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Contents

Abbreviations and acronyms

AD	auto-disable (syringe)
AEFIs	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)
CSCI	WHO/UNICEF Cold Store Certification Initiative
CVI	Children's Vaccine Initiative
CVP	Children's Vaccine Programme
DFID	Department for International Development (UK)
DQA	data quality audit
DT	diphtheria–tetanus toxoid (vaccine)
DTP	diphtheria–tetanus–pertussis (vaccine) (sometimes called DPT)
EPI	Expanded Programme on Immunization
ESARO	WHO UNICEF Regional Office for East and South Asia
FBA	Feilden Battersby Analysts (UK)
GAVI	Global Alliance for Vaccines and Immunization
GPV	Global Programme for Vaccines and Immunizations (formerly V&B)

HBV	hepatitis B virus
HepB	hepatitis B vaccine
Hib	*Haemophilus influenzae* b
IAVM	the International Academy for Vehicle Management
ICC	interagency coordination committee
IEC	information–education–communication
ILR	ice-lined refrigerator
MDVP	multi-dose vial policy
MMR	mumps–measles–rubella (vaccine)
MNT	maternal and neonatal tetanus
MR	measles–rubella (vaccine)
NID	national immunization day
NT	neonatal tetanus
NRA	national regulatory authority
OPV	oral polio vaccine
PAHO	Pan American Health Organization
PATH	Program for Appropriate Technology in Health
PIS	product information sheets
SEARO	WHO Regional Office for South-East Asia
SIGN	Safe Injection Global Network
SNID	subnational immunization day
Technet	Technical Network for Logistics in Health
TechNet21	Technical network for strengthening immunization services
TT	tetanus toxoid
UIP	Universal Immunization Programme
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
VVM	vaccine vial monitor
WHO	World Health Organization
WPRO	WHO Regional Office for the Western Pacific

Preface

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.

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. The Global Alliance for Vaccines and Immunization has been formed, including many of the same partners represented in Technet and SIGN.

The proceedings of Technet 1999 gave the clear message that management and implementation of known technologies must be the priority of health service logistics during the next 10 years, although innovation must be encouraged to continue to solve new and unresolved problems.

Technet was relaunched at the 2001 conference as Technet21. Delegates agreed that the future lies in implementing and further developing these new approaches. The crying need now is the strengthening of immunization management, both programme management and operations management, and to involve immunization managers in developing and testing strategies and policies to achieve this.

Technet21 aims to reach more developing country managers, including those at sub-national and district levels, WHO and UNICEF country staff, plus the traditional Technet logistics members.

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. At the time of writing (early 2003) the new e-forum has built participation to some 1050 subscribers – double the number at the time of the 2001 conference.

The New Delhi 2001 meeting, organized back-to-back with SIGN, welcomed a total of 107 participants including 23 participants representing national immunization programmes from all continents. The Technet consultation occupied the first two days of the five day session, which ran from 27 to 31 August 2001. The proceedings of the SIGN session have been separately published.[1]

[1] Safe Injection Global Network Annual meeting report, 30-31 August 2001. WHO/BCT/DCT/01.04

In conclusion, we would like to express our thanks to the Minister of Health and Family Welfare, Government of India, who inaugurated the joint session, to the WHO Regional Office for South East-Asia (SEARO) and to the India Country Office which hosted the meeting, and, finally, to the conference organizers.

TechNet21 Secretariat

A note on the presentations

Five authors have supplied the editors with written papers to support their presentations. These papers are included in full, with minor editorial interventions. Authored papers are indicated by a double asterisk (**) at the end of the title.

The remaining presentations are set out in summary form. Each of these summaries is based on the editors' interpretation of the presenter's PowerPoint ™ slides and on the conference audio tapes. Ümit Kartoğlu and Andrew Garnett are responsible for any inadvertent errors, omissions or misinterpretations.

1. First session: Opening remarks

1.1 Welcome to delegates

Dr Sarkar (MoH, India) and Dr Paul Fife (UNICEF HQ) welcomed the delegates. Brent Burkholder (WHO/SEARO) greeted the delegates on behalf of SEARO and the regional office.

1.2 The future of Technet

Dr Julie Milstein (WHO HQ) and Dr Ümit Kartoğlu (WHO HQ)

Julie Milstein (WHO HQ) thanked SEARO, the Indian country office, and colleagues in UNICEF for organizing the conference. She went on to summarize the original purpose of Technet and to outline its achievements since its formation. She continued by noting that, as a result of Technet's activities, logistics was no longer considered in isolation, but had become an integral part of immunization operations; operations which in turn were complemented by other health system functions. However, new partners such as the Vaccine Fund, the Global Alliance for Vaccines and Immunization (GAVI) and SIGN were now involved, and immunization was facing new challenges and a wider vision. For these reasons she had concluded that Technet in its existing form should be disbanded and should be replaced by a new network with a new focus on strengthening immunization services.

Dr Ümit Kartoğlu (WHO HQ) outlined progress on the recommendations made in the 1999 Technet proceedings and put forward proposals for a new Technet.

He noted that the Harare report had emphasized that 'management and implementation of known technologies, rather than the development of new ones, must be the priority of health services logistics during the next 10 years', and that 'technologies that will improve immunization services are known today… execution and introduction lags behind'. These technologies are:

- safer and easier injections;
- vaccine vial monitors; and
- communications tools to streamline supply and distribution systems.

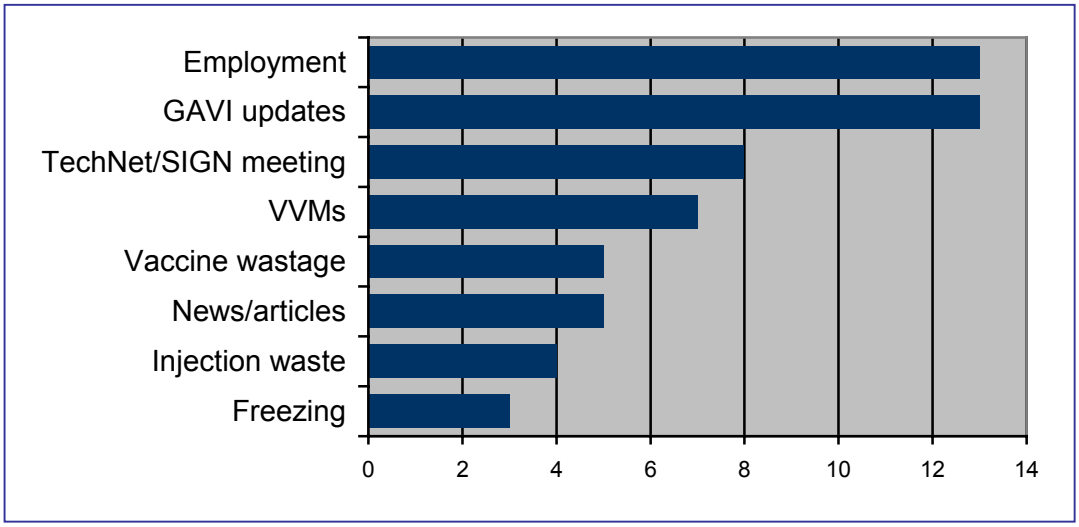
A Technet survey carried out a year after the 1999 conference had indicated that:

- Technet played a useful role; however, there was some division as to what that role should be – at present it is not serving as a useful source of expertise or information.
- Its role should be more pragmatic; it should not be concerned with policy development.
- There was a lack of agreement as to whether Technet should focus its subject range or should broaden it.

- The e-forum should be continued, but in a more useful and more efficient way.
- There was some dissatisfaction with WHO's lack of technical leadership as well as with WHO's relationship to Technet.

An analysis of e-Forum postings between 1 January and 23 August 2001 showed that 62 postings were sent on 25 subjects with a total of 68 contributors appearing 125 times. However, seven contributors accounted for 66% of the total postings, with one contributor appearing in 10% of the postings. A subject analysis of these postings is summarized in Figure 1.

Figure 1: Subject analysis of Technet e-Forum postings, 1 January–23 August 2001



As of August 2001 there were 511 Technet subscribers and there had been a steady but slow increase throughout the previous year.

Based on these survey results, WHO had reconsidered the future of Technet and had decided to relaunch and reinvent it during the 2001 conference under the provisional name of Technet21 or Technet Plus.

1.3 Discussion

Anthony Battersby (Feilden Battersby Analysts, FBA) asked what the role of the proposed 'advisers and experts network' was to be. He suggested that this sounded like a Technet21 within a Technet21.

Ümit Kartoğlu said that the intention was to create a list of key resource people in particular subject areas such as vaccine vial monitors (VVMs), vaccine wastage, etc. These people could be from organizations, nongovernmental organizations (NGOs), universities and other bodies. The idea was to achieve a more solid consensus than had been achieved hitherto with Technet.

Alan Bass said that the idea of a reference panel had been discussed 2–3 years ago. It did not happen then, but the idea is a good one.

Dr Jean Smith (WHO Nepal) commented that she found the Technet postings very useful. In Nepal the polio eradication and immunization officers around the country have email facilities. Relevant Technet postings were often forwarded to them.

Dr Anil Varshney (Program for Appropriate Technology in Health, PATH) commented that something should be done to publicize Technet.

Alan Schnur (WHO China) commented that Technet is evolving and has grown. One objective had been to involve senior management and that, in this, it had been successful. Peter Carrasco (Pan American Health Organization, PAHO) commented that, although there are many discussions on Technet, it has always been very clear in postings that final policy decisions are for WHO to make.

Robert Steinglass (BASICS) asked that there should be a chance to continue discussion of the role of Technet21 before the end of the conference, as it was a vitally important issue.

Bob Davis (UNICEF Regional Office for East and South Asia, ASARO) said that the email forum was not a very effective way of stimulating comments from nationals because of the fear of not following procedures and being seen to criticize senior management. Technet21 must find some way of getting down to district level. It should not be a closed group for the exchange of views between a couple of dozen international experts.

Dr K. Suresh (UNICEF, Delhi) said that, notwithstanding the last comments, it was important to keep the experts on board.

Dr Subhan Sarkar (MOH, India) made the following observations:

- Technet has so far been working in isolation, so countries find it hard to use the recommendations arising from forum discussions.

- Technet needs to look at the requirements of the end users and present a clearer picture of the issues being discussed. There needs to be more dissemination of information to country managers.

- He supports the idea of the ‘advisers and experts network’.

Allan Bass (WHO temporary adviser) commented in his role as current Technet moderator.

- How do we extend the reach of the forum down to operational level? If we do achieve this, how do we obtain their responses?

- He reiterated Bob Davis’s comment about the reluctance that nationals have in responding. In some countries freedom of speech may be a problem. In others there is a perceived need to go through the ‘proper channels’. Most countries exert some degree of ‘spin’ or information control which inhibits free exchanges.

- The recent increase in numbers subscribing to Technet is a clear indication of the extending penetration of the internet.

Anthony Battersby (FBA) asked Dr Kartoğlu to explain the relationship between Technet21 and WHO. Hitherto WHO have not considered Technet findings to be binding and a number of recommendations have not been taken up. He cited the recommendation to introduce low

temperature protection in refrigerators for cold climates as an example. What is to be the new formal relationship?

Dr Ümit Kartoğlu (WHO) agreed that WHO's relationship with Technet was informal. Recommendations are just that – they are not policy decisions. Unlike SAGE, there are to be no institutionalized links with Technet21 and the relationship will remain informal.

Anthony Battersby (FBA) pointed out that there was a difference between the Technet forum and the formal Technet meetings. Recommendations arising from Technet meetings should be carried forward by the agencies. How do we get around this problem?

Dr Julie Milstien (WHO) noted that she personally did not see Technet as a recommendation-making body. Technet21 will be a way to communicate and bring issues to the table. If Technet were to be a recommendation-making body, then it would have to have a Director General, appointed members, etc. The issue for Technet21 is, how do we exchange views and make needs felt?

Robert Steinglass (BASICS) commented that there are more fundamental issues which transcend Technet, for example, the role of logistics in WHO's portfolio. There has never been a greater need than there is now for expertise in this area. Finance is flowing more freely than ever before, but the expertise locked up in Technet is not being deployed sufficiently. WHO needs to use logistics and operational experience more effectively.

Alan Schnur (WHO China) commented that the setting up of the original cold chain unit had been a great advance at the time. The great success of EPI was its contribution to logistics.

Hans Everts (WHO) saw a need to switch from innovation to implementation.

Dr Ümit Kartoğlu (WHO) suggested that participants should follow up this discussion with email suggestions. Technet discussions should lead to concrete results. He agreed that recommendations from Technet should, wherever possible, be picked up by partner organizations.

Themes and conclusions

- There was general agreement that the role of Technet should continue to be discussed throughout the conference.
- There was general agreement on the need to establish an advisers' and experts' network.
- The view was expressed that Technet was not a recommendation-making body.
- There was concern that the e-forum was not a good format for discussions involving country members.
- If the utility of Technet is to be increased, it needs to look at the requirements of the end users and present a clearer picture of the issues being discussed. There needs to be more dissemination of information to country managers.
- In view of the great need for expertise in this area, there was concern about the diminished role of logistics within WHO's portfolio.

Chair: Dr S. Malhotra *(Assistant Commissioner Child Health, Ministry of Health and Social Welfare, India)*

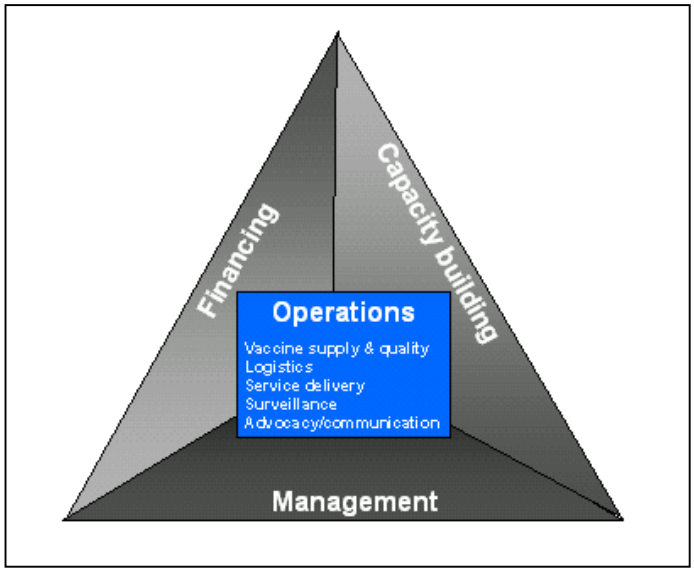
1.4 Introduction: strengthening immunization services

Jean Marc Olivé (WHO HQ)

A successful immunization system may be defined as a system that:

- achieves a minimum coverage of the target population with immunization services;
- has developed a logistics system which successfully provides necessary transport, cold chain and injection devices for immunization services;
- has mechanisms to ensure high quality of vaccines and immunization devices;
- has adequate financing and,
- the ability to introduce new vaccines. Figure 2 illustrates these features.

Figure 2: Elements of an immunization system



Assessment of the status of programme indicators show that despite notable increases in coverage in many countries, immunization rates have stagnated in the last decade, and are dangerously low in several countries. This year over 30 million children will grow up without vaccination. Three million people will die this year from diseases that could be prevented by immunization with existing vaccines.

Some countries with previously very low levels of coverage have quite rapidly managed to reach 50%–60% coverage with improvements in training and quite modest amounts of infrastructure improvements. However, to increase coverage to 80% or more from 60% needs a proportionally much higher level of resource input. In addition, the public demands better quality immunization services, especially regarding vaccine safety, safe injection practices and proper disposal of waste material. More and more, vaccine supply and quality, logistics, communication and advocacy, surveillance and immunization service delivery are recognized as the key elements of successful operations in the field of immunization.

Many new opportunities are arising to promote immunization:

1. International interest in immunization has been revitalized by the Global Alliance for Vaccines and Immunization (GAVI);

2. The global efforts against polio have built an infrastructure and developed national expertise even in countries where immunization programmes have not performed well in the past, and

3. New vaccines are, or shortly will be, available against high priority diseases, particularly Hepatitis B (HepB), *Haemophilus influenzae* type b vaccine (Hib), pneumococcus, and rotavirus.

With all these options in front of them, and with all the other competing priorities which confront them, immunization managers generally focus on short term expediency rather than medium and long term vision for their programme.

We should aim to provide resources to sustain and improve immunization services by working in priority countries mainly to:

- facilitate the developing country process in achieving the GAVI goal of 80% coverage with three doses of diphtheria–tetanus–pertussis (DTP3) vaccine in 80% of their districts by 2005;

- build on infrastructure developed by the polio eradication programme;

- develop and increase national capacity to secure country ownership of their immunization programmes through the interagency coordination committee (ICC);

- increase vaccine management capacity at all levels;

- optimize the impact of immunization services as a component of health delivery, while at the same time ensuring that new opportunities are conducive to this system.

The main strategies to be followed should be to:

- provide additional human resources at country level, both on a short and long term basis, so as to build up national capacity for routine immunization;

- promote and facilitate the use of existing and 'in progress' tools, guidelines and training materials by providing assistance to adjust these materials to country situations; to organize and support these activities; to monitor training activities, and finally to improve communications with and within countries;

- in countries where polio transmission has been interrupted, progressively to integrate polio personnel into routine activities so as to strengthen immunization services;

- support the country ICC to ensure that it fulfils its role as the main catalyst for national ownership and international support, particularly regarding coordination with UNICEF and other GAVI partners;

- use the introduction of new vaccines and injection safety as to way to revitalize immunization services;

- at the operational level, use immunization delivery as a lever to strengthen other basic health interventions.

In conclusion, it should be noted that the national authorities have to be the prime actors and movers for this. There is no standard recipe; local solutions should be sought to confront and to deal with local problems.

2. Second session: Programme sustainability

Chair: Dr S. Malhotra (Assistant Commissioner Child Health Ministry of Health and Social Welfare, India)

2.1 Overview: factors affecting immunization coverage

Dr Subhan Sarkar (Ministry of Health and Social Welfare, India)

Introduction

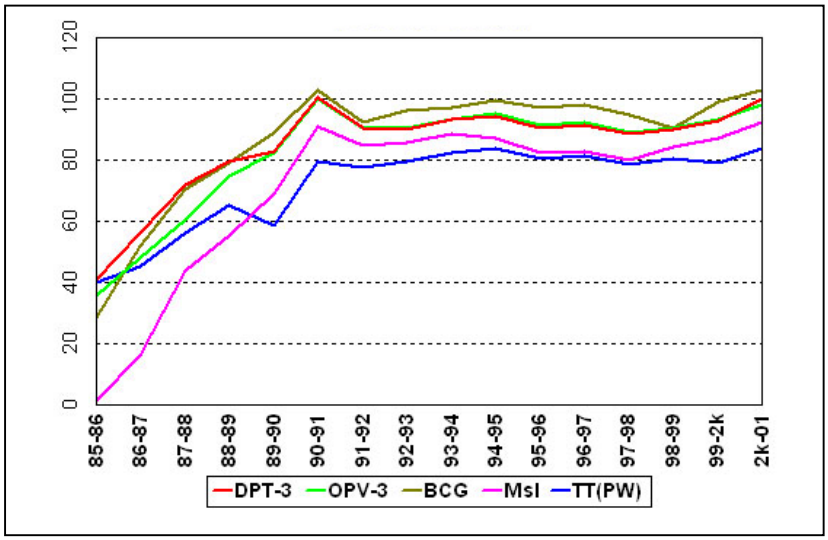
Dr Sarkar began by remarking that the immunization programme in India formed an important part of the national population control strategy. By improving disease control, the intention was that infant mortality would be reduced to such an extent that parents would be encouraged to adopt effective family planning methods.

EPI began in India in 1978. Initially the programme had limited reach and was mostly confined to urban areas. Coverage was poor, achieving a full oral polio vaccine coverage (OPV3) rate of about 40%. Measles vaccine was not offered and the TB control programme was not integrated.

In 1985, a phased universal immunization programme (UIP) was launched, with the aim of covering all districts by the year 1989–90. During this period, coverage rose rapidly, indigenous vaccine production levels were increased and monitoring and evaluation were introduced. The Government of India attached a high priority to UIP as a key component of its social sector development plan – other components being water supply, education, and oil seed production.

Figure 3 shows that, by 1990, coverage of 80–100% was being reported.

Figure 3: Reported immunization coverage 1985–2001



Dr Sarkar remarked that by this stage WHO, UNICEF and other partners had been brought in, the political will was in place, the technologies used were sound, individual States were co-operating, there was a global focus on control of preventable diseases and the whole programme appeared to be operating smoothly.

Emphasis continued to be placed on effective planning and management and on the development of infrastructure. This was supported by training down to the grass-roots level together with a focus on quality of service and monitoring at all levels. The cold chain was developed, surveillance was put in place and a very effective information–education–communication (IEC) was conducted, which significantly improved programme management. Finally, the country became self-sufficient in vaccine production.

A rapid decline in vaccine-preventable diseases took place up until about 1990. This was followed (with the exception of neonatal tetanus, NT) by a continuing period of stagnation.

There was an accompanying decline in infant mortality, from 104/1000 down to 92/1000 in 1990. Thereafter there was a continuing decline to around 74–70/1000. However improvement had stagnated.

The current situation

Dr Sarkar then reported on the current situation in India. By 2001 UNICEF had become the Government of India's major partner and, among other activities, was funding independent coverage surveys. Figure 4 illustrates the trend in evaluated coverage results over four years, for five states. Figure 5 shows the discrepancy between reported and evaluated coverage for seven states for the year 2000/01. Citing examples Dr Sarkar noted that in Andhra Pradesh there was a nearly 50% difference between the two figures. In Bihar both reported and evaluated coverage were very low. However in Tamil Nadu coverage remained high and there was little discrepancy between the two sets of figures.

Figure 4. Evaluated coverage

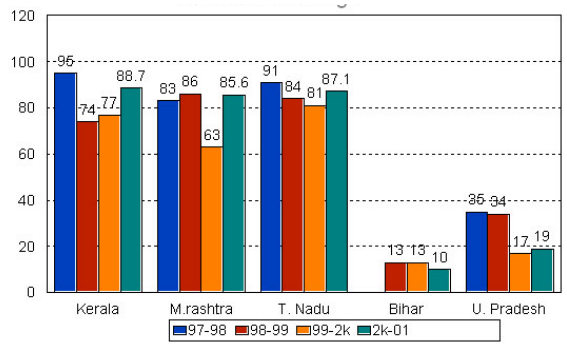
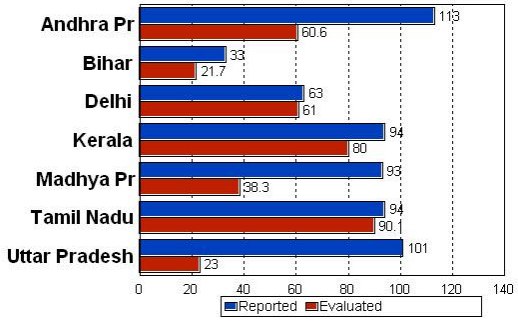


Figure 5: Discrepancy between reported and evaluated coverage for 2000/01



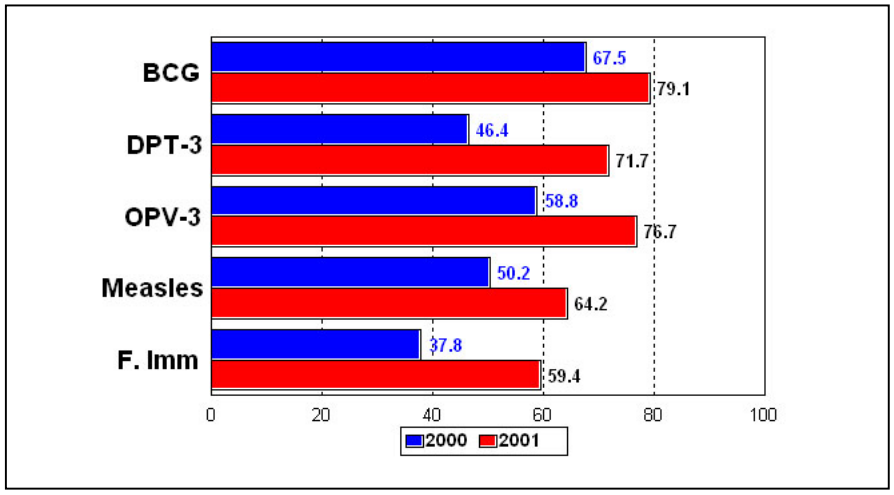
Summing up the current situation, Dr Sarkar noted that a number of factors had adversely affected the performance of the immunization programme. Early successes had encouraged government to load further preventive and curative interventions onto the mother and child health stations. This had led to competing priorities, which had overtaxed the health workers and led to a decline in the priority assigned to EPI. Several other factors had led to further staff overload. These included:

- the continuing increase in population;
- additional outreach work;
- polio eradication programmes;
- leprosy elimination programmes;
- local emergencies;
- increasing urbanization with associated poor infrastructure;
- ageing equipment and vehicles and inadequate plans for replacement; and
- attrition of health workers due to retirement and transfer, resulting in empty posts that were not being filled.

Other operational issues which had affected the programme included global pressures and donor competition.

Dr Sarkar concluded by commenting that all was not bad in India. Problems had been identified, improvements had been implemented and, as illustrated by Figure 6, there had been a significant rise in coverage between the years 2000 and 2001.

Figure 6: Improved coverage between 2000 and 2001



2.2 Discussion

Dianne Phillips (Department of Health, DoH, South Africa) cited a number of similar problems to those outlined by Dr Sarkar, currently arising in South Africa, namely:

- More and more competition between programs.
- There is a growing TB problem as a result of HIV/AIDS. The importance of EPI is fading as a result of these emerging diseases.
- Information/administration overload on health workers because each programme demands more and more.

Peter Carrasco (PAHO) commented that, while health reform was a double-edged sword, it should also be seen as an opportunity. There is a need to highlight reform at the local level.

Dr Mohammed Rahman (EPI Bangladesh) noted that they were experiencing similar problems with coverage. What is the drop-out rate in India?

Dr Sarkar replied that the Indian drop-out rate was 15–20%, but that there was a wide gap between states, arising from monitoring and supervision deficiencies.

Dr Anil Varshney (PATH) noted that a major constraint in achieving good coverage is non-professional bureaucratic intervention.

Anthony Battersby (FBA) made the following comments:

- Dr Sarkar had highlighted that finite human resources is a vital issue to keep in mind if programmes are to be effective.

- Jean-Marc Olivé's presentation did not include a description of how we were to achieve the necessary behavioural changes amongst health workers. For example, there is a huge gap between reported and actual coverage, which must be a consequence of health worker behaviour.

On this subject, Dr K. Suresh (UNICEF, Delhi) noted that there had hitherto been competition between districts as to which one reported the highest coverage. Coverage rates establish the 'grading' of a district in M.o.H. eyes. Consequently there is bureaucratic pressure to report 100% coverage. The bureaucracy has now been told that they have to establish the real facts.

Dr Suresh noted some further factors affecting coverage rates:

- Only in 1998–99 was coverage properly evaluated in the provinces. Until 1995, simple estimation tools were used, comparing the number of outreach sessions planned with the number actually held. This tool was subsequently abandoned. This seems to have been a major factor in the drop in coverage figures. For example, in areas where logistics are difficult, such as Bihar and Uttar Pradesh (UP) provinces, only around 55% of the monthly outreach sessions are actually held.

- People's expectations have risen since the polio campaigns – they now expect home visits for all immunization.

Dr Jean Smith (WHO Nepal). Dr Sarkar's bar chart showed a dramatic improvement in coverage in 2000–2001. What caused this?

Dr Sarkar. The increase was a result of an immunization-strengthening project funded by the World Bank. In addition, the border districts between states are now being covered better. There is now substantial support for the programme in states such as Andhra Pradesh.

Dr Jean-Marc Olivé, responding to Anthony Battersby's question regarding behavioural changes, commented that one has to focus on the field and limit those interventions from outside which lead to misreporting.

Dr Sarkar supported this view. If you can demonstrate improvements you can take the political system with you.

Themes and conclusions

- EPI programme performance – indeed the very importance of EPI itself – is affected by competing vertical programmes and by emerging diseases such as HIV/AIDS.
- Health workers are subjected to information and administration overload because of the demands of competing programmes.
- It is essential to encourage programmes to report coverage accurately. A major constraint on achieving good coverage and obtaining accurate coverage figures is the bureaucratic desire to manipulate results and the consequent pressure that this places on health workers.
- If programmes are to be effective, they need to recognize that human resources are finite and must be deployed efficiently.
- There is a widespread need for behavioural change amongst health workers.

Chair: *Paul Fife* (UNICEF HQ)

2.3 Evidence based planning and programming: what is your coverage and how do you know?

Anthony Burton (WHO HQ) (presenter), Olivier Ronveaux (co-author), Maureen Birmingham (co-author)

Anthony Burton introduced his presentation by commenting that he would draw on some of the issues raised in Dr Sarkar's talk. His first slide illustrated examples of questionable coverage data supplied by a number of countries over the past decade.

Do you believe?

- DTP3 coverage increased from 28% to 68% in Sierra Leone in 1997–98?
- 1990 DTP3 coverage for India of 100%?
- What about 106% DTP3 coverage in Bangladesh?

OPV3 coverage in Kenya 1996–1998: 77% – 36% – 64%?

The theme he wanted to talk about, and the question he wanted to obtain advice on, was how it was possible to obtain reliable coverage data?

He noted that his unit in Geneva had carried out an analysis of coverage data recorded by WHO for the years 1991–1996. 25% of these data were missing and 19% were 'outliers', showing unusual patterns such as DTP3 figures greater than OPV3. The question that arose

from this was whether the data reflected programme performance or whether they were an artifact of the data system itself.

He went on to note that immunization programme performance was influenced by a variety of internal and external factors; as a consequence, programmes could behave in different ways at different times. These factors included:

- Changes in resources:
  - national commitment
  - external donors
- Changes in programme structure, management, or activities:
  - administrative changes such as decentralization
  - changes in vaccination schedules
  - vaccine shortage
  - additional activities – campaigns
  - Changes in the political situation.

The primary goal of immunization service delivery was to achieve high levels of safe coverage. Effective measurement of this service delivery relied upon immunization data being correctly recorded at health facilities and subsequently passed on, consolidated, analysed and used further up the system. For the purpose of calculating accurate coverage figures it was also essential that good denominator data were obtained. See Table 1.

Table 1: What are we aiming for?

What are we aiming for?	
What?	**Where?**
Good recording procedures of vaccinators	Health facility
Accurate and complete consolidation of data	District to central
Data reporting complete and timely	All levels
Data analyzed and used	All levels
Good denominator data	District to central

In general, he considered that reliable denominator data were only available at district level and above. At health facility level, denominator figures tended to be distorted by population movements and service-seeking behaviour.

He noted that there were three ways in which coverage could be measured:

- from the analysis of administrative records;
- from surveys; and

- from best-estimates.

Figure 7 illustrates how coverage is calculated using the first two of these methods. In the *administrative method*, the numerator should include all routine immunizations (by dose) given at health facility level and at routine outreach sessions. Whether or not it should include immunizations given by the private sector remained a matter for debate. In general, campaign immunizations should be separately accounted for.

Figure 7: Calculation of coverage figures

Administrative records

$$\text{\% coverage} = \frac{\Sigma(\text{number of children vaccinated})}{\Sigma(\text{number of children in target population})}$$

Survey

$$\text{\% coverage} = \frac{\Sigma(\text{number of children vaccinated})}{\Sigma(\text{number of children surveyed})}$$

The administrative method

The advantages of the administrative method were that routine data collection formed part of the day-to-day activities of the programme, that data collected could be used at all levels, and that, if the data were collected in a timely manner, they could be used to identify and resolve problems promptly.

He continued by outlining situations where errors could distort the numerator data. For example:

- including “over-ones” (children >1 year) who have received their immunizations late;
- including campaign data, but without adequate data control;
- including inaccurate data received from private practitioners, who may have tax incentives to underreport;
- missing data incorrectly accommodated; and
- poor implementation of the reporting system.

Most routine reporting systems were set up in the late 1970s and early 1980s and were further strengthened in the mid-1980s. They may not be so robust now as they were then. Training and supervision may be inadequate and staff resources may be insufficient. When health staff know or suspect that the data they collect is not used, then they may lose the motivation needed to continue producing accurate reports. Finally there may be pressure or incentives to ‘adjust’ data to satisfy political objectives.

He went on to discuss the issue of missing data. Figure 8 gives an example of a correctly calculated coverage percentage. Figure 9.I shows how this figure could be distorted by missing data in the numerator. Figure 9.II shows how an attempt to correct this by omitting the corresponding denominator could still lead to errors if the performance of the omitted reporting centre was significantly above or below average.

Figure 8: Correctly calculated data

Correctly calculated data

$$\frac{\text{Vacc1} + \text{Vacc2} + \text{Vacc3}}{\text{Tg1+Tg2+Tg3}}$$

$$\frac{310 + 290 + 100}{486 + 300 + 214} = 70\%$$

Figure 9: Coverage calculation distorted by missing data

Coverage calculation distorted by missing data

I. $$\frac{310 + 290 + x}{486 + 300 + 214} = 60\%$$

II. $$\frac{310 + 290 + x}{486 + 300 + x} = 76\%$$

The quality of the denominator was a significant further factor determining the accuracy of the administrative method. Denominators can be distorted by:

- the quality and age of the census data;
- the method of population projection;
- uncertainty at local level arising from migration, service seeking and major population shifts (refugees, etc.);
- adjustments made for 'counter-indications' – for example, omission from the denominator of children with such counter-indications; and
- how the denominator was calculated; whether on the basis of birth numbers or on the basis of surviving infants.

The survey method

The advantage of the survey method was that it addressed both public and private sector performance and that it effectively eliminated the denominator problem – the denominator in this case being simply the number of children surveyed.

However, there were several problems with the method.

- It relied on good study design to achieve the desired level of precision, and this level of precision was getting tighter.
- It assumed that you could generalize from the survey results to the whole country and this might not be valid.

- The length of the survey questionnaire might be excessive and this could lead to boredom and loss of attention on the part of the interviewee, and thus to inaccurate results.

- Methods that relied on parent recall could lead to underreporting or over-reporting.

- Since surveys were generally conducted on the previous year's birth cohort, the data collected were typically one year out of date.

- Surveys were not a routine activity – they required staff recruitment and training.

Typical survey implementation problems included:

- poor household selection – for example drawing the survey frame from the immunization registry, thus ensuring that all selected households had immunized children;

- prompting and interpreting answers; and

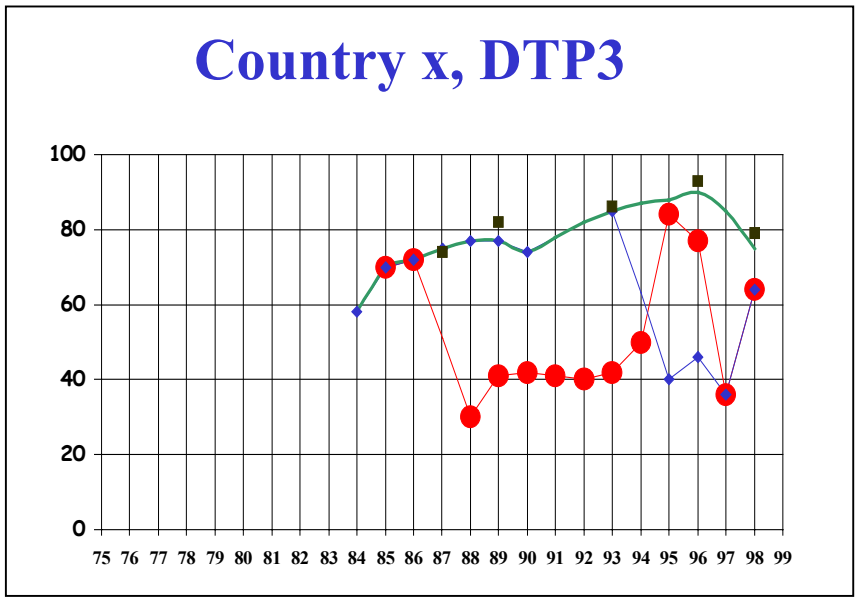
- fraudulent form-filling on the FFUTT principle (Forms Filled Under The Tree) – this could be difficult to detect since it was expected that all forms would be filled in the same hand.

The best-estimate method

The best estimate technique might have to be adopted if data obtained using either of the first two methods was suspect. 'Best estimates' relied on multiple measures of coverage data and on the analysis of trends over time rather than relying solely on data from single periods. They required judgement rather than calculation – these judgements being based on local knowledge. Figure 10 illustrates an example where two sources of data (WHO in red and UNICEF in blue) had been combined and a best-estimate trend line interpolated (green).

In his view, a sensible combination of the three techniques was to collect and analyse routine administrative data, to carry out three to five yearly surveys and to use the best-estimate method to assess trends over time.

Figure 10: 'Best-estimate' example



Data Quality Audits (DQA)

The DQA technique had been developed to support the GAVI fund recommendation that final GAVI payments should be based on the number of reported DTP3 doses per year; analysed using administrative data.

The DQA tool was designed to review and look in depth at the functioning of an immunization system by using improved survey methodologies and by encouraging a more critical review of the data. The expanded annual reporting approach briefly outlined in the presentation combined the three methods described above by asking for 'best estimate' data in addition to administrative and survey results.

DQA was predicated on two premises of the GAVI funding process, namely:

- GAVI's task is to supplement current resources.
- GAVI rewards results.

DQA was specific to GAVI. GAVI funds were allocated on the basis of a performance improvement target agreed with the applicant country. At the end of the funding period GAVI carried out an audit to establish actual performance and paid out on this basis; the DQA method had been developed to carry out these audits, which were conducted by external auditors, accompanied by national counterparts. For this purpose, the method needed to be short term and fairly inexpensive. Figure 11 gives an example.

Figure 11: GAVI funding – example of calculation method

How it works?	
Baseline	100 000 children vaccinated
Goal	110 000 extra (2 years)
Investment	10 000 * US$ 10 = US$ 100 000
Claim	115 000 (2 years later)
How do you know?	
Evidence	Reported DTP3 doses
How good is your reporting system?	
Justification	DQA (one year later)
"Adjustment"	120 000 * .85 = 102 000
Payment	(102 000 -100 000) * US$ 10
Total	year 3 = (2 000 * US$ 10)

He commented that DQA had been pilot tested in seven countries. He also reported that the method was being adapted for internal use by some national programmes as a way of improving their internal data collection and analysis procedures as well as an aid to preparing GAVI applications. Cambodia was cited as an example.

Work was also underway to improve survey methodology – for example to improve the precision and to update the materials and methods used in the classic EPI 30-cluster technique.

In conclusion, Tony Burton asked delegates to consider whether coverage alone was a sufficient measure of immunization programme performance. He listed a number of other indicators that could be looked at including:

- why children were not immunized;
- why children dropped out;
- male/female ratio; and
- socioeconomic ratios.

2.4 Discussion

Bob Davis (UNICEF ESARO) was delighted that discussion of coverage data was so prominent on the first day.

- In his view, the single most important factor in overestimating fully immunized children is the inclusion of measles given below 9 months. Such immunizations should not be included in coverage figures as these are below the WHO limit and are ineffective.

- DQA means a lot of work but is a very good thing.

- The Cambodian use of DQA is exceedingly interesting.

- How many managers have a grip on the AEFI reporting, sharps disposal and completeness of surveillance data at the peripheral level? If you are not sure, DQA can be a refined tool not only a data verification device.

Dianne Phillips (DoH, South Africa) commented that private sector doctors in South Africa are given free vaccine. However, they don't receive new stocks unless they provide coverage data in exchange.

Robert Steinglass (BASICS) commented as follows:

- A very interesting presentation and very good to focus on the data collection element of DQA.

- However, we must not delude ourselves. It requires enormous effort to improve a data collection system. Monitoring processes need to be developed, but international agencies have not supported this.

- Appropriate indicators are still needed. Polio eradication was supposed to improve immunization, but no indicators were provided.

- There are no indicators for routine measles in the current African measles strengthening programme.

- We need to know that countries are achieving and maintaining coverage over time. For example, one such indicator would be 'What percentage of districts show 80% DTP3 coverage over the last 3 year period?'.

Anthony Battersby (FBA) made the following suggestions:

- One way to find out what is happening when there are huge anomalies in the coverage data is to look at the quantity of vaccine distributed in the same time period.

- Another indicator is to ask people why they don't get immunized. This provides very useful operational data.

- 'DQA' is a synonym for 'supervision' – it is a technique for systematizing normal supervisory activities. There is a need to develop this technique so that it can be used for routine purposes without the need for external consultants.

H. T. Raubenheimer (Collaborative Centre for Cold Chain Management, CCCCM, South Africa). Has recorded data been correlated with distribution data on vaccine, syringes, needles and expired vaccine?

Hans Everts (WHO) noted that Polio NIDs often use the data from previous year's NIDs as the denominator. Do other people use this?

Allan Bass (WHO temporary adviser) warned that DQA does not measure the 'truth' of immunization activity as it arises. It only audits the subsequent paper trail.

Anthony Burton responded to the above comments and questions as follows:

- Correlating reported coverage with vaccine supply is a very good idea. The problem is that unless very strange things are going on it is difficult to get a good correlation.
- One could correlate against disease incidence. Dr Sarkar demonstrated this in his presentation. However, disease data has problems. Upon inquiry, for example, measles coverage often rises after an outbreak because immunization has been carried out around the outbreak. One needs to be aware of such anomalies.
- The GAVI DQA approach does not include districts that don't report. Consequently the worst recorders are not included in the coverage data.
- The suggestion to ask why children are not brought for immunization is useful at a qualitative level.
- Swapping vaccine for data is a good idea.

In conclusion Anthony Burton asked the meeting to consider the sobering fact that global DTP3 coverage was now only 73% as compared with the 90% target forecast by WHO in 1990.

Themes and conclusions

- There was general support for the use of data quality audits (DQA).
- The international agencies should be encouraged to support and to fund accurate data collection and routine monitoring systems.
- A range of quantitative and qualitative correlation techniques need to be developed so that official coverage figures can be cross-checked in a variety of ways.
- There was general support for the idea of exchanging vaccine for coverage data in the private sector.

2.5 Financing and political commitment: Annual workplan finance and budgeting

Dr Lepani Waqatakirewa (Ministry of Health, Fiji)

Introduction

Dr Waqatakirewa introduced his presentation on the immunization programme in Fiji. He intended to provide an overview of the programme, to discuss some of the difficulties he faced in obtaining political commitment, and to review issues of cost and financing.

Fiji had a population of 800 000 distributed over 150 islands and with a total area of 180 000 square miles – a significant logistic challenge. He went on to describe the four

immunization schedules used by the programme – schedule A for infants; B for schools; C for ante-natal and D for dropouts. Of these four, schedule A was the most important – see Table 2.

Table 2: Infant immunization Schedule A for the year 2000

Age	Vaccine
Birth	BCG
	OPV 1
	HepB 1
2 months	OPV 2
	HepB 2
	DTP 1/Hib 1
3 months	OPV 3
	DTP 2/Hib 2
4 months	OPV 4
	DTP 3/Hib 3
5 months	HepB 3
9 months	Measles

Over the last few years the infant schedule had undergone a number of changes. The original version covered the standard EPI vaccines; hepatitis B (HepB) had then been introduced, followed by *Haemophilus influenzae* type b (Hib) and finally by DTP/Hib. In future he expected a pentavalent vaccine to be added. There were currently six contact points, but his aim for the future was reduce this so as to keep infant discomfort to a minimum.

Performance monitoring

Dr Waqatakirewa described how programme performance in Fiji was monitored. Vaccine-related monitoring included routine administrative reporting, EPI cluster surveys, analysis of disease prevention data and analysis of missed opportunities based upon health centre and outreach records. Vaccine safety was assured by procuring through UNICEF; adverse events were monitored by analysis of hospital records and research and health centre records, and syringe use was also recorded. Cold chain performance was monitored using temperature and equipment maintenance records. All cold chain maintenance was handled by personnel employed by the programme.

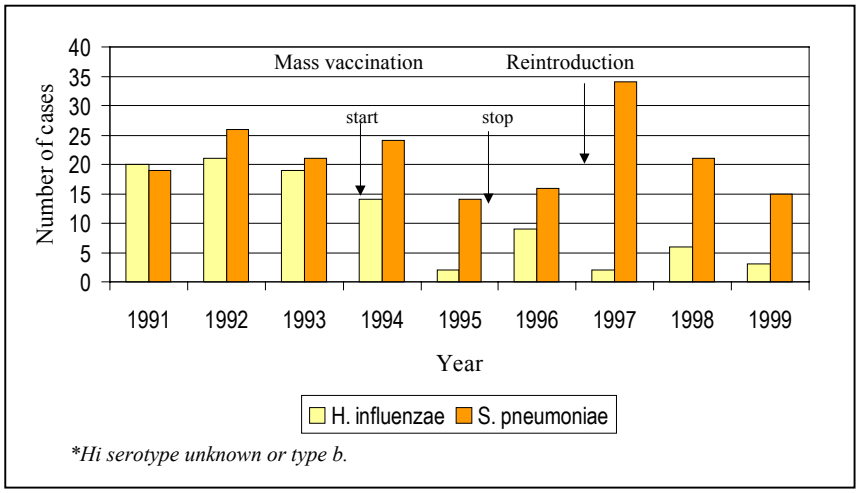
Cluster surveys were carried out every three years, and he went on to discuss the 1999 survey. At that time Hib, which had been introduced in 1994–95, was still being administered as a separate vaccine. Despite cautions received about the risks of introducing another antigen, the survey showed that Hib coverage had been reasonable and had not adversely jeopardized general coverage. He noted that surveys in Fiji typically showed coverage figures some 2–5% higher than the figures obtained from routine administrative reporting.

By the year 2000, polio had been eradicated from Fiji. However AFP surveillance was continuing, along with measles surveillance, as part of the special surveillance activities. Routine surveillance was continuing for all other EPI diseases.

The meningitis problem in Fiji

Dr Waqatakirewa went on to outline specific disease issues in Fiji. Meningitis was a particular problem and a significant contributor to morbidity and mortality in the islands. Figure 12 shows the impact on disease burden brought about by the introduction of Hib in 1993–94 and by its subsequent abandonment from 1995 and 1997. The initial introduction had been donor-funded for a two-year period. When this funding dried up, it had required a significant community awareness and motivation campaign to convince government to allocate internal funding to support its reintroduction as a routine vaccine.

Figure 12: Impact of Hib immunization on *H. influenzae and *S. Pneumoniae* meningitis in children aged <5 years Fiji, 1991–1999**



**Hi serotype unknown or type b.*

Sector roles

Vaccine is given to private-sector general practitioners free of charge on condition that all immunizations are reported through the sub-divisional health system. GPs are only entitled to charge for their time and consumables.

Programme finance

Dr Waqatakirewa commented that the Government of Fiji regarded preventive health as a priority and saw immunization both as a successful public health intervention and a treaty obligation under the Conventions on the Rights of the Child, 1990, and the International Conference of Population and Development , 1994.

On the issue of programme finance, the Ministry of Health's principal objective was to convince the Ministry of Finance to release funds. Often this involved using community pressure to convince the cabinet and the Ministry of Planning to support immunization initiatives. Over the years, there had been a progressive move towards self-financing. This had been partly driven by the need to introduce vaccines, such as Hib, that were additional to the traditional EPI vaccines. To this end, the government had adopted the Vaccine Independence Initiative (VII). Under the terms of this initiative, UNICEF's role in supplying

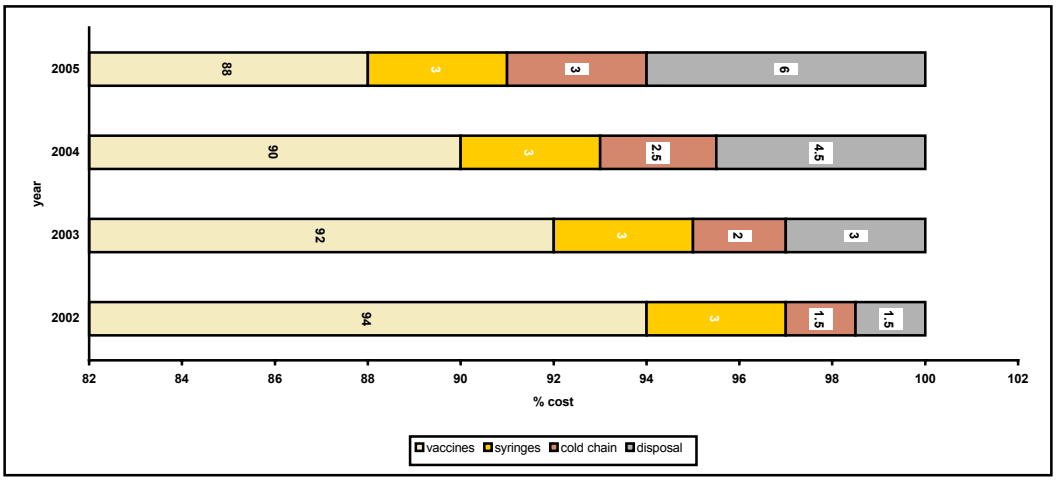
free vaccine had tapered off in the years up to 1997, by which time 100% local funding was finally achieved.

Over the past 20 years, assistance to the EPI programme had been provided both by UNICEF (vaccine costs, vaccine procurement and storage and technical programme support) and by WHO (cold chain equipment and technical and programme support). More recently, within the past 10 years, significant support had been provided by AusAID (HepB and programme support) and by the Japanese International Cooperation Agency (JICA) (campaign vaccines, cold chain equipment and vehicles).

Dr Waqatakirewa reported that, by 2001, his government was spending US$ 320 000 per year on the programme. Of this figure, US$10 000 was for consumables, US$ 5000 for cold chain equipment and US$ 5000 on safety boxes and incineration, and the balance of 94% was spent on vaccines. The programme was now self-financing so far as routine vaccines were concerned. As of 2001, vaccine costs represented 6.5% of the national drugs budget. Donors were continuing to offer funding for measles campaign vaccines, solo-shot syringes, cold chain equipment and incinerators, amounting to a value of US$ 38 000 in all for 2001.

Over the years up to 2005, it was expected that expenditure would be allocated as shown in Figure 13, with a significant rise in disposal equipment costs.

Figure 13: Expenditure forecast for 2002–2005



Conclusions

A number of concerns remained. Wastage rates remained very high for most vaccines – up to six in some cases. Cold chain maintenance costs were also high – solar refrigerators were a particular problem due to salt water corrosion and the lack of effective incineration meant that sharps disposal was becoming an increasing problem. Targets for future activities included research into pneumococcal vaccines leading to subsequent introduction, the introduction of pentavalent vaccine, and a move towards cold chain self-sufficiency.

2.6 The role of the ICC in identifying and covering low immunization coverage areas

Dr Zhou Jun (Ministry of Health, China)

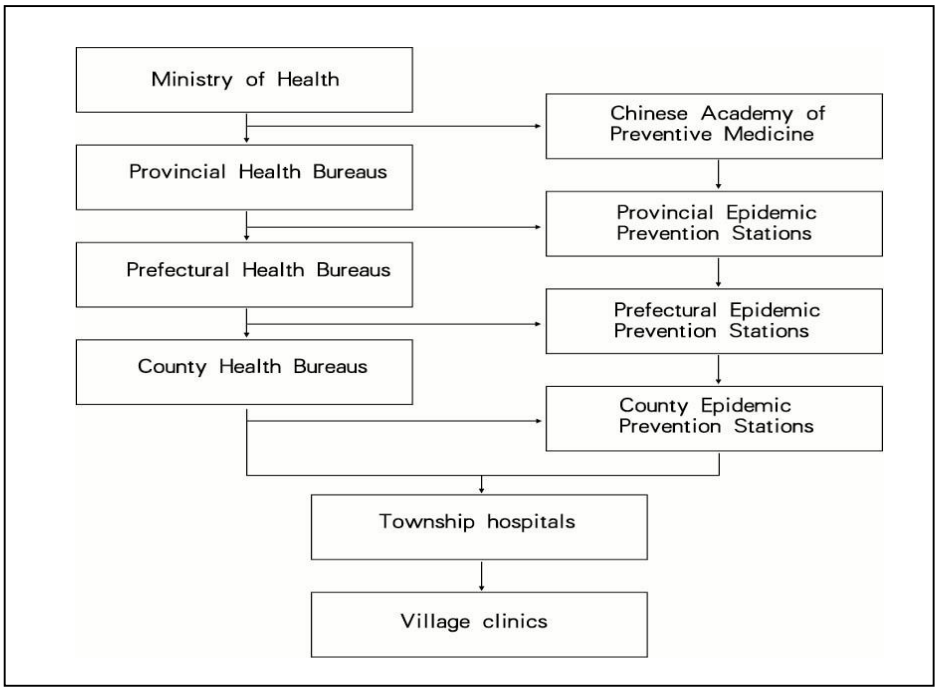
Background

Dr Zhou opened his presentation with some background information on China:

- Population: 1.3 billion; birth rate 15.23 per 1000
- Land area: 9.6 million km^2; borders total 23 238 km
- Administrative details:
  - Province level: 23 provinces; 5 autonomous regions; 4 municipalities; 2 special administrative regions (Hong Kong and Macao)
  - 335 prefectures (including cities)
  - 2863 counties (including cities and districts)
  - 45 500 townships and 740 000 administrative villages

He went on to describe the organization of the health care system, noting that the Epidemic Prevention Stations were responsible for EPI implementation – see Figure 14.

Figure 14: Health organization chart, China



Routine immunization had been introduced in China starting in 1978. Vaccine-preventable disease incidence from 1950 to 2000 showed dramatic decrease due to the impact of immunization programme achievements.

Despite a generally high level of reported coverage, there were pockets of low coverage in certain areas. These included areas with less than six routine immunization rounds per year, poor and remote areas, border areas, and minority group areas as well as the floating population of around 1.5 million children nationwide. In addition, some areas were affected by cold chain equipment shortages and breakdowns.

The ICC in China

Dr Zhou went on to discuss the ICC mechanism in China. The national ICC had been set up in 1991 by the Ministry of Health, with representatives from the ministry and from the Chinese Academy of Preventive Medicine (CAPM), WHO, UNICEF and JICA. The World Bank, Centers for Disease Control and Prevention (CDC), AusAID, Luxembourg and other NGOs were also involved.

The purpose of the ICC was to provide suggestions, to solve problems and to mobilize support. Regular monthly or bimonthly meetings were held to review data, exchange information, determine problems, identify solutions and coordinate efforts. CAPM and the MoH provided feedback on these meetings, passing this to local health departments by means of a monthly immunization update publication. In addition, in between the formal meetings, there was a continuous exchange of information and coordination amongst the ICC members.

Through their work, the ICC had identified four major problems related to immunization coverage:

- poor data quality in routine reporting;
- shortages of cold chain equipment;
- pockets of low routine coverage, and
- lack of budget for new vaccines (specifically HBV).

Poor data quality

Dr Zhou went on to discuss the issue of poor data quality. 1n 1999, the total target population of children under 12 months old was 19.2 million. There were 2887 county level reporting sites and more than 90% of these reported to the national level. Despite this level of reporting, the recorded number of target children was only about 60% of the expected number.

The ICC considered that possible reasons for this shortfall were as follows:

- that not all the targeted children were found and immunized;
- that information was missing from some reporting units;
- that no information had been collected on the immunization of ‘floating children’; and
- that there were reporting errors.

Accordingly the ICC had decided to conduct a survey in areas where there were fewer reported target children than expected. This survey was carried out with funding from UNICEF and support from WHO and JICA. The World Bank immunization project

contributed an improved reporting system and new forms. This initiative resulted in increased monitoring and supervision of the problem at each level. ICC members also participated in EPI reviews.

The survey was carried out in 1999 in three provinces located in north, mid and west China, covering 81 villages. The survey showed that the reported birth cohort in these areas was at least 50% greater than routine coverage reports had suggested. In all, 2024 births were identified and 90% of living children had been fully immunized by the age of 12 months. These results indicated that underreporting of immunization was not due to low coverage as such, but resulted from the failure to submit village-level reports to the township level. The survey concluded that the quality and completeness of the routine immunization coverage reporting system needed to be improved.

Shortages of cold chain equipment

In the 1980s China had established a cold chain system with support from UNICEF. By 1987, this system covered all counties. Much of the equipment was now more than 10 years old and in need of replacement. The lack of the reliable equipment was affecting the number of routine immunization rounds that could be carried out per year and possibly affecting vaccine potency.

In order to overcome these problems the World Bank immunization project had been launched in 1996. This covered 10 provinces, with additional inputs from UNICEF, WHO and JICA (Figure 15). In 1998 China suffered the heaviest flooding in its history and JICA responded by providing US$ 6 million worth of basic cold chain equipment support in seven flood-affected provinces. In 2000, the Chinese Government launched a five-year cold chain project, funded at the rate of US$ 2.4 million per year.

Figure 15: Location of provinces in World Bank funded cold chain project

Pockets of low routine coverage

Dr Zhou noted that, until an outbreak had occurred, it was often difficult to identify areas of low coverage. For example, in Qinghai province, investigations after one imported polio case in October 1999 had revealed routine coverage in the affected county of less than 30–50%. In response to this outbreak, the ICC had taken the following actions:

- held urgent emergency meetings;
- drafted detailed plans and guidelines; and
- mobilized funds for OPV and provided operational expenses for supplementary immunization.

International experts had participated in reviews of immunization activities and management systems in a wide area around Qinghai case.

The ICC played an important role in dealing with the Qinghai outbreak. Two mopping-up rounds where conducted in November 1999, followed by six sub-national immunization days (SNIDs) in 1999 and 2000.

An active search for additional cases had been conducted in hospitals and in house-to-house visits. Laboratory investigations by CAPM and CDC had confirmed the place of importation. No additional cases had been found.

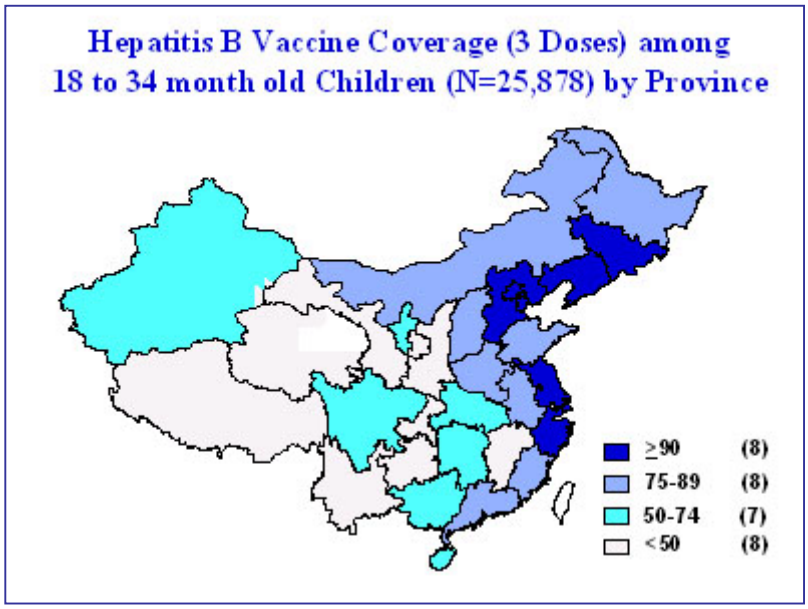
Lack of budget for hepatitis B vaccine

Hepatitis B was a major public health problem in China, with an overall HBsAg prevalence of 9.7%. This corresponded to 120 million people – more than one third of the world's

Hepatitis B carriers. An estimated 280 thousand died each year due to liver cancer and an estimated 130 thousand died each year due to cirrhosis. While other childhood vaccines are free, patients had to pay for HepB vaccine because of a shortage of government funds. This results in low take-up of the vaccine in poverty-stricken areas.

In 1992, the Ministry of Health had recommended routine HepB immunization for infants with advice that doses should be given at 0, 1, and 6 months of age. A dose at birth was recommended, wherever possible, to prevent perinatal hepatitis B virus (HBV) transmission. Figure 16 shows coverage rates for the vaccine – less than 75% on average.

Figure 16: Hepatitis B coverage by province



In order to overcome the budget problem, the ICC had established the China Hepatitis B Foundation (an NGO). This organization provided free vaccine to some poverty areas. The World Bank immunization project also included funds to cover half the cost of HepB vaccine in poverty areas and its target was to increase HepB immunization coverage. There was a GAVI project proposal for support for hepatitis B vaccine to 11 poverty provinces and the Government of China has also agreed to provide funds for vaccine in poverty areas, linked to the GAVI proposal. Figure 17 shows the provinces covered by the GAVI project.

Figure 17: Provinces covered by GAVI-funded hepatitis B project

Conclusions

Dr Zhou concluded his presentation by remarking that the ICC in China had been very successful owing to good cooperation, communication and coordination between the member agencies. The ICC played an important role in the success of routine immunization in China, especially in developing increased immunization coverage.

He expected that the contribution of the ICC would continue over the coming years. This commitment was illustrated by new projects starting up (GAVI, JICA, UNICEF) and by the recently formed safe injections working group. The ICC would also provide assistance with coordination, resource mobilization and advocacy and would coordinate activities aimed at improving HepB vaccine coverage. The ICC would also support evaluation of the financial options for integrating HepB immunization into routine immunization services, the progress of measles control and neonatal tetanus elimination, and would work to maintain China's polio-free status.

2.7 Discussion

Dr Anil Varshney (PATH) asked Dr Lepani if vaccine was provided to the private sector and whether private doctors charged for the service.

Dr Lepani replied that vaccine was provided free of charge. In return private doctors are required to supply coverage data. Doctors could charge patients only for their time and for consumables, such as syringes.

Anthony Battersby (FBA) asked Dr Zhou to comment on circulation in China of HepB vaccine, some of which was free and some of which has to be paid for. How does the programme ensure that the free vaccine is not sold privately?

Dr Zhou replied that this was a short-term issue as all HepB vaccine would be free as of 2002.

Dr S.C Gupta (National Polio, India) asked if China had provincial ICCs.

Dr Zhou replied that there were no ICCs at the sub-national level.

Robert Steinglass (BASICS) asked Dr Lipani what happened in 1993–94 after the initial trial of Hib vaccine and before its subsequent reintroduction?

Dr Lepani replied that the initial batch of Hib vaccine was donated by Pasteur Aventis. After this was used up there was a one-year period to evaluate its effect. The results were used to drum up support to continue the programme. In 1997, the new vaccine was fully funded by the Fijian government. In contrast HepB vaccine is paid for by the Australian government. Recombinant HepB is now used after the initial use of plasma-derived vaccine.

Peter Carrasco (PAHO) commented that a nice story had been told by both contributors. Dr Lepani's talk demonstrated how it was possible to lobby governments effectively to provide additional money for new vaccines. Dr Zhou's talk demonstrated how to use the ICC for dealing with technical problems. He then asked Dr Zhou if there was any Rotary participation in China.

Alan Schnur (WHO China) on behalf of Dr Zhou said that there was an agreement with Rotary to supply OPV, coordinated by WHO. However there are no Rotary clubs in mainland China and Rotary don't sit on the ICC.

Dr Lepani commented that community motivation in Fiji was achieved via the media, via community outreach programmes, by nurses, by local community forums and not least through the church, which is very strong in Fiji and very important for advocacy.

No specific themes and conclusions were drawn for this session.

Chair: Bob Davis (UNICEF ESARO)

2.8 Human resource strengthening

Tom O'Connell (WHO HQ)

Introduction

Tom O'Connell introduced his presentation. He noted that the first four tasks of a sustainable long-term human resources strengthening exercise were:

- to determine the human resources necessary to implement chosen strategies and annual objectives;
- to identify resource gaps and build up training needs;
- to allocate available resources to meet identified needs, making best use of staff knowledge and skills; and
- to develop a strategy for filling any resource gaps.

The working environment

The working environment in which human resources were to be deployed should also be considered and questioned in regard to:

- **Context***:* consider political and social trends, disease burden and donor influence. Are current policies/strategies feasible given the national context?
- **Policies***:* consider national health goals, health sector reform and overall national goals. Are human resources polices/strategies aligned with health sector trends, as well as the needs of staff? Do they fill real national AND staff needs?
- **Support systems***:* consider available resources, educational institutions and the extent of administrative support for human resources strengthening. Is there a process to monitor and evaluate the implementation of human resources policies?

He went on to outline key areas to consider when preparing a human resources development plan. These areas included:

- recruitment and training;
- improving the use and allocation of available staff with particular regard to staffing problems in rural areas;
- improving staff motivation and the workplace environment;
- improving programme management and leadership skills such as supervision, team-building, etc.; and
- dealing with health sector reform – recent experience had shown that this could often have adverse impacts on human resources.

Training

The primary goal of training was to increase staff ability at all levels and to identify and to fill capacity gaps. Two specific criticisms were commonly heard on existing training courses:

1. That there was a gap between the skills needed and skills/knowledge provided by courses.
   Cause: Training not linked to specific, clearly defined needs; it was generic and over-broad and not well related to the day-to-day experience of the trainees.

2. What WAS taught rarely resulted in a sustainable change in practices.
   Cause: The method of training and follow-up was not appropriate for the outcome desired. Often this was not just a training problem, but related to deficiencies in the work-place environment.

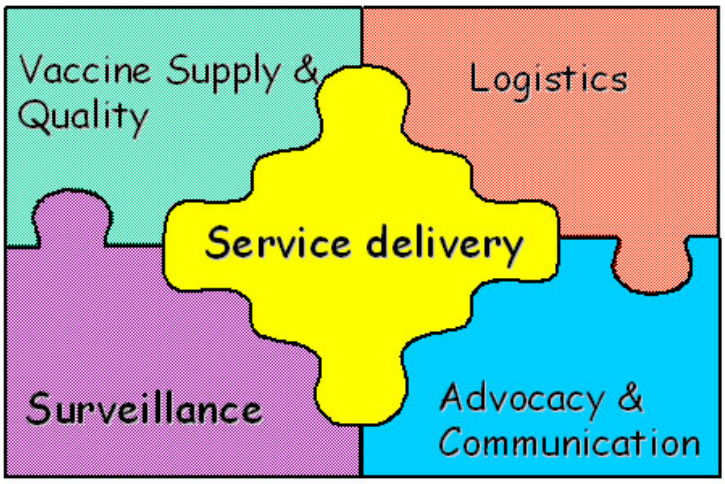
To overcome these criticisms, a training needs assessment should be carried out to establish:

- the skills/knowledge that was required to achieve programme objectives in terms of current activities and in terms of any planned new strategies and technologies; and

- a comparison between expected outcomes and actual outcomes for the previous 2–5 years, and for the current year. Programme indicators should be used to establish which outcome components were due to lack of staff skills, knowledge and the ability to problem solve and to troubleshoot at the levels at which training was directed.

There were five operational components of an immunization system. Each of these components had a set of standard indicators, designed to be applied at national, sub-national and service levels. These indicators could also be used to assess training needs and to identify resource shortages – Figure 18.

Figure 18: The five operational components of an immunization system



Identifying skills gaps

By carrying out a gap analysis and keeping track of training programmes, it should be possible to identify what skills and capabilities were needed in both the short term and the

long term. Once this has been done a realistic training strategy should be developed to fill the gaps, based upon national priorities and available resources. An active and continuous recruitment and training programme was needed; retention of public sector health staff remained a constant issue due to inadequate pay and benefits, poor working conditions and ineffective management.

Training methods and follow-up

The traditional lecture had proved to be a suitable technique for updating basic knowledge. Lectures should be combined with some form of testing and should be followed by periodic updating. Physical skills – for example, training staff in the use of AD syringes – could be dealt with effectively by demonstration, followed by supervised practice and periodic evaluation.

Teaching management and problem-solving skills was much more difficult. Typically this type of training required the intensive use of participatory case studies, role playing and appraisal based on management indicators. Management indicators were notoriously difficult to measure and to apply to training methods. One approach was to use case studies based on actual country data, analysed in detail and in depth. This type of training should be supported with follow-up workshops.

Ensuring sustainability of training

It was essential to establish whether pre-service curricula, such as nurse training, reflected the actual training needs of the country and incorporated the necessary key skills and knowledge to meet these needs. For example, was training provided in safe injection and disposal techniques? It was important to recruit the right people to meet future needs; often the manager had no control over this, but if he or she could influence these decisions, this was desirable. Finally it was important to assess and to evaluate training on a regular basis so that its impact on programme goals could be measured and traced.

Developing a national training plan

There needed to be a national training plan, incorporating the following features:

- *Training*: identifying the specific skills and knowledge required to achieve programme objectives.
- *Pre-service curricula*: designed to meet future needs.
- *Recruitment policies*: designed to fill current and planned needs.
- *A national training coordinator*: preferably responsible for advocacy, implementation and effectiveness of training across the public health sector.
- *Integrated training*: as an effective way to train senior staff.
- *Evaluation:* assessing the impact of training systematically so that methods could be revised as needed.

Strengthening management and leadership

Teaching management and programme supervision skills was very difficult. It needed to be based on cases studies and on problem solving and data analysis. Managers needed to know

how to set priorities – for example, how to choose between routine and special campaigns, how to analyse and use data for planning and budgeting and how to implement, assess and revise plans. Leadership and team-building skills could be developed in many different ways – for example through training workshops or distance learning.

Managing information

Effective use of information was critical to sustainable human resources management. It was essential to pass on the skills and knowledge of experienced staff and to keep track of best practices and lessons learnt. This could be achieved by encouraging peer-to-peer networking and by disseminating information using distance learning, e-mail forums and other techniques. It was important to make sure that information was widely distributed and was confined to staff at the national level. Finally it was vital to improve the collection, analysis and the use of data for all programme areas.

Strengthening motivation

Good staff motivation helped to implement desired changes. Motivation required leadership and team-building skills so that tasks were delegated and staff had increasing participation in decision-making. In terms of compensation, staff could be encouraged to stay in posts by offering training and routes to career advancement. The impact of health sector reform might impact adversely on motivation and there needed to be support and training to manage change.

Improving staff use and staff allocation

Imbalances in staff distribution needed to be addressed so as to overcome the lack of doctors and other specialist staff in rural areas. The impact of privatization needed to be considered as this could lead to reduced coverage and services. The impact of health sector reform might also have an impact on integrated service delivery at the point of contact level.

Health sector reforms

The impact of decentralization required the development of new skills at district levels with a consequent impact on resource allocation, choice of priorities and data use for planning. Integration of service delivery required that focus needed to be maintained on immunization amid competing priorities – including other preventative health services, Integrated Management of Childhood Illness (IMCI), TB, malaria, etc.

Conclusions

In conclusion, Tom O'Connell said that strengthening human resources required the implementation of holistic policies for:

- recruitment and training;
- strengthening management and leadership skills;
- improving management information systems;
- improving motivation and retention of staff;
- effective allocation of staff skills; and
- health sector reform.

2.9 Discussion

H. T. Raubenheimer (CCCCM South Africa) commented that when there is high pressure on skills, staff move rapidly and this is a problem. It also makes student assessment difficult. In terms of sustainability, some staff are only prepared to be re-deployed to certain locations.

Dianne Phillips (DoH South Africa) reinforced what had just been said. Her programme trains wonderful people, but they move on. She also commented that it is very difficult to change staff behaviour when workload is high. A South African training study has demonstrated that even after formal training has taken place; behaviour hardly alters under such circumstances.

James Cheyne (PATH) asked Tom O'Connell to say something about WHO's long-term plans for training.

Tom O'Connell replied that there is a need to take good people and to put them where they are needed. However, nothing can stop them leaving if the private sector offers more money. To overcome this problem it is necessary to focus on key skills, such as problem solving. Developing these skills can give people the motivation to continue. There is need for national training coordinators. He reported that WHO V&B was now more committed to a long-term approach to training.

Dr Subhan Sarkar (MOH, India) commented that there had been no new WHO training material for mid-level managers since the early 1990s. He is looking for guidance from WHO and looking forward to new mid-level management training material.

Samuel Kamau Muchiru (EPI Kenya) asked the following questions:

- What training options do we have as we move towards training of health workers for new vaccines etc?

- What are the practical ways of motivating health workers?

Dr Emmanuel Taylor (WHO/ICP) commented that training is generally assumed to equal knowledge plus skill, but we never talk about attitude training. How can we introduce this important component?

Alan Schnur (WHO China). Training is a timely and important topic. For example, safe immunization target has not been achieved, despite a huge training effort. An advocacy component is required. Often managers are comfortable with lectures, but we need to look at other training materials and methods. In China, there used to be half day training sessions for health workers when they came in to collect vaccine. However, this is not happening any more. Cascade training needs to be developed. In the immunization field, in-service training is, of necessity, vertical and it is important to focus on this programme-based training.

Peter Carrasco (PAHO) commented that this was not the first time that the issue of training had come up. The updating of training modules requires a lot of time and is not a short-term answer to the problem. In addition, many changes are so rapid that programmes cannot afford to wait for centrally updated source material. PAHO is now using one page fliers and handouts in order to get new information to the field as quickly as possible. We must never forget that supervision is the best form of vertical training available – but it doesn't always work.

Patrick Isingoma (MoH Uganda) noted that often when staff collect their allowances they lose their interest in training.

Tom O'Connell addressed some of the issues raised as follows.

- New versions of WHO training material are coming out by the end of October. Later this material will appear on the WHO web site.
- WHO also has fliers, but it is difficult to put these on the web site.
- In his experience, cascade training doesn't work well because there is no follow-up. WHO is now trying to concentrate on training based on problem solving. This training is then reinforced by two or three follow-ups at intervals of several months.
- It is a good idea to plan training for a 10–15 year horizon.
- There needs to be a better system for drawing together training material from other agencies, so that the wheel is not constantly being reinvented. WHO is trying to find a way to achieve this.

Themes and conclusions

- There is a recurring problem caused by trained staff moving on.
- It was agreed that while there is little that can be done to prevent staff leaving if the private sector offers more money, training should focus on higher level skills, such as problem solving. Developing higher level skills can give people the motivation to continue.
- Training needs to be reinforced by follow-up sessions.
- It is very difficult to change staff behaviour when workload is high.
- There is need for a cadre of national training coordinators and for a long-term approach to training, with a 10–15 year horizon.
- There is need for updated WHO training material for mid-level managers, much of which has not been changed since the early 1990s.
- The importance of attitude training should be emphasized.
- An advocacy component is required. Often managers are comfortable with lectures, but we need to look at other training materials and methods.
- Supervision is the best form of vertical training available.
- One-page fliers and handouts are an effective way of getting new information to the field as quickly as possible.
- There needs to be a better system for drawing together training material from other agencies so that the wheel is not constantly being reinvented.

2.10 Advocacy and demand: reducing drop out rates

Koua Anderson Clementine (Ministry of Health, Côte d'Ivoire)

Background

Dr Anderson Clementine opened her presentation with some background information on Côte d'Ivoire:

- Population: 16 938 232
- Land area: 322 600 km^2
- Under ones: 663 248
- Administrative details:
- 16 health regions
- 61 health districts

Problem identification

She went on to note that the country had suffered from a decline in routine EPI performance in the early 1990s. The indicators for 1994 were as follows:

- DTP3 coverage: 41%
- Drop-out rate between DTP1 and DTP3: 35%
- Districts with DTP3 less than 50%: 13%

In response to these problems, revitalization of routine immunization had been achieved as a result of political commitment at the highest level. An EPI Executive Directorate had been established and the government had allocated adequate resources for the task.

Addressing high drop-out rates

Among the priority problems identified was the very high drop-out rate from DTP1 to DTP3, ranging from 15% to 67% in the various districts. The following were the main causes of this high rate.

- Outreach or mobile immunization strategies had either been halted or had become irregular.
- Immunization schedules were inadequate.
- There was inadequate follow-up of children immunized at both fixed and outreach sessions.
- There were missed opportunities.

Field visits were carried out, and discussions were held with district medical officers to reach a consensus on:

- realistic objectives;
- an adequate immunization strategy;
- activities to implement existing methods effectively to reduce drop-out rates; and
- use of monitoring indicators to establish DTP3 coverage and DTP1/DTP3 drop-out rates.

In addition a number of activities were initiated, including the following.

- There was follow-up of children immunized during outreach and mobile strategies – teams used ordinary exercise books for recording purposes.
- Monthly monitoring of immunization coverage was introduced.
- Surveillance and cold chain monitoring were carried out at service delivery level, at district level and at national level.

- Follow-up and evaluation meetings were carried out three times a year (in May, October and December). There was also follow-up of immunization and surveillance activities and identification of obstacles, together with the adoption of corrective measures to reduce drop-out rates.

At the operational level the following changes were introduced:

- standardization of data collection forms;
- training of vaccinators and supervisors; and
- community involvement via local management committees (COGES) and other community organizations.

For the purposes of census, mobilization and active research:

- There was development and rationalization of outreach and mobile strategies.
- Immunization schedules were developed with community participation.
- Consensus was reached with the community on the timing of immunization sessions.

The success of these interventions was striking. Figures 19 to 21 show the effect of these interventions in the district of Mbahiakro over the years 1999 to 2001. At the start of this period DTP3 coverage was 19%. This had risen to 71% by June 2001.

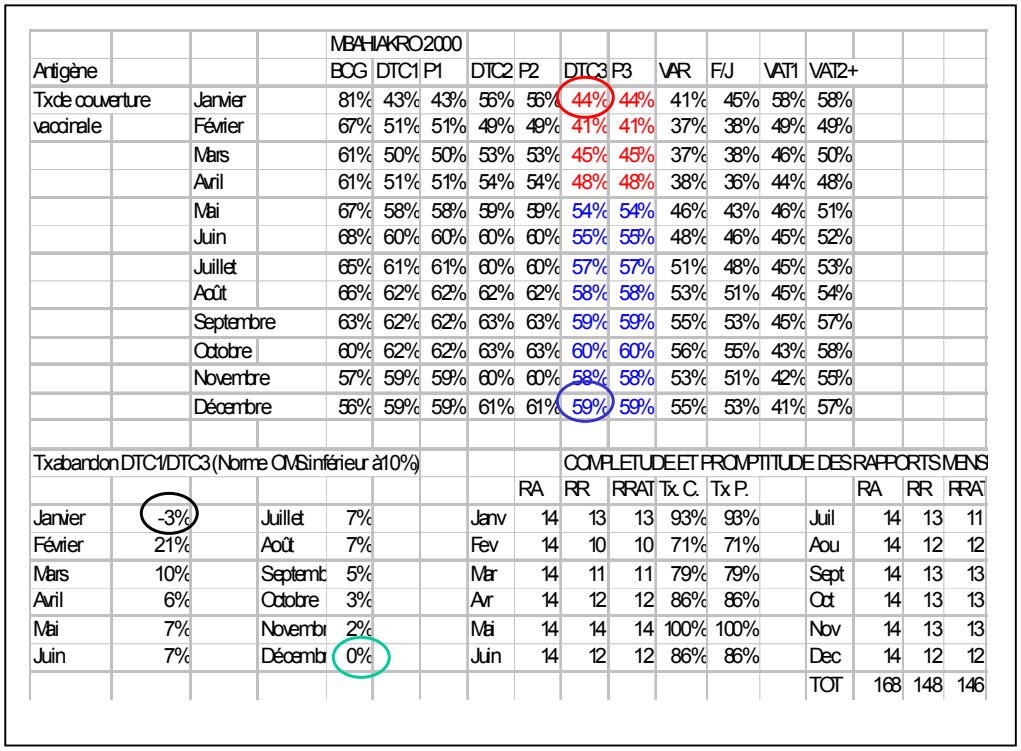
Figure 19: Coverage in Mbahiakro District – 1999

DISTRICT DE MBAHIAKRO 1999

ANTIGENE		BCG	DTC1	P1	DTC2	P2	DTC3	P3	VAR	F.J.	VAT1	VAT2	VAT3
Tx de Couv.	Janvier	35%	40%	33%	26%	22%	19%	19%	24%	28%	41%	30%	
vaccinale	Février	34%	43%	39%	30%	26%	23%	22%	27%	20%	42%	34%	
	Mars	46%	39%	36%	31%	28%	23%	22%	30%	23%	45%	39%	
	Avril	53%	45%	43%	31%	30%	26%	25%	34%	30%	43%	38%	
	Mai	55%	48%	47%	37%	36%	31%	26%	36%	35%	42%	38%	
	Juin	56%	49%	48%	39%	39%	35%	31%	38%	38%	41%	38%	
	Juillet	56%	51%	50%	42%	42%	37%	34%	38%	38%	39%	37%	
	Août	55%	51%	50%	45%	45%	39%	36%	38%	38%	39%	36%	
	Septembre	54%	50%	50%	44%	45%	40%	38%	38%	38%	38%	37%	
	Octobre	52%	49%	49%	43%	43%	40%	38%	37%	37%	39%	36%	
	Novembre	49%	47%	47%	41%	41%	39%	37%	35%	35%	38%	35%	
	Décembre	49%	46%	46%	40%	40%	38%	37%	34%	34%	38%	35%	

Tx abandon DTC1/DTC3 (Norme OMS:inférieur à10%)						COMPLETUDE ET PROMPTITUDE DES RAPPC							
						RA	RR	RRAT	Tx. C.	Tx. P.			RA
Janvier	53%	Juillet	28%		Janv	14	10	7	71%	50%		Juil	14
Février	48%	Août	23%		Fev	14	12	10	86%	71%		Aou	14
Mars	42%	Septembre	21%		Mar	14	14	13	100%	93%		Sept	14
Avril	42%	Octobre	19%		Avr	14	14	12	100%	86%		Oct	12
Mai	36%	Novembre	17%		mai	14	14	13	100%	93%		Nov	14
Juin	29%	Décembre	18%		juin	14	13	12	93%	86%		Dec	14
												TOT	166

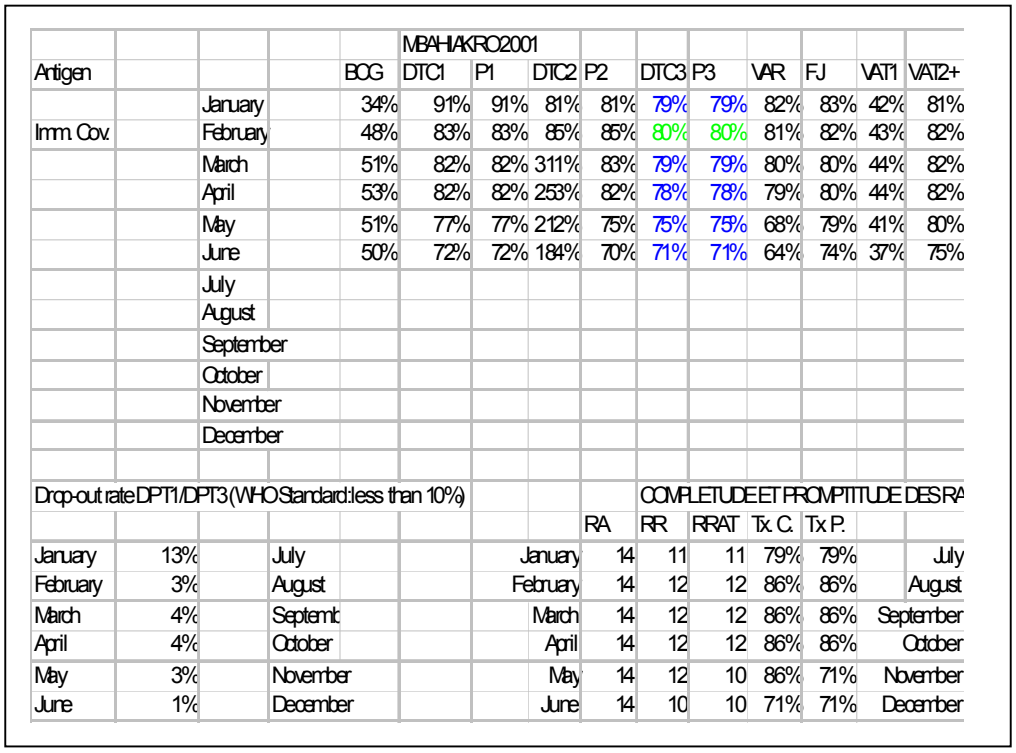
Figure 20: Coverage in Mbahiakro District – 2000



		MBAHIAKRO 2000											
Antigène		BCG	DTC1	P1	DTC2	P2	DTC3	P3	VAR	F/J	VAT1	VAT2+	
Txde couverture	Janvier	81%	43%	43%	56%	56%	44%	44%	41%	45%	58%	58%	
vaccinale	Février	67%	51%	51%	49%	49%	41%	41%	37%	38%	49%	49%	
	Mars	61%	50%	50%	53%	53%	45%	45%	37%	38%	46%	50%	
	Avril	61%	51%	51%	54%	54%	48%	48%	38%	36%	44%	48%	
	Mai	67%	58%	58%	59%	59%	54%	54%	46%	43%	46%	51%	
	Juin	68%	60%	60%	60%	60%	55%	55%	48%	46%	45%	52%	
	Juillet	65%	61%	61%	60%	60%	57%	57%	51%	48%	45%	53%	
	Août	66%	62%	62%	62%	62%	58%	58%	53%	51%	45%	54%	
	Septembre	63%	62%	62%	63%	63%	59%	59%	55%	53%	45%	57%	
	Octobre	60%	62%	62%	63%	63%	60%	60%	56%	55%	43%	58%	
	Novembre	57%	59%	59%	60%	60%	58%	58%	53%	51%	42%	55%	
	Décembre	56%	59%	59%	61%	61%	59%	59%	55%	53%	41%	57%	

Txabandon DTC1/DTC3 (Norme OMS inférieur à 10%)						COMPLETUDE ET PROMPTITUDE DES RAPPORTS MENS							
				RA		RR	RRAT	Tx. C.	Tx P.		RA	RR	RRAT
Janvier	-3%	Juillet	7%	Janv	14	13	13	93%	93%	Juil	14	13	11
Février	21%	Août	7%	Fev	14	10	10	71%	71%	Aou	14	12	12
Mars	10%	Septembr	5%	Mar	14	11	11	79%	79%	Sept	14	13	13
Avril	6%	Octobre	3%	Avr	14	12	12	86%	86%	Oct	14	13	13
Mai	7%	Novembr	2%	Mai	14	14	14	100%	100%	Nov	14	13	13
Juin	7%	Décembr	0%	Juin	14	12	12	86%	86%	Dec	14	12	12
										TOT	168	148	146

Figure 21. Coverage in Mbahiakro District – 2001



		MBAHIAKRO 2001										
Antigen		BCG	DTC1	P1	DTC2	P2	DTC3	P3	VAR	FJ	VAT1	VAT2+
	January	34%	91%	91%	81%	81%	79%	79%	82%	83%	42%	81%
Imm. Cov.	February	48%	83%	83%	85%	85%	80%	80%	81%	82%	43%	82%
	March	51%	82%	82%	311%	83%	79%	79%	80%	80%	44%	82%
	April	53%	82%	82%	253%	82%	78%	78%	79%	80%	44%	82%
	May	51%	77%	77%	212%	75%	75%	75%	68%	79%	41%	80%
	June	50%	72%	72%	184%	70%	71%	71%	64%	74%	37%	75%
	July											
	August											
	September											
	October											
	November											
	December											

Drop-out rate DPT1/DPT3 (WHO Standard: less than 10%)						COMPLETUDE ET PROMPTITUDE DES RA						
						RA	RR	RRAT	Tx. C.	Tx P.		
January	13%	July		January	14	11	11	79%	79%		July	
February	3%	August		February	14	12	12	86%	86%		August	
March	4%	Septembr		March	14	12	12	86%	86%	September		
April	4%	October		April	14	12	12	86%	86%	October		
May	3%	November		May	14	12	10	86%	71%	November		
June	1%	December		June	14	10	10	71%	71%	December		

Figure 22 shows the trends in drop-out rates and DTP3 coverage for all districts from 1994 to 2000. Figure 23 shows the increase in the number of health districts with DTP3 coverage above 50% for the same period.

Figure 22: Trends in drop-out rates and DTP3 coverage from 1994 to 2000

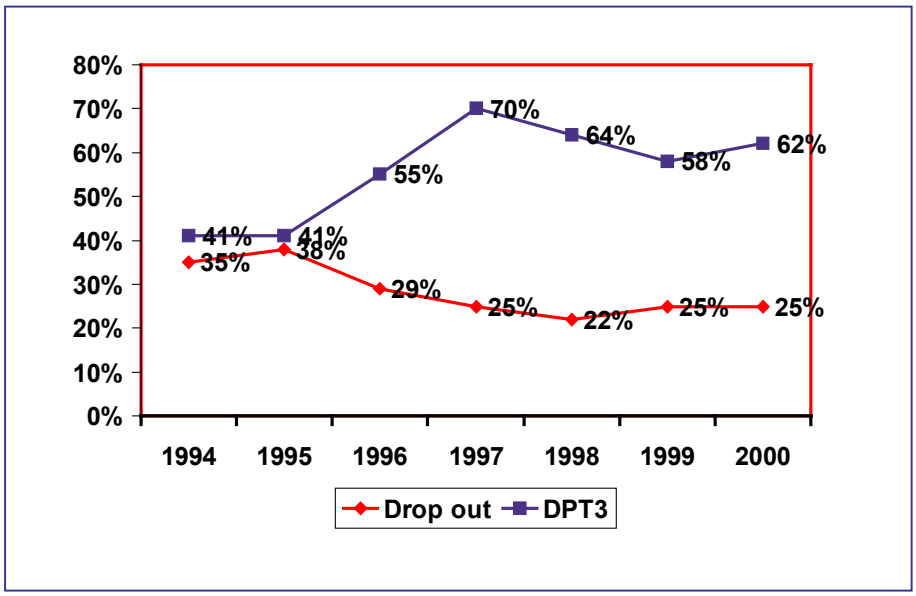
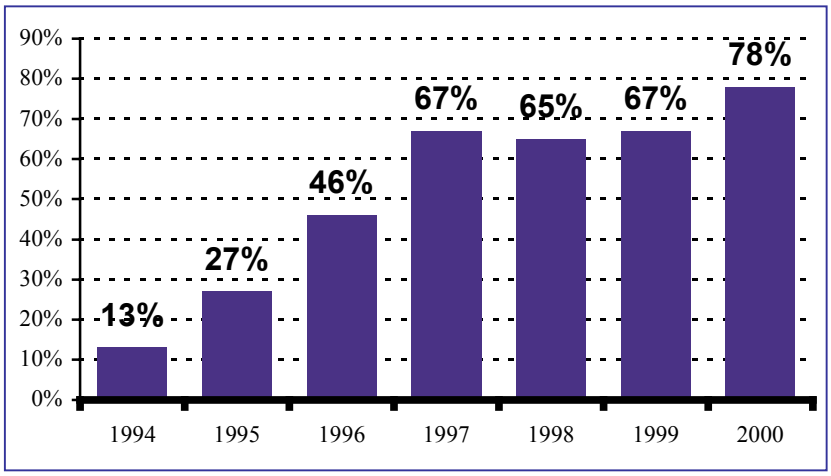


Figure 23: Districts with DTP3 coverage rates above 50% from 1994 to 2000



Dr Anderson Clementine noted that these achievements had been made possible because consensus had been reached with all stakeholders at the operational level. Over the last few years, the number of health districts had increased from 46 to 62. This had involved much training of new district personnel. Further training gains had been achieved in the 'health areas' – a subdivision of the health districts. Drop-out rates had been monitored at the peripheral level and there had been much involvement with the community at village level.

This had resulted in the identification of key problems and the setting of realistic objectives based on existing programme capacity at the operational level. In addition, appropriate strategies to deal with these problems had been agreed and relevant activities, not requiring additional cost expenditure, had been implemented.

Consensus had also been reached with local communities on issues relating to the immunization schedule and their implication for immunization activities. Finally, improved monitoring had been carried out at all levels.

2.11 Discussion

Hans Everts (WHO) asked for the wastage rate during the period analysed.

Patrick Isingoma (MoH Uganda) asked what the statement 'repeat of DTP1' meant? What are they doing with local community leaders? Timely reporting is essential to keep track of progress on drop out rates.

Koua Anderson Clementine responded first to Hans Everts' question. There is no presentation of wastage rate data because Côte d'Ivoire has only recently adopted the multi-dose vial policy. Since 1998, a vial was opened for every child, on demand. In response to Patrick Isingoma's question, duplicate reporting of DTP1 arose during outreach and mobile activities tally sheets were filled up without good records because vaccination cards often get lost. She got around this problem by working with village heads and school teachers to draw up a register of those targeted for 2nd and 3rd dose DTP in the following session.

Robert Steinglass (BASICS) commented that the Côte d'Ivoire approach has great applicability to most other countries with high drop-out rates. It shows that monitoring can be used as an intervention – not just as a management function. Getting staff to understand their own data can improve performance. Is there evidence that there has been improvement in the quality and accuracy of data recorded?

Koua Anderson Clementine replied that the requested programme review ended in July 2001 and that the data sets were pretty close to the administrative data.

Patrick Isingoma (MoH Uganda). How were teachers involved, and were they paid, or was it voluntary? How are they motivated to continue?

Koua Anderson Clementine noted that there was a small expenditure on notebooks used for village outreach recording targeted children. Since 1995, the immunization programme has had its own budget and additional resources have recently been received from GAVI. This has allowed the programme to enlarge community participation from community level up to prefect level. They are now capable of sustaining the programme over the long term.

Themes and conclusions

- It was agreed that the advocacy approach adopted in Côte d'Ivoire has applicability to other countries with high drop out rates.

2.12 Outsourcing transport management in Nigeria

Fred Simiyu (WHO Nigeria) and Ngozi Nebuwa (Riders for Health, Nigeria)

The case for outsourcing transport

Fred Simiyu introduced the case for outsourcing transport management. Management of transport was a major problem throughout Africa. In Nigeria, the challenges were particularly severe owing to problems with terrain, vehicle maintenance, fuel adulteration and security issues. In addition Nigeria had a federal system of government which introduced multiple levels of decision-making. WHO had a large fleet of vehicles (82 in all).

Coupled with this, Nigeria was one of four reservoirs for the wild polio virus in the African region and there was an urgent need for increased mobility for AFP surveillance activities.

As an organization, WHO did not have the specialist skills needed to manage vehicles. Accordingly WHO Nigeria decided on transport outsourcing so as to ensure that functional vehicles were available 100% of the time, operated at a reasonable cost. Riders for Health (RfH) were contracted to provide this service.

The project

The planned project had two components:

- *Fleet management* was made the responsibility of RfH, on the basis of a 'zero breakdown' agreement;

- *Operations management* was handled by the WHO Country Office. Their task was to plan vehicle movements, monitor itineraries, and arrange payments and document experience.

Three groups of people interacted to manage the fleet:

- RfH;

- WHO technical staff , drivers and users;

- WHO Country Office, working through the Administrative Officer and EPI Logistics Officer to liaise with RfH.

Riders for Health

Ngozi Nbuwa stressed that RfH was not primarily a transport organization. Since 1989 it had specialized in training nationals of African countries to operate effective transport management systems. The organization's aim was to contribute to African development by ensuring that vehicles, used in the delivery of public health services, were available for use by health personnel, for the maximum possible time and at the minimum possible cost.

Transport Resource Management

RfH had developed a set of management techniques known as Transport Resource Management (TRM), based upon the proper management of three resources:

3. Vehicles and drivers

- Planned preventive maintenance (PPM), using genuine spare parts, leading to zero-breakdown
- Selection and training of local technicians to carry out PPM
- Driver training to ensure that vehicles were properly driven

4. Money

- A realistic operating cost per kilometre was established at the beginning of the life of each vehicle.
- RfH charged the customer on the basis of this pre-calculated cost per kilometre. This mechanism ensured that funds were always available to cover the costs of replacement parts, fuel, lubricants, etc.

5. People

- People were re-orientated and constantly trained to understand the principles of the TRM management system.
- Customers/partners had to be educated about the principles of the system.

Of these three resources, people-management was generally the most difficult component of a vehicle management system. For example, significant training was necessary to reorientate mechanics to PPM since most African mechanics had hitherto only been used to dealing with emergency repairs. Problems with vehicles generally arose because people failed to understand the need for the planned maintenance regime described in the manufacturer's handbook.

RfH objectives

In addition to Nigeria, RfH were currently operating fleets in Zimbabwe, in the Democratic Republic of Congo, in Kenya and in the Gambia. Their objectives in Nigeria were:

6. To train drivers to drive vehicles safely on all road surfaces in such a way as to ensure the best interests of the vehicles, the drivers, the passengers and third parties. In addition the aim was to train drivers to use the vehicles in the most efficient and cost effective manner.

7. To create and operate a nationwide system throughout Nigeria for managing vehicles, ensuring:

- that fuel and lubricants were always available;
- that vehicle servicing were carried out at appropriate intervals;
- that replacement parts were available when needed; and
- that driving standards were maintained.

8. To ensure that the management system was able to accommodate growth in the size of the vehicle fleet.

9. To provide management data to WHO on the performance and status of the vehicles.

10. To set up efficient and accurate accounting systems so that WHO received up-to-date information on kilometres travelled and the related cost implications.

11. To provide basic insurance and to manage all vehicle insurance matters.

12. To cooperate with third parties whose work or interest was affected by the programme.

13. To replace the vehicles out of running costs, after they had reached the end of their economic lifespan.

In regard to item 8, Ngozi Nbuwa noted that there was an option in RfH's management agreement to charge a mileage cost which included the cost of replacing each vehicle at the end of its economic life – typically after 200 000–300 000 km.

Results and achievements

After two years operation, all the vehicles were still functioning effectively and remained in good condition. The oldest vehicles were close to being replaced. The following tasks had been carried out.

- Drivers had been trained and re-trained.
- A nationwide management system for the 82 WHO vehicles in the fleet had been established;
- Fuel storage tanks had been installed at strategic locations around the country.
- 41 local mechanics (one per state) had been identified and trained.
- A system for the purchase and distribution of replacement parts around the country had been developed.
- A logbook system for vehicle data collection had been set up.
- Software for collating and managing vehicle data had been installed, and staff trained in its use.

Constraints

WHO had been very supportive. However RfH had had no control over the recruitment, treatment and disciplining of drivers because they were directly employed by WHO. Normally RfH employed drivers directly. Initially the WHO Administrative Office had not been very receptive. These problems were being overcome.

WHO's experience

Fred Simyu continued the presentation on behalf of WHO, Nigeria. Deployment of reliable vehicles had been a key factor in ensuring:

- higher mobility for SOs leading to improved community sensitization and supervision for AFP surveillance;
- increase in numbers of stool specimen collection;
- increased detection of acute flaccid paralysis (AFP) cases;
- improved 60-days follow-up of cases by SOs; and
- examination of more cases within 48 hrs of notification.

Figures 24 and 25 illustrate AFP collection and AFP case detection in 2000 and 2001.

Figure 24: AFP stool sample collection 2000 and 2001

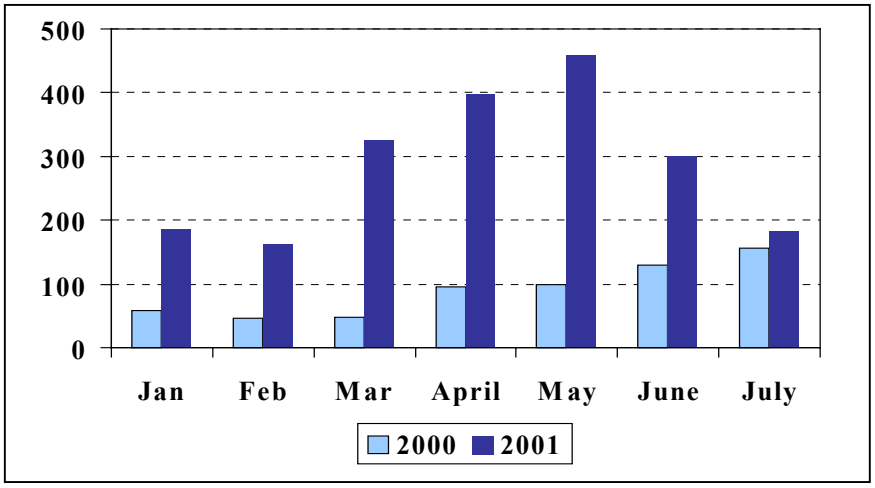
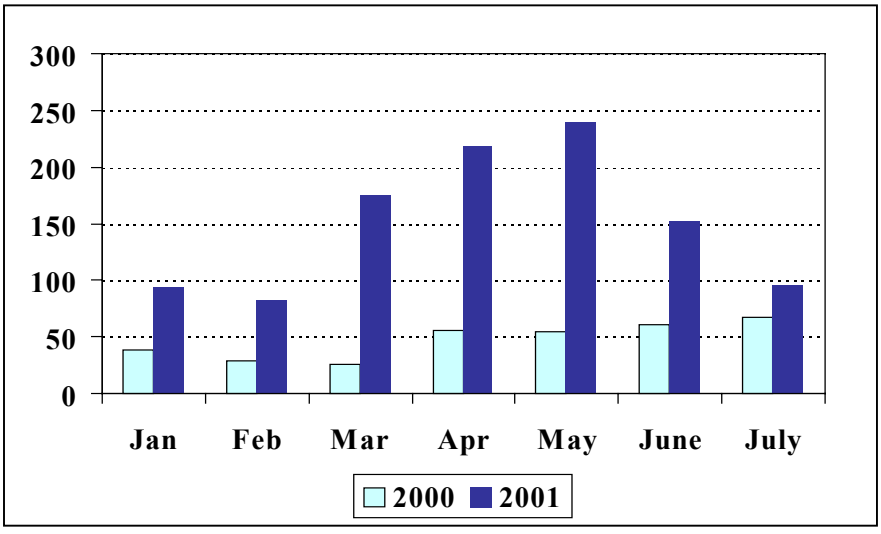


Figure 25: AFP cases detected in 2000 and 2001



As Ngozi Nbuwa had previously noted, there was initially a strong reluctance on the part of the WHO Country Office to participate in the outsourcing experiment. This had resulted in poor coordination with RfH, flawed recruitment of drivers, lack of clear record-keeping within WHO regarding key performance indicators on vehicle availability and efficiency of utilization and operational costs.

Subsequently this negative situation had changed. The current leadership in the Country Office had created an enabling environment for the success of the project. As a result of this, transport management had been discussed at three meetings in the previous month and more meetings were planned; performance monitoring tools were being discussed to assess their suitability, and security was being improved by equipping vehicles with HF radios and emergency medical kits.

Conclusions

Fred Simyu commented that RfH has done a commendable job in keeping the vehicles functional. However, vehicle outsourcing depended upon collaboration right from the start. The general conclusion had been that transport management worked better with outsourcing.

Ngozi Nbuwa advised delegates that RfH had recently set up the International Academy for Vehicle Management (IAVM), based in Zimbabwe.

3. Third session: Vaccine management

Chair: Dr Robert Steinglass (BASICS)

3.1 Vaccine management training project: overview **

Dr Ümit Kartoğlu (WHO HQ)

Immunization programmes in Africa are faced with many challenges. The global objectives of immunization programmes for the next years are:

- to eradicate poliomyelitis, to control measles and yellow fever, and to eliminate MNT;
- to improve coverage and to extend the immunization services to populations that have never before been reached or which remain hard to reach; and
- to introduce new vaccines.

All the programmes designed to achieve the above-mentioned objectives have their own peculiarities, but they have one thing in common: vaccine management.

Programme reviews and many other evaluations conducted over the past years have confirmed that logistics problems remain an obstacle to achieving substantial progress in immunization. Vaccine management, one of the major components of immunization logistics, plays a major role in the low performance observed in these immunization programmes.

One of the influences that led GAVI to focus on infrastructure strengthening is the perception that cold chain and vaccine distribution mechanisms in countries are disintegrating. The real need for better vaccine management practices is demonstrated by the high levels of vaccine wastage in many countries (as recorded on GAVI fund application forms); the failure to adopt policies and equipment that would reduce vaccine wastage such as MDVP (multi-dose vial policy) and VVMs, and the adverse events due, at least partially, to inappropriate vaccine distribution practices.

In the early days of EPI, the focus was on developing a cadre of trained staff; much effort was put into disseminating training manuals and materials and ensuring that training was carried out at all levels. With pressures such as multivalent health staff, high staff turnover rates, and the introduction of new vaccines and technologies, the need for training in better vaccine management practices is now urgent. However, the effort this would take, were it all be done using the traditional WHO cascade-type training approach, would overwhelm existing staff.

The vaccine management training project is being developed as an answer to these concerns. The project looks at techniques to ensure that training and management improvement takes place in a way that will be sustainable, while minimizing the burden on any one level. The

project is based on a five step approach to infrastructure strengthening – an approach that has proven successful in other training activites. These steps are:

- "benchmarking" an ideal system to develop assessment tool and critical indicators;
- performing assessments against indicators;
- developing national plans to address the gaps identified;
- providing technical inputs; and
- monitoring the impact of plan implementation.

This project is being jointly developed by WHO HQ, the WHO Regional Office for Africa (AFRO) and PATH and will be implemented in a group of African countries.

The overall objective of the vaccine management project is to ensure appropriate implementation of policies that can facilitate good vaccine management practices.

In general, two major basic intervention strategies are to be used.

1. Support to assist the translation of global policies into local action

In recent years, WHO and UNICEF have issued new global policies to improve the administration of safe and effective vaccines. If adopted, these policies can improve the efficiency and effectiveness of vaccination programmes, simplify vaccine handling, and reduce vaccine wastage. These policies can improve the availability, quality and safety of immunization efforts. The project uses support strategies to help countries to develop national policies and procedures related to vaccine management. This support activity focuses mainly on the writing of national policies and procedures and on the preparation of activity and evaluation plans.

2. Capacity-building for sustained programme delivery

This strategy focuses on systems development in local administrative structures; organized training and other forms of capacity building; management support at all levels of public sector, and participation in operations and evaluations. Technical inputs are provided in the form of training, using standardized courses held at two training centres in Africa (Ghana and Senegal), both of which have been selected on the basis of pre-defined criteria. The roles of these centres are not limited to providing training only – they are also expected to play a part in performing assessments; facilitating policy workshops; developing curricula. They will also ensure that in-country training is done and that its impact is monitored once trainees return to their own locations.

3.2 Vaccine management – country assessments

Dr Souleymane Kone (WHO Côte d'Ivoire)

The vaccine management training project comprises four main components: assessment, policy workshops, training and monitoring.

Dr Kone started by noting that country assessments made up the second of the five steps outlined by Dr Kartoğlu in his earlier review of the Vaccine Management Project. He intended to discuss the assessment tool itself; the methodology that was used; the results that

had been obtained, by indicator and by level, and, finally, the conclusions that had been drawn from the assessment exercise.

Assessment tool

The assessment tool was designed to investigate vaccine management knowledge and practices amongst health staff operating at the various different levels in a country. This information would then be used to identify knowledge and performance gaps so that suitable support could be provided in the future.

Nine critical indicators had been developed for the assessment. The tool was formulated so that the performance of the vaccine management system could be assessed against each of these indicators at each level in the system (national, sub-national or service delivery). For every indicator there was a set of key questions, each to be scored either zero (no) or one (yes). The sum of these scores was then normalized to give an overall score for the indicator on a scale of zero to five. The nine indicators were:

1. Flexibility of cold chain
2. Vaccine availability
3. Stock recording system
4. Distribution system
5. Cold chain reliability
6. Proper diluent use
7. VVM use
8. Multi-dose vial policy
9. Wastage control

Assessment methodology

The tool was initially being used in 13 countries in the WHO African Region, of which 11 studies had so far been completed. Assessments were carried out at national, sub-national (regions, provinces and districts) and service delivery levels. Sites for sub-national and service delivery assessments were selected using the most recent available DTP3 coverage rate data.

Results

The results of the assessments can be categorized as follows (Table 3):

Table 3. Summary of areas for improvement identified through vaccine management assessments in Africa

Description	Areas for improvement
Flexible cold chain	Lack of individual refrigerator records on the cover
Availability of vaccines	Non-sufficient stock levels Lack of knowledge on how to estimate vaccine needs for one supply period
Stock records	Non-availability of stock records for diluents Not updated balance levels Lack of stock inventories
Vaccine distribution	Lack of established mini and maxi stock levels Lack of a plan for vaccine deliveries Non-observance of 'first expiry first out' principle Not using VVM status as an exception to Earliest Expiry First Out (EEFO) principle
Vaccine storage	Temperature recording being done only once a day Unacceptable temperature levels recorded Maintenance of the cold chain not scheduled/done
Diluents	Non-matching stock levels of diluents with freeze-dried vaccines
VVMs	Lack of knowledge on how to read VVMs Lack of knowledge on how to use VVM information for vaccine management
MDVP	MDVP is becoming a national policy Lack of knowledge on MDVP
Vaccine wastage	Non-availability of vaccine wastage rates Lack of knowledge on how to calculate vaccine wastage No initiatives are taken based on wastage rates when available

Conclusions

Dr Kone concluded by remarking that the assessments carried out so far had highlighted many gaps in the vaccine management systems in the countries visited. In particular, they had revealed weak skills even where training had been carried out. Other shortcomings shown up by the study included improper use of vaccine, including misuse of VVMs; poor or non-existent implementation of MDVP; improper use of diluents; poor stock monitoring and stock control at all levels, and weak or non-existent control of vaccine wastage.

These shortcomings led to big concerns over both disease control and financial control. Poor vaccine management was likely to result in:

- low levels of protection, even where coverage levels were high; and
- missed deadlines for eradication and elimination of target diseases.

Poor financial control was likely to lead to:

- wasted vaccine; and
- increased resource requirements for the immunization programme.

However, Dr Kone noted that opportunities for improvement were available. These included:

- innovative management policies designed to improve vaccine utilization; for example to reduce wastage (VVMs and MDVP) and to improve packaging/vial size;
- better vaccine management tools such as vaccine forecasting tools and stock monitoring and control software; and
- new partnership arrangements leading to increasing accountability, including ICC, VII and GAVI.

New approaches were needed, including a drive to improve training, with an emphasis on practical demonstration rather than classroom-based learning. Training methods should also make full use of follow-up and feedback. Appropriate reporting systems should be introduced making full use of effective manual and software tools and with high level involvement using agencies such as the ICC as well as policy workshops. The Vaccine Management Network was a useful mechanism for exchanging and sharing country experience and information.

3.3 Discussion

Mogens Munk (UNICEF consultant). Vaccine management includes coverage reporting, so where is the software for handling the data? The original stock control system is no longer available because of Y2K incompatibility problems.

Ümit Kartoğlu. The project deals mainly with vaccine from the time it arrives at the central store, until it goes out into the field. It does not deal with coverage issues. It does deal with cold chain issues such as temperature monitoring, shipping of diluents with vaccines, VVMs, wastage checking etc. Stock control can easily be done manually, or by using an Excel spreadsheet.

Dr Anil Varshney (PATH) supported the view that single sheet manual reporting systems are perfectly adequate.

Dianne Phillips (DoH. South Africa) asked where does the reverse cold chain for AFP stool samples fit in to the project?

Ümit Kartoğlu agreed that maybe this should be included.

Dr Subhan Sarkar (MOH, India). At the beginning of EPI we had a clear vision. Now we are talking about multiple systems and multiple data and things are not so simple. Can we think of an integrated approach so that the impact of all these multiple systems is minimized for

management purposes? How do we use the large quantities of data produced by these multiple systems? There is a danger of fragmentation.

Ümit Kartoğlu stressed that the project is addressing problems of vaccine management, not injection safety. However vaccine safety and waste management would be discussed, in separate session, with the participants attending the vaccine management training sessions.

James Cheyne (PATH) wondered whether the evaluation technique could be simplified over time. He noted that process indicators were being used but that there were no outcome indicators – e.g. the correct quantities of vaccine delivered on time to the right place. He asked also whether there was room for judgement in this method or whether it was entirely numerical.

Dr Ümit Kartoğlu, commenting on James Cheyne's question regarding process indicators, said that process indicators were used, but that there are questions which are more outcome oriented. For example, checks on whether facility stocks were adequate at the time of the assessment team's visit. Vaccines were checked through the stock system. Random samples of vaccine were counted by vial.

On the question of assessment team judgement Ümit Kartoğlu commented that the technique is largely quantitative, although some judgement may be exercised. In principal, though, the technique is quantitative because it is designed to achieve common results between different observers.

Anthony Battersby commented that under no circumstances should the technique be simplified. There is an absolute need for the level of detail shown in the presentation. In response to James Cheyne's comment on judgement he noted that judgement was being exercised by the team at the end of the exercise. He further noted that earlier programme reviews in Zambia and Bangladesh had used a similar technique. He asked for clarification of the scoring system used.

In response to the last question, Souleymane Kone said that each indicator had between 3 and 10 questions – for example national cold chain reliability has 10, whilst sub-national has 7. The total score for each indicator is then normalized to give a score between 0 and 5.

Dr Ümit Kartoğlu remarked that, during initial testing, they had considered adding another, more qualitative scale. In addition they considered weighting the individual assessment elements making up the overall score for each sub-system, because some issues have a bigger impact on system performance than others. The final decision was to keep things as simple as possible.

In response to this last point, Anthony Battersby thought that this decision was absolutely correct. He thought that the system should be extended in future to cover other elements of the immunization system.

Søren Spanner (WHO SEARO) asked whether if data loggers had been used to check cold chain temperatures. If not, how do you ensure that temperature records are accurate?

Souleymane Kone responded that temperature records were checked over six months. It is perfectly possible to see from the records whether they have been falsified.

Ümit Kartoğlu commented that if the records showed a constant +5° C for months, then the temperature control indicator was scored zero.

Søren Spanner noted that manual recording only takes place twice a day. This does not tell you whether the cold chain is reliable.

Souleymane Kone commented that they also checked related issues such as standby power availability. He agreed that temperature recording is necessary, but not sufficient, evidence.

Peter Carrasco (PAHO) noted that one of the temperature control indicators that used to be used was the presence or absence of water bottles at the bottom of the refrigerator. Has this been overlooked? Also, was VVM status correlated with temperature records – was there evidence of VVM expiry in refrigerators? He also noted that there was no indicator covering supervision activities.

Gordon Larsen (WHO) asked if the cold chain indicators used were different at national than at the lower level stores.

In response to these questions Souleymane Kone commented as follows:

- Water bottles were not used as an indicator but he agreed this should be added.
- Supervision. The follow up to the review is part of supervision.
- VVM/temperature record correlation was not done, but could be added. Changed VVMs were only found in outreach situations beyond the cold chain.
- Cold chain reliability was taken very seriously. It was the only item with 10 indicators.

K.K. Wadhawan (Consultant). Vaccine is the largest programme cost. Now we find that nobody is bothered about wastage and that it is not recorded, compiled or considered at national level (in India?). Is there a vaccine wastage guideline?

H. T. Raubenheimer (CCCCM South Africa) congratulated Souleymane Kone on his presentation and liked the very practical outcome-based approach. He agreed with Ümit Kartoğlu that judgement can lead to subjectivity. He would like to support the use of weighting factors to increase subtlety. He stressed the need for consistency of approach as between different countries and different assessors.

Allan Bass commented that the presentation was both interesting and useful, but that the results were unfortunately all too familiar. What was the facility sample size at sub-national and service delivery levels?

Alfred da Silva (AMP). Do data collected give cost of wastage? Can you assess loss of coverage due to lack of vaccine? Are these countries ready for new vaccines?

Souleymane Kone. There is a cost of wastage, but this is a very complex issue which could not be evaluated. Loss of coverage may be estimated from EPI programme reviews. The issue of new vaccine introduction is a question for each individual country. The assessment helped show what action was needed to prepare for this in each case.

Islam Ahmed Al Balushi (MoH Oman). Was the Freeze Watch device used as an indicator? Souleymane Kone replied that it was included as a cold chain reliability indicator.

Hans Everts referred back to Søren Spanner's comments regarding temperature monitoring. He suggested that data loggers should be put in the refrigerators of all the inspected stores for 24 hours at the time of each visit. He would like to see more details of the methodology.

For example, was there a question along the lines 'do you take vaccine out of the cold chain, and do you know how to take it out of the cold chain?'

Bob Davis (UNICEF ESARO) was very concerned about the problems reported regarding diluent control. Was measles vaccine observed being reconstituted with warm diluent?

Souleymane Kone. Warm diluent was found in some places.

Ümit Kartoğlu. It was rare to find matching quantities of diluent and vaccine and staff could offer no explanation. It is a big problem.

Mary Catlin (University of Arizona), on the subject of diluent, reported an observation from the field. In Ethiopia and Zambia, she has seen a normal saline product, intended for wound cleaning, being used for reconstituting vaccine.

Gordon Larsen concurred that diluent misuse was a big problem.

Stephane Guichard (UNICEF). How do national level indicators differ from those used at lower levels? Distribution of syringes for reconstitution does not appear to be an indicator.

Ümit Kartoğlu. For each indicator, there are several components. Some only apply at national level, some only at lower levels. For example, use of diluent is not relevant at national level. Only questions regarding stocks of diluent apply at this level.

Fred Simyu (WHO/AFRO). Is a final version of the analysis software available for use at country level for routine reporting and analysis? If possible, analysis should be standardized between countries.

Souleymane Kone. In most countries data is available on wastage, but is not used. Ümit Kartoğlu There are programs available to analyse this data, but they all have drawbacks.

Themes and conclusions

- The vaccine management assessment methodology was widely supported.
- There were conflicting views as to whether the method should be simplified or further elaborated. There was greater support for the view that we are dealing with complex and subtle problems and that these problems merit complex and subtle assessment and analysis. There was general support for the view that the assessment methodology should continue to be refined and developed.
- There was support for the principal of a quantitative methodology such as the one presented, with indicators, not subject to observer bias, consistently applied across countries.
- There was wide agreement that temperature control in the cold chain was a critical factor and that the indicators dealing with this should be strengthened. There was support for the use of data loggers as an assessment tool.
- There was general concern about the misuse of diluent shown up by the assessments.
- It was agreed that procedures for reverse cold chain for AFP stool samples should be added to the training material.

3.4 Document review: Ensuring quality vaccines at country level – guideline draft for comments

Moderator: Gordon Larsen (WHO HQ)

Introduction

Gordon Larsen opened his presentation by commenting that, among the many guidelines available, there had hitherto been no document designed specifically to help country staff guarantee that the quality of vaccines at country level was maintained down to the point of use. The Access to Technologies group in Geneva made every effort to ensure that vaccines purchased through the UN agencies were of the highest possible quality. There was no point in going to all that effort if vaccines were subsequently spoilt before they reached recipient mothers and children.

The draft document that he would be talking about had recently been posted on the Technet e-forum, and was targeted at programme managers and staff. Comments, suggestions and corrections were requested from the delegates. The document contained three sections, as follows:

> ***Part 1:*** Ensuring quality of vaccine production to meet WHO specifications.
>
> ***Part 2:*** Ensuring safe and efficient shipping and care of vaccine on its way to the receiving country.
>
> ***Part 3:*** Ensuring maintenance of quality within countries, from time of arrival down to point of use.

Part 1 – Ensuring quality of vaccine production

Part 1 covered the following topics:

- Ensuring quality of vaccine production. This was mainly the role of WHO Geneva, working with the vaccine manufacturers and the national regulatory authorities (NRAs);
- Pre-qualification of vaccine manufacturers, including review of the product summary file; ensuring consistency of product characteristics; assessments of the NRA in the producing country, and manufacturing facility audits. This procedure had already been published as WHO/VSQ/97.06
- Continued monitoring of pre-qualified vaccines, including rounds of random testing of manufacturing facilities; regular re-evaluations of these facilities every two years; maintaining a list of pre-qualified vaccine manufacturers. This list was updated and posted monthly on the web site at http://www.who.int/vaccines-access/prequalvaccinesproducers.html.

Part 1 was intended to provide country managers with information on available vaccines and to provide a basis for confidence in vaccine purchases made through the UN agencies.

Part 2 – Ensuring safe and efficient shipping

Part 2 covered matters that were mainly the role of UNICEF as the vaccine purchaser working with airlines, transport agencies, freight forwarders, etc. It covered the following topics:

- insulated packaging specifications;
- storage volume standards, labelling and packing requirements; and
- standard shipping procedures, including desired routes and arrival dates; advance notice of arrival; arrival documentation and vaccine arrival reports. The published guideline dealing with these issues had been recently updated as WHO/EPI/CCIS/81.4 rev.6.

Part 2 supplied the country manager with background information on vaccine shipment procedures and was intended to provide a basis for confidence in vaccines delivered through the UN agencies.

Part 3 – Ensuring maintenance of quality within countries

Part 3 dealt with matters that were mainly the role of the MoH, the EPI programme and staff at country level. It covered the following topics:

- procedures for checking vaccine shipments on arrival in the country including inspection of temperature monitoring devices and processing release certificates of the NRA in the country of origin;
- procedures for vaccine lot release for use in-country, covering the respective roles of the NRA in the user country and the EPI manager/national logistics officer;
- procedures for storage and distribution of vaccines throughout the cold chain system;
- stock control systems and stock records, including arrival at stores; maintaining quality during storage, and dispatch procedures for vaccines leaving stores;
- handling of injection equipment and safety boxes;
- vaccine re-constitution and administration at service points, including a guide to safe vaccine reconstitution and a guide to avoiding programmatic errors arising from poor procedures;
- vaccine package inserts;
- reporting of adverse events following immunization (AEFIs), covering the role of UNICEF staff and dealings with the press and other media; and
- summary and annexes.

Part 3 provided guidelines for country managers and staff on actions they needed to take to maintain vaccine quality at all levels within the country.

In summary, the purpose of the guideline was to help the country managers and EPI staff to address the sort of problems raised by Dr Kone in his earlier presentation. Gordon Larsen concluded his talk with a request for questions and comments from the floor.

3.5 Discussion

Dr Anil Varshney (PATH), commenting on Gordon Larsen's presentation, asked for clarification regarding vaccine procurement. In India, local manufacturers are certified locally and for export, but are not certified by WHO. In the light of the guideline requirement that WHO-certified vaccines should be used, should India be using these vaccines?

Dr Julie Milstien replied that there are manufacturers in India who are already pre-qualified and some others who are going through the process. WHO is a secretariat; it does not determine country purchasing policy. She commented that vaccine should be subject to the approval of a fully functioning national regulatory authority.

Dr Mohammed Rahman (National EPI Bangladesh), commenting on Gordon Larsen's presentation, said that there was no vaccine production in Bangladesh and no inspection of received vaccine was carried out by the NRA. Private practitioners procure vaccine independently. How is it possible for him the check quality?

Gordon Larsen replied that, if the NRA does not check vaccine quality, then it must be persuaded to do so. The NRA should also check vaccine imported by private practitioners. The national manager should try to ensure that everybody is using assured vaccine. He noted that there is a performance indicator on vaccine packaging in the guideline.

Peter Carrasco (PAHO) noted that PAHO recommended that there should be a national immunization committee which ruled on vaccine type, quality and storage.

James Cheyne, commenting on Gordon Larsen's presentation, asked if there was a plan to turn the Guideline into training material. Are the topics in the guideline the same as those covered by the assessment method?

Gordon Larsen replied that he was working with Tom O'Connell on training material. He confirmed that the topics covered are the same as those in vaccine management assessment.

Søren Spanner (WHO SEARO) asked if the guideline contained recommendations on vaccine packing. In India some vaccines, e.g. polio, are sent out in very thin boxes.

Gordon Larsen confirmed that there were guidelines for vaccine packaging.

Dr Boi-Betty Betts (WHO/AFRO). What is the target audience for the guideline and will it be used at peripheral level?

Gordon Larsen remarked that the target audience is management and staff. It is not anticipated that peripheral staff will read the document, but it will be useful in whole or in part at national and sub-national level. There is no plan to make a companion guideline for service level use.

Allan Bass. What is the timeframe for the new guideline? When can we see pieces incorporated into new training material?

Gordon Larsen reported that a draft has been prepared for this meeting. Training material is being handled by Tom O'Connor.

Paul Fife (UNICEF). The vaccine quality guidelines will form the basis for material to be used by UNICEF field officers.

Themes and conclusions

- National authorities (e.g. NRA) have final responsibility for vaccine purchasing and control of imports.

4. Fourth session: Vaccine wastage

4.1 Factors affecting vaccine wastage and using vaccine wastage as a tool to monitor the immunization programme

Alan Schnur (WHO China)

Introduction

Alan Schnur opened by remarking that the introduction of new, expensive, vaccines and multivalent presentations meant that discussion of vaccine wastage was now a timely topic – a topic which had not received much attention for quite some time. His presentation would suggest how routine EPI coverage could be improved without major new resources, by building on the experiences and infrastructure of polio eradication.

Definitions of vaccine wastage

He defined vaccine *wastage* as the proportion of vaccine supplied, but not administered to children; usually stated as a rate. The opposite of wastage was *utilization*, which was that proportion of the vaccine supplied which was actually administered to children; also usually stated as a rate.

There were many proposed definitions for what to include in the term 'wastage'. These included: doses provided to children outside the target age group; doses given at incorrect time, etc. In any wastage calculation it was essential to recognize and bear in mind that vial size was 'nominal'. Workers could not obtain 20 doses from a '20-dose vial': usually the yield was only 16 or 17 doses.

Vaccine wastage rates were calculated by comparing the vaccine supplied to the vaccine actually administered to children.

Vaccine multiplication factors were used to calculate how much vaccine to order or supply in order to take account of the extra vaccine needed to compensate for that proportion which could not be administered to children.

Causes of wastage

Wastage could be caused by:

- Service delivery/programmatic reasons, for example:
  - doses in vials are 'nominal'; it is impossible to get 20 doses from '20-dose vial', usually the yield is only 16 or 17 doses;
  - in some settings it is only possible to immunize a few children from a vial – the rest of the vial must be thrown away;

- the wastage rate achieved is affected by the vial size selected: vial size selection depends upon the average session size and the vaccine cost per dose;

- in outreach settings, reserve vials may remain after the ice in the vaccine carrier has melted: if there are no VVMs on the vials, then this vaccine must be discarded.

- Avoidable wastage, for example:

  - expired vaccine remains in unopened vials due to logistics problems or incorrect handling of vaccines;

  - cold chain failure;

  - freezing of DTP, HepB vaccine, TT;

  - vaccine with short shelf life provided by the vaccine manufacturer (for example, one country received measles with only five months shelf life remaining; this subsequently expired in the national store before it could be distributed and used).

He commented that vaccine wastage was an important indicator as it could reveal programme errors, such as:

- too many drops of OPV, wrong dosage;

- incorrectly using reconstituted measles vaccine over several days;

- cold chain failures, poor logistics, not observing first-in first-out principles; and

- false reporting where more immunizations are recorded than the number of vaccine doses distributed.

If too little vaccine was supplied, this adversely affected coverage. If too much vaccine was supplied, then this increased wastage due to expiry. If accurate wastage rates were known then programme managers could more realistically calculate how much vaccine to provide to reduce the risk of such failures. In cases where the MDVP was adopted it was necessary to carry out a 'parallel calculation' of the number of immunization sites: for example if there were 10 children to immunize in six villages on four days, then one 20-dose vial would not be enough.

Selecting vial sizes

Filling vaccine in vials was costly, so smaller vials were more expensive per dose than larger ones. Because of this, the cost to the programme of using multi-dose vials might actually be lower than the cost of using single-dose vials, even if some vaccine remaining in the multi-dose vials had to be thrown away. The following list gives some examples:

Measles vaccine:

- Cost of 10-dose vial = US$ 1.40 (US$ 0.14/dose)
- Cost of 1-dose vial = US$ 0.40 (US$ 0.40/dose)

DTP:

- Cost of 20-dose vial = US$ 1.40 (US$ 0.07/dose)
- Cost of 10-dose vial = US$ 0.85(US$ 0.085/dose)

Hepatitis B vaccine:

- Cost of 10-dose vial = US$ 2.60 (US$ 0.26/dose)
- Cost of 1-dose vial = US$ 0.58 (US$ 0.58/dose)

Opened vial policies allowed some vaccines to be used until the vial was empty – this could reduce wastage. The policy did not affect measles and BCG, which, after reconstitution, must continue to be discarded at the end of every session. The opened vial policy might be re-evaluated as a result of the move away from thiomersal, but the effect of this was not yet clear.

Selecting optimal vial size was complicated, but was closely related to wastage rates. The main principle was that mixing different vial sizes in the same programme should be avoided since more than one form of presentation was known to cause confusion at lower level stores. Once a threshold had been reached, throwing away unused doses from multi-dose vials was normally cheaper than using single dose vials.

Determining acceptable wastage levels

Alan Schnur noted that the figure that represented an acceptable level of wastage was programme-dependent and had to be based upon experience and analysis of local situations. For example, workers in remote areas often needed to open more vials per child than workers in urban areas to maintain a given level of coverage. Consequently higher wastage rates should be accepted in such settings. There was a need to do a parallel calculation of the number of vials required – every small rural health centre needed to have at least one vial of each vaccine per session, regardless of the effect this might have on wastage rates. Avoidable wastage was NOT acceptable. Unopened vials of vaccine should NEVER be allowed to expire before use.

If wastage could be reduced without affecting coverage it was possible to make significant cost savings. Expensive programmatic errors resulting in expired vaccine should be detected, corrected and prevented.

Wastage as a management tool

Wastage rate calculations could be used to detect programme errors, such as:

- if the manufacturer supplies vaccine with short expiry date;
- if health workers give three drops of OPV instead of two;

- if health workers give 0.3 ml of vaccines instead of 0.5 ml;
- if health workers incorrectly use opened measles vaccine and BCG vials over several days;
- cold chain problems; and
- falsified overreporting.

Alan Schnur then presented a series of examples to demonstrate the effect of different wastage rates on coverage and programme costs. Table 4 gives an example of vaccine costs per fully immunized child (FIC) compared with the overall programme cost per FIC.

Table 4: Typical programme costs

Only vaccine cost per fully immunized child	
DTP: 3 x US$ 0.07	= US$ 0.21
BCG: 1 x US$ 0.10	= US$ 0.10
OPV: 3 x US$ 0.09	= US$ 0.27
Measles: 2 x US$ 0.14	= US$ 0.28
HBV: 3 x US$ 0.58	= US$ 1.74
Total	= US$ 2.60 (13%)
Cost of fully immunized child =US$ 20	

Figure 26 gives a first set of examples, where x = the total cost of the programme, n = the number of eligible children and y = cost per FIC. Assuming that 15% of programme cost is vaccine (.15) and the balance is 85% (.85) and assuming that the coverage rate is 40% (.40), then the first example gives a baseline cost per FIC of 1.0y. Reducing wastage by 60% to 0.5 reduces the cost per FIC to 0.9y and increasing wastage by 100% to 0.3 increases the cost per FIC to 1.15y.

Figure 26: Example 1

Vaccine wastage as financial monitoring indicator (1)

- Scenario 1: change wastage/same coverage
- $\frac{.015x + .85x}{.40n} = 1.0y$ (baseline)
- $\frac{.05x + .85x}{.40n} = 0.9y$
- $\frac{.30x + .85x}{.40n} = 1.15y$

Figure 27 gives a second set of examples; by reducing coverage to 30% (0.3), against the baseline programme, cost per FIC increases to 1.33*y*. Reducing wastage to 0.1 and 0.05 at this low coverage rate lowers cost per FIC, but not by very much.

Figure 27: Example 2

Vaccine wastage as financial monitoring indicator (2)

- Scenario 2: reduce wastage/lower coverage
- $\frac{.15x + .85x}{.30n} = 1.33y$
- $\frac{.10x + .85x}{.30n} = 1.27y$
- $\frac{.05x + .85x}{.30n} = 1.20y$

Figure 28 gives a third set of examples; by increasing coverage to 50% (0.5), against the baseline programme, cost per FIC reduces to 0.80*y*. An increase in the wastage rate to 0.3 at this higher coverage rate increases costs per FIC to 0.92*y* – still lower than the baseline figure.

Figure 28: Example 3

Vaccine wastage as financial monitoring indicator (3)

- Scenario 3: higher wastage/higher coverage
- $\frac{.15x + .85x}{.50n} = 0.80y$
- $\frac{.30x + .85x}{.50n} = 0.92y$

Figure 29 gives a final set of examples. Here coverage has been increased to 60% (0.6). Against the baseline programme, cost per FIC reduces to 0.67*y*. An increase in the wastage rate to 0.3 at this coverage rate increases costs per FIC to 0.77*y* and a further increase in the wastage rate to 0.45 increases the cost per FIC to 0.87*y* – still lower than the baseline figure even though the wastage rate is triple the baseline example.

Figure 29: Example 4

Vaccine wastage as financial monitoring indicator (4)

- Scenario 4: higher wastage/lower coverage
- $\frac{.15x + .85x}{.60n} = 0.67y$
- $\frac{.30x + .85x}{.60n} = 0.77y$
- $\frac{.45x + .85x}{.60n} = 0.87y$

Conclusions

Monitoring vaccine wastage was a useful programme monitoring tool which could be used to improve programme quality and to increase programme efficiency. However monitoring wastage for purely economic reasons was not so useful.

A key objective of EPI was to increase coverage. In order to do this, workers needed to open a vaccine vial every time children were presenting. This approach increased coverage and reduced dropouts. Managers needed to be aware that, in the past, staff were afraid of wasting vaccine and often refused to open multi-dose vials for only one child. Training needed to take this into account. Reluctance to waste vaccine resulted in delayed protection, higher drop-out rates and lower coverage.

All partners needed to:

- understand wastage and all its components;
- encourage reduction of avoidable wastage;
- encourage countries to increase coverage and to emphasize wastage of children rather than wastage of vaccine;
- continue to calculate the implications of higher priced vaccines on programme economics;
- work to improve programme management, including monitoring wastage rates, to improve programme activities and coverage;
- note that training can take several years to filter through the system and be implemented;
- note that changed guidelines can take several years to fully and correctly implement and that changes have the potential to create confusion and errors in the interim – for example the VVM and MDVP policies have been around for several years, but are still not fully understood;

- note that in situations where expensive multi-antigen vaccines are only being used on a temporary basis, the renewed emphasis on wastage that the use of this type of vaccine imposes may be difficult to reverse if funding for more expensive vaccine formulations cannot be sustained. This is particularly true of vaccines such as Hib, where training in wastage reduction may engender a similar reluctance to waste cheaper vaccines, such as measles, whose effect on morbidity and mortality are greater.

Discussion points

Alan Schnur concluded by posing the following questions:

- How could monitoring vaccine wastage be used to improve programme performance and to increase immunization coverage?
- What were the risks that an emphasis on vaccine wastage would make workers afraid to open a vial of vaccine for only one child, especially measles vaccine?
- What place should vaccine wastage take in the economic monitoring of the immunization programme?

4.2 Multi-dose vial policy

Peter Carrasco (WHO AMRO)

Introduction

Peter Carrasco opened by noting that PAHO had issued the first multi-dose vial policy (MDVP) in 1992. This policy had subsequently been revised in the October 2000. Table 5 shows the differences between the two policies. The biggest changes had been in the norms for Hepatitis B, the toxoids and OPV:

Table 5: MDVP in 1992 and 2000

	Comparison of times	
	1992	**2000**
• Measles, MR, MMR	8 hours	6 hours
• BCG	8 hours	6 hours
• Yellow fever	8 hours	6 hours
• Hib (freeze dried)	–	6 hours
• Hepatitis B	5 days	30 days
• DTP/TT/Td	5 days	30 days
• OPV	8 hours	30 days

Policy and methods

PAHO had imposed the following conditions on the use of opened multi-dose vials:

1. the expiry date must not have passed;

2. the vaccine must not have been submerged in water;

3. open vials of OPV, DTP, TT Dt, HepB and liquid formulations of Hib that have been taken to the field must not be returned to the refrigerator.

The reason for conditions 2 and 3 were that the region used a lot of wet ice. Consequently submerged septa were commonly observed. In addition it was not uncommon to find needles penetrating the septum because this bad practice aided easy vaccine withdrawal.

At regional level, the methods used for implementing the MVDP included circulation of a memorandum to all countries, together with the issue of policy documents and publication in the EPI Newsletter. In addition, training materials were also circulated.

At country level the MDVP policy was implemented by means of flyers, directives and fact sheets, together with training materials. Figure 30 gives an example of a flyer from Ecuador, which also gives advice on re-capping and safe disposal techniques.

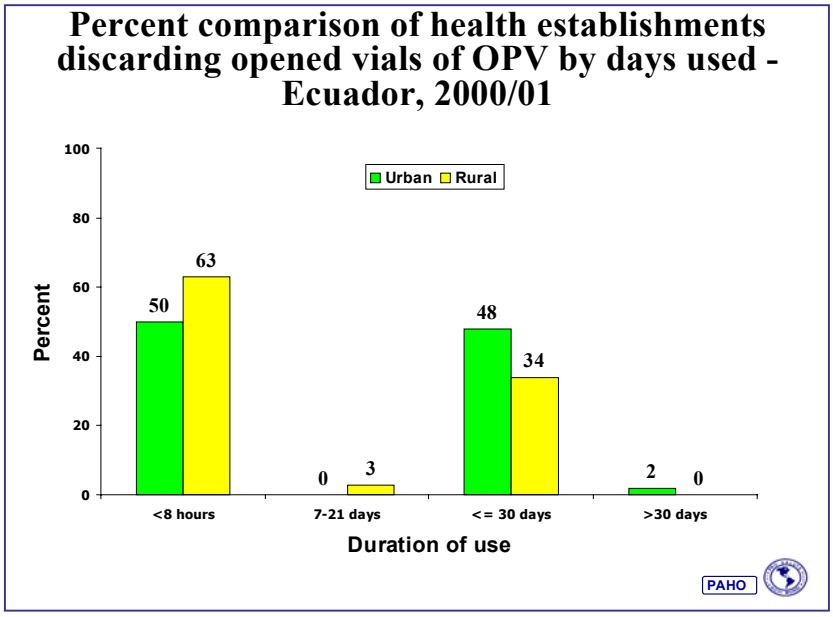
Figure 30: Example of MDVP flyer

Implementation of the MDVP has been monitored using mail surveys, routine supervisory visits and cold chain evaluations. From a management point of view, mail surveys had proved to be a good method for establishing baseline data and conformance. Routine supervisory visits were also good, but questions about the MDVP needed to be incorporated

into data collection forms: such visits also required funding. Cold chain evaluations were an excellent method for collecting data; however, they were very time consuming and expensive.

Figure 31 shows the percentage of health establishments in Ecuador discarding opened vials of OPV and relates this to the duration over which the vials were kept open. These data represented a little under half the health establishments in the country. Even though the MDVP policy had been in force for over five months, roughly 50% still discarded OPV vials after only eight hours of use (the 1992 protocol) and a few were discarding after more than 30 days (the 2000 protocol specifies a maximum of 30 days).

Figure 31: Analysis of discarded OPV vials



Peter Carrasco noted that the old policy had been hard to change in Ecuador because behavioural change was extremely hard to bring about and old habits did not die easily. Furthermore there had been insufficient consistent supervision to make change happen because supervision was not routine and data collection was not standardized. Finally, OPV is very heat labile and melts like ice cream. Keeping it after it has 'melted' goes against the grain for many health workers.

In regard to the results of supervision in assessing the change in the MVDP, no factual and evidence-based data were available. In decentralized environments such as Argentina, the central level had to negotiate access with state or federal health authorities to obtain such data and this was a lengthy and time-consuming process.

Conclusions

In the absence of funds for routine supervision and for policy introduction or revision, it had proved to be quite difficult to obtain wholesale uniform behaviour change within a period as short as 3–6 months. Similarly, without routine data collection in the course of supervisory visits, it was difficult to assess the extent of correct policy implementation.

In countries where decentralization was occurring rapidly, policy implementation and monitoring was extremely difficult and would require additional management effort. Supervisory systems were the central plank of good management and the best means to ensure that a policy was well implemented and managed. In order for supervisory systems to work effectively, adequate budgetary resources were required at all levels.

4.3 Discussion

Hans Everts (WHO) requested that Alan Schnur's presentation be made into a maximum 10 page wastage rate guide. He then raised a number of detailed points concerning the definition of wastage rates.

Carib Nelson (PATH) suggested that a benefit of mono-dose presentations is that they reduce wastage and increase coverage.

Alfred da Silva (AMP) asked if the approach took account of the macroeconomic perspective and how did that impact on production capacity?

Bob Davis (UNICEF ESARO) agreed with the conclusions drawn in Alan Schnur's presentation. Where multivalent vaccines are used, larger presentations should be considered.

Islam Ahmed Al Balushi (MoH Oman) has received a letter of guarantee from a vaccine manufacturer on some short shelf life vaccine. Should he consider this expired vaccine as wastage?

Carib Nelson (PATH). The decision to change to mono-dose presentations is a complex issue. Fore example, the cold chain has to accommodate larger storage volumes. Mono-dose is likely to be most applicable in big cities.

Dr Yvan Hutin (WHO) commented that the open vial policy is becoming a problem due to a growing concern about the spread of pathogens such as Hep C. A recent editorial in the Journal of Infection Control has called for their elimination. What should be done? Certainly we must educate people about good practice and take account of the fact that the developed world wants to get rid of multi-dose.

In response Anthony Battersby pointed out that viruses travel from vial to vial via a needle. If a dirty needle is used, then contamination can occur just as easily with single dose vials. He then asked what happens when the stabilizer is removed from DTP.

Alfred da Silva (AMP). Vaccine manufacturer's output is defined by filling capacity, not by vaccine output.

Anthony Battersby commented that session size is the key to the efficient use of vaccine. In turn, session size is determined by the number of health facilities. Vaccine use is also affected by health staff perception. For example, in the former Soviet Union there are many health facilities serving small populations and 10 dose measles is not viable. The reason for this is that health workers cannot bring themselves to discard the residue of multi-dose vials remaining at the end of the session. You have to consider different presentations of the same vaccine in a programme to take account of session size.

Peter Carrasco (PAHO). Right now the global supply of low-dose vaccines is limited or unavailable. For example, yellow fever vaccine is only supplied in 20-dose presentations

and measles–mumps–rubella vaccine (MMR) is only being offered in a 10-dose presentation, despite the fact that this latter vaccine is very expensive. This is a real constraint which will lead to unavoidable programmatic wastage.

Anthony Battersby noted this point and remarked that it would have significant implications for GAVI applications.

Ümit Kartoğlu commented on the issue of wastage calculations versus costs. In the case of yellow fever, for example, 40% wastage on a 10-dose vial is no more expensive per immunized child than 70% wastage on a 20-dose vial. Consequently, in this case, the higher wastage figure would have no economic effect on the programme.

Mary Catlin (Univ. Arizona). In his talk, Alan Schnur commented that a 20-dose vial only yields 16–17 immunizations. Is it possible to specify overfilling to compensate for this?

Alan Schnur replied that this issue had been around since the 1980s. It is necessary to discuss yield figures with the manufacturer and take account of the actual versus nominal volume when calculating vaccine requirements.

Bob Davis (UNICEF ESARO). Vaccine costs should be assessed on the basis of price per usable dose.

Shanelle Hall (UNICEF). She has seen no studies on this subject. However, with OPV, the problem has been addressed. The yield depends upon drop size, which in turn depends on factors such as the angle at which the dropper is held for delivery.

Bob Davis (UNICEF ESARO) thought that it should be easy for UNICEF/WHO to obtain feedback from the field. Vaccine yield is a serious problem that needs to be addressed.

Dr Julie Milstein (WHO) commented that it was easy to measure vaccine volume and that NRAs do this as part of the licensing process. Changing the filling is easy, changing the licence is not. Reputable manufacturers do overfill. WHO has not heard complaints about the yield of injectable vaccines – only about the yield of lyophilized vaccines; however if there is evidence from the field, WHO should be informed.

On the subject of thiomersal, this adjuvant is not going to be eliminated any time soon, and what is to follow is still awaited. Current WHO protocols require that any new stabilizers should allow the multi-dose vial policy to continue. The removal of thiomersal will not only require vaccine re-licensing, but will also need new filling lines equipped to a much higher standard of sterility.

On the subject of single-dose presentations, world manufacturing capacity does not exist to provide all vaccines in single-dose form. World freeze-drying capacity is already just about saturated. For example single-dose MMR would cut capacity 30-fold as compared with multi-dose monovalent vaccine. The decision to change to single-dose presentations should not be made without consideration of global needs.

Robert Steinglass (BASICS) remarked that there was field evidence of under-filling going back to the 1970s and 1980s. WHO must address this issue.

K.K. Wadhawan (consultant). The largest recurrent programme cost is vaccine. Therefore it is necessary to determine what wastage is avoidable, and what is unavoidable. There should be tools for monitoring and reporting wastage and we should concentrate particularly on

reducing unavoidable wastage. In India, vaccine is ordered on the basis of a 100% coverage rate even though coverage is much less than this. If coverage reaches 100% there will be a shortage of vaccine in all countries.

Dr K. Suresh (UNICEF – Delhi). You have to consider human factors when dealing with the wastage issue. Health workers have many responsibilities and the analysis of wastage is only one of these. In India the health worker may feel that he has to fabricate the wastage data in order to avoid being penalized by those who audit vaccine use.

When we talk about the open vial policy, have we considered refrigerator hygiene as a factor?

Peter Carrasco commented that in the PAHO region, refrigerator hygiene was checked. The relevant factors are that the refrigerator should be clean, no food should be stored in it, and the vial septum should not be touched.

Commenting on Anthony Battersby's remarks on session size, Allan Schnur agreed with his point but commented that session frequency was also critical at the periphery. Micro-planning is needed and there should be a dynamic relationship between all levels of the programme.

Commenting on the under filling issue he wondered whether there was really any need for action. Provided programme managers were aware of the problem, wastage rates can be adjusted accordingly.

Commenting on K.K. Wadhawan's remarks he noted that one should always deduct the balance of stock in hand when ordering for the following year. Tools are needed to monitor usage and correct orders at all levels.

Commenting on Dr K. Suresh's remarks he noted that this reinforces the need to set aside time to communicate down the chain of command. Health workers sometimes conceal expired vaccine in refrigerators to avoid being charged personally for wastage.

Jean-Marc Olivé noted that the message about wastage should reach GAVI. A question for Peter Carrasco was: have you ever evaluated the original 1992 MDVP?

Islam Ahmed Al Balushi (MoH Oman). It is essential to be completely specific when tendering for vaccines. For example, countries often don't specify minimum shelf life. We don't want manufacturers to take advantage of such oversights. Sometimes national stores may take a similar cavalier attitude towards shelf life when dispatching to lower level stores.

If the manufacturer issues a formal letter it is possible to re-validate nominally expired vaccine. However this confuses staff, unless the expiry date is changed on every vial.

Dianne Phillips (DoH South Africa). On the subject of revalidated vaccine raised by Mr Al Balushi she commented that SA always insists that vials are fully re-labelled to avoid confusing health workers. She commented that in SA OPV is kept after outreach sessions because VVMs are used. They also find that they have to throw out vaccine because refrigerators are switched off at the weekend. Regarding Hib vaccine, she had been told by one manufacturer that this lyophilized multivalent vaccine cannot be refrozen because this damages the conjugates. She wondered whether this was true of measles. She also noted that single dose presentations of this vaccine require large storage volumes. Finally she

commented that Alan Schnur's wastage rate calculations were too complex for her to use in SA.

Gordon Larsen (WHO) said that WHO should check Dianne's report about Hib.

Paul Fife (UNICEF) remarked that there was a lack of wastage rate data flowing back to UNICEF and that these data are needed by the Supply Division. What is the policy on taking open vials out of the health centre in areas where ice is used? Are there ways to keep the vial septum out of the slush water?

Peter Carrasco, in response to Jean-Marc Olivé, confirmed that PAHO did evaluate the original MDVP. However this was only an evaluation of conformance – they never looked at wastage rates, as these data were too difficult to obtain. Coverage is the final measure. Wastage is less important. OPV in tubes can suffer from nozzle seepage when stored in ice. Chlorinated water de-activates the vaccine – hence vials cannot be reused after outreach sessions.

Robert Steinglass (BASICS) requested that WHO attend to the wet ice problem in the next issue of the product information sheets (PIS). Maybe a reusable sealed plastic pouch could be used to keep opened vials dry.

Allan Bass commented that vaccine cannot be frozen when it is packed with diluent. Monitoring of wastage rates should be carried out at all levels and monitoring systems must accept rate variability as between urban and rural areas.

Gordon Larsen (WHO) noted that opened vials taken out of the cold chain should not be returned to refrigerators.

Themes and conclusions

- There was general support for the idea that Alan Schnur's presentation should be developed into a wastage guideline.
- While there were conflicting views on the precise definition of different categories of wastage, there was general agreement that coverage and vaccine availability are more important indicators than wastage. Wastage rate data needs to be treated with caution because so many other factors are involved, and a high wastage rate does not necessarily imply higher vaccine costs. There is need for micro-planning in different parts of the system and this may lead to differential wastage rates.
- Programmes should be aware that, by choosing single dose presentations on a large scale, they may compromise vaccine availability for other countries.
- The concern raised by Dianne Phillips regarding Hib re-freezing needs to be investigated by WHO V&B.
- WHO V&B should investigate the issue of vial yield.
- WHO ATT should investigate products that can keep open vial septa dry when ice is used for outreach activities.
- Technet should provide UNICEF with data or references on the subject of wastage rates.

5. Fifth session: Round table: Present and future of cold chain and VVMs

Moderator: Ticky Raubenheimer

Participants: Søren Spanner (WHO SEARO), Carib Nelson (PATH), Hans Everts (WHO HQ), Shanelle Hall (UNICEF Supply Division), Debbie Kristensen (PATH)

5.1 A field study of vaccine freezing in Madhya Pradesh and Nepal

Søren Spanner (WHO SEARO)

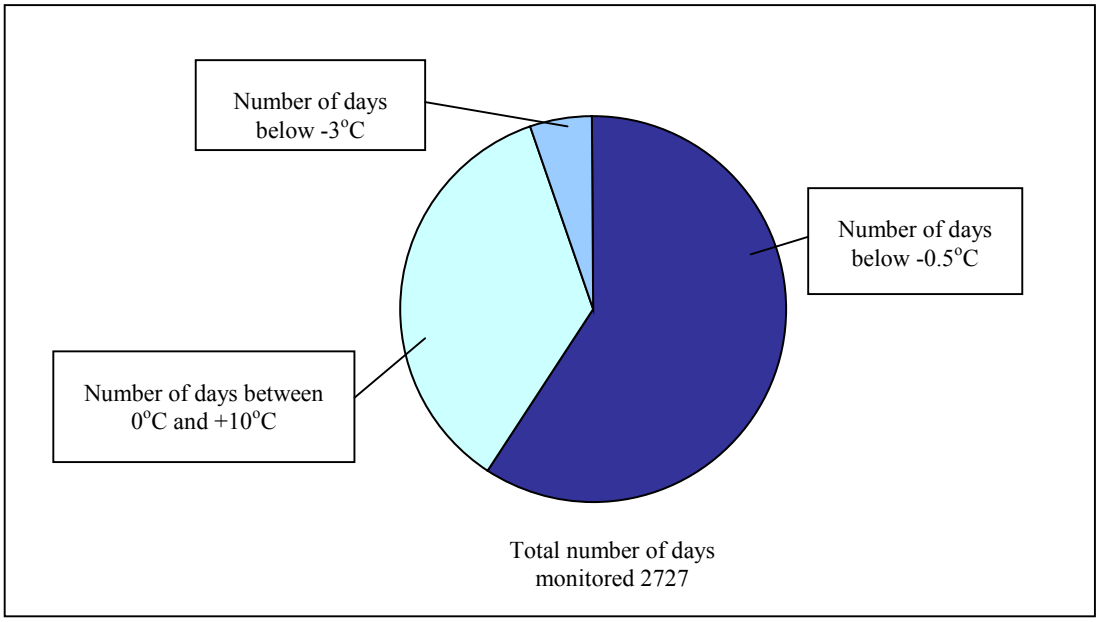
Introduction

Søren Spanner opened by saying that he wanted to share his concern about the cold chain being too cold. With the GAVI-funded introduction of HepB vaccine, this was becoming a very serious problem because HepB vaccine freezes at about -0.5°C. He had found that the cold chain was too cold in many places and that this placed HepB at risk.

Madhya Pradesh study

He reported on a two-year study that he had carried out in Madhya Pradesh, India. Electronic data loggers had been placed in the centre of 12 ice-lined refrigerators (ILRs). The results showed that, for over half the 2727 days monitored, the temperature had been below -0.5°C. See Figure 32.

Figure 32: Results of Madhya Pradesh study



In many places, the ILRs were being used without the ice lining. In such cases the temperature could reach -5°C to -10°C – below the temperature at which tetanus toxoid freezes.

He summarized the reasons why freezing occurred in older generation ILRs:

- ice-lining thermostat wrongly set;
- normal thermostat wrongly set;
- ice-lining switch wrongly set.

In these older generation ILRs, the ice-lining thermostat was set to a temperature of -3°C in the warmest ice pack. When a power cut occurred, the ice lining would melt and the internal temperature would rise to (say) +10°C. After the power returned, the cabinet temperature, near to the coldest ice packs, could briefly fall as low as -4°C to -6°C, or even lower, before all the ice packs were frozen and the normal thermostat took over. Figure 33 shows a temperature trace which demonstrates the effect of such incorrect thermostat settings.

Figure 33: Effect of wrongly set ice-lining switch and thermostat

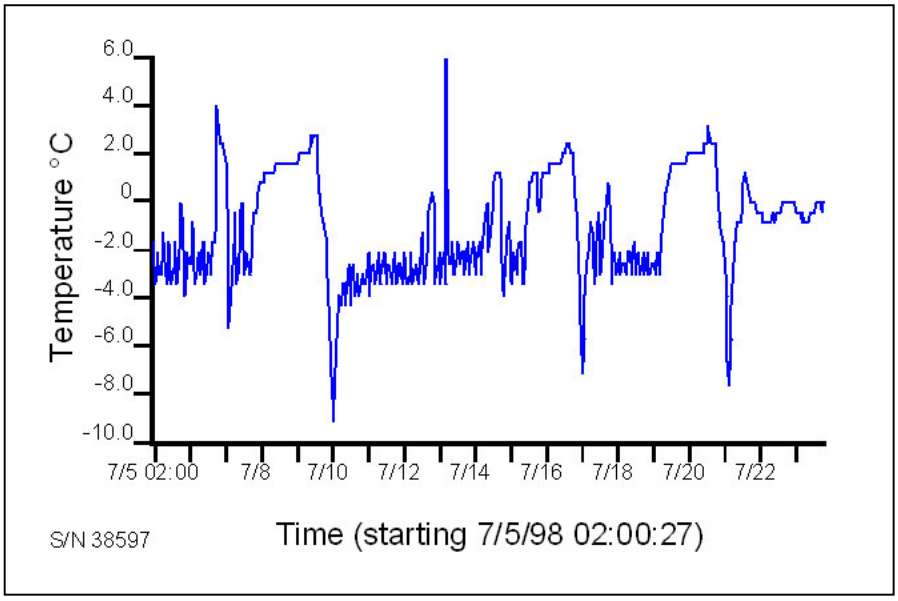


Figure 34 shows the temperature trace for an ILR that had been incorrectly set, followed by the temperature trace after the thermostat had been corrected (after 11/14).

Figure 34: ILR temperature trace

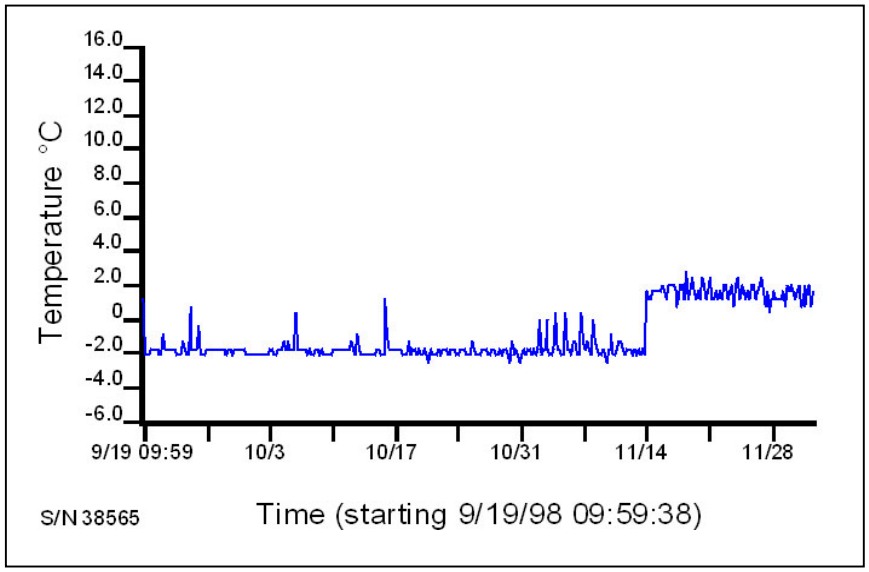
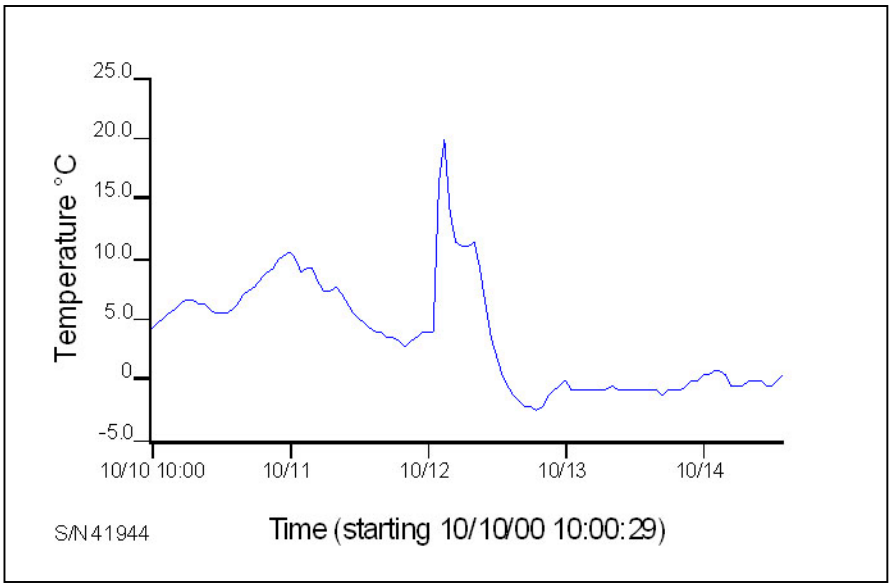


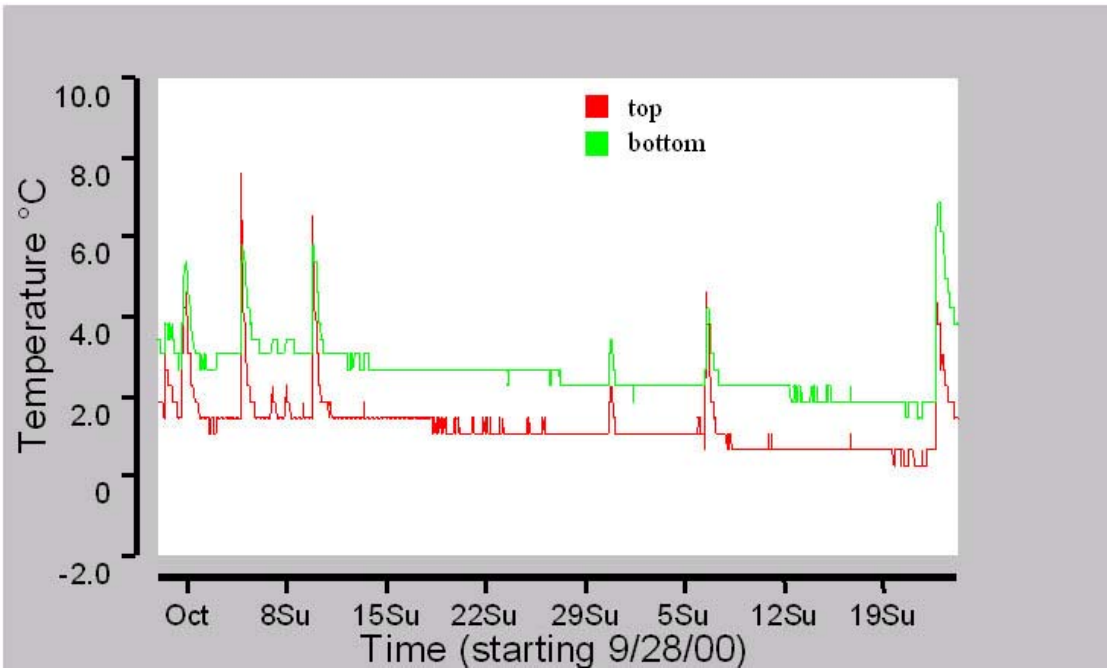
Figure 35 shows what happens if, following a power cut, the health worker believes the temperature is too high and adjusts the thermostat to compensate.

Figure 35: Incorrect use of thermostat



The new generation ILRs had largely overcome the temperature control problem by substituting an electronic thermostat. Even after a power cut, the temperature in these units should never drop below 0°C. Figure 36 shows a temperature trace for a new generation unit.

Figure 36: Temperature trace for new generation ILR



Nepal study

He briefly reported on a two-month study that he had recently carried out on Electrolux RAK100^{TM} ILRs in Nepal. Here, the average temperature recorded had been +0.9°C and the lowest temperatures had been -3.5°C, with nearly half the hours recorded being below 0°C.

Conclusions and recommendations

A 108 litre capacity ILR containing 36 000 doses of frozen HepB vaccine represented a financial loss of around US$ 8000. Such losses were unacceptable.

Søren Spanner recommended that the WHO test specifications for new equipment should be changed to prohibit the temperature anywhere inside the cabinet from dropping below zero, under any circumstances. He also recommended that ILR thermostats on all older generation models should be locked with gaffer tape at the minimum setting (maximum temperature), and that additional ice packs should be place in the cabinet to buffer the temperature.

He concluded by remarking that the new generation ILRs were better, but that the potential for freezing vaccine still remained if they were incorrectly used.

Conclusions

- WHO specifications for ice-lined refrigerators need to be changed.
- Thermostats on old technology ILRs need to be locked at the highest temperature setting with gaffer tape.
- More ice packs should be used in old technology ILRs.
- New technology ILRs are better, but can still freeze HepB vaccine.

5.2 Recent ILR specification changes and their implementation

Hans Everts (WHO HQ)

Hans Everts responded to the points made in Søren Spanner's presentation. He noted that the test specification currently in force did not permit negative temperatures. However, until recently temperature excursions to -1°C had been accepted. Since the beginning of 2000, this was no longer the case. All manufacturers had been told that negative temperatures would no longer be tolerated. Most manufacturers were now complying with this requirement.

However, he noted that test reports were based on the thermostat being set at the manufacturer's recommended setting. This still left the possibility of misuse in the field. Søren Spanner had suggested that test reports should be based on worst-case settings and this and other solutions were being discussed.

He reported that Sibir^{TM} had changed the position of the thermostat probe in their models and had added a protective rack in front of the evaporator. One other manufacturer was doing something similar.

He concluded by requesting participants to provide feedback from the field in order to ensure that these design changes were being implemented and that temperature zone stickers were being provided on all new appliances, as agreed with the manufacturers. It remained necessary to deal with the problem of existing equipment already in the field.

5.3 Toward a more flexible cold chain **

Carib Nelson (PATH)

Introduction

Vaccine storage in midwives' homes? Vaccine transport without ice? Vaccine storage in air-conditioned rooms? These are some examples of possible "flexible cold chain" strategies.

There are several potential advantages to a more flexible cold chain, including:

- reducing the risk of freezing in a refrigerator or cold box that is too cold;
- extending outreach without the need for cold boxes or ice;
- overcoming cold chain capacity limitations that may otherwise discourage use of mono-dose presentations;
- simplifying transport, e.g., without refrigerated trucks or ice packs;
- reducing distribution cost through simplification or elimination of some equipment;
- encouraging innovation among health workers to find new ways to deliver vaccines more efficiently and safely.

Vaccine vial monitors are an important part of a flexible cold chain strategy since they give health workers the ability to determine whether a vaccine has been exposed to too much heat. This allows the freedom to deviate from the rigid cold chain without sacrificing vaccine safety. Hepatitis B vaccine is extremely heat stable. The VVM for hepatitis B vaccine (and TT and some DTP vaccines) indicates that these vaccines are stable up to the time-temperature limits shown in Table 6.

Table 6: Time-temperature limits for VVM for hepatitis B vaccine

Temperature ºC	Days to end-point
40	17
35	35
30	75
25	164
20	368
15	847

Indonesia's flexible cold chain experience

Indonesia has adopted an innovative national policy for hepatitis B vaccine in Uniject™ pre-filled injection devices. This vaccine is typically used by midwives for neonatal home visits. They store the vaccine in their homes and carry it to home visits at ambient temperatures. Initially, when VVMs were not attached to Uniject devices, the vaccines were allowed to stay out of the cold chain for one month. As VVMs are introduced, the vaccines are allowed to remain out of the cold chain until the VVM, or the expiry date, indicates the need to discard. Over the last two years Indonesia has delivered about 1 000 000 hepatitis B doses in Uniject devices, following this flexible cold chain policy. PATH has been monitoring the use in three provinces and has found no VVMs indicating over-exposure to heat.

Indonesia cold chain study

PATH is working with the Indonesian Ministry of Health to investigate additional ways to minimize the volumetric impact of hepatitis B in Uniject devices on the cold chain. Initial investigations found the transport of vaccine from the national manufacturer to the provinces using refrigerated trucks to be one of the more expensive and space-limited links in the cold chain. The use of electronic temperature monitors and alternative transport systems, such as the post office and cargo delivery services, were evaluated and found to be safe and cost-effective for hepatitis B vaccine transport.

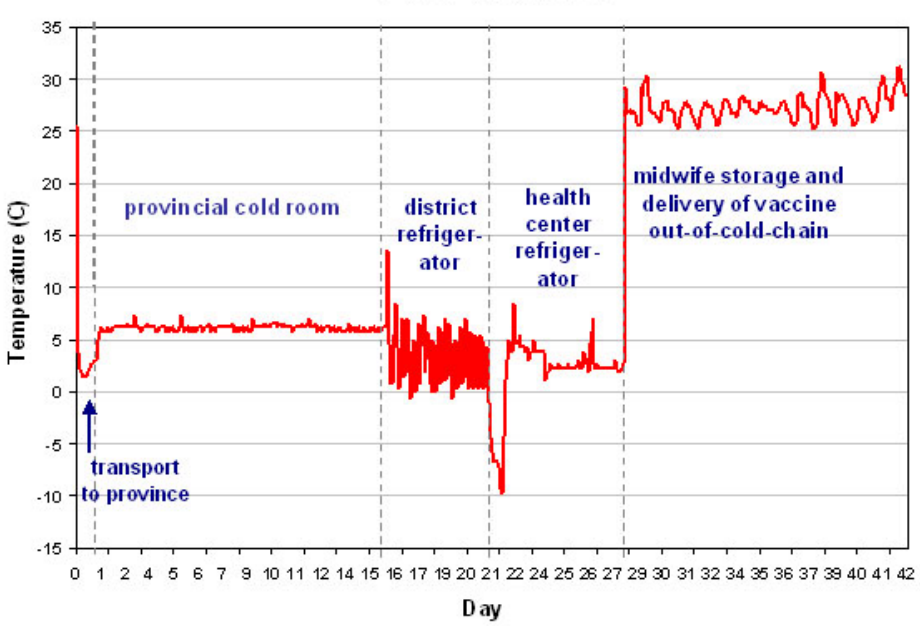
To find additional "weak links" in the cold chain, the study conducted a baseline monitoring of cold chain temperatures during distribution to several health centres in two provinces. Of 14 shipments that were monitored, 12 experienced freezing temperatures at one or more points in the cold chain. Ten froze during district or sub-district transport in cold boxes, six froze during district-level storage (primarily ice-lined refrigerators) and three froze during health centre storage (primarily RCW dual-power refrigerators).

The following graph shows the temperatures experienced by the vaccine during the cold chain from the manufacturer to the point-of-use (see Figure 37). Freezing was encountered at both the district level refrigerator and the health centre refrigerator. Note that the midwife

Uniject™ is a trademark of BD.

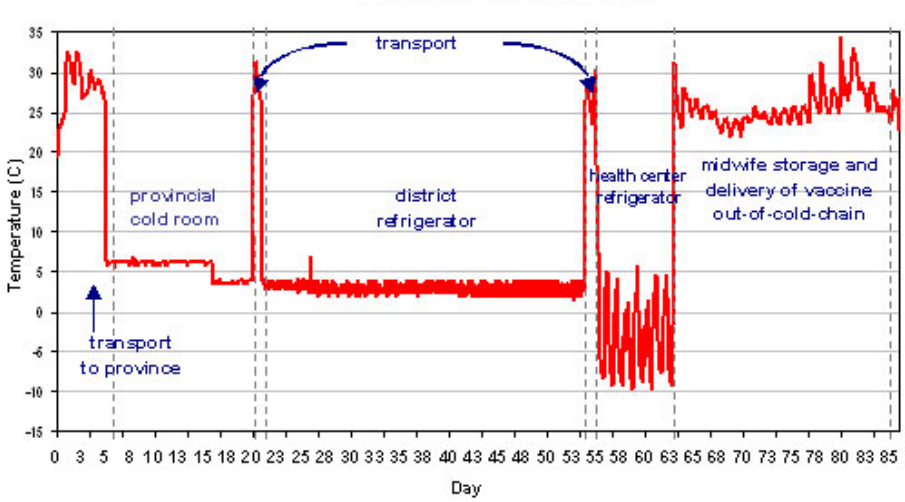
storage and delivery did not cause excessive temperatures and the vaccines were much "safer" during this ambient storage than during refrigeration.

Figure 37: Temperatures experienced by the vaccine during the cold chain from the manufacturer to the point-of-use, Indonesia cold chain study, Phase 1 (Baseline)



The second phase of the study monitored the temperatures of vaccine delivered to the provinces via the postal service and then transported to the districts and health centres without ice. Between the ambient temperature transport legs, the vaccines were stored in the standard provincial cold rooms, district refrigerators and health centre refrigerators. An example of the ambient transport is shown in the graph (Figure 38). Note that ambient transport did not subject the vaccines to excessive temperatures; however; this batch was frozen during health centre refrigeration.

Figure 38: Temperatures experienced by the vaccine during ambient transport Indonesia cold chain study, Phase 2 (ambient transport)



The next phase of the study will monitor vaccines stored in air-conditioned rooms at the district level and stored at ambient temperatures at the health centre level. The combination of ambient transport and elimination of district and health centre refrigeration will result in a greatly reduced occurrence of freezing without excessive heat exposure. A dramatically simplified cold chain may be possible for hepatitis B vaccine in Indonesia.

Possible flexible cold chain strategies

There are several possible strategies for more flexible cold chains, including:

- ambient outreach and field storage (the approach taken by Indonesia);
- ambient transport (such as the postal service delivery and no ice pack transport being modelled in Indonesia);
- air-conditioned room storage (such as the district-level air-conditioned room storage being modelled in Indonesia);
- fast distribution, especially in campaigns, efficient distribution and use of vaccine could eliminate the need for some or all components of the cold chain;
- domestic refrigerators set at higher temperatures. Although domestic refrigerators may not have optimum temperature control or hold over time, when set to a higher temperature (10°–20°C) they could provide safe and reasonably priced vaccine protection.

How to introduce flexible cold chains

Cold chain flexibility will be highly dependent on the unique environmental and distribution systems within each country. Ambient temperature ranges, distribution opportunities, VVM adoption, as well as the stability of the specific vaccines must all be considered when designing a flexible cold chain. An organization such as Technet could facilitate experimentation and adoption of flexible cold chain strategies in several ways by:

- providing guidelines on how to design new approaches and where they might be most appropriate;
- providing documentation of examples from countries such as Indonesia that are implementing flexible cold chain programmes and studies;
- sponsoring regional demonstration programmes to allow programme managers to see and understand local opportunities for cold chain flexibility.

A flexible cold chain approach could not only reduce vaccine freezing and simplify equipment, but together with VVMs, it could empower managers and health workers to make more efficient and cost-effective vaccine distribution decisions.

5.4 Training requirements for introduction of vaccine vial monitors**

Debbie Kristensen (PATH)

Background

The purpose of this presentation is to highlight the fundamental training messages that need to be conveyed and the steps that need to be taken prior to introduction of VVMs on all

vaccines. VVM training to date has largely focused on the use of VVMs for polio national immunization days (NIDs). This training must now be extended to all those who handle vaccines for both routine immunization and campaigns. Without training, the VVMs are likely to be ignored and the benefits will not be realized.

A few countries are already using VVMs on vaccines other than polio, and some countries expect to receive new vaccines with VVMs in the very near future. For example:

- Indonesia currently uses VVMs on hepatitis B vaccine in a pre-filled mono-dose syringe format.
- Viet Nam expects to receive 3 million doses of measles vaccine with VVMs from the Japan International Cooperation System later this year.
- Japan BCG is prepared to deliver 1.5 million ampoules of BCG with VVMs for UNICEF orders.
- The Partnership for Child Health will provide 9 million doses of tetanus toxoid in pre-filled mono-dose syringes with VVMs to target countries, beginning with Burkina Faso in late 2001.
- At least two Indian producers of hepatitis B vaccine are incorporating VVMs onto their products.

Benefits of VVMs

If policy makers and end-users clearly understand the benefits of this technology, they will be better motivated to devote time and effort into learning how to use it.

- **Health workers can use VVMs to prevent delivery of heat-damaged vaccine.** VVMs provide a warning signal when vaccine has been heat-damaged and should be discarded.
- **VVMs can be used to manage stock** by identifying which vaccines have received some heat exposure, but are still good, and should be used first.
- **VVMs reduce unnecessary vaccine wastage.** They can identify useable vaccine after a cold chain failure or after an outreach trip.
- **VVMs can facilitate the relaxation of the cold chain, where desired** – with a side benefit of preventing freeze-damage to sensitive vaccines.
- **VVMs can be used to detect cold chain problems** if individual facilities document vaccine discards due to VVM status. The data can be used to identify where problems are occurring and to focus resources on the cold chains of those facilities.
- **VVMs facilitate outreach** – as seen during numerous polio NIDs. If OPV can be transported for days without ice, just imagine how long the other vaccines will last under similar conditions.

Categories of VVMs

Four categories of VVMs are currently available (see Table 7). Each vaccine from each manufacturer is assigned to a category by WHO. For example, most heat stable vaccines

such as hepatitis B and tetanus toxoid, will have a VVM30 that will last up to 30 days at 37°C. In contrast, the VVM2 for polio vaccine lasts only two days at the same temperature.

Table 7. VVM reaction rates by category of heat stability

Category (vaccine)	No. days to end point at +37°C	No. days to end point at +25°C	No. days to end point at +8°C
A: High stability	30	193	More than 18 months
B: Medium stability	14	90	More than 18 months
C: Moderate stability	7	45	More than 18 months
D: Least stable	2	Na*	140

*VVM (Arrhenius) reaction rates determined at two temperature points

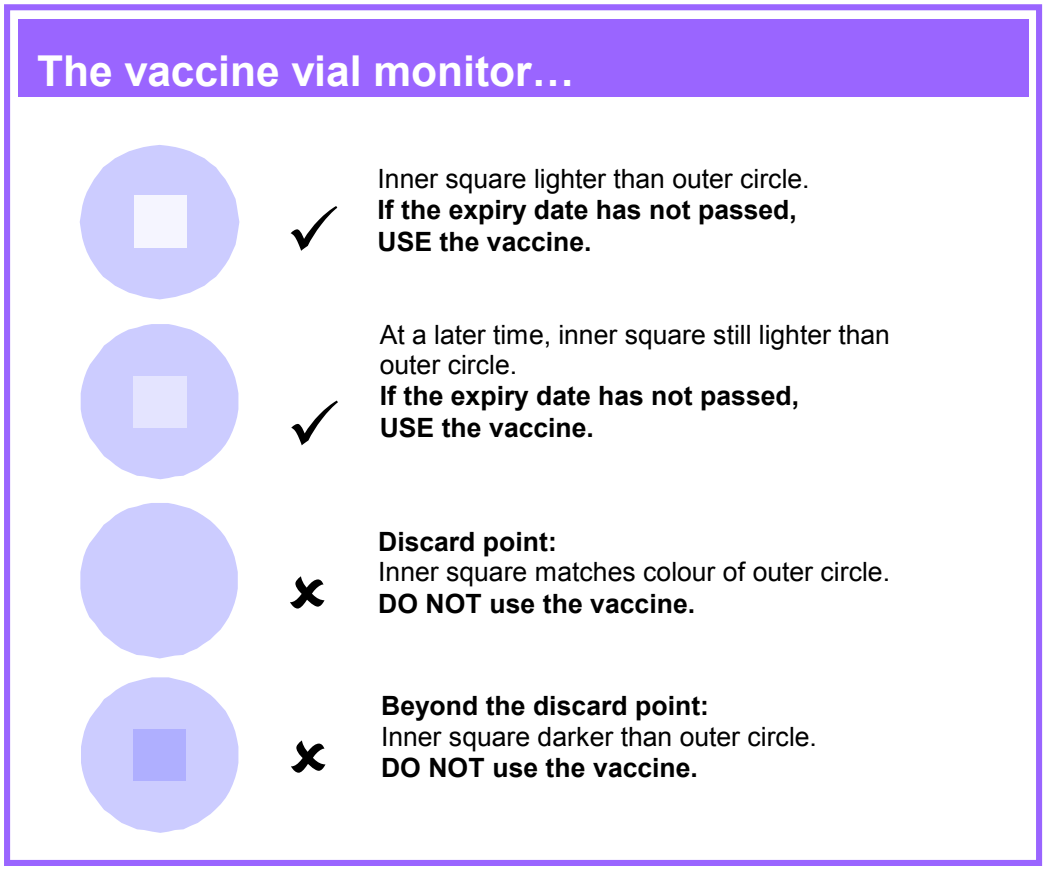
Important training messages

When conducting training, the following information should be conveyed:

4. **How to read and interpret the VVM**. The chart below (Figure 39) and others like it show only four of the points in the continuum of the colour change of the inner square of the VVM from light to dark. This simple tool has been successfully used for training throughout the world.

   Note: In a few instances, however, this chart has been mistakenly used as a quality control device to reject lots of vaccine at central stores because the centre square of the VVMs on the vaccine did not exactly match the colour of the centre square of the first VVM on the chart. The chart is not meant to be used for this purpose. It is a qualitative tool, not a quality control device.

Figure 39: How to interpret VVM colour



5. **The location of the VVM.** For liquid vaccines, the VVM will almost always be located on the vaccine vial label. The exception is that one brand of OPV has a VVM on the wing cap of the tube. For freeze-dried vaccines, the VVM will be located on the cap of the vial or the top of the ampoule. The reason for this is that the VVM is no longer valid after the vaccine is reconstituted and it should therefore be discarded when the vial is opened.

6. **Reminders of the need to discard reconstituted vaccines within 6 hours.** This is an important point that should be reinforced during VVM training to ensure that health workers understand that VVMs and the multi-dose vial policy for liquid vaccines do not change the way that freeze-dried vaccines are handled after reconstitution.

7. **VVMs are reliable tools and different vaccines will have VVMs that change colour at a different rate**. The interpretation and use of the VVM, however, is identical for all vaccines. Training needs to include information about the reliability of the VVM and the real stability of vaccines in order to build confidence in the tool.

   Note: In several East African countries, health workers have been discarding oral polio vaccine when the VVM indicates some heat exposure, but is not yet at match point. Presumably there is fear about any level of heat exposure and they are taking even more conservative action than necessary, wasting vaccine that is not heat damaged. Such conservatism may be overcome by explaining the independent laboratory validation that

has been performed on all four types of VVM, the release testing that is conducted by both the VVM and vaccine manufacturers, and the approval of the tool by WHO.

Programme implications

In addition to training, there are some other steps that countries can take to prepare for broader VVM introduction:

Procurement – Those countries procuring their own vaccines or accepting donations can request that manufacturers supply all vaccines with VVMs that meet WHO specifications.

Vaccine distribution – There may be initial transition periods where countries receive a mix of vaccines with and without VVMs. Ideally, the vaccines with VVMs will be sent to areas with the poorest cold chains.

Policy – Countries may want to tie adoption of the multi-dose vial policy for liquid vaccines to the availability of VVMs on those vaccines. The VVMs will provide added information on the heat-exposure status of the opened vials of vaccines. Countries might also consider flexible cold chain policies for vaccines with VVMs. Note: Indonesia is already studying possibilities for relaxing storage temperatures for their mono-dose hepatitis B vaccine presentation. Such changes can help to overcome cold chain capacity constraints, prevent freeze-damage and decrease costs.

Wastage monitoring – If countries are monitoring vaccine wastage, it could be beneficial to include the reasons for discarding vaccines on their forms. Discards due to a VVM indication of excessive heat exposure could be specifically noted on inventory forms and reported to supervisors. Such data can be used to help identify cold chain problems. Note: 80 000 doses of heat-exposed OPV were discovered due to VVMs in Uttar Pradesh, India. A follow-up investigation revealed problems with the cold chain that were previously unknown and can now be corrected.

Sources of information on VVMs

Most of the documents listed below are available from WHO. A few are being revised to incorporate information about the availability of VVMs on other EPI vaccines. For those of you who have experience with these documents already, this is an ideal time to provide feedback on them to Ümit Kartoğlu at WHO (kartogluu@who.int) or to Debbie Kristensen (dkriste@path.org) at PATH so that improvements can be incorporated.

Policy documents

- Quality of the cold chain: WHO–UNICEF policy statement on the use of vaccine vial monitors in immunization services (WHO/V&B/99.18). English and French.

- WHO Policy Statement: The use of opened multi-dose vials of vaccine in subsequent immunization sessions (WHO/V&B/00.09). English, French, and Spanish.

Reference documents

- Specifications for vaccine vial monitors (WHO/E6/IN5). English.

- Testing the correlation between the vaccine vial monitor and vaccine potency (WHO/V&B/99.11). English and French.

Training materials

- The vaccine vial monitor – training guidelines (WHO/EPI/LHIS/96.04[1079]). English. **Under revision.**

- Temperature monitors for vaccines and the cold chain. (WHO/V&B/99.15). English and French. **Under revision.**

- Making use of the vaccine vial monitor – flexible management for polio supplementary immunization activities (WHO/V&B/00.14). English and French.

- Giving safe injections: introducing auto-disable syringes (PATH/SEA/00.12). English, French and Russian. **Under revision.**

- Vaccine vial monitor training cards (PATH 1999). Distributed by WHO/AFRO. English, French and Portuguese.

Training aids

- Vaccine vial monitor poster. This poster shows different colour changes recorded by the VVM and how to interpret them. Useful for training purposes and as a guide on the wall of a health centre (WHO – CCPS/20 [4027]). English and French.

- Vaccine vial monitor sticker. A rectangular sticker showing four different stages of colour change registered by the VVM (WHO – CCST/05 [3013]). Size 10.5 x 11 cm. English, French, Russian and Spanish.

- Temperature monitoring and handling of freeze-dried vaccines poster (WHO – CCPS/21[4031]). English and French.

5.5 The timeline for VVM implementation on all antigens

Shanelle Hall (UNICEF Supply Division)

Shanelle Hall reported that VVM specifications for all antigens had been completed and issued to vaccine manufacturers in August 1999. UNICEF's 1999 tendering round had included a request for the supply of vaccines with VVMs and the 2000 round had attracted VVM offers from two companies. The tender for 2001 to 2003 had also included a VVM requirement and a number of manufacturers had offered to comply.

She noted that, although the VVM requirement was in place, implementation was proving to be more difficult than had previously been thought. A work plan had now been agreed with WHO, and discussions were underway with Lifelines and the vaccine manufacturers to deal with the commercial and technical issues. No timeline was yet in place and she would report back when a programme had been agreed.

5.6 Monster or monitor: how well to we manage our vaccines?

Dianne Phillips (Department of Health, South Africa)

Dianne Philips gave a rapid résumé of some training material she had prepared to demonstrate the use of VVMs on OPV vaccine to a group of pharmacists who had been failing to look after vaccines correctly. The material posed the following questions:

- What do you know about a vaccine vial monitor (VVM)?
- What does the VVM tell me?
- What is its function? Does it measure the journey or the passenger?
- What happens if the cold chain is broken?
- What happens if I put the vaccine in boiling water for a short while?
- What does it mean when the colours change in each of the following ways:
  - inner square is white in colour;
  - inner square has changed to pale grey – still lighter than the outer square;
  - inner square is now the same colour as the outer circle;
  - inner square is now darker than the outer circle – beyond 'discard point'?
- What about expiry date? What does it tell me?
- Which vials will you use?

5.7 Discussion

Anthony Battersby commented that it was good to see freezing back on the agenda. An informed decision on raised storage temperatures is the key, because if we can accept higher limits, then new technologies can be brought into play. The original limits were selected as an insurance policy against cumulative bad behaviour in the cold chain. He reported on recent work, monitoring temperatures in cold boxes, which indicates that it is not possible to prevent temperatures dropping below zero, even when ice packs are conditioned correctly. If we could raise the upper storage temperature then this would allow eutectics to be considered.

On the question of domestic refrigerators, he pointed out that refrigerators adjusted for use in hot climates often freeze vaccine at night.

In the question of VVMs he noted that users have a real problem reading the indicators when the VVM spot is just lighter or just darker than the background. Would it be possible to start with a grey spot and finish black?

Mogens Munck (UNICEF consultant) reminded the meeting of his 1998 Technet paper on eutectics, which proposed that their use should be reconsidered. Eutectics, such as Glauber's salt (sodium sulphate decahydrate), would eliminate the need for ice pack freezers. He circulated a paper setting out the results of recent laboratory experiments, commissioned by UNICEF, carried out at CSIR Johannesburg earlier this year. He requested that WHO evaluate this work and move forward to field testing.

Dr K. Suresh (UNICEF, Delhi).The flexible cold chain experiments in Indonesia seem encouraging, but has it been tested epidemiologically? He suggested serological testing before the experiment is extended further.

Mikko Lainejoki (UNICEF) proposed that the use of domestic refrigerators be seriously reconsidered.

Dr Anil Varshney (PATH) inquired about a problem in the past in India with regard to VVM status and OPV potency.

Dianne Phillips (DoH South Africa) showed training material about VVMs prepared for use in South Africa.

Robert Steinglass (BASICS) noted that the presentations in this session revealed that there was an array of tasks still to be completed to ensure a satisfactory cold chain. He suspected that there were not enough people attending to the details and that GAVI is moving too fast and is ignoring some basic cold chain problems. He found Søren Spanners's presentation particularly alarming.

In the early days, WHO was committed to putting operational officers in the countries. He wondered if Alan Schnur was now an exception. It is easy to get bogged down in details, but operations and logistics tasks are far from complete. A serious injection of reality is needed.

Alan Schnur (WHO China) made the following points:

- In operations beyond the cold chain, we have to look at the risks from vaccine exposure to low temperatures as well as high temperatures – e.g. northern China in winter.
- We must remember that measles has to be kept cold when it is reconstituted – thus there is still a need for ice.
- In his experience, domestic refrigerators with water bottles operate satisfactorily for up to 6 hours without electricity.
- China is now working on a water-jacketed vaccine refrigerator for use in situations where power cuts are less than 4 hours. The projected unit cost is US$ 200 to US$ 300.

Peter Carrasco (PAHO) noted the following:

- Do the VVMs for vaccines other than OPV have the same colour transition?
- Are manufacturer's inserts being changed to reflect the use of VVMs?
- Polio outbreaks have occurred as a result of OPV heat exposure.
- Yellow fever vaccine is more heat labile than OPV.
- US manufacturers have phase change materials that operate between +2° C to +4° C.
- We must be careful not to cause confusion. Changes in the temperature guidelines are difficult to implement in the field.
- Vaccine-preventable disease incidence in PAHO and globally is getting worse.

Ümit Kartoğlu (WHO) made the following comments about VVMs:

- Colour change is the same for all four types.

- Japan BCG is ready to supply 1.5 million doses to UNICEF with VVMs attached. However no training material for this product has yet been prepared.

- Vietnam is receiving measles with VVMs.

Dr Ted Prusik (Lifelines Technology Inc.) explained that the VVM colour change is caused by a solid state reaction, which starts light blue-purple and changes to dark-blue purple. Grey and black is not achievable.

Shanelle Hall confirmed that VVM data will be on the inserts of VVM-equipped vaccines.

Dr Boi-Betty Betts (WHO/AFRO). There are VVM training cards, illustrating 24 different scenarios, which are very valuable. These cards should be added to the PATH training materials list.

Allan Bass shared the concerns about vaccine freezing in refrigerators and cold boxes. In 1984 the Consumers' Association carried out a cold box study and found that 15% of DTP vaccine froze in an RC25 cold box. We now need to repeat these tests. Similar discussions to this one have been taking place for more than ten years. We know that the cold chain is destroying vaccine and the evidence suggests that many vaccines are actually safer in the health worker's pocket than they are in the cold chain. How do we move the matter forward and how are we going to make decisions? There needs to be a working group and somebody must be made responsible for setting this up.

Dr Emmanuel Taylor (WHO/ICP) noted that discussions such as this always omit the need for 'good housekeeping'. Some cold stores are like dustbins. If we insist that they are well arranged staff come to understand the problem better. A good quality environment leads to good quality outputs.

Carib Nelson. There is indirect evidence from Indonesia of a large diphtheria outbreak that may have arisen following the use of frozen vaccine. The Indonesian flexible cold chain experiment shows one way in which this sort of problem could be avoided.

Søren Spanner. We urgently need to concentrate on procuring new cold chain equipment that does not freeze vaccine. Equally urgently we need an action plan to prevent existing equipment destroying vaccine. Domestic refrigerators are not the answer. For example the 'frost free' models used in Sri Lanka can reach -2° C. As Alan Bass has suggested, a working group needs to be set up and the initiative for this should come from WHO Geneva.

Debbie Kristensen agreed with Anthony Battersby that VVM training materials should include more guidance about colour recognition close to discard point. In regard to the India OPV and VVM problem, a WHO consultant conducted a complete investigation and her recollection is that the investigation revealed problems with both the laboratory testing of the OPV and the handling of the vaccine prior to labelling. There was no problem with the performance of the VVMs.

Hans Everts noted that there had been a long discussion before it was agreed to standardize at the current +2°C to +8°C and this temperature range is now shown on vaccine manufacturer's inserts. Manufacturers would not be happy if a further change were to be made. He agreed that eutectics should be looked at again. Robert Steinglass's point is well taken. Operational issues have not been given the attention they deserve since the reorganization within WHO. However, there are more staff present at country level than ever before, and operations have not ceased to exist. Nevertheless, he suggested that

Technet should recommend that WHO strengthen operations activities. Allan Bass strongly seconded this suggestion.

Hans Everts said he very much supported pilot projects on flexible cold chain. There would be a major shift involved if responsibility for flexible cold chain decision-making were to be delegated to countries, as suggested by Carib Nelson.

In regard to VVM knowledge he noted that, in Africa, staff have been trained to use VVMs during NIDs. There is evidence that health workers do know how to use VVMs but may limit their knowledge to campaign settings and not use the indicators for routine activities. It has taken three to four years to get this far. He hoped that knowledge on the wider use of VVMs would be picked up faster, but he acknowledged that it would be a long-term project.

Ümit Kartoğlu (WHO) agreed that small-scale working groups are very critical for the success of Technet. He wants to bring these groups back to life. There will also be some soft programmatic working groups dealing with issues such as wastage issues and drop-out rates.

The moderator summarized the meeting. Various speakers have contrasted the issue of human versus machine performance – we need to re-evaluate the fit between the two. We need to combine good judgement, good housekeeping, good manufacturing practice and good vaccine distribution practices. Those countries that are prepared to carry out practical initiatives are to be commended. Supervision, guidance and training are critical. Provided training is good we should not be wary of local decision-making.

Themes and conclusions

- There was general agreement that vaccine freezing is a continuing and serious issue in many countries and that the GAVI process and the introduction of new vaccines has the potential to exacerbate this problem.
- There was general agreement that the use of eutectics, as a potential solution to the problem of vaccine freezing, should be further investigated and field-tested.
- There was general agreement that flexible cold chain initiatives should be supported and their outcomes should be properly monitored.
- Participants debated the use of domestic refrigerators for vaccine storage, but were unable to agree on their suitability.
- There was agreement that additional training material and effort is needed to prepare for broader VVM introduction.
- Technet should recommend that WHO Geneva immediately set up a working group to address the problem of vaccine freezing. The working group should urgently provide technical solutions to the following problems: vaccine freezing in refrigerators; vaccine freezing in cold boxes; and vaccine freezing in cold climates during operations beyond the cold chain.
- Technet should strongly recommend that WHO strengthen its in-country operations activities.

6. Sixth session
Logistics

Chair: Dr Jean Smith (WHO Nepal)

6.1 WHO-UNICEF Cold store certification initiative **

Andrew Garnett (WHO Temporary Adviser, UK)

Background

Immunization programme reviews conducted in many countries during the past few years have shown that logistics problems continue to remain an obstacle to achieving substantial progress in immunization. In particular, poor management of the vaccine cold chain, one of the major components of the logistics of immunization, plays a major role in the low performance observed by these review teams.

One of the factors that led GAVI to focus on infrastructure strengthening is the perception that cold chain and vaccine distribution mechanisms are disintegrating in many countries. The real need for better vaccine management practices can also be seen in the high levels of wastage observed (and recorded on GAVI fund application forms) and in the prevalence of adverse events. These adverse events arise, at least partially, as a consequence of incorrect vaccine storage and distribution practices. In addition, the failure of programmes to implement the multi-dose vial policy and to use VVMs also contributes to the problem of vaccine wastage.

There is a continuing need to monitor the use of cold chain equipment and to ensure that recommended vaccine management procedures are followed. The principal function of the cold chain is to ensure that vaccine is kept at the correct temperature so as to maintain its potency from the time it leaves the vaccine manufacturer, through shipping and storage, until the moment it is administered. To this end, it is recommended that the equipment used for fixed storage (cold rooms, refrigerators and freezers) and for storage during transport (cold boxes and vaccine carriers) should comply with a set of performance standards defined by WHO and UNICEF. In addition, stock management procedures have been established so that vaccines are stored at the national and sub-national levels of the cold chain no longer than is necessary.

With the introduction of additional vaccines that are very sensitive to freezing as well as to heat (such as HepB and Hib), good vaccine management becomes an ever more vital activity. Without it, planned targets will not be achieved. In addition, these new vaccines are expensive. This increases the risk of major financial losses occurring in cold chains that are poorly managed and poorly maintained.

In order to address growing concerns on vaccine management practices globally, V&B/ATT has already introduced a project on vaccine management training. This project aims to promote good vaccine management practice. For the first phase of this project, 13 countries

from Africa have been selected. There are plans to extend the project to all other regions by 2003.

Three important issues need emphasizing as a consequence of recent developments in immunization practice and progress in the technologies and methods used in vaccine management:

8. **Efficient vaccine management** is critical if vaccines are to be delivered at their full potency to a final cold chain location, from where they can be taken out to fast chain.

9. **The availability of VVMs** on all internationally procured vaccines will allow a relaxation of some of the very inflexible rules for operating the cold chain. This will permit more individual national initiatives, while still ensuring safe vaccine storage and handling. A good understanding of the parameters which affect vaccine potency is a prerequisite for any country that chooses to implement a flexible cold chain.

10. **Increased pressure** will be put on the cold chain over the next few years as a result of health sector reform, the integration of delivery of essential services with GAVI and the availability of new vaccines in new lower-dose presentations.

There are many existing documents that provide advice on establishing and managing cold chain systems. However, these documents do not sufficiently emphasize the importance of system performance evaluation.

All of the above factors have shown the need for better understanding and tighter control of vaccine management. Accordingly, WHO and UNICEF have jointly launched an initiative which will encourage countries to obtain formal recognition that their vaccine storage facilities conform to agreed global standards.

The Cold Store Certification Initiative

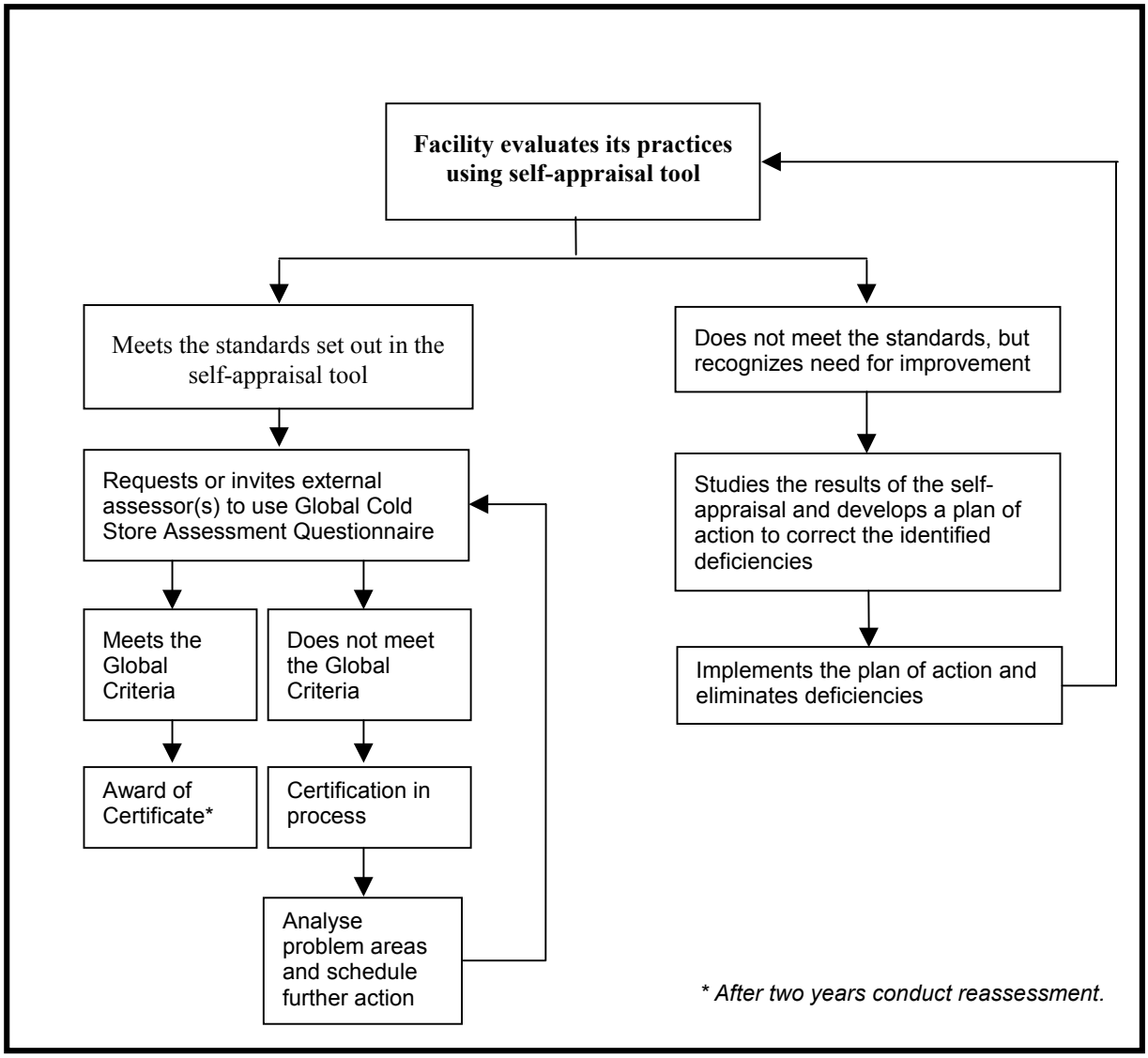
The Cold Store Certification Initiative is intended to encourage programmes to adopt practices that fully protect vaccines and to promote and support efficient stock management and vaccine distribution systems in the current rapidly changing environment. In addition, a number of cold chain management documents are in the process of being updated to take account of new vaccines and updated practices.

The proposed initiative will be targeted at national stores. The certification procedure will begin with a process of self-appraisal by the facility itself. This initial self-assessment will enable managers to identify equipment and practices that hinder efficient vaccine management. Once this process has been carried out, facilities will be in a position to identify and to make any necessary changes.

When a facility is satisfied that it meets a high standard, this achievement can be ratified by means of an external evaluation process. This evaluation will benchmark the facility against a set of internationally agreed cold chain management standards. Provided these standards are met, the facility will be awarded with an Efficient Cold Store Certificate. Should the facility fall short of the benchmark requirements, the inspection team will recommend changes. Provided these changes are relatively minor, the team will also issue the facility with a Certificate of Commitment. This intermediate stage in the certification process is intended to encourage the facility to correct defective practices and to re-apply for full certification. See Figure 40 below.

It is not intended that the external inspection team should evaluate and certify sub-national and service level stores. However, it is intended that the assessment tools to be developed will include protocols that can be adapted for inspecting sub-national and service level facilities. These inspections will be carried out by national inspectors who have been trained in the use of these tools. The certification process will therefore include an evaluation of a country's progress in training staff to carry out this sub-national inspection activity and of their subsequent progress in carrying out the inspection process itself.

Figure 40: Cold store facility certification process*



6.2 Discussion

Dr Subhan Sarkar (MOH, India). When defining the indicators, we need to be clear whether we are intending to certify a store or a cold chain system.

Dianne Phillips (DoH, South Africa). Indicators should not be different for public and privately run stores. The administration procedures may vary, but the basic performance criteria should not.

Andrew Garnett said that he had in mind the need to examine contractual arrangements with private service providers as part of the review process for privately run stores. Dianne Phillips agreed with that.

Dr Ümit Kartoğlu (WHO) outlined the background to the initiative. The Crown Agents' questionnaire had been based on the current edition of the vaccine stores guideline that was now being revised. It had proved to be extremely difficult to make assessments using this tool, because it was too detailed. We are looking here for something like the baby-friendly hospital approach – a set of essential criteria for a cold store.

Dr Jean Smith (WHO Nepal). Is certification to be mandatory, or is it to be voluntary? If mandatory, what are the penalties?

Andrew Garnett. Certification is voluntary. The underlying purpose is for countries to prove to themselves that their vaccine storage is up to international standards.

Dr Ümit Kartoğlu (WHO) agreed that the purpose was to bring prestige to a country and to encourage participation.

Anthony Battersby What happens if a cold store does not get a certificate? For example, can UNICEF then supply it with vaccine?

Andrew Garnett commented that this was the purpose of the intermediate stage certificate – to allow a store to be on an improving course leading up to certification.

Anthony Battersby asked whether the intention was to certify cost-effectiveness or simply to certify adequate technical standards. There were some countries where contracting out was the sensible route to take – for example, South Africa.

Andrew Garnett. The purpose of this discussion is to establish these criteria.

Mikko Lainejoki (UNICEF) asked if it was intended that private companies or international consultants would be used for the assessment process.

Søren Spanner (WHO SEARO), having already done some work on certification, thought that it would be easier for countries to apply to donors for vaccine if stores were certified.

Dr Subhan Sarkar (MoH, India) thought that certification could be dangerous in cases where stores suffer from poor electricity, etc. The store's reputation might be damaged if it was not certified and donors might only supply certified stores. Is there to be an internal assessment stage before certification is applied for? If there is, then certification could follow on much later.

Andrew Garnett confirmed that self-assessment was intended to be the first stage in the process and that some programmes may not want to go beyond this stage.

Søren Spanner (WHO SEARO) thought that self-assessment should be a tool to help countries. Certification might then follow.

Tony Burton (WHO) was concerned about the idea of certification. The alternative would be a clear articulation of minimum standards to drive an internal evaluation and external validation process. Certificates are most useful to external organizations. He agreed with Anthony Battersby's point – should a programme receive funds if its store is not certified? In his view, certification of cold stores differed from the baby-friendly hospital approach, which was intended principally to reassure clients of the hospital rather than outside agencies. He would rather see assessments feeding a central repository of data on national cold stores. This would achieve the benefits of certification without the need for a formal seal of approval.

Peter Carrasco (PAHO) agreed that stores need to be assessed, given the existing value of vaccine and the imminent introduction of new, more expensive antigens and new cold rooms. However, certification is too risky. Self-administered assessment is the correct approach, with the results made available to WHO on request.

Hans Everts (WHO). Would it be possible to link the initiative to GAVI process – not as a condition of funding, but as a GAVI service?

Tom O'Connell (WHO) suggested that evaluation criteria should be weighted. For example, one could define three or four different performance levels leading to progressively higher levels of certification.

Andrew Garnett suggested a methodology similar to that described earlier by Souleymane Kone.

Anthony Battersby was not clear that GAVI was relevant. This is a technical issue and WHO is the relevant technical agency. What happens if a WHO-certified store fails? Have WHO lawyers been asked to comment on the legal implications?

Dr Ümit Kartoğlu (WHO) suggested that modified versions of the assessment criteria should be used to evaluate the lower level stores. International inspectors would inspect the national store and would train groups of internal assessors who would check the lower levels stores. He argued for a step-by-step approach down towards the peripheral stores.

Andrew Garnett suggested that one of the criteria for certification should be the capacity to assess level stores.

Anthony Battersby understood that the initiative was only directed at national stores. Certifying lower level stores would be an enormous task and would have to include certification of the distribution system.

Dr Ümit Kartoğlu (WHO). The intention was to certify the stores themselves – not the system as a whole. The purpose was to establish minimum global standards.

Dr Subhan Sarkar (MOH, India) wanted the initiative to be an evaluation, not a certification process. Certification could endanger progress. India has no national store, 108 regional stores, 600 district stores and 22 000 peripheral units with refrigeration.

Søren Spanner (WHO SEARO). Certification is important. Vaccine is worth millions of dollars. He gave examples of stores in India without fuel for emergency generators and without ink for temperature chart recorders.

Hans Everts (WHO). Certification should be reserved for the national level. It would be very compromising to certify at the sub-national level. We need to consider how to deal with countries that have no national store.

Paul Fife (UNICEF).Some of the issues discussed came up in the initial discussions about the initiative. He agreed that certification should be a step-by-step process, starting at national level.

Dr Ümit Kartoğlu (WHO) finished the discussion by saying that a working group would develop the global indicators and would look at the depth of detail required at different levels in the system.

Themes and conclusions

- There was general agreement that some form of rigorous assessment of vaccine stores was required.
- There was considerable concern expressed about the implications of extending the formal certification process beyond national level stores. Several contributors considered this to be an impractical ambition.
- It was generally agreed that the initiative should initially concentrate on national level stores.
- Some contributors expressed concern about the whole idea of formal certification. There was a worry that stores which failed to achieve certification might be blacklisted by donor agencies and deprived of vaccine. Other contributors argued that most, if not all, of the benefits of certification could be achieved through a process of self-assessment.
- WHO should investigate the legal implications of formal certification.

6.3 Product information sheets – making a live guide for countries

Mikko Lainejoki (UNICEF Supply Division)

Introduction

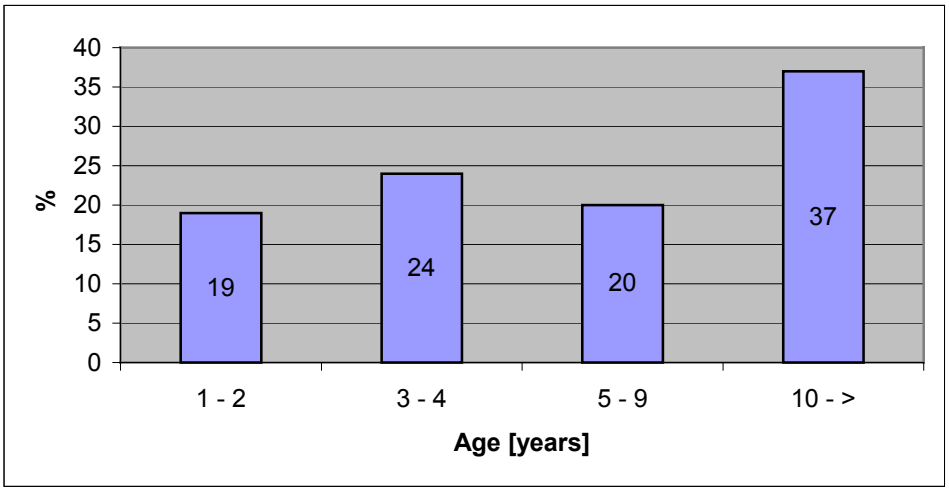
Mikko Lainejoki started by quoting the current criteria for including equipment in PIS, namely that: "The criteria for inclusion is that each item of equipment must be independently tested in accordance with standard test procedures and found to meet established specifications for performance."

Some of the practical problems encountered as a result of current specification and test procedures were that:

- the cold chain was over-specified and equipment was excessively costly;
- test results were often obtained on tailor-made samples and frequently these results bore no relation to test results on real production samples;
- no consideration was given to the manufacturing process, the financial situation of the company and feedback from the field, etc.;
- life-time 'approval' was given to the product and the manufacturer or supplier based on initial testing of tailor-made samples. Such long-term approval was never given to other items specified by WHO and UNICEF – e.g. items such as vaccines, pharmaceuticals and nutritional products.

Figure 41 shows the distribution of test results by age in PIS 2000. This shows that 37% of the products listed had not been re-tested for 10 years or more and more than half (57%) had not been re-tested for at least 5 years.

Figure 41: Age of test results in PIS 2000



PIS plus – a live guide

There was a need to emphasize that the PIS document was *not* a listing of items or suppliers approved or endorsed by WHO or UNICEF for use in EPI; rather it was a guide to help field workers and partner organizations to select suitable equipment, based solely on technical merit. Although the PIS specifically stated that items listed were 'not approved or endorsed by WHO/UNICEF', in practice people often referred to 'WHO-approved equipment'. This caused problems with donors, particularly when there was a proposal to use locally-manufactured equipment – donors were reluctant to fund such purchases unless the equipment was 'WHO-approved'.

There should be a move towards commercial standards, such as ISO, and each PIS section should include a brief generic description of the minimum requirements for the equipment covered by that section.

The guide needed to be more flexible, to take account of local solutions. However the decision to use local products should be based on the risks associated with a particular product range. He suggested, for example, that auto-disable (AD) syringes, solar powered systems and ice-lined refrigerators should remain out of bounds for local manufacture; whereas vaccine freezers could be accepted subject to certain preconditions and ice pack freezers, vaccine carriers and voltage stabilizers could quite reasonably be made locally.

He gave examples of the savings that could be made through local purchase. A vaccine carrier manufactured in Nepal cost US$ 1.50, whereas the cheapest unit in the PIS was around US$ 3.00 and others were US$ 9.00 or more. Similarly, the PIS-listed voltage stabilizers, manufactured in Europe and not tested since 1987, cost around US$ 270, whereas units manufactured in India by an ISO 9001-certified manufacturer cost no more than US$ 60.

The new guide should be expanded to include:

- basic proven solutions for the disposal of injection supplies; the Médecins Sans Frontières (MSF) guide for emergency situations contained practical guidance on this subject;

- options for meeting training needs, for example, outsourcing repair skills for central level cold stores and for compression and solar-operated units.

Over the past 20 years 200–300 cold chain technicians have been trained to repair compression units at the cost of some US$ 10–15 000 per head. He doubted that many of these had continued to work within the health sector. He suggested the idea of a 'Fitters for Health (FfH)' initiative based on the Riders for Health model.

UNICEF Supply Division could help to decrease the overload in Geneva by cooperating more closely with WHO/Geneva on PIS-related issues. He suggested:

- forming a small dynamic PIS team for regular quarterly consultations on equipment, for example: inclusion of new items; deletion of obsolete ones; reviewing feedback from the field; drawing up new specifications, etc.;

- keeping a repository of cold chain reviews at UNICEF; these provided valuable performance-related feedback from the field.

Sharing information with the field

There needed to be much better sharing of information from the field. On the technical side, UNICEF regularly purchased approximately 65% of all the items listed in the PIS. Routine feedback was important because it could be used in the course of negotiations with suppliers as a way of forcing them to take action to correct reported problems. He suggested the following possible communication routes:

- via an email account with UNICEF;

- via the UNICEF web site at www.supply.unicef.dk;

- via the WHO web site;
- via Technet e-forum postings;
- PIS Plus Newsletter (similar to the old Cold Chain Newsletter, issued 2–3 times a year); and
- via regional immunization meetings.

6.4 Price deflation in the product information sheets: what is happening and why? **

Robert Davis (UNICEF ESARO)

The last time I presented on this subject, five years ago in Manila, the buyer of cold chain equipment was in a weak position. The market in conventional fridges and freezers had seen a shaking out of small competitors, with consequent domination by the "big three" European makers of conventional fridges, namely, Electrolux, its wholly owned subsidiary Sibir, and Vestfrost, in which Electrolux has a large minority position.

This gradual shakeout of small competitors left the big three, as recently as five years ago, standing astride the world like a colossus. An oligopoly was setting prices in the way that oligopolies do. The last five years have seen a reversal of the two decades of inflation which we saw up to 1996. This is largely the result of the entry into the cold chain of two new actors, one from India and one from South Africa. Their entry may have a durable impact on the pricing of both solar and conventional cold chain. In the case of conventional units, the focus of my talk today, that impact is already visible.

Deflation is not an everyday phenomenon, since cutting prices means cutting profits. So it is remarkable that between 1993 and 1998 Electrolux chopped US$ 300 off the price of its ILR, then another US$ 150 in 2000. Other models from larger European suppliers saw similar price cuts. The most likely explanation for this unusual behaviour is the entry into the international cold chain market of Zero, a family-owned firm in Pretoria. Zero had limited international markets until 1994, when the trade embargo on South Africa was lifted. Zero is new to the international cold chain market, and is learning fast from its early mistakes, notably its dispatch to a few hot zone countries like Niger and Zaire of models designed for temperatures up to 32º. Those temperate zone models are still in stock, and are still suited for climates like those of Madagascar, which has put in two large orders for Zeros. Zero now also makes five products for the PIS, including two designed for temperatures up to 43º. These may find a durable market in central and western Africa, for example, and perhaps farther afield.

Electrolux has tried without success to buy out Zero, as it did successfully with Sibir. It is hard to see how this David and Goliath drama will play out, as Zero, with facilities only in South Africa, looks eastward for partnerships to expand its manufacturing and marketing base.

Three other trends bear watching. I will now discuss these in turn.

Farewell to OPV

OPV will soon cease to define our cold chain, as the South Americans have already discovered. Domestic refrigerators are coming into their own as suitable alternatives to more expensive models. Since 1992, when South America had its last case of polio, the South Americans have been able to concentrate on how to store measles and more heat stable vaccines at the lowest cost. The current PIS lists a domestic refrigerator conversion kit from Colombia which, if generalized outside the Americas, could lead to further cuts in the price of refrigerators listed in the PIS. There are dozens of units which will protect OPV. How many will protect all other vaccines? Certainly scores, perhaps hundreds.

Indonesia already buys from outside the PIS. In Ethiopia, local authorities have started to buy domestic refrigerators for vaccines on the local market. We can deplore this trend, which risks compromising our OPV between now and 2010, but states are sovereign, and the ultimate impact of local purchase of cold chain will be downward pressure on the prices of PIS equipment.

Ice production

During the last few years of polio NIDs, we have seen a greater need for ice making at the district and health centre level. This demand, exemplified by the seven new icemakers in the current PIS, will shrink as polio campaigns decline to a few hard core countries in central and eastern Africa. The measles NIDs for which we are now gearing up in many countries will not be repeated twice or thrice a year, and will not reverse the declining demand for icemakers.

GAVI impact on cold chain

Another trend to watch is the impact on cold chain capacity of GAVI-provided vaccines.

Quadrivalent DTP–HepB takes up about the same space as DTP, and it poses few volume constraints, but the pentavalent vaccine, also provided through GAVI, will mean resizing of cold chains, perhaps down to district and even the health facility level. Pentavalent, when supplied in two-dose vials, takes up four times as much space per dose as the DTP which it replaces. Some front-opening health facility refrigerators from Electrolux, Sibir and Zero have enough space for pentavalent vaccine. Other health facility refrigerators, such as the otherwise attractive Electrolux RCW 50 series, seem to have been designed without reference to pentavalent vaccine, and may prove too small for some health facilities in countries which introduce pentavalent vaccine, or which choose monovalent HepB vaccine instead of DTP–HepB.

A separate GAVI impact, on which data are not yet available, is the possible effect on cold chain purchases of GAVI sub-account 1, which can be used, at the recipient's discretion, for purchase of cold chain. As the 2006 deadline approaches for phase-out of CFC refrigerators, some countries may choose to use GAVI funding to replace their existing stock of ageing CFC refrigerators, especially if prices continue to fall.

Table 8 shows the price erosion of recent years. This is almost certainly linked to the arrival of a new kid on the block in the large and competitive African market.

Table 8: Conventional refrigerators and freezers, lowest quoted price for bulk orders

Make and model	PIS 1983	PIS 1985	PIS 1993/94	PIS 1998	PIS 2000	Recent price trend
E3/22, Electrolux RCW 42 EK	427	499	1006	1197	959	↓
E3/24,Electrolux ILR, TCW 1151/1152	607	670	1772	1477	1311	↓
E3/27, Vestfrost freezer, SB 300	250	250	409	399	---	↓
E3/57, Vestfrost MK 142			427	430	386	↓
E3/64, Dulas Ice liner			1206	1071	1556	↑
E3/75,Vestfrost MK /MF 4010			600	565	507	↓
E3/85, Sibir V170KE Fridge/freezer				1196	1106	↓
E3/87, Sibir V 110 KE fridge				870	805	↓
E3/89, Zero PR 245 Fridge/freezer				512	611	↑
E3/91, Electrolux RCW 50 EK					1144	NA
E3/95, Zero PF 230 Ice pack freezer					816	NA
E3/96,Vestfrost MF114 Chest freezer					284	NA
E3/102, Zero GR 265 Fridge/freezer					729	NA

Source: PIS

In Table 9, I am showing what might be a trend, or perhaps only a straw in the wind. Will the Indians and the South Africans, both new to the PIS, get small geographical niches in the global market, or are they the beginning of a larger trend? Will the long hoped for decline in the price of photovoltaic panels finally bring down the price of solar close to that of conventional power sources? I don't know. Let's look at this question at our next Technet meeting.

Table 9. Manufacturers listing products in Section E3 of the PIS*

	1983	1985	1993/94	1998	2000
Solar	No listings	Aeg-Telefunken BPSolar Dansorp Leroy-Somer Polar Prods Solarex Solavolt	BPSolar Comesse FNMA NAPS Polar Prods Solarenergie Sun Frost Unitechnica	BPSolar Comesse NAPS Sun Frost TATA	BPSolar Comesse Electrolux NAPS (Fortum) Norcoast *Solamatics* Dulas Sun Frost TATA
Conventional	Asko Brodrene Electrolux Kinsho-Mataichi Philips **Sanyo** **Sawafuji** Sibir Vestfrost	Asko Brodrene Electrolux Kinsho-Mataichi Marvel Philips **Sanyo** **Sawafuji** Sibir Vestfrost	Electrolux LEC Sibir Vestfrost	Electrolux LEC Sibir Vestfrost **Zero**	Electrolux LEC Sibir Vestfrost **Zero**

* Manufacturers from outside the USA and Europe are noted in **bold.**

6.5 Vaccine arrival reports

Shanelle Hall (UNICEF Supply Division)

Introduction

Shanelle Hall reported progress on the introduction and implementation of the standard UNICEF vaccine arrival report (VAR). As a result of some serious feedback from the Russian states regarding UNICEF vaccine shipments, the 1996 Technet had recommended that the VAR procedure be implemented.

In terms of responsibilities, it was agreed that WHO and UNICEF would develop the VAR and the guidelines for implementation; recipient governments would accept and take ownership of the vaccine; UNICEF Country Offices would assist in implementation and reporting, and UNICEF Supply Division would be responsible for record keeping and follow-up with manufacturers, forwarders and WHO.

The VAR system

The VAR was developed in 1998 and included in the international shipping guidelines. It was also included in UNICEF tender documents, but initially only for two or three countries. Subsequently the VAR and the shipping guidelines were revised and would be introduced

generally under the umbrella of ensuring vaccine quality at country level – see Gordon Larsen's presentation.

There were a number of reasons why vaccine shipments needed to be checked on arrival:

- to assure the quality of vaccines at point of delivery;
- to record vaccine ID (type, manufacturer, batch, expiry);
- to provide indicators for monitoring vaccine deliveries in order to:
  - monitor maintenance of cold chain during transport;
  - monitor compliance/deviations with shipping instructions;
  - ensure adequate record keeping of information related to vaccine;
  - form the basis for documenting claims or demand corrective action.

UNICEF procured approximately 1500 shipments per year, delivering to 100 countries, from 10–15 free carrier (FCA) locations. To avoid problems, every shipment required close coordination between the manufacturer, the freight forwarder, UNICEF Supply Division, the UNICEF Country Office and the recipient government. Mishaps could occur if any one of these parties failed to perform correctly.

There were three components in the vaccine arrival reporting process:

1. Inspection of the vaccines: covering type and quantity of vaccine, diluents and droppers and inspection of shipping indicators;
2. Inspection of the vaccine documentation;
3. Completion of the vaccine arrival report.

Five items of shipping documentation were needed in the country before the vaccine arrived so that the shipment could be processed through customs and accepted by the NRA. Generally these documents were sent by fax. The five items were:

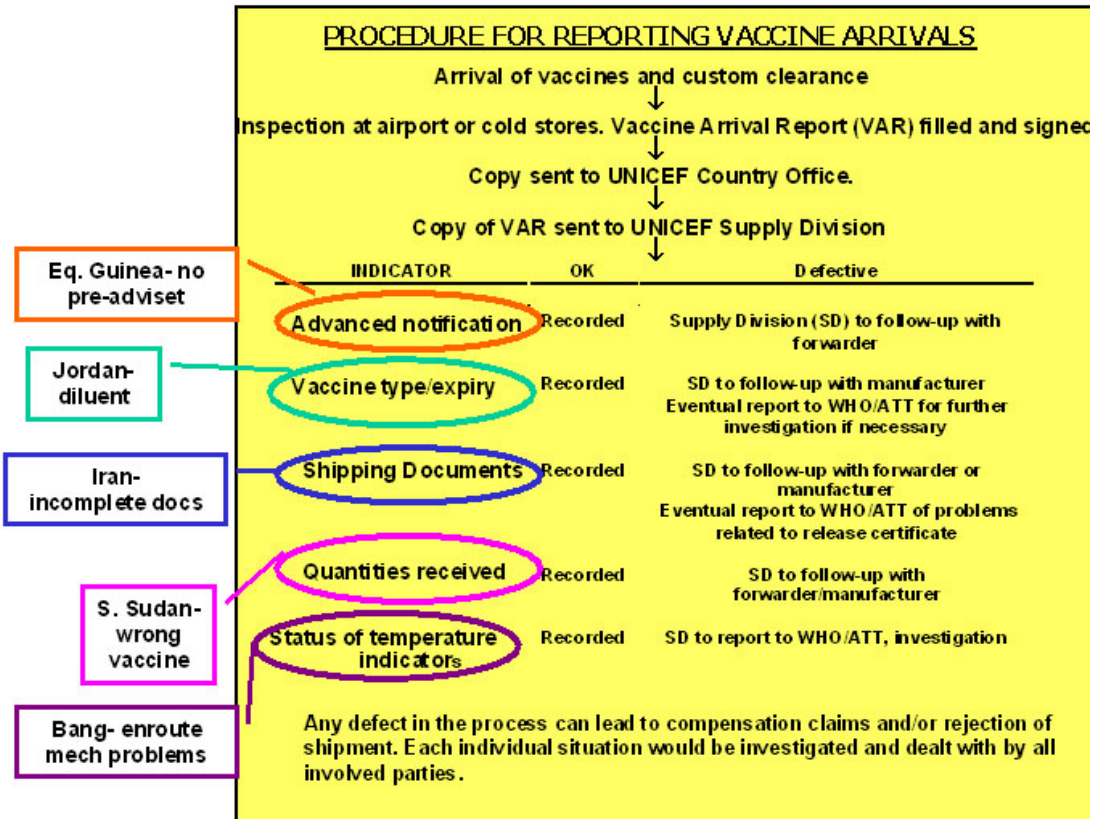
1. Pre-advice notice
2. Airway bill
3. Packing list (1 batch per box)
4. Release certificates
5. Invoice.

The VAR itself could be shipped with documents, sent by email or made available on the internet. Finally some countries might require test protocols – these were generally shipped via DHL.

Figure 42 shows the procedure for reporting vaccine arrivals. For each indicator, Shanelle Hall cited examples of things that could go wrong. In Equatorial Guinea 45 000 doses of

BCG had been lost because the pre-notification documentation was not received. In Jordan, a batch of vaccine was received, but the accompanying diluent had no expiry date recorded on the vials, packaging or accompanying documentation. In Iran, incomplete documentation held up vaccine in customs. In South Sudan, the wrong vaccine was shipped and in Bangladesh 20 million doses of OPV had been received without dry ice because the aircraft had been delayed by mechanical failure – in this instance the indicators showed that the vaccine had not been compromised.

Figure 42: Reporting vaccine arrivals



6.6 Discussion

Robert Steinglass (BASICS), commenting on Mikko Lainejoki's presentation, suggested that people in the field should be encouraged to submit comments on the use of equipment listed in the PIS in a similar way to the Amazon.com reader's comments. In response to Bob Davis's presentation, he pointed out that OPV does not define the end of the cold chain – it is the reconstitution of measles vaccine which does this. In response to Shanelle Hall's presentation he suggested that the proposed removal of the transhipment data from the VAR was inadvisable, as this information was the only way that the recipient could track the transhipment points. Are there instructions to the end user on how to file the report?

Patrick Isingoma (MoH Uganda) noted that split consignments were a big problem and that there was no section on the VAR for getting feedback on this.

Anthony Battersby said that he was deeply relieved that the PIS was not going to disappear. Adequate funding was necessary to ensure that the document was accurate and that the information in it was of good quality. The new edition should not become too large – simplicity is very important to people in the field. He agreed that a feedback system would be helpful, especially if a filtering mechanism took place in Copenhagen with the results posted on the Technet e-forum.

In response to Bob Davis, he reiterated earlier comments on the use of domestic refrigerators. These can use a lot of fuel, which is a big problem with gas and kerosene models. So-called 'frost free' models have a zone specifically designed to cool pre-chilled meals to below 0° C. Vaccine placed in this zone will freeze.

The VAR should have a space for comment over time.

Shanelle Hall agreed that this was a valid point. UNICEF does not send out split shipments unless this is agreed to by the recipient.

Alan Schnur agreed that the PIS was very useful. He agreed with the need for user feedback. The PIS helps country managers to justify purchase decisions in the face of 'non-technical' pressure at local level. In China, some of the PIS specifications are unnecessarily high (e.g. 'hot zone' appliances are not needed), so China plans to develop its own specifications. In response to Bob Davis's comments he noted that quality control, repair and maintenance in country needed to be considered. In regard to the VAR, he suggested that it should carry the UNICEF logo to encourage its completion and return.

Dr Mohammed Rahman (National Immunization Programme, Bangladesh) asked who was responsible for inspecting vaccine after arrival in country. He noted that vaccine sometimes arrived without supporting documentation.

Shannelle Hall replied that the receiving government should inspect the vaccine at the airport or at the central stores. The inspection report should then be returned to UNICEF Supply Division via the UNICEF country office. No vaccine should arrive without supporting documentation.

Peter Carrasco repeated his suggestion that water bottles in refrigerators would prevent the vaccine freezing problem. In regard to vaccine freezing during transport he referred to a study in Canada using warm ice packs.

Mary Catlin (University of Arizona) suggested that every page of the new PIS should carry a footer giving the contact address for feedback. There was no use having this in one place only, as users only dip in and out of the document.

Souleymane Kone (WHO Côte d'Ivoire) suggested that the new PIS should include information on service support items such as computer software and recording forms.

Anthony Battersby in response to Alan Schnur noted that the PIS does list equipment graduated by climate zone. In response to Peter Carrasco, he noted that water bottles do no help prevent freezing in modern 'frost free' appliances. In addition, allowing multiple products into a cold chain creates a maintenance nightmare.

Hans Everts (WHO) strongly supported the PIS. He agreed that feedback from the field is needed, but commented that it was very difficult to obtain. For example, in 2000 there was a manufacturing problem on one piece of equipment and this problem was only reported by

one user. He agreed that we should not go on adding equipment. He commented that much of the introductory material is never read, but, on balance, thought that it should be retained. He was not persuaded about the idea of including software, etc.

Dr Emmanuel Taylor (WHO/ICP) recommended that the VAR be filled in both by the national immunization services' cold chain officer and the UNICEF field officer – generally UNICEF deals with this on its own.

H. T. Raubenheimer (CCCCM South Africa) asked how it would be possible to ensure that feedback comments were valid unless the complaint had first been evaluated. He recently received a user complaint about some equipment in SA. He took the local manufacturer to task, but subsequent investigations indicated that the problem was probably caused by user misuse. In SA they are intending to publish the PIS electronically on a local web site and to have closed user groups so that local comments can be received and processed.

Bob Davis thought that Alan Schnur's idea of a national PIS for large countries was a good one but there was a risk of adverse influence on the content as a result of pressure from local commercial interests.

Themes and conclusions

- There was universal support for the continuation of the product information sheets.
- The recommendation from UNICEF to form a small dynamic team (one member from WHO, one from UNICEF, one from a partner organization, e.g. PATH) to deal promptly with PIS issues (specifications, inclusion of new products or deleting obsolete ones) was supported.
- There was general agreement that a system should be implemented for obtaining, evaluating and circulating product defect reports from the field.
- The possibility of including a section on software and forms should be investigated.
- The content of the introductory material should be reviewed.
- The idea of a national version of the product information sheets for large countries was discussed and agreed to be worth considering. It was agreed that there was a risk that specification quality might be compromised by local commercial pressure.
- The new UNICEF Vaccine Arrival Report was welcomed.
- There was further discussion on the use of domestic refrigerators.

7. Seventh session: Working with GAVI

Chair: Dianne Philips (Department of Health, South Africa)

7.1 Challenges in introducing new vaccines

Pem Namgyal (WHO HQ)

Introduction

Dr Namgyal outlined the near-term programme for the introduction of new vaccines through the Vaccine Fund. In total, 37 countries would be introducing HepB and/or Hib in their immunization programmes by 2002. HepB introduction was planned in 28 countries, with three more approved for 2003. Pentavalent vaccine, incorporating HepB and Hib, would be introduced in nine countries, with a further two approved for 2003.

Issues to be addressed before introduction of a new vaccine

A number of general issues needed to be addressed before a realistic decision could be taken to introduce a new vaccine. These issues included: an assessment of disease burden and of the cost effectiveness of immunization against the target disease; the strength of the health delivery system and its ability to absorb the additional workload, and an assessment of the political commitment to, and the financial sustainability of, the proposal.

In addition, a number of issues specific to the immunization system needed to be considered. These were as follows:

- *Cold chain and logistics issues*. Consider what assessments are required in order to ensure that there is adequate storage capacity and that rapid and smooth transport of vaccines occurs. Establish what policies and procedures are in place and what training and manpower issues need to be tackled.

- *Vaccine procurement issues*. GAVI-funded vaccines were now procured by UNICEF, so countries need not worry too much about this issue.

- *Training issues*. Consider how health workers, logisticians and data managers should be trained for the new vaccine(s), what training materials (tools and guidelines) need to be produced and when training will take place.

- *Injection safety and waste management issues*. Review policy on injection safety. Consider sharps disposal and other waste management issues and consider how the introduction of AD syringes will be managed.

- *Information, education and communication issues*. Establish whether there is an advocacy plan in the country and whether adequate social mobilization has been done.

- *Monitoring and reporting issues.* Establish whether EPI forms have been adequately modified to include the new vaccines. Consider what changes are necessary to monitor the coverage for the new vaccine(s) in order to assess progress.

- *Phase-in planning issues.* Establish when the new vaccination programme will start and how the new vaccines will be phased in.

What is being done?

Dr Namgyal outlined the work that was being done on the following topics, to support the introduction of new vaccines:

- *Disease burden.* Many countries already had enough data to demonstrate the burden of disease, especially for HepB. Several estimates had also been carried out using the CDC model, which was specifically designed to use existing available data to establish disease burden. A mechanism was being put in place to allow more such studies to be carried out. In regard to Hib, more than 15 assessments had so far been carried out globally, by WHO and by others.

- *Effectiveness*. Sufficient scientific data existed to support the use of HepB and Hib and to show the dramatic impact on disease reduction after these vaccines were introduced.

- *Immunization system and sustainability issues.* A systematic GAVI mechanism was now in place to support weak countries that, owing to financial constraints, had not hitherto had access to the new vaccines. This global partnership included GAVI, the ICCs and the Independent Review Committee, which reviewed every application before it finally went to the GAVI board for approval.

Technical support

In almost all regions, WHO had now appointed a focal person responsible for new vaccines (in AFRO there were two) and to provide technical support to countries in the region. Their responsibility was to assist in:

- assessment of EPI system readiness for new vaccines;

- disease burden assessment;

- preparing GAVI application;

- technical support for any issues related to new vaccines, including routine immunization activities; and

- coordination with other immunization partners.

Quarterly activity returns to WHO were showing that more than 50% of the working time of these new appointees was spent in advising on routine activities. The introduction of new vaccines should not be seen as an isolated activity – it was integrated with immunization strengthening.

Tools for new vaccine introduction

A number of tools had been developed to support the introduction of new vaccines; these included:

- HepB management guidelines;
- Hib management guidelines;
- Fact Sheets for HepB and Hib;
- new vaccine introduction checklist;
- Hib and HepB disease burden modules; and
- a cost-estimating tool for introducing new vaccines.

Technical assistance

Technical assistance was being provided by WHO and other partners, in the following areas:

- *Logistics and cold chain assessment*. GAVI applications needed to be supported by an EPI review, carried out within the previous three years. A logistics and cold chain assessment was one of the key elements of the EPI review for new vaccine introduction. These assessments were often carried out by regionally-based logisticians.
- *Disease burden assessment*. The Hib Rapid Assessment Tool was being introduced, as was the HepB Burden of Disease assessment module developed by the CDC. Burden of disease assessment was an ongoing exercise.

Coordination and preparatory meetings

At present, the African Region was the primary focus, because this was the region where most new vaccine introductions were taking place. A number of coordination meetings had taken place: for example, a meeting in Uganda to develop vaccine introduction work plans; three meetings in Harare to sensitize on new vaccines issues; a meeting in South Africa to plan and train for laboratory surveillance for Hib; and a meeting at Abuja, to make detailed plans of action for new vaccine introduction in approved countries. Similar meetings were taking place in other regions, including the European Region, the South-East Asia Region, the Western Pacific Region and the Eastern Mediterranean Region.

Potential roles for Technet

Technet could assist with the introduction of new vaccines by providing technical consultancies. These included: cold chain assessments and injection safety and waste management assessments, together with the development of country-specific vaccine introduction plans. In addition, there was a need to review and develop technical guidelines relating both to the new vaccines themselves and to their introduction, and a need to assess the impact of new vaccine introduction on existing immunization programmes. Within the African Region, a systematic plan was already in place to monitor these impacts.

Conclusions

Dr Namgyal concluded by commenting that there were difficult issues that needed to be faced. First, there was the risk of polarization between the traditional EPI programme and the new vaccines. In his view this polarization should not take place. The current new vaccine introductions should be seen as part of a continuum between the original smallpox programme and a much more developed future programme that could include up to 20 vaccines. Second, he accepted that many challenges remained, and that programmes required support and strengthening. However, he did not believe that we should wait for traditional six-vaccine immunization programmes to improve before introducing new vaccines. Rather, the introduction of new vaccines provided an opportunity to reassess the immunization policy and systems in a country so that we could continue to help strengthen them.

7.2 Discussion

In presenting his paper, Pem Namgyal accepted Robert Steinglass's earlier concerns about the pace of introduction of new vaccines. Programmes should avoid creating polarization between existing and new vaccines. Although there are many challenges to the introduction of new antigens, he believed that new vaccines will strengthen EPI.

Søren Spanner (WHO/SEARO) stressed that a thorough cold chain assessment is a very important precursor to the introduction of new vaccines. The assessment should use data loggers – not rely on temperature records and time-of-inspection readings. Knowing, as we do, that many cold chains are too cold, why are we introducing HepB?

Anthony Battersby endorsed Søren Spanner's comments. In the former Soviet Union the introduction of HepB is proceeding even though it is known that there are many freezing situations. The introduction of new vaccines must be done at a pace that countries are able to absorb. The word 'new' should be avoided when talking about the addition of new vaccines.

He was concerned about what would happen in three year's time when UNICEF donations end. Some countries have already had to abandon HepB vaccine because they have been unable to sustain the cost of vaccine purchase.

Robert Steinglass (BASICS) commented that GAVI assessment teams do not include members with adequate operational expertise. Unqualified people are certifying that countries are ready to receive new vaccine. There is a need for a simple synthesis document listing the steps to be taken by a country throughout the vaccine introduction process.

In response to Anthony Battersby's comments, Pem Namgyal agreed that sustainability was a major consideration on everybody's mind. The ICC is supposed to deliberate on sustainability issues before introduction. He thought Robert Steinglass's suggested synthesis document was an excellent idea and would consider this recommendation.

Themes and conclusions

- Concern was expressed that the GAVI process was moving ahead of the ability of some programmes to absorb new vaccines. In particular, concern was expressed about the risk of frozen vaccine.
- There is concern that GAVI assessment teams do not have adequate operational expertise.
- WHO should consider producing a synthesis document that lists the steps to be taken by a country throughout the vaccine introduction process.

7.3 Document review: estimating costs for new vaccine introduction

Moderator: Ulla Kou (WHO HQ)

Introduction

Ulla Kou outlined the objectives of the new guidelines. These were, first, to facilitate planning and budgeting of new vaccine introduction and, second, to form part of a cost-effectiveness analysis of new vaccine introduction. This information was needed to assist with completing GAVI application forms and to facilitate smooth introduction of the new vaccine. The guidelines were not yet complete and she commented that she was seeking assistance on a number of outstanding technical issues from delegates.

The target audience for the guidelines included immunization services managers, logisticians and transport managers, national health planners and health economists.

Methodology

She outlined the methodology used in the guideline. The basic costing principle used was the 'ingredient approach'. This involved identifying every item needed for a proposed new vaccine introduction, specifying unit costs of each item and multiplying the unit costs by the individual quantities.

The key determinant for the work load and cost analysis was the choice between a combination (multivalent) vaccine and a monovalent vaccine. In case of a *combination vaccine*, provided there was no change in vial size or in the thermal stability of the vaccine, it was only necessary to look at the recurrent costs for vaccines and disease surveillance, and at the capital ('one-off') costs for training, changes in stationary, advocacy and communication. However, in case of a *monovalent vaccine*, it was also necessary to look at recurrent costs for the additional syringes, safety boxes and waste management facilities that would be required, together with additional staff salaries and additional capital and recurrent costs for the distribution system.

Figures 43, 44 and 45 show the formulae proposed in the draft guideline for estimating vaccine costs, syringe costs and safety box costs. Further development work was required on these.

Figure 43: Estimating vaccine costs

Total costs = unit price x number of doses *(n)*

n = i x b x d x (1/(1-w)) x (1 + r)

i = immunization coverage rate

b = birth cohort

d = no. of doses per fully immunized child

w = wastage rate (in percent)

r = reserve stock (in percent) (25%?)

Figure 44: Estimating syringe costs

Total costs = unit price x annual no. of syringes *(s)*

s = n x (1/(1-w)) x (1+r)

n = Number of injections administered per year

w = Wastage rate (in percent) (5%?)

r = Reserve stock (in percent) (25%?)

BUT with less wastage than for vaccines, the calculation will give less annual syringes than no. of doses. Is that correct??

Figure 45: Estimating safety box costs

Again, price *(p)* times quantity *(n)*

n = s/a x (1/(1-w))

s = no. of syringes

a = capacity of the safety box

w = wastage rate (in per cent) (10–15%)

A further section on the cost of waste management remained to be completed. The aim was to use a rule of thumb, with costs given as percentage of syringe costs. Case studies in South Africa and Tanzania were under way to establish whether this method was sufficiently accurate.

The addition of a new monovalent vaccine to a schedule was likely to have an effect on the distribution system, because the volume of vaccine to be handled would increase. Consequently it was necessary to establish whether there was a need to expand the transport system and/or to increase refrigerated storage capacity. This could be done by comparing the capacity currently available with the capacity required after introducing the new vaccine. This exercise should be carried out at each level in the delivery system.

Vaccine volume calculator and guideline annexes

WHO had developed a spreadsheet tool to assist with the calculation process. This tool was in addition to the annexes in the guideline. It tabulated the volume per dose of existing and new vaccines and could be used to carry out a quick assessment based on *percentage increases* in volume needed. The annexes also included a method for calculating the *total additional volume needed* in cubic metres per transport load at national, regional and district level (grossing factor included). There were worksheets for both transport and cold storage. The following is an example of a volume calculation.

Vaccine storage volume per FIC with existing schedule: 53.5 cm^3

Vaccine storage volume per FIC after introduction of Hep B 10-dose vial:
65 cm^3

Transport:

Increase of 21% in storage space needed

Cold storage, National level:

Increase of 25% in storage space needed at +4°.

Expansion of distribution system

In cases where the transport and storage system needed expansion, costs were calculated by identifying capital and recurrent cost needs, i.e. vehicles, refrigerators, additional maintenance, etc. This calculation was very country-specific.

Salaries

Provided the new vaccine fitted in with the existing immunization schedule, salaries were not likely to increase significantly as a result of the introduction of a new vaccine, because the opportunity cost was fairly low.

Surveillance and monitoring

Additional costs for surveillance and monitoring would include the costs of personnel, training, equipment; supplies, etc. (see Annex 6).

Other costs

Other costs could include social mobilization, training and stationary. Mostly these were one-off cost items. The list needed expansion.

Comments received so far

Comments received so far had included requests to add a section on the costs of reconstitution syringes, to expand on methods for estimating costs of training and advocacy/communication and to rethink the method used for estimating syringe needs.

7.4 Discussion

Anthony Battersby made the following comments on the proposed calculation methodology:

- Syringe numbers should be estimated on the basis of the number of children to be immunized. The quantity should definitely not be the same as number of vaccine doses.

- The disposal cost of syringes roughly equals the purchase cost.

- When estimating vaccine storage capacity, you need to consider shelf length.

- Larger vaccine carriers may be needed.

H. T. Raubenheimer (CCCCM South Africa) commented that the introduction of each new vaccine needs to be approached very carefully. Training should be treated as a recurrent cost, and training capacity may need to be expanded.

Dianne Phillips (DoH South Africa). The model should allow for reconstitution syringes. It also should allow for the safe disposal of used vials.

Carib Nelson (PATH). The document should be open to flexible cold chain alternatives. For example, Uniject HepB in Indonesia is being used outside the cold chain.

Dr Emmanuel Taylor (WHO/ICP) commented that it was important to allow for the cost of dry storage for cold boxes, etc. It was also important to look at vaccine-packing volumes because these vary widely between manufacturers. The largest known volume should be used to ensure a safety margin.

Ümit Kartoğlu (WHO) commented that volumetric requirements are more complicated than suggested by the model. You can balance volumes against supply intervals and, by so doing, it may be possible to absorb another antigen without additional cold chain resources. In regard to packed volume, international shipping volumes are being updated. Previously a maximum allowable volume was specified. Now, however, volumes can vary by as much as 1:3 between manufacturers. WHO is trying to set a standard for deliveries to donor-dependent countries. Only if you know precisely where your vaccine is coming from can you be sure of its volume.

Johnnie Amenyah (John Snow Inc). The first task is to forecast requirements. The model is currently using the birth cohort as a basis, but previous coverage figures are more accurate. Many programmes have underestimated the training requirements for new vaccine introduction. Effective logistics evaluation systems also need to be put in place, as well as effective information systems. There is no 'one-size-fits-all' model – you need to look at the technicalities of different approaches.

Dr Heidi Larson (UNICEF). Advocacy and communication is a recurrent cost, as is stationery. The model should also factor in the cost of assessing the existing system.

Hans Everts (WHO) noted that there are different needs for equipment at national and sub-national levels.

Ulla Kou responded that this was an incremental cost analysis and hence, costs such as training and stationary were assumed as capital costs, as they are only one-off costs during the time of introduction. After the new vaccine is introduced the cost of continuing will be subsumed under normal management costs. The model does assume a coverage rate when estimating vaccine requirements.

Themes and conclusions

- Syringe costs should be modelled on a more realistic basis. Reconstitution syringes should be included in the model.
- Training, advocacy, communication and information system costs should be more accurately modelled.
- Alternative strategies need to be evaluated to establish the most efficient use of existing cold chain equipment – for example, by modelling changes in delivery interval.
- The model should allow for alternative cold chain strategies, including flexible cold chain.
- The model should include additional costs of dry storage.
- Programme assessment costs should be included.

7.5 Forum discussion: GAVI and Technet working together

Moderator: Paul Fife (UNICEF HQ)

Introduction

Paul Fife posed a number of questions:

- Did GAVI and Technet have areas of common interest?
- How does GAVI work?
- How does Technet work?
- What were the options for working together?
- What were the next steps?

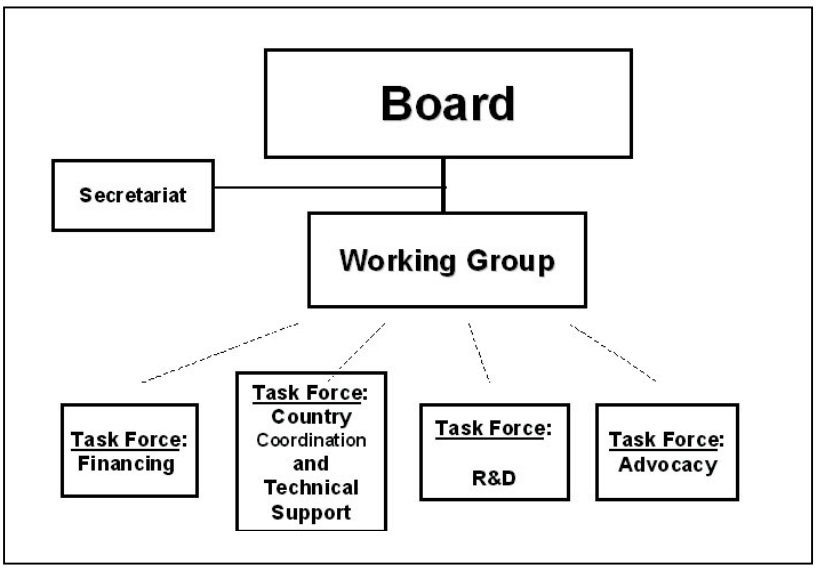
He commented that Technet and GAVI shared many common interests, including waste management, AD syringes, wastage rates, strengthening national programmes, improving capacity and increasing access – indeed, all the topics that had been discussed over the previous two days. GAVI was not solely concerned with new vaccines.

Structure of GAVI

He described the structure of GAVI – see Figure 46. The GAVI Board set the policies of the alliance. The GAVI Working Group was responsible for the implementation of the decisions of the GAVI Board. The small GAVI secretariat – five professional staff and two secretaries housed in the European regional office of UNICEF in Geneva – facilitated coordination between the partners and managed the review of country proposals to GAVI / the Vaccine Fund. Four GAVI task forces had been established to address specific issues of concern to

the Board. In addition, regional groups had been formed to help coordinate technical support and information sharing between the national and international levels.

Figure 46: Structure of GAVI



How GAVI works

He went on to describe how GAVI worked through its six regional working groups. These were located in West and Central Africa; Eastern and Southern Africa; East Asia–Pacific; South Asia; the Middle East and in Europe's newly independent states. In addition, there were the interagency coordinating committees at country level, together with governments and partners.

The four GAVI task forces were responsible for the day-to-day activities of the organization. Table 10 sets out the remit of each one.

Table 10: GAVI task forces

1. **Advocacy** (**ATF**) – building demand, programme communications	**UNICEF**
2. **Country Coordination** (**TFCC**) – capacity building, support to countries	**UK and WHO**
3. **Financing** (**FTF**) – sustainable financing, current and future vaccine purchase	**World Bank and USAID**
4. **Research and Development** (**TFR&D**) – select projects for vaccines and technologies	**WHO, industry, academia**

Each task force was managed by its respective lead agency(ies), and included representatives of the relevant partner agencies. The Advocacy Task Force was chaired by UNICEF; the Task Force for Country Coordination was co-chaired by WHO and the Government of Norway; the Financing Task Force was chaired by the World Bank and USAID; and the Research and Development Task Force was co-chaired by WHO, National Institutes of Health (NIH) and Chiron Vaccines.

In addition, regional groups had been formed to help coordinate technical support and information sharing between the national and international levels. Technical and operational issues were assigned between the task forces as shown in Figure 47.

Figure 47 Technical and operational issues

- Task Forces
  - FTF (procurement & forecasting sub-groups)
    - product choice
    - vaccine wastage
  - TFCC – and RWG
    - Consultants management
    - Technical support to countries
- R&D
  - Technology agendas
- Advocacy
  - Injection safety
- GAVI partners
  - Development of guidelines and materials
- Independent Review Committee
- Working Group (Vaccine Fund policy discussions)
- GAVI Secretariat (Country guidelines for Vaccine Fund support)

How Technet works

Technet was a network of individuals, many of whom already took part in GAVI-related work. Indeed, Technet members were involved with all aspects of GAVI, apart from the Board. Technet had a secretariat located at WHO in Geneva. There were regular Technet forum meetings – usually every 18 months, and a moderated Technet e-forum.

Earlier in the day, the idea of setting up Technet working groups had been suggested. In regard to this suggestion it would be useful to prioritize issues for the groups, to agree on terms of reference and to discuss group leadership and group management issues.

Working together

Paul Fife saw a need further to define Technet's role and its structure and functioning. For example, it would be interesting to explore liaison with the regional working groups (and with the Task Force for Country Coordination). Links should also be explored with the

R&D Task Force, particularly in relation to the technologies agenda. The possibility of Technet participation in organizing operations and logistics courses for field staff could be explored.

7.6 Discussion

Robert Steinglass (BASICS). An orientation session on logistics operations is needed with a more focused approach to give newly recruited people the necessary skills to maintain WHO/UNICEF credibility.

Bob Davis (UNICEF ESARO). The new vaccines are very expensive. GAVI/Technet needs to concentrate more on costing studies. There are not enough skilled people to cover VVM introduction and the vaccine freezing issue. Eutectics may be the way forward for protecting vaccine – the programme cannot afford to waste donor money as a result of poor vaccine management.

Anthony Battersby stressed the importance of developing and introducing a cheap vial freeze indicator. Robert Steinglass's point about training is critical. New people must be briefed both inside and outside countries. WHO used to do this, but it is no longer happening and it must be reintroduced.

Peter Carrasco (PAHO). Technet/GAVI needs to prioritize an action list. In the key GAVI countries we need to use the tools we already have to look at the cold chain. The tools need to be simplified and made available. WHO Geneva needs to coordinate these tools and identify consultants who can use them.

Alan Schnur (WHO China). GAVI attended the Harare Technet meeting and email communication has continued. Historically, the Children's Vaccine Initiative (CVI) was not well connected to Technet and this lack of connection led to poor results. GAVI and Technet need to support each other and the details of this relationship need to be worked out.

Dr Pem Namgyal (WHO). Yesterday the key issue was 'where is Technet going?' Have we resolved this? Based on a one-week membership of the Technet community he observed that Technet is not organization, but it is quite obvious that its members have expertise in the area of logistics. Technet should perhaps expand beyond this single area of expertise, but resources are needed to facilitate the necessary interactions to allow this to happen. Meetings at 18 month intervals are maybe not frequent enough. He agreed with Ümit Kartoğlu that the forum needs to be renewed to make it more visible. He suggested that technical background sheets should be produced from time to time. Technet has a valuable commodity but needs a new marketing strategy. He cautioned against a formalized structure. Technet should remain a loose, informal but bonded set of people.

Dr K. Suresh (UNICEF – Delhi) agreed that Technet needs to be strengthened – 10 years back it used to be a major information source. Technet needs to be able to bring together and disseminate information on issues such as waste management on which many groups are already working, but in a disconnected fashion.

Tom O'Connell (WHO) argued for small groups of high-level people to deal with technical matters. Larger groups would dilute effort and reduce decision-making abilities.

Dr Michael Free (PATH) asked whether Technet was a subset of GAVI. A show of hands suggested that the meeting thought it was.

Dianne Phillips (DoH South Africa). Technet needs to show that it can 'add value' to GAVI. It needs to get back its visibility.

Dr Ümit Kartoğlu (WHO) asked what is to be done next. The meeting had not yet discussed action points, although it had highlighted important issues such as vaccine wastage. The reality is that Technet is much the same as it was before; the direction to be taken was agreed at Harare in 1999, and the recent Technet survey has shown how things should now develop. The future lies in implementing and further developing new approaches, and there is a crying need to strengthen immunization management. The major functions of Technet are: as a network, to ensure the availability of experts and to continue to provide a mechanism for generating new ideas; at national level, to improve immunization services; and, at country level, to bring a field perspective to GAVI proposals.

He felt that the e-forum should be used as a means for achieving consensus and that the existing format discouraged people from contributing because the tone was too harsh. We should work to create a better atmosphere – the moderator's role is to bring people's ideas together and to consolidate them. Technet should develop contacts with the universities and important issues should not be allowed to disappear just because newer issues come up for debate.

He suggested working groups should be set up to cover the following issues:

- vaccine management
- vaccine wastage
- vaccine freezing
- global minimum standards for cold stores
- product information sheets
- time temperature indicators
- transport management

Each working group should meet at least once a year and some groups may need greater technical skills than others. In particular, vaccine freezing is a real problem. There needs to be a core of active members who will do the actual work – he was not suggesting that members of the groups be elected. On the question of resources, WHO and UNICEF need to agree how this work is to be funded.

Paul Fife (UNICEF) suggested that Technet should not alter its name. He thought that too many subject areas had been raised and that many of these would be better discussed at regional level immunization managers meetings. Technet is a network that needs to define its linkages with other organizations. For example, are issue relating to AD syringes and waste management to be made SIGN's responsibility?

Peter Carrasco (PAHO) commented that Technet should be responding to country's problems. All the items that Ümit Kartoğlu had listed were already present five years ago. Funding is the key issue.

H. T. Raubenheimer (CCCCM South Africa) commented that his own organization became established by linking up experience and knowledge with others. SA has benefited tremendously over the past four years from its relationship with Technet. He felt that interaction through the e-forum was of limited value because surveys have shown that only 1% of e-forum readership groups actually contribute to discussions. Teleconferencing may be one way forward.

James Cheyne (PATH), responding to previous contributions, urged that the e-forum should not be stopped and that the tone should not be changed as robust discussion was its strength. There should be no central Technet administration, otherwise it would die. However, if it did die it would inevitably reappear in another form. The issue is – how to make Technet reach out further and how to make it more useful?

Anthony Battersby remarked that a week's worth of discussion has been shoehorned into two days. The issue for Technet members is that we need to improve our credibility. The e-forum should remain in its current form – if the moderator were to edit contributions this would just absorb time and money. A small group should be set up to decide the membership and roles of the working groups and the function of the 18 monthly conferences. Technet comprises five interest groups – WHO, UNICEF, NGOs, countries and consultants. At present Technet exists at the whim of WHO – it would be better to assemble a group which represents all five interest groups to focus on the way ahead. In response to Michael Free's point, he commented that GAVI is dependent on Technet – not the other way round.

Alan Shnur (WHO China). The meeting does not give us enough time to reach a consensus. He agreed that Technet and the e-forum should continue. The working groups should be developed. He asked for a vote of thanks to Alan Bass for his work as moderator.

Hans Everts (WHO) also agreed that Technet should retain its name and that the e-forum should continue. There should be no 'shadow' email exchanges – it was up to the moderator to moderate. He urged caution over the working groups – Technet had been there before and found them not to be workable. He suggested the use of two or three referral groups instead.

Dr Yvan Hutin (WHO) commented that SIGN was also a network. The benefits of SIGN to SIGN members were: advocacy; development of a common strategic framework; development of validation methodologies such as assessment tools; and the exchange of technical information. The SIGN e-forum is now more of a newsletter and this is an excellent way of dissemination news and documents.

Dr Jean Smith (WHO Nepal), speaking as a country-based member, found the e-forum very useful. Those who contribute to the forum are the leading experts and she saw no problem in this. The e-forum should be encouraged – not abandoned.

Alan Bass confirmed he would do whatever the meeting decided. He disagreed with Hans Everts on the issue of working groups. For example, the VVM working group greatly influenced the way in which VVMs were introduced, and the waste management group was also very useful. Working groups need good chairpersons, who lead and are provocative.

Dianne Phillips (DoH South Africa) said that she had benefited enormously from the e-forum. The plenary meetings are also stimulating and important and she agreed with Alan Bass about the role of working groups.

Robert Steinglass (PATH) observed that Yvan Hutin had made an important point. GAVI should post documents on Technet for comment. When, for example, GAVI has an important issue to decide, such as vial size, why not ask the Technet e-forum for advice?

Dr Ümit Kartoğlu (WHO) thanked the meeting for these comments. Three major points had come up for decision: the continuation of the e-forum; the introduction of working groups; and the continuation of the 18 monthly conferences. He asked for an endorsement from the meeting, which was given unanimously.

Themes and conclusions

- Orientation sessions on logistics operations are needed to give newly recruited people the necessary skills to maintain WHO/UNICEF credibility. Technet should assist with this training process.
- The Technet Conference raised a number of key issues which should be addressed urgently by the proposed working groups. These issues are: vaccine management; vaccine wastage; vaccine freezing; global minimum standards for cold stores; the continuation and development of the product information sheets; time temperature indicators (including vial freeze indicators) and transport management.
- The Technet Conference resolved to strengthen links with GAVI, and Technet members should strive to make the network more visible.
- The Technet Conference resolved to continue the moderated e-forum.
- The Technet Conference resolved to establish working groups to find solutions to key logistic issues.
- The Technet Conference resolved to continue the 18-monthly meetings.

8. Technet21 recommendations

Participants of New Delhi 2001 meeting agreed to re-launch Technet under the new name of Technet21. It was agreed that the principal tasks of the Technet21 secretariat and the Technet21 membership should be:

- to maintain a list of experts in immunization service delivery on a validated database kept at the Technet21 secretariat;
- to access the expertise of the Technet21 membership by posting job announcements and technical queries on the Technet21 e-Forum;
- to work with GAVI and its partners, and also with countries and regional working groups, to provide a mechanism for generating and exchanging ideas on how to improve immunization services at the national level;
- to provide a 'reality check' on policy and technology options that are proposed by WHO and other GAVI partner organizations by bringing a field perspective to these proposals.

In order to achieve these tasks, four major working modalities were defined:

1. **Revitalization of working groups to address emerging issues in the field of immunization service delivery**

   Working Groups should be established to address emerging issues to carry out specific tasks in support of solving operational problems. Working groups should work towards immediately producing a product or a range of products in addressing field problems as well as proposing further research, if necessary.

   The following working groups were recommended to be established by the Technet21 secretariat (not in priority order):

- prevention of vaccine freezing;
- vaccine wastage;
- time temperature monitoring;
- immunization waste disposal;
- best practices for cold chain (including certification of cold stores);
- management and supervision tools; and
- introduction of new vaccines.

In addition to selecting the members it was recommended that the Technet secretariat should manage and organize the working groups. Each group should be provided with terms of reference specifying the product(s) to be delivered and should communicate using a combination of e-mail exchanges, teleconferencing, and meetings.

2. Evolving the Technet21 e-Forum in a more productive format

Recent Technet surveys have shown that readers are looking for more useful and conclusive information. In the light of this finding it was agreed that the Technet21 secretariat should provide the Technet21 subscribers with details of the new proposed format in order to obtain additional feedback.

3. Convening regular global meetings every 18 months

Technet21 should continue to have regular global meetings every 18 months. In conjunction with the new role of Technet21, it is critical that representatives from national immunization programmes participate in these meetings to facilitate good exchange of experience, feedback from the field and discussion of emerging issues that need to be addressed in the short term.

4. Establishing new mechanisms to work closely with GAVI

Provided it is effectively engaged, Technet21, as a network of experienced technical experts in immunization, could be an extremely valuable resource for GAVI groups. In order to facilitate the interaction between Technet21 members and GAVI instruments and to effectively harness the capabilities of the network, the Technet21 members suggest the following:

- Technet21 should become an official arm of the GAVI Task Force for Country Coordination and Technical Support.

- Technet21 should commit to providing the best available advice on programmatic and technical issues as requested by GAVI groups. To facilitate access to Technet21 members, specific tasks or requests should be directed to the Technet21 secretariat. The secretariat in turn should pass the request to relevant Technet21 members through the Technet21 e-Forum and ask them to provide an appropriate response.

- Dr Ümit Kartoğlu, from the Technet21 secretariat should be included in the GAVI Research and Development Task Force technology agenda steering group so as to facilitate Technet21 member participation in the development and implementation of technology-related activities.

Annex 1:
Formal inauguration

Dr Rafai, Regional Director of SEARO, outlined the importance of the Technet/SIGN meeting. He noted the growing body of published evidence that, globally, unsafe injections had caused up to 22.5 million hepatitis B infections, 2.7 million hepatitis C infections and 98 000 HIV infections. The reuse of syringes without sterilization was a particular concern and the high cost of treatment of the resultant disease burden was a serious drain on resources in developing countries. Over 95% of injections given globally were for curative purposes. The frequency of such injections was extremely high and was exposing the population to blood borne pathogens – accordingly there was a need for national policies, cutting across both preventive and curative services, to reduce the frequency of injections.

Dr Rafai went on to outline the history of Technet and SIGN and to stress the success of immunization in reducing mortality and morbidity amongst children and mothers. He noted that, for immunization to maintain a significant public health impact, it was necessary to achieve coverage rates of 80% or more. Coverage had been declining in recent years. A predominant theme of the 2001 Technet meeting was the need to overcome low coverage and to sustain high coverage rates. A further challenge over future years was to optimize resources in developing countries and to prepare for the introduction of new and under-utilized vaccines. Safe disposal of used injection equipment added a complex issue to health care waste management; there was a need to develop tools to alert and to educate communities on this issue.

WHO was committed to support governments and would continue to facilitate and assist immunization programmes in conjunction with GAVI and donor partnerships. Asia was a region where unsafe injection practices were a particular problem and there was a need to send a strong signal to the region on this subject in order to overcome complacency.

Dr Paul Fife (UNICEF HQ), on behalf of UNICEF, thanked the Government of India and WHO colleagues for organizing the meeting. He stressed the importance of Technet and SIGN as pathfinders for public health. However, the bad news was that much more needed to be done and that programmes had become weaker in many countries over recent years. The consequences of this, together with the growing problem of unsafe injections, needed to be considered against a background of change and constraint in the health sector; including health sector reform, an expanding private sector and the HIV/AIDS pandemic.

The good news was that the importance of health was now high on the political agenda. It had been recognized that good health was a prerequisite for sustained human development and for poverty reduction. There was an increase in partnerships aimed at addressing these problems. He highlighted two issues that needed to be addressed by the conference. First, the global policy on safe injections was a big challenge and there was a duty to examine all the operational and financial implications of this initiative. Second, the future of Technet needed to be debated; a plan should be drawn up to enable the forum to function effectively in the years to come.

He concluded by emphasizing UNICEF's continuing commitment to support national governments and to stress the importance attached to immunization in UNICEF's medium-term plan for 2002–2005.

Mr A. Rajah, H.E. the Minister of Health and Family Welfare – Government of India, welcomed delegates. He noted that India was facing daunting tasks in its drive to improve immunization coverage, to introduce new vaccines and to meet the injection safety challenge. Issues confronting the immunization programme included stagnation, and in come cases, an actual decline in coverage; poor physical access to immunization in some areas; poor maintenance of cold chain equipment; delays in providing injection equipment; issues relating to community education, and poor knowledge and motivation on the part of health workers.

The Government of India had entered into partnerships with national and international agencies with the aim of overcoming these problems. The polio eradication programme had provided valuable experience in accessing hard-to-reach populations and the immunization programme was now focusing on providing regular immunization sessions, even in outreach settings. Programme reviews were being carried out in districts around the country and the government was providing resources to tackle injection safety.

A recent UNICEF evaluation had indicated that there had been a 10% increase in fully immunized children in the previous year, with a national FIC rate of 59%. However, millions of children were still being deprived of new vaccines such as hepatitis B. With a 25 million strong birth cohort India also needed to look at new solutions, such as multivalent vaccines so as to reduce the number of contacts per child. Hepatitis B immunization was being introduced in selected cities and districts, with assistance from GAVI. AD syringes would be used for this programme, leading to an expanded use of safe injection technologies over the coming years.

Repeating the disease statistics outlined by Dr Rafai, Mr Rajah stressed his ministry's commitment to the injection safety initiative and the challenge of establishing effective policies for minimizing the therapeutic injection burden. With greater reliance now being placed on disposable injection equipment, there was also a need to find practical and affordable solutions to prevent syringe and needle reuse and to deal with the huge problem of final disposal. In conjunction with the safe injection policy, baseline surveys of injection practices in India would be carried out.

Dr Julie Milstein (WHO HQ) concluded the inauguration session with a vote of thanks.

Annex 2:
Agenda

Day 1: Monday, 27 August 2001

08:30–09:00	Registration
09:00–09:20	Opening remarks and election of chairperson and rapporteur
09:20–10:00	Reporting on progress on TechNet 1999 recommendations and future of TechNet *Ümit Kartoğlu, WHO HQ*
10:00–10:15	Introduction: Strengthening immunization services *Jean Marc Olivé, WHO HQ*

Programme sustainability

10:15–10:30	Overview: Factors affecting immunization coverage *Dr Subhan Sarkar, Ministry of Health and Social Welfare, India*
10:30–11:00	***Break***
11:00–11:45	Evidence based planning and programming: What is your coverage and how do you know? *Anthony Burton, WHO HQ*
11:45–12:15	Financing and political commitment: Annual workplan finance and budgeting *Dr Lepani Waqatakirewa, Ministry of Health, Fiji*
12:15–12:45	Access and outreach: Selective antigen strategy (CANCELLED) *Jeffrey Partridge, southern Sudan WHO, Kenya*
12:45:13:15	The role of the ICC in identifying and covering low immunization coverage areas *Dr Zhou Jun, Ministry of Health, China*

13:15–14:15 ***Lunch***

14:15–14:45 Human resource strengthening

Tom O'Connell, WHO HQ

14:45–15:15 Advocacy and demand: Reducing drop out rates

Koua Anderson Clementine, Ministry of Health, Cote d'Ivoire

15:15:15:45 Outsourcing transport management in Nigeria

Fred Simiyu, WHO Nigeria and Ngozi Nebuwa, Riders for Health, Nigeria

15:45–16:15 Polio opportunity: How polio funded personnel could be dedicated to improve access to immunization? (CANCELLED)

Jeffrey Partridge, southern Sudan WHO, Kenya

16:15–16:30 ***Break***

Vaccine management

16:30–16:45 Vaccine management training project: Overview

Ümit Kartoğlu, WHO HQ

16:45–17:15 Vaccine management – Country assessments

Souleymane Kone, WHO Côte d'Ivoire

Inauguration of Technet & SIGN meetings

17:30–18:00 Presided by H.E. the Minster of Health and Family Welfare, Government of India

Tea/Coffee

Day 2: Tuesday, 28 August 2001

Vaccine management – continued

08:30–09:00 Document review: Ensuring quality vaccines at country level: guideline draft for comments

Moderator: Gordon Larsen, WHO HQ

Vaccine wastage

09:00–09:30 Factors affecting vaccine wastage and using vaccine wastage as a tool to monitor the immunization programme

Alan Schnur, WHO China

09:30–10:00 Multi-dose vial policy

Peter Carrasco, WHO AMRO

10:00–10:30 Break

Cold chain and VVMs

10:30–12:30 Round table: Present and future of cold chain

Moderator:

Participants: Søren Spanner – WHO SEARO, Hans Everts, WHO HQ, Carib Nelson – PATH, Shanelle Hall – UNICEF Supply Division, Debra Kristensen – PATH

Logistics

12:30–13:00 WHO–UNICEF Cold Store Certification Initiative

Andrew Garnett, WHO Temporary Adviser, UK

13:00–14:00 Lunch

14:00–14:30 Product information sheets – Making it a live guide for countries

Mikko Lainejoki, UNICEF Supply Division

14:30–14:45 Price deflation in the product information sheets: What is happening and why?

Robert Davis, UNICEF ESARO

14:45–15:15 Vaccine Arrival Reports

Shanelle Hall, UNICEF Supply Division

15:15–15:45 ***Break***

Working with GAVI

15:45–16:15 Document review: Estimating costs for new vaccine introduction

Moderator: Ulla Kou, WHO HQ

16:15–16:45 Challenges in introducing new vaccines

Pem Namgyal, WHO HQ

16:45–17:30 Forum discussion: GAVI and TechNet working together

Moderator: Paul Fife, UNICEF HQ

Wrap up

17:30–18:00 Recommendations and action points

18:00 Adjourn

Annex 3:
List of participants[1]

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