

**ZAMBIA  
UPDATING IMMUNIZATION POLICY  
WITHIN THE CONTEXT OF  
HEALTH SECTOR REFORM**

16 February to 14 March 1998

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## ACRONYMS

AFP	Acute Flaccid Paralysis
BASICS	Basic Support for Institutionalizing Child Survival
CBoH	Central Board of Health
EPI	Expanded Programme on Immunization
FAMS	Financial and Administrative Management System
GRZ	Government of the Republic of Zambia
HC	Health Centre
MOH	Ministry of Health
NFNC	National Food and Nutrition Commission
NIDs	National Immunization Days
PHN	Public Health Nurse
UCI	Universal Child Immunization
UTH	University Teaching Hospital, Lusaka
VVM	Vaccine Vial Monitor
UNICEF	United Nations Children's Fund
USAID	United States Agency for International Development
WHO	World Health Organization

## **I PURPOSE OF VISIT**

The purpose of this consultancy was to assist the Government of the Republic of Zambia (GRZ), the Ministry of Health (MOH), and the Central Board of Health (CBoH) to review and update its immunization policies. The consultancy follows on from the review of immunization activities in September and October 1997, when the review team recommended that policies, standards, and guidelines should be updated. The scope of work is attached in Appendix A.

## **II BACKGROUND**

The review of immunization conducted in September and October 1997 by a multidisciplinary team of national and international members was Zambia's first formal review in 13 years. The EPI manual was last revised in 1992 and since then there have been a number of technological developments (such as vaccine vial monitors [VVMs]) and policy recommendations (such as the use of opened vials of non-reconstituted vaccine at subsequent sessions) that had not been formally considered for application to Zambia's immunization policies. In addition, since 1991, when the Movement for Multiparty Democracy won the elections and formed a government, the health sector has been undergoing a radical conceptual reform, the implementation of which is now reaching health services at the periphery. Both factors—technical developments and changes arising from health sector reform—meant that immunization policies needed to be brought up-to-date within the new organizational structures and administrative systems for technical support, planning, funding, management, and monitoring.

## **III ACTIVITIES**

The international consultant, Rachel Feilden (BASICS), travelled to Zambia on 16 February, where she joined two local consultants, Leo Chivundu (WHO consultant on leave from UCI Secretariat) and Brenda Katukula (UNICEF consultant, NIDs coordinator, 1996 and 1997) to develop proposals for updating immunization policy. Before this team started work, BASICS consultant Alasdair Wylie had discussed the list of issues identified in the 1997 review with CBoH's reproductive and child health specialist (responsible for immunization) and donor partners, especially UNICEF, whose child health officer had made detailed comments on the review team's recommendations. The outcome of a two-day meeting on logistics for immunization held in January 1998 had also moved the discussions forward (see, under separate cover, Minutes of the Meeting on EPI logistics held at Ibis, 29-30 January 1998).

The team divided the issues into those involving an update of policy, those requiring an updated guideline to clarify operational issues, and those which could be addressed simply by updating the manuals (the EPI manual, and the Integrated Technical Guidelines for Frontline Healthworkers May 1997). This approach is explained in greater detail on pages 2 and 3 of the proposals for updating policy, attached in Appendix D.

A large number of documents was assembled, including reference material from WHO, international publications, published and unpublished reports from Zambia, unpublished data from UCI Secretariat, and e-mail communications from the EPI Technical Network. Knotty technical queries were forwarded to BASICS/Washington, who supplied support via e-mail. The consultant left various materials in Zambia, including a set of South Africa's three-volume manuals for EPI as an up-to-date model of clarity and completeness.

The original intention was for this consultancy to prepare the proposals for updating policy and to facilitate a consensus meeting at which the policy proposals would be finalized (see Appendix A), ready for forwarding to the MOH for endorsement. The number of issues requiring attention and the key players to be consulted in preparing the proposals made it necessary to divide the tasks into two phases.

Phase One      Preparation and circulation of the briefing document containing the policy proposals

Phase Two      An interval to consider and comment on the proposals, the consensus meeting, and forwarding the finalized proposals to the MOH

This change of strategy was agreed to at a meeting on Friday, 6 March.

Appendix B shows the schedule of activities, and Appendix C shows people met during phase one. The international consultant left Zambia on 9 March, completed the first draft of the briefing document on 12 March, and dispatched it to Lusaka.

#### **IV      RESULTS, CONCLUSIONS, AND RECOMMENDATIONS**

The briefing document (Appendix D) was photocopied by UNICEF Zambia and distributed by the two local consultants to about 150 recipients, including the 73 District Health Management Teams. The cover letter from the CBoH invited readers to send their comments on the proposals in advance of a consensus meeting planned for 21-22 April 1998. Copies were also distributed to BASICS/Washington and to some international consultants who had been involved with the 1997 review, inviting their comments.

#### **V      FOLLOW-UP ACTION**

The local consultants collected the comments received from Zambian readers, and the international consultant received comments from other readers by e-mail, which were forwarded to the team members in Zambia.

Preparations for the consensus meeting (confirming the date and venue, sending letters of invitation) were closely coordinated between the CBoH and the local consultants, the BASICS team in Lusaka, and BASICS/Washington. The international consultant returned to Zambia on 17 April for the consensus meeting (phase two), which will be described in a subsequent trip report covering activities during April and May 1998.

## **APPENDIXES**

**APPENDIX A**  
**SCOPE OF WORK**



**BASICS**  
**SCOPE OF WORK DESCRIPTION**

- A) Name Rachel Feilden
- B) Account Code 000-ZA-51-025
- C) Destination Zambia
- D) Dates o/a February 16 to March 18 1998
- E) Fee days up to 24 days contingent on a departure date of March 12 (otherwise 20 days for a March 7 departure and 22 days for March 10)
- F) Scope of Work

BASICS consultant Rachel Feilden will visit Zambia from o/a February 16 to March 12, 1998 to assist the GRZ/MOH/CBoH to review its immunization policies. This review is necessitated in light of changes brought about by health sector reform and the increasing emphasis on district level management of health services. Working closely with the CBoH and cooperating partners, the consultant will

- Identify key policy issues for review in the context of a decentralized health sector environment,
- Develop a draft EPI policy statement for each of the areas identified,
- Co-facilitate a review meeting of CBoH and cooperating partners,
- Develop strategies for dissemination of the policy statements

Ms Feilden will work as a member of a three-person team to carry out this assignment. She will be available to brief and debrief with USAID/Lusaka.

**APPENDIX B**  
**SCHEDULE OF ACTIVITIES**

### **Schedule of Activities, 17 February to 12 March 1998**

- 17 Feb Arrival in Lusaka Met Alasdair Wylie
- 18 Feb Briefing at BASICS with Dr Remi Sogunro and Emily Moonze  
Briefing with Ms Nyirenda and Dr Huijts at CBoH  
Briefing at WHO with Dr Ngoma
- 19-21 Feb Started work with local consultants, Ms Chivundu and Ms Katukula  
Mapped issues and approach at CBoH, reviewed documents  
Identified key players to be interviewed for each issue  
Outlined background for updating policy on each issue
- 22 Feb Sunday
- 23 Feb Continued with outlining background and policy proposals
- 24 Feb Met Chikuta Mbewe at CBoH to discuss FAMS manual and training  
UTH D Block, Isolation Ward, and Family Health immunization in practice  
Making appointments Paediatrics Dept, Virology Lab, School of Nursing
- 25 Feb Met Dr Paul Zeitz at CBoH  
Met Ms Rose Lungu at National Food and Nutrition Commission
- 26 Feb Met CBoH Procurement Specialist and UCI Logistics Officer  
Met Dr Chombo and Prof Bhat at UTH  
Visit to Virology Lab to get latest AFP data and hepatitis B data  
Met Mr Din at National Cold Chain Workshop
- 27 Feb Met Dr Abdikamal and Dr Kafula at BASICS  
Met Christiane Rudert, UNICEF
- 28 Feb Team working on analysing measles data and policy proposals
- 1 March Sunday
- 2 March Met Nurse Tutors at UTH to discuss training on immunization, classroom and practical experience, injection technologies and protocols
- 3 March Team identified issues for follow-up through individuals or documents including interpretation of measles coverage
- 4 March Met Dr Dean Phiri, National Manager, at Anchor House (MOH)
- 5 March Met HMIS group at CBoH, Monitoring & Evaluation Directorate
- 6 March Visit to Kaunda Square Health Centre, and visited households in the vicinity of the recent measles outbreak, checking Child Health Cards  
Meeting to outline progress to date, and plan completion of scope of work  
Met Joyce Tembo in CBoH to discuss Quality Assurance
- 7 March Team preparing policy proposals, discussed measles with Dr de Vries
- 8 March Sunday
- 9 March Final arrangements with team and departure for UK
- 10-12 March Finalizing briefing document and dispatch to Lusaka for distribution

**APPENDIX C**  
**PEOPLE MET**

## **People Met**

### Ministry of Health (MOH)

Dr Roy Chimba, Epidemiologist  
Dr Dean Phiri, MCH  
Ms Sarah Syamuleya, MCH

### Central Board of Health (CBoH)

Directorate of Systems Development  
Dr Gavin Silwamba  
Ms Jenny Meya Nyirenda  
Dr Ini Huijts

### Directorate of Monitoring and Evaluation

Mr Bornwell Sikateyo  
Ms Anne Young  
Dr Gerard de Vries  
Ms Joyce Tembo

### Directorate of Health Services Commissioning

Ms Peggy Fulilwa  
Ms Christine Mushe Zulu  
Mr Chikuta Mbewe

### UCI Secretariat

Mr Akhtar Din  
Mr Francis Mutumbisha  
Ms Madeleine Siame

### University Teaching Hospital (UTH)

Dr Olwyn Chomba, Head of Paediatrics Department  
Prof G J Bhat, Paediatrics Department

### UTH School of Nursing/Midwifery

Ms Margaret Maimbolwa, Principal Nursing Tutor  
Ms Alice Hazemba, Ms Tolosi Mwinga, Ms Zacara Eneless

### UTH wards and Family Health section providing immunizations

Ms Mercy Nyambe, Ms Dorothy Zangata, Ms Maureen Banda, Ms Elizabeth Kazwe

### UTH Virology Laboratory

Dr Monze, Dr Reiko Saito

## **People Met (continued)**

Kaunda Square Urban HC  
Sister Mwangata (I/C) and staff  
Ms Banda, Lusaka District PHN

National Food and Nutrition Council (NFNC)  
Ms Rose Lungu

Institute of African Studies  
Dr Mubiana Macwanji (also via BASICS)

### **BASICS**

Dr Remi Sogunro  
Ms Mary Kaoma  
Ms Emily Moonze  
Dr Rodwell Kafula  
Dr Abdikamal AliSalad  
Ms Catherine Mukwakwa  
Mr Alasdair Wylie (consultant)  
Mr Don Sharp (consultant)

HMIS team  
Ms Mimi Church

Irish Aid  
Ms Finola Finnan

UNICEF  
Ms Christiane Rudert, Child Health Officer

USAID  
Dr Paul Zertz

WHO  
Dr Mary Shilalukey Ngoma

**APPENDIX D**

**PROPOSALS FOR UPDATING  
IMMUNIZATION POLICY  
WITHIN THE CONTEXT OF  
HEALTH SECTOR REFORM (12 MARCH 1998)**

**PROPOSALS FOR UPDATING  
IMMUNIZATION POLICY  
WITHIN THE CONTEXT OF  
HEALTH SECTOR REFORM**

**A briefing document  
prepared for  
GRZ/MOH/CBOH**

**by**

**L B Chivundu, R M Feilden and B Katukula**

**First draft**

**12 March 1998**



# PROPOSALS FOR UPDATING IMMUNIZATION POLICY WITHIN THE CONTEXT OF HEALTH SECTOR REFORM

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## GLOSSARY

AEFAPP	Adverse Event Following Any Parenteral Procedure
AEFI	Adverse Event Following Immunization
AFP	Acute Flaccid Paralysis
BCG	Bacillus Calmette-Guerin
CBOH	Central Board of Health
CFC-free	Chloro-Fluoro-Carbon-free
CHW	Community Health Worker
CSO	Central Statistics Office
DDP	Delivered, Duty Paid
DHB	District Health Board
DHMT	District Health Management Team
DPT	Diphtheria, Pertussis and Tetanus vaccine
DYSSSY	Dynamic Standard Setting System
EDMSS	Essential Drug and Medical Supplies Store
EPI	Expanded Programme on Immunization
FAMS	Financial and Administrative Management System
FIC	Fully Immunized Child
GPV	Global Programme for Vaccines and Immunization
GRZ	Government of the Republic of Zambia
HBsAg	Hepatitis B surface antigen
HC	Health Centre
HCAC	Health Centre Advisory Committee
HIV	Human Immunodeficiency Virus
HMIS	Health Management Information System
HRIT	Health Reform Implementation Team
IMCI	Integrated Management of Childhood Illness
JICA	Japan International Cooperation Agency
MOH	Ministry of Health
NHC	Neighbourhood Health Committee
NFNC	National Food and Nutrition Commission
NT	Neonatal Tetanus
OPV	Oral Polio Vaccine
QA	Quality Assurance
TBA	Traditional Birth Attendant
TST	Time, Steam, Temperature
TT	Tetanus Toxoid
UCI	Universal Childhood Immunization
UHC	Urban Health Centre
UNICEF	United Nations Children's Fund
UTH	University Teaching Hospital
VAPP	Vaccine Associated Paralytic Poliomyelitis
VII	Vaccine Independence Initiative
VVM	Vaccine Vial Monitor
WHO	World Health Organization
ZDHS	Zambia Demographic and Health Survey

## PROPOSALS FOR UPDATING IMMUNIZATION POLICY WITHIN THE CONTEXT OF HEALTH SECTOR REFORM

### Introduction

The review of immunization carried out in September and October 1997 made several recommendations to update policies, standards and guidelines within the context of health reform. This briefing paper has been prepared to assist GRZ/MoH/CBoH in reviewing its policy on immunization.

Since 1984, GRZ has been implementing the Universal Childhood Immunization (UCI) programme, managed by a secretariat based at the central MoH offices. Policies were developed using WHO guidelines, and the most recent edition of the EPI Manual was prepared in 1992. Since then, a number of technological developments have occurred which offer opportunities for increasing the cost-effectiveness of immunization services. Epidemiological evidence from research studies has been assessed and disseminated. WHO has issued new guidelines based on countries' experiences of strategies for preventing childhood diseases with vaccines (for example the global eradication of polio).

Using the wealth of local and international information available, the existing policies have been reviewed within the context of health sector reform, and proposals for updated policies have been drafted. All the proposals are designed to help attain the goal and objective of immunization, summarized in the 1997 review team's final presentation.

The goal of immunization is to reduce morbidity and mortality from vaccine preventable diseases, doing no harm in the process.

The objective of immunization services can be summarized as follows:

- for all antigens in the schedule, to provide potent vaccine
- correctly administered
- safely
- properly documented
- at a time when the client is susceptible and prior to exposure

The draft proposals are contained in this document, which is being circulated widely in preparation for a consensus meeting planned for a date at least three weeks hence. Comments from all readers are welcome.

## **How to use this document**

The issues raised by the 1997 review team and during subsequent discussions have been divided into three levels

- policy issues requiring a decision or clarification by the Ministry of Health
- issues requiring a guideline, to be prepared by Central Board of Health
- topics requiring an update or clarification in manuals, reporting formats, and records, including the Child Health Card

The next page shows 14 issues arranged in three columns corresponding to the three categories above. If a policy decision is required, guidelines and manuals will clearly need to be harmonised with the policy. Issues requiring a guideline must also be covered in manuals for health workers. This document gives details of topics in the third column only if such details are relevant to exploring the issue.

The numbers in the left-hand column show the chapters where each issue is presented. Each chapter describes the background and presents the draft proposal, with the implications of adopting it and of continuing with the status quo. Many issues are interrelated, and chapters are cross-referenced. A list of documents referred to in the text is in Chapter 15.

Policy issues requiring a decision, a guideline and/or updating in the manuals

	Policy requiring a decision	Issues needing a guideline	Topics to be updated in manuals and on forms
	<b>SCHEDULE</b>		
1	Adding a fourth dose of OPV under1	Yes	Yes
2	Clarification of policy on immunization against measles	Strategies for controlling measles and preventing outbreaks	Yes
3	Clarification of TT schedule	Eliminating neonatal tetanus	Yes
	<b>FIRST, DO NO HARM</b>		
4	Safety of injections and safe disposal choice of equipment	Follow up of adverse events following any parenteral procedure (AEFAPP)	Yes
	<b>COST-EFFECTIVENESS</b>		
5	Use of opened vials of non-reconstituted vaccine at subsequent sessions	Cold chain quality criteria for local decisions on use of opened vials	Re-emphasize correct CC practices including VVMs with policy update
6	Session frequency	Yes	Yes
7		Vaccine quantification	Yes
8		Reporting notifiable diseases, use of surveillance data	Tallying doses NIDs, FIC < 1, off-schedule measles, boosters, schools
9		Use of data for Q A (quality assurance)	Community monitoring of eligibles, drop-outs
10	Cold chain equipment suitable for vaccines	Yes	User manuals for the type of equipment issued
11	Adding new antigens	No	No
12	Global / regional targets	Yes	Yes
	<b>MANAGEMENT</b>		
13	Logistics from centre to district	Yes, and from District to Health Centres	Yes
14	Vaccine Indep Initiative (VII) and other funding	Planning for all supplies, equipment and spares	No (refer to 5 and 7)

## 1 Adding a fourth dose of OPV under 1

### Background

The profile of acute flaccid paralysis (AFP) cases reported 1995, 1996 and 1997 is shown in Table 1.1. Zambia should report 47 AFP cases per year (1/100 000 children under 15) if the surveillance system is functioning properly. Six provinces did not report any AFP case in 1997. Guillain-Barre syndrome should be reported as an AFP case. Underreporting is consistent with health centre staff's knowledge about AFP assessed during the 1997 review, 55% knew the case definition of AFP, and 60% knew the reasons for AFP surveillance. A small majority of HC staff (53%) said that both the HC and the community should detect and report AFP cases. However, 32% did not mention the hospital in their answer.

Only one-fifth of the expected AFP cases were actually reported during 1997, this means that it is impossible to know whether or not wild polio virus is still circulating in the country. Five surveillance officers will be assigned to CBoH and the Regional Directorates to assist with strengthening this essential component of polio eradication.

**Table 1.1**

**Summary of line listings from Virology Laboratory, University Teaching Hospital**

Indicator	1995	1996	1997
AFP cases reported	45	22	7
Proportion of expected AFP cases reported	1.00	0.46	0.15
Youngest AFP case	5 months	4 months	2 years
Cases positive for wild polio virus by lab results	7	0	0
Number of cases "discarded" <sup>a</sup>	3	0	1
Number of cases "confirmed" <sup>a</sup>	42	22	6
At least one AFP report sent during the year (by Region and Province)			
North Central	Yes		
Central		Yes	
Northern			
South-East		Yes	Yes
Eastern		Yes	Yes
Lusaka Urban	Yes	Yes	
South-West		Yes	
Southern			Yes
Western			
North West	Yes		
North Western	Yes	Yes	
Copperbelt	Yes	Yes	
Luapula	Yes	Yes	

- a A "discarded" case is classified as definitely not a polio case. To be "discarded" a case of AFP must have two good stool samples (i.e. taken at least 24 hours apart within 14 days of onset of AFP) which reached the lab  $\leq 3$  days from the time they were collected, and have two negative laboratory results. If two good stool samples are lacking then a clinical exam establishing no residual paralysis at the 60-day follow-up could also result in discarding the case. Most cases lacked one or more of these indicators and therefore had to be classified as "confirmed".

Asked how they would respond to an AFP case, 53% of HC staff would investigate and report, but 32% did not mention making an investigation. This is serious because stool samples are needed in order to classify the case.

As part of the global campaign to eradicate polio, Zambia conducted NIDs in 1996 and 1997 (two rounds each year) and is planning NIDs for July/August 1998. NIDs coverage was 87% in 1996 and 91% last year. Routine coverage reported for OPV3 has exceeded 80% since 1994. ZDHS (1996) showed 84% of children aged 12-23 months had OPV3 (89.2% for urban residence, 81.2% for rural), and OPV3 before first birthday was 78.7%.

WHO's *Immunization Policy* (1996) recommends that the routine immunization schedule should include four doses of OPV in the first year of life (p. 24).

Administration of a dose of OPV at birth - in addition to the 3-dose schedule - "leads to higher sero-conversion rates at a younger age than occur with a 3-dose schedule" (De Xiang et al. 1986, Weckx et al. 1992). Studies in Romania showed that vaccine-associated paralytic poliomyelitis (VAPP) was associated with the first dose of OPV in children who had received many injections (Strebel *et al.*), providing OPV at birth avoids this risk because newborns will not have had injections.

If an additional dose is not given at birth, the fourth dose can be given at the same time as the measles dose or at any other contact at least 4 weeks after OPV3. Data on sero-conversion rates under this alternative schedule are being sought.

ZDHS (p. 107) shows that 47% of deliveries are institutional, with a three-fold difference between urban and rural areas (77% and 27% respectively). Health reform policies are designed to provide cost effective health care as close to the community as possible. It will take time to reduce the barriers to access posed by distances and poor physical infrastructure in rural areas, where the proportion of home deliveries is unlikely to change dramatically in the medium term. WHO does not recommend a special visit to give OPV0 to a baby born at home. The suggestion that CHWs or TBAs might be able to collect a vial of OPV from the HC is not feasible for managerial and logistics reasons.<sup>1</sup> The first contact with child health services for the majority of infants will continue to be when the first dose of DPT and OPV is due.

Should the minimum age for DPT1/OPV1 be reduced to 6 weeks? This would link up with the 6-week post natal check-up, and would minimize the period of infants' exposure to the four diseases prevented by these antigens. In some countries the schedule is stated in terms of "from 6 weeks" for DPT1/OPV1, "from 10 weeks" for DPT2/OPV2, and "from 14 weeks" for DPT3/OPV3, stating that the interval between doses must be at least four weeks.

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<sup>1</sup> (a) If the vial was transported in the vaccine carrier, icepacks would be needed and the RCW42 takes 48 hours to freeze icepacks, thus routine child health clinics would be disrupted for the sake of one dose of OPV0 and the whole exercise would involve two round trips between the community and the health centre. (b) If the vial was carried outside the cold chain and the VVM stayed within the acceptable range the unused doses in the vial would have to be discarded, involving massive wastage (refer to Chapter 5).



### Proposal for changing the policy

Every child should have four doses of OPV before its first birthday (These doses are to be given on schedule irrespective of any NIDs doses or mopping up )

If a child is seen at a child health clinic before it is 2 weeks old, OPV0 should be given at the same time as BCG Under no circumstances should OPV0 be given after two weeks of age

The age for DPT1/OPV1 should be lowered to 6 weeks, emphasizing that the interval between doses must be at least 4 weeks

If a child missed OPV0 then it should be given the fourth dose of OPV at the same time as the measles dose (9 months) The "booster" dose at 18 months should be removed from the schedule

<b>CHILD RECEIVES</b>	<b><u>EITHER A</u></b>	<b><u>OR B</u></b>
Birth or at first contact	BCG	BCG
Birth to 13 days	OPV0	X
From 6 weeks	OPV1/DPT1	OPV1/DPT1
At least 4 weeks later	OPV2/DPT2	OPV2/DPT2
At least 4 weeks later	OPV3/DPT3	OPV3/DPT3
At 9 months	X, Measles	OPV4, Measles
At 18 months	X, DPT booster	X, DPT booster

### Implications of changing the policy

Zambia's immunization schedule will be harmonized with WHO recommendations, and some additional protection against wild polio virus will be achieved

Period of exposure to risk will be shortened by two weeks (DPT1/OPV1)

Policy on plotting weight-for-age, especially for babies under 2 months, needs to be followed up with NFNC and the Child Health Inter-Agency Group (For example if health workers plot the weight taken at 6 weeks on the 2-month line on the weight-for-age curve, and not halfway between months 1 and 2, this small error will understate the baby's progress by about 15%, refer to Child Health Card for a baby aged 6 weeks weighing 4 kg) Supervisors have observed that some staff ask mothers to return at 2 months rather than weighing at 6 weeks, data on current practices are needed to assess the level of effort required to update skills

Layout of the Child Health Card will have to be modified to include OPV0 and OPV4 The OPV booster dose (18 months in the current schedule) will be removed from the old card

OPV0 is the only dose in the schedule which is ignored if the child's first contact is after 2 weeks old If OPV0 is not given within the first two weeks, the space for recording this dose on the Child Health Card should be filled with an X at the time of the first contact Symmetrically, staff administering the OPV0 dose should write an X in the OPV4 box at the same time as they record the OPV0 dose This unique procedure will

require special training for both the Child Health Card and the "Children under 5 Register" (HIR 3). All staff will have to be briefed on the subtleties of this "either/or" schedule.

The new "Children under 5 Register" is already printed with the OPV booster dose timed for 18 months, OPV4 can be recorded in this space. Guidelines from HMIS will be needed on this procedure. In future printings OPV4 should be moved to the section for "Under 1 services". The DPT booster remains at 18 months (refer to Chapter 3).

The new HMIS does not report OPV0, so coverage for this dose cannot be monitored through the routine reporting system. If there were a need to assess coverage for OPV0, it could be done by sampling the child register at health centres, or through coverage surveys. How to assess it in a maternity ward is not yet clear to us.

The tally sheet for HMIS shows OPV3. This would be altered to tally when the child completes its four doses of OPV under 1 ("Four doses under 1" means when OPV3 is given to children who had OPV0, or when OPV4 is given to children without OPV0). Guidelines from HMIS will be needed. The experience of training staff in the new procedure for tallying TT doses will indicate the feasibility of tallying "four doses of OPV under 1", refer to instructions for using the Safe Motherhood Register, HIR 3.

Clinical supervision will have to be intensified, and given a much higher priority in the allocation of District resources (especially transportation).

New health information messages will have to be prepared, printed and distributed. There is concern that changing the clear message of the current schedule ("come when the baby is 2 months old") to the complex either/or schedule involved in implementing "four doses of OPV under 1" with OPV0 or OPV4 will confuse mothers and compliance with the schedule will be damaged. Operational evidence is being sought from other countries which have adopted OPV0 with the objective of four OPV doses under 1.

The new health information messages will also have to tackle the subject of why it is a good thing to give an additional dose of OPV at an earlier age, but it is a bad thing to give an additional dose of measles at an earlier age (refer to Chapter 2).

OPV is an additional item to be supplied to maternity wards. As ambulatory primary care services are moved out of hospitals, new logistics and cold chain systems will have to be developed (resupply, storage space and stock control).

Assuming zero wastage, the additional cost of vaccine for implementing the policy of four doses under 1 (and cancelling the dose at 18 months) would be about \$22,000 (see Table 1.2). If the policy proposal for use of opened vials of OPV at subsequent sessions is accepted, wastage of OPV will fall, but not to zero (refer to Chapter 6).

IMCI has trained staff in Lusaka Urban and Copperbelt Provinces on the OPV0 schedule, emphasizing that this dose must not be given after the 13th day. The training has not mentioned the goal of 4 OPV doses under one. These staff would need to have the updated information positively confirmed.

**Table 1 2**

**Minimum additional cost of vaccine for the policy of 4 doses of OPV under 1**

Cost/10-dose vial of vaccine in the national store <sup>a</sup>	\$0 844
Number of eligibles	390,000
less Boosters given in 1996	-172 204
Additional doses (if 100% coverage with 4 doses)	217,796
Additional vials (zero wastage)	21,780
Cost of these doses	\$21,847

a Delivered into the national store, and all duty and tax paid (i.e. Incoterms are DDP)

**Alternative proposal**

The complexities described above and the level of effort required to implement the proposed schedule properly need to be weighed in light of the additional protection afforded by adding OPV0 in Zambia (epidemiological data are being sought). An alternative proposal is to -

Update the policy on OPV booster dose, moving it from 18 months to 9 months. This would harmonize policy for OPV with the objective of giving four doses under 1, and would be relatively simple to implement.

**Implications of continuing the status quo**

Zambia's present schedule for OPV diverts slightly from WHO's global recommendations.

Instead of expending the effort required to change the schedule, staff and supervisor energy can be focused on improving surveillance for AFP, measles and neonatal tetanus, developing strategies for identifying eligibles and increasing participation in the available immunization services (building community involvement).

The curriculum being taught for IMCI differs from the national policy, suggesting that the national immunization schedule is for guidance rather than policy. IMCI courses on both OPV0 and the starting date for DPT1/OPV1 would need to comply with national policy.

- Refer to
- 5 Use of opened vials of OPV, DPT and TT at subsequent sessions, Cold chain quality
  - 7 Vaccine quantification
  - 8 Reporting notifiable diseases
  - 14 Vaccine Independence Initiative and other funding

## 2 Clarification of policy on immunization against measles

### Background

The epidemiology of measles is dynamic, changing over time as immunization services alter the pool of susceptibles (WHO, 1996). Measles cases and coverage reported to WHO (1997 p119, p176) from 1982 to 1996 are shown in Chart 2.1

WHO/AFRO (1995) has summarized five characteristics of changing measles epidemiology after the introduction of immunization in Southern Africa

- In the first phase the size of epidemics decreases and the average annual total of cases declines,
- Secondly the interval between epidemics increases,
- Thirdly, the average age of measles cases rises (because the majority of susceptibles are now older),
- Fourthly the proportion of cases occurring among immunized children (especially among under-5s) will be higher. However, reporting of cases may be biased in favour of immunized children because
  - Carers who have their children immunized are more likely to seek treatment even for mild cases. Carers who do not have their children immunized are less likely to seek treatment unless the illness is severe,
  - Up to 20% of all rash and fever illnesses are not measles, misdiagnosed cases are more likely to be immunized than unimmunized,
  - In Zimbabwe, two studies have shown that measles vaccine is given to 10-15% of children before 9 months of age. These children are less likely to be protected (sero-conversion rate at 6 months is 50% and at 7 months is 65%) but they will be classified as immunized if they contract the disease
- Fifthly, the case fatality rate decreases partly because fewer cases occur in young infants for whom the mortality risk is higher

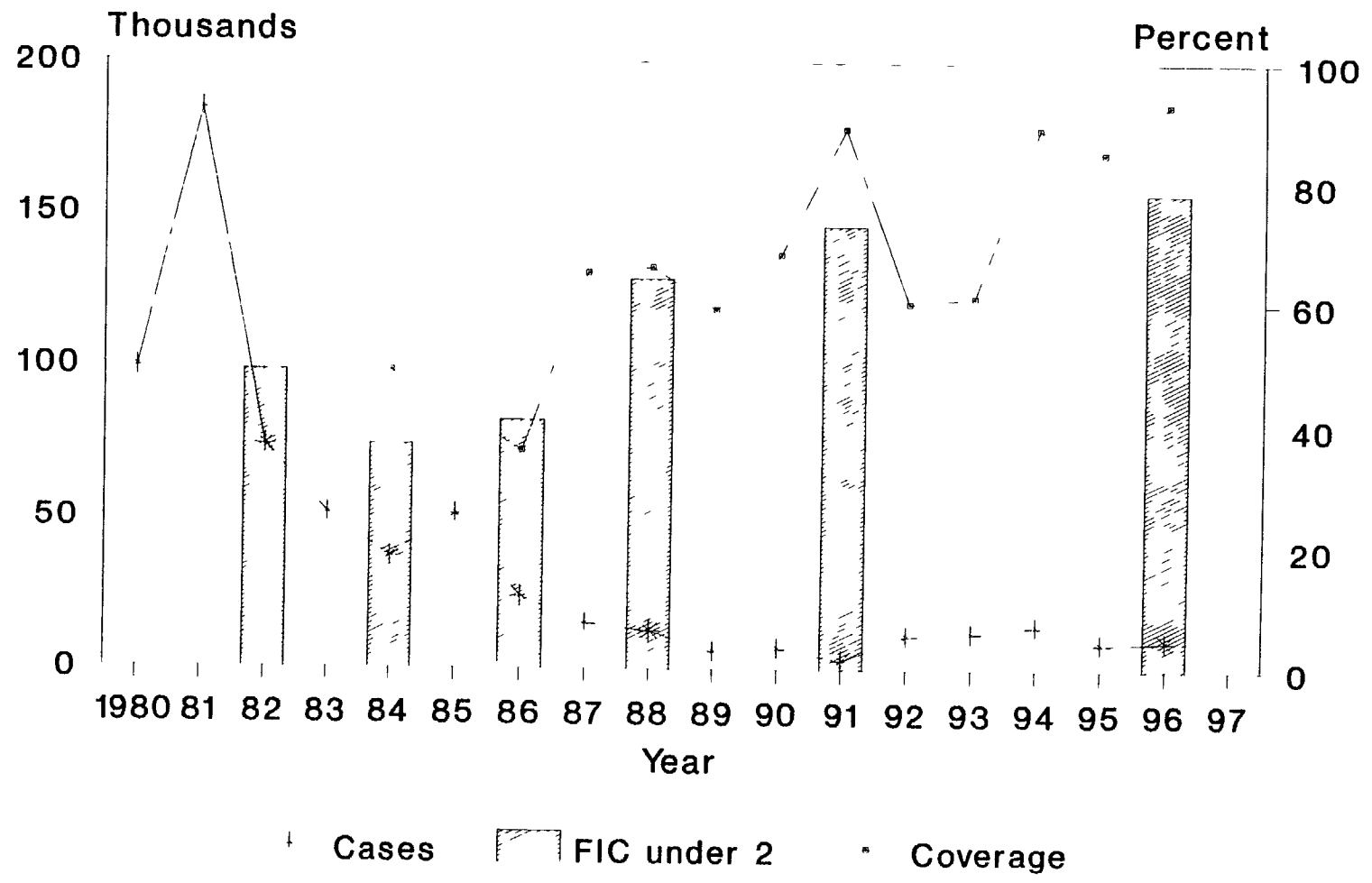
In Lusaka the case fatality rate among children hospitalized with measles disease from January 1993 to December 1994 was highest in the 12-47 month age-group (17.8%), and 14.2% in cases under 12 months. Measles vaccine coverage for Lusaka Urban was reported as 58% in 1993 and 93% in 1994. One-third of hospitalized cases at UTH were under 12 months (Mpabalwani *et al*). Data on the immunization status of measles cases hospitalized during 1997 are currently being analysed.

Nation-wide, the net effect of immunization activity in 1996 is estimated to be 8 000 measles deaths prevented, but 3 100 measles deaths not prevented (Immunization Review 1997)

The routine reporting system classifies cases into under-5s and others. Age-specific profiles of measles cases are created during outbreak investigations but so far the line listings have not recorded the child's date of birth and the date of measles immunization. The data now being processed will be added to Table 2.1

### Zambia Measles cases and immunization coverage, 1980-1997

Chart 2 1 Measles cases and immunization coverage, 1982-1997



**Table 2 1**  
**Summary of cases investigated during measles outbreak in Mpulungu**  
**September-December 1997**

	Cases	Immunized	Not immunized	Imm status not known	
0-8 months					too young for imm
9-11 months					
12-23 months					
24-35 months					
36-47 months					
48-59 months					
5-9 years					
10-14 years					
15+ years					

For ten years (1982 to 1992) the national policy was to administer measles vaccine at 7 months. If case investigations listed date of birth and date of measles dose, it would be possible to calculate the child's age when immunization was given, to demonstrate the effect of immunizing children younger than 9 months.

Knowing the age when the child was immunized is important because health professionals need to understand why early doses are counterproductive (up to half the children will not sero-convert, and the carer may not return for the scheduled dose). Health workers and their community partners (DHBs, HCACs and NHCs) need to have a way of explaining why measles disease sometimes occurs in immunized children. Confidence in immunization - among staff and clients - may be adversely affected unless this issue is addressed in an open and well informed manner. The proposals described below depend on community support for raising coverage and identifying children who do not yet have a documented dose of measles vaccine.

Chart 2 1 shows that reported coverage passed 80% in 1994 and has remained above that level. Some districts report impossibly high coverage (in excess of 100%). The following factors contribute to this anomaly:

- The official denominators from CSO differ from districts' estimates of their eligible populations (refer to NIDs evaluation of the first round, 1997)
  - 35 districts thought they had more eligibles, 16 thought they had fewer eligibles
  - District estimates aggregated into Provincial groupings varied from 28% higher than the official estimates, to 1% below the CSO figure
  - The net effect of summing District estimates was 5% higher than the national figure from CSO
- Using CSO denominators 19 districts reported measles doses to under-1s in excess of the official number of eligibles (1996 data)

- Where BCG coverage also exceeds 100%, measles coverage has been recalculated using the number of BCG doses as the denominator (see Chart 2.2) After this adjustment, five districts still have coverage over 100% (Monze, Lusaka Urban, Solwezi, Luanshya and Mufumbwe) There are also 44 districts with coverage below 80%, and no data from two districts (Nchelenge and Mufulira)
- Analysis by Region and Province shows wide variations between coverage levels in the districts within each administrative/managerial grouping (see Chart 2.3)
- During site visits to HCs in Lusaka staff explained that if there is an outbreak they follow a 1995 guideline and administer measles vaccine to children aged 6 to 8 months, telling the mother to return for the 9 month dose HCs may tally the early doses separately, but at District level these doses are aggregated with the doses administered at 9+ months and all are reported as doses to under-1s One HC explained that they had never received instructions to stop the 6 month dose, their last monthly report showed that 57% of the 255 measles doses for under-1s were administered at 6 months The extent to which early doses are given needs to be assessed, especially in the other districts reporting coverage over 100%, for example coverage estimates for that HC may be twice as high as actual coverage
- Measles coverage for under-1s, measured by survey, was 75.8% with a drop-out between BCG and measles (under 1) of 21.6% (ZDHS, 1996, p 111) Another 11% of children got their measles before 2 years of age, raising under-2s coverage to 86.5% [ZDHS could analyse early doses from their raw data]

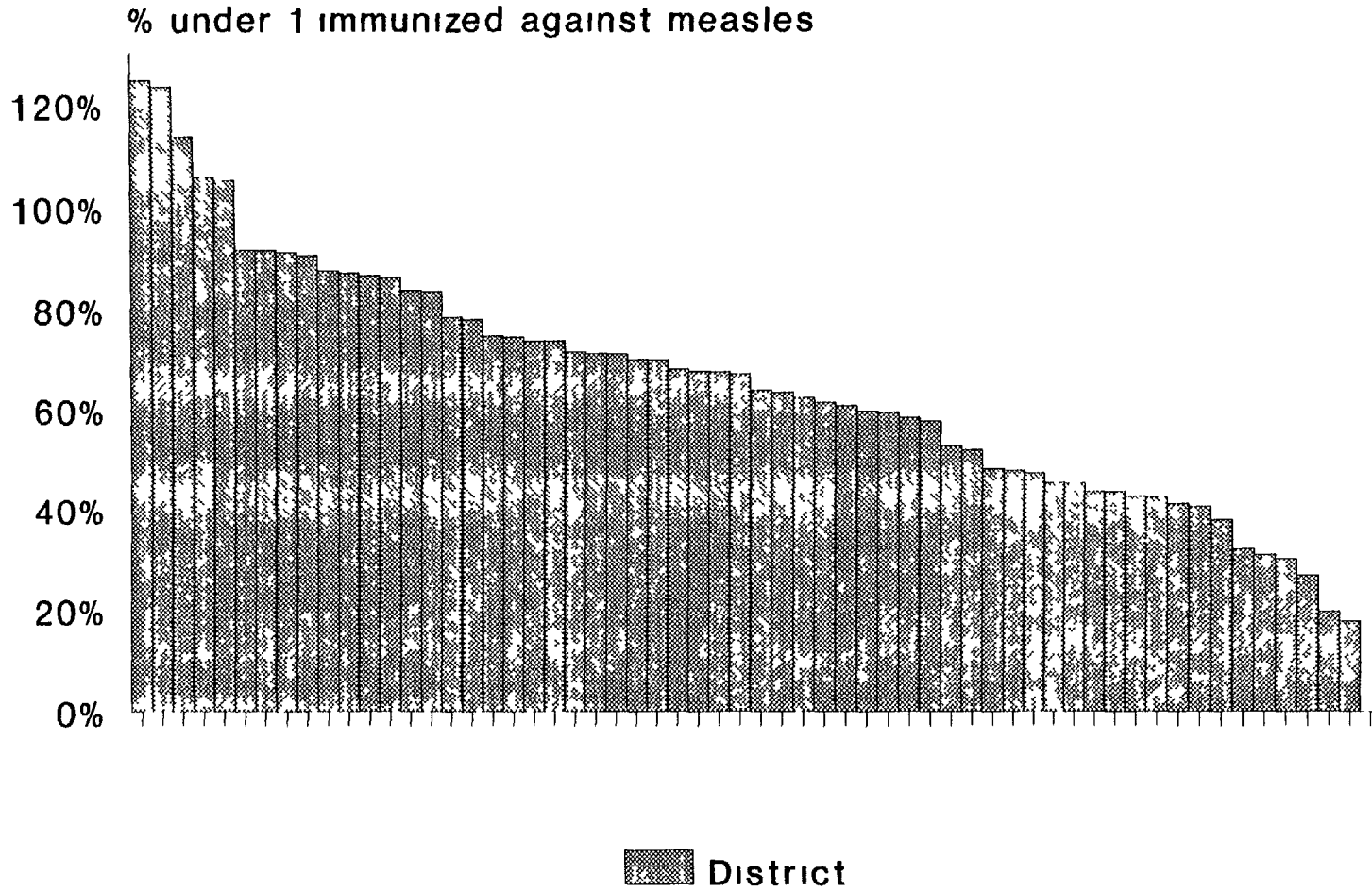
Taking the ZDHS survey data as the most accurate official assessment of coverage, more than one-third of children are unprotected at 12 months of age 24.2% from lack of dose, plus 11.4% from lack of sero-conversion among the immunized Subtracting the 11% who get a dose after 12 months, the number of unprotected children accumulates every four years to a group the same size as the total number of under-1s The situation is exacerbated to the extent that doses are given too early

WHO recommends that measles dose should be given at 9 months of age in developing countries (1996, p 11) This strategy is predicted to lead to sero-conversion in at least 85% of infants Zambia adopted the 9 month schedule as policy in 1992

Because there is no herd immunity from measles immunization, epidemics occur even where coverage is above 90% when the pool of susceptibles (never immunized plus the 15% of immunized who failed to respond) has accumulated to a critical size Instead of adding a routine second dose to the schedule, WHO recommends choosing a strategy appropriate to the local epidemiological profile, and levels of coverage

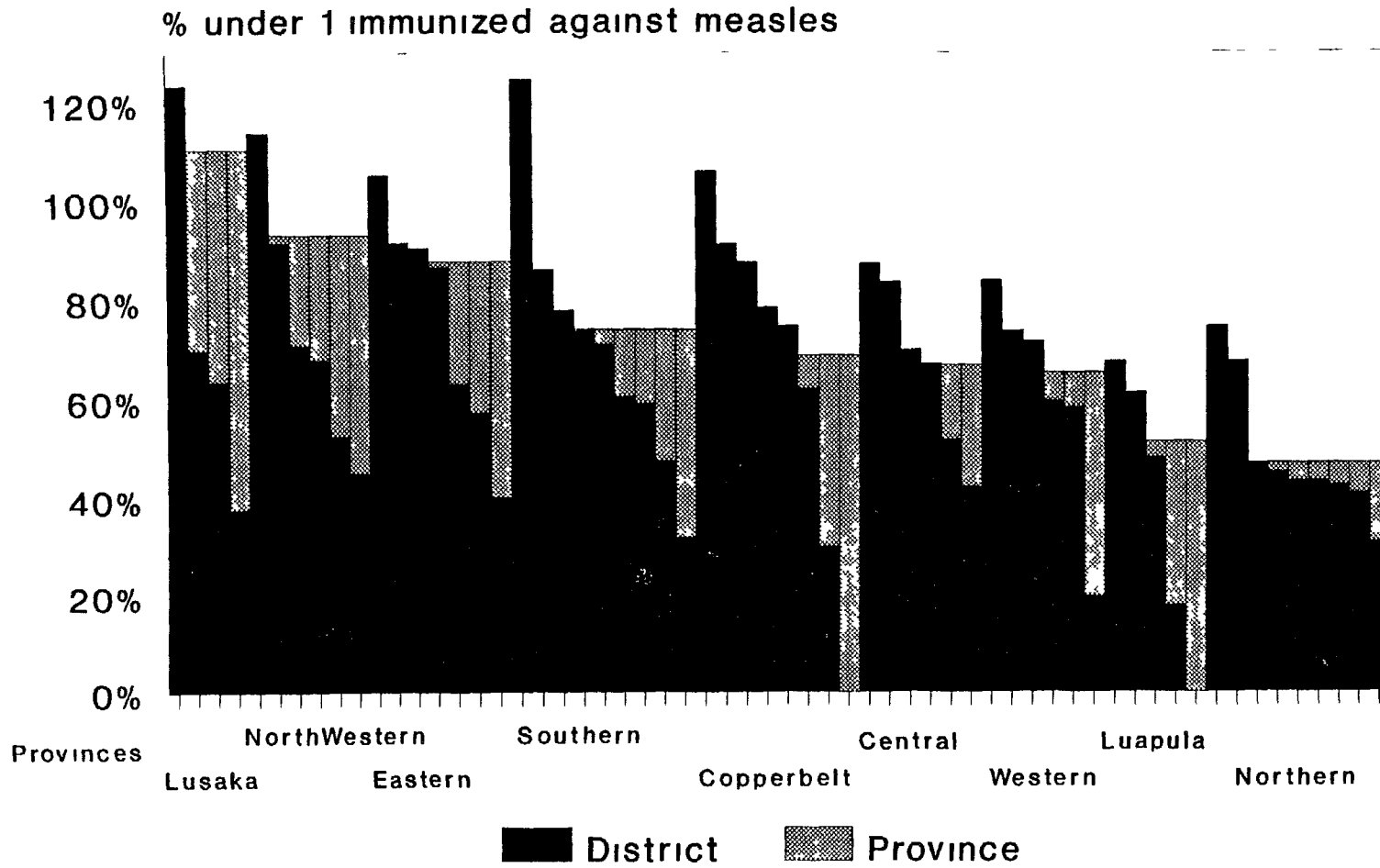
- Measles control raise coverage to 95%
- Measles outbreak prevention improve coverage among high risk populations and use supplementary immunization to prevent an outbreak
- Measles elimination strategies are under intense discussion at global level

### Zambia Measles coverage < 1 in 1996, by District





### Zambia Measles coverage < 1 in 1996, by province & district



From the data presented above, Zambia is facing the first challenge of raising coverage for a single dose at 9 months (or before first birthday) to 95%. Districts who think that their coverage is very high should reassess whether they are actually immunizing the same children twice (especially in urban areas). During community visits it was not difficult to find children under 5 who had never had a dose of measles vaccine. The proposed guidelines describe an approach to increasing the level of protection against measles disease.

### **Proposal for clarification of policy**

The immunization schedule contains one dose of measles, to be given at 9 months or as soon as possible thereafter.

### **Proposals for measles control strategies in the guidelines**

#### **1. Raise routine coverage**

This involves a fundamental re-assessment of existing coverage including -

- age of dose
- number of doses per child
- tallying of doses
- coverage among visitors and temporarily absent residents

District supervisors should assess the extent to which HCs are routinely giving early doses, or giving early doses during outbreaks, where are these doses counted (on tally sheets, on monthly reports)?

Community based surveys following pretested guidelines (to be developed) should feed into a process such as the dynamic standard setting system (DYSSSY) used by HRIT to gain insight into (a) factors which inhibit attainment of 95% coverage and (b) how to achieve 95% coverage in that neighbourhood.

Active, community based registration of eligibles using school exercise books (Burkholter) will enable the local leaders and village headmen (e.g. sibbuku, nduna) to identify eligibles on time, and follow up defaulters. The data items (column headings for the exercise book) should be identified in the guidelines (experience from population). In urban areas, the community should give special attention to identifying visitors and returning residents, and ensuring that they have a documented measles dose.

Health staff have some experience of applying the triple-A approach (assessment, analysis, action) which can be used to great advantage in improving this area of child health services. They and their supervisors can monitor the effectiveness of the chosen activities (the plan/do/check/act cycle in the Quality Assurance Notebook).

## 2 If an outbreak occurs

It is too late to start mass immunization because susceptibles (never immunized plus immunized who did not acquire immunity) may already be incubating the disease

- Health staff, with Neighbourhood Health Committees, should identify where index case came from, and determine the factors relating to the outbreak to understand the contributing factors. The approach will benefit from using DYSSSY as above, with input from staff responsible for epidemic surveillance (district surveillance committee, regional staff). Provide feedback to the community, emphasizing the need for 95% coverage, no immunization in the vicinity of the cases
- In the surrounding sections/zones/villages (i.e. territory covered by one NHC) mobilize those NHCs to intensify their identification of unimmunized eligibles under 5 years old. Provide outreach to immunize children over 9 months and under 5 who lack a record of immunization. **THIS IS OUTREACH, NOT A MASS CAMPAIGN**. Focus resources on the highest risk group (i.e. 9 months to 59 months), interrupt transmission from older to younger children
- Guideline will contain a format for collecting information on cases (refer to epidemic surveillance system). The analysis must divide cases according to age (year of birth), and age in months for under-1s. Instead of reporting a simple "yes" if the case was immunized, record the date of immunization so that surveillance can monitor cases in the cohorts immunized before 9 months of age
- Guideline will explain the factors which contribute to cases occurring in immunized children (sero-conversion rates of around 85% in healthy children, lower sero-conversion in undernourished children, no sero-conversion in HIV+ children). Understanding these factors will help to build confidence and enhance participation in child health services
- HC staff and supervisors should check the quality of cold chain and vaccine handling procedures, such as breaks in the power supply, stock-out of paraffin, the temperature of the diluent at time of reconstitution. Supervisors should observe how staff handle vaccine during sessions

Action should be focused to use resources in the most effective way. Staff and community partners should consider what activities have to be cancelled or deferred in order to implement the chosen action

Measles control measures are not constrained by the same time constraint as NIDs for polio eradication (when all eligibles must receive the vaccine within a few days of each other). Measles immunization can continue over several weeks, according to the availability of resources (especially skilled staff)

### **Implications of clarifying the policy**

Control of measles disease will be tackled more effectively and surveillance, the essential element in moving towards outbreak prevention, will be strengthened

Community participation would provide surveillance for eligibles, defaulters, visitors and cases at the level of the neighbourhood, extending the resources (time, local knowledge) available for combating measles

Fewer unnecessary injections will be given, and the effectiveness of measles immunizations will increase (more children will sero-convert if immunized at the correct age)

Routine reporting of measles doses will reflect coverage more accurately, and routine reporting of cases should also improve. This will provide a more robust data base at HC and district level for developing strategies for raising coverage and monitoring progress towards the target

Co-ordination with the epidemic surveillance system will be required for detailed investigation of outbreaks (refer to Chapter 8)

Resources (staff time) will be required to develop the guidelines (including pretesting). Training will be required at all levels

Resources will be directed into routine activities rather than responding to crises. For the strategy to be effective, resources must be allocated and used for outreach to underserved populations, even if only three or four visits per year can be made (e.g. nomadic fishing communities)

Detailed guidelines outlining the logistics implications of outreach strategies must be prepared, giving specific examples covering the types of cold chain equipment and icepack freezing capacity available at HCs. For example an RCW42-EK can freeze four icepacks in 48 hours, so outreach to a distant fishing camp would require icepacks frozen elsewhere, and transport for the RCW25 cold box (safe cold chain for 7 days)

### **Implications of continuing the status quo**

Measles coverage will overstate the true situation, leading some districts to believe that they are ready to move on to outbreak prevention strategies. This would divert precious resources, especially staff attention and energy, away from the fundamental objective of maintaining coverage at 95% of the eligibles in the catchment area

### 3 Clarification of TT schedule

#### Background

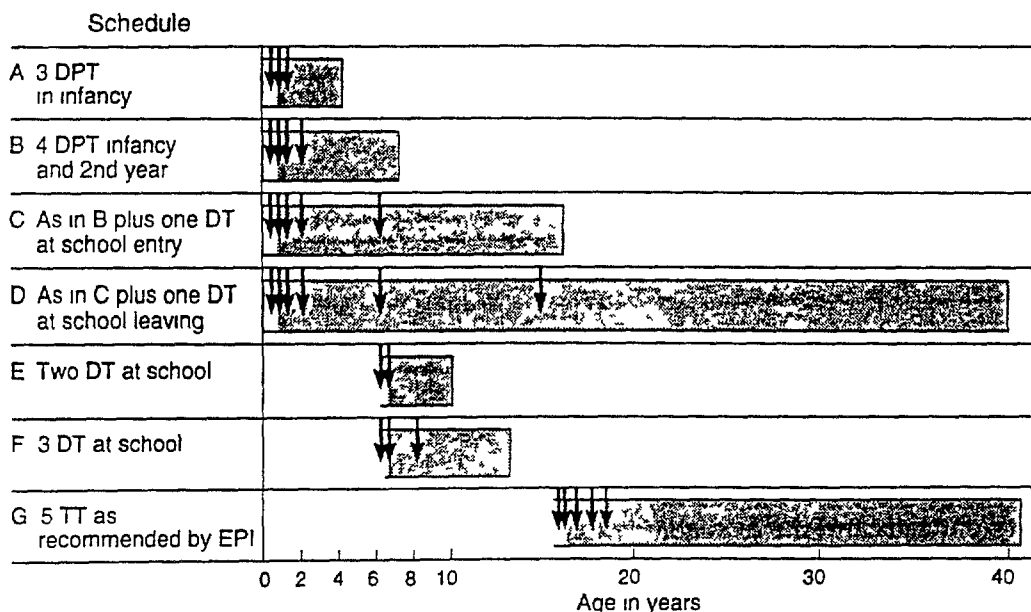
Since January 1990 Zambia has followed the schedule of five lifetime doses of TT for all women of childbearing age to protect the unborn child against neonatal tetanus (NT) At present the immunization schedule includes three doses of DPT under 1, a booster dose of DPT at 18 months, and two doses of TT to school children (Grades I and VII) The EPI Manual (p 2-3) states that -

- ◇ Women who have a documented record of DPT3 during childhood can be considered as having received two of their five lifetime doses of TT,
- ◇ Any documented TT doses received at school should be included in the required five lifetime doses

DPT3 in infancy confers immunity against tetanus until 4 years of age Adding the DPT booster dose at 18 months extends the duration of immunity to 7 years of age Adding the TT at school entry extends the duration of immunity to about 15 years of age One more TT dose confers lifetime immunity against tetanus (see Chart 3 1)

Chart 3 1

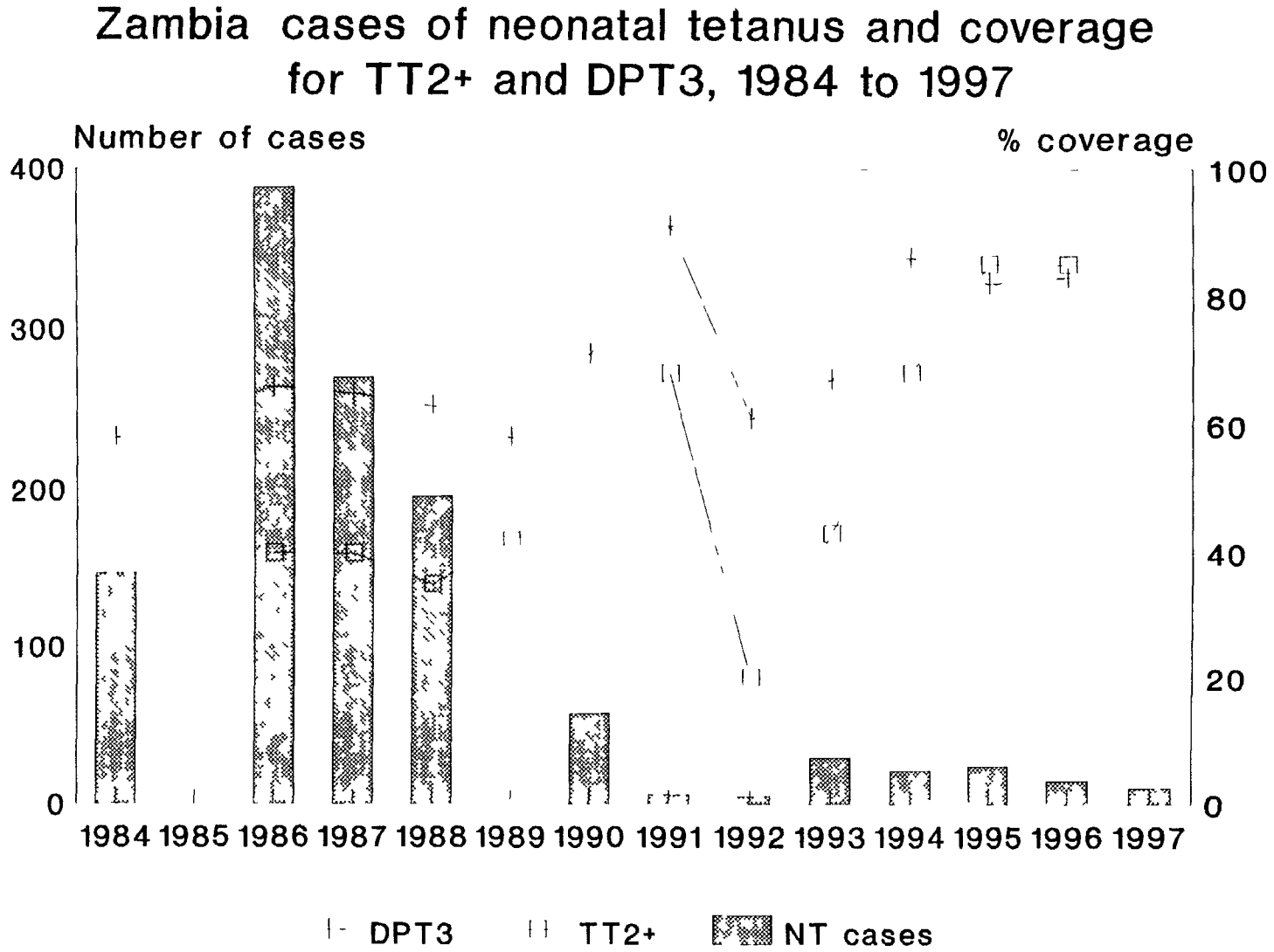
Expected duration of immunity after different immunization schedules



Source WHO (1996) p 16

Coverage for TT2 declined sharply in 1992 (see Chart 3 2) In 1994 the method of calculating coverage was updated to follow WHO's recommended indicator, TT2+, which accounts for previous doses, by 1995 coverage had passed 80% The survey data on coverage from ZDHS did not measure TT2+ as defined by WHO Neither the

Chart 3 2 Cases of neonatal tetanus and coverage for TT+ and DPT3, 1984 to 1997



survey questionnaire nor the analysis accounts for TT doses administered during previous pregnancies<sup>2</sup>. The question of interest is whether the enumerated child was protected against NT. Other indicators from ZDHS are summarized in Table 3.1

**Table 3.1**

**Antenatal care and deliveries in Zambia, 1992-1996 (n=7 159 live births)**

Indicator	%
Antenatal care received from trained medical personnel	96%
Two or more antenatal visits	92%
First antenatal visit earlier than the sixth month of pregnancy	61%
Delivery attended by	
doctor, midwife or nurse	47%
traditional birth attendant	5%
relative or other person	41%

Source: ZDHS, p 105

The WHO goal was to reduce the incidence of NT cases to fewer than one per 1000 live births in every district of all countries by the end of 1995. In Zambia eight districts reported NT in 1993, of which five reported more than one NT case, these five were identified as high risk for intensified NT elimination activities (Malek, 1994). A count from hospital records showed more NT cases than the number reported by the district.

Indicators collected during the 1997 review are summarized in Table 3.2. Three out of 20 HC staff interviewed had identified a case of NT in the last 20 months, if this rate of NT were extrapolated to the whole country, it would imply 27 cases per year. However, one-third of the staff interviewed were not familiar with an adequate definition of neonatal tetanus. The real number of cases is likely to be higher than the 10-15 cases reported nationally over the last two years.

**Table 3.2**

**Knowledge of HC staff regarding neonatal tetanus, and identification of cases**

Indicator	%	n
Knows definition of neonatal tetanus <sup>a</sup>	68%	19
Knows at least two actions in response to a NT case <sup>b</sup>	53%	19
Had any case of NT identified in the last 20 months <sup>c</sup>	15%	20

- a HC staff mentioned at least two of the following: 1 baby sucked normally at birth, 2 baby stopped sucking, 3 baby developed spasms, 4 baby had convulsions, 5 baby died
- b HC staff mentioned at least two of the following: 1 report to District, 2 immunize mother of the case, 3 immunize unprotected women in the neighbourhood

<sup>2</sup> ZDHS reports the number of doses administered during a particular pregnancy (refer to p 105-106, and the questionnaire, Section 4A, Items 410 and 411). For example the highest coverage for "Two doses or more" is for the first child born (52%), if health staff are following the schedule of five lifetime doses. The ZDHS methodology guarantees that the reported number of doses falls as birth order rises.

The HMIS uses the concept of the protected pregnancy in the Safe Motherhood Register (HIR 3) and provides a matrix and a detailed explanation for assessing whether the pregnancy is protected against tetanus. In the HMIS, individual doses of TT (reported in the old information system) will no longer be reported by HCs.

The HMIS does not include school health services. The MoH has not been receiving any reports of immunizations given in schools, although anecdotal information indicates that teenage girls have received TT in Lusaka Urban. An additional dose of TT at school entry doubles the duration of immunity (from 7 years to 15 years, see Chart 3.2). [School enrolment figures for 7 year olds to be added here.] Another dose at 15 confers lifetime immunity but secondary school enrolment for girls is about one-quarter [information being checked].

### **Policy Proposal**

A single dose of TT should be given at school entry. No further doses of TT should be given in school.

[no change to the existing policy of five lifetime doses]

### **Proposals for the Guidelines and Manuals**

The concept of the protected pregnancy should be adopted throughout, adhering to the following schedule of five lifetime doses:

- Women with a documented record of DPT3 during childhood should be considered as having received two of their five lifetime doses of TT,
- Women with a documented record of DPT3 + DPT booster during childhood should be considered as having received three of their five lifetime doses of TT,
- Any documented TT doses received at school should be included in the required five lifetime doses.

Thus a woman with DPT3, DPT booster, and one TT at school already has four of her five lifetime doses, she needs only one more dose of TT for lifetime protection.

A strategy of active follow-up of every NT case should be initiated, using a four-pronged approach which involves visiting the community:

- Contact Neighbourhood Health Committee or local leaders to explain need for TT
- Immunize the mother (to start protection for subsequent pregnancies) and find out why her last pregnancy was not protected
- Meet the birth attendants serving the community, including the one who attended the delivery, and discuss safe practices and upgrading of skills
- Assess all women in the community for TT immunization status, and provide maternal health services including immunization. Arrange with community leaders for follow-up and second doses of TT.



Protocols for use during this community follow-up will be developed in conjunction with the epidemic surveillance system (also refer to the safe motherhood policy)

### **Implications of the proposals**

TT card should be updated to show DPT primary series (dates), DPT booster (date) and school doses, with a layout which encourages correct interpretation of the woman's level of immunity

Staff training and health education messages must be refocused to communicate the concept of the protected pregnancy

Unnecessary doses of TT (i.e. in excess of five) will no longer be given, reducing both vaccine consumption and the number of injections

The epidemic surveillance system is a crucial component of improving health staff's skills in identifying and reporting cases of NT, and taking appropriate action

For implications regarding training birth attendants and supporting them with regular contact and supplies refer to the forthcoming report by MoH on TBAs (March 1998) and the safe motherhood policy

### **Implications of continuing the status quo**

Neonatal tetanus will continue to be under-reported, and the appropriate response to cases will be lacking

- |          |   |  |
|----------|---|--|
| Refer to | 5 | Use of opened vials of TT at subsequent sessions           |
|          | 8 | Reporting of notifiable diseases, use of surveillance data |

## 4 Safety of injections

### Background

In the 1980s Zambia's health facilities were equipped with steam sterilizers and stoves or hot plates so that staff could provide sterile equipment for immunization injections. In 1990 the UNICEF technical officer for UCI commented that Health Centre drug kits had a parallel system using conventional disposables for curative injections (A Malvavin, pers comm). The present policy is that sterilizable equipment should be used for immunization.

A rapid assessment of logistics and safety of injections using WHO/AFRO's survey protocol was conducted in January/February 1997. This study noted

- the need to repair faulty gaskets and valves on sterilizers
- TST (Time, Steam, Temperature) spots have not yet been introduced in Zambia
- inadequate management of stock leading to shortages of injection equipment
- where disposables are used for immunization they are reused if there is a stock-out
- unsatisfactory disposal of contaminated waste, and lack of awareness about sharps disposal boxes
- health staff's knowledge about sterile procedures and correct administration of immunization injections was commendable

The protocol followed during the review in September/October 1997 required the team to observe immunization sessions in order to assess behaviour and practices as well as knowledge and equipment. The data are shown in Table 4.1, and are analysed further in Table 4.2. Of the 24 HCs visited, 71% were using sterilizables with 54% depending on sterilizables alone. Comparing type of equipment with procedures for administering injections, correct injection technique during the immunization session was observed in a higher proportion of the HCs using only sterilizables, compared to those using disposables exclusively or in addition to sterilizables.

Fears about abscesses resulting from the use of steam sterilized equipment were raised in 1992. In a list of 14 errors observed in injection practices (Daniel, 1994) only one could be attributed to limitations of the equipment itself - namely that in hard water areas the mineral deposits coat the inside of the sterilizer and block the needles and syringes, necessitating more frequent resupply. Ten of the 14 errors would not be addressed by changing the type of injection equipment to disposables. Nevertheless in 1993 a pilot study using the "Autodestruct" syringe began in five compounds of Lusaka. The feedback was that no abscesses were reported, and staff found that they could work twice as fast, resulting in reduced queues at the under-5s clinics. No more "Autodestruct" syringes were procured by donors, and some Districts started using conventional disposables on an *ad hoc* basis.

**Table 4 1**  
**Indicators of injection safety at child health clinics**

Key	Indicator (number of standards checked by observation <sup>a</sup> )	Yes	n <sup>b</sup>
C22	Needles and syringes are adequate to meet needs	79%	24
C23	Sterilizing equipment, spares, fuel & supplies are available	83%	24
S7	Syringe and needle sterilizations meet standards	85%	20
S13	All EPI injections are given with sterile needle & syringe	89%	18
S14	All clinical injections given with sterile needle & syringe	80%	15
S15	EPI injections correct reconstitution, administration, dose	78%	18
S17	Sterile technique meets standards	50%	18

Source 1997 Review of immunization EPI-INFO rec files for Cold Chain/Logistics and Service Delivery

- a Items used for checking whether standards were met
- C22 Amount of injection equipment in stock, compare with workload (session size, eligibles)
- C23 Check inventory and stock for these items, including stove or electric plate
- S7 Check 4 points for steam sterilizer  
sterilizables placed in water to soak immediately after use, syringe barrel and plunger, and needles all separated on rack, fresh water used for each session of sterilization, 20 minutes' sterilisation, from time water in cooker comes up to pressure  
Check 2 points for disposables  
needles/syringes are in sealed cellophane package, equipment is within expiry date
- S13, S14 Sterile needle and sterile syringe for every injection Sterilizables assembled using sterile forceps
- S15 Check 11 items, including site, administration (intra-dermal/IM/subcutaneous), dose, size of needle, for BCG/DPT/measles, and diluent, reconstitution for BCG and measles
- S17 Injection site cleaned with sterile water on sterile gauze or cotton wool, sterile needle and syringe used, needle remains assembled to barrel (not changed after drawing up), new sterile gauze or cotton wool used to compress injection site
- b Denominator changes because sessions were not observed during all site visits

**Table 4 2**  
**Indicators of injection technique according to type of equipment used**

Injection equip for immunization	n	Location of HC		Are S15 and S17 both Yes <sup>a</sup>			n
		Urban	Rural	Yes <sup>a</sup>	One no	Both no	
Sterilizables only	13	4	9	5	2	2	9
Sterilizables and disposables	4	1	3	1	2	-	3
Disposables only	7	3	4	2	3	1	6
Total	24	8	16	8	7	3	18

- a S15 is answered Yes if EPI injections are correct in terms of reconstitution, administration and dose, S17 is answered Yes if HC staff's sterile technique meets standards See Table 4 1

The findings from Daniel's report require closer consideration -

- Staff prefer disposable equipment because of its speed and ease of use, but reducing the time spent with each patient may be counterproductive. The review team found that lack of communication between staff and carers is a major missed opportunity, only 50% of staff consistently told carers when to return, and exit interviews with carers showed that they knew when to return at only 44% of HCs surveyed. Effective two-way communication takes a little time.
- The problem of congestion in children's clinics can be addressed in more effective ways than changing the type of injection equipment. Several developments arising from health reforms make it possible to reduce overcrowding. For example, local budget for outreach means the HC can provide services closer to the family. HCs' use of Assessment, Analysis and Action enables them to find solutions which will improve clinic flow (e.g. cleaning needles and syringes immediately after each session, sterilizing should be done the day before a session so that everything is ready first thing in the morning).
- The cost implications of using disposable injection equipment are enormous - five to six times more per fully immunized child than for sterilizables, excluding the cost of destroying the by-products.
- Few cost comparisons include disposal costs because in developing areas the incineration technology is generally not available. Small incinerators designed for HCs are now being developed, but so far only half of the "disposable" technology is available, it generates 100 times more contaminated waste than sterilizables, without a viable means of destruction, failing the test of "no bad legacy" (Battersby, 1997).
- Budgetary constraints and flawed stock management mean that supplies run short. When sterilizables run short, the needles get blunt, in hard water areas the equipment accumulates a layer of mineral salts. When fuel for the stove runs short or the hot plate does not work, staff can use a fire (a second best strategy). When conventional disposables run short attempts may be made to sterilize them, but they are designed for a single use, the barrel and piston distort, the seals leak and it is impossible to administer the measured dose properly. When Autodestructs run short there is nothing that staff can do apart from cancel immunization activities.

A recent WHO paper ranks the risk of poor compliance for each type of injection equipment, leading to disease transmission (1) patient-to-patient, (2) patient-to-health worker, and (3) patient-to-community (Zaffran *et al*, 1997). This risk analysis does not take adequate account of the likelihood that stock-outs will occur. Almost every user of disposable equipment is honest enough to say "We do sometimes run out." Even the fear of running out causes some staff to misuse the equipment (Battersby, 1996). The review data show that disposables do not improve staff technique in giving immunization injections. One in five clinical injections observed (given with disposables) failed to meet the standards for sterile equipment.

A recent study of perceived health risks among staff at UTH demonstrates that problems associated with equipment for injections and other parenteral procedures are

not confined to the ambulatory primary health care services (reference from C Kasongo)

When injections must be given, the objective is to provide them safely. This has been especially important for immunization services, which invite a healthy client to undergo a procedure involving a degree of risk. One approach for minimizing that risk is to give as few injections as possible. A complementary approach is to choose injection equipment that is sustainable and affordable, in order to ensure that sufficient supplies are always available. The epidemiological profile of blood borne pathogens in Zambia (refer to Chapter 11) means that it is essential for health staff, managers and donor partners to make it a priority to reach this objective, not only for immunization injections but for all parenteral procedures.

Daniel (1994) noted that there was a lack of monitoring of adverse events following immunization (AEFI), but despite efforts to establish an AEFI reporting system, by 1994 none of the HCs reported any abscesses or adverse reactions.

“This is probably mainly because health staff are aware of the legal processes following possible deaths after unsafe practices, which was the case [with] the five deaths after DPT injections in Lusaka Urban.”

These events attracted widespread publicity which was thought to be responsible for a decline in coverage figures in 1992/1993. There are still no protocols or formats for reporting abscesses or other adverse events following immunization or any other parenteral procedure.

The issue of drawing back when giving injections has been discussed. The usual procedure of drawing back is necessary when injecting curative drugs, but drawing back introduces a risk that protein matter could remain in the needle and syringe. This risk must be minimized by emphasizing thorough flushing and cleaning of sterilizable equipment immediately after use.

Operational data on the useful life of needles and syringes used in Zambia's HCs is not yet available. This makes it difficult to assess whether the supply of new sterilizable equipment is adequate. The review team identified problems at a few HCs which had failed to replace the sterilizable needles and were using very blunt ones. There has never been any provision of sharps boxes for disposing of sterilizables when they are no longer usable.

### **Proposal for policy on safety of immunization injections**

Immunization injections are to be administered using equipment sterilized under pressure in steam sterilizers.

If sterilization equipment is not demonstrably reaching the required standards (using the TST spots) then immunizations should not be given.

## **Proposal for guidelines on adverse events following any parenteral procedure**

Guidelines for reporting adverse events following any parenteral procedure (AEFAPP) should include a dual reporting channel from the patient or community (NHC) to both the Health Centre Advisory Committee and the District Health Board

Guidelines for investigating AEFAPP should be developed in conjunction with the epidemic surveillance system WHO's document, *Surveillance of adverse events following immunization* (1997 revised edition) provides a starting point

Quality assurance standards for safety of injections and other parenteral procedures (including laboratory procedures) should be developed

Procedures should be developed for establishing an audit trail for disposed sharps waste

## **Implications of the proposal**

Equipment adequate to the workload must be procured and distributed Spare parts such as valves and rubber seals must be procured and distributed as needed New needles and syringes must be procured in sufficient quantities to meet health centre requirements, operational data based on experience in Zambia are needed to calculate the quantities (refer to National Cold Chain Workshop report prepared for presentation 29/30 January 1998) Preliminary studies in Romania indicated that the vapour purifier dramatically extends the useful life of needles and syringes in hard water areas If further trials show that the vapour purifier is successful under field conditions then this equipment should be procured and supplied for all steam sterilizers

Equipment for heating the steam sterilizer should be added to the inventory of essential equipment for HCs (refer to District Planning Guidelines, Volume I) This equipment can be procured locally and should meet the following criteria reliable, easy to maintain, availability of spare parts, and a suitable power source for the HC

TST spots (time, steam, temperature indicators) should be procured and supplied in sufficient quantities for every batch of sterilization TSTs change colour when they have been exposed to sufficient heat and pressure for the required length of time If TSTs fail to change colour, the reason must be identified and the problem corrected

Disposable syringes cost five times more per fully immunized child than sterilizables in soft water areas TSTs add less than US\$0.02 per sterilization cycle (WHO, 1997) The quantity of TSTs required should be worked out based on the number of immunization sessions (bottom up quantification, pull system refer to Chapter 7)

Existing low cost incineration equipment should be tested for its suitability in the Zambian setting, and if suitable it should be supplied to all HCs with a compatible source of power

### **Implications of continuing the status quo**

A mixed array of injection equipment will continue to be procured by Districts on an *ad hoc* basis, without due regard to the immediate cost implications or the dangers to public health posed by the absence of safe and effective methods of disposal

Disposable syringes will not be destroyed safely and may be reused

When abscesses occur they will continue to be treated (as casualty cases), but the cause of the problem will not be identified or addressed. Rumours will proliferate, and confidence in the quality of health services will be undermined

- Refer to 8 Reporting notifiable diseases, use of surveillance data  
13 Logistics from centre to district

## 5 Use of opened vials of non-reconstituted vaccine at subsequent sessions

### Background

The present policy in Zambia is that opened vials should be discarded at the end of a session. If session size is small then wastage will be high (refer to Chapter 6, Session Frequency). Table 5.1 shows wastage rates and multipliers, based on consumption in 1993, 1994 and 1995. These figures are substantially higher than those cited in WHO's illustrative method for forecasting vaccine quantities (WHO, 1997, p. 7).

**Table 5.1**

**Vaccine Usage Indicators: Average wastage and average multipliers, 1993 to 1995**

Antigen	Doses/ vial	Percent Wastage <sup>a</sup>		Multiplier <sup>b</sup>	
		Zambia	WHO	Zambia	WHO
BCG	20	79%	50%	4.92	2.0
OPV	20	62%	38%	2.73	1.6
DPT	20	56%	38%	2.25	1.6
Measles	10	70%	38%	3.42	1.6
TT	20	82%	38%	5.68	1.6

a. Percent wastage is (Doses thrown away / Total doses consumed) x 100

b. The multiplier is (Total doses consumed / Doses administered)

Source: WHO AFRO Logistics Project, Larsen and Chindedza (November 1996)

In 1995 WHO issued a policy statement on *The use of opened vials of vaccine in subsequent immunization sessions*. The relevant sections of the policy are as follows:

**1. The revised policy applies only to vaccines which**

- meet WHO requirements for potency and temperature stability,
- are packaged according to ISO standard 8362-2,
- contain an appropriate concentration of preservative.

NOTE: Vaccines supplied via UNICEF meet these requirements.

**2. For such vaccines, the revised policy states that**

2.1. Opened vials of OPV, DPT, TT, DT and hepatitis B vaccines may be used in subsequent immunization sessions provided that each of the following three conditions is met:

- the expiry date has not passed, **and**
- the vaccines are stored under appropriate cold chain conditions (0°C to +8°C) **and**
- opened vials which have been taken out of the health centre for immunization activities (e.g. outreach, NIDs) are discarded at the end of the day.





2.2 Opened vials of measles, yellow fever and BCG vaccines must be discarded at the end of each immunization session

2.3 An opened vial must be discarded immediately if any of the following conditions applies

- if sterile procedures have not been fully observed, or
- if there is even a suspicion that the opened vial has been contaminated, or
- if there is visible evidence of contamination, such as a change in appearance, floating particles, etc

***Rationale for changing the previous policy***

Two issues dictate EPI policy on the use of opened vials of non-reconstituted vaccine

***1 Potency***

The potency of an opened vial of vaccine over time is determined primarily by

- the heat stability of the particular vaccine, and
- whether or not the vaccine has been reconstituted

The potency of OPV, TT, DPT, DT and hepatitis B is a function of heat stability and opened vials of these vaccines remain potent as long as they are stored under appropriate cold chain conditions (0°C to +8°C) and the vial's expiry date has not passed

***2 Safety***

The safety of an opened vial of vaccine is primarily dependent on

- the risk of contamination with a pathogenic organism, and
- the bacteriostatic/virucidal effect of preservatives in the vaccine vial

Reconstituted measles, yellow fever and BCG vaccines do not contain preservatives and must never be kept beyond the session during which they are reconstituted

Note A revised version of this policy statement is expected during March 1998

**Background on Cold Chain Quality in Zambia**

A refrigerator is listed as essential equipment for health centres in the District Action Plan inventory (CBOH, 1997)

The cold chain equipment inventory survey conducted in June and July 1997 included 1,236 refrigerators and freezers, of which 11% were not working. The 1997 review of immunization activities showed that 2 out of 16 rural HCs (13%) had no working fridge, and 3 out of 8 urban HCs were using the District store for their cold chain. This and other indicators of the status of the cold chain are shown in Table 5.2. The review also found that some Districts have bought refrigerators which are not suitable for storing vaccine (refer to Chapter 10)

Equipment is only part of the cold chain, equipment and supplies have to be managed and used correctly by staff. Health workers' knowledge and practices for maintaining cold chain and handling vaccine are summarized in Table 5.2. With only 27% knowing the shake test to identify DPT that has been frozen, it is likely that a proportion of immunized children and women have received a wasted injection of impotent vaccine.

In addition to these indicators, a few dangerous practices were seen during the review: changing the needle after drawing up and before injecting the dose, and opening vials with needles stuck in the septum both during sessions and inside fridges. Leaving a needle in the septum implies changing the needle, which contravenes the protocol for maintaining aseptic technique.

**Table 5.2**

**Quality of cold chain equipment and management at health centres (1997 Review)**

Indicator	% Yes	n
Refrigerator at HC, and working <sup>a</sup>	79% <sup>a</sup>	24
Is the refrigerator used by the HC clean <sup>b</sup>	83% <sup>b</sup>	23
Is there a thermometer in the fridge <sup>c</sup>	96%	23
Temperature in correct range (0° to +8°C)		
- at the time of the review team's visit <sup>c</sup>	86%	22
- on all the days for which it was recorded <sup>c</sup>	60%	20
- for all HCs in the sample over 1-2 months <sup>c</sup>	50% <sup>c</sup>	24
Vaccine was all within expiry date	91%	22
Vaccine in use is kept cold and out of the light at session site	91%	21
Opened vials are discarded at end of session (no opened vials were found in fridge)	86%	22
Knows the shake test	27%	22
Knows how to interpret VVM on OPV	78%	23
Described correct action in case the fridge breaks down	96%	23

a Excludes 3 UHCs which do not have own equipment but are sharing District refrigerator. If these 3 are included as having access to a fridge, 92% of HCs have such access.

b Refrigerators recorded as not clean were all in the same District supervision problem.

c This figure includes HCs with no fridge and indicates the overall consistency of cold chain.

Source: 1997 Review of immunization Cold Chain and Logistics EPI-INFO rec file.

### Proposal for policy

Zambia should adopt the policy of using opened vials of non-reconstituted vaccine in subsequent sessions, as long as correct cold chain temperatures are maintained in storage during transport, and during the session, and as long as health workers handle the vaccine correctly.

## Implications of the proposal

Training and supervision is required to introduce the policy and to implement it safely. An implementation plan is needed, covering training of District staff (TOT) and guidelines for introducing and implementing the policy at facility level.

Health facilities lacking adequate cold chain do not meet the criteria laid down in the policy, so should continue to discard opened vials at the end of the session. Cold chain involves a combination of equipment and human activity (see Table 5.2). District supervisors must assess each facility's cold chain to decide whether the policy can be implemented there.

- An assessment of equipment (including vaccine carriers and icepacks) should be carried out at least twice<sup>3</sup> per year, as part of updating the cold chain inventory and planning for maintenance and replacement of equipment.
- Supervisors must also assess staff's knowledge and practices when handling and administering vaccine. Appropriate action must be taken by supervisors to ensure that vaccine is handled properly and administered safely.

It is anticipated that wastage will fall substantially for OPV, DPT and TT administered at static sessions, and that expenditure on these vaccines will fall. Monitoring stock levels at both health centres and district stores (as laid down in the Stores Manuals and HMIS) will be essential to establish the new levels of consumption and wastage, and to adjust the calculations for quantification. There will still be wastage of OPV from discarding any vial whose VVM indicates that it should not be used. The policy does not affect consumption of BCG or measles vaccines.

Where the District vaccine store is also used for storing vaccine issued to the urban HC, stock issued to the urban HC must be recorded as per CBOH's stores management manual (1998), and be separated in some practical fashion. For example the UHC's stock could be kept in plastic containers. Stock that is taken to the UHC sessions and returned thereafter (including opened vials of OPV, DPT and TT) must be kept separate from stock awaiting dispatch to other HCs. Separation of these stocks is also essential for monitoring vaccine consumption by the UHC, which should achieve substantial reductions in wastage by implementing the opened vial policy. In the longer term, all urban HCs should ideally have their own separate refrigerator.

## Implications of continuing the status quo

The donors who fund Zambia's immunization services are unwilling to pay for the present extraordinary levels of vaccine wastage.

Refer to	6	Session frequency
	7	Vaccine quantification
	9	Use of HMIS for quality assurance
	11	Cold chain equipment suitable for vaccines

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<sup>3</sup> Refer to p 5 of "Report on 2 Visits to Zambia" in Munck and Din (1997).  
*First draft, 12/3/1998*

## 6 Session frequency

### Background

After the global push for universal child immunization in 1990 the term "supermarket approach" was promoted. Some Districts have never adopted this approach as it is inconsistent with their level of resources.

Larsen and Chindedza (1996) linked the supermarket approach to low average attendance and high wastage rates. The review team calculated the number of children expected for measles dose at each session using data on under-1s and sessions scheduled per month (see Table 6.1). Assuming that all eligible children attended on schedule,

- 5 out of 14 rural HCs would give fewer than 3 measles doses per session,
- 3 out of 7 urban HCs would give fewer than 3 measles doses per session.

Staff had scheduled many more sessions than were needed for the eligible population, leading to extraordinary levels of wastage nationally (refer to Chapter 5).

The idea of never missing an opportunity to immunize a child has been translated into the advice "Do not hesitate to open a vial even for a single eligible child or woman" (EPI Manual). This policy can result in stock-outs which delay or deny vaccination to those who come to scheduled sessions, sometimes for large numbers of eligibles.

- The review team observed an outreach session attended by 72 children due for measles dose but the health worker had only two vials of measles vaccine.
- Fewer than half the HCs visited had enough stock of all antigens to provide the expected number of doses at sessions scheduled for the following week.
- If these HCs had opened one extra vial of the antigen in shortest supply, two-thirds would not have had sufficient stock for the following week's scheduled sessions.

The review team identified multiple aspects of missed opportunities -

- For 31% of mothers interviewed in the community, scheduled services were always held as advertised, but 62% said sessions were mostly held or sometimes held.
- Although 53% of health centres held all of their scheduled sessions in the last month, 47% missed one or more scheduled sessions, and 13% of the randomly selected HCs visited provided no immunization services at all during the last month.
- Only half of the health workers observed consistently told the mothers when to return, and at 44% of the health centres visited, mothers interviewed on exit did not know when they should return.

One way to reduce the number of unimmunized children and women who show up at random is to ensure that all carers and eligible women know when immunization services are available, and to provide these services reliably, as advertised. Improving stock management, and keeping a safety stock of one supply cycle in reserve, as described in the new FAMS manual, will help to reduce the present backlog of missed opportunities caused by stock-outs of vaccines or the diluent for measles or BCG.

**Table 6 1**

**Eligible population compared with sessions scheduled, indicating where session frequency appears too high for the workload (assuming coverage is 100%)**

Health Centres	Births/ year	Births/ month	<1s/ month	Sessions / month		Measles doses/ session <sup>a</sup>	Too many sessions <sup>a</sup>	Vaccine for next week <sup>b</sup>
				Scheduled	Held			
<b>RURAL</b>								
R 4-1	124	10	52	6	4	2	←	✓
R 5-2	146	12	61	20	0	1	←	NO
R 3-1	207	17	86	8	8	2	←	✓
R 9-2	306	26	128	20	20	1	←	NO
R 7-2	320	27	133	7	0	4		NO
R 6-1	362	30	151	14	14	2	←	✓
R 8-2	370	31	154	6	0	5		NO
R 12-2	408	34	170	8	8	4		NO
R 2-1	412	34	172	10	9	3		(✓)
R 3-2	455	38	190	12	12	3		NO
R 10-2	536	45	223	11	11	4		NO
R 10-1	538	45	224	6	6	7		(✓)
R 2-2	608	51	253	10	9	5		NO
R 11-2	1,064	89	443	30	26	3		✓
R 6-2	Insufficient data			Has no fridge, no vaccine, no sessions				NO
R 7-1	Insufficient data			Has ample stock of vaccine				✓
<b>URBAN</b>								
U 4-2	370	31	154	12	12	3		NO
U 8-1	623	52	260	26	26	2	←	NO
U 12-1	742	62	309	26	23	2	←	✓
U 11-1	803	67	335	34	34	2	←	✓
U 9-1	1 000	83	417	26	25	3		NO
U 1-2	1,620	135	675	30	22	5		✓
U 1-1	3,960	330	1,650	41	21	8		NO
U 5-1	Insufficient data			Uses District store but low on BCG				✓

- a How many children would the health worker expect to see for measles immunization per session? Assuming one dose of measles per child and 100% coverage, this is calculated as children per month divided by scheduled sessions. The arrow marks where only 1 or 2 children are expected for their measles dose at any given session.
- b (✓) means that next week's scheduled sessions will reduce stock of one or more vaccines to zero. There are no spare vials to open for unscheduled immunizations.

For many years vaccine was regarded as comprising a small proportion (about 10%) of the cost of immunization. However, a cost-effectiveness analysis in Tanzania (1987) found that vaccine comprised 42% of total EPI costs. The concept of the "supermarket approach" is still based on the premise that vaccine is cheap. This approach encourages high levels of wastage, which causes concern among the donors who pay for the vaccine (Minutes, 1996)

Planning session frequency appropriate to the workload will entail reasonable utilization rates for this precious and finite resource. For many HCs, especially in rural areas, integrated services can be provided by outreach once a week, once a month, or at longer intervals in hard-to-reach areas with seasonal problems of accessibility. A more appropriate metaphor is the market day when customers gather at an agreed place and time to use the promised services.

The supermarket approach may be appropriate and feasible in some health centres which have sufficient staff. However, it has been pointed out that the concept of never hesitating to give an immunization is inconsistent with the injection technology used in Zambia. Opening the steam sterilizer for one injection means that 41 unused needles and syringes (in a single rack sterilizer) have to be resterilized in order to sterilize the one used needle and syringe.

## **Proposal**

Policy should emphasize that the frequency of sessions for integrated health services should be planned to cover the eligible population within the resources available.

## **Implications of the proposal**

The supermarket approach will not be a central tenet of policy. Guidelines and manuals will describe a range of alternative strategies for providing integrated health services.

Guidelines need to describe ways of planning activities to cover all settlements in the catchment area according to the number of eligibles and expected session size in each place.

Guidelines will emphasize reducing missed opportunities, shifting the emphasis from opening vials to removing the various constraints described above. The DYSSSY (dynamic standard setting system) introduced to districts by the HRIT provides an approach for identifying problems and implementing solutions which are appropriate for low coverage, high drop-outs and late doses in a particular catchment area. The review team's observations suggest that many solutions lie within the control of staff, especially in the quality of their interactions with clients (refer to Chapter 9).

### **Implications of continuing the status quo**

Wastage rates will continue to be extraordinarily high for BCG (20-dose vials) and measles vaccine (the highest cost per dose) if the opened vial policy is adopted. If this policy is not adopted wastage rates for all vaccines will continue to be high.

Policy will continue to emphasize an approach which fails to address the causes of missed opportunities identified by the 1997 review.

- Refer to
- 5 Use of opened vials of non-reconstituted vaccine at subsequent sessions
  - 7 Vaccine quantification

## 7 Vaccine quantification

### Background

Until now, forecasts of the quantity of vaccine required have been prepared at national level. These forecasts are based on estimates of the multiplier (how much more vaccine is required than the number of doses to be administered) which is derived from vaccine wastage, calculated from total doses administered of each vaccine and the total quantity of vaccine used in the process (refer to Table 5.1). The estimates of wastage depend upon accurate stock records and complete reporting of all doses administered.

Recently this system has not worked well, the review team noted a number of serious problems with stock management and stock records at national level, including both expiry of stock while still in the national store and insufficient stock of all vaccines except BCG at the time of the review (refer to Review Report, Appendix II and Appendix III). This combination of excess and shortfall suggests that over the previous two to three years, weak stock management at national level has led to insufficiently accurate quantification of vaccine requirements.

The review team also found that forecasting is not controlled by a national focal point, is fragmented, lacks transparency and is not designed to ensure a steady supply with adequate safety stock. Nor is there a national focal point for procurement, which is performed by individual donors, making co-ordination very difficult.

During the workshops for preparing 1998's plans the Districts were presented with a method for estimating their vaccine requirements that was based on the top-down method of forecasting described above (refer to "Steps in calculation [sic] vaccine required"). What is needed is a logical, transparent guideline for bottom-up forecasting based on the number of sessions planned by health centres.

UNICEF Supply Division (1997) issued a vaccine forecasting guideline which indicates that sessions can be calculated as the number of settings multiplied by session frequency. The example illustrating the approach assumes that all settings will offer sessions at the same frequency. Table 6.1 shows that the number of sessions scheduled per month varies widely between HCs. The estimates for Zambia produced using this guideline were discarded because they diverged so widely from past consumption.

Table 6.1 also shows that more than half the HCs surveyed during the 1997 review did not have enough stock of all vaccines to provide for next week's scheduled sessions. In general HC staff did not keep any stock records, this gap is being addressed by the FAMS training in stores management.

The HMIS will report BCG doses, DPT3, OPV3 and measles doses administered to under-1s (refer to HIA 2). Data for all doses administered will not be reported, so the old methods for estimating vaccine requirement will no longer be possible. New indicators must be developed using the data available from the HMIS and the stock management system.



### **Proposal for guidelines**

Guidelines for bottom-up quantification of vaccine requirements are needed, designed for use by health staff and District Health Management Teams

The forecasting parameters for HCs should reflect the number of sessions held, the expected attendance at static and outreach sessions, and the vial size (i.e. the maximum number of doses that can be obtained from one vial)

District's vaccine requirements should be based on an aggregate of their health centres' individual requirements

Safety stocks must be factored in for each level of the system, including the national store, which should never have less than 3 months' requirement in stock

### **Implications of the proposal**

Bottom up quantification should help both HCs and Districts to increase their awareness of the amount of stock they actually use and the amount they need in order to avoid running out of any antigens for scheduled sessions. Better bottom-up quantification and improved stock management should reduce the missed opportunities caused by stock-outs, thus improving coverage of immunization on time (under-1)

The details of the guideline depend on several policy decisions proposed in this document (see below)

A new indicator for monitoring vaccine consumption needs to be developed using data available through HMIS and FAMS. The new indicator will be linked to coverage of the final dose, or in the case of TT, the coverage of protected pregnancies

### **Implications of continuing the status quo**

The status quo cannot be continued because the data for forecasting vaccine requirement using wastage and multipliers are no longer available through the HMIS

- Refer to
- 1 Adding a fourth dose of OPV under 1
  - 2 Clarification of policy on immunization against measles
  - 3 Clarification of TT schedule
  - 5 Use of opened vials of non-reconstituted vaccine at subsequent sessions
  - 6 Session frequency
  - 14 Vaccine Independence Initiative and other funding

## 8 Reporting notifiable diseases, use of surveillance data

### Background

All of the diseases prevented by immunization are reported using the HMIS formats and aggregated quarterly by CBoH's Directorate of Monitoring and Evaluation. This is a change from the previous system which reported monthly.

For some diseases special analysis is required. For example measles outbreaks tend to be seasonal, and preventive action can be timed to forestall such outbreaks using monthly data on incidence. Rather than including every item that could be monitored in the HMIS, GRZ has chosen a strategy of keeping the HMIS user-friendly for front line health workers. More detailed data will sometimes be needed for analysing the local profile of disease outbreaks and planning appropriate action. This document has identified the epidemic surveillance system as a crucial component of strategic action plans for reducing morbidity and mortality from preventable diseases, refer to

- Chapter 1 on AFP surveillance,
- Chapter 2 on measles control,
- Chapter 3 on eliminating neonatal tetanus, and
- Chapter 4 on adverse events following parenteral procedures

These chapters have also identified underreporting of AFP and neonatal tetanus, and misdiagnosing rash and fever cases as measles. Part of the underreporting can be attributed to gaps in health workers' knowledge, documented during the 1997 review

40% did not know the reasons for AFP surveillance,  
45% did not know the case definition of AFP,  
32% did not mention the hospital in their description of who should detect and report AFP cases (crucial for follow-up of cases)

5% did not give an adequate case definition of measles disease<sup>4</sup> and when asked who should detect and report measles cases,  
11% did not mention that the HC in their answer, and  
28% would wait for more than one measles case to be reported before taking action

32% did not give an adequate case definition of neonatal tetanus (refer to Table 3 2),  
47% did not know the appropriate actions to take in response to a case of NT

Cases of AFP and NT are relatively rare, and HC workers and DHMTs need special support from staff responsible for epidemic surveillance to build capacity and skills. CBOH's Monitoring and Evaluation Unit and the Regional Directorates are receiving short term technical assistance from WHO to establish the epidemic surveillance system.

<sup>4</sup> Health worker mentioned three or more of the following: fever, cough, rash, conjunctivitis  
*First draft, 12/3/1998*

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## **Proposal for guidelines on surveillance for diseases prevented by immunization**

Guidelines for DHMTs, HC workers and community partners are needed for AFP surveillance, data to collection during measles outbreaks, response to any case of neonatal tetanus, and investigating adverse events following parenteral procedures. The guidelines should also describe the strategies outlined in this document.

### **Implications of the proposal**

The epidemic surveillance system must be developed, and staff to implement it must be in place, with the resources necessary to carry out the tasks (e.g. transport).

All staff will need their skills updated and orientation in use of the new guidelines.

Identification of cases will be more accurate, leading to more complete reporting and more effective response by health workers, DHMTs and regional managers.

### **Implications of continuing the status quo**

Underreporting will continue. Response to outbreaks will continue to be *ad hoc*, using resources ineffectively and diverting attention from strengthening routine activities.

- Refer to
- 1 Adding a fourth dose of OPV under 1
  - 2 Clarification of policy on immunization against measles
  - 3 Clarification of TT schedule
  - 4 Safety of injections

## 9 Use of data for quality assurance

### Background

The objective of quality assurance (QA) is to ensure health care of optimal quality using pertinent data to analyse and monitor quality and then to correct deficiencies

Since 1994 the HRIT has trained all districts in the concept of QA. When this concept is applied to immunization services it combines quantitative inputs (e.g. supplies, fuel, reports) with the quality of services provided. The 1997 review assessed a variety of quality indicators (refer to Table 4.1, Table 4.2, Table 5.1, Table 6.1), additional indicators are summarized in Table 9.1

**Table 9.1**

**Indicators of the quality of child health services observed at sessions (n=22)**

Indicator	% of sessions
All of the sessions scheduled last month were held	48%
Observed session started on time	42%
Staff had friendly interchange with clients	72%
Children were screened correctly for immunization	75%
Sick children were screened and referred for immunization	37%
Caretakers screened correctly for TT immunization	35%
Data were recorded correctly on child health card	90%
Data were recorded correctly in Children Under 5 Register	76%
Client was told of reaction to BCG and DPT	17%
Clients was told when to return (observing interaction)	50%
Clients know when to return (exit interview)	44%
Clients know reaction to BCG and DPT and what to do	24%
Mother was happy with the service (community survey)	72%
Review Team member would take own child to this HC	47%

Source: 1997 Review of immunization

Table 9.1 outlines the scope for improving the quality of communications between health workers and mothers, for example if all mothers who attended knew when to return then the drop-out rate for under-1s (21.6% for BCG to measles dose - ZDHS) would be greatly reduced and measles coverage would exceed 95%. The community surveys found mothers who said they had been turned away for coming too late (i.e. 11.30 for one HC). Other aspects of missed opportunities are described in Chapter 6.

Community partnership is a key component of improving quality. Health staff can enlist the assistance of Neighbourhood Health Committees, CHWs and TBAs to identify eligibles, to encourage the carers to bring the child to scheduled sessions, and to follow up no-shows or drop-outs using the Children Under 5 Register or local lists of eligibles. The HMIS's concept of the Public Health Flag reinforces the role of NHCs.

and Health Centre Advisory Committees in monitoring and assuring quality. The review team suggested that drop-out rates (e.g. BCG to DPT3) would provide an indicator of immunization coverage and completeness of care which gives enough time to correct shortcomings before the defaulters' first birthday.

### **Proposal for guidelines on quality assurance**

Guidelines for QA techniques should be developed using the specific indicators available from immunization inputs and activities. The guidelines should encourage people to ask

- Are we doing things right? (efficiency)
- Are we doing the right thing? (effectiveness)

These guidelines should be co-ordinated with the guidelines on safety of injections, use of opened vials (quality of cold chain), and vaccine quantification (monitoring consumption using the new stock management protocols) to ensure that HCs never run out of essential supplies.

DHBs, DHMTs, HCACs and NHCs should emphasize to health workers the role of two-way communication in service delivery.

### **Implications of the proposal**

Health workers and their supervisors will be better equipped to manage the many aspects of resources and planning involved in providing child health services. The effectiveness of their effort is thus likely to improve, thus preventing more childhood illness.

### **Implications of continuing the status quo**

Activity will continue to be somewhat unfocussed, lacking the crucial ingredient of analytical assessment to feed into action plans. Resources will be used at less than optimal effectiveness.

- Refer to
- 4 Safety of injections
  - 5 Use of opened vials of non-reconstituted vaccine at subsequent sessions and Cold Chain Quality in Zambia
  - 6 Session frequency
  - 7 Vaccine quantification

## 10 Cold chain equipment suitable for vaccines

### Background

The national stock of cold chain equipment has been built up since 1976. The total purchase price is estimated to have been \$3 million, two-thirds of which was spent on 288 solar refrigerators (accounting for 23% of all 1,236 items). The inventory records are managed by the Cold Chain Workshop. Keeping these records up-to-date depends on feedback from the Districts.

Overall, 89% of the refrigerators and freezers were reported to be working as of July 1997. Almost 40% of Districts (24/64) reported no units not working, but one of these Districts had 5 more HCs than the total equipment reported. Management indicators of service delivery should show whether Districts have enough working equipment for every HC to have active cold chain (see Table 10.1). At least 13 Districts have insufficient working equipment, involving a total shortfall of 34 HCs (3.5% of 959 HCs). However, the calculations in Column A do not account for storage equipment at District level. Column B shows the situation assuming that each District store needs two units - refrigerator and freezer. With this interpretation, 9.2% of HCs do not have a working refrigerator.

**Table 10.1**

**Working equipment in Districts, compared to number of HCs**

Working equipment is	Col A Districts	Col B Districts
Insufficient for the number of HCs	13	30
Sufficient for one unit per HC	11	8
One spare working unit in the District	6	6
Two+ spare units but <30% extra	14	10
Spare units for 30%-49% of HCs	12	6
Spare units for 50%+ of HCs	8	4
Total	64	64

Source: Munck and Din (1997), Annexes 3, 4 and 5

The 1997 inventory identified 26 known models of equipment (965 units) which accounted for 78% of all equipment. Another 99 units (8%) were other models, and for the remaining 180 units (14%) the model was not known. An accurate inventory makes it possible to plan procurement of spare parts for the models in use, and thus realize the full potential of the initial investment by regular maintenance and prompt repairs. It is virtually impossible to manage spares and repairs for models bought at random.

Substantial investments were made in training cold chain technicians at District level. Several of these staff have now moved into management positions on the DHMT, and

others have left the health service. The present availability of trained technicians at District and sub-Regional level is not known.

The 1997 review found that some Districts have bought domestic refrigerators when they were unable to repair their cold chain equipment. Domestic refrigerators are not suitable for storing vaccine, as demonstrated by WHO's cold chain studies in European countries. The life cycle cost analysis<sup>5</sup> shows that a domestic fridge is several times more costly than equipment designed for vaccine storage. [Data from South Africa] These estimates take account of the value of vaccine destroyed by cold chain failures, which include the refrigerator running too warm (above +8°C), or too cold and thus freezing DPT and TT (and hepatitis B vaccine).

In the past, donors have equipped Zambia's cold chain using models designed for the purpose, the technology provides a safety net against interruptions in power supply, and a safety margin covering weak links in cold chain management (for example only 27% of health centre staff interviewed during the review knew how to identify damaged DPT, refer to Chapter 5). The move to District procurement requires clear guidelines that specify the models on a "shopping list" which meets not only WHO's criteria for inclusion in the Product Information Sheets, but also criteria specific to Zambia. The 1998 District Planning Guidelines took a similar approach in specifying the types of vehicles that would be available through the revolving fund.

## Proposals

Districts must use cold chain equipment which is designed for storing vaccine. They may choose which models to buy from a "shopping list" prepared by CBOH and meeting criteria specified by the MOH.

International procurement will be needed to make equipment available to Districts from central stores, bought in advance on a revolving fund basis. Districts should not embark on international procurement themselves.

Donor procurement should be from the same "shopping list" to minimize the variety of models in the cold chain, thus enabling the National Cold Chain Workshop to carry the appropriate range of spares.

A policy for disposing of donated equipment should be drawn up so that defunct items can be formally removed from the inventory. Technical criteria for disposal and legal aspects (e.g. regulations from the Board of Survey<sup>2</sup>) should be specified in the policy.

## Implications of the proposals

The criteria for including equipment on the "shopping list" must be specified, these criteria might include the following:

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<sup>5</sup> Cost per litre of vaccine stored per year during the useful life of the equipment  
*First draft, 12/3/1998*

- 1 Stores vaccine safely as per WHO laboratory tests, this will mean the equipment qualifies for inclusion in WHO's *Product Information Sheets*, and is CFC-free
- 2 Has a good user guide
- 3 Ease of maintenance
- 4 Availability of spares
- 5 Suitable power source for Zambian conditions
- 6 Good performance record when used by health workers
- 7 Cost-effective as measured by "whole life cost per litre stored per year," this encapsulates the useful life of the equipment (including costs of spares and maintenance) and the ability to store vaccine safely (minimum cost of vaccine damaged in storage and hence discarded)

Some illustrative whole life cost calculations are available from South Africa's EPI

Requiring Districts to use equipment with a higher initial price implies continuing investment in cold chain technicians expertise to keep the equipment running properly for the whole of its anticipated useful life

- Will Districts be required to employ qualified cold chain technicians who are trained in repairing CFC-free models?
- How will the provision and funding of training be organized?

### **Implications of continuing the status quo**

The cold chain will continue to diversify, including unsuitable models which expose vaccines to the risk of losing potency without this necessarily being recognised by staff

The cold chain inventory will continue to age with expired equipment clogging precious storage space and confusing the interpretation of the inventory data

Districts whose cold chain technicians have moved into other jobs may use local repair shops which are not familiar with the technical requirements of the vaccine fridges, or of the CFC-free equipment gassed with R134a. If the DHMT is aware of these highly technical issues, they will be dependent on neighbouring Districts, the Region or the National Workshop for repairs

Refer to 5 Use of opened vials of non-reconstituted vaccine at subsequent sessions and Cold Chain Quality in Zambia



## 11 Adding new antigens

### Background

When new antigens become available, WHO updates its recommendations on the immunization schedule. Hepatitis B vaccine was added to the recommendations for universal childhood immunization for countries where the hepatitis B carrier prevalence (HBsAg) is 8% or greater (by 1995) and for all countries by 1997 (WHO, 1996).

The following data are based on analysis conducted in 1992 and 1993, reported by the Virology Laboratory at UTH (1994)

- A survey of 586 urban Lusaka children aged 0-15 found 1.7% were HBsAg+
- A survey of 2,280 pregnant women attending antenatal clinics in six areas found that HBsAg+ rates varied between 4.1% and 14.9%
- Data from blood donors at UTH shows 9.9% of male donors and 5.0% of female donors were HBsAg+ in 1992-1993
- Children admitted to UTH and their mothers were tested for HBsAg during the same period, 6.2% of children and 4.7% of their mothers were HBsAg+. These are sick children who are likely to have parenteral procedures (e.g. diagnostic tests) so infection control and sterility of instruments (especially sharps) is crucial.

These data refer to the situation five years ago, at that time Zambia was already a country of medium to high endemicity and would benefit from the protection afforded by hepatitis B vaccine.

However, the vaccine would have to be funded from a sustainable source (refer to Chapter 14). Although the price has fallen dramatically over the last few years, it is still three to four times more costly than measles vaccine. The opened vial policy can be applied to Hepatitis B vaccine so wastage would be minimal, but even so, the addition of this antigen to the universal childhood immunization schedule would increase the total funding required for vaccines by about 50% (Feilden, 1995).

Some countries have adopted a policy of immunizing the highest risk groups (e.g. medical workers exposed to occupational risk) against hepatitis B.

### Proposal

A process should be established for considering whether to include new antigens

- (a) for groups whose occupation exposes them to a high risk of infection,
- (b) in the universal childhood immunization schedule.

### Implications of the proposal

Consideration of new antigens should be based on the epidemiological profile and trends of the disease in question, technical recommendations from WHO, resource requirements, and sustainable and cost-effective strategies.

Sustainability should be assessed in conjunction with other priority diseases which can be prevented

**Implications of continuing the status quo**

There is no process for addressing the issue of new antigens

- Refer to
- 4 Safety of injections
  - 5 Use of opened vials of non-reconstituted vaccine at subsequent sessions
  - 14 Vaccine Independence Initiative and other funding

## 12 Global/regional targets

### Background

GRZ joined the global effort to eradicate polio. The holistic epidemiological concept of this effort (NIDs plus AFP surveillance) was not implemented for the first two years of NIDs, so one of the expected benefits to routine health services - a strengthened surveillance system - is only now being addressed (refer to Chapter 8). Lateness of promised funds also meant that districts had to divert resources from scheduled activities in order to carry out NIDs. Shortfall of expected external funding is one explanation of why GRZ's line item for immunization has not been allocated to funding vaccine - it was used for transport and allowances for the NIDs (refer to Chapter 14).

Donor interest in conducting urban measles campaigns (using Autodestruct syringes) has already been raised, before a thorough assessment of the most appropriate and feasible strategy has been completed (refer to Chapter 2).

During the 1997 review, the basic indicators for national immunization targets (WHO Module 2) were not filled in, and the space for other targets was left blank.

If and when new global initiatives emerge, GRZ should be ready to assess the full implications of signing up, in terms of financial commitments, resource requirements (especially health workers' time and transport) and diversion of energy into objectives which may not coincide with more urgent national priorities.

### Proposal

National goals for immunization need to be updated regularly, and be framed explicitly within the context of integrated child health services and health sector reform.

### Implications of the proposal

GRZ/MOH/CBOH will be ready to respond to regional (Southern Africa and Africa) and global initiatives which request or require participation from member states.

Implementing the goals of GRZ's long term plans can be harmonized with wider goals.

### Implications of continuing the status quo

Energy and resources will continue to be diverted in a manner which lacks a holistic approach to implementation, possibly introducing unsustainable and/or inconsistent strategies and technologies.

- Refer to
- 1 Adding a fourth dose of OPV under 1
  - 2 Clarification of policy on immunization against measles
  - 4 Safety of injections

### 13 Logistics from centre to district

#### Background

The 1997 review team expressed a mixture of optimism and caution regarding the best arrangement for logistics in the reformed structures. A draft report prepared for CBOH, Directorate of Health Services Commissioning (October 1997) is not explicit about how the cold chain logistics for immunization would be integrated. At present the former logistics arrangements (centre to provincial store, province to district store) are in a state of uncertainty. Where provincial transport is no longer functioning, distant districts are clubbing together to cover transport costs.

A meeting on integrating UCI logistics was held in January 1998. A number of recommendations were made and next steps were identified.

Recommendation	Next steps
The whole procedure for procuring vaccines remains with UNICEF until EDMSS develops capacity vis a vis infrastructure and manpower	CBOH/MOH to give a mandate to EDMSS to develop a plan for integrating immunization logistics into EDMSS structures EDMSS to develop a draft plan before a consultative meeting in April 1998 at which human resources needed for immunization logistics would be considered Donor partners to assist with capacity building for logistics if EDMSS so requested
Keep UCI personnel and central level storage of vaccine stocks at Old Medical Stores, until EDMSS is ready	CBOH to request MOH to retain the relevant staff and facilities beyond the April deadline for delinkage, to cover the period of transition
Maintain investments in provincial cold chain infrastructure for some regions	CBOH to identify sites housing immunization cold chain infrastructure at provincial level, and maintain staff during the period of transition EDMSS to consider this provincial infrastructure in its plan
Distribution will continue to be done by the districts in the interim period	CBOH to inform districts of the interim arrangements
Develop a transition plan for transport from central level to provinces	UCI Secretariat to assess the available transport and draft a plan for distribution
Districts are to maintain their current storage systems	CBOH to inform districts of the recommendation

Source: Minutes of meeting at Ibis, 29-30 January 1998

The future management of EDMSS is currently uncertain. If EDMSS management is contracted to the private sector the handling and distribution fees for immunization supplies need to be carefully considered. Vaccines are funded entirely by donors (who also provide much of the other supplies such as injection equipment and spare parts),

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and the introduction of a commercial element may not be consistent with their mandate. Until the details of EDMSS management and procurement mechanisms are decided, it is not possible to evaluate whether the proposed arrangements will be appropriate for immunization supplies: vaccines, injection supplies, and spare parts for injection equipment.

### **Proposal**

Donor partners should provide GRZ/MOH/CBOH with technical assistance (even if not requested by EDMSS) to ensure that any logistics system proposed for handling immunization supplies and equipment will be suitable for meeting the objectives of immunization services.

### **Implications of the proposal**

The proposed logistics system will receive detailed scrutiny, making it possible to avoid potential problems which would interrupt the continuous supply of essential products.

The proposed system will be transparent to donor partners, thus reducing uncertainty over future funding and support.

### **Implications of continuing the status quo**

The present uncertainty will continue.

Refer to 10 Cold chain equipment suitable for vaccines

## 14 Vaccine Independence Initiative and other funding

### Background

Until now, donors have funded all of Zambia's vaccines, which cost somewhere between \$850 000 and \$1 293 000 per year (depending on wastage). JICA has been funding BCG and measles vaccine for several years but does not plan to continue funding recurrent budget indefinitely. In 1996 JICA's vaccine budget was cut by 30% and in 1997 they presented the MoH with a plan for a phased reduction of 20% per year, by 2001 there will be no more JICA funds for vaccines.

Zambia's total dependence on donors for vaccine funding exposes child health services to the risk that if donor priorities shift their focus, the government has made no provision to support this cost-effective public health priority.

The Vaccine Independence Initiative (VII) has been discussed for several years. In January 1998 a meeting at Ibis Gardens recommended that a long term plan for implementing the VII should be developed, the next steps included development of the plan by a working group consisting of the CBoH (Directorate of Systems Development), MoH (Planning Unit and Child Health Unit), Essential Drugs and Medical Supplies Store, South-East Region, UNICEF, WHO and BASICS.

The MoH has a budget line for immunization. In 1997, K 93 million of this budget line was allocated to NIDs to pay for vehicle repairs. The review team discussed with MoH whether GRZ would start to pay for some vaccines. In principle the central level planners are positive about GRZ participation in vaccine funding, because the ownership conveyed through this financial involvement would promote holistic planning, and greater sensitivity to the resource implications of policy decisions.

### Proposal

A definite amount of money from the budget line should be earmarked for vaccines, and protected. The amount should increase year by year in co-ordination with donor commitment of funds.

### Implications of the proposal

GRZ will have a larger stake in ensuring that precious resources are used efficiently and effectively.

Commitment of funds must be made a priority in order to maintain the necessary stocks in the pipeline without interruption of supply.

### Implications of continuing the status quo

The government commitment to child health services will lose credibility, making it increasingly difficult to raise funding from donors, who are aware that other countries with lower GNP per capita have started paying for some of their vaccines.

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