

**ZAMBIA REACHING CONSENSUS ON
UPDATING IMMUNIZATION POLICY
WITHIN THE CONTEXT OF
HEALTH SECTOR REFORM,
AND FOLLOW-UP ACTIVITIES**

17 April to 14 May 1998
and beyond

Rachel Feilden

BASICS Technical Directive 000-ZA-51-025
USAID Contract Number HRN-C-00-93-00031-00

TABLE OF CONTENTS

ACRONYMS

I	PURPOSE OF VISIT	1
II	BACKGROUND	1
III	ACTIVITIES	1
IV	RESULTS, CONCLUSIONS AND RECOMMENDATIONS	5
V	FOLLOW-UP ACTION REQUIRED	7
	REFERENCES	9

APPENDIXES

APPENDIX A	SCOPE OF WORK
APPENDIX B	SCHEDULE OF ACTIVITIES
APPENDIX C	PEOPLE MET
APPENDIX D	CONSENSUS MEETING TO UPDATE IMMUNIZATION POLICY PROGRAMME, PRESENTATIONS AND DISCUSSIONS
APPENDIX E	UPDATING IMMUNIZATION POLICY WITHIN THE CONTEXT OF HEALTH SECTOR REFORM
APPENDIX F	MEMO GANTT CHART AND MATRIX FOR IMMUNIZATION ACTIVITIES
APPENDIX G	CHILD HEALTH CARD
APPENDIX H	TECHNICAL ASSISTANCE FOR DEVELOPING STRATEGIES TO CONTROL MEASLES AND PREVENT OUTBREAKS IN ZAMBIA DRAFT SCOPE OF WORK (13 MAY 1998)
APPENDIX I	QUANTIFICATION OF VACCINES
APPENDIX J	CORRECT INTERPRETATION OF VVMS
APPENDIX K	OPENED VIAL POLICY ADDITIONAL QUESTIONS AND ANSWERS
APPENDIX L	FURTHER ANALYSIS OF DHS DATA
APPENDIX M	WHO RECOMMENDATIONS FOR BCG AND FOR HIV-INFECTED INDIVIDUALS
APPENDIX N	FLOW CHARTS OF LOGISTICS FOR AFP SURVEILLANCE

ACRONYMS

AEFAPP	Adverse Event Following Any Parenteral Procedure
AFP	Acute Flaccid Paralysis
BASICS	Basic Support for Institutionalizing Child Survival
BCG	Bacille Calmette Guerin
CBoH	Central Board of Health
CSO	Central Statistical Office
DHS	Demographic and Health Survey
DPT	Diphtheria, Pertussis, Tetanus
DT	Diphtheria, Tetanus
EDMSS	Essential Drug and Medical Supplies Store
EPI	Expanded Programme on Immunization
FAMS	Financial and Administrative Management System
GRZ	Government of the Republic of Zambia
HC	Health Centre
HIV	Human Immunodeficiency Virus
HMIS	Health Management Information System
IMCI	Integrated Management of Childhood Illness
MSL	Medical Stores Limited
MoH	Ministry of Health
NFNC	National Food and Nutrition Commission
NHC	Neighbourhood Health Committee
NIDs	National Immunization Days
OPV	Oral Polio Vaccine
PHN	Public Health Nurse
SIDA	Swedish International Development Authority
TST	Time, Steam, Temperature
TT	Tetanus Toxoid
UCI	Universal Child Immunization
UNICEF	United Nations Children's Fund
USAID	United States International Development Agency
UTH	University Teaching Hospital Lusaka
VVM	Vaccine Vial Monitor
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 reach consensus on updating Zambia's 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, and the consultancy in February and March 1998, which produced the briefing document, *Proposals for Updating Immunization Policy within the Context of Health Sector Reform* (12 March 1998). The scope of work for the present consultancy is attached in Appendix A.

II BACKGROUND

The review of immunization conducted in September and October 1997 by a multi-disciplinary team of national and international members was Zambia's first formal review in 13 years. The EPI manual was last revised in 1992. 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 inclusion in 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.

During the consultancy in February and March, a team of one international and two local consultants prepared proposals for updating policy. During March and April, the briefing document containing these proposals was circulated to more than 150 recipients, including all 73 district health management teams (DHMTs). This completed the first phase of the original scope of work (see Trip Report, *Zambia Updating Immunization Policy Within the Context of Health Sector Reform*, 16 February to 14 March 1998). After an interval during which readers could consider and comment on the proposals, key players were invited to attend a consensus meeting at which the policy proposals would be finalized, ready for forwarding to the MOH for endorsement. The present consultancy was to assist with this second phase of updating immunization policies in Zambia.

III ACTIVITIES

The international consultant, Rachel Feilden (BASICS), arrived in Zambia on 18 April, where she joined two local consultants, Leo Chivundu (WHO consultant, EPI Desk Officer on leave

from UCI Secretariat) and Brenda Katukula (UNICEF consultant, NIDs co-ordinator in 1996 and 1997) to prepare for the consensus meeting on updating immunization policy. New Minister of Health Prof. Nkando Louo had placed a general moratorium on workshops until their benefit could be evaluated, however, this meeting had the specific objective of reaching consensus on the proposals circulated in the briefing document and was allowed to proceed. It was scheduled over two mornings (21-22 April 1998), was chaired by the acting director-general of CBoH and his deputy, and involved about 30 participants. Appendix D contains the agenda, presentations, and discussions during the consensus meeting.

There were several issues that required further work after the consensus meeting.

a) Policy on free universal immunization

This policy is implicitly stated as part of the health reforms (services to under-5s are to be provided free of charge). A statement confirming that immunizations are free of charge was drafted and included in the updated policy proposals to be presented to the Ministry of Health for endorsement (see Appendix E, page 2). The consensus meeting participants had raised the possibility of compulsory immunization enforced by laws or regulations, but rejected compulsion in favour of persuasion.

b) BCG policy

The briefing document did not contain any proposals for updating the BCG schedule, and the consensus meeting raised a question about the utility of repeating BCG immunizations for school children with no scar. The team undertook to obtain clarification of policy from WHO/Headquarters in Geneva (see Section IV).

c) Immunization of people with known or suspected asymptomatic HIV infection

One of the paediatricians who read the briefing document, but could not attend the consensus meeting commented that there was 'no chapter on AIDS'. Clarification of latest policy recommendations was provided by WHO/Headquarters in Geneva (see Section IV).

d) Child health card

If the MOH endorses the proposed updates to the immunization schedule, then the child health card's immunization section will have to be revised. The team prepared a sample layout to the precise scale required in order to fit it on the existing size of A4 card, and circulated a memo describing these revisions and other points that should be taken into consideration during final revisions to the card (see Appendix G).

e) TT card

The language and details of the TT card still need to be reviewed (see Section V).

f) Technical assistance for developing measles control strategies

At a follow-up meeting held on 24 April at the BASICS office in Lusaka, the CBoH and three donor partners all expressed interest in the provision of technical assistance for developing

Zambia's measles control strategies CBoH asked the team working on immunization policy to draft a terms of reference BASICS/Zambia had already requested BASICS/Washington for input on this topic, which Mark Weeks had sent on 20 April With input from the WHO epidemiologist Gerard de Vries, Weeks' memorandum and his article for Bull WHO, and BASICS/Washington, the team drafted a scope of work which was sent to BASICS/Zambia and thence to CBoH (see Appendix H)

g) Quantification of vaccines

The multidisciplinary group working on quantification of drugs and medical supplies asked the team for advice about vaccine quantification, and we met one of the international consultants for a brief discussion The findings from the 1997 review of immunization, repeated in Table 6.1 of the briefing document (see Trip Report, 16 February to 14 March 1998), reflect the health centres' and districts' *ad hoc* approach to stock management, and demonstrate that the operational systems did not prevent stock-outs of one or more vaccines, partly because health centre staff did not keep stock records

After the consultant left Zambia, UNICEF's child health officer sent some specific questions about how to estimate vaccine requirements from the bottom up In response, draft guidelines for bottom-up quantification were prepared (see Appendix I), based on the findings of the 1997 review and assume that the approaches adopted by HMIS and FAMS will be implemented

For example CBoH's manual on stores procedures (January 1998) requires stock records to be kept, and a one month's safety stock to be maintained

The discipline and good management principles promoted by CBoH's FAMS guidelines, combined with the interpretation and use of data implicit in the HMIS, together provide the foundations for bottom-up quantification of vaccines, and robust estimates of vaccine requirements

h) Distribution of immunization supplies

The team met the managing director of Medical Stores Limited (also referred to as EDMSS—Essential Drug and Medical Supplies Store—a new entity which is expected to replace MSL) to discuss the plans for distributing vaccines and other immunization supplies MSL was preparing the draft plan that CBoH had mandated in January 1998 during the meeting at Ibis Gardens The managing director explained that MSL trucks deliver drugs and medical supplies once per month to every district on a continuous route This involves lower mileage than the present *ad hoc* system, whereby some districts and some provincial (sub-regional) staff come in to Lusaka to collect vaccines The managing director referred the team to a background paper by Arne Thorfinn prepared in June 1995 (This paper was obtained from SIDA, its discussion of transport requiring continuous cold chain is limited to five lines of text) The team undertook to prepare a memorandum suggesting which immunization supplies in addition to vaccines could be distributed on a monthly basis (see Section IV)

i) Correct interpretation of VVMs

Preparation for the 1998 NIDs was in progress during this consultancy, and the 1997 evaluation of the 1997 NIDs had just been printed. We noticed that the NID tally sheet provides space for staff to record "*Number of OPV Vials discarded because VVM turned black*."

During the review of immunization services in September and October 1997, the review team had seen no evidence of any posters or visual information on how to interpret VVMs, even though NIDs had been conducted for the past two years¹. A memo describing the correct discard point was written to the reproductive and child health specialist (see Appendix J), attaching one copy of the colour poster created by the South African EPI. This poster provides a superb example of clear visual information on the correct interpretation of VVMs.

The international consultant left Zambia on 28 April, and followed up the outstanding issues with the local consultants by fax and e-mail.

j) Opened vial policy

The local consultants were updating the manual and guidelines and asked for clarification on the number of days that the vial should remain open and whether an opened vial can be taken out of the health centre on outreach the day after it is opened at a static session. These questions are not directly addressed in WHO's "Questions and Answers" (DIP 96 07). The response faxed to Lusaka on 7 May is shown in Appendix K.

k) Further analysis from demographic and health survey

During the preparation of the briefing document, the team found that the DHS's way of analysing doses of TT received by pregnant women does not provide an estimate of coverage with TT2+, because the analysis does not take into account any TT doses received before the enumerated pregnancy. The team also wanted information on the age at first immunization contact for babies born at home, in order to tailor guidelines for the introduction of OPV0 to the best available information. Specifically, we wanted to know what percentage of home-delivered babies were brought for their first immunization within 14 days of birth, for urban areas and for rural areas. The USAID technical advisor suggested that the team present these requests to DHS, and the questions in Appendix L were sent to Macro International. Further communication with BASICS/Washington and WHO/Geneva confirmed that there is concern about how to measure TT2+ coverage and that DHS is aware of the problem in their methodology.

¹ This misunderstanding of the VVM's discard point is consistent with problems identified during the EPI Technet Meeting in Copenhagen (March 1998), one presentation demonstrated that when the stages of VVM shade change are photocopied the photocopied version shows no difference between Stage 3 (the inner square the same colour as the outer circle), and Stage 4 (the inner square darker than the outer circle, or black).

l) Flow charts of logistics for AFP surveillance

The WHO epidemiologist planned to present information on the requirements for AFP surveillance to the paediatricians' professional meeting. The consultant described the charts of AFP logistics that had been presented at the EPI Technet Meeting (Copenhagen, March 16-20, 1998). The draft document on AFP logistics was obtained from WHO Geneva and forwarded to WHO in Lusaka. Appendix N shows the two charts.

Appendix B shows the schedule of activities, and Appendix C shows people met, including those who attended the consensus meeting.

IV RESULTS, CONCLUSIONS AND RECOMMENDATIONS

The proposals for updating policy were finalized during the consensus meeting and summarized in a document (Appendix E) for CBoH to present to the MOH, which is responsible for policy. This document was faxed to Lusaka on 7 May.

It is recommended that the MOH endorse the proposed updates of immunization policy as soon as possible.

The discussions during the consensus meeting and afterwards underlined the interrelated nature of many of the issues. A Gantt chart was drafted showing the expected timing of key related activities, with a matrix showing the connections with other elements of health services. The team drafted the Gantt chart and matrix together, and fair copies were faxed to Lusaka on 5 May (see Appendix F). The chart and matrix form the embryo of a plan for implementing the updated immunization policies and for proceeding on issues that still require further analytical work (such as measles control strategies).

A plan of action for implementing the updated immunization policies—especially informing central, regional, and district staff of the implications—should be developed and implemented.

Quantification of vaccines

The multidisciplinary team developing CBoH's quantification guideline used Appendix I during preparation of the CBoH guideline. District staff were involved in developing the CBoH guideline, which was ready for a wider pretest by late May.

Participation in the multidisciplinary group working on quantification should continue, beginning with feedback on the latest draft of the guidelines. The subject matter should be extended to cover other supplies (e.g., TST spots and incinerator boxes).

Distribution of immunization supplies

The immunization supplies (in addition to vaccines) that could be distributed on a monthly basis were identified in the updated policy proposals (see Appendix E, Section 10). They include three sizes of sterilizable needle, three sizes of sterilizable syringe, TST spots for demonstrating effective steam sterilization, incinerator boxes (holding 100 x 0.5ml needles and syringes), and steam sterilizers and their spares. Sterilizers, repairs, and spares have been handled by the National Cold Chain Workshop, but the complementary injection equipment (needles and syringes) is distributed by the UCI logistics group, functioning independently of the workshop.

In terms of frequency of resupply, injection supplies and equipment cover a spectrum from once per 20-50 uses for needles, once per 50-200 uses for syringes, one TST spot per sterilization cycle, and less frequent replacement for sterilizers' spare parts (such as seals and pressure valves). The objective is to arrange the logistics for regular and intermittent supply and periodic replacement so that the chosen systems support the operational requirement to provide safe injections. The monthly delivery proposed in the integrated logistics plan may serve this purpose better than the present mixed system of provincial (sub-regional) collection once per quarter and forwarding to districts, plus districts collecting directly from Lusaka.

The section of the integrated logistics plan (October 1997) that covers supplies used for immunization includes estimates of vaccine volumes, but is incomplete in terms of operational detail.

CBoH and donor partners should scrutinize the distribution plan being prepared by MSL to ensure that the proposed arrangements will be suitable for meeting the objectives of immunization services (see Appendix E, Section 9).

WHO's policy recommendations on BCG and for HIV-infected eligibles

Updated information from the EPI Unit in WHO Geneva was obtained in early June (see Appendix M) and the recommendations are summarized below.

- Countries with a high incidence of tuberculosis (TB) infection (as in Zambia) should immunize against TB.
- BCG should be given as soon after birth as possible. Immunization of preterm infants should begin at the same chronological age recommended for term infants (i.e., as soon after birth as possible).
- There is no evidence that the degree of protection from BCG is related to scar formation. WHO does not encourage multiple doses of BCG.
- It is recommended that individuals with known or suspected **asymptomatic** HIV infection receive all EPI vaccines, including BCG, as early in life as possible, according to the national immunization schedule.

- Children with **symptomatic** HIV infection (i.e., AIDS) should **not** be given BCG, but should receive all other vaccines

(WHO's entire BCG policy is currently being revised, and updated recommendations should be ready before the end of the year. Further clarification is still being sought about operational experience with a two-dose measles schedule for children with known or suspected asymptomatic, or symptomatic HIV infection, this refinement will require follow up.)

News about the future of UCI

In late May, the acting director-general of CBoH gave the news that UCI is being retained as a programme for the next two years, during the period of transition. The 1997 review did not make a detailed assessment of UCI management because at that time (September/October 1997), delinkage was scheduled for 1 January 1998, and the functions of the UCI secretariat were due to be absorbed into CBoH. At present, delinkage has been postponed indefinitely. If the present structure and modus operandi continue unchanged, it is likely that the severe problems with management at the national level will continue. These problems include a titular national manager in the MOH who is physically separated from the staff involved in the day-to-day details, counterproductive compartmentalization of interrelated functions, lack of continuity in institutional memory and documentation, and inadequate management of the national vaccine store, upon which several observers have reported over the last few years.

It is therefore recommended that the present management structure for immunization at national level be reviewed and reformulated

- to clarify lines of responsibility and authority
- to develop administrative structures, management operations, procedures, and problem solving approaches so that the staff at central level are able to work effectively on preparing the regions and districts to address the vast list of quality improvement tasks outlined in the review and implied by the updates in immunization policy

This suggestion was mentioned informally to Dr. Silwamba while he was in Washington, but has not been discussed in Zambia.

V FOLLOW-UP ACTION REQUIRED

The persons or organizations responsible for each action are suggested in parentheses.

- 1 Follow up on the timetable for MoH endorsement of the policy proposals (BASICS/Z)

- 2 Forward WHO recommendations for BCG policy and immunizations for eligibles with known or suspected HIV/AIDS to Zambia (Feilden), and update the policy proposals, guidelines, and manuals accordingly (team)
- 3 Follow up on progress with a consultancy to assist GRZ/MoH/CBoH with developing a measles control strategy for Zambia (BASICS/Z and BASICS/W)
- 4 Revise the proposed layout of the immunization section of the child health card (see Appendixes G and M) to remove the reference to repeating the BCG dose if there is no scar (to be decided)
- 5 Follow up on the development of the child health card (BASICS/Z)
- 6 Prepare a revised version of the TT card, including the relevant parts of the chart (see Appendix D, page 4-18) as suggested by consensus meeting participants (team) [No DPT will be given to children 6+ years]
- 7 Review updated guidelines and manuals, including the guideline for quantification of vaccines and other supplies (to be decided)
- 8 Review the MSL/EDMSS plan for distribution of immunization supplies to districts (BASICS/Z possibly with some TA) A scope of work for a full logistics assessment for continuous cold chain may be required (Feilden could draft it)
- 9 Agree on items to be supplied by MSL/EDMSS, and items through the National Cold Chain Workshop (CBoH and donor partners)
- 10 Prepare a detailed work plan for implementing the updates in immunization policy and operating procedures (CBoH/UCI)
- 11 Follow up with DHS and WHO on problems of measuring coverage with TT (BASICS/W and Feilden)
- 12 Follow up with WHO regarding the problem of photocopying the VVM shade changes (Feilden)

REFERENCES

- Central Board of Health (1997) Integrated supply management system Framework and plan of action On the road to integrating the supply system of the essential healthcare package Draft prepared for Directorate of Health Services Commissioning by Elvira Beracochea and Morgens Munck (October 1997)
- Central Board of Health, Zambia (1998) Manual on Stores Procedures for Districts January 1998
- Ministry of Health and Central Statistical Office (1996) Zambia Demographic and Health Survey 1996 DHS, Macro International Inc , Calverton, Maryland, USA
- Minutes of the meeting on EPI logistics held at Ibis, 29th-30th January 1998
Compiled by M Siame and E Moonze 6 February 1998
- Thorfinn, Arne (1995) Medical Stores Limited logistic collaboration with Ministry of Health Zambia A background paper June 1995 10pp (Obtained from SIDA, Swedish Embassy, Lusaka)
- Weeks R M, Barenzi J F Z, Wayira J R M (1992) A low-cost, community-based measles outbreak investigation with follow-up action Bulletin of WHO Vol 70, 1992, pp317-321
- World Health Organization (1996) Questions and Answers on Introduction of Vaccine Vial Monitors (VVMs) and New WHO/EPI Policy on the Use of Opened Vials of Vaccine Draft 2 7 Feb 1996 (DIP 96 07)
-

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 April 13- May 2, 1998
E) Fee days	17 days
F) Scope of Work	

Request approval for BASICS Consultant, Rachel Feilden, to travel to Lusaka, Zambia o/a 15-28 April 1998 to assist the CBoH prepare for and conduct an immunization policy meeting on 21-22 April 1998. This policy meeting follows earlier TA from the consultant in September 1997 and February 1998 in which reviews were conducted of the EPI program and the immunization policies of the GRZ/MOH/CBoH.

During this trip, the consultant will play a role in

- collecting and collating feedback on the briefing document,
- developing the final agenda for the immunization policy meeting to be held 21-22 April,
- assembling and preparing materials for the meeting,
- implementation of the meeting,
- and, following the meeting, finalize the briefing document for presentation to MoH/CBoH, identify materials needing adaptation, guidelines needing preparation, and other actions related to implementing the recommendations arising from the meeting

APPENDIX B

SCHEDULE OF ACTIVITIES

Schedule of Activities, 17 February to 12 March 1998

- 18 April Arrival in Lusaka Met Ms Leo Chivundu and Ms Brenda Katukula
Read comments received from Districts and other correspondents
- 19 April Sunday, prepared overheads for the consensus meeting
- 20 April Preparations for the consensus meeting, overheads made at UNICEF
Briefing with Dr Gavin Silwamba, finalized agenda for the meeting
- 21 April Preliminary meeting with Dr Silwamba
Consensus meeting at Pamodzi Hotel 09 00 to 13 00
Prepared the chart showing build-up of measles susceptibles
- 22 April Consensus meeting at Pamodzi Hotel 09 00 to 13 30
- 23 April Follow up on the consensus meeting and preparing memo of next steps
Meeting at Medical Stores Limited to discuss their distribution plan
- 24 April Meeting at BASICS office, also attended by CBoH, UNICEF and WHO staff to
clarify and agree next steps
Asked SIDA to find and copy Thorfinn's analysis of distribution routes
- 25 April Prepared document summarizing policy updates to present to MoH
Drafted scope of work for technical assistance with measles control strategy
suitable for Zambia and e-mailed it to BASICS Washington
Prepared revisions to Child Health Card
- 26 April Sunday
Met Gerard de Vries to discuss measles strategy, met HMIS Team to follow up
implications of the proposed policy updates, Paul Hartenberger gave news of the
preliminaries to the Donor Meeting on 27-28 April
- 27 April Ms Katukula met Chief Inspector of Schools to discuss interaction with Ministry
of Education regarding immunizations for school-age children
Distributed memo to the Child Health Card Committee with proposed revisions
and updates
Met Gerard de Vries to discuss terms of reference for measles control consultancy
- 28 April Distributed memo on correct interpretation of VVMs
Briefing with Dr Remi Sogunro
Meeting with Martin Auton on quantification of vaccines
Departure from Lusaka
- 29th April to
11th June Follow-up on vaccine quantification, scope of work for TA on measles
control, BCG schedule, revision of TT card, Gantt chart of activities, and
matrix showing interactions with other elements of health service delivery,
training, and the planning cycle

APPENDIX C

PEOPLE MET

People Met

Central Board of Health (CBoH)

Directorate of Systems Development

Dr Gavin Silwamba

Ms Jenny Meya Nyirenda

Dr Imi Huijts

Directorate of Monitoring and Evaluation

Mr Bornwell Sikateyo

Ms Anne Young

Dr Gerard de Vries

Directorate of Health Services Commissioning

Ms Peggy Fulilwa

Mr Martin Auton

UCI Secretariat and National Cold Chain Workshop, Old Medical Stores

Mr Akhtar Din

Mr Francis Mutumbisha

Ms Magdalene Siame

Medical Stores Limited

Mr Oliver Hazemba

BASICS

Dr Remi Sogunro

Ms Mary Kaoma

Ms Emily Moonze

Dr Abdikamal Alislad

HMIS project team

Ms Mimi Church

Dr Jap Koot

Dr Mariat Wiebenga

UNICEF

Ms Christiane Rudert

USAID

Mr Robert Clay

Dr Paul Zeitz

WHO

Ms Patricia Kamanga

(continued)

**Participants in the Consensus Meeting to Review Immunization Policy,
Pamodzi Hotel, 21-22 April 1998**

	NAME	DESIGNATION	ORGANIZATION
1	Jenny Meya Nyirenda	Reproductive and Child Health Specialist	CBOH
2	Leo B Chivundu	EPI Desk Officer	MOH
3	Christiane Rudert	Project Officer, Child Health	UNICEF
4	Mutinta Moonga	Clinical Advisor to the Director General	CBOH
5	Magdalene Siame	Child Health Unit	MOH
6	Emily Moonze	Training Coordinator	BASICS
7	Abdikamal Alisalad	Child Health Advisor	BASICS
8	Mary Kaoma	Training Advisor	BASICS
9	Patricia Kamanga	Nurse/Midwife	WHO
10	Akhtar Din	National Cold Chain Officer	MOH
11	Mariann Lyby	Capacity Building Advisor	CBOH/DSD
12	Oliver Hazemba	Managing Director	MSL
13	Francis C Mutumbisha	EPI Logistics	MOH
14	G B Silwamba	Director, Systems Development	CBOH
15	R Sichalwe	Sales Officer	MSL
16	Prof C Chintu	Professor of Paediatrics	Sch of Medicine
17	Dr R Chimba	Epidemiologist	MOH
18	Imi Huijts	Child Health Advisor	CBOH
19	Remi Sogunro	Chief of Party	BASICS
20	Rachel Feilden	Consultant	BASICS
21	B M Katukula	Consultant	UNICEF

21 April only

22	J Nyoni	Human Resources Manager	CBOH
----	---------	-------------------------	------

22 April only

23	Dr E M Chomba	Managing Director	U T H Board
24	Prof G J Bhat	Associate Professor/Consultant, U T H	Sch of Medicine
25	Festus Lubinga	Programme Assistant	JICA

APPENDIX D

**CONSENSUS MEETING TO
UPDATE IMMUNIZATION POLICY PROGRAMME,
PRESENTATIONS AND DISCUSSIONS**

Consensus Meeting to Update Immunization Policy Programme, Presentations and Discussions

Programme

Introduction, by Dr Gavin Silwamba, Acting Director-General, CBoH

[Overheads are shown in boxes]

Chapter numbers refer to the briefing document, *Proposals for Updating Immunization Policy within the Context of Health Sector Reform* (12 March 1998), circulated to all invitees during March and April. The reader is referred to that document for a detailed discussion of each topic.

Appendix E contains the revised policy proposals.

**MEETING TO REACH CONSENSUS ON PROPOSALS FOR
UPDATING IMMUNIZATION POLICY
WITHIN THE CONTEXT OF HEALTH SECTOR REFORM**

Programme

Tuesday 21st April 1998

09 00	Welcome and Introduction Objective of this meeting Topics covered today	Dr Silwamba
09 15	Vaccine Independence Initiative and other funding (Chapter 14)	R Feilden
09 45	Logistics from centre to district (Chapter 13)	B Katukula
10 15	Cold chain equipment suitable for vaccines (Chapter 10)	LB Chivundu
10 45	Break	
11 00	Adding new antigens (Chapter 11)	R Feilden
11 30	Global and regional targets (Chapter 12)	JM Nyirenda
12 00	Additional policy issues	
12 15	Summary of consensus on the policy issues	Chair

Wednesday 22nd April 1998

09 00	Welcome and Introduction Objective of this meeting Topics covered today Difference between policies and strategies	Chair
09 15	Adding a fourth dose of OPV under 1 (Chapter 1)	B Katukula
09 45	Clarification of policy on immunization against measles (Ch 2)	LB Chivundu
10 15	Clarification of TT schedule (Chapter 3)	R Feilden
10 45	Break	
11 00	Safety of injections and safe disposal choice of equipment (Ch 4)	R Feilden
11 30	Use of opened vials of non-reconstituted vaccine at subsequent sessions (Chapter 5)	LB Chivundu
12 00	Session frequency (Chapter 6)	B Katukula
12 15	Additional policy issues	
12 30	Summary of consensus on the policy issues	Chair

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

Introduction

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 Zambia's EPI Manual was prepared in 1992. Since then, there have been a number of developments

- Some technological developments 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)

The first review of immunization for 13 years was carried out in September and October 1997. It made several recommendations to update policies, standards and guidelines within the context of health reform. Following the review, GRZ/MoH/CBoH asked a team of three people - Leo Chivundu, Brenda Katukula and Rachel Feilden - to assist in reviewing policy on immunization, within the context of health sector reform

- The first step was to prepare a briefing paper which contained draft proposals for updating policies
- The second step was to circulate that briefing paper to key players and all the districts, inviting readers to comment on the proposals
- The third step is this meeting, the objective of which is to reach consensus on the proposals for updating and clarifying policies

A total of 14 issues were identified. 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 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

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 meeting is concentrating on the policy issues requiring a decision or clarification by the Ministry of Health. Based on those decisions, the manuals and guidelines and strategies can then be updated

Updating immunization policy

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

- Issues requiring a policy decision
- Issues needing a guideline
- Topics to be updated in manuals and on forms

This meeting is to reach consensus on policy decisions

14 Proposal for funding vaccines

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

The discussion started with an update on the progress of the committee appointed in January to develop a long term plan for implementing the Vaccine Independence Initiative (VII). Points arising from the discussion

- There are other essential supplies (such as immunization injection equipment) which have been funded 100% by donors, and for which Zambia should start providing some funds
- This issue has been discussed since 1990 and should have been solved by now
- District Health Boards could allocate some of their budgets, 90% of their drugs are imported so vaccine is not particularly special
- A similar suggestion was made at the January meeting at Ibis, but the Districts rejected it because of their experience of a shortfall in received funds compared with allocated funds
- Vaccines are perceived to be a government responsibility and immunizations are for the public good. Children cannot advocate for themselves. There is a growing ability in the region to buy vaccines. For now, vaccines should continue to be donated to the districts and not pass through the credit card system of procurement that applies to drugs
- Immunization is one of the non-negotiable activities which will continue for ever, vaccine procurement should be a government responsibility. Once the Districts have included vaccine in their budgets, will the UCI Secretariat still continue?
- Vaccine falls under the category of public health and prevention and should be included in the drugs and medical supplies for which the Districts prepare their plans and budgets. Funding for vaccine should not depend on donors, the government should put that money aside
- The best solution would be to include vaccines in the basket. The control mechanism on District performance is to withhold money to failing Boards. CBoH has received no answer about this funding from the government, which appears to have no real commitment to contributing for vaccines, so the design of the basket should be reconsidered and reconfigured to include vaccines
- Within the basket, part of the money from GRZ could be allocated to a subheading specifically for vaccines
- For this year (1998) the available basket funding was allocated in the last quarter of 1997. Last year 80% was for drugs and 20% for laboratory supplies, vaccines were not included but there is a commitment to do so
- The commitment should be a figure or a percentage, clearly identified just as salaries are

The discussion ended with agreement that the commitment was to factor vaccines into the 1999 budget for essential drugs and medical supplies, and this timing was added to the proposal "Other immunization supplies" were also added, and defined in the revised proposals (see Appendix E)

13 Proposal for logistics from centre to district

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

The discussion of logistics was initially somewhat intertwined with cold chain issues. Here the comments referring to distribution are highlighted (Cold chain is discussed in the next session, on Chapter 10)

- A decision was taken in January to retain the Provincial stores as Sub-regional stores, with a skeleton staff, during an interval of transition to a new distribution system. This was based partly on a perceived need to keep emergency drugs closer to the Districts for rapid epidemic response, and was discussed at the last Directors' Meeting
- Following the discussions at the Ibis meeting in January, CBoH commissioned MSL/EDMSS to study the logistics system but the future management of EDMSS is an unknown. MSL expects to complete its study within days
- We lack information on exactly how the distribution system for routine supplies requiring cold chain is working now. The Provincial stores still have deep freezers and fridges, the storage capacity is there, and could be shifted to the Regions. At Old Medical Stores, UCI staff have observed that both Provincial staff and District staff come to collect vaccines on the same day
- It was suggested that storekeepers could refuse to supply Districts who come in on a single purpose mission to collect vaccines. However, during the period of transition and until the new system is working, we cannot refuse to supply Districts. They also do other tasks when they are in the capital
- The spirit of the reforms was that the Regions should not provide logistics or distribute supplies, their role should be technical
- A policy decision is needed on the best solution for cost-effective distribution. Then guidelines are needed for what the Districts should do

The discussion was concluded with agreement that

- a) the study being completed by MSL (due date 29th April 1998) should be scrutinized by all concerned. The framework for this scrutiny could follow the recommendations and next steps from the Ibis meeting, repeated in the briefing paper (page 49)
- b) The proposal (above) should be changed to a recommendation that GRZ/MoH/CBoH should ask donors for assistance to ensure that any logistics system proposed for handling immunization supplies and equipment will be suitable for meeting the objectives of immunization services
- c) the policy proposal for logistics awaits the outcome of the MSL study and the assessment of its suitability

The present policy on transport conditions for vaccines was confirmed (no change)



10 Proposals for policy on cold chain equipment for vaccines

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?) should be specified in the policy.

An example of a new approach to procuring suitable equipment with donated funds was described.

South Africa's decentralized system provides an example of managing donated funds for cold chain while respecting the provinces' autonomy.

- The national cold chain manager prepared a "shopping list" of equipment suitable for storing vaccine at different types of facility,
- The national cold chain manager asked the Provinces to complete an audit of their cold chain equipment.
- The national level and the provinces reached consensus on the amount of the donated funds that would be allocated to each province, which then prepared a business plan to explain and justify the equipment for which it was indenting, chosen from the shopping list up to the value of the province's allocation.
- When the national level was satisfied with the business plan, the equipment was provided.

- Chipata District had sent a comment that they would like to be able to procure the equipment they needed directly, reflecting frustration over delays and shortages. This comment led to a clarification in the wording of the second policy proposal.
- UCI should purchase a stock of replacement equipment and spares for a limited set of models. The useful life of equipment varies, the first kerosene models run for 20 years, the electric models do not last as long.
- If the policy denies Districts the possibility of buying, how long do we anticipate that they will be without the cold chain they need?
- The two MOH units, Medical Equipment and the Vehicle Centre, have joined hands and formed a new Board [Vehicle Service and Medical Equipment Management Board] last November, but the National Cold Chain Workshop is not part of this Board. In the long run, both logistics and cold chain will be integrated as part of the reforms.
- Regarding international shipment, the temperature exposure of vaccines is monitored using Cold Chain Monitor (CCM) cards and vaccines are shipped with icepacks. However, the cold room at the airport is not working and is so old it is not worth repairing. Cold chain must be maintained at the airport as part of policy.
- The arrangements for ensuring correct maintenance of cold chain equipment, building technical capacity in this area, and providing spares should be included as responsibilities of the new Board. The National Cold Chain Workshop manager's proposals for central stocks (based on past experience with this equipment) provide the basis for what items should be procured in advance for the Districts to obtain/purchase when needed.
- The criteria in the "shopping list" should state that the user guide must be in English.
- Regarding the cumbersome procedures for disposing of government owned or donated items, the Board can make its own procedures.

The policy proposal covering this last point was made into a recommendation, along with a recommendation to obtain information from the national inventory of cold chain equipment to develop accurate guidelines on the frequency with which this equipment will need replacement.

11 Proposal for policy on adding new antigens

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

- There used to be a policy of providing hepatitis B vaccine for medical staff but it was too pricey and was dropped
- Given the difficulties of tracking the original source of infection (e.g. from family or friends, or from a health worker) the best strategy is protection as early in childhood as possible (universal infant immunization)
- There should be a cost analysis of the relative merits of (a) versus (b)
- The programme got to the point of considering introduction of hepatitis B vaccine but under the terms of the Vaccine Independence Initiative it would never get funding (refer to discussion of Chapter 14 above)
- The issue is not only adding antigens but also removing antigens or doses. This led to a discussion of the effectiveness of BCG and the need to reconsider the schedule for BCG doses, which had not been covered in the briefing document (see Appendix F)

The participants suggested a policy proposal that the immunization schedule is to be reviewed every two years, and recommended that an Expert Committee on Antigens should be convened for this purpose

12 Proposal for national goals

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

- The need to have clear national goals was recognized, as it is important to know where Zambia stands, what is its policy position, with respect to global and regional (Eastern and Southern Africa) targets. NIDs are a case in point
- There should be a national cut-off point. Guidelines should state “if X happens then Y must happen”. Guidelines should be area specific to account for variations within Zambia
- Goals and targets may be based on coverage, on reducing disease incidence, or on cases (as in the HMIS). The goals to be included should be itemized in guidelines
- Inter-District meetings could be used to disseminate updated guidelines

The wording of the proposal was amended from “integrated child health services” to “preventive health services”, and a phrase added to recognize the different areas of the country

Additional policy issues, Day 1

Following from the discussion of goals and NIDs coverage goals, some participants had encountered people who refused to allow their children to be immunized. The meeting discussed legal compulsion: if the law threatens people with court if they refuse to participate, consider the state’s legal position if the service is not provided and the child gets the disease. Instead of compulsion we should be advocating for children’s rights, how do we oblige our people to participate? The state has a responsibility to protect others (the public good). This discussion ended with agreement to draft a policy on eligibility, access to and use of immunization services.

The usefulness of specific strains of BCG vaccine was queried especially in relation to HIV. [Research is in progress at the University Teaching Hospital on the rates of TB in HIV+ cases who were immunized with BCG compared with those who were not.] This matter can be taken up by the proposed Expert Committee on Antigens.

Day 2

1 Adding a fourth dose of OPV under 1

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

CHILD RECEIVES	<u>EITHER A</u>	<u>OR B</u>
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

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

Several members of the IMCI Group were present and confirmed that OPV0 has already been adopted as policy, in line with neighbour's policies in the wider Region, and is included in IMCI training The benefit of earlier protection will be important when NIDs cease and polio eradication moves to the mopping up phase

The presentation clarified that it is the CHILD who gets either A or B, the proposal is not for two different policies but for one policy with two possibilities depending on the age when the child is first seen. The layout and wording of the proposal was revised accordingly.

The revised proposals will specifically refer to the reduction in the minimum age for DPT1/OPV1 to 6 weeks.

For clarity, the wording of the schedule was altered to specify the earliest age for OPV2/DPT2 (from 10 weeks) and OPV3/DPT3 (from 14 weeks), while mentioning the minimum interval of 4 weeks between doses.

A question whether Zambia should be using DT instead of DPT was answered by the information that 1 child in 300,000 will have a serious reaction to DPT, so in an eligible population of 600,000 it is unnecessary to obtain DT.

The need to revise the Child Health Card was raised, and the team undertook to draft an updated layout for the card which reflects the proposed policy updates.

2 Presentation on need to clarify policy on immunization against measles

Background

WHO policy: measles dose at 9 months or as soon after as possible.

GRZ adopted this policy but changed in 1982 to give measles at 7 months until 1992, when the policy reverted to the WHO recommendation.

Measles epidemiology has trends which change over time as a result of immunization activity.

Routine reported coverage is higher than DHS figures [see chart].

Visits to HCs and review of Child Health cards in the community revealed double dosing (6 months and 9 months) by some HCs.

Using data from the Zambia Demographic and Health Survey the number of susceptibles (never immunized + immunized but did not sero-convert) was calculated, and the build-up of the pool of susceptibles tracked. After four years of immunization at current levels of coverage, there will be a pool of susceptibles equal to one annual cohort of infants (see chart).

District coverage (reported to the national level) varies widely nationwide, and these variations are found within Regions. This makes regional and national monitoring of immunization activity vital in the effort to control measles (see chart).

Zambia cases of neonatal tetanus and coverage for TT2+ and DPT3, 1984 to 1997

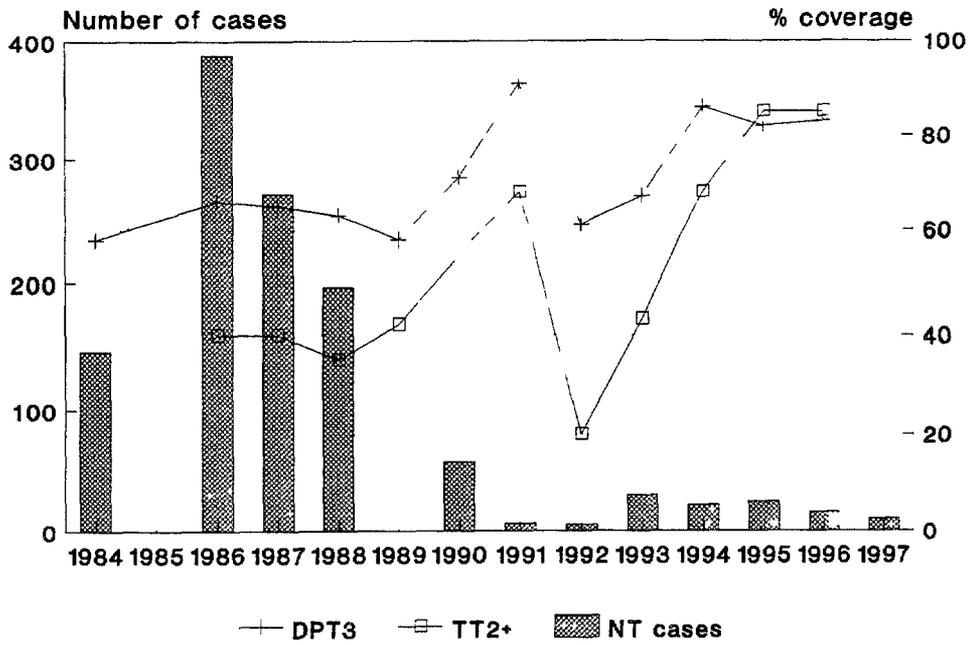
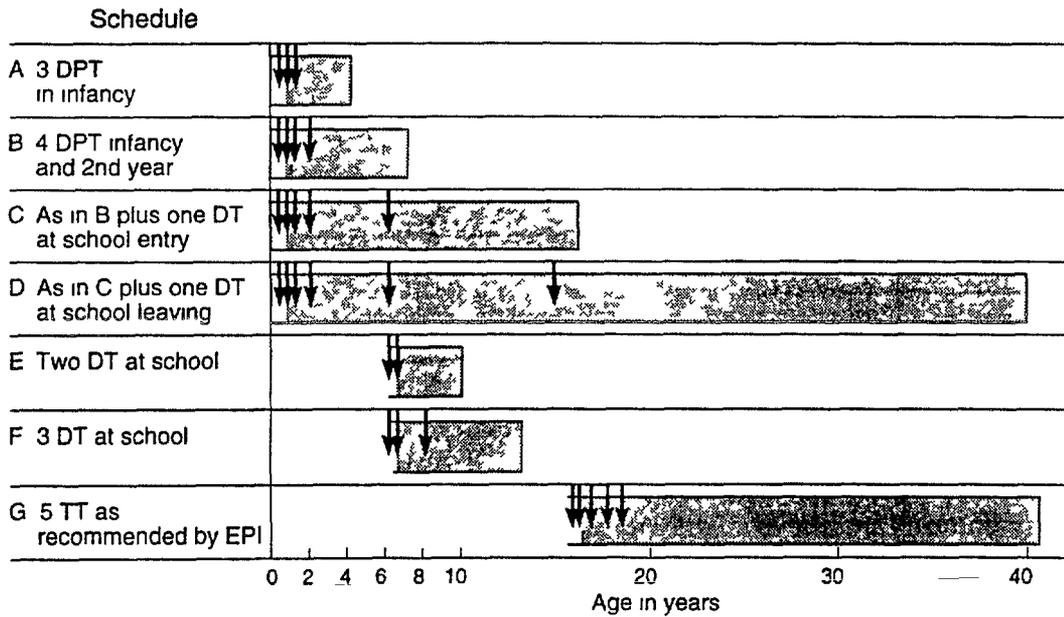
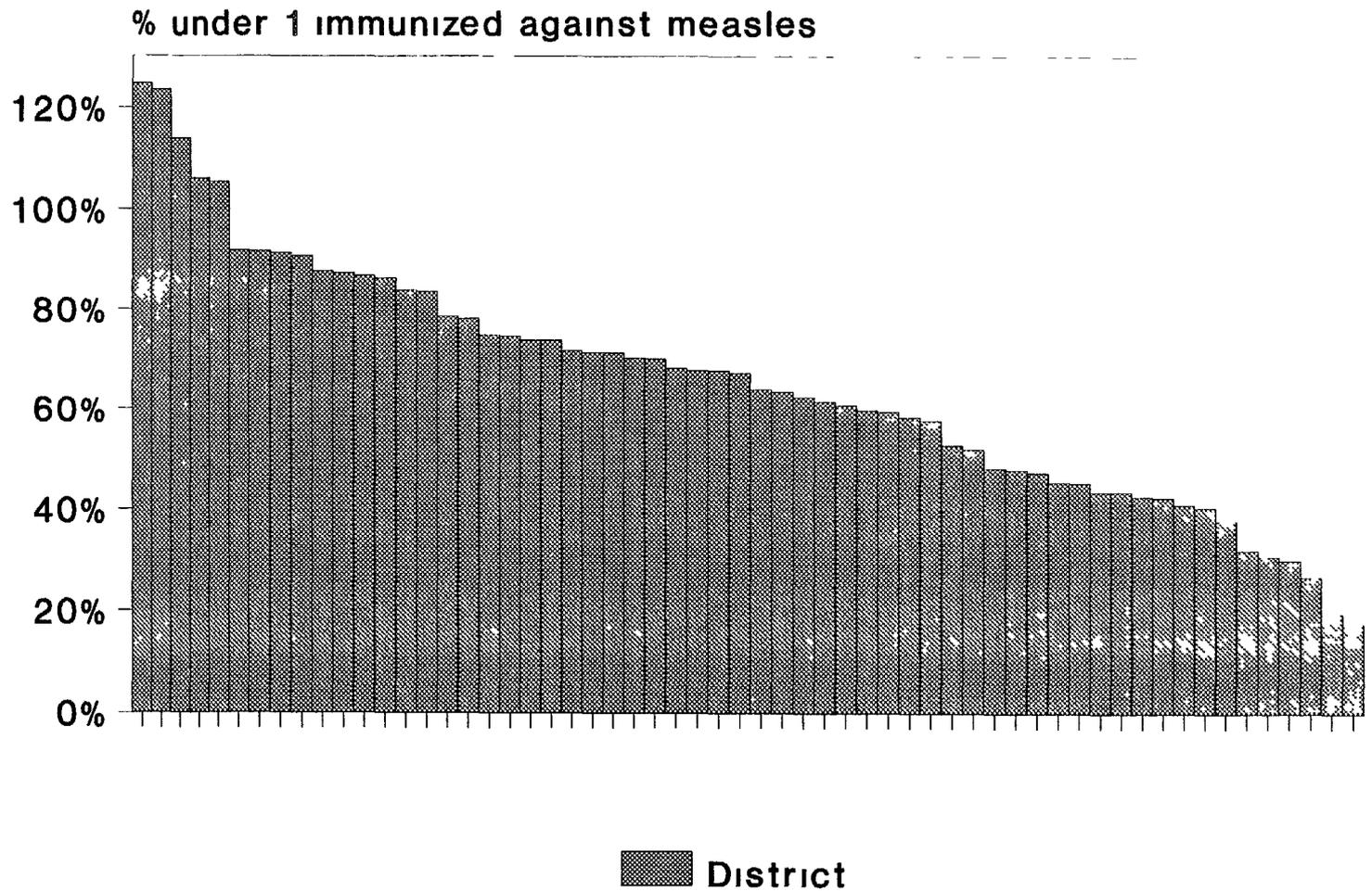


Figure 1 Expected duration of immunity after different immunization schedules



Zambia Measles coverage <1 in 1996, by District



23

Proposal for clarification of policy on immunization against measles

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

The problem of denominators was raised in connection with the coverage figures shown. There are two sets of denominators in use: one from CSO and the Districts' own estimates.

The wording "as soon as possible thereafter" was discussed. Some wanted a specific age to be mentioned (e.g. before first birthday), others said this is not always practicable (as in hard to reach areas).

- Early measles cases admitted to UTH have been investigated, the mothers were young and had themselves been immunized. Perhaps the epidemiology of the disease is now changing in response to different maternal antibodies acquired through immunization rather than through contracting measles. This is a topic that could be considered by the proposed Antigen Committee and the Monitoring and Evaluation Unit in CBoH.
- The guidelines for outbreak control have been issued in the past, how long should outbreak control continue? Monitoring and Evaluation Unit could contribute to predicting when outbreaks are expected.

Analysis of current outbreaks shows that most cases are under-5s and most are not immunized, so the principle strategy is still to raise coverage to 95%. Strategies for acceleration of measles control are under development, and new guidelines for implementing the most appropriate strategy for Zambia will be prepared. Any supplemental dose that may be given as part of measles control strategy will not be part of the routine schedule.

The proposal was accepted as it stood, and the guidelines for measles control will cover the details of implementation strategies.

3 Proposal for clarification of policy on TT

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

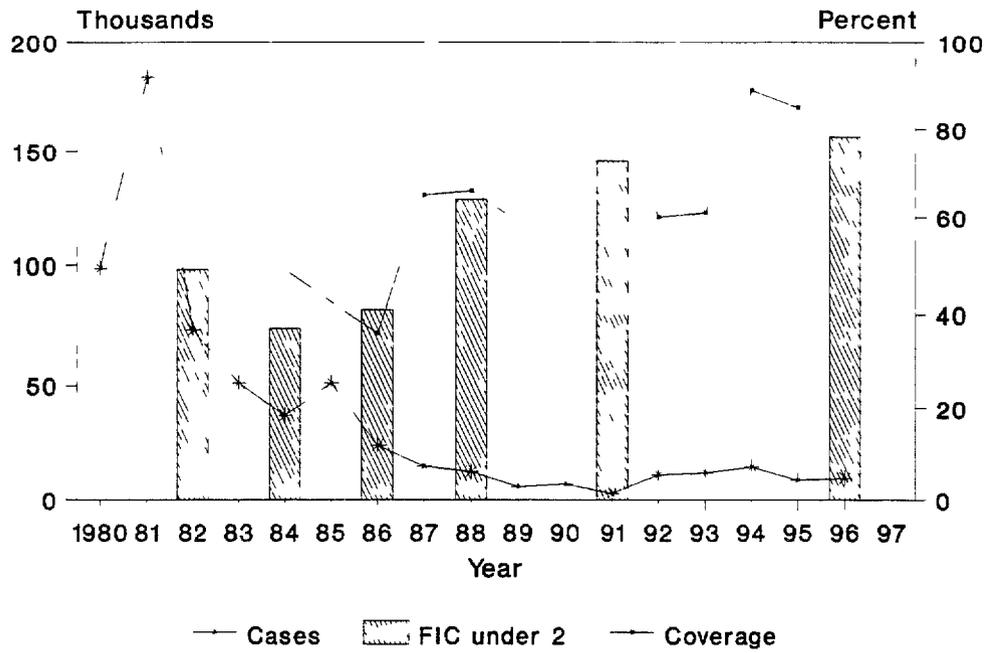
The following points were raised by the participants

- The policy on TT at school applies to boys as well as girls
- The elements of the chart which apply to Zambia are Line C and Line G Districts should know that they are striving to give one more dose to a woman of childbearing age if they have already covered all children as in C Training should include a chart for the protected pregnancy
- Training should ensure that people know how to report it [HMIS does not include school health]
- There are implications for quantifying TT for the school dose
- This part of immunization policy should be linked up with school health and health education messages Some participants favoured a policy that children must show their Child Health Card, with a complete record of immunizations, in order to be enrolled in school [This point was taken up by the team with the Ministry of Education, see Section IV]
- Cases of tetanus have been seen recently in UTH and traced to supply problems which should be addressed before insisting on complete immunization for school enrolment
- Guidelines must specify procedures in case of a neonatal tetanus death, and link up with surveillance

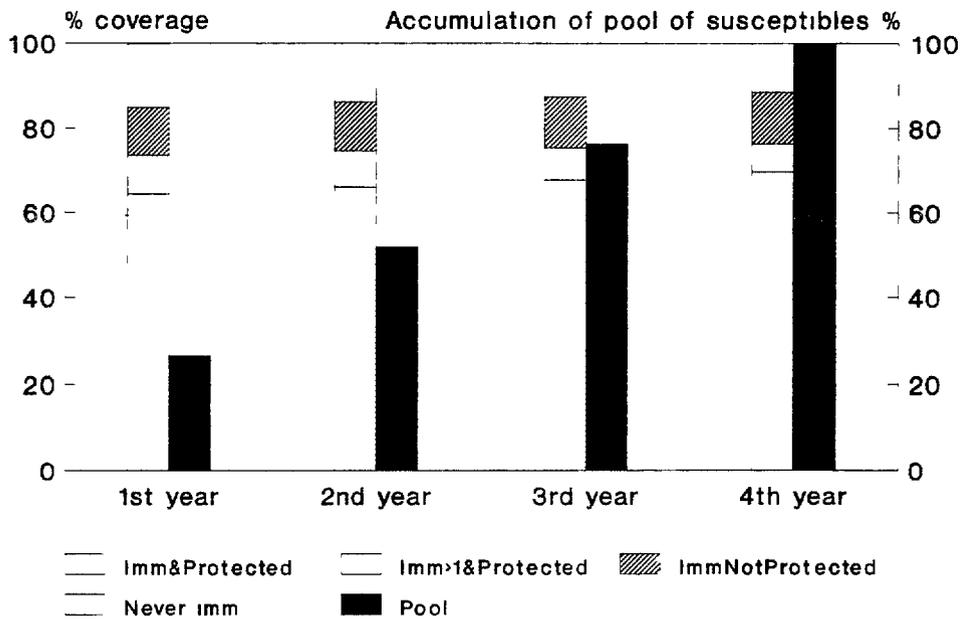
The wording was amended to specify boys as well as girls

35

Zambia Measles cases and immunization coverage, 1980-1997



Measles coverage accumulation of the pool of susceptibles



4 Safety of injections

The WHO Expanded Programme on Immunization defines a safe injection as one that -

- does no harm to the recipient,
- does not expose the health worker to avoidable risk,
- and does not result in waste that puts others at risk

Three guiding principles for clinical waste management policy

- 1 A holistic approach waste destruction must not simply move contamination from one environment to another
- 2 The polluter must pay
- 3 No bad legacy today's actions should not leave behind problems for future generations

The participants were also referred to the new study by Kane *et al* * which gives regional estimates of transmission of Hepatitis B, Hepatitis C and HIV through unsafe injections

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

A J Kane, M A Kane, J Lloyd, M Zaffran Unsafe injections in the developing world and transmission of blood-borne pathogens review of the literature and regional estimates Circulated at the Technet Consultation, 16-20 March 1998

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

The discussion covered the following points

- MSL/EDMSS supplies conventional disposables, is it necessary to have a policy which specifies only one type of injection equipment for immunization?
- Conventional disposables create a far greater volume of contaminated waste than sterilizable equipment. The policy should cover disposal (the need for disposal boxes) and include good management of waste in the environment
- Parents have questions about the steam sterilized equipment. Some parents bring their own syringes
- There should be a policy on how often to replace the steam sterilized injection equipment, i.e. before the needle is so blunt it makes a hole in the baby's arm. The whole system needs to be polished up to assure safety. TST spots have just arrived in Zambia for the first time and will help to give staff confidence in their sterilizers, and also to identify when the sterilization procedure is not up to standard
- The routine of sterilizing immunization injection equipment will improve the clinical practices in general
- It is the District's responsibility to provide the necessary equipment. The inventory in CBoH's *District Guidelines* should be updated to include the hot plate or stove required to heat the steam sterilizer
- How will procurement and distribution of these specialized supplies be added to the integrated supplies system? MSL is not used to handling these items but as they are consumables it makes sense to distribute them to Districts on a regular basis

The consensus was that participants did not want a dual policy on injection equipment, but that disposables could be used where proper disposal facilities are available. The details defining proper disposal need to be specified in the guidelines

The guidelines for AEFAPP (adverse events following any parenteral procedure) should be sent to the Monitoring and Evaluation Unit for follow-up

5 Proposal for policy on use of opened vials of non-reconstituted vaccine at subsequent sessions

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

The first clarification was that the policy does **not** apply to reconstituted vaccines (BCG and measles vaccine) This reaction reflects the need to be very clear in training

Participants wanted clarification on how many days or months the opened vial could be kept, and after what time frame it should be discarded They asked for the policy to be more specific in terms of correct cold chain and correct handling of vaccine

These issues will be addressed in the guidelines which will reinforce all the standards promoted for safe and correct cold chain and vaccine handling [See Appendix L]

6 Proposal for policy on session frequency

The frequency of sessions for integrated health services should be planned to cover the eligible population within the resources available

The discussion was taken up by those with a clinical focus who feared that the policy would lead to one immunization session per month (and hence many missed opportunities through lack of service), and those with a management orientation who found the proposal to be consistent with developing quality services through planning

This discussion highlighted the need for guidelines to spell out with practical examples what “covering the eligible population” means and the implications for the choice of location for sessions, and the frequency of sessions at each location This policy links closely with quantification of vaccines and other supplies (see Chapter 7, not presented at the consensus meeting) The concept was contrasted with the so-called “supermarket approach”, and likened to the local market day when everyone knows certain goods and services will be available Participants identified the role of advertising this “market day” to ensure that parents knew when immunization would be available in their area

Additional policy issues, Day 2

a) BCG

As mentioned above, the briefing document did not contain a specific update of the schedule for doses of BCG, and there was a request to add a chapter on this antigen. The poor correlation between scar and protection suggests that the policy of repeating BCG doses to school children without a scar should be discontinued. The team undertook to follow up this point (see Appendix F)

b) Eligibility and Participation

The team undertook to draft a policy which addresses these issues, including the existing policy that services for under-5s are free of charge. The participants agreed that legal measures should not be brought to bear on conscientious objectors. Guidelines on social mobilization should be developed to address the issue of refusers.

Following the consensus meeting the policy proposals were revised (see Appendix E) and submitted to CBoH for the MOH's endorsement.

APPENDIX E

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

[This document was prepared by the team after the consensus meeting, and the final copy was sent by courier to the local consultants in Lusaka on 8th May 1998]

(N B Footnote on page 2 that contains updated information)

UPDATING IMMUNIZATION POLICY WITHIN THE CONTEXT OF HEALTH SECTOR REFORM

Introduction

Immunization activities were reviewed at all levels of the health system in September and October 1997 see the Review Team's document,

Sustaining and improving benefits of immunization within Zambian Health Reform

Following the Review Team's recommendations, immunization policy, standards and guidelines were intensively reviewed in February and March 1998, and the resulting briefing paper,

Proposals for updating immunization policy within the context of health sector reform

was circulated to 147 key players, including all the district teams. In the briefing paper the issues raised by the review, and during subsequent discussions, were divided into three levels

- Issues requiring a policy decision
- Issues needing a guideline
- Topics to be updated in manuals and on forms

Comments were received from several districts, and from a number of national bodies and international partners. On 21st-22nd April 1998 a meeting was held to reach consensus on immunization policy issues.

The policies in the following pages are designed to support the goal and objectives summarized below

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

In the following pages the proposed updates to immunization policy are shown in boxes, giving a reference to the relevant chapter in the *Proposals* document, which includes the implications of adopting the new policies and of continuing with the status quo. Some issues await the outcome of studies or further analysis, and the recommendations of the Consensus Meeting on these issues are presented here. When the proposed policy updates have been endorsed by the Ministry of Health, the manuals will be updated and detailed guidelines for implementing the policies will be developed.

1 Eligibility access to and utilization of services

Raised by the Consensus Meeting

Zambia's policy is universal child immunization meaning that all children are eligible for all the doses in the schedule at the stated ages, or as soon thereafter as possible. The priority is to complete the primary schedule before the child's first birthday. School age children and pregnant women are also eligible as defined in the schedule.

Immunization services are to be provided free of charge.

All means possible will be used to convince parents, carers and the community to have eligible children and women immunized.

In the 1980s efforts were made to involve the Ministry of Education, to reinforce universal immunization by requiring children to bring their Child Health Card when they enrol in primary school. This requirement is still applied by some pre-schools.

Children enrolling for Grade One will have their immunization status checked and updated to maximize protection of school age children **

2 The Immunization Schedule

2 a) Adding a fourth dose of OPV under 1

2 b) Starting DPT1/OPV1 at 6 weeks

Refer to Chapter 1 of *Proposals*

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 he/she 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 first and second dose, and between second and third dose, must be at least 4 weeks.

The "booster" dose for OPV at 18 months should be removed from the schedule.

AT THIS AGE	CHILD RECEIVES
Birth or at first contact	BCG
Birth to 13 days	OPV0
From 6 weeks	OPV1/DPT1
From 10 weeks*	OPV2/DPT2
From 14 weeks*	OPV3/DPT3
At 9 months	Measles
At 18 months	DPT booster

* Or at least 4 weeks after the previous dose

continued

** DPT should not be given to children age 6+ years. If the child had no doses of DPT and had received TT, then the second and third dose of TT are needed at least 1 month and 6 months, respectively, after the first and second doses of TT.

If a child missed OPV0 then he/she should be given the fourth dose of OPV at the same time as the measles dose (9 months) as follows -

Birth or at first contact	BCG
From 6 weeks	OPV1/DPT1
From 10 weeks*	OPV2/DPT2
From 16 weeks*	OPV3/DPT3
At 9 months	OPV4, Measles
At 18 months	DPT booster

* Or at least 4 weeks after the previous dose

2 c) Clarification of policy on immunization against measles

Refer to Chapter 2 of *Proposals*

The immunization schedule contains one dose of measles, to be given at 9 months or as soon as possible thereafter, preferably before the first birthday

The guidelines will give details of the strategies for measles control (raising coverage of under-1s to 95%), including surveillance, analysis and use of data, and improving operational performance

2 d) Clarification of policy on TT (preventing tetanus and neonatal tetanus)

Refer to Chapter 3 of *Proposals*, especially Chart 3.1

A single dose of TT will be given to boys and girls at school entry. No further doses of TT should be given in school.

The existing policy of five lifetime doses continues unchanged.

Each pregnancy must be protected against neonatal tetanus, 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

44

3 Policy on safety of immunization injections

Refer to Chapter 4 of *Proposals*

The WHO Expanded Programme on Immunization defines a safe injection as one that -

- does no harm to the recipient,
- does not expose the health worker to avoidable risk,
- and does not result in waste that puts others at risk

Immunization injections are to be administered using equipment sterilized under pressure in steam sterilizers. Needles and syringes are to be replaced as soon as they reach the end of their useful life

Disposable injection equipment (conventional disposables or autodestruct/solo shot devices) may only be used where proper disposal facilities are available, complying with the third element of the definition of a safe injection

If sterile injection equipment is not available (e.g. the TST (time/steam/temperature) spots show that sterilization equipment is not reaching the required standards, or there is no equipment in stock) then immunizations should not be given

Recommendations 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 by CBoH's Directorate of Monitoring and Evaluation 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

4 Policy on use of opened vials of non-reconstituted vaccine at subsequent sessions

Refer to Chapter 4 of *Proposals*. In 1995 WHO issued a revised policy statement on the use of opened vials of vaccine at subsequent immunization sessions. The relevant sections 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, such as thiomersal (injectable vaccines only)

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

Zambia adopts the policy of using opened vials of non-reconstituted vaccine (OPV, DPT, TT) 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.

The existing policy of discarding reconstituted vials of BCG and measles vaccine at the end of the session (maximum 6 hours) remains unchanged.

Guidelines will include the standards specifying correct cold chain and vaccine handling, details about the time limits for keeping opened vials of OPV, DPT, TT, and special rules for outreach sessions.

5 Policy on session frequency

Refer to Chapter 6 of *Proposals*

The frequency of sessions for preventive health services will be planned to cover the eligible population within the resources available

6 Policy on cold chain equipment for vaccines and other immunization equipment

Refer to Chapter 10 of *Proposals*

Districts and health facilities 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

Suggested criteria are

- 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 in English
- 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)

International procurement to make equipment and spares available to Districts will be done only by the central level, bought in advance on a revolving fund basis (Districts will not embark on international procurement themselves)

Donor procurement will be from the same "shopping list" to minimize the variety of models in the cold chain, thus enabling the central level (e.g. the National Cold Chain Workshop) to carry the appropriate range of spares

Recommendation

A policy for disposing of donated equipment should be drawn up (e.g. by the Vehicle Service and Medical Equipment Management Board) so that defunct items can be formally removed from the inventory. Technical criteria for disposal and legal aspects should be specified in the policy.

Additional information from the National Cold Chain Workshop's inventory is needed in order to develop guidelines on the lifespan of the various types of vaccine storage equipment

7 Policy on adding new antigens

Refer to Chapter 11 of *Proposals*

The immunization schedule will be reviewed at least every two years

Recommendation

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

The review should also consider whether to make any adjustments in the present schedule (e.g. add or subtract doses of existing antigens, alter the age of administration). The process should include assessing the epidemiological impact, benefits and costs, and operational implications.

An Expert Committee on Antigens based in the CBoH should be convened for this purpose.

8 Policy on national goals

Refer to Chapter 12 of *Proposals*

National goals for immunization will be updated regularly, and be framed explicitly within the context of preventive health services and health sector reform, taking into account the capabilities of the different areas of the country.

Some examples of topics for goals and targets include

- completeness and timeliness of reporting
- coverage per antigen, fully immunized under one, drop-out rates (area specific, using definitions and denominators in the HMIS)
- disease reduction
- response to cases of diseases preventable by immunization (refer to clinical training, to HMIS procedures and to the epidemic surveillance system)

9 Logistics from centre to district

Refer to Chapter 13 of *Proposals*. The following confirms the present policy on transport of vaccines.

During transportation all vaccines must be kept below 8°C, and DPT and TT must be kept above 0°C. Time in transit between storage points (refrigerators or freezers) must be minimized.

Work is in progress on a proposal for changing the management and operational arrangements for vaccine distribution between the centre and the districts.

Recommendation

Any logistics system proposed for handling immunization supplies and equipment should be scrutinized by GRZ/MoH/CBoH and donor partners, in order to ensure that the proposed arrangements will be suitable for meeting the objectives of immunization services

10 Policy on funding vaccines and other immunization supplies

Refer to Chapter 14 of *Proposals*

A definite amount of money from the 1999 budget will be earmarked for vaccines* and other immunization supplies**, and protected. The amount should increase year by year in co-ordination with donor commitment of funds

* Vaccines include BCG (20-dose only),
OPV, DPT, TT (20-dose or 10-dose),
Measles (10-dose only)

** Other immunization supplies include
BCG needles (26G) and syringes (0.05 ml), sterilizable/reusable
other needles (22G) and syringes (0.5 ml), sterilizable/reusable
mixing needles (18G) and syringes (5 ml), sterilizable/reusable
TST (time, steam, temperature) spots
incinerator boxes
steam sterilizers

APPENDIX F

**MEMO. GANTT CHART AND MATRIX
FOR IMMUNIZATION ACTIVITIES**

To Jenny Meya Nvirenda,
Reproductive and Child Health Specialist, CBoH
From Rachel Feilden, Leo Chivundu, Brenda Katukula
Consultants on immunization policy, standards and guidelines
Date as of 28th April 1998
Subject Time line and matrix for co-ordinated progress

After the meeting at the Basics office on Friday 24 April we drafted a time line showing activities which are already planned and which affect immunization (refer to Figure 1) Some of these may have changed since we prepared the chart, for example we have marked the HMIS roll-out phase as starting on 1st June but this schedule may have been revised as a result of the donor meeting

Figure 1 also shows additional efforts which are implied by the updated policies and for strengthening and sustaining immunization activities in general (e.g. see under Guidelines) The timing of PHP training needs to be filled in Any other activities which affect implementation of the updated policies, standards and guidelines should be added

We would like to draw your attention to the need to conclude the updating of the Child Health Card Ideally the revised format should be ready in time for the introduction of HMIS nation-wide However, it is important that the updates are very carefully considered by all key players and that the original concept of the card is retained (please refer to our memo on this subject)

We also drafted a matrix which summarizes some interconnections between guidelines on immunization and other systems and key players (refer to Figure 2) This should help with co-ordinating the work on updating immunization guidelines

* Note In both Figure 1 and Figure 2, immunization supplies include the following

- BCG needles (26G) and syringes (0.05 ml), sterilizable/reusable
- other needles (22G) and syringes (0.5 ml), sterilizable/reusable
- mixing needles (18G) and syringes (5 ml), sterilizable/reusable
- TST (time, steam, temperature) spots
- incinerator boxes
- steam sterilizers

A separate memo requested by the Manager of Medical Stores Limited gives the rationale for including steam sterilizers (part of injection equipment) with injection supplies

Figure 1 Time line summarizing activities and schedules interacting with updating immunization policy, standards & guidelines

Planned activities and milestones	April	May	June	July	August	Sept	Oct	Nov	Dec	1999
Immunization policy updates completed Proposals endorsed by MoH	X	X								
Disseminate results of consensus meeting		XXX								
Manuals updated	X	X X X X	X X X X							
Guidelines developed, field tested and introduced for										
Quantification of vaccines & supplies*					X					
Replacement of equipment					X					
Distribution plan from Med Stores Ltd	X	Scrutinize plan								
Measles control		TORs for TA								
Surveillance system		Regions' epidemiologists hired								
NIDs				X	X					
Child Health Card updated		XXXXX								
HMIS roll out nation wide 1 June 1998			X							
District action plans and budgets including FAMS training & quantification					XX	XXXXX	X			
Med Stores Ltd quantification							XXXXX	XX		
PHP training (timing?)										
Co-ordination with Ministry of Education		letter					Background information prepared and distributed			Schools start

* See Note on page 1

52

Figure 2 Some interconnections between guidelines on immunization and other systems and key players

FAMS Financial and Administrative Management System NCCW National Cold Chain Workshop
 OMS Old Medical Stores VSMEMB Vehicle Service and Medical Equipment Management Board
 MSI Medical Stores Limited HMIS Health Management Information System
 EDMSS Essential Drug and Medical Supplies Store DHMT District Health Management Team

Guidelines	FAMS stock control/ management	OMS/MSL/EDMSS	NCCW/VSMEMB	HMIS	Epidemic Surveillance System	Quality Assurance	DHMT's Regions, CBoH	Training institutes	Donor partners
Quantification	Vaccines and supplies*	Quantities requested and issued		Eligibles, sessions, attendance	Any stock shortages?	✓	Training, supervision	Use of FAMS and HMIS	✓
Equipment replacement	For injection equip/supplies	For injection equip/supplies	Cold chain equipment, inventory for useful life		Is cold chain functioning?	✓	Stoves added to inventory	Use of steam sterilizers & cold chain equipment	✓
Distribution system	Supply* cycle	System for each District	Transport implications	Link output and stocks	Any stock shortages?	✓	Deliver to HCs or HCs collect?	✓	✓
Measles control	Supplies in stock?	Supplies distributed?	Cold chain equipment adequate?	Recording and use of routine data	Investigate outbreaks	✓	Monitor activity and morbidity, follow up	✓	✓
Surveillance	Supplies in stock?	Supplies distributed?	Cold chain equipment adequate?	Recording and use of routine data	Follow up on cases	✓	Follow up, supervise activities	✓	✓

* See Note on page 1

53

APPENDIX G

CHILD HEALTH CARD

(See page 6 in the Proposed Layout for Immunization Records concerning BCG)

To Jenny Mev a Nyirenda, Reproductive and Child Health Specialist,
Directorate of Health Systems Development, CBoH

From Rachel Feilden, Leo Chivundu, Brenda Karukula
consultants on immunization policy review

Re Revising and updating the Child Health Card

Date 27th April 1998

Following the consensus meeting on updating immunization policy, we have identified the updates that will be needed on the parent held record once the Ministry of Health endorses the proposed policy changes

1 Concept of the card

The card is a record held by the parent or carer. It should remain as a two-sided A4 format card, retaining the concept of linking any illnesses with the child's age and nutritional status by recording these episodes on the growth chart

In February NFNC explained the desire to expand the information on the card, and we were shown a three-page model. We have discussed this development with key players who did not attend that meeting of the Card Development Group, who all agreed with our view that this expanded format should not be adopted, for the following reasons

- a) The complexity of the three-page model departs significantly from the concept of the parent-held record, which is to provide a visual connection between growth and episodes of illness. The card is not intended to be a clinical record
- b) Space can be made for recording Vitamin A doses on the growth chart itself at the appropriate ages, thus helping to remind staff when these periodic supplements must be provided. An extra page is not needed
- c) Health staff are not yet using the simple card correctly (refer to Prof Bhat at UTH) and training effort should be focussed on improving the use of the simple model
- d) The resources required for printing the multi-page record would be better spent on a plastic sleeve or envelope to protect the one-page card until the child is school age

2 Title of card

The present name (Children's Clinic Card) departs from the concept that this is the child's own card, and is to be presented at every contact with the health services (not just the Children's Clinic or Well Child Clinic). It appears to be widely referred to as the Child Health Card or the Under-5 Card. Children receiving TT at school will be over 5 years old, so the most appropriate name seems to be the Child Health Card

3 Identifying information on child, parents and family

On the old card the space for recording information (depth of the boxes) is equal for the first six rows. This is not logical because some items (e.g. where the family lives) involve more information, and need more space. The address may change, so may the clinic, therefore these items need deeper boxes. Child's name, Mother's name, Father's name, and the line for birthday and birthweight, will not change, so they can be narrower, thus gaining space to deepen the other boxes (see attached layout, page 4)

SS

Registration number for parents is not used and can be dropped

The current card has a special space for recording *Date first seen*

This is interpreted to mean the date when the mother first brings the baby to the children's clinic

- If child is delivered by trained staff the birth weight should be measured and recorded (in the space provided here and on the first thick line on the left side of the growth chart) and it will be clear from these two items that the child was seen at birth
Hospital staff leave the details of the clinic blank
- If the child was delivered elsewhere by a trained person and comes to this clinic after some days or weeks, then the clinic staff fill in the name of the clinic and registration number, making it possible to trace the date first seen at this clinic
- If the child is delivered at home and is first seen at the clinic after some days or weeks, it will be weighed (but this will not be a birthweight) and should receive BCG (and OPV 0 if it is less than 2 weeks old) so the date first seen will be available from the growth chart and immunization record

Surveys of immunization status do not use *Date first seen*, instead they find the interval between birth and first dose received, using date of birth and the dates of doses administered. For monitoring purposes *Date first seen* can be found from other data items on the card, and we do not see the need for a separate data item

A more useful piece of information might be where the baby was delivered. If it was delivered by trained staff, a birthweight should be recorded, see below)

Birthday

is one of the most important pieces of information and should take precedence

Birthweight

To be recorded in kilos to the nearest tenth of a kilo (e.g. 3.2 kg). Circle where child was delivered. If child was not delivered by trained staff it is unlikely that birthweight was measured, and we suggest writing the date first seen in this space to prevent incorrect data being recorded

Brothers and Sisters

On the draft revised card shown to us in February, the entire concept of this section has been fundamentally changed by adding the word "*Live*". The paediatricians at UTH use the family history of siblings who died as part of the assessment of this child's risk factors (refer to Prof. Bhat)

If subsequent pregnancies follow closely this child's health may be affected, so younger siblings should also be recorded as and when they arrive

It is essential to retain the original concept

All live births of older siblings are to be recorded, plus subsequent arrivals, noting siblings' health problems, especially fatalities, their cause and at what age
--

The proposed layout on page 4 summarizes the suggestions above, including appropriate vertical spacing. It is shown next to the current layout

4 Immunization Records

The proposed policy changes involve the following

- providing space for BCG repeated dose (if no scar)
- adding OPV at birth, and changing the OPV booster dose to OPV 4
- putting the names of the diseases prevented by DPT in the same order as the names of the antigens
- removing the words “or soon after” from the measles schedule (none of the other doses have this text)
- improving the use of space for recording immunizations beyond the primary series

Please refer to the attached layout on page 5 (current card and proposed card)

5 Growth Chart

The revised draft format has put the entire growth chart (birth to 60 months) on one page. This has reduced the size of the chart, making it more difficult to use. We recommend returning to the former layout with birth to 36 months on one side, and 36 to 60 months on one-third of the other side. This arrangement allows sufficient space for including the Vitamin A supplements on the chart itself, as you showed us when we discussed this in March.

It is not clear what benefit is gained from the pictures at the bottom of the chart, and this space could be utilized for Vitamin A supplements.

Finally, on the revised card the interpretation of the line shows four CONSECUTIVE losses of weight as being a danger sign. This is quite misleading. We recommend that the interpretation remain as it is on the present card, that is

- one month without gain is a danger sign
- one month with a loss of weight is very dangerous

We hope that these comments will be useful in finalizing the updates to the card.

cc Mrs Rose Lungu, NFNC
Dr Kafula, Dr Abdikamal, Mrs Kaoma, BASICS
Dr Mary S Ngoma, WHO
Dr Paul Zeitz, USAID
Mr B Sikateyo and HMIS Team, CBoH
Prof Bhat, UTH



Proposed layout for identifying information on child, parents and family

Present layout

Proposed layout

Children's Clinic Card

Clinic		Child's no	
Child's name			
Boy/Girl			
Mother's name		Registration No	
Father's name		Registration No	
Date first seen	Birthday birthweight		
Where the family live address			

BROTHERS AND SISTERS		
Year of birth	Boy/Girl	Remarks

Child Health Card

Clinic		Child's No	
Child's name			
Boy / Girl			
Mother's name or Caretaker's name			
Father's name			
Birthday		Birthweight	
Where the family live address			

BROTHERS AND SISTERS		
Year of birth	Boy/Girl	Remarks

Alternative layout, showing the place of delivery and whether attended by health staff, trained birth attendant, or family and friends

Child Health Card

Clinic		Child's No
Child's name		Boy / Girl
Mother's name or Caretaker's name		
Father's name		
Birthday	Birthweight	
Place of delivery Hospital / HC / home	Delivered by Health staff / TBA / other	
Where the family live address		

BROTHERS AND SISTERS		
Year of birth	Boy/Girl	Remarks

Proposed layout for immunization records

Present layout

Proposed layout

IMMUNISATION RECORDS

IMMUNISATION AGAINST TUBERCULOSIS (TB)	
BCG <i>(at birth)</i>	Date <input style="width: 60%;" type="text"/>
	Scar <input style="width: 60%;" type="text"/>

IMMUNISATION AGAINST POLIO	
OPV 1 <i>(at 2 months)</i>	Date <input style="width: 60%;" type="text"/>
OPV 2 <i>(at least 4 weeks after OPV 1)</i>	Date <input style="width: 60%;" type="text"/>
OPV 3 <i>(at least 4 weeks after OPV 2)</i>	Date <input style="width: 60%;" type="text"/>
OPV Booster <i>(at least 1 year after OPV 3)</i>	Date <input style="width: 60%;" type="text"/>

IMMUNISATION AGAINST WHOOPING COUGH TETANUS AND DIPHTHERIA	
DPT 1 <i>(at 2 months)</i>	Date <input style="width: 60%;" type="text"/>
DPT 2 <i>(at least 4 weeks after DPT 1)</i>	Date <input style="width: 60%;" type="text"/>
DPT 3 <i>(at least 4 weeks after DPT 2)</i>	Date <input style="width: 60%;" type="text"/>
DPT Booster <i>(at least 1 year after DPT 3)</i>	Date <input style="width: 60%;" type="text"/>

IMMUNISATION AGAINST MEASLES	
MEASLES <i>(9 months of age or soon after)</i>	Date <input style="width: 60%;" type="text"/>

SCHOOL IMMUNISATIONS	
<input style="width: 90%;" type="text"/>	Date <input style="width: 60%;" type="text"/>
<input style="width: 90%;" type="text"/>	Date <input style="width: 60%;" type="text"/>
<input style="width: 90%;" type="text"/>	Date <input style="width: 60%;" type="text"/>
<input style="width: 90%;" type="text"/>	Date <input style="width: 60%;" type="text"/>

OTHER IMMUNISATIONS	
<input style="width: 90%;" type="text"/>	Date <input style="width: 60%;" type="text"/>
<input style="width: 90%;" type="text"/>	Date <input style="width: 60%;" type="text"/>
<input style="width: 90%;" type="text"/>	Date <input style="width: 60%;" type="text"/>
<input style="width: 90%;" type="text"/>	Date <input style="width: 60%;" type="text"/>

IMMUNIZATION RECORDS

IMMUNIZATION AGAINST TUBERCULOSIS (TB)	
BCG <i>(at birth)</i>	Date <input style="width: 60%;" type="text"/>
If no scar, repeat dose **	Date <input style="width: 60%;" type="text"/>

IMMUNIZATION AGAINST POLIO	
OPV 0 <i>(at birth to 13 days)</i>	Date <input style="width: 60%;" type="text"/>
OPV 1 <i>(at 6 weeks)</i>	Date <input style="width: 60%;" type="text"/>
OPV 2 <i>(at least 4 weeks after OPV 1)</i>	Date <input style="width: 60%;" type="text"/>
OPV 3 <i>(at least 4 weeks after OPV 2)</i>	Date <input style="width: 60%;" type="text"/>
OPV 4 (only if no OPV 0) <i>(at 9 months)</i>	Date <input style="width: 60%;" type="text"/>

IMMUNIZATION AGAINST DIPHTHERIA, WHOOPING COUGH AND TETANUS	
DPT 1 <i>(at 6 weeks)</i>	Date <input style="width: 60%;" type="text"/>
DPT 2 <i>(at least 4 weeks after DPT 1)</i>	Date <input style="width: 60%;" type="text"/>
DPT 3 <i>(at least 4 weeks after DPT 2)</i>	Date <input style="width: 60%;" type="text"/>
DPT Booster <i>(at 18 months or at least 1 year after DPT 3)</i>	Date <input style="width: 60%;" type="text"/>

IMMUNIZATION AGAINST MEASLES	
Measles <i>(at 9 months)</i>	Date <input style="width: 60%;" type="text"/>

OTHER IMMUNIZATIONS	
<input style="width: 90%;" type="text"/>	Date <input style="width: 60%;" type="text"/>
<input style="width: 90%;" type="text"/>	Date <input style="width: 60%;" type="text"/>
<input style="width: 90%;" type="text"/>	Date <input style="width: 60%;" type="text"/>
<input style="width: 90%;" type="text"/>	Date <input style="width: 60%;" type="text"/>

** Since this memo was distributed, the team received information from WHO/Geneva advising that the BCG dose should not be repeated if there is no scar. Please refer to Appendix M

APPENDIX H

**TECHNICAL ASSISTANCE FOR
DEVELOPING STRATEGIES TO CONTROL MEASLES AND
PREVENT OUTBREAKS IN ZAMBIA:
DRAFT SCOPE OF WORK (13 MAY 1998)**

Technical Assistance for developing strategies to control measles and prevent outbreaks in Zambia

Draft Scope of Work (revised 13 May 1998)

Background

Over the last 15 years, immunization in Zambia has substantially reduced morbidity and mortality due to measles (Chivundu *et al* , Chart 2 1) The effect of immunization activity in 1996 is estimated to have prevented 8 000 deaths, but another 3 100 measles deaths were not prevented (Foster *et al* , 1997) The choice of appropriate strategies for measles control and prevention of outbreaks is complicated by the following factors, some of which are unique to Zambia

- For ten years (1982 to 1992) the national policy was to administer measles vaccine at 7 months, at this age the sero-conversion rate is about 65%, so the effective level of protection was lower for that cohort, in which one now expects to see more measles cases than under a policy of immunizing at 9 months
- Case investigations of severe measles in children as young as 2 months at University Teaching Hospital have found that some of the mothers are young enough to have acquired their immunity through immunization rather than infection
- Measles cases in young infants continue, and put pressure on health workers and local leaders to “do something ” (For example a health centre has made a unilateral decision to introduce a two-dose schedule 6 months and 18 months)
- In 1995 guidelines on outbreak response gave instructions to immunize at 6 months and 9 months for the duration of the outbreak Some health centres have continued to give two doses as routine
- The reporting system is designed for the one dose schedule, and monthly aggregations of tally sheet data substantially over-estimate coverage by health centres which are giving two doses
- There are wide variations in reported coverage between districts (Chivundu *et al* , Chart 2 2)

The extent of double dosing is not known but can be estimated by comparing reported data with cross sectional data from the Zambia Demographic and Health Survey

- 7 districts report measles coverage above 100% for under-1s, and 17 districts report measles coverage above 100% for under-2s After adjusting for uncertainties over the true denominators (by taking BCG doses to under-1s as the denominator) 5 districts still have coverage above 100% for under-1s (Chart 2 2)
- ZDHS reports that measles coverage for under-1s was 75 8% in 1996, with another 10 7% getting their primary measles immunization before their second birthday, bringing coverage for under-2s to 86 5%

The surveillance system is not yet sufficiently developed to provide reliable or complete reports of measles cases

- At the Regional meeting of EPI Managers in Livingstone (March 1998) Zambia's UCI Secretariat had received reports of 2 000 cases of measles in 1997, for the whole country (population almost 10 million)
- A field visit to Kitwe District (population 400 000) revealed that during 1997, 2 843 measles cases had been recorded by the urban health centres, and 408 cases by the hospital

Regional surveillance officers are currently being recruited (interviews were held on 30th April 1998) These four positions are funded by WHO for one year, with a possibility to extend funding for a further period These surveillance officers will need on-the-job training

A certain amount of information has already been collected by UCI Secretariat staff with support from the WHO country office The short-term WHO epidemiologist has also assembled data from field visits and the routine reporting system Further data are available from paediatricians' studies in hospitals

Scope of Work

The circumstances described above make it a matter of urgency to assemble and analyze relevant data on the epidemiology of measles in Zambia, to identify appropriate strategies and to develop guidelines for districts to follow in controlling measles Technical assistance to the Ministry of Health/Central Board of Health is required for these tasks

Step 1 Assembling information on measles

Data assembled by the UCI staff, the WHO consultant epidemiologist and selected hospitals will be collected together and summarized according to source (e.g. routine reporting system, sentinel sites, selected hospital admissions, trends over 10-20 years for selected locations)

Step 2 Investigations of outbreaks

Small scale, rapid investigations of outbreaks in the community should be conducted to gain insight into the factors associated with the outbreak These investigations should include the service providers' operational practices

For example Weeks *et al* found that

- the highest age-specific attack rates in Kampala were in the 12-23 month age group, which should have been immunized before their first birthday,
- coverage in the surveyed communities was 48% (based on self-contained denominators) which is too low to control measles

Further operational investigation of the immunization services found that

- access to services was not the problem but lack of knowledge about the immunization schedule hindered uptake,
- cold chain was not a problem but maintenance and stock control needed attention

Step 3 Use the information

The information collected in Steps 1 and 2 will be analyzed to plan long term strategies for improving measles control and determining additional information needs

- a) Identify appropriate strategies for the range of epidemiological profiles found in Zambia (e.g. low coverage/hard-to-reach population/periodic epidemics, high coverage/high population density/annual outbreaks) with decision trees to assist with choice of the most appropriate strategy for a particular situation
- b) Develop operational guidelines for districts to
 - ⇒ understand and interpret their data,
 - ⇒ reassess the coverage figures reported by their health centres, including drop-outs before first birthday (BCG to DPT3, and BCG to Measles),
 - ⇒ carry out community assessments of why some people's children are not immunized (for example is it a problem with health services - provision of services, stock-outs, health worker behaviour, etc - or with parents' or carers' motivation or access?),
 - ⇒ identify high risk groups (geographical, cultural including nomadic populations, religious, socio-economic, age cohorts)
 - ⇒ choose appropriate strategies for addressing their situation in the most effective way possible, identifying the necessary resources,
 - ⇒ respond to reported cases of measles effectively, including supporting health centres in appropriate therapeutic and prophylactic use of Vitamin A and appropriate strategies on referral and admission of cases,
 - ⇒ motivate political decision makers and partners to support the strategies,
 - ⇒ advocate for support for measles control and outbreak prevention
- c) Identify further research or special studies needed to improve the understanding of the epidemiological picture of measles in Zambia

The international consultant will work with MoH/CBoH, the Regional surveillance officers, District staff, local consultants and key players. It is envisaged that most of Step 1 would be completed by local staff and consultants, with long distance guidance from the international consultant over a period preceding his/her visit, and Step 2 and Step 3 would be conducted in Zambia. Sufficient time must be scheduled to make field visits for the rapid small-scale outbreak investigations and to work with Regional and District staff based outside Lusaka.

References

- Chivundu LB, Feilden RM and Katukula B (1998) Proposals for updating immunization policy within the context of health sector reform. A briefing document prepared for GRZ/MoH/CBoH BASICS/UNICEF/WHO, 12 March 1998
- Foster SO *et al* (1997) Sustaining and improving benefits of immunization within Zambian Health Reform (draft)
- Weeks RM, Barenzi JFZ, Wavira JRM (1992) A low-cost, community-based measles outbreak investigation with follow-up action. Bulletin of WHO Vol 70, 1992, pp317-321

APPENDIX I
QUANTIFICATION OF VACCINES

The following draft was prepared in response to a request from UNICEF's Child Health Officer, who is a member of the team preparing guidelines for quantifying supplies for immunization activities

Extracts from the covering explanatory letter

Your questions about how one moves from estimates for vaccines given once (based on expected births) to estimates for the multidose vaccines are answered in D and J

This [guideline] is extremely long I have tried to make it step-by-step transparent and believable and logical

I have [addressed] the dilemma over EPI's tradition of keeping stock records in doses by including an instruction to convert everything to vials at line (e) on Worksheet D 2 In the long run the practice of recording doses does not make sense because one cannot issue a dose (except if the vials are single dose) All of the estimates depend on how many vials you have to open, so counting doses can obscure the objective of ensuring that the Health Centres and hospitals have an appropriate amount of stock

Incidentally, Worksheet D2 will give a degree of transparency of what has been going on with stock management at District level, including what is now in the fridges and freezers, that will help enormously (IF the Districts fill it out) because then one will know what is in the pipeline However not all Districts even keep stock records (vis Lusaka Urban which I surveyed during the review)

I think [that] the national level [should] fill out Worksheet D2 as well - at present no-one seems to have responsibility for the day-to-day stock management, and producing a coherent D2 (checked by a site visit) could be used as a mechanism for [clarifying functional responsibilities and introducing better working practices at the national store]

I have not suggested that Districts use a wastage rate Wastage reflects what has happened in the past, including absence of service because of stock-outs It seems much more important to plan proactively for covering the entire eligible population

Don't hesitate to get in touch - I know that this draft will need refining and being made more user-friendly

Rachel Feilden
FBA Health Systems Analysts

13th May 1998

HOW MUCH VACCINE DO WE NEED? DRAFT GUIDELINES FOR BOTTOM-UP QUANTIFICATION

This approach assumes that the opened vial policy will not be implemented in time for the District Workshops, so for purposes of this quantification all existing rules on discarding will continue. This may err on the side of generous estimates, but that is better than running out. It also reduces the threat that many changes in procedures and policy all at once (and with a relatively weak central infrastructure) may jeopardize the system, which is running relatively robustly on reasonably good habits.

For OPV, the assumption of 100% coverage means that (three doses under 1 plus the booster at 18 months) can be seamlessly replaced by (four doses under 1).

STEP 1 Specify your population data

A Use the best available local estimate of the target population

This is consistent with the HMIS approach. Thus Siavonga knows that it had a massive increase in population over the last three years and should use the figures in which it has the greatest confidence.

B Use LIVE BIRTHS PER YEAR as the estimate of eligibles

Ideally each District would calculate

$$\text{Live Births} = \text{Total population} \times \text{Crude Birth Rate}$$

but we don't have CBR readily available per District.

This gives a higher figure than under-1s because of infant mortality.

However, for now taking 4% of the total population is close enough and what everyone is used to doing.

Do not use coverage in the quantification, our responsibility is to provide immunizations for all infants, and quantification should be based on covering all infants. Districts with low coverage should be planning to improve their coverage and must plan to ensure that they have sufficient vaccine for doing this.

STEP 2 Estimate annual requirement

There are three methods for doing this:

I Historical consumption

This means taking the amount of each antigen that you used last year and assuming that you will do the same this year.

If this method is chosen, ask:

Did we ever run out of vaccine last year?

If so, how much should we have used?

Are we going to do everything precisely the same as last year?

The review of immunization found that 54% of the health centres visited at random did not have enough vaccine to provide ALL antigens at the sessions scheduled for the following week. At least one District store had NO DPT. Therefore there are some large and serious questions over using "what we did last time" as a method of quantification.

II Wastage Rates and Multipliers

The wastage rate tells how much of all the vaccine used was thrown away. The wastage rate is defined as

$$\frac{(\text{Total doses used} - \text{doses administered})}{\text{Total doses used}} \times 100\%$$

The numerator (Total doses used - doses administered) is Doses Discarded, doses are discarded in three main ways

- i) after sessions, when all unused doses in opened vials are thrown away
- ii) through cold chain failure (e.g. frozen DPT or TT)
- iii) through stock management failure (vaccine reaches expiry date while in stock)

The wastage rate is between 0% and 100%

The multiplier is derived from the wastage rate. It gives an estimate of how much more vaccine we need than the number of doses we plan to administer to eligibles. The multiplier is defined as

$$\frac{\text{Total doses used}}{\text{doses administered}}$$

The multiplier is never less than 1.0 and in practice would never be exactly 1.0, even with single dose vials a few will get dropped, or discarded for legitimate reasons. If you use less than one dose to administer a dose, you are under-dosing (or something else is going on which requires investigation).

Table 1 shows the relationship between doses administered, discarded, and the multiplier for the vial sizes Zambia has had until now.

The top part (1.1) shows the illustrative wastage rates and multipliers from WHO.

The bottom part (1.2) shows the actual wastage rates and multipliers for Zambia from 1993 to 1995.

Points of interest

- The illustrations from WHO do not correspond closely to Zambia's patterns of vaccine consumption, Zambia has experienced far higher wastage than the WHO figures for all vaccines.
- In practice the wastage rates differ even for vaccines which are given at the same time and the same number of doses per eligible in the same presentation (vial size) see OPV and DPT for Zambia.

Table 1 Vaccine Usage Indicators

1.1 Illustrative wastage rates and multipliers from WHO

Antigen	Doses/vial (consumed)	Percent wastage ^a	Multiplier ^b	Doses thrown away ^c	Doses administered ^c
BCG	20	50%	2.0	10.0	10.0
OPV	20	38%	1.6	7.6	12.4
DPT	20	38%	1.6	7.6	12.4
Measles	10	38%	1.6	3.8	6.2
TT	20	38%	1.6	7.6	12.4

1.2 Actual wastage rates and multipliers in Zambia, 1993 to 1995

Antigen	Doses/ vial (consumed)	Zambia Percent wastage ^a	Zambia Multiplier ^b	Doses thrown away ^c	Doses administered ^c
BCG	20	79%	4.92	15.8	4.2
OPV	20	62%	2.73	12.4	7.6
DPT	20	56%	2.25	11.2	8.8
Measles	10	70%	3.42	7.0	3.0
TT	20	82%	5.68	16.4	3.6

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

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

c Per vial of the stated size

With smaller vial sizes for OPV, DPT and TT the wastage rates and multipliers should be lower, but we do not know what they will be for Zambia

If the opened vial policy is endorsed by the Ministry of Health, past consumption figures for OPV, DPT and TT no longer provide a reliable guide for wastage rates and multipliers

III The Bottom-Up, Session Based Method

The remainder of this note presents an approach to this method of quantification Building on A (target population) and B (live births per year) for each health centre,

C How many births do they expect per month?

Divide B by 12

Now the approach is to identify an appropriate number of sessions. One way to do this is to provide the number of sessions that results in a feasible workload for health staff considering all the tasks they will carry out at a session

D How many children will be seen for immunization each month?

The number of individuals coming each month is worked out from C, assuming 100% coverage

We expect that the number of visits will be kept to a minimum, so with 100% coverage there would be

C x 1 babies getting BCG (and OPV0 once introduced)

C x 1 getting OPV1 and DPT1

C x 1 getting OPV2 and DPT2

C x 1 getting OPV3 and DPT3

C x 1 getting Measles (and OPV4 if OPV0 was not given - when policy is updated)

C x 1 getting DPT Booster (and OPV booster until policy is updated)

This makes 6 (SIX) cohorts of monthly births. So C x 6 is the maximum number of children that a health facility would expect to see for routine immunizations in one month (Note that this is all sessions combined to give a monthly total)

E How many women will receive a dose of TT per month?

Zambia follows the policy of five lifetime doses of TT, and the HMIS tracks the protection of the unborn child against neonatal tetanus (see Safe Motherhood Register, HIR 3, attached)

For simplicity of the quantification, we will assume that women coming for antenatal care do not have documented evidence of their childhood immunizations with DPT or TT. If every woman is to have no more than 5 doses of TT in her entire life, then we can estimate the number of TT doses as follows:

E 1 Number of women of childbearing age = 22% x total population
(check 22% is between one fifth = 20% and one quarter = 25%)

E 2 Childbearing age group is from 15 to 45 years, that is, a period of 30 years

E 3 For every woman to receive 5 doses of TT in a 30 year period, that works out to the equivalent of one dose every 6 years

E 4 Therefore the total number of TT doses that will be administered per year will be one-sixth of the number of women in the childbearing age-group

E 5 Therefore the number of TT doses that will be administered per month will be E 4 divided by 12

This estimate of the maximum number of TT doses applies to areas with regular antenatal services

E 6 In areas which have not had antenatal services there will be a backlog of unprotected women. In such areas more doses of TT will be given during the catch-up or service expansion phase

In practice, the details are more complicated

- some women (generally those who are pregnant for the first time) will have two doses
- if health staff are screening women correctly, TT3 can be given 6 months after TT2
- most women who are on their second or third pregnancy will have one dose (TT4 or TT5)
- by the fourth pregnancy a woman should have already received her five lifetime doses (assuming that the third dose was given 6 months after TT2)
- women with a documented history of DPT are counted as having already had TT1 and TT2 already, and will receive one dose per pregnancy for their first three pregnancies

F How many sessions are needed each month to cover the eligible population?

One way of thinking about this is to divide the expected workload into portions that are feasible for the HC's level of resources (staff, transport)

- Urban clinics will generally be offering a daily service - usually their catchment population is large enough that daily sessions are needed to cover the eligibles
- Some urban HCs have found that they can reduce clinic congestion and improve coverage by doing outreach to carefully selected locations
For example talk to the Sister-in-Charge at Kaunda Square, Lusaka, which has some peri-urban communities 15 km distant from the HC
- Rural HCs usually have a mixture of static sessions and outreach
- Outreach visits may be made less often than once per month
 - If there are many small scattered communities with few eligibles, outreach to each community could be conducted once every two months. Effective co-ordination with the Neighbourhood Health Committee is essential to ensure that all eligibles attend the session and children complete their immunization before first birthday
 - If eligibles live in areas which are inaccessible during certain seasons, then outreach should be planned for the months when it is possible to provide the service (and with nomadic populations, when they are likely to be available vis the fishing communities visited by Leo during the measles outbreak)

Maps are one of the "five major analytic tools" used by the HMIS (see p 41 and p 48 of Procedures Manual for Health Centres March 1998) and they should be used by both urban and rural HCs when choosing the sites for outreach and planning frequency of sessions

G How many children are expected at each session?

How many women will receive TT per session?

Sessions should be divided into

- Regular static sessions at HC (several per month)
- Regular outreach sessions (by location) (at least one per location per month)
- Periodic outreach sessions (fewer than 12 per year to each location)

Health staff expect to see each child
 once for BCG
 four times for OPV *
 four times for DPT **
 once for Measles

* Three doses under 1 plus the booster at 18 months will be replaced by four doses under 1 when the Ministry of Health has endorsed the policy updating proposals

** Fourth time is for booster dose at 18 months (or one year after DPT3)

So at an average session (assuming no drop-outs and no deaths) staff should be giving

- the same number of doses for BCG as for Measles
- four times more OPV doses and DPT doses

H How many doses in a vial?

The table below gives some reasonable assumptions about the maximum number of doses it is possible to administer from a vial of a certain number of doses, for each vaccine. In practice health staff have found that different manufacturers fill to different guidelines, so we have used conservative estimates here

Table 2 Number of doses that can be administered from one vial, for each vaccine, according to vial size

Vial size	10-dose vial	20-dose vial
BCG	not available	17
OPV	8	17
DPT	8	17
Measles	8	not available
TT	8	17

I Which vial size is going to be provided from central level?

For the next few months there will be two vial sizes in the system for OPV, DPT and TT

WHAT WILL DISTRICTS BE TOLD? DO THEY HAVE A CHOICE ABOUT VIAL SIZE??

J How much vaccine will be needed for routine sessions?

Work this out

- for static sessions and outreach sessions
- per 4 weeks (month)
- then per year

Once health staff know the answer to G (number of children expected at each type of session) they combine this information with H (doses obtained from a vial) and I (vial size supplied) to work out how many VIALS of each vaccine they will need per month for all the children served by these sessions

For women, we have not given the total session size, which is affected by the number of visits pregnant women choose to make (Fewer antenatal visits per pregnancy seem to be made as parity rises see Zambia Demographic and Health Survey, Chapter 8)

Table 3 Ready reckoner for number of vials needed according to session size, for each antigen

a	b	c	d	e
	Maximum doses from one vial	Number receiving this vaccine	Number of vials needed	Session size Total attendance
BCG 20-dose vials only	17	1 to 17	1	1 to 102
		18 to 34	2	103 to 204
		35 to 51	3	205 to 306
OPV, DPT 10-dose vials	8	1 to 8	1	1 to 12
		9 to 16	2	13 to 24
		17 to 24	3	25 to 36
		25 to 32	4	37 to 48
		33 to 40	5	49 to 60
		41 to 48	6	61 to 72
OPV, DPT 20-dose vials	17	1 to 17	1	1 to 25
		18 to 34	2	26 to 51
		35 to 51	3	51 to 76
		52 to 68	4	77 to 102
		69 to 85	5	103 to 127
Measles 10-dose vials only	8	1 to 8	1	1 to 48
		9 to 16	2	49 to 96
		17 to 24	3	97 to 144
		25 to 32	4	145 to 192
		33 to 40	5	193 to 240
		41 to 48	6	241 to 288
TT 10-dose vial	8	1 to 8	1	
		9 to 16	2	
		17 to 24	3	
		25 to 32	4	
		33 to 40	5	
		41 to 48	6	
TT 20-dose vial	17	1 to 17	1	
		18 to 34	2	
		35 to 51	3	
		52 to 68	4	
		69 to 85	5	

Example A health centre has a population of 7 200 and takes 4% of this figure to estimate that there will be 288 births per year. Dividing by 12 indicates an average of 24 births per month. Altogether the staff work out that with 100% coverage they can expect to see 144 children for immunization every month

- 24 for BCG/OPV0
- 24 for OPV1 and DPT1
- 24 for OPV2 and DPT2
- 24 for OPV3 and DPT3
- 24 for Measles/fourth dose of OPV if not already given at birth
- 24 for booster dose of DPT

They also estimate that there are 1,584 women of childbearing age in their catchment population, of which 264 will need TT per year giving an average of 22 TTs per month

The staff have scheduled a weekly session at the health centre, and have three outreach sites with 2, 3 and 4 births per month respectively, they visit these sites once per month. If all of the children resident near the outreach sites attend the outreach sessions, then the health staff can expect the remaining 15 newborns per month (24 in catchment area less 9 (=2+3+4) at outreach) to attend the static sessions

Applying the logic in D, the staff estimate that the average size of the static sessions for immunization will be 6 cohorts x 15 = 90 children per month, spread between 4 sessions, making an average of 22 to 23 children needing an immunization per static session. At each static session, the staff expect that

- 3 or 4 children will get BCG
- 14 or 15 will get OPV
- 14 or 15 will get DPT
- 3 or 4 will get Measles
- 5 or 6 women will get TT

They go through a similar exercise for the outreach sites to estimate the number of doses of each antigen that will be administered every month

	H Post 1	H Post 2	H Post 3	
- BCG	2	3	4	
- OPV	8	12	16	
- DPT	8	12	16	
- Measles	2	3	4	
- TT	2-3	3-4	4-5	
Children attending (session size)	12	18	24	calculated as 6 x births/month

Using either the estimated doses of each vaccine (Column c in Table 3) or the estimated number of children attending for immunizations (Column e in Table 3), they work out how many vials they will need for each session. (The answer is the same using Column c or Column e)

The staff summarize their monthly requirement (see Table 4)

Space has been given for two vial sizes for OPV, DPT and TT as these vaccines are coming in 10-dose vials in 1998

Table 4 Monthly requirement for vaccines

	Vial size	Vials/static session	Multiply by sessions	Vials at outreach sessions			Total vials
				HP 1	HP 2	HP 3	
BCG	20-dose						
OPV	10-dose						
	20-dose						
DPT	10-dose						
	20-dose						
Measles	10-dose						
TT	10-dose						
	20-dose						

Table 4 Monthly requirement for vaccines - filled in for the example

	Vial size	Vials/static session	Multiply by 4 sessions	Vials at outreach sessions			Total vials
				HP 1	HP 2	HP 3	
BCG	20-dose	1	4	1	1	1	7
OPV	10-dose	2	8	1	2	2	13
	20-dose	1	4	1	1	1	7
DPT	10-dose	2	8	1	2	2	13
	20-dose	1	4	1	1	1	7
Measles	10-dose	1	4	1	1	1	7
TT	10-dose	1	4	1	1	1	7
	20-dose	1	4	1	1	1	7

The estimates above have taken a month to be 4 weeks. There are 13 cycles of 4 weeks in one year (52 weeks), so to ensure that there is sufficient vaccine in the estimate, multiply the "monthly" totals by 13 to get an annual estimate.

STEP 3 Estimate requirement for special efforts

If the health centre will undertake any special efforts such as schools immunization with TT, or outreach into hard-to-reach areas, or mopping up, they will need vaccine in addition to the routine. The quantity of vials needed should be estimated using the number of eligibles (to work out how many doses will be administered) and Table 2 (doses obtainable from a vial of a given size).

STEP 4 Calculate annual requirements

Combine the annual requirements for routine immunization and the requirements for special efforts to obtain an annual quantity of vaccines needed by each health centre.

This concludes the Health Centre's quantification of the vaccine they require for covering their eligible population

STEP 5 Add on safety stock for HCs

FAMS guidelines include keeping a safety stock of one month's requirement. This is based on the assumption that health centres will be resupplied (either by delivery from the District, or collection by HC staff) ONCE PER MONTH. The idea of the safety stock is that the HC never runs out of vaccine.

This safety stock is thus equivalent to one/twelfth ($1/12 = 8.33\%$) of the annual quantity required. Conceptually, the last safety stock will still be IN THE PIPELINE at the end of the year. So although we need an additional 8.33% to keep HCs properly stocked through the end of the year, this quantity should roll over into next year's consumption.

STEP 6 Hospitals

Hospitals give BCG to newborns (and OPV0 when the Ministry of Health has endorsed the policy and when the health system has introduced the new policy). Hospitals also immunize paediatric patients at risk, especially against measles. The quantities required by hospitals must be added to the estimates.

NOTE: In urban areas where most BCG is administered in maternities, the HCs affected should review their estimates of BCG required.

STEP 7 Total estimates from all facilities

Add together all the HC and hospital requirements.
See Worksheet D 1 on page 13.

STEP 8 District Summary of Vaccine Quantification and Stock Balances

See Worksheet D 2 on page 14. The Districts should prepare items 8 a through 8 g before they come to the planning workshop.

At present the situation is complex because the pipeline contains vaccines in two vial sizes (presentations).

It is VITAL that separate stock cards are kept for each presentation. Storekeepers must keep separate stock cards for OPV 10-dose vials and OPV 20-dose vials. The same applies to DPT and TT.

If vaccine stock records are kept in doses, the District managers must know whether those doses are in small or large vials. If you do not understand why this is VITAL, look at Table 3 and Table 4 (filled in example).

Our constraint is VIALS not doses, and it is VIAL SIZE that must be identified on the stock card in order to keep track of whether stocks are adequate for requirements.

- 8 1 What was actually used last year?
 To calculate this (d) for each vaccine you need three numbers
 a) Opening balance on 1 January 1997
 b) Stock received during 1997 add up all the receipts recorded on stock cards
 c) Closing balance on 31 December 1997
 d = a + b - c
- 8 2 If stock records are kept in doses, convert the total doses into vials
 If (d) is in doses, divide it by the vial size (10 or 20) to get the number of vials
 and write the answer in (e) on the worksheet
- 8 3 Look closely at the District's stock records
 Was there ever a stock-out of any vaccine? If so how many days did it last?
 Was there ever a stock-out of diluent (BCG or measles)? For how many days?
 Record the answer in (f) on Worksheet D 2
- Was any stock discarded because of cold chain failure? If so, how many vials?
 Was any stock discarded because it expired, or was too close to expiry date to
 distribute to health centres? If so, how many vials?
 Any other loss of stock at District level?
 Record the answer in (g) on Worksheet D 2 _____
- 8 4 Compare the result from (7) with the analysis of last year's stock levels, stock-
 outs, consumption and losses
 h) Copy the bottom line (totals) from Worksheet D 1 into line (h)
 How do the session-based quantities compare with last year's consumption?
 i) Will you have enough vaccine? Are the totals in (h) sufficient?
 If the answer is NO, write **NO** on line (i)
 If the answer is YES, write a ✓ on line (i)
 Do the estimates in (h) give you far too much vaccine? (Remember to check for
 stock-outs which may indicate that last year's stocks were insufficient) Go back
 to the health centres' estimates and look at the number of children expected at
 static sessions Are any HCs planning many more sessions than necessary for
 covering their eligibles and thus consuming remarkable quantities of vaccine?
 What will you do about this?¹
 j) If (i) is **NO**, write a revised total on line (j)
 If (i) is ✓, copy the totals in (h) into (j)
- 8 5 How much safety stock is needed?
 This is estimated according to the supply interval (k)
 - At District level, FAMS guidelines assume a one-month resupply interval In
 this case the safety stock is one month
 Write 1 in (k) and 1/12 on the line below (total x 1/12)

¹ Refer to letter from Chivundu, published in Vaccine and Immunization News, Number 6,
 March 1998, page 11

- Some Districts are still collecting or receiving vaccines quarterly (from Old Medical Stores, or from the Provincial/Sub-Regional Stores) In this case they need a safety stock of three months

Write 3 in (k) and 3/12 on the line below (total x 3/12)

- 1) Calculate the amount of safety stock for each vaccine
either $1/12 \times$ the final (revised) total in (j)
or $3/12 \times$ the final (revised) total in (j)

8 6 Add safety stock in (l) to (j), the final (revised) total you used to calculate (l)
This gives the annual requirement (m)

8 7 Indicate the quantities now in stock
This allows us to know throughout Zambia how much is in the pipeline It will help us to avoid the massive wastage that has occurred at national level due to ordering too much of certain vaccines
See (n) on Worksheet D 2

8 8 Calculate the additional stock needed for next year
Subtract current balance (n) from the annual requirement (m)
See (o) on Worksheet D 2

* * * * *

Worksheet D 1

Vaccine Requirements for Health Centres and Hospitals see page 13

Worksheet D 2

District Summary of Vaccine Quantification and Stock Balances see page 14

Drafted by
Rachel Feilden,
BASICS consultant
14 May 1998

Please send comments to Christiane Rudert, UNICEF Lusaka

Worksheet D 2 District Summary of Vaccine Quantification and Stock Balances

Prepared by _____ on date _____ for District _____

		BCG 20 dose vials	OPV 10 dose vials	OPV 20-dose vials	DPT 10 dose vials	DPT 20 dose vials	Measles 10-dose vials	TT 10 dose vials	TT 20 dose vials
a	Opening balance 1 Jan								
b	+ Stock received								
c	- Closing balance 31 Dec								
d	Vaccine used last year (a+b-c)								
e	If (d) is in doses, convert to vials								
f	Stock outs Total days								
g	Vials discarded from District								
h	Total vials from Worksheet D 1								
i	Are these totals sufficient?								
j	Final (revised) totals								
k	Supply interval is ___ months								
l	Safety stock total x ___ / 12								
m	Annual requirement								
n	Vials now in District store								
o	Additional vials needed for next year (m - n)								

APPENDIX J
CORRECT INTERPRETATION OF VVMS

To Jenny Meva Nyirenda, Reproductive and Child Health Specialist,
Directorate of Health Systems Development, CBoH

From Rachel Feilden
consultant on immunization policy review

Re Updating guidelines on the interpretation of VVMs

Date 28th April 1998

On the NIDs tally sheets used in 1997 (POLIO 4 1 National Immunization Days Tally Sheet, NID Form 5) the stock control tally at the bottom of the page says

D Number of OPV Vials used or discarded because VVM turned black

The vial should be discarded when the VVM reaches the discard point, that is when the inner circle is the same colour as the outer circle, or darker

The discard point is perfectly illustrated on the attached poster from South Africa I hope that the 1998 NIDs will take the opportunity to emphasize the correct interpretation of VVMs and to keep track of whether any vials reach the discard point

Please share this information with the NIDs Coordinator and other key players, and show them the poster Thank you

APPENDIX K

**OPENED VIAL POLICY:
ADDITIONAL QUESTIONS AND ANSWERS**

**Extract from memo sent on 7th May 1998
by International Consultant RM Feilden
to Local Consultants LB Chivundu and BM Katukula,
in response to their questions**

5 Number of days an opened vial of DPT, OPV or TT can be kept

Rules

5a) Cold chain must be maintained. If it is broken, opened vials cannot be kept.

5b) If there is the slightest suspicion of contamination in an opened vial it must be discarded. Note that opened vials lying on their sides in water at the bottom of the refrigerator will probably be contaminated. The opened vials must be kept upright, preferably in a plastic container.

5c) During transportation to outreach sessions it would be extremely difficult to guarantee that the opened vials did not tip over. Therefore opened vials will not be taken on outreach.

(This also avoids the discussion of whether to take an opened vial which has only one or two doses remaining.)

5d) Any opened vial that has been on an outreach session must be discarded at the end of the outreach session.

[An early draft of the WHO policy says discard all opened vials when a fresh supply of vaccine arrives. This did not make sense to a lot of people and I left it out of the text copied into the Proposals for Updating Immunization Policy document, page 29, and also left it out of the revised text of policies sent earlier today (page 5). In 1998 WHO replaced the "fresh supply" rule with the rule based on expiry dates, above.]

5f) For vials with VVMs (only OPV so far) if the VVM has reached the discard point then whether it is opened or not, you discard it.

The rules for reading the VVMs are as follows:

Rule 1: If the inner square is lighter than the outer circle, the vaccine may be used.

Rule 2: If the inner square is the same colour as or darker than the outer circle, the vaccine must not be used.

Please be sure that these two rules are included in the preparations for the NIDs.

5g) If there is an opened vial in the refrigerator, it must be used before another vial of that vaccine is opened (for static sessions). No vials should be opened before the session starts. One vial of each type of vaccine should be used and finished before opening the next vial.

5h) The updated WHO policy contains a guideline for managers as follows:

"although there is no scientific data to suggest that a time limit is required, for programmatic reasons managers may find it best to set the actual time limit to 2 months or any period which is found practical given the frequency at which immunization sessions take place."

(continued)

Data from Zambia The 24 facilities sampled in the review provided at least 4 sessions in the previous month if they were doing any immunizations at all (some did not)

Observing all these rules (a) to (g) in a HC that is providing regular static sessions will ensure that no vial of DPT, TT or OPV will remain open in the refrigerator for as long as a month

Therefore a simple and practical rule for Zambia is as follows the longest period that an opened vial may be kept, while observing all the other rules, is one month

Scenarios such as the health worker being unable to provide sessions because he/she is away on compassionate leave/sick leave etc can be answered by another question who is watching the refrigerator twice per day to ensure that cold chain is maintained (a)?

5i) It must constantly be stressed that this policy does not apply to BCG or measles vaccine It only applies to vaccines which arrive in liquid form

6 Can opened vial be taken on outreach?

No See 5b) and 5c)

People climb in and out of vehicles, tipping up the carrier, or are transporting supplies on the back of a motorbike which gives a bumpy ride, so vials don't remain upright

APPENDIX L
FURTHER ANALYSIS OF DHS DATA

E-mail sent on 9 June 1998
to Elizabeth Sommerfelt at
Macro International, Inc , Calverton, Maryland, USA
from Rachel Feilden

Dear Ms Sommerfelt,

I was recently in Zambia as part of a team funded by BASICS, WHO and UNICEF working on updating immunization policy. Rebecca Fields at BASICS Washington gave me your name and e-mail address so that I could follow up some queries relating to the Demographic and Health Survey.

The team used the findings from Zambia's 1996 Demographic and Health Survey (ZDHS) in our situation analysis, and it was very useful to have independent data from a cross-sectional survey (with self-contained denominators) for assessing coverage of each immunization dose.

The team working on the immunization updates has two requests:

1. Immunization against neonatal tetanus

For TT2+, the national immunization programme has estimated coverage (whether the enumerated pregnancy was protected against neonatal tetanus) from TT1/2/3/4/5 aggregated from tally sheets. We wanted to obtain an independent assessment of coverage for TT2+. The ZDHS data on tetanus toxoid vaccinations in Table 8.3 showed an inverse relationship between birth order and doses received, at levels of coverage which seemed inconsistent with the level of access to antenatal services (96% with at least one visit).

After looking at the ZDHS survey instruments (Section 4A, Q410 and Q411) we realized that the analysis reported in Table 8.3 does not show TT2+ but instead shows the number of TT doses received during a particular pregnancy (none, one, two or more). So if health workers are following the immunization schedule correctly, then the finding that there is an inverse relationship between birth order and doses received is what one would expect. But it does not tell us the proportion of pregnancies which are protected against neonatal tetanus.

Would it be possible to rerun the analysis, creating a link between Last Birth and Next-To-Last Birth for those records with Last Birth's birth order greater than 1, and accumulating the TT doses reported by the woman for each successive pregnancy? We could obtain a complete picture for women who told the interviewers about their first and second pregnancies.

(continued)

A comment For assessing quality of service,

- a) women with 2+ pregnancies should not be receiving two or more doses of TT (they should have received two doses during the first pregnancy and the recommended timing of boosters precludes two during the second and subsequent pregnancies)
- b) women should have completed their five lifetime doses during their fourth pregnancy at the latest, and those who have reached their fifth pregnancy and receive two doses are probably being over-dosed

However, the layout of Table 8 3 suggests that a woman should receive two TT doses during every pregnancy This encourages a misinterpretation of the TT immunization schedule recommended by WHO

It would be a great help to immunization services if in future the questionnaires, constructed variables and presentation of the findings were to reflect the recommended schedule of doses and the objective of TT immunization (i.e. to ensure that each pregnancy is protected against neonatal tetanus with the minimum number of appropriately spaced doses) For example the groupings for birth order could more usefully be 1, 2-4, 5+ (see (b) above) No woman should receive more than two doses during one pregnancy so the category of "Two or more doses" should separate out the 3+ doses and highlight them as an incorrect and risky practice which wastes resources

2 Age of infant when first dose was given

It is anticipated that Zambia will update its immunization schedule to include OPV0, which can be given from birth to 13 days, but no later It would be very useful to know the age at which the surveyed infants received their first dose This is most likely to be BCG, but it may be DPT1 or OPV1

Ideally the information on first dose would be reported in days (e.g. 0=day of birth), and reported according to urban/rural populations, and place of delivery (hospital, other health facility, at home) In the future we expect that all children born in hospital will receive OPV0 So we are especially interested to know how soon after a home delivery these infants are brought to a health facility for their first dose, the most disaggregated data (frequency distribution of age in days) according to place of delivery would be very useful in planning and preparing staff for the change in policy

Thank you in advance for your attention to these requests, and I look forward to hearing from you

Yours sincerely,
Rachel Feilden
FBA Health Systems Analysts
consultant for BASICS Washington

APPENDIX M

**WHO RECOMMENDATIONS FOR
BCG AND FOR HIV-INFECTED INDIVIDUALS**

BCG Selected Policy Sections

The target diseases

The EPI recommends that all countries immunize against poliomyelitis, diphtheria, pertussis tetanus and measles, and that countries with a high incidence of tuberculosis (TB) infection should immunize against TB. Hepatitis B vaccine should be integrated into national immunization programmes in all countries by 1997 (EPI 1992c). Immunization against yellow fever is recommended in endemic countries. Table 1 summarizes the information on the EPI target diseases which is most relevant to the design of control programmes.

Tuberculosis, caused by *Mycobacterium tuberculosis* (*M. tuberculosis*), caused an estimated 2.6 million deaths worldwide in 1990. The pandemic of HIV infection and an increase in multi-drug-resistant tuberculosis bacteria have profoundly worsened the public health burden of tuberculosis.

BCG Although BCG is the most widely used vaccine in the world (85% of infants received a dose of BCG in 1993), estimates of efficacy vary widely and there are no reliable immunological markers of protection against tuberculosis. Clinical efficacy in preventing pulmonary TB has ranged from zero protection in the southern United States and in South India/Chingleput, to approximately 80% in the UK (Fine and Rodrigues 1990). There is no consensus on the reasons for this variation. Efficacy does not depend on BCG strain or manufacturer (Milstien and Gibson 1990). Some studies suggest that efficacy is reduced if there has been prior sensitization by environmental mycobacteria, but the evidence is not consistent. The degree of protection has not correlated with the degree of tuberculin test sensitivity induced by immunization, nor with BCG scar size. Data showing that BCG protects against tuberculous meningitis and against miliary tuberculosis (estimated 75-86% protection (Rodrigues et al 1993)) have led to a hypothesis that BCG protects against bloodborne dissemination of the bacteria, but does not limit the growth of localized foci that occurs in pulmonary TB. BCG also protects against leprosy, although the estimated efficacy has varied from 20% in Burma to 80% in Uganda (Fine 1989). Because efficacy against pulmonary tuberculosis is doubtful, the mainstay of the tuberculosis control programme is case-finding and treatment. BCG immunization at birth, however, will reduce the morbidity and mortality from tuberculosis among children.

Age at initiating vaccination The response to vaccines may be affected by maternal antibody transferred *in-utero* to the foetus, and by the maturity of the immune response. Although immaturity of the immune system reduces the response to some polysaccharide vaccines (see section 8) young infants respond adequately to the EPI vaccines. Furthermore babies born prematurely respond adequately to the EPI vaccines without any increase in side effects (Bernbaum et al 1984, Conway et al 1987, 1993, Roper & Day 1988, Smolen et al 1983). Immunization of preterm infants should begin at the same chronological age recommended for term infants (Amer Academy Pediatr 1991, ACIP 1994, EPI 1988).

Because BCG is thought to be most effective in preventing tuberculous meningitis and disseminated disease in infants and young children (Camargos et al 1988, Jin et al 1989, Micelli et al 1988, Sirinavin et al 1991, ten Dam 1990a, Wasz-Hochert et al 1988), the EPI Global Advisory Group recommended in 1990 that BCG should continue to be given as soon after birth as possible in all populations at high risk of tuberculosis infection. However, further research is needed on the long-term effectiveness of BCG given in infancy. In some countries where the risk of tuberculosis infection is low, BCG vaccine is administered to school-age children. In England and Wales, for example, BCG vaccine is offered to tuberculin-negative school children at 10-13 years (Department of Health 1990) and appears to provide more than 70% protection against tuberculosis for at least 10 years (Research Committee 1980). Many countries of central and eastern Europe administer BCG at birth and give additional doses to tuberculin-negative children at later ages (see section 5), there is no evidence that multiple doses provide increased levels of protection.

BCG There is much controversy over the effectiveness of repeated doses of BCG vaccine. Several European countries conduct routine tuberculin tests in immunized children and repeat BCG immunization in children until they develop a BCG scar and/or become tuberculin-positive. However, there is no evidence that the degree of protection from BCG is related to scar formation or to tuberculin conversion (Comstock 1971). On the other hand, there is evidence from some BCG trials that the protection afforded by BCG decreases with time after immunization, and some authors believe that repeating BCG immunization increases its efficacy (Kubit et al 1983, Lugosi 1987), and revaccination is not associated with adverse events. The EPI recommends that research also be conducted on the long-term effectiveness of BCG given in infancy, including the prevention of tuberculosis in adults who acquire HIV infection, the efficacy of different seed lot vaccines, and the safety and efficacy of BCG in HIV infected infants (EPI 1991a).

The safety of EPI-recommended vaccines in HIV-infected individuals

As HIV-infection results in a progressive deterioration of the immune system, there has been concern that the use of live vaccines could result in severe vaccine-associated disease in those individuals. To date there has been no reported increase of adverse reactions in HIV-infected persons to the live vaccines OPV and measles, nor to DPT and hepatitis B vaccines, which contain no live organisms (Clements et al 1987, LePage et al 1992, McLaughlin et al 1988, Onorato et al 1988, Ryder et al 1993). Concern has been expressed that simultaneous administration of multiple antigens (even inactivated vaccines) might theoretically accelerate the disease process. Clinical and laboratory data do not support this (Onorato & Markowitz 1992).

Isolated cases of disseminated BCG disease (generalized infection due to BCG) have been reported among infants with asymptomatic HIV infection (Blanche et al 1986, CDC 1985, Houde et al 1988, Micelli according to ten Dam 1990b, Ninane et al 1988, Vilmer et al 1984). However, prospective studies comparing BCG immunization in HIV-infected and uninfected infants have failed to show any difference in the risk of local or regional complications (Lallemant-LeCoeur et al 1991, Ryder et al 1993). There have however been reports of severe reactions in adults with symptomatic AIDS who received BCG vaccine (CDC 1985, Reynes et al 1989). There is a concern that OPV could be associated with an increased risk of paralytic polio in

contacts, since many parents of HIV-infected infants are themselves infected with HIV. In countries such as the USA where many adults lack immunity to poliomyelitis because wild virus circulation has ceased, there may be a theoretical advantage in administering killed polio vaccine (ACIP 1994). However, in developing countries, adults have naturally-acquired immunity and the risk of paralysis in contacts is likely to be very low.

The immunogenicity of EPI-recommended vaccines in HIV-infected individuals

Most HIV-infected children have the capacity to mount both cellular and humoral immune responses during the first two years of life, decline in these responses occurs during the next two years (Borkovsky et al 1992). Studies of the immunogenicity of EPI-recommended vaccines have shown satisfactory seroconversion rates in the early stages of infection. However the proportion of responders decreases with progression from HIV infection to AIDS. In a study in Zaire, a similarly high proportion of children with perinatally acquired HIV infection and children without HIV infection acquired protective antibody levels to tetanus and poliovirus types 1, 2 and 3, but the response to diphtheria was lower (71%) in HIV-infected children than in uninfected children (99%) (Ryder et al 1993). The response to measles vaccine is also lower in HIV-infected than non-infected infants (Cutts et al 1993, Oxtoby et al 1988), and is related to severity of HIV infection. In a study in Zaire, among HIV-uninfected, asymptomatic HIV-infected, and symptomatic HIV-infected children, 89%, 77% and 36% respectively seroconverted after Schwarz vaccine at age 9 months (Oxtoby et al 1988). Antibody levels induced by the EPI vaccines tend to be lower in HIV-infected individuals and to fall more rapidly over time than in non-infected persons (Onorato et al 1988, Ryder et al 1993). However, HIV-infected women have been shown to develop levels of tetanus antibody after two doses of vaccine during pregnancy similar to those of seronegative women (Baende et al., quoted in Onorato and Markowitz 1992).

Several studies have demonstrated an impaired response to HB vaccine in HIV-infected adults, who have lower seroconversion rates to the primary series of 3 doses of HB vaccine and more rapid loss of antibody to surface antigen than individuals not infected with HIV (Geseman et al, 1988). Nonetheless HIV-infected persons who respond to vaccine appear to be protected against serious illness and against chronic surface antigen carriage. Study of the response to HB vaccine in HIV-infected infants is needed.

Current WHO/UNICEF recommendations for immunization of HIV-infected individuals

In collaboration with UNICEF WHO has established guidelines for the immunization of children and women of childbearing age with EPI-recommended vaccines (EPI 1987a, EPI 1987b, CDC 1992, SPA/EPI 1987, GPA/EPI 1989) (Table 9). It is recommended that individuals with known or suspected asymptomatic HIV infection receive all EPI vaccines as early in life as possible according to the nationally recommended schedules. Because of the risk of early and severe measles infection these infants should receive a dose of standard measles vaccine at 6 months of age with a second dose as soon after age 9 months as possible (GPA/EPI 1989) [CLARIFICATION ON THIS IS AWAITED FROM WHO]. Individuals with symptomatic HIV infection can receive all the EPI vaccines except BCG and yellow fever vaccines.

Table 10 World Health Organization/UNICEF recommendations for the immunization of HIV-infected children and women of childbearing age

Vaccine	Asymptomatic HIV infection	Symptomatic HIV infection	Optimal timing of immunization
BCG	yes	no	birth
DPT	yes	yes	6,10,14 weeks
OPV *	yes	yes	0, 6, 10, 14 weeks
Measles	yes	yes	6 and 9 months
Hepatitis B	yes	yes	As for uninfected children
Yellow fever	yes	no**	—
Tetanus toxoid	yes	yes	5 doses***

* IPV can be used as an alternative for children with symptomatic HIV infection

** Pending further studies

*** 5 doses of tetanus toxoid for women of child-bearing age as for non-HIV infected persons

BCG should not be given to children with symptomatic HIV infection (i.e. AIDS). In asymptomatic children, the decision to give BCG should be based on the local risk of tuberculosis

- Where the risk of tuberculosis is high, BCG is recommended at birth or as soon as possible thereafter, in accordance with standard policies for immunization of non HIV-infected children,
- In areas where the risk of tuberculosis is low but BCG is recommended as a routine immunization, BCG should be withheld from individuals known or suspected to be infected with HIV

Children with known or suspected HIV infection are at increased risk of severe measles. Such children should be offered measles vaccine as early as possible. Standard WHO recommendations for children at high risk of contracting measles are to immunize with measles vaccine at 6 months of age with a second dose at 9 months. Children with known or suspected HIV infection should be considered to be in this high-risk category and receive measles vaccine at 6 months of age, followed by a second dose at 9 months (GPA/EPI 1989). [PLEASE NOTE THAT WHO HAS BEEN ASKED TO SUPPLY OPERATIONAL EVIDENCE FROM COUNTRIES WHICH HAVE IMPLEMENTED THIS 2 DOSE STRATEGY FOR ELIGIBLES IDENTIFIED AS HIGH RISK.]

APPENDIX N

**FLOW CHARTS OF LOGISTICS
FOR AFP SURVEILLANCE**

93

**Extracts from
Logistics for Surveillance
prepared by EPI Unit, WHO, Geneva**

draft of 5 May 1998

pages 4-5

This topic was presented at the EPI Technet Meeting in Copenhagen, 16-20 March 1998, by Dr Maureen Birmingham. The participants requested that WHO prepare a poster showing the processes and flows of specimens and information for AFP surveillance (see Figure 3 and Figure 4 overleaf)

IV Steps to micro-plan surveillance logistics

The following steps are used to micro-plan the logistics needed for effective surveillance

Step 1 Define the surveillance process (i.e. what is supposed to happen) for each health event under surveillance

Step 2 Determine how data and specimens should flow

Step 3 Review the six universal functions of surveillance and determine what logistical elements and actions are needed. In other words, define the “what, who, where, when, and how” for each health event under surveillance

Step 4 Define the supportive functions that will be needed in terms of training, supervision and resource management

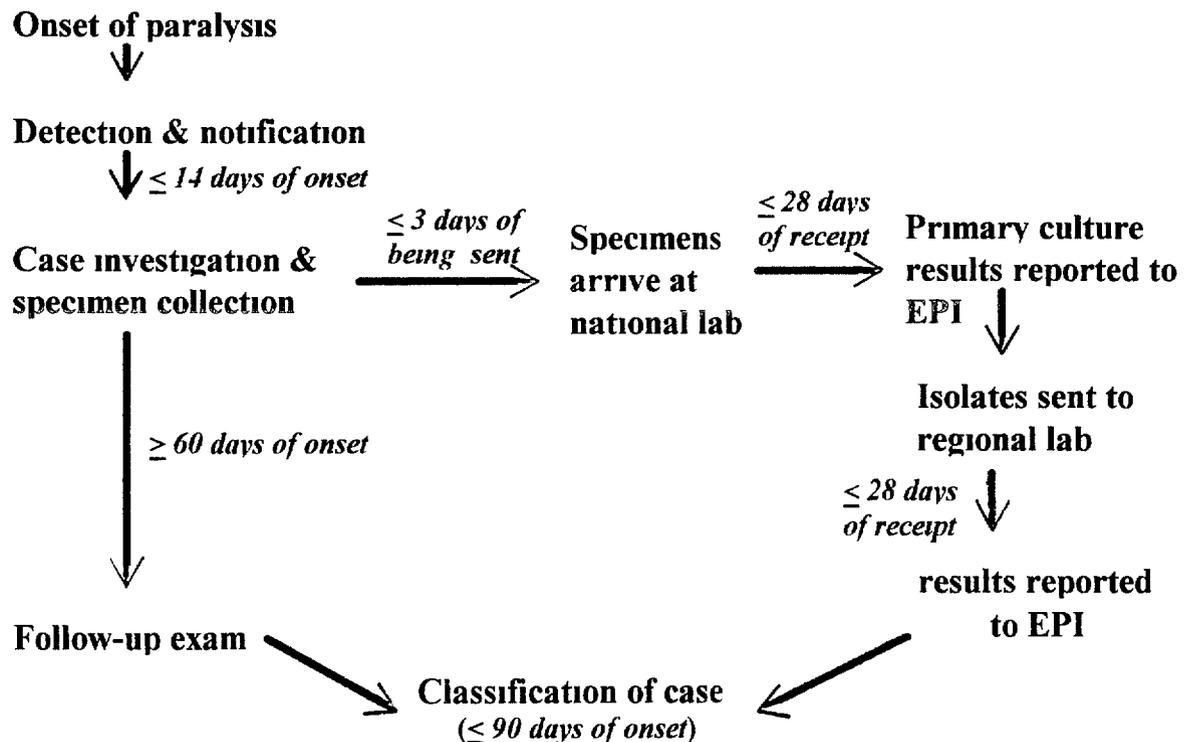
Step 5 Include this micro-plan of surveillance logistics in an overall plan to strengthen surveillance

The following section describes these steps in more detail and provides examples

Step 1 Define the surveillance process

The process of surveillance for each health event in the surveillance system can usually be depicted in a diagram (figure 3)

Figure 3 The process of acute flaccid paralysis (AFP) surveillance for the global polio eradication initiative



Step 2 Define the flow of data and specimens

Data flow

Data should flow from the point of detection to central levels, usually in a hierarchical manner so that staff at each level can monitor the population under his/her jurisdiction. Although data at *all* levels should be analyzed, the data at more central levels should be consolidated, synthesized and provided routinely as feedback to those providing the data. The following questions should be asked regarding data flow at each level of the system:

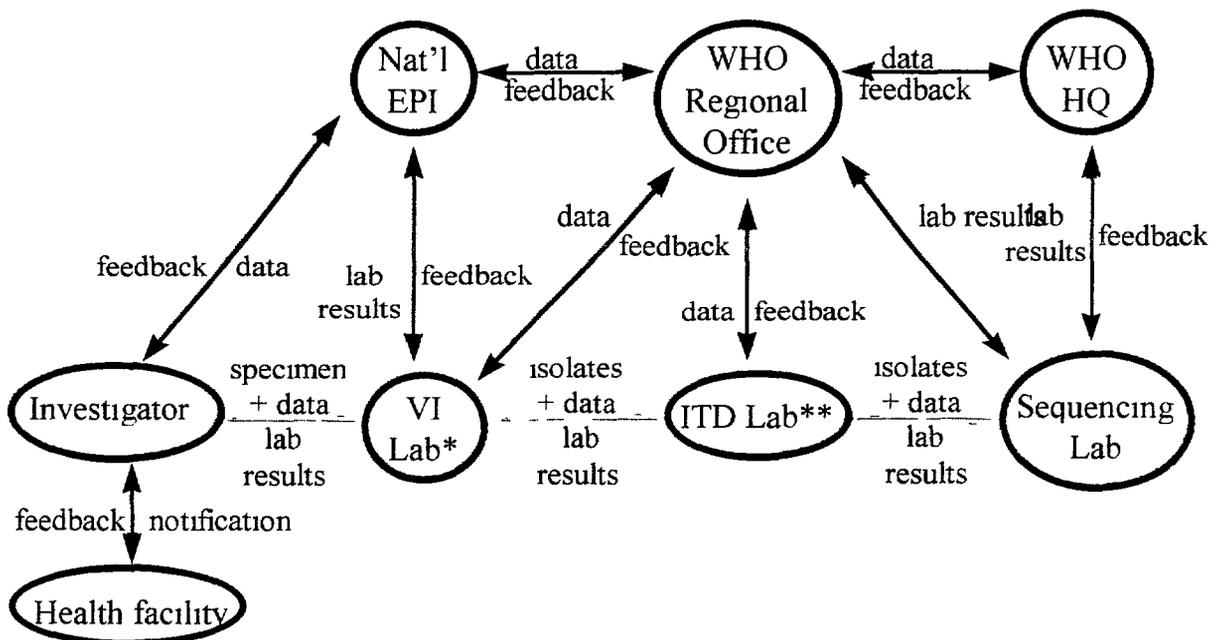
- how many and where are the reporting sites?
- who is responsible for sending data at each reporting site?
- what is the completeness and timeliness of reporting from each site?
- what options are possible for sending data from each site (mail, messenger, radio, fax, telephone, email)?
- which is the most efficient and feasible way to send data?

There are many new technologies available to facilitate data exchange and communications. However, the introduction of new communications/data transfer equipment into an area will *not* overcome poor management of data, and should take into account the implications for training, (including the frequency of staff turnover), as well as the supply and maintenance needs.

Specimen flow

Specimens should flow as directly and efficiently as possible from the point of collection to the laboratory. This often requires some means of transport or a courier service. The flow of laboratory results should also be clearly defined to ensure appropriate and timely action and prevent inappropriate reactions (figure 4). Results should always be sent to the sender of the specimen. Depending upon the disease in question, other key people, departments or disease control programmes may also need to receive laboratory results.

Figure 4 An example of data and specimen flow for AFP surveillance



* VI = Virus isolation
** ITD = Intra type differentiation