

WHO/V&B/03.18  
ORIGINAL: ENGLISH

# Monitoring vaccine wastage at country level

Guidelines for programme managers



Vaccines and Biologicals

World Health Organization

## Conceptual framework:

### Factors affecting vaccine wastage and tools available for reducing it

Factors affecting vaccine wastage		Tools available for reducing vaccine wastage
6.1 Factors related to vaccines and syringes	Vial size	7.1 Changing vial size
	Dead space in syringes	7.10 Improved vaccine management practices
6.2 Factors related to national policy	Coordination of donor efforts	7.4 ICCs
	Procurement practices	7.6 Improved procurement practices
	VVM introduction	7.2 VVM
	VVM in tender documents	7.2 VVM
	Quality and management of cold chain	7.8 Prevention of freezing
	Vaccine distribution and transport	7.8 Prevention of freezing
	Effective VVM use	7.2 VVM
	Temperature monitoring	7.8 Prevention of freezing
Communication and supervision	7.10 Improved vaccine management practices	
6.3 Factors related to logistics	Stock control	7.5 EEFO
	Alternative cold chain	7.10 Improved vaccine management practices
	Quality and management of cold chain	7.8 Prevention of freezing
	Vaccine distribution and transport	7.8 Prevention of freezing
	VVM use	7.2 VVM
	Temperature monitoring	7.8 Prevention of freezing
Communication and supervision	7.10 Improved vaccine management practices	
6.4 Factors related to immunization practice	Vaccines discarded at end of session	7.3 Multidose vial policy
	Reconstitution practices	7.9 Safe immunization practices
	Cold chain failures	7.8 Prevention of freezing
		7.2 VVM
	Session size	7.7 Optimizing frequency of sessions
Contamination	7.11 Use of zip-lock bags	

(Numbers refer to sections where subjects are discussed)

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World Health Organization  
Department of Immunization, Vaccines and Biologicals  
CH-1211 Geneva 27, Switzerland**  
• *Fax:* + 41 22 791 4227 • *Email:* [vaccines@who.int](mailto:vaccines@who.int) •

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# “Mali bila daftari huliwa pasipo na habari”

*Khiswabili saying<sup>†</sup>*

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<sup>†</sup> “Wealth without record disappears without notice”.



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# Abbreviations

°C	degree Celsius
AD	auto-disable (syringe)
AFRO	WHO Regional Office for Africa
AMRO	WHO Regional Office for the Americas
BCG	bacille Calmette-Guérin (tuberculosis vaccine)
CCCCM	Collaborative Centre on Cold Chain Management
cm	centimetres
cm <sup>3</sup>	cubic centimetres
DCVMN	Developing Country Vaccine Manufacturers Network
DTP	diphtheria, tetanus (toxoid) and pertussis vaccine
EEFO	earliest-expiry-first-out
EMRO	WHO Regional Office for the Eastern Mediterranean
EPI	Expanded Programme on Immunization
ESARO	UNICEF Regional Office for East and South Africa
EURO	WHO Regional Office for Europe
EVSM	(WHO-UNICEF) Effective Vaccine Store Management initiative
FIFO	first-in-first-out
GAVI	Global Alliance for Vaccines and Immunization
GP	general practitioner
HepB	hepatitis B (vaccine)
Hib	<i>Haemophilus influenzae</i> type b (vaccine)
IFPMA	International Federation of Pharmaceutical Manufacturers' Associations
ILR	ice-lined refrigerator
ISO	International Organization for Standardization
ml	millilitres
m <sup>2</sup>	square metres
m <sup>3</sup>	cubic metres

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MDVP	multidose vial policy
MMR	mumps–measles–rubella (vaccine)
MR	measles–rubella (vaccine)
NID	national immunization day
NRA	national regulatory authority
OPV	oral polio vaccine
PATH	Program for Appropriate Technology in Health
PC	personal computer
PIS	product information sheets
r	random number
s	sampling interval
SAGE	Strategic Advisory Group of Experts (WHO)
SEARO	WHO Regional Office for South-East Asia
Td	tetanus toxoid and diphtheria (reduced component) vaccine
TT	tetanus toxoid (vaccine)
UNICEF	United Nations Children’s Fund
VAR	vaccine arrival report
V&B	Department of Vaccines and Biologicals (WHO)
VVM	vaccine vial monitor
WHO	World Health Organization
WPRO	WHO Regional Office for the Western Pacific
YF	yellow fever (vaccine)

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# Glossary

<b>Cluster sampling:</b>	A sampling methodology that involves: 1) dividing the population into subgroups or clusters that are not necessarily (and preferably not) homogeneous; 2) drawing a random sample of the clusters; and 3) selecting all or a random sample of the persons in each cluster. When each cluster comprises persons in a localized geographic area, such as a county, cluster sampling is especially useful for national surveys.
<b>Dead space:</b>	Space occupied by the hub and the needle such that after the delivery of a full dose of a vaccine the liquid in these sections is wasted.
<b>Denominator:</b>	The number below the line in a ratio; divisor; population at risk.
<b>Intermediate vaccine store:</b>	A secondary store or substore that receives vaccine either from a primary vaccine store or another intermediate vaccine store and distributes vaccine to lower levels.
<b>Nominator:</b>	The number above the line in a ratio; dividend.
<b>Primary vaccine store:</b>	A principal or main store that receives vaccine from the supplier.
<b>Proportional rate:</b>	The number of cases of a particular condition as a proportion of the total number of cases of all conditions.
<b>Random number:</b>	A number randomly selected from a table of random numbers.
<b>Random sampling:</b>	A method in which chance alone determines who will be included in the sample, removing any possibility of selection bias.
<b>Rate:</b>	A ratio that expresses the frequency of a characteristic per 100 (or per 1000, per million, etc.) persons in the population at a given time.
<b>Sample size:</b>	The optimum number of subjects to be recruited to answer the main objective(s) of the study

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<b>Specific rate:</b>	When the numerator and the denominator of a rate are confined to a specific category (e.g. males, children under 5, Asians, etc.) it is referred to as a specific rate; e.g. age-specific death rate, sex specific morbidity rate, etc.
<b>Systematic sampling:</b>	A type of random sampling where study units are arranged in some kind of sequence as in a directory or in a series of index cards, and a predetermined fraction of the population is selected as the study sample.
<b>Vaccine vial monitor:</b>	A label containing a heat-sensitive material which is placed on a vaccine vial to register cumulative heat exposure over time. The combined effects of time and temperature cause the inner square of the vaccine vial monitor to darken gradually and irreversibly. A direct relationship exists between the rate of colour change and temperature: the lower the temperature, the slower the colour change; the higher the temperature, the faster the colour change.

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# 1. Introduction

The World Health Organization reports over 50% vaccine wastage around the world. Despite the availability of many tools for reducing such wastage, high wastage rates are still occurring in countries. Because of increasing EPI vaccine costs during the last two years, tightening vaccine security and the introduction of new and underused vaccines through the Global Alliance for Vaccines and Immunization (GAVI), countries are looking more closely than before at vaccine wastage. Moreover, GAVI has requested countries to bring down vaccine wastage rates: “The country would aim for a maximum wastage rate of 25% set for the first year with a plan to gradually reduce it to 15% by the third year. For vaccine in single-dose or two-dose vials the maximum wastage allowance is 5%. No maximum limits have been set for yellow fever vaccine in multidose vials.”<sup>1</sup>

This document reviews the factors affecting vaccine wastage and discusses the tools available for reducing wastage and their relationships to each other, with the aim of providing assistance to programme managers to establish a system for monitoring vaccine wastage as a programme quality indicator.

Vaccine wastage can be expected in all programmes. The questions arise as to whether any of the wastage is preventable and, if so, how to prevent it. Wastage in unopened vials is usually attributable to cold chain and stock management problems and can be minimized. Wastage in opened vials cannot be eliminated, but can be reduced by the introduction of the multidose vial policy (MDVP), the effective use of vaccine vial monitors (VVMs), and improved immunization strategies and practices.

Vaccine wastage is an important factor in calculating vaccine needs. If incorrect figures are used the country concerned may face serious vaccine shortages or be unable to consume received quantities, leading to increased wastage through expiry. It is therefore crucial that all immunization points using vaccines and that the stores handling them monitor their use continuously. Such monitoring can provide programme managers with good guidance on the introduction of corrective actions to reduce wastage whenever necessary.

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<sup>1</sup> *GAVI inception report.*

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## 2. What is vaccine wastage and how is it calculated?

Since wastage is defined as loss by use, decay, erosion or leakage or through wastefulness,<sup>2</sup> it is wise to begin a discussion of wastage by considering vaccine usage. Usage is firmly established and generally acceptable practice or procedure. Since vaccines are designed to be administered to prevent certain diseases, vaccine usage can be defined as the proportion of vaccine issued which is administered, i.e.<sup>3</sup>

$$\text{Vaccine usage (rate)} = \frac{\text{Number of doses administered}}{\text{Number of doses issued}^4} \times 100$$

Vaccine wastage is the opposite of vaccine usage and is given by:

$$\text{Vaccine wastage rate} = 100 - \text{vaccine usage rate.}$$

### 2.1 Types of vaccine wastage

One way of classifying vaccine wastage is to distinguish the reasons for it as either system-related or programme-related. However, this is confusing since some wastage in unopened vials cannot be considered as system wastage. For example, vials taken for an outreach session, even if not used, do not usually return to the cold chain if VVMs are not attached. This wastage occurs because of programme implications but involves unopened vials.

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<sup>2</sup> Webster's New Encyclopedic Dictionary, BD & L, New York, 1993.

<sup>3</sup> The "time" aspect of formulas in this document is not indicated so that each can be presented in one line. It should be kept in mind that the phrase "in a given period" (month, year or supply period) should be attached to each formula.

<sup>4</sup> Number of doses issued includes doses used for immunization and all doses discarded or lost for any reason (including expiry, VVM indication, cold chain failure, freezing, missing inventory or routine discard of open vials of vaccine at the end of a session).

**Fig. 1. In many national immunization programmes, unopened vials taken for outreach, if not used, do not return to refrigerators if VVMs are not attached**



In this manual, vaccine wastage is classified as occurring “in unopened vials” and “in opened vials”. Expiry, VVM indication, heat exposure, freezing, breakage, missing inventory and theft are the forms of vaccine wastage affecting unopened vials. This type of wastage occurs at all levels of an immunization system (in all storage facilities, during delivery/transportation and at service level). Vaccine wastage in opened vials may also occur because doses remaining in an opened vial at the end of a session are discarded, the number of doses drawn from a vial is not the same as that indicated on the label, reconstitution practices are poor, opened vials are submerged in water, and contamination is suspected. The reaction of a baby to immunization may also cause the dose administered to be wasted, especially in the case of oral vaccines. In this circumstance, more than one dose is required to immunize a child.

**Table 1. Types of vaccine wastage**

Vaccine wastage in unopened vials	Vaccine wastage in opened vials
<ul style="list-style-type: none"> <li>• Expiry</li> <li>• VVM indication</li> <li>• Heat exposure</li> <li>• Freezing</li> <li>• Breakage</li> <li>• Missing inventory</li> <li>• Theft</li> <li>• Discarding unused vials returned from an outreach session</li> </ul>	<p>In addition to the types listed in the previous column:</p> <ul style="list-style-type: none"> <li>• Discarding remaining doses at end of session</li> <li>• Not being able to draw the number of doses indicated on the label of a vial</li> <li>• Poor reconstitution practices</li> <li>• Submergence of opened vials in water</li> <li>• Suspected contamination</li> <li>• Patient reaction requiring more than one dose</li> </ul>

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Expired vials, heat-damaged vials, frozen vials or vials with VVMs beyond the discard point should not be kept in a cold store, refrigerator or freezer, as they may be confused with those containing vaccine of good quality.<sup>5</sup> If unusable vaccines have to be kept for a period before disposal, e.g. until accounting or auditing procedures have been completed, they should be kept outside the cold chain, separated from all usable stocks and clearly labelled “*Damaged/expired vaccine – do not use*” in order to avoid mistaken use.

Similarly, only vaccine stocks that are fit for use should be included in stock records. Damaged or expired vaccines should not appear in available stock balances. If such vaccines have to be kept until accounting or auditing procedures have been completed, details should be recorded on a separate page or card pending disposal.

Since damaged vaccine cannot be used the stock records should be adjusted and the loss should be recorded on a *Loss and adjustment report* (Annex 1).

Once disposal has been authorized, damaged items should be disposed of safely by incineration or other nationally approved means.

Vaccination points may be required to return all damaged vaccine vials.

## 2.2 Vaccine wastage calculations in vaccine stores

Because vaccine stores handle only unopened vials the above formula cannot be applied to primary and intermediate vaccine stores. For years, an erroneous practice was used to calculate vaccine wastage rates by simply using primary store figures and the number of children immunized nationwide.

**WARNING**

**This formula should NOT be used for calculation of national vaccine wastage rate**

Vaccine usage (rate) = 
$$\frac{\text{Number of children immunized nationwide}}{\text{Number of doses issued from the primary store}} \times 100$$

The use of this formula to calculate vaccine wastage rates from primary store figures is quite erroneous and cannot reflect the true situation because all vaccines distributed from the primary store are considered as used in the field, which is never the case. This calculation can only work in situations where vaccine distribution is well designed and flows very smoothly without any deviation from what has been planned. This also implies smooth vaccination operations at field level without any interruptions. One recent exercise carried out by a group of countries in Africa showed NEGATIVE vaccine wastage rates in some countries, mainly because of interrupted deliveries and the introduction of pulse campaigns for catching up: in the field, existing stocks were used and more children were immunized than would have

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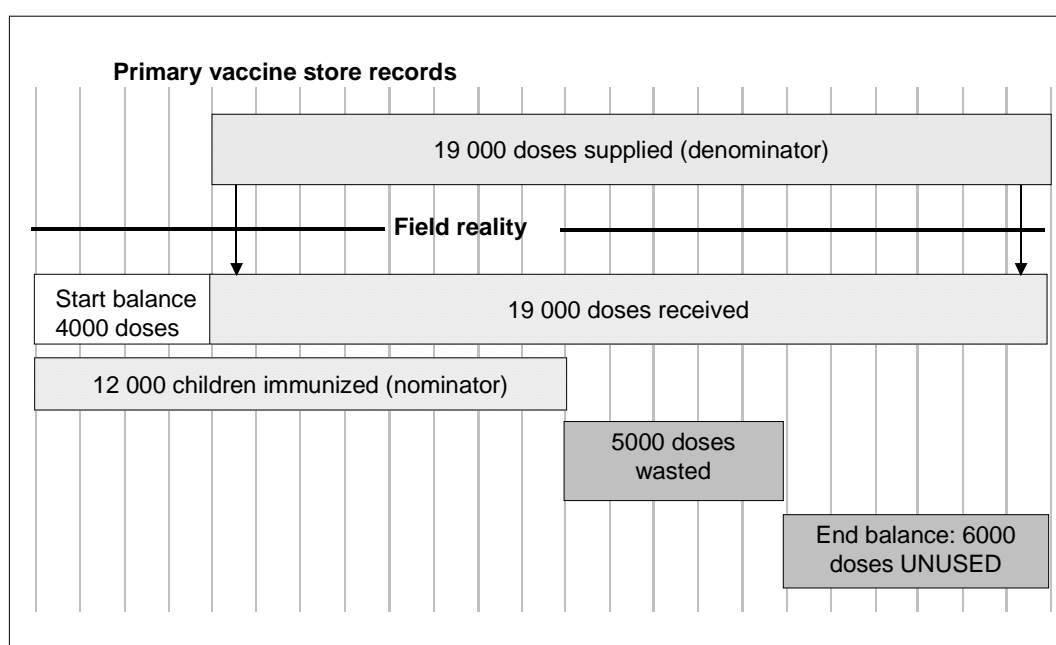
<sup>5</sup> For detailed information on recording losses, refer to WHO-UNICEF Effective Vaccine Store Management Initiative Module 2, Model Quality Plan (WHO/V&B/03.15 Mod2).

been possible with new deliveries received during the calculation period. This calculation can also be very misleading if used for a newly introduced vaccine since in such circumstances there is a zero start balance in the field.

Moreover, the calculation of vaccine wastage annually on a national basis is a “postmortem” exercise and is too late for corrective measures to be taken. In addition, this calculation cannot provide any information on types of wastage, such as would be required for the planning of corrective measures.

The problems associated with the denominator of the above formula can be explained visually (Fig. 2).

Fig. 2. Problems associated with using number of doses issued from primary vaccine store in nationwide vaccine wastage calculation



In Fig. 2 the lightly shaded boxes are included in the national calculation, the white box (start balance in the field) is ignored, and the darkly shaded boxes represent wasted doses.

If each unit represents 1000 doses the use of primary vaccine store figures gives vaccine wastage as 37%, whereas it is really 29%.<sup>6</sup> In cases where a higher start balance is available, especially in regional/district calculations, negative vaccine wastage rates can be calculated from vaccine store figures. One argument that could be brought against this is that the start balance neutralizes the effect of the end balance in the field. This argument is valid only if they are equal, a very unlikely situation. Furthermore, this calculation is more erroneous for vaccine wastage calculations for the first year in respect of vaccines newly introduced into an immunization programme.

<sup>6</sup> No details are given here of the calculation of the 29% wastage rate. The reason for the discrepancy is made clear in Annex 2.

However, this does not mean that nothing should be monitored at the primary level and in intermediate vaccine stores. The best vaccine wastage indicator for vaccine stores is the proportional vaccine wastage in unopened vials.

This can easily be calculated as follows.

$$\text{Proportional vaccine wastage rate in unopened vials} = \frac{\text{Number of doses discarded}}{\text{Start balance} + \text{number of doses received}} \times 100$$

The number of doses discarded includes all discards of unopened vials because of expiry, VVM indication, heat exposure, breakage, freezing, missing inventory and theft. This rate, which is specific for vaccine stores, should not be used for comparison with the vaccine wastage rate explained above. It gives the management performance levels of vaccine stores, since these only handle unopened vaccine vials. Because this category of wastage can be minimized the question arises as to what is the acceptable level for such failures.

Vaccines delivered during the calculation period should not be subtracted from the denominator because, if any quantities of vaccine are damaged during transportation, this wastage is recorded in the sender's vaccine store account.

### 2.3 Vaccine wastage calculations at service level

All immunization points monitor their coverage rates on a monthly basis. Similarly, vaccine usage and wastage should be monitored monthly at all service points. This has to be a self-audit and should be used as a managerial tool as well as for producing new forms and/or tables to submit to higher levels.

The formula given at the beginning of this section can be detailed as follows.

$$\text{Vaccine usage (rate)} = \frac{\text{Number of doses administered}}{\text{Number of doses issued}} \times 100$$

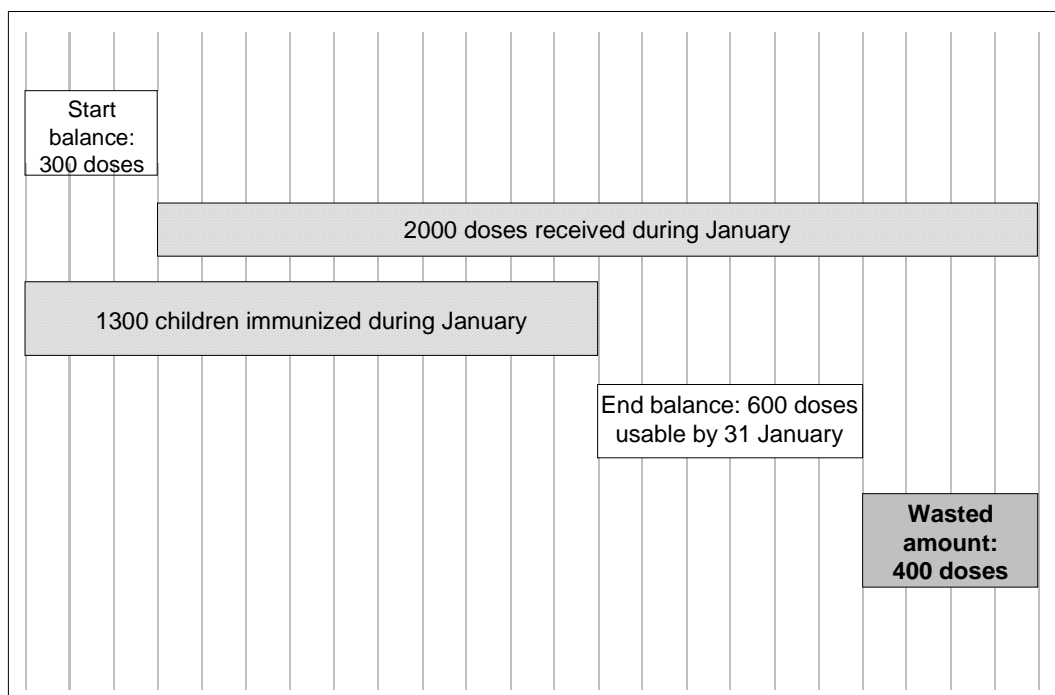
$$\text{Vaccine usage (rate)} = \frac{\text{Number of doses administered}}{\left\{ \begin{array}{l} \text{Number of} \\ \text{usable doses} \\ \text{at beginning of} \\ \text{period} \end{array} \right\} + \left\{ \begin{array}{l} \text{Number of doses} \\ \text{received during} \\ \text{period} \end{array} \right\} - \left\{ \begin{array}{l} \text{Number of} \\ \text{usable doses in} \\ \text{stock at end of} \\ \text{period} \end{array} \right\}} \times 100$$

It is always recommended that calculations are based on numbers of doses rather than on numbers of vials. If numbers of vials are used the calculations are complicated because of variation in the number of doses in a vial.

### Example

Yenice Health Centre received 2000 doses of DTP vaccine in 20-dose vials in January. Monthly reporting indicated that 1300 children were immunized. There was a start balance of 300 doses on 1 January and by 31 January the stock level was 600 doses.

Fig. 3. Calculation of vaccine wastage at service level



On the basis of the above formulas:

$$\text{Vaccine usage rate} = \frac{1300}{300 + 2000 - 600} \times 100 = 76\%$$

$$\text{Vaccine wastage rate} = 100 - 76 = 24\%.$$

The vaccine wastage rate can also be calculated without going through vaccine usage, as follows.

$$\text{Vaccine wastage (rate)} = \frac{\text{Number of doses wasted}}{\text{Number of doses supplied}} \times 100$$

In detail this formula is:

$$\text{Vaccine wastage (rate)} = \frac{\left\{ \begin{array}{l} \text{Number of} \\ \text{usable doses} \\ \text{at beginning} \\ \text{of period} \end{array} \right\} + \left\{ \begin{array}{l} \text{Number of} \\ \text{doses} \\ \text{received} \\ \text{during period} \end{array} \right\} - \left\{ \begin{array}{l} \text{Number of} \\ \text{usable doses} \\ \text{in stock at} \\ \text{end of period} \end{array} \right\} - \left\{ \begin{array}{l} \text{Number of} \\ \text{doses} \\ \text{administered} \end{array} \right\}}{\left\{ \begin{array}{l} \text{Number of} \\ \text{usable doses at} \\ \text{beginning of} \\ \text{period} \end{array} \right\} + \left\{ \begin{array}{l} \text{Number of doses} \\ \text{received during} \\ \text{period} \end{array} \right\} - \left\{ \begin{array}{l} \text{Number of usable} \\ \text{doses in stock at} \\ \text{end of period} \end{array} \right\}} \times 100$$

---

Using the above figures in this formula:

$$\text{Vaccine wastage rate} = \frac{300 + 2000 - 600 - 1300}{300 + 2000 - 600} \times 100 = 24\%$$

In these calculations the vaccine wastage rate includes wastage in both unopened and opened vials. Since discards and losses of unopened vials should always be recorded, a detailed analysis of vaccine wastage is also possible at all service levels. Details of vaccine wastage give programme managers an improved understanding of problems, which can then be addressed. The vital matter is that of reducing vaccine wastage. In order to make a plan for inclusion in the inception reports, as required by GAVI, the sources of wastage have to be revealed. If the reasons for wastage are unknown, plans are bound to be unrealistic and may have a negative impact on immunization coverage.

Details of advanced calculation of vaccine wastage rates are given in Annex 2.

## 2.4 Wastage factor

In vaccine forecasting the vaccine wastage factor is used rather than the rate. The vaccine wastage factor indicates how much additional vaccine should be ordered in order to allow for the given wastage rate.

$$\text{Vaccine wastage factor} = \frac{100}{100 - \text{Vaccine wastage rate}}$$

Since [100 – vaccine wastage rate] equals the vaccine usage rate, the formula can also be written as:

$$\text{Vaccine wastage factor} = \frac{100}{\text{Vaccine usage rate}}$$

For the above example:

$$\text{Vaccine wastage factor} = \frac{100 - 29}{100} = \frac{71}{100} = 1.4$$

This means that 1.4 times more vaccine should be ordered so as to cover the estimated 29% vaccine wastage.

**Vaccine wastage must be calculated at all levels  
on a routine and regular basis.**

Although direct calculation is possible it is always recommended that usage rates be used as a start point in calculating wastage.<sup>7</sup>

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<sup>7</sup> See Annex 2 for other ways of calculating the vaccine wastage factor.

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## 3. What is an acceptable wastage level?

It is not possible to advocate a universally acceptable vaccine wastage level. Acceptable wastage levels vary between programmes in the light of experience and the analysis of local situations. For example, remote services have to open more vials per child than urban services, and as a result higher wastage rates are expected in rural areas.

Similarly, in locations where a great majority of the population can only be reached through outreach services, higher wastage rates are expected. A study of DTP and HepB vaccine wastage was conducted in the Lao People's Democratic Republic in 2001.<sup>8</sup> Villages were grouped according to their distance from a fixed immunization site. Wastage rates were lower in villages that immunization teams could reach on foot or by bicycle or canoe and from which they could return to base the same day than in locations where the teams had to stay overnight. In the Lao People's Democratic Republic, around 38% of the population live in remote areas, corresponding to 53% of villages. It was concluded that higher immunization coverage could only be achieved if higher wastage rates were accepted.

Vaccine wastage rates are not usually plotted against immunization coverage rates. They are evaluated in isolation, making it impossible to see whether they should be considered high, low or reasonable. For example, a DTP wastage rate of 40% may be considered high in a country with 50% immunization coverage but acceptable in a country where more than half the population can only be reached through outreach activities.

It is also important to know the type of vaccine wastage. A high wastage rate attributable to opening a multidose vial for a small session size in order to avoid missed opportunities is more acceptable than wastage attributable to freezing or expiry. However, it should be noted that higher vaccine wastage is expected with freeze-dried vaccines since they must be discarded within six hours of opening, whereas liquid vaccines can be used in subsequent sessions for up to 4 weeks.

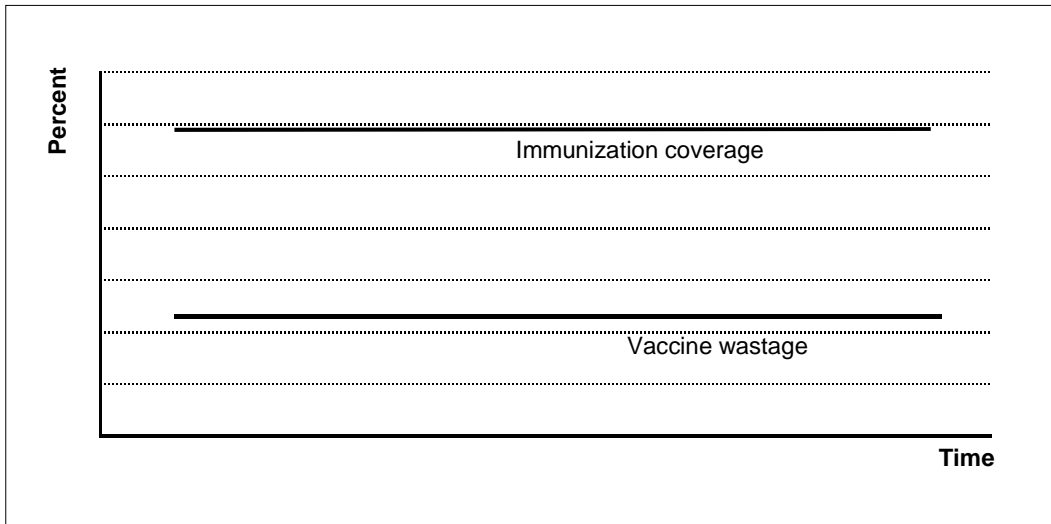
The relationship between vaccine wastage rate and immunization coverage is the key to deciding whether wastage is really high. Both should be analysed over a period of time rather than at a given point in time in order to reveal trends. Figs. 4-9 indicate possible reasons for different trends in vaccine wastage and immunization coverage rates.

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<sup>8</sup> *Richard Duncan, Global Alliance for Vaccines and Immunization support to introduce hepatitis B vaccine, Lao People's Democratic Republic, 26 February to 11 May 2002, MR/2002/0066, WHO WPRO.*

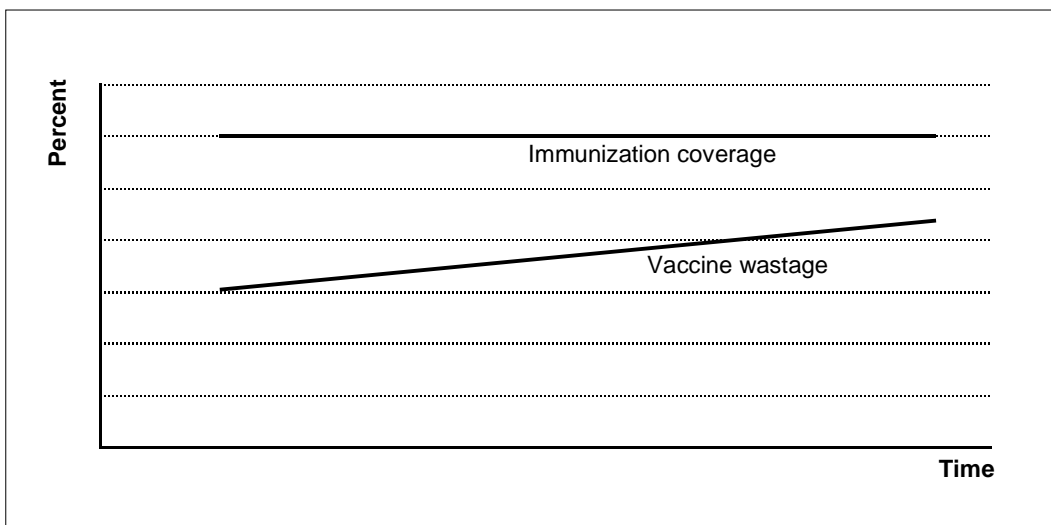
If immunization coverage and vaccine wastage rates follow the same trend (with little fluctuation) in a given period it is essential to know the reasons for the trend in order to understand whether wastage can be reduced (Fig. 4). Reports of the same vaccine wastage without any change in immunization coverage often indicate that wastage is not really understood or analysed but is just repeated over the years. Such situations should be carefully analysed.

Fig. 4. Relationship between vaccine wastage and immunization coverage



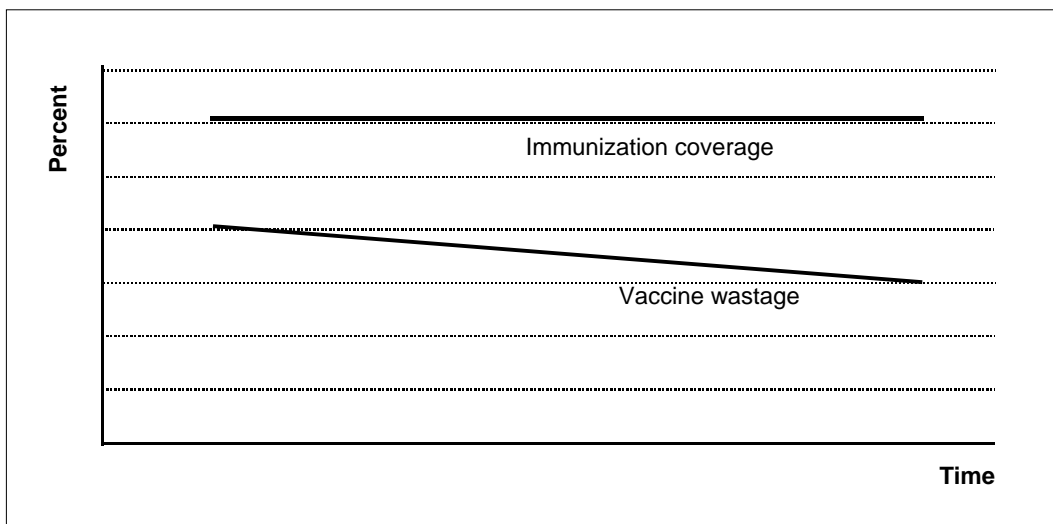
If vaccine wastage increases at a certain point over a period of time while the immunization coverage rate remains the same, potential causes such as expiry or cold chain failure during storage and transportation should be investigated (Fig. 5). Although most wastage can be expected in unopened vials, discards may involve both opened and unopened vials. The fact that immunization coverage remains level indicates that, despite increased wastage, the programme has had enough vaccines to replace these losses. This may also indicate a need to review the vaccine forecast so as to determine if more vaccine than necessary was ordered and received.

Fig. 5. Relationship between vaccine wastage and immunization coverage



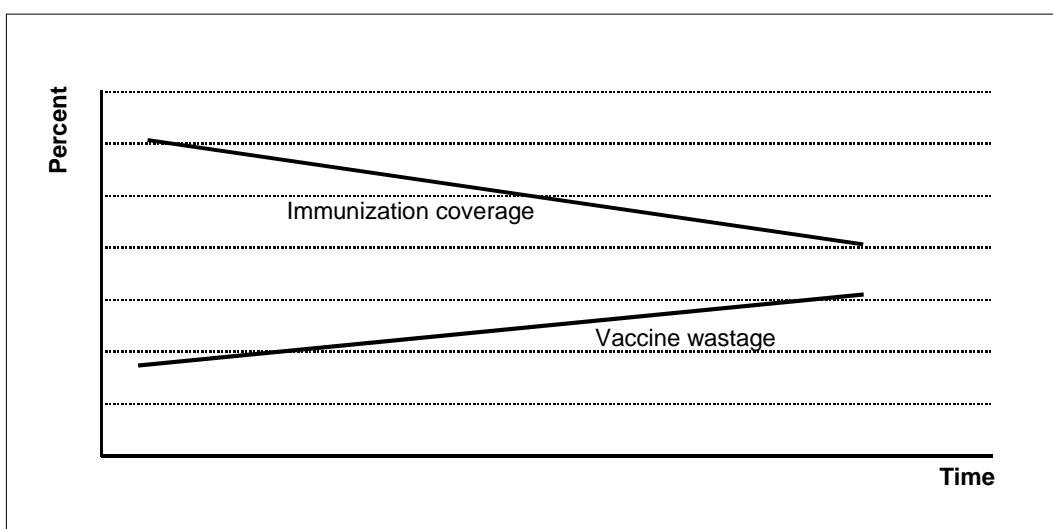
If vaccine coverage remains the same while wastage decreases (Fig. 6), programme managers should investigate the validity of the data and the reasons for the fall in the wastage rate. If an improvement in the effectiveness of vaccine management is responsible, this should be documented and attention should then be concentrated on improving coverage rates.

Fig. 6. Relationship between vaccine wastage and immunization coverage



If the immunization coverage rate decreases while the vaccine wastage rate increases (Fig. 7), vaccine damage in unopened vials is indicated, resulting in losses where the system cannot replace the vaccine. Consequently, planned immunizations cannot be achieved. The problem is most likely to be at the storage level and/or during vaccine transportation. Depending on the type of vaccine, freezing or heat exposure of a bulk quantity may be responsible. The first step in analysing the data should be to rule out expiry discards.

Fig. 7. Relationship between vaccine wastage and immunization coverage

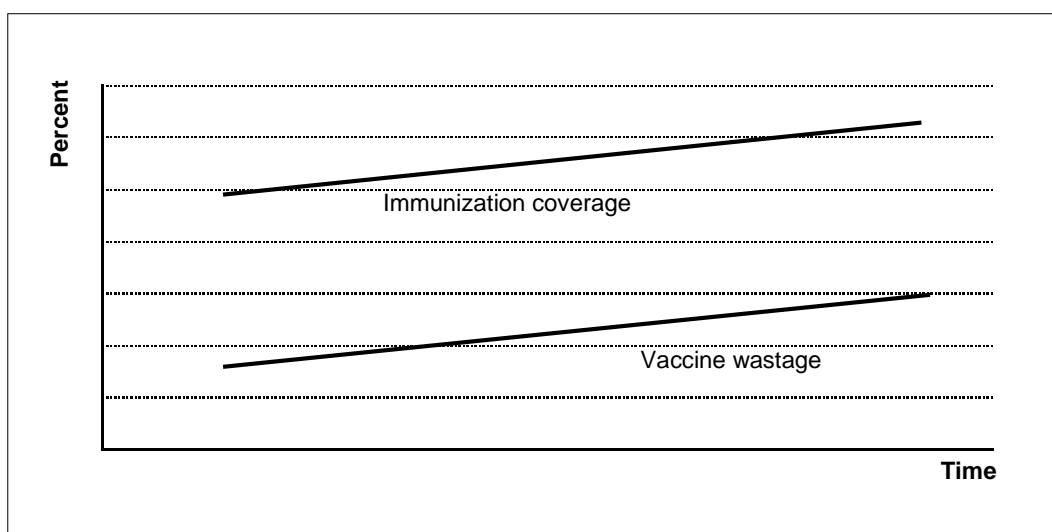


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Fig. 8 illustrates a very typical instance of increased outreach activities resulting in increased immunization coverage and vaccine wastage. Although high vaccine wastage rates are expected in increased outreach activities, the following questions have to be answered in order to determine possible means of keeping vaccine wastage as small as possible:

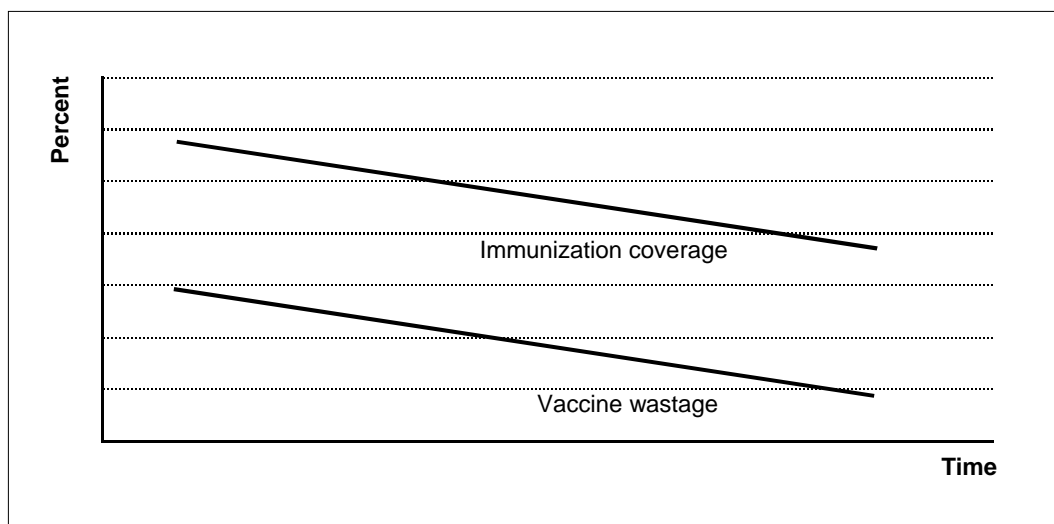
- Is the multidose vial policy practised for liquid vaccines?
- Do health workers take more unopened vials (without VVMs) than they need and discard them if unused on returning to the health centre?
- How well are populations informed about outreach activities (would larger sessions sizes be possible)?

Fig. 8. Relationship between vaccine wastage and immunization coverage



If both rates are decreasing the most likely reason is that the number of immunization sessions has been reduced, resulting in refusals to immunize children attending on non-session days and in missed opportunities (Fig. 9). Reducing the number of outreach activities may have the same effect. No matter what the reasons, the situation must be studied in detail in order to understand whether the approach to reducing vaccine wastage causes a similar decrease in immunization coverage. A successful initiative to reduce vaccine wastage should not result in a reduction in immunization coverage.

Fig. 9. Relationship between vaccine wastage and immunization coverage



In reality these situations may not appear as isolated cases. More often a combination of many factors is involved. Any unusual relationship between immunization coverage and vaccine wastage should be analysed.

As mentioned earlier, vaccine wastage in unopened vials is unacceptable and should be minimized. The WHO–UNICEF Effective Vaccine Store Management (EVSM) initiative on improving vaccine management practices in primary and intermediate vaccine stores involves the calculation of proportional vaccine wastage in unopened vials in vaccine storage facilities and considers 1% wastage to be acceptable.<sup>9</sup> Among the reasons for wastage in unopened vials, only accidental breakage and missing inventories are considered unavoidable. Bad management is a primary cause of unopened vials being discarded because of expiry and heat exposure and freezing in the cold chain. It is essential to minimize these factors.

Expiry is only acceptable in emergency operations where vaccines are positioned in certain locations because of the possibility, for example, of war spreading to a particular region and displacing people. Although such circumstances are regularly reviewed the amount of vaccine being kept in case the possibility turns into reality may eventually prove to be more than the programme in question can absorb. Such operations should work out mechanisms for rotating vaccines so as to keep maximum shelf-life available in conflict situations.

The relationships between immunization coverage and vaccine wastage are summarized in Table 2.

<sup>9</sup> WHO–UNICEF Effective Vaccine Store Management Initiative, Module 2, Model Quality Plan (WHO/V&B/03.15 Mod2).

**Table 2. Problematic time trend relationships between immunization coverage and vaccine wastage**

<b>Immunization coverage</b>	<b>Vaccine wastage</b>	<b>Where to focus</b>
Same	Same	Types of vaccine wastage should be analysed in order to determine whether new tools could be introduced to reduce wastage.
Same	Increasing	Focus on the storage and transportation of vaccines, because increasing wastage while coverage remains the same indicates wastage in unopened vials.  If the increase is too high, vaccine forecasts should be reviewed so as to understand whether too much vaccine is being ordered.
Same	Decreasing	Validation of the data is the first step. Since wastage is decreasing, special attention should be given to determining how to increase immunization coverage.
Decreasing	Increasing	Vaccine damage occurs in unopened vials. Consequently, losses occur where the system cannot replace the vaccines and therefore planned immunizations cannot be achieved. The problem is likely to be found at the storage level and/or during vaccine transportation (either freezing or heat damage). The first step in analysing the data should be to rule out expiry discards.
Decreasing	Decreasing	The possibility has to be considered that measures used to reduce wastage contribute to decreased immunization coverage. Likely reasons are a reduced number of immunization sessions and a refusal to give immunization where this would require multidose vials to be opened, in order to prevent high wastage.
Increasing	Increasing	This circumstance may arise because of increased outreach activity. The implementation of the multidose vial policy (MDVP), effective VVM use and the organization of sessions during outreach activities should be examined in order to determine whether vaccine wastage can be reduced.

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# 4. Monitoring vaccine wastage at sentinel sites

## 4.1 Monitoring vaccine wastage in health care facilities

As discussed in Chapter 3, all immunization points should monitor their vaccine wastage rates as they monitor their immunization coverage. However, compiling such information for an entire country may not be considered manageable. This depends on whether the flow of information in the country concerned is satisfactory.

One option is to use representative sentinel reporting sites. The procedure for defining such sites is described in Annex 3.

## 4.2 Sample forms for reporting from sentinel sites

Sentinel sites should report directly to the director of the national immunization programme or to a unit designated to compile the reports. Reporting should take place monthly throughout the year. The national immunization programme may request additional information to be included in the reports. However, data should not be requested if they are not going to be processed and used.

Table 3 provides a generic sample data reporting form for monitoring vaccine wastage.

**Table 3. Sentinel site vaccine wastage reporting form  
for service level (sample)<sup>10</sup>**

Vaccine wastage for		[enter type of vaccine here]		
Name of health facility		Reporting period	Month .....	Year .....
Region	Province	District		
Target population for month				

Date	Start balance	Number of doses received	Number of doses discarded (unopened)	Number of doses opened for use	Number of children immunized	End balance
	A	B	C	D	E	F
						(A + B) – (C + D)
1 Sept 02	500	1000	160	740	640	600
2 Sept 02	600			120	90	480
3 Sept 02	480					480
	480					480
<b>TOTAL</b>	500	∑ (column B)	∑ (column C)	∑ (column D)	∑ (column E)	From TOTAL row: (A + B) – (C + D)

Rate	Formula	Monthly result
Vaccine usage rate (H)	$(E \times 100)/(A + B - F)$	
Vaccine wastage rate (I)	$100 - H$	
Immunization coverage rate <sup>11</sup>	$(E \times 100)/\text{target population for month}$	

<sup>10</sup> The same form is presented in Annex 3 with detailed/advanced additional calculations indicating different types of vaccine wastage. The contents of Table 3 should be considered as the minimum required.

<sup>11</sup> For vaccines given in more than 1 dose (i.e.. DTP in 3 doses), vaccine wastage calculations are affected by wastage occurring in all doses whereas the coverage rate (DTP1, DTP2 and DTP3) will only reflect the completed immunization rate (DTP3). Ideally, in these situations, vaccine wastage should be analysed against the immunization performance rate, calculated as the sum of [(children immunized with DTP1 + DTP2 + DTP3)\*100/(target group for DTP1 + DTP2 + DTP3)]. For practical reasons the target group can also be multiplied by the number of doses given for a particular vaccine. In the case of DTP, column E includes all children who receive the first, second and third doses of DTP. In coverage calculations, therefore, the target group should be multiplied by 3.

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### 4.3 Monitoring vaccine wastage in vaccine storage facilities

Vaccine storage facilities should be included in the regular monitoring of vaccine wastage. All vaccine storage facilities in selected regions of a country should be included in addition to 10 health care facilities selected by the above mentioned methodology. If there are more than 10 vaccine storage facilities in a selected region, random or systematic sampling should be used to identify 10 sentinel vaccine storage facilities for routine reporting.

Table 4 provides a generic sample data reporting form for monitoring vaccine wastage in vaccine storage facilities.

Table 4. Vaccine wastage monitoring form for sentinel site storage facilities (sample)

Vaccine wastage for		[enter type of vaccine here]	
Name of vaccine store		Reporting period	Month .....
			Year .....
Region		Province	District

Start balance	Number of doses received	Number of doses distributed	Number of doses discarded because of:					Total number of doses discarded	End balance	Proportional wastage rate (specific ONLY to stores)	
			Expiry	VVM indication	Heat exposure	Freezing	Breakage				Missing inventory
A	B	C	D	E	F	G	H	I	J	K	L
									$\Sigma (D+...+I)$	$(A + B) - (C + J)$	$(J \times 100)/(A + B)$

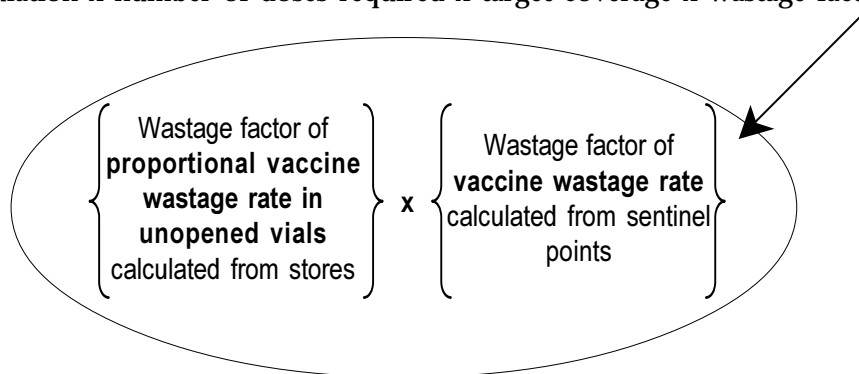
\* If vaccines are damaged during distribution and discarded, this should be entered as WASTAGE in the sending store account.

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## 5. Incorporating vaccine wastage rates in estimates of vaccine needs

Since vaccine wastage is calculated at two different settings (vaccine stores and service level), both results should be used in estimating vaccine needs. Vaccine wastage rates calculated from vaccine store records and health centres cannot be combined since they measure and mean different things (note that the denominators of the two formulas are not the same). This manual does not explain how to estimate vaccine needs by means of different formulas. The most direct and most commonly used formula is given as an example below. Both vaccine wastage rates must be included as translated into a wastage factor in the formula.

Target population x number of doses required x target coverage x wastage factor



For example, if the proportional vaccine wastage rate from vaccine stores is calculated to be 5% and the vaccine wastage rate from sentinel points is 23%, the first requirement is for these to be converted into wastage factors.

$$\text{Wastage factor for proportional vaccine wastage rate} = \frac{100}{100 - 5} = \frac{100}{95} = 1.05$$

$$\text{Wastage factor for vaccine wastage rate} = \frac{100}{100 - 23} = \frac{100}{77} = 1.29$$

In this case the wastage factor to be included in the formula is:

$$1.05 \times 1.29 = 1.35$$

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The wastage rates cannot be merged. If they were, the total wastage rate would be  $5\% + 23\% = 28\%$ , giving a wastage factor of 1.39, whereas the above formula only gives a wastage factor of 1.35. Some readers may consider this difference to be small, as for HepB vaccine the difference for a 500 000 birth cohort would only be 48 000 doses, translating into US\$ 24 000 if the vaccine were in a 10-dose presentation.

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## 6. Factors affecting vaccine wastage

Many factors contribute to vaccine wastage, ranging from the vaccine to the vaccinator. They are not independent of each other. The presence of one factor may trigger the appearance of another.

Factors affecting vaccine wastage can be categorized in different ways. No matter how they are categorized, wastage in unopened vials is avoidable and should be treated as unacceptable.

Vaccine wastage is believed to be higher at the service level than elsewhere. In many countries, however, vaccine wastage in unopened vials is quite high in vaccine stores. One reason is that vaccine stores keep large quantities of vaccines, and if something goes wrong the whole amount is at risk of being damaged and therefore discarded. It is important that cold stores track wastage within their terms as explained in section 2.2.

### 6.1 Factors related to vaccines and syringes

#### *Vial size*

More wastage is reported with the larger vial sizes unless they are used in mass immunization activities. Different vial sizes allow immunization managers to choose the best presentation for the purposes of specific programmes. Smaller vials cost more than larger ones containing the same vaccine, resulting in a higher cost per immunized child. Moreover, smaller vials require greater cold chain and vaccine transportation capacity than larger ones.

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### Fears of meningitis vaccine wastage

*By Alan MacDermid, Herald News, 22 September 1999*

Health chiefs have mounted a search for small-scale stocks of meningitis vaccine after fears that some of the supply being gathered for Scottish students could end up down the sink.

A large proportion of the meningitis C vaccine intended to protect the 85 000 students enrolling in universities and colleges comes in 50-unit vials.

There is not yet enough of the new conjugate vaccine, which protects indefinitely, to go round all those eligible, and the existing vaccine is being offered to students as a stopgap.

It protects for only 5 to 10 years and is normally used to immunize large numbers where an outbreak has already been identified.

Dr Harry Burns, Director of Public Health for Greater Glasgow Health Board, said, "If you are a GP with a 50-dose vial and you have only three students to vaccinate, there is the potential for a lot of waste".

A Scottish Executive spokesman said, "The vaccine is made in smaller quantities than 50 and we are trying to source these. All the evidence is that we will have 90 000 units available by November, which will be enough to cope".

### *Dead space in syringes*

All syringes have a dead space and WHO defines the maximum allowable dead space for different types of syringes. For the 0.5-ml auto-disable (AD) syringe the maximum allowable dead space is 50 microlitres.<sup>12</sup> In the case of 0.05-ml AD syringe, the maximum allowable dead space is 25 microlitres.<sup>13</sup> Vaccine manufacturers are expected to overfill vials so as to compensate for vaccine wastage attributable to dead space in syringes and therefore to ensure that the number of doses indicated on the label can be drawn from the vial.

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<sup>12</sup> 0.5-ml auto-disable syringe, product specification E8/DS1, 1 October 1999.

<sup>13</sup> 0.05-ml auto-disable syringe, product specification E8/DS.2, 1 January 1998.

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For example, two-dose DTPw–HepB + freeze-dried Hib from GSK is overfilled by 0.3 ml to compensate for the following losses<sup>14</sup>:

- loss in DTPw–HepB vial (remaining liquid) : 0.05 ml up to 0.1 ml;
- loss in needle lumen to reconstitute Hib : +/- 0.05 ml;
- loss in vial with reconstituted Hib (remaining liquid) : +/- 0.05 ml;
- loss in lumen of needle for injection : +/- 0.05 ml;
- loss during de-airing of syringe before injection : +/- 0.05 ml.

Failure to use syringes of assured quality meeting WHO standards may increase wastage if the syringes have a larger dead space.

## 6.2 Factors related to national policy

### *Procurement practices*

Poor vaccine forecasting may result in increased vaccine wastage. Countries may receive more vaccines than are needed annually, leading to the expiry of vaccines before they can be used. Another possibility is that countries may receive correct quantities overall but have insufficient cold chain capacity to accommodate deliveries, with the result that vaccines are at risk of exposure to adverse temperatures.

The choice of a wrong vial size for procurement may also contribute to increased vaccine wastage if there is not enough cold chain capacity.

### *Coordination of donor efforts*

Countries may appeal to several donors with the same request or some donors may have special interest in some countries and particular programmes. If these efforts are not coordinated, countries may end up receiving more vaccines than their programmes can use or maintain in the cold chain.

### *Vaccine vial monitor (VVM) introduction*

VVMs were first used with OPV during 1996. They have now been delivered with more than 1.5 billion doses of OPV to more than 80 countries. Starting in 2001, VVMs were included as product specifications through tenders by UNICEF for all other EPI vaccines. GAVI also requires the use of VVMs with vaccines. VVMs cannot be properly used if health workers are not trained in good time. A failure to identify health workers who need refresher training on VVM use may also result in the incorrect use of VVMs and some increase in vaccine wastage.

### *VVM in tender requirements*

If countries procure their own vaccines and do not include VVMs as a tender requirement, immunization programmes cannot benefit from this wastage reduction tool. It is now routine practice to discard vaccines without VVMs if exposure to heat caused by cold chain failures has occurred.

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<sup>14</sup> Personal communication, Paul Tollet, GSK.

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### *Discarding of doses remaining in opened vials at end of day*

Countries that have not adopted MDVP have greater wastage rates for liquid vaccines. However, where sterilizable syringes are used or other sources of contamination of opened vials are not under control, countries may have difficulties in adopting MDVP nationwide.

## 6.3 Factors related to logistics

### *Stock control*

Good stock control practices require vital information on vaccines to be recorded when they are received, during storage and when they are leaving the store for distribution. If expiry dates are not recorded and followed up properly, storekeepers may dispatch a batch that expires later than the ones kept at the store. This is called non-compliance with the earliest-expiry-first-out (EEFO) principle.<sup>15</sup> When vaccines are received at the store, the status of time-temperature indicators such as VVMs should be checked and recorded. During storage the storage temperatures should be monitored and any changes in time-temperature indicators should be recorded. The only exception to the EEFO principle involves the earlier release of vaccine vials with VVMs showing more heat exposure (approaching the discard point) than vaccine vials with earlier expiry dates but with VVMs showing less heat exposure.

### *Alternative cold chain*

An alternative cold chain, especially at national level, may be of value in countries having excess vaccine for whatever reason. In the case of non-availability a push-down distribution approach mostly results in vaccines from the primary vaccine store being sent to the intermediate stores and therefore to immunization points without a check being made as to whether the cold chain capacity can really absorb them. This puts the vaccines at risk of expiry or of being exposed to improper temperatures because of a lack of adequate storage capacity. Alternative cold chain capacity is also of value in emergency situations, e.g. the flooding of stores.

An assessment conducted in an African country in March 2002 revealed the presence of a 57-month worth stock of DTP and a 59-month worth stock of measles vaccine (expiring in June 2002) in one health facility.

### *Quality and management of cold chain*

Cold chain equipment that is not compatible with WHO-UNICEF product information sheets (PIS) cannot ensure the storage temperatures required for different types of vaccines. Moreover, if not well maintained, PIS-compatible equipment may malfunction and may put vaccines at risk of exposure to unacceptable temperatures.

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<sup>15</sup> *EEFO handling is safer than first-in-first-out (FIFO) handling. In general when two batches of vaccine are delivered at different times, the one arriving second will have a later expiry date. However, this is not always the case, particularly when vaccines are obtained from different sources.*

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Ice-lined refrigerators provide a good example of this problem. Longer hold-over times in an ice-lined refrigerator than in other models are possible because the inside of the cabinet is lined with water-filled tubes or ice packs. This water stays frozen as long as electricity is available. When the supply fails, the ice gradually melts and keeps the cabinet cool. However, when the electricity supply is restored, the compressor has to operate extensively in order to freeze the water lining again within a limited number of hours, and, occasionally, the temperature in the vaccine storage area at the base of the appliance falls below 0°C. Freeze-sensitive vaccines should NOT, therefore, be stored within 20 cm of the base of these models. Some models have a mark inside the cabinet which indicates areas potentially dangerous for the storage of such vaccines.

Similarly, if not managed well, freeze-sensitive vaccines may become frozen in cold rooms at +2°C to +8°C. In these cold rooms the evaporator coil temperature is around -5°C and the temperature of the outlet air may be below 0°C. As a result there is a risk that freeze-sensitive vaccines will be destroyed if they are stored too close to the evaporator outlet.

### *Temperature monitoring*

If the temperature in cold chain equipment for storing vaccines is not monitored and controlled regularly, vaccines may be at risk of exposure to unacceptable temperatures, resulting in wastage. Experience shows that the national cold store is the most critical element of an immunization system because this is where vaccines are received, stored and distributed in bulk. When there is an equipment or management failure at the primary level, large quantities of vaccine may be destroyed in a matter of a few hours. The immunization services of an entire country may thus be placed at risk and the financial loss can reach millions of dollars.

### *Vaccine distribution and transportation practices*

If correct practices are not followed during transportation, vaccines may be damaged by exposure to excessive heat or to freezing temperatures. When this happens there is increased vaccine wastage and supplies may become inadequate.

Not observing the EEFO principle during deliveries may also result in locations receiving vaccines with a short shelf-life which cannot be consumed in the time available.

If a programme does not allow a two-way distribution system<sup>16</sup> whenever necessary, excess vaccines at lower levels will be left to be either expired or damaged and therefore discarded.

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<sup>16</sup> A two-way distribution system allows excess unopened vials of vaccine to be sent back up the chain for redistribution. Such a system can only be used if managers are confident that excess vaccine at lower levels is kept under recommended storage conditions. In this regard, using and recording the status of time-temperature indicators in stock records is vital.

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### *Reading and/or using VVM status*

If storekeepers do not know how to read and interpret VVMs and make informed choices in distribution they may put vaccines at risk. For example, if vaccine vials with VVMs showing comparatively low heat exposure are sent out before vaccine vials with VVMs approaching the discard point, the vaccines kept in store will be at risk of reaching their discard point during storage. Also, if health workers do not pay attention to VVMs or do not know how to read them, they may unnecessarily discard unopened vials after an outreach session or cold chain failure rather than using the VVMs in order to determine which vials to keep.

### *Communication and supervision*

In cases where global policies to reduce vaccine wastage are adopted at national level, good communication down to service level and effective supervision are needed to ensure that the policies are translated into local action. A lack of effective communication and supervision causes policies to remain on paper only.

## 6.4 Factors related to immunization practice<sup>17</sup>

### *Liquid vaccines discarded at end of session (or before four weeks)*

If multidose vials of liquid vaccine presentations are not kept for subsequent sessions (up to four weeks) and are thrown away at the end of a session, vaccine wastage rates are reported to be high.

### *Reconstitution practices*

If the whole content of diluent is not used to reconstitute powder vaccine, fewer doses are available in the vaccine vial for vaccination. Moreover, vaccines reconstituted with the wrong volume of diluent are likely to cause adverse events following immunization.<sup>18</sup>

### *Cold chain failures*

Cold chain failures may expose vaccines to high temperatures if storekeepers and/or health workers do not know what to do in such cases.

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<sup>17</sup> Vaccine requirements are calculated on the basis of target age groups. The use of a vaccine outside the target group is considered to represent wastage. All programmes are required to report children immunized in the target groups. In theory, children immunized outside target age groups should not be included in this reporting. The wastage attributable to this factor is not discussed further in this manual.

<sup>18</sup> Vaccine and Biologicals Update: Vaccine reconstitution, WHO, Vol. 34, December 2000.

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### *Session size*

Small session size increases wastage if larger dose presentations are used. However, the opening of a new vial, even for one child, in order to avoid a missed opportunity, is always a promoted practice and should not be considered undesirable.<sup>19</sup> The golden rule should be to avoid compromising vaccination coverage. However, the way in which the problem of small session size is tackled can differ between outreach activities and fixed-site immunization points.

### *Injection practices (contamination)*

Poor injection practices may cause contamination of vaccine vials. If a health worker suspects contamination he or she should not use the vial in question and should discard it. This results in increased wastage. If opened multidose vials are submerged in water they are considered to be contaminated and must be discarded. Submerging frequently occurs if crushed ice or ice cubes are used in cold boxes for transporting vaccines.

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<sup>19</sup> *The opportunity cost of contact with an infant always has higher value than the vaccine cost. Therefore, it is always recommended to open a vial of vaccine for one infant or a small number of infants.*

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# 7. Tools available for reducing vaccine wastage

None of the tools<sup>20</sup> listed below is a panacea for reducing vaccine wastage. One tool may become more effective in reducing wastage if combined with other appropriate tools. Whatever tool is used, there is only one output control indicator that should NOT be negatively affected: vaccination coverage. This has to be borne in mind when appropriate tools are being selected.

## 7.1 Changing the vial size

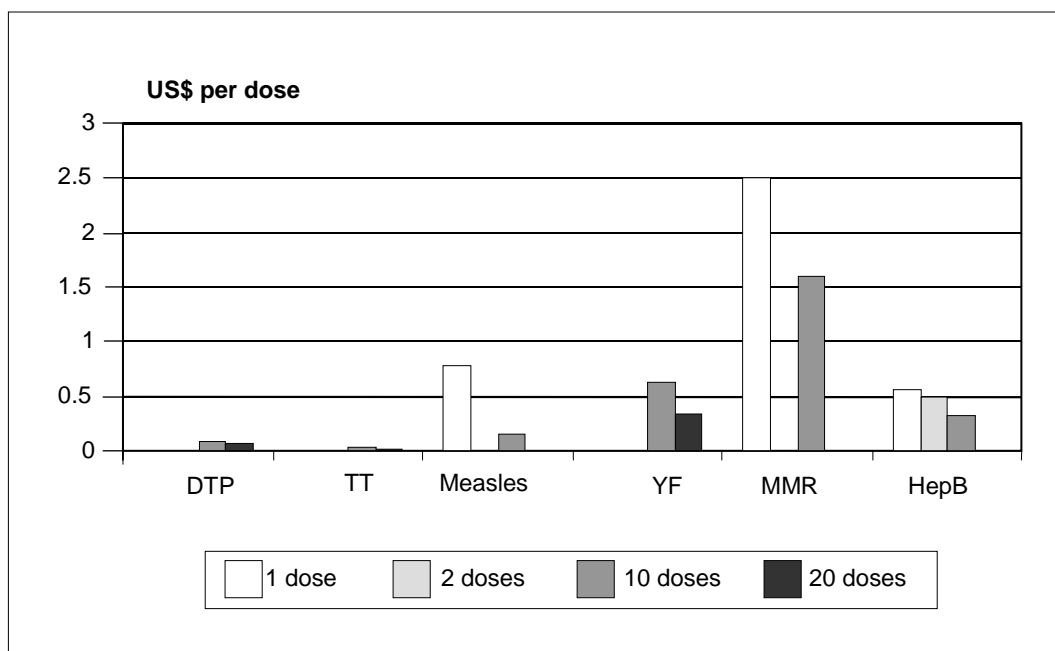
Naturally, the use of smaller vaccine presentations results in less vaccine wastage. GAVI requires countries to target 15% vaccine wastage with multidose vials while only 5% is permitted for two-dose presentations. However, the decision to change the vial size for smaller presentations is not easy, as many other factors have to be considered.

In some presentations there are not large differences in respect of the price per dose and the required storage volume. For example the costs per dose for 20-dose and 10-dose DTP vaccine are US\$ 0.034 and \$0.063 respectively. The 20-dose presentation requires 2.5 cm<sup>3</sup> of cold storage volume per dose and the 10-dose presentation requires 3.0 cm<sup>3</sup>. Several examples of vaccine prices are given in Fig. 10.

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<sup>20</sup> *Tools include technological solutions as well as policies and practices.*

Fig. 10. Weighted average price per dose, 2002 prices, UNICEF Supply Division



The storage volume per dose of vaccine also varies. It is determined by the type of vaccine, the number of doses per vial or ampoule, the physical size of the vial or ampoule and the bulkiness of the external packaging. Donor-dependent countries should ensure that a safe worst-case figure is obtained for each antigen. This is because the manufacturer of a vaccine may not be known until a shipment arrives.

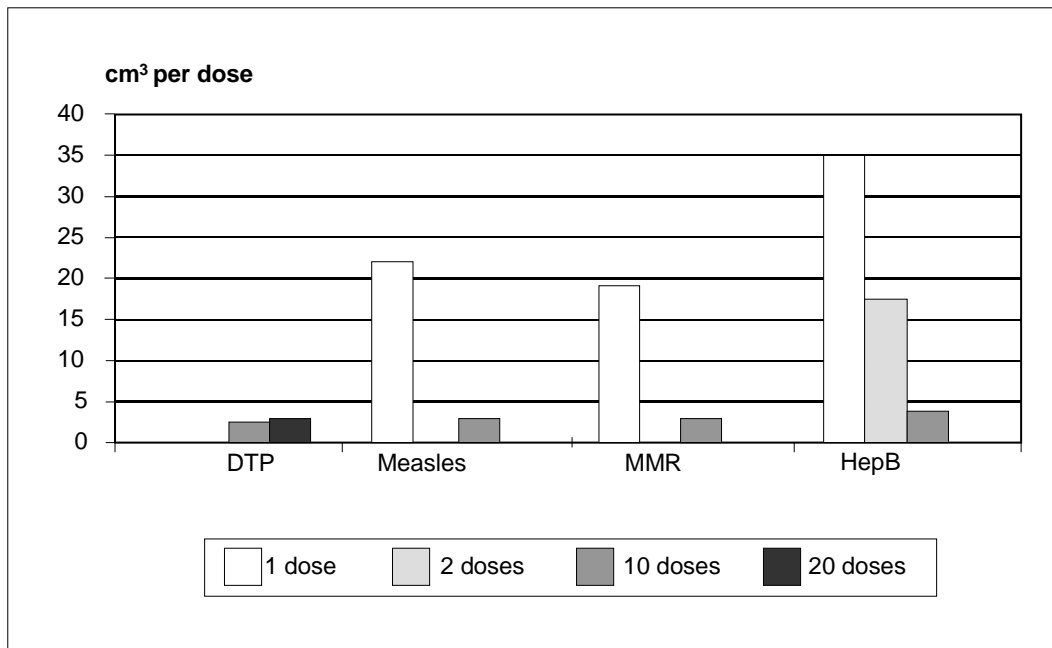
Two of the most reliable sources of information on vaccine volumes are: the *Guidelines on the international packaging and shipping of vaccines* (WHO/V&B/01.05), Geneva, WHO, 2001; and the *Vaccine volume calculator* (WHO/V&B/01.27).<sup>21</sup>

In countries where vaccines are purchased directly from the national budget, figures should either be based on data obtained from all the manufacturers who regularly supply vaccines or from the latest version of the WHO *Vaccine volume calculator*.

A comparison of volume requirements is given in Fig. 11.

<sup>21</sup> 'Guidelines on the international packaging and shipping of vaccines' can be downloaded from: <http://www.who.int/vaccines-documents/DocsPDF99/www9942.pdf>  
'Vaccine volume calculator' can be downloaded from:  
<http://www.who.int/vaccines-documents/DocsPDF01/www586.pdf> (Memo) and  
<http://www.who.int/vaccines-documents/excel/www586.xls> .

Fig. 11. WHO-recommended maximum packed volumes per dose<sup>22</sup>



Deciding on the best size of a freeze-dried vaccine presentation is more complicated than for a liquid vaccine. World manufacturing capacity is not sufficient to provide all vaccines in single-dose form. Global freeze-drying capacity is already almost saturated. Thus, for example, single-dose MMR vaccine would cut global capacity 30-fold as compared with multidose measles vaccine. Therefore, the decision to change to single-dose presentations should not be made without consideration of global needs, which can be verified through WHO's Vaccines and Biologicals Department.

BCG is one of the freeze-dried vaccines for which many countries report quite high wastage rates. In 2001, UNICEF conducted a review of the cost-effectiveness of changing from a 20-dose vial to a 10-dose vial. The information that UNICEF received from BCG vaccine manufacturers indicated that making this change was not a viable option for both economic and technical reasons.<sup>23</sup> The price given by BCG vaccine manufacturers for a 10-dose vial is only 2% to 8% lower than that of a 20-dose vial. Consequently, the price saving is not offset by the savings attributable to the reduction of wastage. The small price difference between the two vial sizes largely arises because key production economies are based on the number of vials produced rather than on the number of doses (including, the price of the special glass for ampoules/vials, production and lyophilization lines are based on ampoule/vial quantities rather than doses). Therefore, it is more economical to waste vaccine than to reduce the vial size. In addition, according to the BCG vaccine manufacturers supplying UNICEF, the potency and the stability of the vaccine are likely to be affected by the reduced quantity of vaccine in each ampoule/vial to be diluted. Furthermore, the manufacturers claim that it would be very difficult to fill the correct amount of vaccine for a 10-dose vial because of the very limited volume of freeze-dried vaccine involved.

<sup>22</sup> Packed volume includes the vaccine vial, the packet containing the vaccine vial and any intermediate packaging.

<sup>23</sup> TechNet21 e-Forum. Post00478E. Vaccine wastage, 23 July 2002.

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The mixing of different vial sizes in the same programme should be avoided except in the case of supplementary immunization activities. Such mixing creates additional logistical difficulties.

## 7.2 Vaccine vial monitor

Vaccines exhibit no visible change with heat exposure. Before the development of the VVM, health workers had no means of identifying whether vaccine had suffered damage from heat exposure at any point during transportation and/or storage. National recommendations for vaccine handling have consequently been very conservative in order to prevent the use of vaccines damaged by heat. Health workers were trained to discard all vaccines after breaks or suspected breaks in the cold chain. If a health centre refrigerator malfunctions overnight, the vaccine is thrown away as soon as the problem is discovered. In some places, health workers are instructed to discard all vaccine that has been taken to the field twice without being used, even if no heat exposure has occurred. Such precautions against possible heat damage result in large amounts of usable vaccine being discarded.

The VVM can change this situation. Its gradual and irreversible colour change makes it possible to assess cumulative heat exposure and the remaining shelf-life of vaccines, even with vials which have been out of the cold chain or stored in a malfunctioning refrigerator.

WHO recommends that VVMs be used in order to:

- ensure that administered vaccine has not been damaged by heat;
- reduce vaccine wastage;<sup>24</sup>
- facilitate immunization outreach, increase access and consequently increase immunization coverage;
- pinpoint cold chain problems;
- manage vaccine stocks.

VVMs are time-temperature-sensitive labels attached to vaccine vials.<sup>25</sup> Through a gradual and irreversible colour change the VVM warns health workers that a vaccine has been degraded by unacceptable exposure to heat and that it should be discarded. The colour change is related to the stability curve of the vaccine concerned. Once the colour change is complete the vial should no longer be used.

In addition, changes in the appearance of a VVM before this limit is reached serve to guide health workers to use the most exposed vials of vaccine first. It should be noted that VVMs do not directly measure vaccine potency but give information about the main factor affecting potency, i.e. heat exposure over a period of time. The VVM does not register information about freezing factors that may contribute to vaccine degradation.

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<sup>24</sup> *In some cases, VVM introduction may initially increase wastage. VVMs may lead to discards as they expose weaknesses in the cold chain that were unseen before VVM introduction.*

<sup>25</sup> *Quality of the cold chain: WHO-UNICEF policy statement on the use of vaccine vial monitors in immunization services. WHO/V&B/99.18.*

There are four different types of VVM designed for different types of vaccine, depending on their heat stability (Table 5).

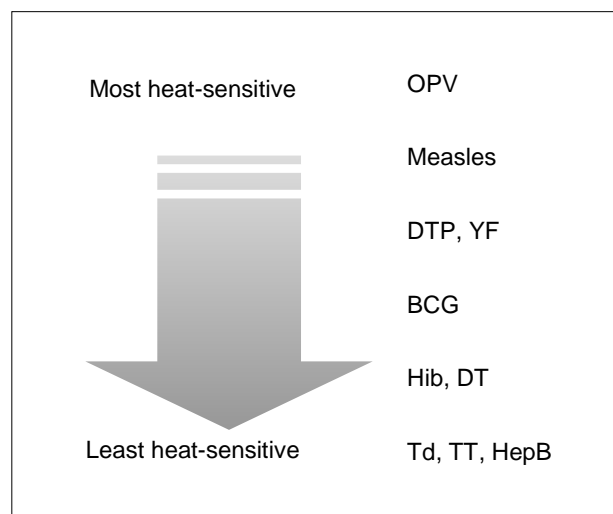
Table 5. VVM reaction rates by category of heat stability

Category (Vaccine stability)	Days to end-point at +37°C	Days to end-point at +25°C	Time to end-point +5°C
VVM30 (High stability)	30	193	> 4 years
VVM14 (Medium stability)	14	90	> 3 years
VVM7 (Moderate stability)	7	45	> 2 years
VVM2 (Least stable)	2	NA*	225 days

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

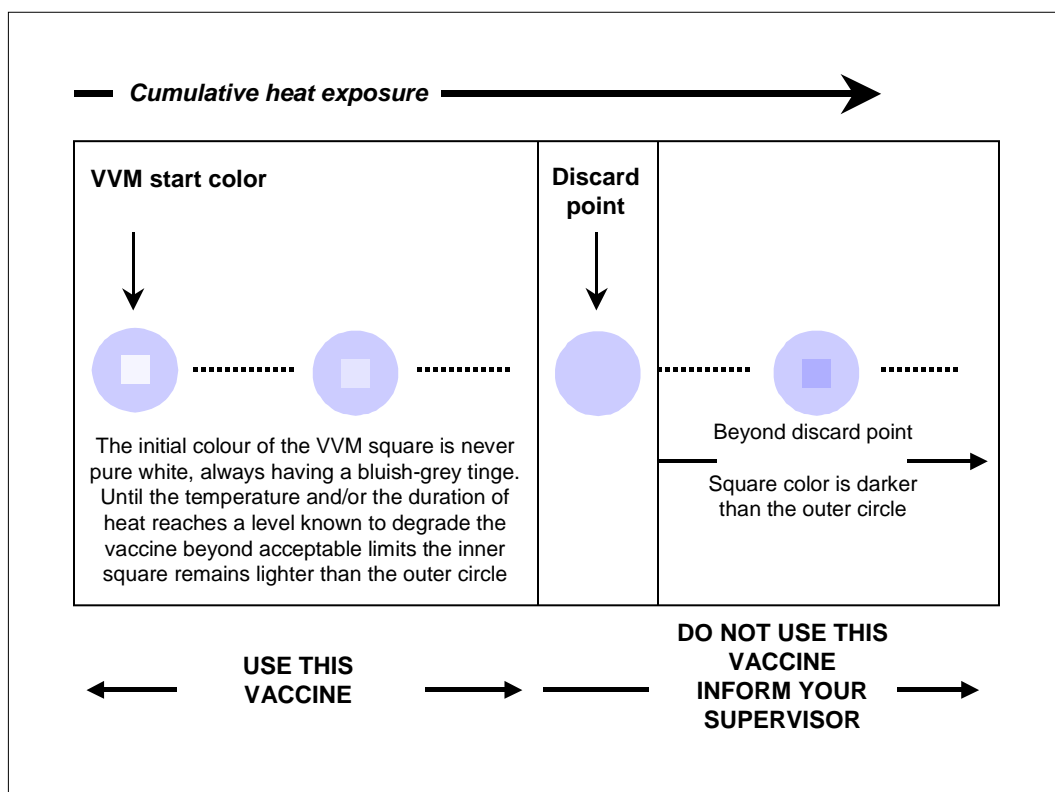
The commonly used EPI vaccines can be ranked according to their sensitivity to heat (Fig. 12).

Fig. 12. Heat stability of vaccines



Depending on the categories into which they fall, VVMs reach their end-points after different intervals. Thus, for example, VVM2 on OPV (the most heat-sensitive vaccine) reaches its end-point in 48 hours at 37°C, whereas VVM30 on HepB (one of the most heat-stable vaccines) takes 30 days to reach its end-point at this temperature.

Fig. 13. How to read a VVM



The first polio NIDs in southern Sudan took place between 16 and 21 February 1998. For the first round, 650 000 doses were distributed. About 400 000 were used; 16 000 were returned to the Lokichokio primary store, of which 1370 showed some heat exposure and none were past the discard point.<sup>26</sup> The same exercise without VVMs would have resulted in discarding all unused vaccines taken to outreach. Turkey documented a dramatic VVM impact both on unopened and opened OPV vials during NIDs in 1997.<sup>27</sup> Wastage reduction in unopened vials was reported to be 77% while it was 45% in opened vials. In Nepal, 33% wastage reduction was reported in opened OPV vials during NIDs in 1997.<sup>28</sup> In Bhutan, over a period of six months in 1997–1998, colour changes in VVMs led to OPV wastage of only 0.6%.<sup>29</sup> In Viet Nam, in a 2002 measles campaign, hard-to-reach communes with very weak and/or no cold chain were reached mainly by relying on VVM potential. This resulted in reducing the number of supply trips and consequently the cost.<sup>30</sup>

<sup>26</sup> SNIDs in southern Sudan. WHO, unpublished report, 11 October 1999.

<sup>27</sup> Afsar OZ, Altay B. Vaccine vial monitors impact study during 1997 national immunization days in Turkey. WHO/EPI/TECHNET.98/WP.23.

<sup>28</sup> Aylward B, Luna J, Ojha GP, et al. Impact of VVMs on wastage and cold chain monitoring during NIDs in Nepal. WHO/EPI/TECHNET.98/WP.9.

<sup>29</sup> Kristensen D. Vaccine vial monitor impact study results, Kingdom of Bhutan, July 1997 through November 1998. PATH, November 1999.

<sup>30</sup> TechNet21 e-Forum. POST0445E: Impact of vaccine vial monitors (VVM) on the use and delivery of measles vaccine, 12 April 2002.

Fig. 14. VVM on hepatitis B vaccine showing no heat exposure



It is critical that all countries procuring vaccines from national budgets through international bid-tender include VVMs in tender specifications. All donor countries and agencies should also have policies for including VVMs in their donations.

At the 19<sup>th</sup> Immunization Managers Meeting of the WHO Eastern Mediterranean Region held in Casablanca, Morocco on 24–27 June 2002, the following recommendations were adopted on VVM inclusion in tender documents.

**Morocco recommendations, June 2002: vaccine quality and management**

2. Vaccine security is becoming an increasing problem both at the global level and in the Region. This situation is exacerbated by multinational vaccine manufacturers leaving the traditional vaccine market in order to take advantage of higher profit margins and by the increasing divergence of vaccine products used between developing and industrialized countries. In addition, planning to meet supply is adversely affected by a lack of good planning for vaccine needs on the part of countries, and by strategies for utilization which are less than optimal. To contribute to vaccine security, countries are urged to develop demand forecasting, to establish plans to improve vaccine management and to consider vaccine availability when reviewing or planning for new immunization strategies.
4. Vaccine wastage should be monitored monthly at all immunization points and should be evaluated together with immunization coverage.
5. **Countries purchasing their own vaccines should include VVMs among the minimum requirements for all EPI vaccines in tender documents.**
6. Countries are encouraged to conduct studies on documenting the freezing risk/problem of freeze-sensitive vaccines, to take appropriate measures to protect them from freezing on arrival and during storage and transportation, and to report the results in 2003.

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The donation policy of the Japanese International Cooperation Agency stipulates that vaccines have to meet WHO-UNICEF criteria, including the use of VVMs.

VVMs can be incorporated into national regulatory authority (NRA) documents as part of the minimum requirements for all vaccines. Thus, for example, in 2002 the Republic of Korea, during restructuring of its NRA, included VVMs as a cold chain improvement tool for all vaccines.

### 7.3 Multidose vial policy

The multidose vial policy (MDVP), previously called the open vial policy, was introduced in 1995 and revised in 2000 on the basis of scientific data collected on the safety and potency of vaccines recommended for use in immunization services by WHO.<sup>31</sup> The revised policy applies only to OPV, DTP, TT, DT, HepB, and liquid formulations of Hib vaccines that meet WHO requirements for potency and temperature stability, are packaged according to ISO standard 8362-2, and contain an appropriate concentration of preservative, such as thiomersal (injectable vaccines only).

Multidose vials of OPV, DTP, TT, DT, hepatitis B, and liquid formulations of Hib vaccines from which one or more doses of vaccine have been removed during an immunization session *may be used* in subsequent immunization sessions for up to a maximum of four weeks provided that all the following conditions are met:

- the expiry date has not passed;
- the vaccine is stored under appropriate cold chain conditions;
- the vaccine vial septum has not been submerged in water;
- aseptic technique has been used to withdraw all doses;
- the VVM, if attached, has not reached its discard point.

Liquid injectable vaccines such as DTP, TT, DT and hepatitis B contain preservatives that prevent the growth of bacterial contamination. Should contamination take place within a vial, the preservatives prevent any increase in bacterial growth over time and actually decrease the level of contamination.

The implementation of MDVP requires a series of operational provisions such as the proper training of personnel, the availability of AD syringes to ensure aseptic technique, training in and use of VVMs for monitoring heat exposure, and the re-evaluation of vaccine wastage rates for vaccine forecasting. It is estimated that the adoption of MDVP would result in wastage rates declining to approximately 15–20%.

The implementation of MDVP in Bhutan resulted in dramatic decreases in the wastage of liquid vaccines. In comparison with baseline data from the districts, wastage decreased by 49% for OPV, 27% for DTP, 56% for TT and 24% for HepB vaccine.<sup>32</sup>

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<sup>31</sup> WHO policy statement: *The use of opened multidose vials in subsequent immunization sessions.* WHO/V&B/00.09.

<sup>32</sup> Kristensen D. *Vaccine vial monitor impact study results, Kingdom of Bhutan, July 1997 through November 1998.* PATH, November 1999.

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The revised policy does not change recommended procedures for handling vaccines that must be reconstituted, that is, BCG, measles, YF and some formulations of Hib vaccines.<sup>33</sup> Once they are reconstituted, vials of these vaccines must be kept at 2-8°C and must be discarded at the end of each immunization session or after six hours, whichever comes first.

Most freeze-dried (lyophilized) vaccines do not contain preservatives and consequently must not be kept for longer than the manufacturer's recommended limit and never longer than *six hours* after they are reconstituted.

#### Avoiding programme errors

**Toxic shock.** Reconstituted vaccine is an ideal environment for growing a number of organisms. Live vaccines do not contain a preservative (as many of the other types of vaccines in multi-dose containers do). Once the vial is contaminated with staphylococcus or other organism from improper handling, the organism grows extremely fast. As it grows, it produces a deadly chemical called a toxin. If a contaminated vial is kept (even in the refrigerator), by morning there is enough toxin in the vial to kill an infant. A number of instances are recorded when several infants have been given the remains of the reconstituted measles vaccine from the previous day. They have died in shock several hours later. This is called "toxic shock syndrome". If toxic shock syndrome happens, at least two programme errors have occurred together: non-sterile reconstitution/ injection technique, and failing to discard the vaccine after 6 hours.

*from WHO, Vaccines and Biologicals Update, Vol.34, December 2000*

#### 7.4 Interagency coordination committees

Interagency coordination committees (ICCs) could be used in a very dynamic way to review different aspects of immunization programmes, including vaccine wastage, forecasting, and the coordination of donors' efforts in order to avoid more vaccines arriving in countries than can be utilized.

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<sup>33</sup> *Haemophilus influenzae type b vaccine (Hib), now in use in the immunization services of several countries, is available in different formulations and combinations, including liquid single-antigen, liquid combined with other antigens, and freeze-dried for reconstitution with a diluent or with another liquid vaccine (DTP). All liquid formulations of Hib vaccine contain a preservative and can be used in subsequent immunization sessions. The freeze-dried formulation contains no preservative. After reconstitution with a diluent it must be discarded at the end of the session or within six hours, whichever comes first (as for BCG, measles, and YF). Certain formulations of lyophilized Hib vaccine are supplied with DTP liquid vaccine. However, although these can be used safely over an extended period, implementing a decision to use them requires additional management and supervision activities, and is not therefore recommended in the absence of specific training of personnel.*

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## 7.5 Earliest-expiry-first-out principle

EEFO handling is safer than first-in-first-out (FIFO) handling. In general, when two batches of vaccine are delivered at different times, the second to arrive has a later expiry date than the other. However, this is not always the case, particularly when vaccines are obtained from different sources. The expiry date should always be checked and the vaccine with the shortest shelf-life should be distributed first, even if it arrived last.

All stocks must be distributed well before their expiry date is reached in order to allow sufficient time for them to pass through the distribution system and reach the user. Newly arrived stocks generally have a longer period before expiry than those which have been in storage for some time. Thus, older stocks with shorter expiry dates should normally be distributed first so as to ensure that supplies are properly rotated and that no batch or lot remains too long in storage. All vaccines and diluents must be systematically arranged in the store so as to facilitate an EEFO stock management system.

During the period when vaccines remain in storage, the expiry dates of the stock should be checked regularly to ensure that older batches are distributed before more recent arrivals. In addition, the integrity of the stocks should be checked by reviewing the status of the VVM on each vial. Any significant colour change in a VVM during the period that vaccines have remained in storage indicates a weakness in the cold chain system. Repair or maintenance of the cold chain equipment may be needed.

Heat-exposed vaccine may have to be issued ahead of its EEFO sequence, and in such cases the reason should be recorded. However, this measure should be taken with care because it may cause a displaced batch to reach its expiry date before it can be used. It is also necessary to consider whether the vaccine is being sent to a place where it will be used quickly or to a place where it will remain in storage longer. However, the remaining shelf-life of a vaccine as indicated by the expiry date may be short. In this event the VVM indication may, exceptionally, be ignored when a decision is being made on which vaccine to issue first. In principle, four factors should be taken into account in the decision-making process: the remaining shelf-life of the vaccine, the VVM indication, expected dispatches and the possibility of full consumption of issued vaccine.

## 7.6 Improved procurement practices

Improved procurement practices mean better vaccine forecasting with more realistic wastage rates in order to prevent the arrival of excess amounts of vaccine.

It is quite important that countries understand the implications of all vaccine management functions (session size planning, forecasting, use of diluents, reducing wastage) so that the use of scarce vaccines can be optimized.

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### WHO/UNICEF responding to scarce vaccine supply market

“... In response to the SAGE recommendations of 2001, WHO and UNICEF have further intensified their work with vaccine manufacturing partners in industrialized, middle income and developing countries through direct discussions, meetings, and through their affiliations with IFPMA and DCVMN.

In addition, substantial work has been done to inventory accurate production and capacity figures for all vaccines for human use produced by manufacturers, in as much as this is possible, while gathering demand related data for specific vaccines. Extensive work has been done in the area of vaccine management to better manage the issues of cold chain, logistics and distribution at country level...”

*S. McKinney, presentation to SAGE, 2002*

### 7.7 Optimizing immunization session frequency with session size and vial size

Clearly, wastage can be reduced by increasing the size of sessions (a session as often as enough children can be assembled to use up a whole vial) and decreasing their frequency. However, this may result in compromising coverage. Among the tools available for reducing wastage, that of session size has the greatest potential for negatively affecting vaccination coverage. Consequently, this option should be reviewed with great caution before putting it into practice.

If a selected approach to reduce vaccine wastage results also in reducing immunization coverage, **consider** other approaches.

### 7.8 Prevention of freezing

The freezing of vaccines has been well documented but remains one of the poorly addressed problems in vaccine management. With the introduction through GAVI of expensive new vaccines such as HepB, the most freeze-sensitive vaccine, vaccine freezing has become a topic on which national managers seek advice. Previously, when freezing occurred in a full load of DTP in a 108-litre ice-lined refrigerator (ILR), the cost of the loss was around US\$ 1500, whereas today if a full load of HepB were frozen in the same refrigerator the loss would more than five times greater, i.e. \$8200.

Vaccine freezing is preventable and should therefore be treated as unacceptable. All possible measures should be taken to prevent wastage attributable to this cause.

The freezing of vaccines may occur when vials are exposed to freezing temperatures either during storage or transportation (Table 6). Studies have shown freeze damage to vaccines at all levels of the cold chain.

Table 6. Where vaccines are exposed to freezing temperatures

During	Locations
Storage	Cold rooms
	Environments with low ambient temperature
	Refrigerators
Transportation	Air cargo
	Cold boxes with ice or ice packs

In order to avoid freezing in cold rooms, the following safety measures should be taken.

- Refrigeration units should be arranged so that no shelving lies within the plume of cold air close to the evaporator.
- Alternatively, the evaporator should be fitted with a mesh cage to prevent vaccine being stored within the danger zone.
- Ceiling-mounted units should not be positioned directly above shelving units. Instead they should be mounted in the centre of circulation aisles. If they have to be mounted above a shelving unit, the top shelf should be at least 75 cm below the evaporator and vaccines should not be stacked in the danger zone.
- The air outlet from ceiling-mounted evaporators should be directed away from any shelving in close proximity.

In cold climates the temperature inside poorly or intermittently heated buildings where vaccine is stored can easily drop to near or below 0°C. In this circumstance, vaccine stored in refrigerators and cold rooms is likely to freeze. HepB vaccine freezes and is destroyed at -0.5°C. Toxoids such as DTP, DT and TT freeze and are destroyed in the temperature range of approximately -5°C to -10°C.

There are two solutions to this problem.

1. **Permanently heat the vaccine store:** None of the vaccine refrigerators that currently meet WHO specifications offer any protection against ambient temperatures close to or below freezing. Work is being done to overcome this problem and the situation may change. Meanwhile, reliable seven-day-a-week heating is essential in stores or health facilities where vaccines are kept in refrigerators.
2. **Heat the cold room:** Cold rooms at +2°C to +8°C should be fitted with frost protection heater circuits unless the space containing the cold room is permanently heated and the heating system is totally reliable.

Freeze-sensitive vaccines should NOT be stored within 20 cm of the base of an ice-lined refrigerator. Some ILR models have a mark inside the cabinet which indicates areas potentially dangerous for the storage of these vaccines.

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Other ways to reduce freezing in refrigerators are as follows.

- Do not adjust thermostats when vaccines arrive or try to cool a refrigerator quickly after a power outage.
- Set the thermostat so that the refrigerator temperature is around 4°C during the coldest part of the day. Monitor temperatures first thing in the morning and during the hottest part of the day. Once the 2°C to 8°C range is achieved, do not adjust the thermostat.
- In RCWs, store freeze-sensitive vaccines well away from the evaporator plate. Do not remove the separator wall in RCWs.

The conditioning of ice packs is the key to preventing freezing through the use of frozen ice packs during vaccine transportation. Conditioning should be incorporated as a standard practice in vaccine packaging areas. Alternatively, chilled water packs can safely be used with cold boxes for transportation not exceeding 48 hours. (See Annex 5 for summary of use of chilled water packs in vaccine transportation.)

#### Conditioning ice packs

When icepacks are removed from a freezer at (say) -25°C they need to be kept at room temperature for long enough to allow the temperature of the ice at the core of the icepack to rise to 0°C. This process is called "conditioning". The standard advice has been that an icepack is adequately "conditioned" as soon as beads of water cover its surface. Experiments have shown that this is not always the case and that cold-sensitive vaccines -particularly HepB - can still freeze inside the cold box even when icepacks have apparently been conditioned correctly. When icepacks are laid out on a table they create their own microclimate. This extends the conditioning process. The following procedure is recommended:

- Lay out icepacks, preferably in single rows but never in more than two rows.
- Leave a 5cm space all round each icepack.
- Wait until there is a small amount of liquid water inside the icepacks. This will take up to one hour at +20°C ambient temperature and rather less at higher temperatures. Shake one of the icepacks every few minutes. The ice is conditioned as soon as it begins to move about slightly inside its container.

*From: Establishing and improving primary and intermediate cold stores for vaccines,  
WHO/V&B/02.34*

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## 7.9 Safe immunization practices

For all vaccines, including freeze-dried vaccines, safe immunization injection practices must be followed. A new sterile syringe and needle must be used for each new dose given, and the correct route and dosage must also be observed for each type of vaccine.

### 7.10 Improved vaccine management practices

Because of the number of changes in vaccines, presentations and global vaccine handling practices over the past several years, including the introduction of new and underused vaccines through the GAVI process, the need for training in vaccine management has increased. One of the influences that led GAVI to focus on infrastructure strengthening was the perception that cold chain and vaccine distribution mechanisms in countries were disintegrating. A need for better vaccine management practices has also been demonstrated by high levels of wastage in many countries (and recorded on GAVI fund application forms), a lack of utilization of policies and equipment that would reduce vaccine wastage such as MDVP and VVMs, and adverse events attributable at least partially to inappropriate vaccine distribution practices.

In the early days of EPI the focus was on developing a cadre of trained staff, and a great effort was put into the dissemination of training manuals and materials and ensuring that training was carried out at all levels. Pressures such as high staff turnover rates and the introduction of new vaccines and technologies mean that there is a vital requirement for training in better vaccine management practices.

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### **Global Training Network / Vaccine Management Training Cluster**

As part of the Global Training Network (GTN), Vaccine Management Training Cluster (VMTC) activities, a series of workshops are conducted on a regular basis by WHO accredited global training centres.

Vaccine management is a generic term encompassing various aspects of activities, programmes and services involving the use and disposal of “vaccines”, from the manufacturers to the end-users. Vaccines are delicate products, which are easily destroyed if handled incorrectly. Experience has shown that cold chain and particularly, the national cold store are the most critical elements of any immunization system. Because vaccine management is composed of several service levels, plans related to each level must be developed, and regularly updated to ensure an effective and efficient service delivery. These levels are:

- Inventory and forecasting
- Stock control
- Distribution
- Storing and handling of vaccines
- Long term replacement plans for equipment
- Standard procedures for use of vaccine in immunization programmes
- Monitoring systems for vaccine storage
- Transport management
- Operational management

Currently two training courses are being conducted for different target audiences:

**“Cold store management”** training course is designed for primary, intermediate cold store managers, and the cold chain managers at the ministerial level. National immunization managers are also included among the target group as the secondary audience because of their supervisory responsibilities over the cold stores.

**“Vaccine management”** training course is designed for national and sub-national immunization managers. Although it addresses some of the issues of the field, such as implementation of multi dose vial policy, managerial aspect of these issues are taken as the focus. Operational details and/or how to train field health workers on these issues are not covered with this training.

#### **7.11 Prevention of submergence of vials in water**

In some programmes there may be no choice but to use crushed ice in transport boxes during peak outreach activities. If vaccines are not well protected, opened vials may be submerged in water from melting ice. These vials are considered as contaminated and must be discarded. The only way to prevent submergence is to use zip-lock bags. All opened and unopened vials must be kept in zip-lock bags in order to prevent any direct contact with water. This practice also prevents labels from becoming wet and lost (vials without labels must be discarded).

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## 8. Conclusions

The introduction of new vaccines has presented a challenge in immunization services but has also brought considerable opportunities for better demand calculations and the monitoring of immunization coverage and vaccine wastage. Countries receiving GAVI support are now requested to reduce their wastage rates to 15% for 10-dose and 20-dose presentations within three years. WHO reports indicate that vaccine wastage amounts to approximately 50% globally.

No matter how successful a programme is, some vaccine wastage can be expected. Many factors influence vaccine wastage. Improved vaccine management practices are the key to addressing vaccine wastage as a whole.

Vaccine wastage is best classified as occurring in either unopened or opened vials. Wastage in unopened vials results from incorrect/inappropriate vaccine storage and transportation practices and mainly occurs at or between primary and intermediate vaccine storage facilities. Wastage at the service level occurs as a consequence of a combination of many factors and mainly involves opened vials.

All immunization points monitor their performance by monitoring immunization coverage. The monitoring of vaccine wastage rates on a regular basis by all immunization points brings additional value to this quality performance indicator. The analysis of immunization coverage and vaccine wastage rates over a period of time allows health workers and immunization managers to identify areas that need improvement. The evaluation of wastage in isolation, without any consideration of coverage, makes it impossible to conclude whether it should be considered high or acceptable.

The management of a vaccine store is best evaluated through the monitoring of proportional vaccine wastage in unopened vials. The global criteria for effective vaccine management laid down in the WHO-UNICEF Effective Vaccine Store Management require cold stores not to discard more than 1% of vaccines that are handled.

If the reasons for vaccine wastage are not known the problem cannot be addressed, because measures may not be appropriate and may result in compromising immunization coverage.

The key concepts and activities associated with tackling vaccine wastage are indicated below.

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### *Monitor vaccine wastage regularly*

1. All immunization points should monitor their vaccine usage and wastage on a monthly basis. This has to be done as a self-audit and not for the sake of submitting data to higher levels.
2. Vaccine stores should monitor their wastage rates on a monthly basis.
3. All immunization services should establish a sound vaccine wastage monitoring system. Sentinel reporting should be considered in preference to the compilation of data from all parts of the country concerned.
4. The minimum data that have to be collected at the service level are:
  - start balance;
  - doses received;
  - doses discarded unopened;
  - doses opened for use;
  - number of children immunized.
5. The calculation of vaccine usage at the service level should always be encouraged as the first step. Vaccine usage can easily be calculated as follows:

$$\text{Vaccine usage rate} = \frac{\text{Number of children immunized}}{\text{Start balance} + \text{doses received} - \text{end balance}} \times 100$$

6. Vaccine wastage can easily be calculated from the vaccine usage rate:  
Vaccine wastage (rate) = 100 – vaccine usage rate.
7. Vaccine stores should focus on handling performance, which can be expressed as proportional vaccine wastage in unopened vials.

$$\text{Proportional vaccine wastage rate in unopened vials} = \frac{\text{Number of doses discarded}}{\text{Start balance} + \text{number of doses received}} \times 100$$

8. Since vaccine wastage is calculated at two different settings, both figures from these calculations should be incorporated in demand forecast calculations. The wastage factor for a country is given by multiplying the wastage factors calculated from these two different wastage rates:

$$\text{Wastage factor} = \left\{ \begin{array}{l} \text{Wastage factor of} \\ \text{proportional vaccine} \\ \text{wastage rate} \\ \text{calculated from stores} \end{array} \right\} \times \left\{ \begin{array}{l} \text{Wastage factor of} \\ \text{vaccine wastage rate} \\ \text{calculated from sentinel} \\ \text{points} \end{array} \right\}$$

9. The vaccine wastage rate at the service level should be monitored against the immunization coverage for the same period. Any changes in the trends of wastage rate and immunization coverage should be carefully analysed.

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*Consider all factors when making a decision*

10. The use of smaller vaccine presentations results in less vaccine wastage. However, changing the vial size so as to reduce vaccine wastage should be carefully studied, since there may be negative implications regarding vaccine storage volume, transportation cost and operations.

*Adopt global policies nationally so as to increase the effectiveness of the system*

11. The effective use of VVMs not only ensures that vaccine administered has not been damaged by heat but also reduces vaccine wastage. VVM use also facilitates immunization outreach and increases access and, consequently, immunization coverage.
12. It is recommended that all countries procuring vaccines from their national budget include VVMs among the minimum requirements for vaccine purchase.
13. The implementation of MDVP results in dramatic decreases in the wastage of liquid vaccines, because multidose vials of vaccine from which one or more doses have been removed during an immunization session *may be used* in subsequent sessions for up to four weeks.
14. EEFO handling is safer than FIFO handling. It is strongly recommended that countries revise policy so as to adopt EEFO handling for issuing vaccines.
15. Countries should pay more attention to the implications of all vaccine management functions in order to optimize the use of fragile vaccine supplies.

*Prevent freezing*

16. The freezing of vaccines is one of the major reasons for wastage. Freezing occurs at all levels of the cold chain. Practices that avoid the risk of freezing must be followed and promoted.

*Do not compromise immunization coverage*

17. Whatever measures are taken to reduce vaccine wastage, they should not compromise immunization coverage. If a selected approach to reducing vaccine wastage results in reducing immunization coverage, other approaches should be considered.

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## 9. Further reading

1. *Quality of the cold chain: WHO-UNICEF policy statement on the use of vaccine vial monitors in immunization services.* Geneva: World Health Organization; 1999 (unpublished document WHO/V&B/99.18).
2. *Vaccines and Biologicals update*, December 2001;34.
3. *Vaccine vial monitor – training guidelines.* Geneva: World Health Organization; 1996 (unpublished document WHO/EPI/LHIS/96.04).
4. *Getting started with vaccine vial monitors: questions and answers for field operations.* Geneva: World Health Organization; 2002 (unpublished document WHO/V&B/02.35).
5. *Making use of vaccine vial monitors, Flexible vaccine management for polio.* Geneva: World Health Organization; 2000 (unpublished document WHO/V&B/00.14).
6. *Two simple ways to use less vaccine: How to use vaccine vial monitors, and when to use opened vials of vaccine.* EPI update 30/1996.
7. *Temperature monitors for vaccines and the cold chain.* Geneva: World Health Organization; 1999 (unpublished document WHO/V&B/99.15).
8. *Quality of the cold chain: WHO-UNICEF policy statement on the use of vaccine vial monitors in immunization services.* Geneva: World Health Organization; 1999 (unpublished document WHO/V&B/99.18).
9. *WHO policy statement: The use of opened multi-dose vials of vaccine in subsequent immunization sessions.* Geneva: World Health Organization; 2000 (unpublished document WHO/V&B/00.09).
10. Hoffman PN. *Ability of vaccines to withstand repeated bacterial challenges.* London: Central Public Health Laboratory, October 1993 (a WHO study).
11. *Ensuring the quality of vaccines at country level.* Geneva: World Health Organization; 2002 (unpublished document WHO/V&B/02.16).
12. *Adopting global vaccine management policies for national use.* Geneva: World Health Organization; 2002 (unpublished document WHO/V&B/ 02.32).
13. *Guidelines on the international packaging and shipping of vaccines.* Geneva: World Health Organization; 2001 (unpublished document WHO/V&B/01.05).
14. *Establishing and improving primary and intermediate vaccine stores.* Geneva: World Health Organization; 2002 (unpublished document WHO/V&B/02.34).

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15. *Vaccine volume calculator*. Geneva: World Health Organization; 2001 (unpublished document WHO/V&B/01.27).
  16. *WHO-UNICEF Effective Vaccine Store Management Initiative. Module 2. Model quality plan*. Geneva: World Health Organization; 2003 (unpublished document WHO/V&B/03.15 Mod2).
  17. Paul KD, Carib MN, John SL. Single-dose versus multi-dose vaccine trails for immunization programmes in developing countries. *Bulletin of the World Health Organization*, 2003;81:726–731.



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# Annex 2:

## Advanced vaccine wastage calculations

Only the overall vaccine wastage rate can be calculated by the service level using the formulas given in the main part of this document. As previously discussed, specific and proportional rates help programme staff to understand where wastage is occurring and to choose the most appropriate remedies.

In order to calculate detailed vaccine wastage rates the following information is required:

- start balance;
- doses received;
- doses discarded unopened;
- doses opened for use;
- number of children immunized.

This information is recorded in various forms in many settings. If it is available, the following information can be generated monthly on the basis of the formulas given, without undue expenditure of time.

End balance = (start balance) + (doses received) – (doses discarded unopened) – (doses opened for use)

$$\text{Vaccine usage rate} = \frac{\text{Number of children immunized}}{\text{Start balance} + \text{doses received} - \text{end balance}} \times 100$$

Replacing the end balance formula in the above usage rate formula:

$$\text{Vaccine usage rate} = \frac{\text{Number of children immunized}}{\text{Doses discarded unopened} + \text{doses opened for use}} \times 100$$

The denominator indicates the number of doses issued during the period in question and includes doses discarded from unopened vials and doses opened for use. The formula can then be used to calculate the vaccine wastage rate:

$$\text{Vaccine wastage rate} = 100 - \text{vaccine usage rate.}$$

---

This wastage rate includes wastage in both unopened and opened vials. For routine purposes it may not be necessary to calculate the breakdown of this rate on a regular basis. Nevertheless, the availability of the information listed above makes it possible to calculate the following details:

- unopened-vial-specific vaccine wastage rate;
- opened-vial-specific vaccine wastage rate;
- proportional vaccine wastage rate in unopened vials;
- proportional vaccine wastage rate in opened vials.

Vial-specific wastage rates reveal the reasons behind overall wastage. Unopened-vial-specific wastage plus opened-vial-specific wastage always equals the vaccine wastage rate. However, the proportional vaccine wastage values for unopened and opened vials do not equal the overall wastage. They are useful in indicating what proportions of unopened and opened vaccine are being wasted.

The formulas for the above-mentioned indicators are as follows.

$$\text{Unopened-vial-specific vaccine wastage rate} = \frac{\text{Doses discarded unopened}}{\text{Start balance} + \text{doses received} - \text{end balance}} \times 100$$

$$\text{Opened-vial-specific vaccine wastage rate} = \frac{\text{Doses opened for use} - \text{number of children immunized}}{\text{Start balance} + \text{doses received} - \text{end balance}} \times 100$$

$$\text{Proportional vaccine wastage rate in unopened vials} = \frac{\text{Doses discarded unopened}}{\text{Start balance} + \text{doses received} - \text{doses opened for use}} \times 100$$

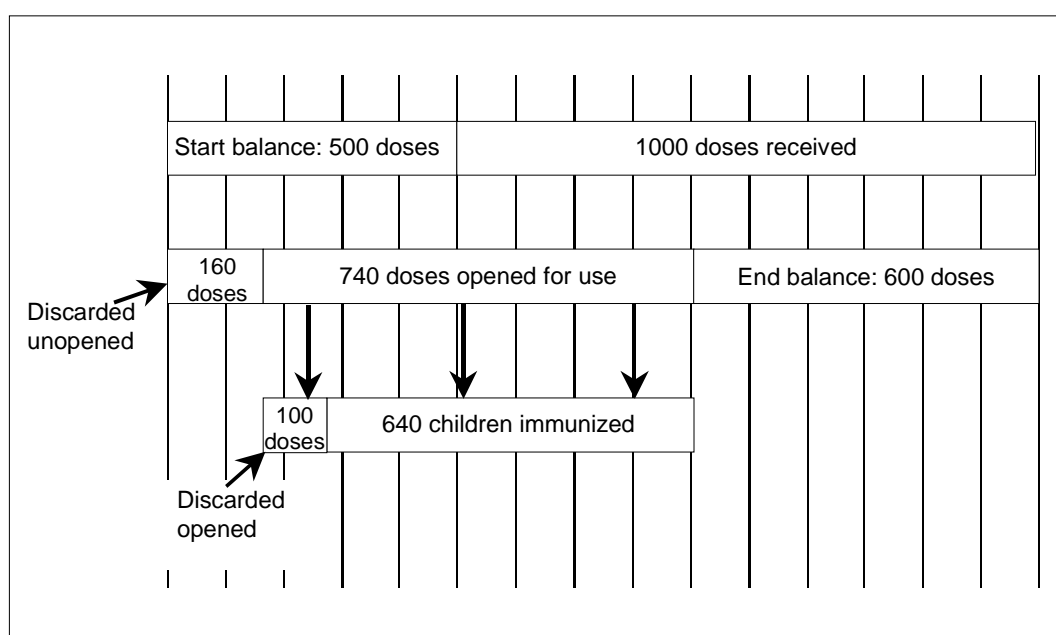
$$\text{Proportional vaccine wastage rate in opened vials} = \frac{\text{Doses opened for use} - \text{number of children immunized}}{\text{Doses opened for use}} \times 100$$

Because the denominators for the vial-specific rates are the same, the sum of these two specific rates is equal to the overall wastage rate. However, the denominator in the proportional vaccine wastage rate in unopened vials is the number of unopened vials handled during the period, whereas for opened vials the denominator is the total number of doses opened for use.

We can illustrate how these indicators work by referring to the following figures for DTP vaccine reported by Yenice Health Centre:

- start balance (1 July), 500 doses;
- doses received during July, 1000;
- doses discarded unopened in July, 160;
- doses opened for use, 740;
- number of children immunized in July, 640;
- end balance (end of month), 600 doses.

Fig. 15. Calculation of detailed vaccine wastage at service level



Substituting these figures in the formulas:

$$\text{Vaccine usage rate} = \frac{640}{500 + 1000 - 600} \times 100 = 71\%$$

$$\text{Vaccine wastage rate} = 100 - 71 = 29\%$$

$$\text{Unopened-vial-specific vaccine wastage rate} = \frac{160}{500 + 1000 - 600} \times 100 = 18\%$$

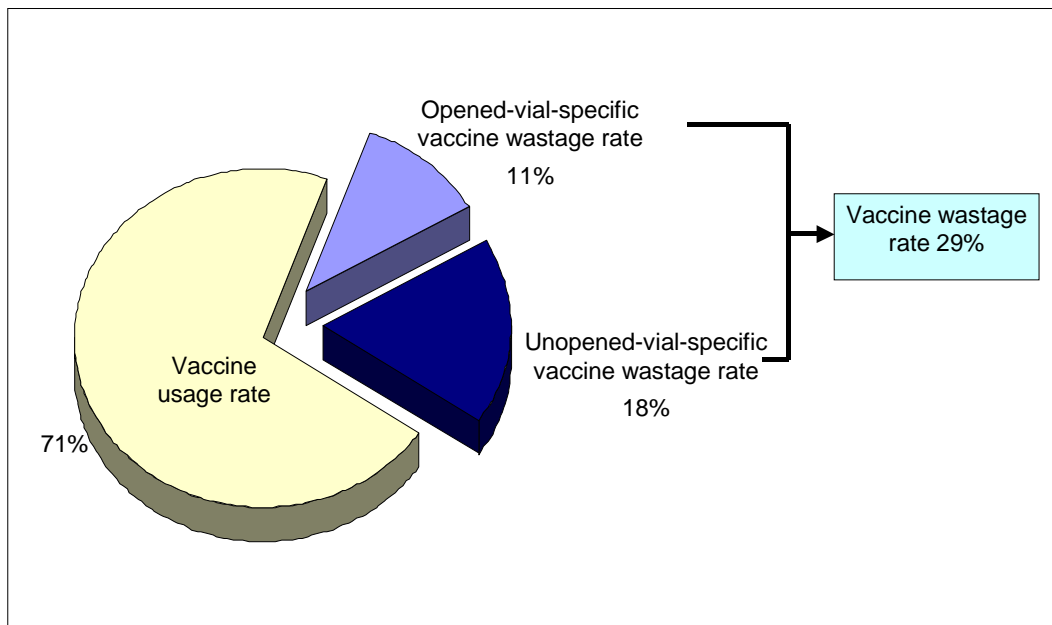
$$\text{Opened-vial-specific vaccine wastage rate} = \frac{740 - 640}{500 + 1000 - 600} \times 100 = 11\%$$

$$\text{Proportional vaccine wastage in unopened vials} = \frac{160}{500 + 1000 - 740} \times 100 = 21\%$$

$$\text{Proportional vaccine wastage in unopened vials} = \frac{740 - 640}{740} \times 100 = 14\%$$

The relationship between vial-specific wastage rates and overall wastage and vaccine usage is illustrated in Fig. 16

Fig. 16. Relationship between vial-specific wastage, vaccine wastage and usage rates



*Another way of calculating the vaccine wastage factor*

In addition to calculating the vaccine wastage factor as described in section 2.4 it can be calculated by means of other formulas.

There is a more direct way of calculating the wastage factor than via usage and wastage rates. It involves replacing the vaccine usage rate formula in the wastage factor formula presented below, to give the vaccine usage ratio of doses per administration.

$$\text{Vaccine wastage factor} = \frac{100}{\text{Vaccine usage rate}}$$

Substituting for vaccine usage rate (see section 2.3):

$$\text{Vaccine wastage factor} = \frac{100}{\frac{\text{Number of doses administered (children immunized)}}{\left\{ \begin{array}{l} \text{Number of} \\ \text{usable doses at} \\ \text{the beginning of} \\ \text{period} \end{array} \right\} + \left\{ \begin{array}{l} \text{Number of doses} \\ \text{received during} \\ \text{period} \end{array} \right\} - \left\{ \begin{array}{l} \text{Number of} \\ \text{usable doses in} \\ \text{stock at end of} \\ \text{period} \end{array} \right\}} \times 100}$$

---

The above formula uses stock records, which can be replaced with more detailed immunization records for another calculation. Both formulas would give the same result. The nominator of the above formula equals the sum of doses administered and wasted.

$$\left\{ \begin{array}{l} \text{Number of} \\ \text{usable doses} \\ \text{at beginning} \\ \text{of period} \end{array} \right\} + \left\{ \begin{array}{l} \text{Number of} \\ \text{doses} \\ \text{received} \\ \text{during period} \end{array} \right\} - \left\{ \begin{array}{l} \text{Number of} \\ \text{usable doses} \\ \text{in stock at} \\ \text{end of period} \end{array} \right\} = \left\{ \begin{array}{l} \text{Number of} \\ \text{doses} \\ \text{administered} \end{array} \right\} + \left\{ \begin{array}{l} \text{Number of} \\ \text{doses} \\ \text{wasted} \end{array} \right\}$$

When replaced with the above equation the new formula for the wastage factor would be:

$$\frac{\left\{ \begin{array}{l} \text{Number of} \\ \text{doses} \\ \text{administered} \end{array} \right\} + \left\{ \begin{array}{l} \text{Number of} \\ \text{doses} \\ \text{wasted} \end{array} \right\}}{\text{Number of doses administered}}$$

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# Annex 3:

## Monitoring vaccine wastage at sentinel sites

### How to define sentinel sites<sup>35</sup>

#### *Principle*

The sampling unit for sentinel sites is the health care facility that performs immunization services. Two-stage cluster sampling is proposed as the easiest method to obtain a representative sample of health care facilities. Self-weighting is ensured in such a sample through (1) a choice of regions in which clusters are selected by using probability proportional to population size, and (2) equal numbers of sampling units in each cluster.

#### *First stage*

##### Division of the country into regions

The country should be divided into regions or other administrative areas, e.g. districts, provinces, that are (1) non-overlapping, i.e. no village should be located in two regions, and (2) exhaustive. i.e. all geographical areas of the country are included. The level of regions or other administrative areas should be chosen so that (1) the number exceeds eight and (2) each contains at least 10 primary health care facilities. If it is impossible to find regions with at least 10 such facilities, adjacent regions may be merged to form larger ones containing a sufficient number of primary care facilities.

##### Choice of regions with a probability proportional to population size

From the whole country, eight geographical regions are selected with a probability proportional to the total population size. This is done in the following six steps.

##### Step 1: Rank all regions in a table

All regions should be entered in the first column of a table in the most convenient order (Table 7).

##### Step 2: Determine the population of each region

The population of each region should be entered in column 2 next to the name of the region (e.g. 30 000 for region 10, Table 7). Census data, even if outdated, or the best available equivalent, should be used.

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<sup>35</sup> Adapted from "Tool for the assessment of injection safety"(WHO/V&B/01.30).

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### Step 3: Calculate the cumulative population size

The cumulative population size should be calculated for each region and entered in column 3 next to the population size. For region 1, the cumulative population size is the population of region 1. For region 2, the cumulative population size is the population of region 1 + the population of region 2. For region  $n$ , the cumulative population size is the population of region 1 + the population of region 2 + (...) + the population of region  $n$ , e.g. 565 000 for region 10 (Table 7). For the last region, the cumulative population size is the population of region 1 + the population of region 2 + (...) + (...) + the population of the last region. The total should be the country's population.

### Step 4: Calculate the sampling interval

The sampling interval  $s$  should be calculated by dividing the country population by eight (the number of regions selected). For example:  $1\ 177\ 000/8 = 147\ 125$  (Table 7).

### Step 5: Choose a random number between 1 and the sampling interval

A number  $r$  should be selected at random between 1 and the sampling interval (country population divided by eight, the number of regions selected). For example: 85 350 (Table 7).

Within each of the eight regions selected, a cluster of 10 facilities is chosen where vaccine wastage is reported regularly.

### Step 6: Identify the clusters

First cluster: column 4 of Table 7 should be used to identify the region in which the cluster is located. The first region selected is that for which the cumulative population size (column 3) is greater than the random number  $r$ , which is greater than the cumulative population size of the preceding region. The random number  $r$  should then be entered in column 4 opposite the region. Thus, for example, 85 350 is smaller than 100 000 (cumulative population size for region 3) but greater than 70 000 (cumulative population size for region 2), so region 3 is selected as containing the first cluster (Table 7).

Second cluster: The second region selected is that in which the cumulative population size (column 3) is greater than  $r + s$ , while  $r + s$  is greater than the cumulative population size of the preceding region. The number  $r + s$  should then be entered in column 4 corresponding to the region. Thus, for example,  $85\ 350 + 147\ 125 = 232\ 475$  is smaller than 425 000 (cumulative population size for region 7) but greater than 125 000 (cumulative population size for region 6), so region 7 is selected as containing the second cluster (Table 7).

This procedure is followed eight times so as to select the regions by adding the sampling interval  $s$  each time to the number in column 4 and by identifying the region for which the cumulative population (column 3) is greater than the new number while the new number is greater than the cumulative population size of the preceding region. In some cases the new number may fall in the same region. In this case, the region is selected twice, and 2 x 10 facilities are selected from this region. Thus region 7 is selected twice (Table 7).

**Table 7. Example of selection of regions with a probability proportional to population size**

Name of region	Population size population size	Cumulative identify clusters	Numbers to
Region 1	50 000	50 000	
Region 2	20 000	70 000	
Region 3	30 000	100 000	85 350
Region 4	10 000	110 000	
Region 5	5 000	115 000	
Region 6	10 000	125 000	
Region 7	300 000	425 000	232 475 379 600
Region 8	50 000	475 000	
Region 9	60 000	535 000	526 725
Region 10	30 000	565 000	
Region 11	120 000	685 000	673 850
Region 12	80 000	765 000	
Region 13	90 000	855 000	820 975
Region 14	30 000	885 000	
Region 15	20 000	905 000	
Region 16	70 000	975 000	968 100
Region 17	52 000	1 027 000	
Region 18	40 000	1 067 000	
Region 19	90 000	1 157 000	1 115 225
Region 20	20 000	1 177 000	
Total	1 177 000		
Sampling interval		147 125	
Random number		85 350	
Regions selected			

### *Second stage*

In each of the eight selected regions a cluster of 10 health care facilities is selected. A list of all facilities in the region should be obtained. Either random sampling or systematic sampling can be used to select the health care facilities for assessment.

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### Random sampling

From the list of facilities, 10 are selected at random by means of a random number table (Annex 4) or serial numbers on bank notes.

### Systematic sampling

Health care facilities in the region are displayed on a list and a ranking number is assigned to each facility. The total number of facilities is divided by 10 (the number of health care facilities to be selected in the region) in order to obtain the sampling interval  $s'$ . A random number  $r'$  between 1 and the sampling interval  $s'$  is chosen. The health care facilities selected are those with ranking numbers  $r'$ ,  $r' + s'$ ,  $r' + (2 \times s')$ ,  $r' + (3 \times s')$ , etc. until  $r' + (9 \times s')$ . The sampling intervals  $s'$  and ranking numbers  $r'$  are different from those used for the selection of clusters (first stage).

This sampling methodology is not possible if a list of facilities cannot be obtained.

### Sample size

The total sample size is  $8 \times 10 = 80$  health care facilities.

**Table 8. Sentinel site vaccine wastage reporting form for service level (sample)**

Vaccine wastage for		[enter type of vaccine here]		
Name of health facility		Reporting period	Month .....	Year .....
Region	Province	District		
Target population for month				

Allow enough number of rows to cover all working days in a month

Date	Start balance	Number of doses received	Number of doses discarded (unopened)	Number of doses opened for use	Number of children immunized	End balance
	A	B	C	D	E	F
						(A + B) – (C + D)
1 Sept 02	500	1000	160	740	640	600
2 Sept 02	600			120	90	480
3 Sept 02	480					480
	480					480
<b>TOTAL</b>	500	∑ (column B)	∑ (column C)	∑ (column D)	∑ (column E)	From TOTAL row: (A + B) – (C + D)

Rate	Formula	Monthly result
Vaccine usage rate (H)	$(E \times 100)/(A + B - F)$	
Vaccine wastage rate (I)	$100 - H$	
Proportional wastage rate in unopened vials	$(C \times 100)/(A + B - D)$	
Proportional wastage rate in opened vials	$(D - E) \times 100/D$	
Unopened-vial-specific wastage rate	$(C \times 100)/(A + B - F)$	
Opened-vial-specific wastage rate	$(D - E) \times 100/(A + B - F)$	
Immunization coverage rate <sup>36</sup>	$(E \times 100)/\text{target population for month}$	

<sup>36</sup> For vaccines given in more than 1 dose (i.e. DTP in 3 doses), vaccine wastage calculations are affected by wastage occurring in all doses where the coverage rate (DTP1, DTP2 and DTP3) only reflects the completed immunization rate (DTP3). Ideally, in these situations, vaccine wastage should be analysed against the immunization performance rate, calculated as the sum of [(children immunized with DTP1..2..3)\*100/(target group for DTP1..DTP2..DTP3)]. For practical purposes, in the above formula given in the table the target group can also be multiplied by the number of doses given for a particular vaccine. In the case of DTP, column E includes all children who received the 1<sup>st</sup>, 2<sup>nd</sup> and 3<sup>rd</sup> doses of DTP. In coverage calculations, therefore, the target group should be multiplied by 3.

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# Annex 4:

## Random numbers

30327	18630	50546	66082	41159	12769	69069	98638	78132	89538	76499	07762
64274	43724	09355	95905	69762	61880	27973	33864	58883	27749	24279	96874
52933	23102	68353	73543	39262	95359	15207	34248	72167	78690	44926	10234
99814	52582	88678	52288	06399	89836	39795	25021	89157	10896	80219	31220
10839	96272	18566	71901	05841	86756	83596	72543	00415	93504	28442	99089
64532	28043	50186	97891	46841	47915	60099	46086	51850	98324	03459	88883
79369	56944	72950	96578	23520	59823	18115	19043	77052	05354	16622	13489
72473	18311	07590	41773	74186	76260	77228	41641	25009	67033	75902	08062
06636	31445	70284	28510	58351	79903	38862	66538	81912	62540	33253	36275
14542	14401	59741	18269	68473	00089	56795	89496	71563	25054	37607	32433
97264	30998	86509	05592	27533	73713	36500	31583	70693	16205	60212	98391
48304	13561	61015	55500	34097	95897	47526	60599	80484	67998	75364	89855
44050	25991	24140	98786	59568	69527	77301	35688	12901	95838	13636	75538
61927	12986	56083	58176	96857	76473	55149	48214	57438	04245	04760	82538
67278	02794	59883	81342	25203	74719	58920	62413	64613	28324	75909	05819
51232	71654	62291	86512	38261	68726	80823	44703	61216	40650	86571	31293
76008	18571	70444	50997	41898	97275	45214	75034	93415	79833	30986	25380
53457	92759	15692	40749	20252	94374	32165	85560	72065	91110	91093	43358
02064	42003	29082	66895	46284	60962	81016	42875	39296	73757	47712	59994
96189	93080	72408	50326	21036	67021	66129	05168	72255	46507	40295	82526
60096	18267	88451	20780	13376	86668	37511	77393	45213	54311	41379	46401
92126	74740	62446	49825	03170	07455	80177	07330	82473	86672	14009	91144
27529	41624	97142	03527	40490	82516	26105	23749	90809	85200	76387	71039
28416	05879	41462	72666	13340	46835	82130	89467	59123	49790	06486	10759
88913	26034	01297	81988	63710	52088	28572	78239	69020	17901	05184	21165
67587	21470	75583	30475	79729	82931	83741	80164	87779	20366	96277	69796
26517	06828	85161	01052	56508	65644	68683	40747	70616	74203	76242	32994
43848	96986	41937	47235	28638	73600	29431	03206	18655	22372	93589	53032

(Taken from: Weller SC, Romney AK. Systematic data collection.  
*Qualitative Research Method Series 10. California: Sage Publications; 1988.*)

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# Annex 5:

## Summary of WHO study on use of chilled water packs for vaccine transportation

Recent discussions initiated by TechNet21 on conditioning ice packs to prevent freezing have prompted WHO to take a close look at its recommendations on the transportation of vaccines. WHO completed a series of controlled laboratory and field tests to assess the impact of chilled water packs (at +2°C to +8°C) on the cold life of vaccine transportation boxes.

The tests were conducted for the following reasons.

1. Current policy recommends that ice packs be fully conditioned. They must be kept at room temperature for a period of time in order to allow the temperature of the ice at the core of each one to rise to 0°C. The only way to check this is to shake the ice pack and verify whether it begins to move about slightly inside its container. Field observations show that programmes face a serious compliance problem in respect of conditioning. The practice is found to be impractical and unrealistic since it requires approximately more than one hour at an ambient temperature of 20°C.
2. The *Guidelines on the international packaging and shipping of vaccines* set two conditions for freeze-sensitive vaccines. One of them concerns the prevention of freezing:

*Vaccines must be packed to ensure that:*

- the warmest storage temperature of the vaccine does not rise above +30°C in continuous outside ambient temperatures of +43°C for a period of at least 48 hours;
- for vaccines sensitive to freezing only, the coolest storage temperature of the vaccine must not fall below +2°C in continuous external temperatures of -5°C for a period of at least 48 hours.

The guidelines do not require frozen ice packs to be used for class B and class C packaging, which includes all freeze-sensitive vaccines. The current practice of vaccine manufacturers is to use cold packs at 2°C to 8°C for freeze-sensitive products for which the freezing temperature is the most critical.

3. No technology is available to provide the necessary low temperatures for OPV while preventing freeze-sensitive vaccines from freezing in the same cold box. If freeze-sensitive vaccines are packed with OPV in the same box, wrapping the freeze-sensitive vaccines in order to prevent freezing is ineffective.

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This study was conducted on the hypothesis that using chilled water packs during vaccine transportation can safely replace the use of ice packs to prevent freezing of freeze-sensitive vaccines. The plan was to translate favourable results into a policy change in vaccine transportation, mainly focusing on:

- a recommendation to distinguish shipments of OPV from all other vaccines at country level;
- a recommendation to use chilled water packs (2°C to 8°C) for the transportation of all vaccines other than OPV.

At the request of WHO, laboratory and field evaluations were performed to characterize the thermal stability of cold boxes in which chilled water packs were used instead of frozen ice packs in order to maintain cool conditions. The cold boxes/vaccine carriers included RCW25/CF, RCW2/CF (tested at CSCIR, South Africa), BK-VC 1.6CF, CB20-5U-CF (tested at Blow Kings, India) and the insulated international vaccine transport box (tested at BioFarma, Indonesia). VVMs were used to determine whether vaccine stability was maintained.

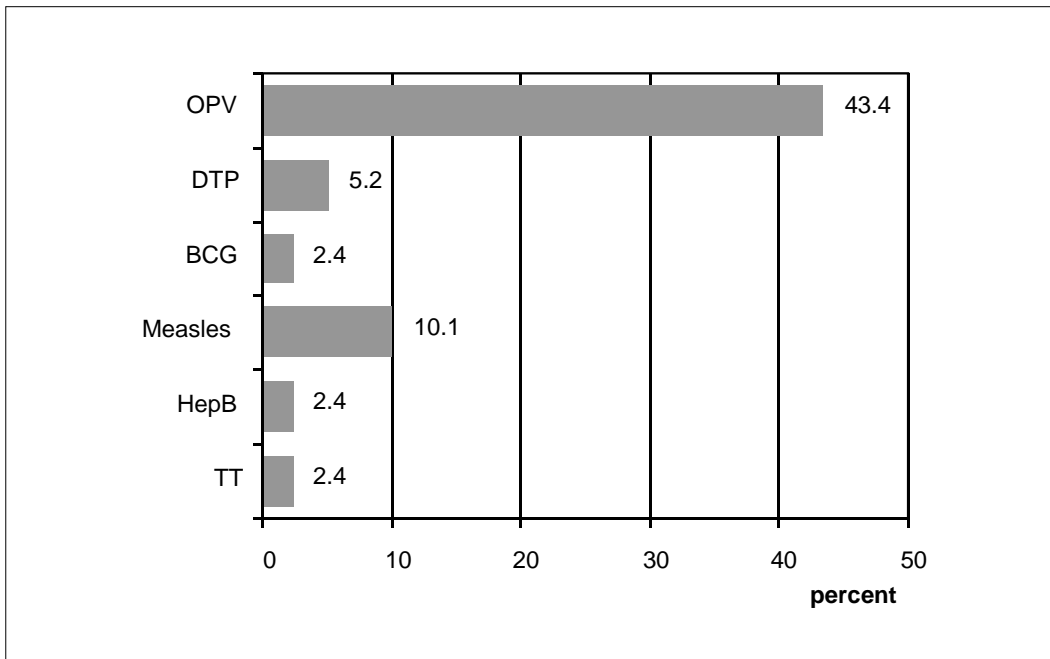
The thermal stabilities of vaccine cold boxes commonly used for vaccine transportation were evaluated in the laboratory. Instead of frozen ice packs, ice packs were filled with tap water and chilled to either +2°C or +8°C (chilled water packs) and tested with vaccine carriers at ambient temperatures of +43°C and +32°C. One set of tests was done without chilled water packs at an ambient temperature of +43°C. A set of four VVMs (VVM2, VVM7, VVM14, VVM30) were attached to the dummy vaccine vials, to which a thermocouple was also attached. Temperatures were monitored at five-minute intervals using a Grant Squirrel data logger: thermocouples recorded three distinct temperatures for each vaccine carrier.

In addition to the laboratory studies, vaccine transportation with chilled water packs was monitored in Nepal, Turkey, and Zimbabwe.

Recorded temperature data were then used to calculate the percentage life of VVM used, on the assumption that if all other factors affecting vaccine stability besides heat were controlled a VVM reading could be used as a proxy for commenting on the life of vaccine.

With the worst-case scenario involving the use of the international shipping box (which does not have a proper lid seal) if chilled water packs were used with a dummy vaccine load, the box being exposed to +43°C ambient temperature for a period of 48 hours, with the hottest thermocouple reading and this exposure being repeated four times, the life losses indicated in Fig. 17 would be recorded by VVMs.

**Fig. 17. Percent life loss calculated on basis of VVM reaction following four times transportation between primary store, three-level intermediate stores and service level**



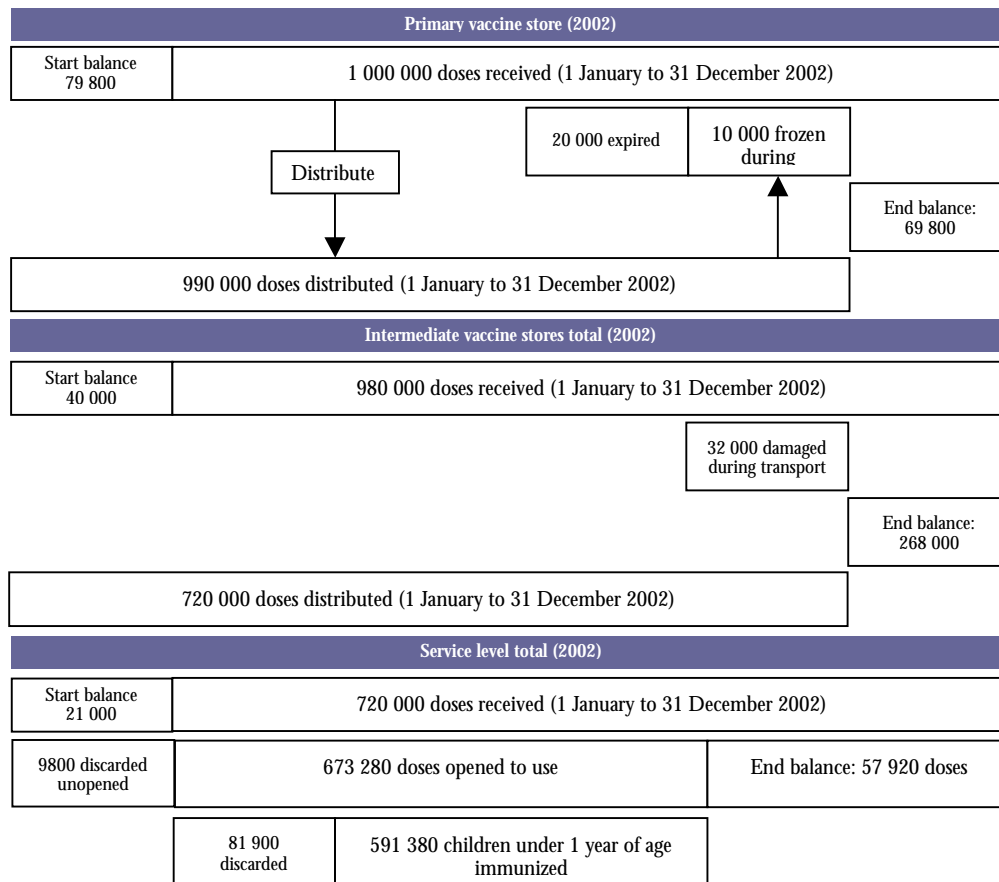
*Each transportation is assumed to be done at a continuous temperature of +43°C for a period of 48 hours with a minimum temperature reading inside the vaccine transport box recorded as 11.5°C, a maximum of 25.3°C, and an average of 18.9°C throughout each journey.*

An analysis of the results of the “no packs” option showed that the highest temperature recorded was 41.2°C, with an average of 33.1°C, which is above the recommended value in the international shipping guidelines. Nevertheless, this could still be an option for highly heat-stable vaccines such as HepB and TT, provided that VVMs were attached to the vials.

On the basis of these results, the use of chilled water packs appears to be a legitimate and safe practice for vaccines other than OPV.

# How to calculate vaccine wastage

Three-dose schedule, target population 300 000 children aged 0–11 months, DTP vaccine in 10-dose vials, estimated vaccine wastage 25% (wastage factor 1.33), targeted immunization coverage 80%.



(Boxes not to scale)

## Proportional vaccine wastage rate in unopened vials (for vaccine cold stores)

For primary vaccine store =  $(20\,000 + 10\,000) / (79\,800 + 1\,000\,000) = 2.7\%$

For intermediate vaccine stores =  $32\,000 / (40\,000 + 980\,000) = 3.1\%$

Total (primary + intermediate) =  $(20\,000 + 10\,000 + 32\,000) / (79\,800 + 40\,000 + 1\,000\,000) = 5.5\%$

## Service level calculations

Vaccine usage rate =  $591\,380 / (21\,000 + 720\,000 - 57\,920) = 86.6\%$

Vaccine wastage rate =  $100 - 86.5 = 13.4\%$

Unopened-vial-specific vaccine wastage rate =  $9\,800 / (21\,000 + 720\,000 - 57\,920) = 1.4\%$

Opened-vial-specific vaccine wastage rate =  $(673\,280 - 591\,380) / (21\,000 + 720\,000 - 57\,920) = 12.0\%$

Proportional vaccine wastage in unopened vials =  $9\,800 / (21\,000 + 720\,000 - 673\,280) = 14.5\%$

Proportional vaccine wastage in opened vials =  $(673\,280 - 591\,380) / 673\,280 = 12.2\%$

Immunization coverage rate =  $591\,380 / (300\,000 \times 3) = 65.7\%$

**National wastage factor** =  $[100 / (100 - 5.5)] \times [100 / (100 - 13.4)] = 1.06 \times 1.15 = 1.22$

With the same assumptions as above,  $300\,000 \times 3 \times 1.22 \times 0.80 = 878\,400$  doses should be ordered for 2003 (available stock ignored)

## If the old formula is used (as shown in Chapter 2)

Vaccine usage rate =  $591\,380 / (79\,800 + 1\,000\,000 - 69\,800) = 58.6\%$

Vaccine wastage rate =  $100 - 58.6 = 41.4\%$

National wastage factor =  $100 / (100 - 41.4) = 1.71$

## Compare these results with correct calculations above

With the same assumptions as above,  $300\,000 \times 3 \times 1.71 \times 0.80 = 1\,231\,200$  doses should be ordered for 2003 (available stock ignored), i.e. **352 800 doses would be ordered unnecessarily.**

The Department of Vaccines and Biologicals was established by the World Health Organization in 1998 to operate within the Cluster of Health Technologies and Pharmaceuticals. The Department's major goal is the achievement of a world in which all people at risk are protected against vaccine-preventable diseases.

Five groups implement its strategy, which starts with the establishment and maintenance of norms and standards, focusing on major vaccine and technology issues, and ends with implementation and guidance for immunization services. The work of the groups is outlined below.

The *Quality Assurance and Safety of Biologicals team* ensures the quality and safety of vaccines and other biological medicines through the development and establishment of global norms and standards.

The *Initiative for Vaccine Research* and its three teams involved in viral, bacterial and parasitic

diseases coordinate and facilitate research and development of new vaccines and immunization-related technologies.

The *Vaccine Assessment and Monitoring team* assesses strategies and activities for reducing morbidity and mortality caused by vaccine-preventable diseases.

The *Access to Technologies team* endeavours to reduce financial and technical barriers to the introduction of new and established vaccines and immunization-related technologies.

The *Expanded Programme on Immunization* develops policies and strategies for maximizing the use of vaccines of public health importance and their delivery. It supports the WHO regions and countries in acquiring the skills, competence and infrastructure needed for implementing these policies and strategies and for achieving disease control and/or elimination and eradication objectives.

## Department of Vaccines and Biologicals

Health Technology and Pharmaceuticals

World Health Organization

CH-1211 Geneva 27

Switzerland

Fax: +41 22 791 4227

Email: [vaccines@who.int](mailto:vaccines@who.int)

or visit our web site at: <http://www.who.int/vaccines-documents>

