? Once you have determined where you are in the training process, you may want to go directly to that stage and read those guidelines. Do not feel that you have to read the sections in sequence.
- Aim for early success. Trying to implement all of the guidelines in this handbook at one time will lead to chaos and confusion. Start with one or two tasks that will make your training more effective. Once those are addressed, move on to others.
- Be sure to read the "Other Ways to Use This Information" section of the handbook. You will find a lot of practical ideas there.

Performance needs assessment

There are many factors that affect the performance of healthcare workers. It is often hard to know why healthcare workers are not providing high-quality services. A **performance needs assessment** (PNA) will identify performance gaps or problems and give you the information you need to determine what can be done to improve job performance. A PNA is part of a

process called performance improvement that is used to solve performance problems by involving healthcare providers, their facilities, clients, and the community in improving services.

The purpose of a PNA is to identify performance gaps or problems and determine the most appropriate interventions to improve worker performance. These are the steps in conducting a PNA:

- Define desired performance. Ask, “What is the healthcare provider expected to do?” “How well is the provider expected to perform?” “Under what conditions?” “With what frequency?”

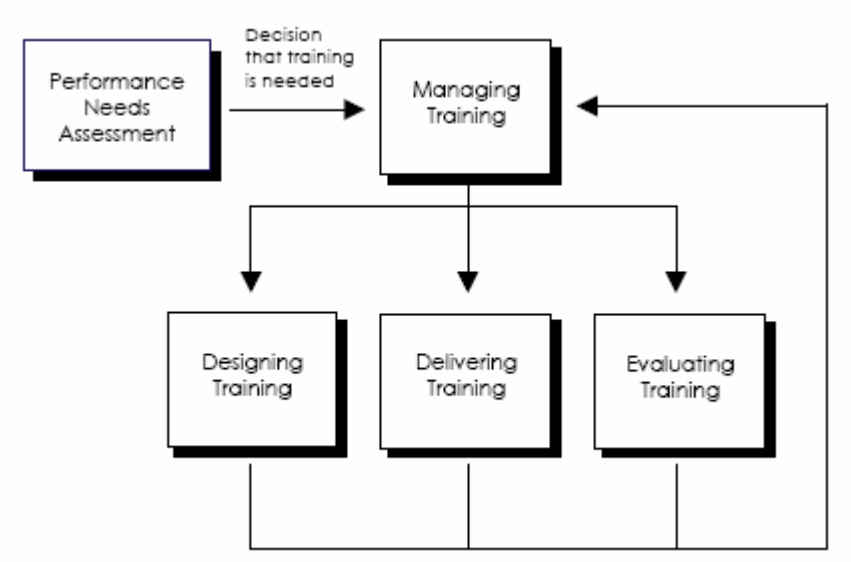
- Describe actual performance. Focus on the performance of an individual or a group. The difference between the desired performance and the actual performance is called the *performance gap*.

- Conduct a *root cause analysis* to find out why there is a performance gap. Gather information from as many people as possible who come in contact with the healthcare service (e.g., providers, supervisors, clients, community members).

- Select the appropriate intervention(s) to improve performance. If the cause of poor performance is deficient knowledge or skills, training is the appropriate intervention.

The information collected in the PNA will be useful for all stages of training (see figure below). The *training manager* can use the information to guide the design, delivery, and evaluation of training. The *training designer* needs to know what knowledge and skills are required to improve performance on the job. The *trainer* will use the information to help learners achieve the course objectives. The *training evaluator* must understand the work environment to determine whether training has closed the performance gap.

Stages of Training



Within each stage, there are essential tasks to be completed to progress through that stage. We give you information about why these tasks are important and how to ensure that they are being carried out. We do not tell you how to do these tasks—such information is beyond the scope of this handbook. Within each stage, there are "tips" to help put the tasks into action. Finally, at the end of the handbook we offer other ways the information can be used.

Managing Training

- Confirm that the performance needs assessment has been conducted and that training will close the performance gap
- Plan, acquire, and manage resources to achieve training outcomes
- Select the training design team
- Establish a monitoring and evaluation strategy
- Manage training logistics
- Communicate with learners and their supervisors before training
- Provide followup support for learners and supervisors after training

Designing Training

- Verify the performance gap and goal of training
- Gather background information about the learners and identify the knowledge, skills, and attitudes they need to acquire
- Identify content resources
- Write the learning objectives
- Develop the training plan
- Develop or adapt training materials
- Develop or adapt evaluation instruments

Delivering Training

- Establish and maintain credibility
- Conduct training in a responsive and collaborative way
- Create a learning environment where participants feel comfortable and safe
- Provide supportive feedback
- Use effective communication and presentation skills
- Use effective facilitation skills
- Provide motivational incentives and positive reinforcement

- Provide opportunities for practical application of knowledge and skills
- Monitor the process of training and make adjustments, as needed

Evaluating Training

- Determine learners' satisfaction with training
- Determine whether learners have met the learning objectives by giving and scoring knowledge evaluations
- Determine whether learners have met the learning objectives by giving and scoring skill evaluations
- Improve training using information from the knowledge and skill evaluations
- Monitor and evaluate performance on the job
- Determine the effectiveness of training as an intervention to improve performance

The full handbook is available for download by clicking here

Annex 2 : Jet Injector

Jet Injector for Mass Immunization

Introduction:

At the recent TechNet 2004 meeting in Antalya, Turkey, a poster and presentation was provided for the Jet Injector for Mass Immunization project, which is a joint technical collaboration between PATH and Felton International. Darin Zehrung (PATH) and Anatoly Loskutov (Felton) represented the project. The injector is a Multi-Use Nozzle Jet Injector (MUNJI) and is designated HSI-500 (human subcutaneous injector). The injector design is based upon previous Russian-based injector designs that were used for decades in the former Soviet Union. The HSI-500 is intended for use in mass immunization campaigns such as measles. The HSI-500 utilizes auto-disable, disposable "protector caps" that prevent cross-contamination from one injection to the next. In addition, the HSI-500 utilizes a reusable fluid path and nozzle, which will require cleaning and steam sterilization, not in a field environment but rather at a central district or hospital level, taking advantage of the existence of autoclaves used for sterilizing surgical instrumentation and equipment. Steam sterilization of the fluid path and nozzle would occur inside a low-cost, autoclavable pouch that would ensure sterility of the fluid path until the moment of use. The cost per injection for use in mass immunization campaigns has been projected to be less than current auto-disable (AD) needle and syringe cost.

Currently in Romania, a MUNJI with a disposable “anti-contaminant device” (Dermojet) is utilized for military and healthcare injections. In the 1990’s, Romanian authorities conducted intradermal injections of various vaccines using the Dermojet injector with the anti-contaminant device. A follow-up assessment of 22,714 healthy subjects was conducted, and no cases of clinical viral hepatitis B (HBV) or hepatitis C (HCV) were reported, and no seroconversion to positivity for HBV or HCV markers were reported. It was the conclusion of study researchers that “jet injectors can be safely used in medical practice if they are protected by the sterile anti-contaminant disposable device.”[1] A similar level of safety is anticipated for the HSI-500 Injector with Protector Cap.

[1] Dimache G, Croitoru M, Balteanu M, Butur D, Negut A, Dimache A, Paul F, Barbu A, Velea L, Alexandrescu V, Isacu F. A Clinical, Epiedemiological and Laboratory Study on Avoiding the Risk of Transmitting Viral Hepatitis During Vaccinations with the Dermojet Protected by an Anticontaminant Disposable Device. Vaccine 1997;15(9): 1010-3.

Specifications for HSI-500 Injector with Protector Cap:

- Minimum rate of 6 injections per minute (360 per hour)
- Fixed 0.5 mL dose
- Subcutaneous injection
- Cost per injection less than AD needle and syringe

Development and Safety Testing Status:

Current plans call for safety testing of the device in humans utilizing hepatitis B infected as well as healthy volunteers in order to detect HBV and human serum albumin in the next injection dose (after administering a subcutaneous injection into the deltoid region of each subject). Additionally, a field trial would be conducted in order to introduce the technology into a suitable country to further evaluate user and logistical considerations regarding device use and implementation. A pivotal WHO Jet Injector Safety Committee meeting is planned for March 31. It is anticipated that this committee will accept plans for safety testing of the device in order to eventually inform a reversal and/or modification of current WHO policy regarding use of this class of jet injectors. The TechNet group recommends waiting on the outcome of the WHO Jet Injector Safety Committee meeting, after which a decision will be made regarding the TechNet position on this jet injector.

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Annex 3 : Grid-connected Syringe Melters

Anthony Battersby and Terry Hart

BACKGROUND :

Melting syringes at the point of use has a number of advantages over other means of destruction:

- Avoids sharps being transported and thus risking getting into the general waste
- Keeps responsibility for sharps destruction in the hands of the person creating the waste
- Does not produce any polluting gases
- Provides a simple clinic based device.

DEVICES :

Two melting devices were presented:

- A grid connected device (mains electricity)
- A solar device (following Annex 4)

Each unit is able to melt a container of used syringes and render it to a solid block of plastic with the needles embedded. The former uses a reusable cassette to hold the syringes while the latter melts the syringes within a standard cardboard safety box which is then discarded complete with the block of plastic.

The electric unit costs under $1,000 while the solar model will be about $250. Both prices are target prices and will be influenced by the volume of sales achieved. The electric unit consumes 1kwH per cycle and takes 90-105 minutes while the solar model takes 4 hours.

Both units are at the development stage and both have undergone initial field trials. The electric unit in Palestine for a month and the solar model in Senegal for 12 months.

TECHNET MEMBER COMMENTS

Concern over infection control. Both units achieve temperatures above 190^{o}C for more than 70 minutes which is sufficient to sterilise under dry heat conditions. Both will need to be fully tested in laboratories to confirm performance. The electric model is based on the "Demoliser®" which has passed all US operating standards.

What happens during electricity failure? The unit stops and has to be restarted. When it is restarted the heating cycle restarts form the condition when the power returns. For example if the temperature is within the operating range it will immediately continue the melting cycle.

How does the solar model track the sun? By a simple water balance.

What can be done with the plastic? It can be recycled,(in Senegal they are proposed to be used to make fence posts) buried, used as building blocks.

CONCLUSIONS

The meeting concluded that Technet should endorse the need for this important category of equipment and steps should be taken to develop commercial models of a range of products both mains connected and solar powered.

WAY FORWARD

1. Find mechanisms for funding development, possibilities include:
    - Development grant to prepare a business plan that could, be given to venture capitalists
    - Gaining guarantees from donors to buy a specific number of units say 1,000 to encourage existing developers to continue investment in development
2. Finalise the specification and offer it to interested developers
3. Find sites for field testing and possible provide financial support for field testing

Annex 4 : IT Power India Solar Melter

Purpose:

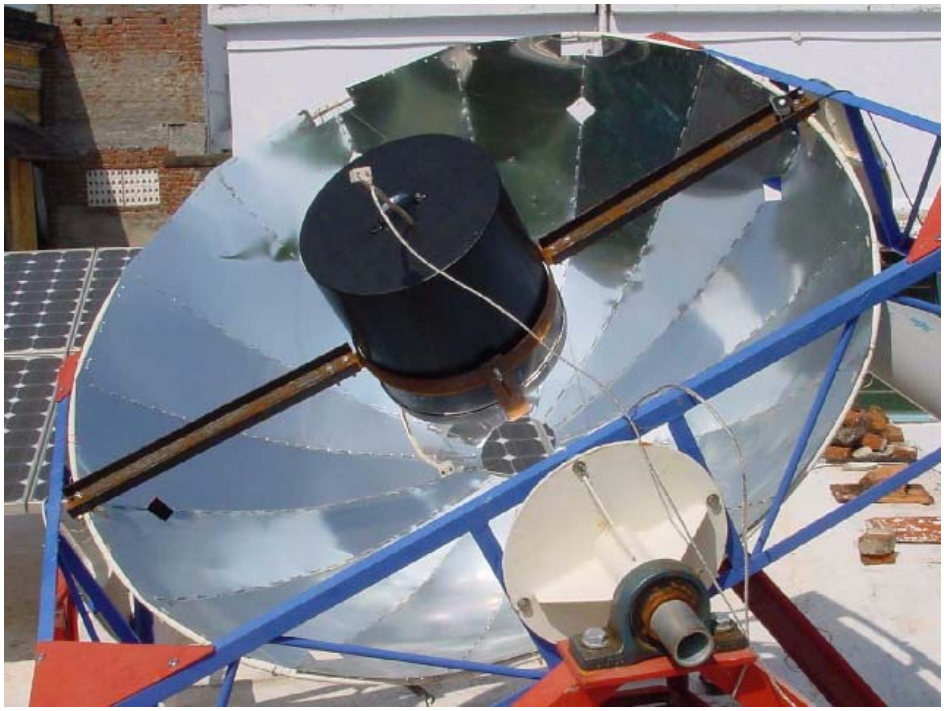
To Destroy Syringes (and other infectious waste) at ***Non Electrified*** (Rural) Health Facilities

Capacity:

1 Safety box (100/150 syringes) per sunny day or 1-2Kg other infectious waste

Cost:

USD250 Ex Works, Recurrent costs of USD50 per 3 yrs



Economics:

USD 0.6 – 1.0 per Kg of waste if used 2 times/week.

Features:

- Melts Syringes in Safety Box
- Plastic residue can be stored and sold commercially
- Simple to operate
- Only requires sunshine to operate
- Very low levels of maintenance

Environmental Impact:

GHG Emissions (Global Warming) ……Zero
Ozone Depletion……Zero
Dioxin and Furan Emissions……Zero

Annex 5 : Refrigerants in Cold Chain Equipment

THE ISSUE :

Should WHO and National EPI programs support the inclusion of Hydrocarbon (HC) refrigerants in vaccine cold chains ?

CURRENT SITUATION :

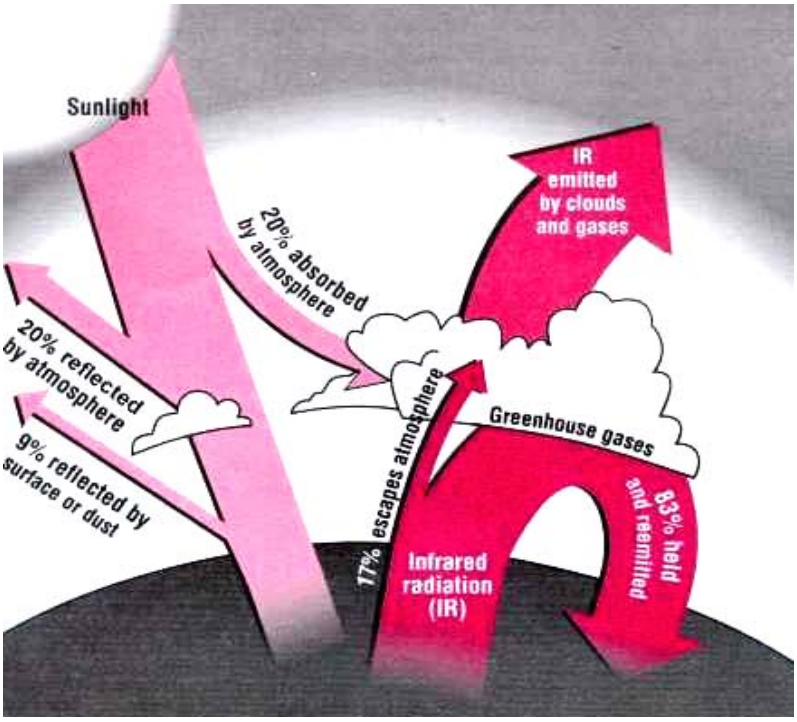
Technet Recommended the transition from CFC to HFC refrigerants (1996) but refrained from inclusion of a recommendation to include HC since little operational experience existed and concerns of safety were raised.

THE CHANGING SCENARIO :

- Widespread manufacture of HC domestic refrigerators
- Compressor manufacturers now market HFC and HC compressors

INCLUSION OF HC REFRIGERANTS MEANS :

- Scope to convert CFC refrigerators in service to HC rather than discard them
- Scope to transgress from present HFC based equipment to HC (This will be a future environmental requirement)
- Adoption of environmentally friendly cold chain equipment



OPERATIONAL BENEFITS :

- Simpler and less stringent standards of maintenance for maintenance technicians

- Adoption of a longer term solution which will not require that tooling for maintenance technicians be changed again.

DRAWBACKS :

- Safety concerns (One cigarette lighter full of refrigerant/fridge)
- HC refrigerants not readily available to meet servicing needs in many developing countries

Annex 6 : Electronic Temperature Monitoring

1. History Temperature Monitoring

   - 1985 Development chemical Temperature Monitor
   - 1986 First prototypes – first supplies – accreditation WHO laboratory
   - 1990 Development StopWatch Card
   - 1999 Request for an electronic temperature monitor
   - 1999 Foundation of Q-tag AG
   - 2000 Development of the Q-tag
   - 2001 Production Q-Tag 1
   - 2002 Production Q-Tag 2
   - 2002 Development of Freeze-tag
   - 2003 Production Freeze-tag

2. Two new easy to use and reliable products for cold chain distribution

Q-tag 2 / Q-tag 2R*

Freeze-tag®

*** R = repeated use**

Q-tag 2 / Q-tag 2R* : Electronic indicator to monitor the temperature during the transport of perishable goods

- Measures the time
- Monitors the temperature
- Shows range violations

The time / temperature parameters as well as the transportation time are programmable according to customer requirements.

- <u>History function (after STOP)</u>
  - Step by step indication of temperature on every segment
  - Indication of related alarms

- Test function (after STOP)
  - Display verification on every segment
  - Verification of correct temperature measurement

- Data retention (after STOP)
  - Data retention time is 2 months
  - Q-tag display can be used as a legal document
  - Q-tag display can be photocopied or scanned

Freeze-tag® : Electronic indicator to monitor the temperature of frost-sensitive goods

- Display shows OK sign
- Alarm condition has not been violated

- Safe : reliable monitoring of the temperature during transport and/or storage
- Easy : direct display / without any computer analyses

- Good value : nevertheless precise and exact

For more details you are invited to visit the Berlinger & Co. AG (Switzerland) website at

http://www.berlinger.ch

ANNEX 7 : Waste Disposal Unit Guideline

IT Power India presented a draft guideline document on Waste Disposal Unit. The document is divided into four chapters : 1) The Waste Disposal Unit incorporating the De Montfort incinerator, 2) Installation, 3) Training, and 4) Maintenance and Planning.

FOCUS OF THE CURRENT GUIDELINE

- It introduces the Waste Disposal Unit (WDU) inclusive of the De Montfort Small-Scale Incinerator (SSI) designed to destroy health care waste produced in PHFs.
- It shows how a WDU should be arranged at a PHF for efficient operation.
- It provides technical drawings and material specifications required to procure and construct a WDU.
- It provides a step-by-step operating guide to facilitate quality incineration and ensure safety for operators, health care personnel and the general public.
- It outlines maintenance procedures to be followed to assure reliable operation.
- It defines training needs for operators, supervisors and quality control technicians.

Information on how to identify an PHF for installation of a WDU, and how waste should be collected, transported, and stored at a single location to justify the capital investment and amortisation of the equipment is provided in the training module *Safe Disposal of Syringes and Needles in the Context of Health Care Waste Management Systems*.[1]

The WDU is only one element of a HCWM system and must be used as an integral part of an HCWM system for it to be effective.

THE WDU AND ITS COMPONENTS

If correctly built, maintained and operated according to "**Best Practices**", the De Montfort incinerator can eliminate infectious and non-infectious waste, simply, quickly and with minimal environmental consequence.

All queries about this document should be addressed to Terry Hart, IT Power (India)

[1] *An Overview of GAVI/ITF Workshops during 2002/2003 for the WHO Taskforce on Immunization (TFI),* John S. Lloyd, Luanda 3-5 December 2003.

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