Vaccine Presentation Assessment Tool

Analytical approach and user guide

For use with the Vaccine Presentation Assessment Tool (VPAT) Excel model

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Acknowledgements and disclaimer

The Vaccine Presentation Assessment Tool (VPAT) was developed by Andrew Garnett through a project of the PATH Malaria Vaccine Initiative (MVI), with financial support from the Bill & Melinda Gates Foundation.

The VPAT was originally designed for malaria vaccines; it was subsequently extended for use with other new vaccines, with financial support from the GAVI Alliance.

Development of the model would not have been possible without the input and assistance of:

- Alan Brooks, PATH Malaria Vaccine Initiative
- Robin Biellik, PATH Immunization Solutions
- Osman Mansoor, UNICEF
- Ulla Griffiths, London School of Hygiene and Tropical Medicine
- Rosamund Lewis, GAVI Alliance
- Tracey Goodman, WHO, Immunization Vaccine and Biologicals
- Souleymane Kone, WHO, Immunization Vaccine and Biologicals
- Zarifah Reed, WHO, Immunization Vaccine and Biologicals

DISCLAIMER

This model is intended to be a resource. It does not reflect the position of any organization or individual, and the developers are not responsible for decisions taken based upon the model. The reliability of results produced using the model is dependent upon accurate, context-specific cost data. The sources and dates of the figures currently included in the model are as indicated in the various data tables. Users are responsible for modifying and updating these data to suit their own purposes.

Contents

Acronyms

°C	Degrees centigrade
AD	Auto-disable (syringe)
BCG	Bacille Calmette-Guérin (tuberculosis vaccine)
cm	Centimeters
cm3	Cubic centimeters
DT	Diphtheria and tetanus toxoid (vaccine)
DTP	Diptheria-Tetanus-Pertussis vaccine
DTP	Diphtheria-tetanus-pertussis (vaccine)
EPI	Expanded Programme on Immunization
FITG	Fully Immunized Target Group
GAVI	GAVI Alliance (formerly The Global Alliance for Vaccines and Immunization)
HepB or HB	Hepatitis B vaccine
Hib	*Haemophilus influenzae* type b (vaccine)
HPV	Human Papillomavirus (vaccine)
JE	Japanese Encephalitis (vaccine)
lts or l	Liters
m3	Cubic meters
MDVP	Multi-dose vial policy
MMR	Mumps-measles-rubella vaccine
MR	Measles-rubella vaccine
OPV	Oral polio vaccine
PIS	WHO/UNICEF Product Information Sheets
PQS	Performance, Quality, Safety (WHO replacement for PIS system)
Td	Tetanus toxoid with reduced component diphtheria (vaccine)
TT	Tetanus toxoid (vaccine)
UNICEF	United Nations Children's Fund
UNICEF-SD	UNICEF Supply Division
VPAT	Vaccine Presentation Assessment Tool
VPPAG	Vaccine Presentation and Packaging Advisory Group
WHO	World Health Organization
YF	Yellow fever vaccine

1. Purpose

The vaccine presentation assessment tool (VPAT) is designed to model the logistical and financial impact of adding a new vaccine to an immunization schedule. The tool can be used in the following ways:

1. To help establish the most suitable format for a novel vaccine by modelling alternative presentations and packaging. Typically this exercise will take place during early discussions between the public sector and the vaccine manufacturer before these critical manufacturing decisions have been finalised.
2. To assess the impact of adding a new vaccine to a schedule, particularly when this vaccine is available on the market in alternative presentations.
3. To analyse the effect of substituting a new vaccine for an existing one—for example, moving from a series of multi-dose single antigen vaccines to a single-dose combination vaccine.

The output from the tool will provide an analytical basis to support collaborative evidence-based discussions on these impacts, internally within the public sector, and externally with vaccine manufacturers and with target countries.

In the case of a novel vaccine, the desirable endpoint of this process is to ensure that the presentation for a new vaccine balances the following factors:

- Vaccine manufacturing and filling line capacity and restrictions.
- The need to minimize impact on cold chains and waste streams.
- The need to minimize wastage whilst taking account of typical session size(s).
- The need to achieve the lowest possible cost per delivered dose.
- Acceptability of the vaccine presentation(s) to health workers.

Cost and volume data and various default settings are located on a series of data tables which can be changed and/or updated as needed.

1.1 Analytical approach

VPAT's analytical approach is based on a notional 'fully immunized target group' (FITG)[1]. The user defines a context-specific framework which takes account of the immunization schedules, session sizes, cold chain structures, etc. that are typical of the country(s) or region(s) where the target vaccine is to be deployed.

The tool is intended to provide a 'broad brush' analysis at the scale of a whole country of a region. It takes no account of detailed operational issues such as differential vaccine delivery strategies, variations in average session size and coverage in urban, rural and campaign settings, drop-out rates and other modifying factors which may be very significant at the local scale.

Introducing such complicating factors into the model would require so many assumptions that the relatively simple conclusions that can be drawn from using the tool would be obscured.

[1] VPAT estimates the cold chain volume required for the fully immunized child, plus vaccines, such as TT, given to childbearing aged women (CBAW). The term FITG includes both the individual child and its mother.

1.2 Review process

Earlier versions of the tool have been reviewed by members of the Vaccine Presentation and Packaging Advisory Group (VPPAG) and by Dr Ulla Griffiths at the London School of Hygiene and Tropical Medicine.

1.3 User feedback

Users are encouraged to send feedback on the use of this tool to PATH, suggesting areas for correction and improvement. Users who make modifications which upgrade or extend the functionality of the spreadsheet are asked to send a copy of the revised tool to abrooks@malariavaccine.org and to andrew@agarnett.demon.co.uk so that the changes can be moderated and improved versions circulated to other users.

2. Tool structure

VPAT is an Excel spreadsheet. Figure 1 outlines the tool's worksheet structure grouped under the following four headings:

Data entry worksheets:

- Product-specific data entry tables used to characterise the vaccine under investigation.
- Context-specific data entry tables used to define the immunization schedule to which the new vaccine is to be added.
- Context-specific data entry tables used to describe the cold chain structure in which the vaccine will be stored and distributed (from a single to a five-level system).

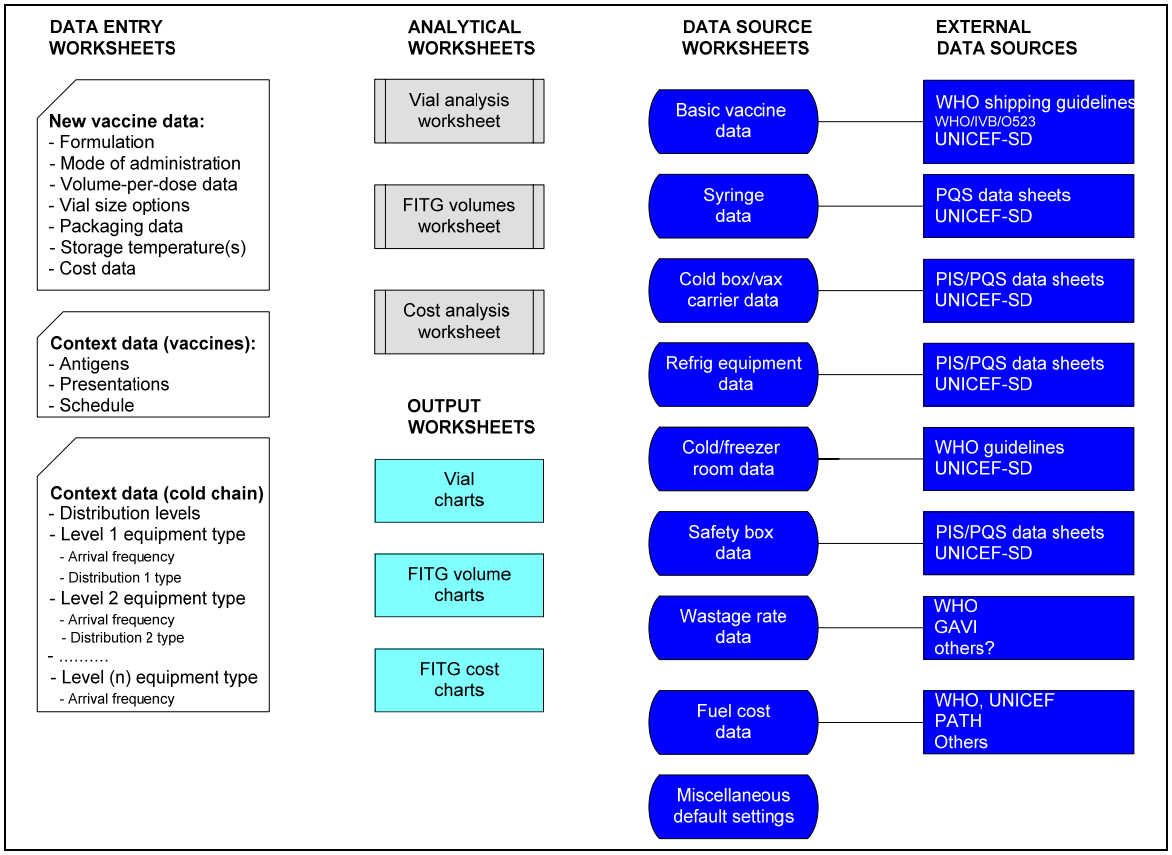
Analysis worksheets:

- The data listed above are processed by a series of analytical modules. These allow the user to undertake 'what-if' analyses covering alternative vaccine formulations and presentations, different vaccine delivery and vaccination schedule options, varying cold chain structures and distribution strategies, etc.

Output worksheets:

- Results of the analysis are summarized on a series of charts.

Figure 1 – VPAT worksheet schematic



Data source worksheets:

- A series of look-up tables hold relevant background data on existing vaccines, cold chain equipment, energy costs, etc. Data in these tables are fully referenced to the relevant source documents; most will need to be updated regularly. In particular in the case of context specific data, such as local energy costs, transport costs, average route distances, etc., the user should enter realistic figures based on the country or region at which the analysis is directed.

3. General procedure

VPAT is based on a three step process which can be used to investigate the impact of the target vaccine in an iterative manner. The suggested

3.1 **Step 1:** Define the target vaccine profile (Worksheet: *New vax*)

The user enters the following data for the target vaccine. Items in brackets are formulation-dependent:

- Vaccine formulation: Liquid, liquid-liquid[2] or lyophilized.
- Number of doses per FITG.
- Vaccine storage temperature.
- (Diluent/dropper[3] storage temperature).
- (Whether vaccine and diluent/droppers are stored together or separately).
- Choice of types of presentation to be analyzed. 'Single-dose'[4], 'compact pre-filled' [5] and 'other pre-filled' options are pre-positioned in the input table; up to six further options can be defined.
- Vaccine volume-per-dose in secondary packaging and in shipping containers.
- (Diluent/dropper volume per dose in secondary packaging and in shipping containers).
- AD-syringe (and reconstitution syringe) sizes for each of the presentation options.
- Notional cost-per-dose options to be used in the vial size analysis. The basic cost-per-dose defined here is the single-dose purchase price.
- Cost differentials (positive or negative) for each of the chosen presentations, as compared with single-dose[6].

3.2 **Step 2:** Define the context (Worksheet: *Context*)

In order to assess the overall impact of introducing the target vaccine, the analytical modules require information on the context within which it is to be introduced. Two data categories specify this context:

Base schedule:

- Types of vaccine in the base schedule.
- Number of doses per FITG.
- Presentation characteristics for each vaccine (extracted from the *Vax data* look-up table).
- Average wastage rate for each vaccine.
- Purchase cost-per-dose for each vaccine.

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[2] This option is included because the formulation of the malaria vaccine, for which an early version of VPAT was developed, may be supplied as a 2 vial all-liquid vaccine, requiring reconstitution.

[3] If the vaccine is administered orally, droppers will likely form part of the presentation and these may be supplied separately.

[4] Single-dose must always be included in the analysis - this is the base presentation against which others are compared.

[5] For example, Uniject®, a single-dose pre-filled flexible plastic capsule and needle assembly manufactured By Becton & Dickinson.

[6] For normal presentations there may be a saving in the vial and filling costs for the larger presentations. Pre-filled presentations will typically be more expensive than standard single-dose, but this additional cost will be partially or wholly offset by savings in syringe and waste disposal costs.

- Which (if any) of the base schedule vaccines is to be replaced by the target vaccine.

Storage and distribution system characteristics:
- Number of storage levels, starting with primary level[7] and ending with the health facility store.
- Type of cold chain equipment used at each storage level.
- Vaccine arrival frequency at each level.
- Mode of transport between each level.
- Mean travel distance between each type of store[8].

3.3 **Step 3:** Vial size break-even analysis (Worksheet: *Vial anal*)

The vial size modelling algorithm for the target vaccine works in the following way:

1. A break-even wastage rate can be calculated for each multi-dose or pre-filled vaccine presentation at each possible purchase price point, such that the cost per delivered dose of any particular combination is equal to the cost per delivered dose for the single-dose baseline presentation. Excel's goal-seeking feature is used to perform this computation.
2. It follows that, if the calculated wastage rate for a particular combination of price and vial size is realistically achievable, then that combination is operationally equal to, or more efficient, in terms of cold chain capacity requirement, than a single dose baseline presentation.
3. Alternatively the user can enter wastage rate data from known sources to establish how any particular combination of presentation and vaccine price is likely to perform against the single-dose baseline.

3.4 **Step 4:** Analyse FITG volumes (Worksheet: *FITG vol*)

The data from the three previous steps are used to establish FITG volumes for the base schedule and for each of the selected new vaccine presentations. These data are then consolidated and presented in a series of charts, each of which compares the base schedule volume with the volumetric effect of each of the chosen new vaccine presentations. The seven charts are as follows:

- Storage volumes at primary and high level intermediate level[9] at +2°C to +8°C.
- Storage volumes at primary and high level intermediate level at -20°C.
- Storage volumes at low level intermediate stores[10] at +2°C to +8°C.

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[7] The level at which vaccine arrives from the vaccine manufacturer. Typically this is a national store, but it could be a regional store.

[8] Depending on the context, this could be the outward trip distance or the round trip distance. For example, if distribution is radial, and there is no backloading, use mean round trip figures. If distribution is a series of delivery 'rounds', use the mean delivery round distance.

[9] The assumption is that any vaccines stored at -20°C (typically only OPV) are always separated out and stored frozen at national and regional levels in accordance with current WHO recommendations. If the new vaccine also has to be kept frozen, the charts will demonstrate this. If it is kept at +2° to +8°C the -20°C chart will show no change. Diluents and droppers that do not need refrigeration are stored outside the cold chain.

[10] In this category of store, all vaccines, including OPV, are stored at +2° to +8°C. Diluents and droppers that do not need refrigeration remain outside the cold chain.

- Storage volumes at health facility stores[11] at +2° to +8°C.
- Shipping volumes (with vaccine stored in insulated shipping containers) from the vaccine manufacturer to the primary store.
- Syringe and safety box volumes. Syringe FITG volumes are measured in their card shipping cartons. Safety box FITG volumes are measured in flat-pack form.
- Assembled safety box volumes. This chart gives an indication of the effect of each of the chosen presentations on the waste stream. The FITG volumes here are calculated using the WHO-specified minimum syringe capacity for safety boxes.

The FITG module uses the wastage rate figures for the target vaccine that were calculated, or entered in **Step 3**. The user selects and reviews the wastage rates for one price point at a time.

3.5 **Step 5:** Analyse FITG costs (Worksheet: *Cost anal*)

The *Cost anal* worksheet uses data from the *New vax* and *Context* worksheets and consists of six tables:

- Table 1 computes unit costs for commodity purchase, distribution and waste disposal.
- Table 2 computes unit costs for cold storage at each level in the cold chain.

The underlying source of these data for both these tables is the series of inbuilt data source worksheets (see Figure 1) and the description of the distribution system which was defined in **Step 2**.

- Table 3 uses Tables 1 and 2 to calculate combined costs per purchased dose for each of the alternative presentations of the target vaccine.
- Table 4 does the same thing for each of the existing vaccines which were selected in **Step 2**.

The key output from both these tables are the three columns grouped under the heading *Costs per purchased dose* and sub-headed *Increasing with vaccine wastage, Reducing with vaccine wastage* and *Varying with the number of doses per vial.* Refer to **Annex 1** for a detailed description of the underlying methodology.

- Table 5 Uses Table 3 to calculate the combined costs per FITG for each version of the target vaccine taking account of the price and wastage rate combination that the user has selected using the 'Select this row' buttons on the *Vial anal* worksheet.
- Table 6 performs a similar calculation on the existing vaccines.

The data from Tables 5 and 6 are then consolidated and presented graphically on the *FITG cost charts* worksheet, as follows:

- Vaccine purchase costs per FITG.
- Total system costs per FITG.
- Support cost breakdown per FITG. Support costs comprise the logistical costs of storing and distributing the vaccine, the costs of purchasing syringes and safety boxes and the costs of distributing these and safely disposing of them after use.

[11] At this level, all vaccines and diluents are kept refrigerated at +2° to +8°C. Only droppers are stored at ambient temperature.

3.6 Data sources

The data source modules are as follows:

1. *Vaccine data:* This table provides data on all the basic EPI vaccines and presentations, including: volume per dose figures for vaccines and diluents, storage temperature data and syringe requirements data. The vaccine-related figures are taken from WHO/VB/05.23: *Guidelines on the international packaging and shipping of vaccines.* Additional vaccines can be added to the table as needed.
2. *Syringe data:* This module tabulates and analyses data on the standard range of PQS pre-qualified AD syringes supplied by the UN agencies. It also includes data on reconstitution syringes[12].
3. *Safety boxes:* This module tabulates and analyses data on the standard range of pre-qualified card safety boxes supplied by the UN agencies.
4. *Cold boxes and vaccine carriers:* This module tabulates and analyses data on the standard range of cold boxes and vaccine carriers supplied by the UN agencies.
5. *Refrigeration equipment:* Cold rooms, freezer rooms, ice-lined refrigerators, compression-cycle refrigerators and freezers, absorption-cycle refrigerators (gas and kerosene) and solar refrigerators are covered by this module. Data are analysed and consolidated to provide the 'life cost/cm³ @ 1 arrival per annum' figures used in the *Cost analysis* module – see Annex 1.
6. *Defaults:* This module includes the following default settings:
   - Distribution costs.
   - Energy costs.
   - Economic life for refrigeration equipment.
   - Peak utilization factor settings for refrigeration equipment.
   - Commodity factors: syringe wastage rate and safety box over-order rate.
   - Cold box bulking factor setting.
   - Commodity purchase, freight and end-of-life disposal costs.
   - Unopened vial wastage rate settings (adjustable by vial size).

[12] Reconstitution syringes are not included in the PIS or PQS systems. Limited data have been obtained from UNICEF-SD.

4. Spreadsheet details

The spreadsheet has been developed in MS Excel 2003. It comprises a workbook with 18 worksheets.

4.1 Security, setup and general user notes

1. *Macros:* The spreadsheet contains macros. Users should 'enable macros' on startup to ensure full functionality.
2. *Protection:* The spreadsheet is supplied with all data entry cells blank, worksheet cells 'locked' and as a password-protected 'read-only' file[13]. To remove the 'read-only status, save a working copy for use on each project.
3. *Protection:* There is no password protection on the worksheet 'lock' so users can go to Tools/Protect and unprotect an individual worksheet if they so wish. Do not do this unless you wish to see the underlying algorithms. Users are strongly advised not to modify algorithms or change worksheet tab titles otherwise they risk corrupting the worksheet or the macros.
4. *Frozen windows:* Several of the worksheets have 'frozen' windows. To fit alternative screen resolutions users may need to unprotect and then unfreeze these sheets. Alternatively, change the zoom setting.
5. *Conditional formatting:* Some worksheets contain conditional formatting. Typically cells may be selectively 'greyed out' when certain choices are made - for example, selection of 'Liquid' vaccine in the *New vax* worksheet removes the option to enter data on reconstitution syringes.
6. *Active data entry cells:* You must enter data in every white cell in an active column or row.
7. *Optional data entry cells:* Pale yellow cells are for entering optional data, or data which overrides a standard setting. Titles to optional entries are highlighted in mauve.
8. *Deleting data:* To remove unwanted data in the white or pale yellow cells simply highlight the individual cell or range and press 'delete' or use the appropriate 'Clear' button to delete previous entries in the worksheet.

A standard cell colouring convention is used throughout the workbook. Figure 2 shows this.

Figure 2 – Cell colouring conventions

Mandatory data entry	CR/FR
Inactive data entry field	1.20
Protected formula result	123
Optional data entry title	Description
Optional data entry field	123
Data from a directly modifiable source table	123
	123
Source data for analysis	123

[13] Three worksheets are kept unlocked to allow macro buttons to work – see Note B on the *Notes* worksheet.

4.2 Spreadsheet design

The workbook contains five types of worksheet, identified by tab colour:

- **Information**: *Notes.*
- **Data entry**: *New vax, Context* and *Vial anal*
- **Analysis tables**: *FITG vol* and *Cost anal.*
- **Charts**: *Vial charts, FITG vol charts, FITG cost charts*.
- **Chart tables**: *FITG vol tables, FITG cost tables* – these contain summary data for the charts worksheets. They are not formatted for printing and need not be consulted by the general user.
- **Data source tables**: *Defaults, Vax data, Refrig data, CB-VC data, SB data, Syringe data.*

Wherever possible, data entry worksheets are designed so that they fit the screen without need for scrolling. Embedded guidance notes are provided where appropriate.

The purpose of each worksheet is explained below.

4.2.1 Cover

The cover sheet carries the name of the new vaccine under investigation and an optional data set ID which the user can enter on the *New vax* worksheet.

Output: The worksheet is formatted for printing.

4.2.2 Notes

The worksheet contains basic user notes and release information.

Output: The worksheet is formatted for printing.

4.2.3 New vax worksheet

Use this worksheet to *e*nter data about the new vaccine that is to be analyzed. Many of the cells contain drop-down-lists from which to select an appropriate option. Enter other relevant data in the remaining white cells. Enter override data in the yellow cells only if this is necessary - otherwise rely on the system defaults.

Tables, 1, 2 and 3 contain mandatory white fields. Note that in Table 2 you must indicate which presentation options you wish to analyze by entering an 'x' in the 'Check' column. Data in these rows will be ignored unless the check column is activated.

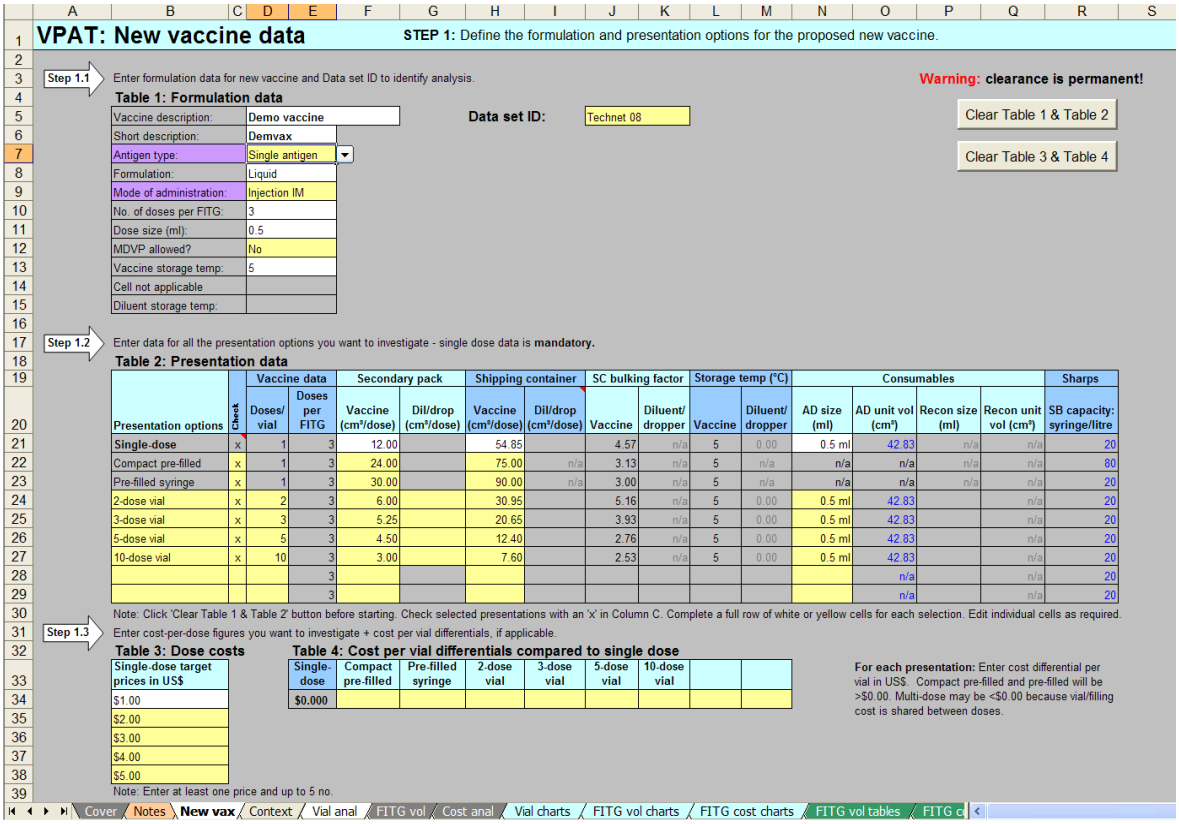
Table 4 need only be completed if there is a known cost-per-dose differential between single-dose and on or more of the other chosen presentations.

To clear the data in any of the tables, press the appropriate ‘Clear’ button.

Output: The worksheet is formatted for printing.

See Figure 3.

Figure 3 – *New vax* worksheet



4.2.4 Context worksheet

Use Table 1 to enter data about the context into which the new vaccine will be introduced. Set up this 'base schedule' using the drop-down list of standard vaccines. Define a wastage rate for each of the vaccines. In the absence of good field-derived data, using the wastage rates proposed by GAVI (2008)[14] is a reasonable basis for the analysis. The issue of wastage rates is further discussed in Annex 1 – A1.2.

Use Table 2 to characterize the storage and distribution system (up to 5 storage levels are allowed). Drop-down lists are used to specify the storage and transport equipment. If necessary use Tables 3, 4 and 5 and the yellow cells in Table 2 to override standard settings imported from the data tables (default values are in blue text).

If the new vaccine is to replace one or more of the existing vaccines in the schedule, use the drop-down list in the Table 1 'Replace vaccine' column to enter 'yes' against the chosen vaccine(s). VPAT will then take account of this replacement when calculating system volumes and costs.

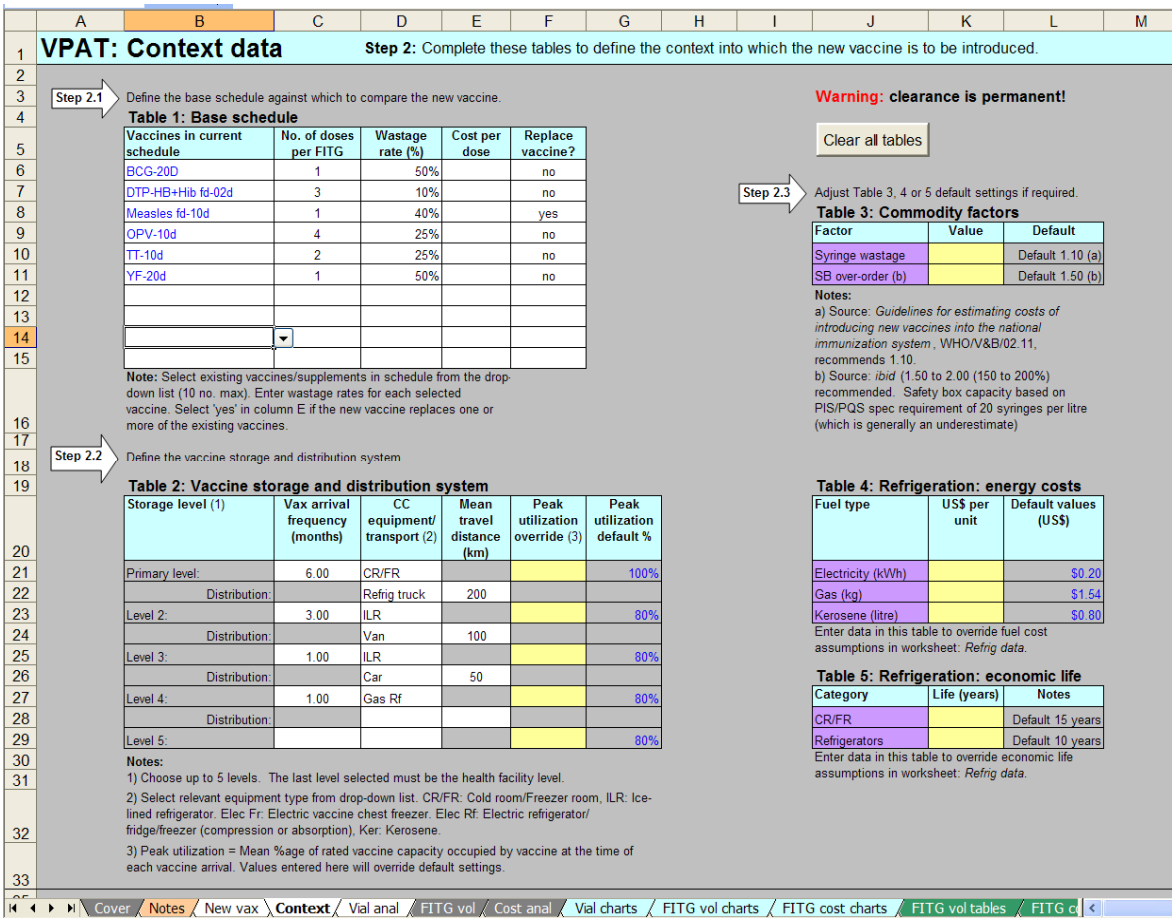
The latest vaccine cost data can be obtained from UNICEF Supply Division[15].

See Figure 4.

[14] *GAVI Alliance Handbook: Country proposal and monitoring processes.* 2008. http://www.gavialliance.org/resources/Handbook_in_English.pdf

[15] For example: http://www.unicef.org/supply/index_gavi.html

Figure 4 – *Context* worksheet



VPAT: Context data

Step 2: Complete these tables to define the context into which the new vaccine is to be introduced.

Step 2.1 Define the base schedule against which to compare the new vaccine.

Table 1: Base schedule

Vaccines in current schedule	No. of doses per FITG	Wastage rate (%)	Cost per dose	Replace vaccine?
BCG-20D	1	50%		no
DTP-HB+Hib fd-02d	3	10%		no
Measles fd-10d	1	40%		yes
OPV-10d	4	25%		no
TT-10d	2	25%		no
YF-20d	1	50%		no

Note: Select existing vaccines/supplements in schedule from the drop-down list (10 no. max). Enter wastage rates for each selected vaccine. Select 'yes' in column E if the new vaccine replaces one or more of the existing vaccines.

Step 2.2 Define the vaccine storage and distribution system

Table 2: Vaccine storage and distribution system

Storage level (1)	Vax arrival frequency (months)	CC equipment/ transport (2)	Mean travel distance (km)	Peak utilization override (3)	Peak utilization default %
Primary level:	6.00	CR/FR			100%
Distribution:		Refrig truck	200		
Level 2:	3.00	ILR			80%
Distribution:		Van	100		
Level 3:	1.00	ILR			80%
Distribution:		Car	50		
Level 4:	1.00	Gas Rf			80%
Distribution:					
Level 5:					80%

Notes:
1) Choose up to 5 levels. The last level selected must be the health facility level.
2) Select relevant equipment type from drop-down list. CR/FR: Cold room/Freezer room, ILR: Ice-lined refrigerator. Elec Fr: Electric vaccine chest freezer. Elec Rf: Electric refrigerator/ fridge/freezer (compression or absorption), Ker: Kerosene.
3) Peak utilization = Mean %age of rated vaccine capacity occupied by vaccine at the time of each vaccine arrival. Values entered here will override default settings.

Warning: clearance is permanent!

Clear all tables

Step 2.3 Adjust Table 3, 4 or 5 default settings if required.

Table 3: Commodity factors

Factor	Value	Default
Syringe wastage		Default 1.10 (a)
SB over-order (b)		Default 1.50 (b)

Notes:
a) Source: *Guidelines for estimating costs of introducing new vaccines into the national immunization system*, WHO/V&B/02.11, recommends 1.10.
b) Source: *ibid* (1.50 to 2.00 (150 to 200%) recommended. Safety box capacity based on PIS/PQS spec requirement of 20 syringes per litre (which is generally an underestimate)

Table 4: Refrigeration: energy costs

Fuel type	US$ per unit	Default values (US$)
Electricity (kWh)		$0.20
Gas (kg)		$1.54
Kerosene (litre)		$0.80

Enter data in this table to override fuel cost assumptions in worksheet: *Refrig data*.

Table 5: Refrigeration: economic life

Category	Life (years)	Notes
CR/FR		Default 15 years
Refrigerators		Default 10 years

Enter data in this table to override economic life assumptions in worksheet: *Refrig data*.

Cover | Notes | New vax | **Context** | Vial anal | FITG vol | Cost anal | Vial charts | FITG vol charts | FITG cost charts | FITG vol tables | FITG c

4.2.5 Vial anal worksheet

Use this worksheet to establish realistic wastage rates for each of your *New vax* choices.

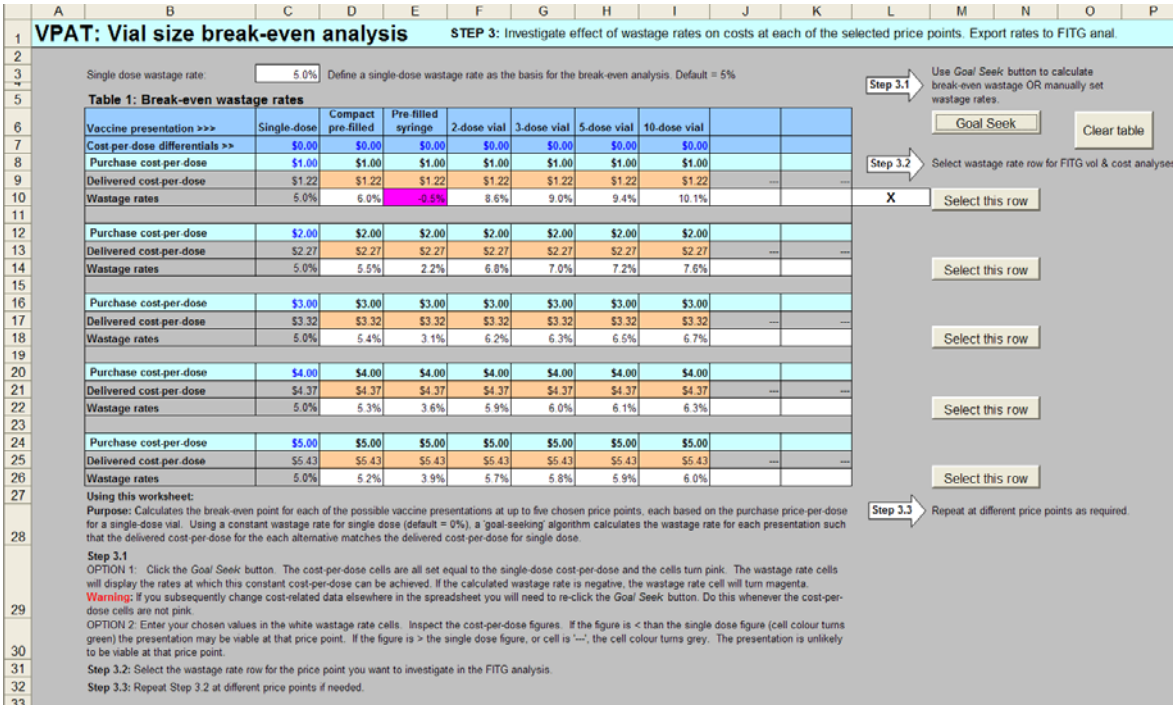
Start by entering a wastage rate for the single-dose presentation in the top white cell. 5% is the figure used by GAVI[16], but field evidence may suggest another figure.

Option 1: Click the 'Goal seek' button to calculate the break-even wastage rates – all the *Delivered cost-per-dose* cells will turn pink and the cost per dose in each row will exactly equal the cost-per-dose for the basic single-dose presentation. Read off the relevant wastage rates against each combination and assess whether they are achievable. In Figure 5 below, at a price of $3.50 per dose, the calculated wastage rate of 8.8% for 2-dose may be achievable, whereas the wastage rate of 10.0% for 10-dose vials is clearly not.

If the extra-over cost of a pre-filled presentation as defined in Table 4 of *New vax* is very high, a negative wastage rate may be calculated by the goal seeking algorithm. When this occurs, the cell is highlighted in magenta. The cell will also change to magenta if Table 3 of *New vax* is not fully completed – i.e. one of the purchase cost-per-dose rows is set to $0.00. Ignore these rows. Cell E10 in Figure 5 shows an example; in this case for a pre-filled syringe presentation.

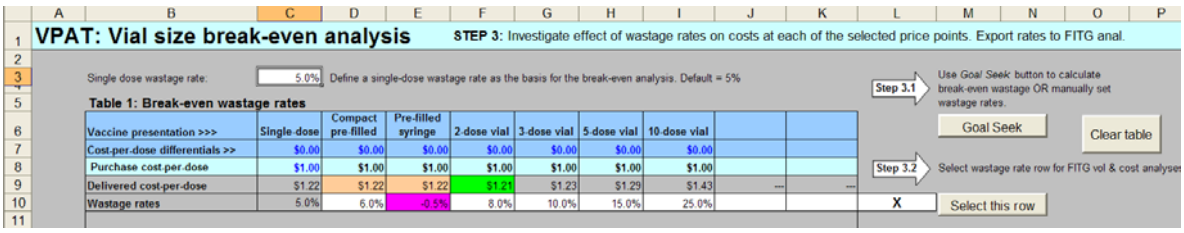
[16] *GAVI Alliance Handbook: Country proposal and monitoring processes.* 2008. http://www.gavialliance.org/resources/Handbook_in_English.pdf

Figure 5 – *Vial anal* worksheet – Option 1



Option 2: Enter a specific wastage rate in one or more of the white *wastage rate* cells. The algorithm will then calculate the delivered cost-per-dose for that rate at the chosen vaccine purchase price. A delivered cost-per-dose that is lower than the delivered cost-per-dose for single-dose is highlighted in green (e.g. 2-, 3- and 5-dose below); one that is higher is highlighted in grey (e.g. 10-dose below). One that is identical to single-dose will again become pink. See Figure 6.

Figure 6 – *Vial anal* worksheet – Option 2



Finally, choose the wastage rate row you want to analyse in the remaining worksheets by pressing the relevant 'Select this row' button. You can return to select another row at any point. In Figures 5 and 6, row 10 has been selected.

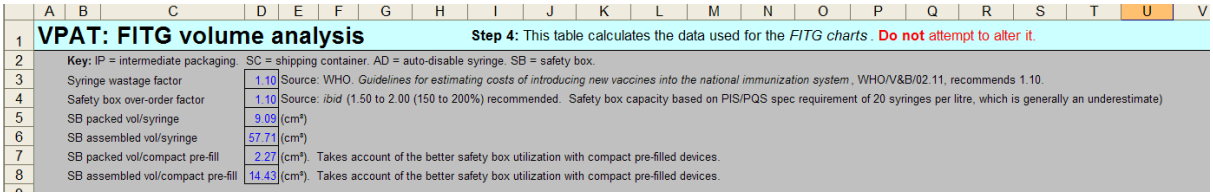
Output: The worksheet is formatted for printing.

4.2.6 FITG vol worksheet

This table calculates volume and other data per Fully Immunized Target Group. These data are further analyzed in the *FITG tables* worksheet, which in turn provide the data for the *FITG vol charts*. No user action is required.

The small table at the top of the worksheet imports default factors from the data source worksheets – see Figure 7. These factors are used to calculate the volume of syringes and safety boxes. Syringe volumes are calculated on the basis of the WHO/GAVI bundling policy – namely 1.1 AD administration syringes per delivered dose of vaccine and 1.1 reconstitution syringes per vial of vaccine. The syringe and safety box wastage and over-order factors can be altered in Table 5 of the *Defaults* worksheet.

Figure 7 – *FITG anal* worksheet – syringe and safety box factors



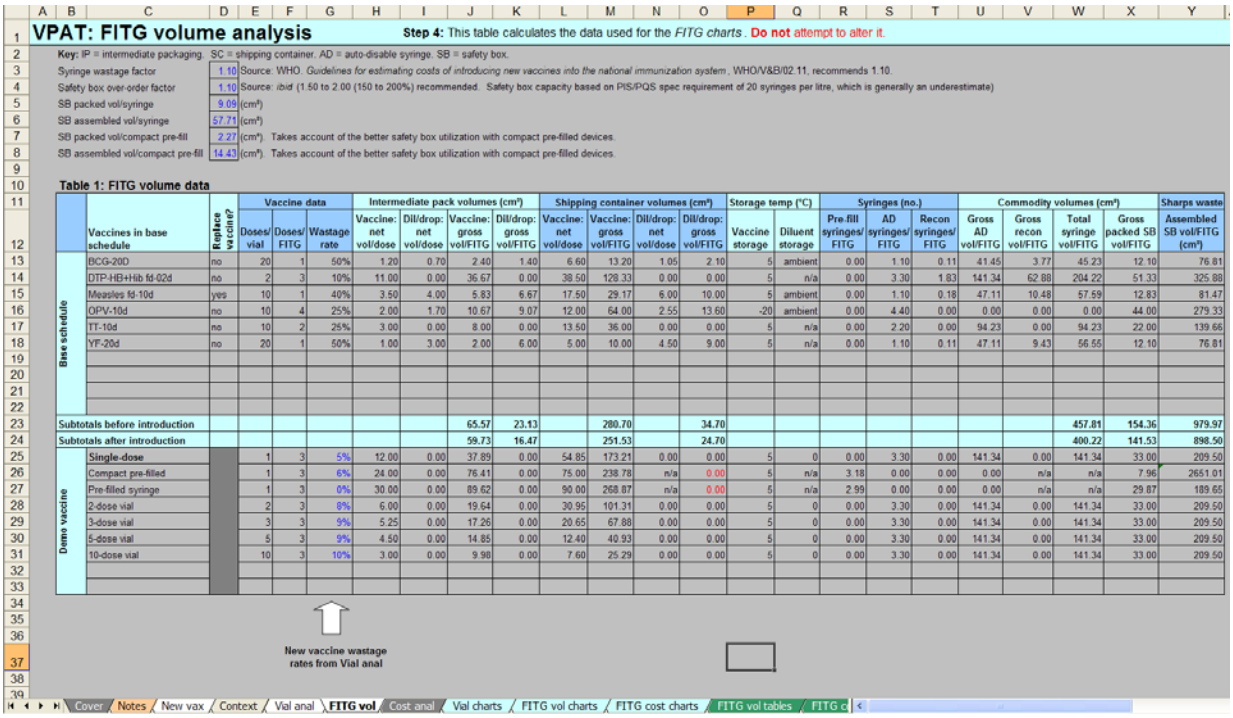
VPAT: FITG volume analysis — **Step 4:** This table calculates the data used for the *FITG charts*. **Do not** attempt to alter it.

Key: IP = intermediate packaging. SC = shipping container. AD = auto-disable syringe. SB = safety box.

Syringe wastage factor	1.10	Source: WHO. *Guidelines for estimating costs of introducing new vaccines into the national immunization system*, WHO/V&B/02.11, recommends 1.10.
Safety box over-order factor	1.10	Source: *ibid* (1.50 to 2.00 (150 to 200%) recommended. Safety box capacity based on PIS/PQS spec requirement of 20 syringes per litre, which is generally an underestimate)
SB packed vol/syringe	9.09	(cm³)
SB assembled vol/syringe	57.71	(cm³)
SB packed vol/compact pre-fill	2.27	(cm³). Takes account of the better safety box utilization with compact pre-filled devices.
SB assembled vol/compact pre-fill	14.43	(cm³). Takes account of the better safety box utilization with compact pre-filled devices.

Figure 8 shows the complete worksheet.

Figure 8 – *FITG anal* worksheet



VPAT: FITG volume analysis — **Step 4:** This table calculates the data used for the *FITG charts*. **Do not** attempt to alter it.

Key: IP = intermediate packaging. SC = shipping container. AD = auto-disable syringe. SB = safety box.

Syringe wastage factor	1.10	Source: WHO. *Guidelines for estimating costs of introducing new vaccines into the national immunization system*, WHO/V&B/02.11, recommends 1.10.
Safety box over-order factor	1.10	Source: *ibid* (1.50 to 2.00 (150 to 200%) recommended. Safety box capacity based on PIS/PQS spec requirement of 20 syringes per litre, which is generally an underestimate)
SB packed vol/syringe	9.09	(cm³)
SB assembled vol/syringe	57.71	(cm³)
SB packed vol/compact pre-fill	2.27	(cm³). Takes account of the better safety box utilization with compact pre-filled devices.
SB assembled vol/compact pre-fill	14.43	(cm³). Takes account of the better safety box utilization with compact pre-filled devices.

Table 1: FITG volume data

	Vaccines in base schedule	Replace vaccine?	Vaccine data: Doses/ vial	Doses/ FITG	Wastage rate	Intermediate pack volumes (cm³): Vaccine: net vol/dose	Dil/drop: net vol/dose	Vaccine: gross vol/FITG	Dil/drop: gross vol/FITG	Shipping container volumes (cm³): Vaccine: net vol/dose	Vaccine: gross vol/FITG	Dil/drop: net vol/dose	Dil/drop: gross vol/FITG	Storage temp (°C): Vaccine storage	Diluent storage	Syringes (no.): Pre-fill syringes/ FITG	AD syringes/ FITG	Recon syringes/ FITG	Commodity volumes (cm³): Gross AD vol/FITG	Gross recon vol/FITG	Total syringe vol/FITG	Gross packed SB vol/FITG	Sharps waste: Assembled SB vol/FITG (cm³)
Base schedule	BCG-20D	no	20	1	50%	1.20	0.70	2.40	1.40	6.60	13.20	1.05	2.10	5	ambient	0.00	1.10	0.11	41.45	3.77	45.23	12.10	76.81
	DTP-HB+Hib fd-02d	no	2	3	10%	11.00	0.00	36.67	0.00	38.50	128.33	0.00	0.00	5	n/a	0.00	3.30	1.83	141.34	62.88	204.22	51.33	325.88
	Measles fd-10d	yes	10	1	40%	3.50	4.00	5.83	6.67	17.50	29.17	6.00	10.00	5	ambient	0.00	1.10	0.18	47.11	10.48	57.59	12.83	81.47
	OPV-10d	no	10	4	25%	2.00	1.70	10.67	9.07	12.00	64.00	2.55	13.60	-20	ambient	0.00	4.40	0.00	0.00	0.00	0.00	44.00	279.33
	TT-10d	no	10	2	25%	3.00	0.00	8.00	0.00	13.50	36.00	0.00	0.00	5	n/a	0.00	2.20	0.00	94.23	0.00	94.23	22.00	139.66
	YF-20d	no	20	1	50%	1.00	3.00	2.00	6.00	5.00	10.00	4.50	9.00	5	n/a	0.00	1.10	0.11	47.11	9.43	56.55	12.10	76.81
Subtotals before introduction								65.57	23.13		280.70		34.70								457.81	154.36	979.97
Subtotals after introduction								59.73	16.47		251.53		24.70								400.22	141.53	898.50
Demo vaccine	Single-dose		1	3	5%	12.00	0.00	37.89	0.00	54.85	173.21	0.00	0.00	5	0	0.00	3.30	0.00	141.34	0.00	141.34	33.00	209.50
	Compact pre-filled		1	3	6%	24.00	0.00	76.41	0.00	75.00	238.78	n/a	0.00	5	n/a	3.18	0.00	0.00	0.00	n/a	n/a	7.96	2651.01
	Pre-filled syringe		1	3	0%	30.00	0.00	89.62	0.00	90.00	268.87	n/a	0.00	5	n/a	2.99	0.00	0.00	0.00	n/a	n/a	29.87	189.65
	2-dose vial		2	3	0%	6.00	0.00	19.64	0.00	30.95	101.31	0.00	0.00	5	0	0.00	3.30	0.00	141.34	0.00	141.34	33.00	209.50
	3-dose vial		3	3	0%	5.25	0.00	17.26	0.00	20.65	67.88	0.00	0.00	5	0	0.00	3.30	0.00	141.34	0.00	141.34	33.00	209.50
	5-dose vial		5	3	0%	4.50	0.00	14.85	0.00	12.40	40.93	0.00	0.00	5	0	0.00	3.30	0.00	141.34	0.00	141.34	33.00	209.50
	10-dose vial		10	3	10%	3.00	0.00	9.98	0.00	7.60	25.29	0.00	0.00	5	0	0.00	3.30	0.00	141.34	0.00	141.34	33.00	209.50

New vaccine wastage rates from Vial anal

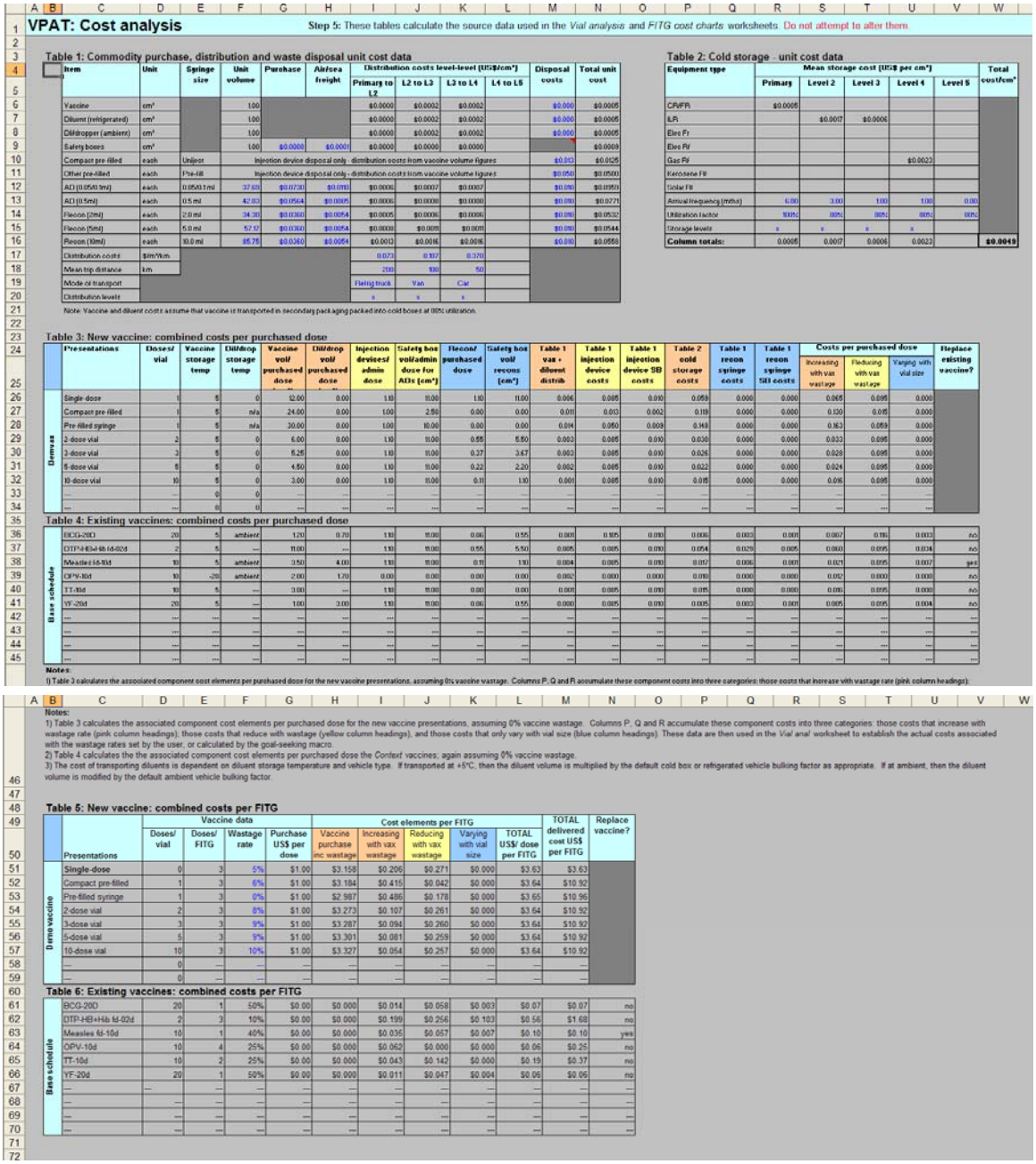
Cover | Notes | New vax | Context | Vial anal | FITG vol | Cost anal | Vial charts | FITG vol charts | FITG cost charts | FITG vol tables | FITG c

Output: The worksheet is formatted for printing.

4.2.7 Cost anal worksheet

The tables in this worksheet use data from the previous worksheets and from the database tables to establish the 'cost-per-delivered-dose' for each of the selected new vaccine presentation options. These data are subsequently used in the hidden *FITG cost anal* worksheet, which drives the *FITG cost charts.* No user action is required. Figure 9 shows the complete set of six tables.

Figure 9 – *Cost anal* worksheet



VPAT: Cost analysis

Step 5: These tables calculate the source data used in the *Vial analysis* and *FITG cost charts* worksheets. Do not attempt to alter them.

Table 1: Commodity purchase, distribution and waste disposal unit cost data

Item	Unit	Syringe size	Unit volume	Purchase	Airsea freight	Distribution costs level-level [US$/cm³] Primary to L2	L2 to L3	L3 to L4	L4 to L5	Disposal costs	Total unit cost
Vaccine	cm³		1.00			$0.0000	$0.0002	$0.0002		$0.000	$0.0005
Diluent (refrigerated)	cm³		1.00			$0.0000	$0.0002	$0.0002		$0.000	$0.0005
Dilidropper (ambient)	cm³		1.00			$0.0000	$0.0002	$0.0002		$0.000	$0.0005
Safety boxes	cm³		1.00	$0.0000	$0.0001	$0.0000	$0.0000	$0.0000			$0.0009
Compact pre-filled	each	Uniject	Injection device disposal only - distribution costs from vaccine volume figures							$0.043	$0.0126
Other pre-filled	each	Pre-fill	Injection device disposal only - distribution costs from vaccine volume figures							$0.050	$0.0500
AD (0.05/0.1ml)	each	0.05/0.1 ml	37.69	$0.0730	$0.0193	$0.0006	$0.0007	$0.0007		$0.093	$0.0959
AD (0.5ml)	each	0.5 ml	42.83	$0.0564	$0.0005	$0.0006	$0.0008	$0.0008		$0.093	$0.0771
Flecon (2ml)	each	2.0 ml	34.30	$0.0360	$0.0054	$0.0005	$0.0006	$0.0006		$0.093	$0.0532
Flecon (5ml)	each	5.0 ml	57.17	$0.0360	$0.0054	$0.0008	$0.0009	$0.0011		$0.093	$0.0544
Flecon (10ml)	each	10.0 ml	85.76	$0.0360	$0.0054	$0.0012	$0.0016	$0.0016		$0.093	$0.0556
Distribution costs	$/m³/km					0.073	0.107	0.370			
Mean trip distance	km					200	100	50			
Mode of transport						Fleing truck	Van	Car			
Distribution levels						x	x	x			

Note: Vaccine and diluent costs assume that vaccine is transported in secondary packaging packed into cold boxes at 80% utilization.

Table 2: Cold storage - unit cost data

Equipment type	Mean storage cost [US$ per cm³] Primary	Level 2	Level 3	Level 4	Level 5	Total cost/cm³
CP/FR	$0.0006					
ILR		$0.0017	$0.0006			
Elec Fr						
Elec Fil						
Gas Fil				$0.0023		
Kerosene Fil						
Solar Fil						
Annual frequency (mths)	6.00	3.00	1.00	1.00	0.00	
Utilization factor	100%	80%	80%	80%	80%	
Storage levels	x	x	x	x		
Column totals:	0.0006	0.0017	0.0006	0.0023		**$0.0049**

Table 3: New vaccine: combined costs per purchased dose

	Presentations	Doses/ vial	Vaccine storage temp	Dilidrop storage temp	Vaccine vol/ purchased dose	Dilidrop vol/ purchased dose	Injection devices/ admin dose	Safety box vol/admin dose for AEIs (cm³)	Recon/ purchased dose	Safety box vol/ recons (cm³)	Table 1 vax + diluent distrib	Table 1 injection device costs	Table 1 injection device SB costs	Table 2 cold storage costs	Table 1 recon syringe costs	Table 1 recon syringe SB costs	Costs per purchased dose: Increasing with vax wastage	Costs per purchased dose: Reducing with vax wastage	Costs per purchased dose: Varying with vial size	Replace existing vaccine?
Dense	Single-dose	1	5	0	12.00	0.00	1.00	11.00	1.00	11.00	0.006	0.005	0.010	0.059	0.000	0.000	0.065	0.005	0.000	
	Compact pre-filled	1	5	n/a	24.00	0.00	1.00	2.50	0.00	0.00	0.011	0.013	0.002	0.119	0.000	0.000	0.130	0.015	0.000	
	Pre-filled syringe	1	5	n/a	30.00	0.00	1.00	10.00	0.00	0.00	0.014	0.050	0.009	0.149	0.000	0.000	0.163	0.059	0.000	
	2-dose vial	2	5	0	6.00	0.00	1.10	11.00	0.55	5.50	0.003	0.005	0.010	0.030	0.000	0.000	0.033	0.005	0.000	
	3-dose vial	3	5	0	5.25	0.00	1.10	11.00	0.37	3.67	0.003	0.005	0.010	0.026	0.000	0.000	0.028	0.005	0.000	
	5-dose vial	5	5	0	4.50	0.00	1.10	11.00	0.22	2.20	0.002	0.005	0.010	0.022	0.000	0.000	0.024	0.005	0.000	
	10-dose vial	10	5	0	3.00	0.00	1.10	11.00	0.11	1.10	0.001	0.005	0.010	0.015	0.000	0.000	0.016	0.005	0.000	
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	...	...	0	0	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	

Table 4: Existing vaccines: combined costs per purchased dose

Base schedule	BCG-20D	20	5	ambient	1.20	0.70	1.10	11.00	0.06	0.55	0.001	0.005	0.010	0.006	0.003	0.001	0.007	0.010	0.003	no
	DTP-HB+Hib fd-02d	2	5	---	11.00	...	1.10	11.00	0.55	5.50	0.005	0.005	0.010	0.054	0.029	0.005	0.060	0.005	0.034	no
	Measles fd-10d	10	5	ambient	3.50	4.00	1.10	11.00	0.11	1.10	0.004	0.005	0.010	0.017	0.006	0.001	0.021	0.005	0.007	yes
	OPV-10d	10	-20	ambient	2.00	1.70	0.00	0.00	0.00	0.00	0.002	0.000	0.000	0.010	0.000	0.000	0.012	0.000	0.000	no
	TT-10d	10	5	---	3.00	...	1.10	11.00	0.00	0.00	0.001	0.005	0.010	0.015	0.000	0.000	0.016	0.005	0.000	no
	YF-20d	20	5	---	1.00	3.00	1.10	11.00	0.06	0.55	0.000	0.005	0.010	0.005	0.003	0.001	0.005	0.005	0.004	no
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Notes:

i) Table 3 calculates the associated component cost elements per purchased dose for the new vaccine presentations, assuming 0% vaccine wastage. Columns P, Q and R accumulate these component costs into three categories: those costs that increase with wastage rate (pink column headings).

Notes:

1) Table 3 calculates the associated component cost elements per purchased dose for the new vaccine presentations, assuming 0% vaccine wastage. Columns P, Q and R accumulate these component costs into three categories: those costs that increase with wastage rate (pink column headings); those costs that reduce with wastage (yellow column headings), and those costs that only vary with vial size (blue column headings). These data are then used in the *Vial anal* worksheet to establish the actual costs associated with the wastage rates set by the user, or calculated by the goal-seeking macro.

2) Table 4 calculates the the associated component cost elements per purchased dose the *Context* vaccines, again assuming 0% vaccine wastage.

3) The cost of transporting diluents is dependent on diluent storage temperature and vehicle type. If transported at +5°C, then the diluent volume is multiplied by the default cold box or refrigerated vehicle bulking factor as appropriate. If at ambient, then the diluent volume is modified by the default ambient vehicle bulking factor.

Table 5: New vaccine: combined costs per FITG

	Presentations	Vaccine data: Doses/ vial	Doses/ FITG	Wastage rate	Purchase US$ per dose	Cost elements per FITG: Vaccine purchase inc wastage	Increasing with vax wastage	Reducing with vax wastage	Varying with vial size	TOTAL US$/ dose per FITG	TOTAL delivered cost US$ per FITG	Replace vaccine?
Dense vaccine	Single-dose	0	3	5%	$1.00	$3.150	$0.206	$0.271	$0.000	$3.63	$3.63	
	Compact pre-filled	1	3	6%	$1.00	$3.184	$0.415	$0.042	$0.000	$3.64	$10.92	
	Pre-filled syringe	1	3	0%	$1.00	$2.987	$0.486	$0.178	$0.000	$3.65	$10.96	
	2-dose vial	2	3	8%	$1.00	$3.273	$0.107	$0.261	$0.000	$3.64	$10.92	
	3-dose vial	3	3	9%	$1.00	$3.287	$0.094	$0.260	$0.000	$3.64	$10.92	
	5-dose vial	5	3	9%	$1.00	$3.301	$0.081	$0.259	$0.000	$3.64	$10.92	
	10-dose vial	10	3	10%	$1.00	$3.327	$0.054	$0.257	$0.000	$3.64	$10.92	
	---	0	---	---	---	---	---	---	---	---	---	
	---	0	---	---	---	---	---	---	---	---	---	

Table 6: Existing vaccines: combined costs per FITG

Base schedule	BCG-20D	20	1	50%	$0.00	$0.000	$0.014	$0.058	$0.003	$0.07	$0.07	no
	DTP-HB+Hib fd-02d	2	3	10%	$0.00	$0.000	$0.199	$0.256	$0.103	$0.56	$1.68	no
	Measles fd-10d	10	1	40%	$0.00	$0.000	$0.035	$0.057	$0.007	$0.10	$0.10	yes
	OPV-10d	10	4	25%	$0.00	$0.000	$0.062	$0.000	$0.000	$0.06	$0.25	no
	TT-10d	10	2	25%	$0.00	$0.000	$0.043	$0.142	$0.000	$0.19	$0.37	no
	YF-20d	20	1	50%	$0.00	$0.000	$0.011	$0.047	$0.004	$0.06	$0.06	no
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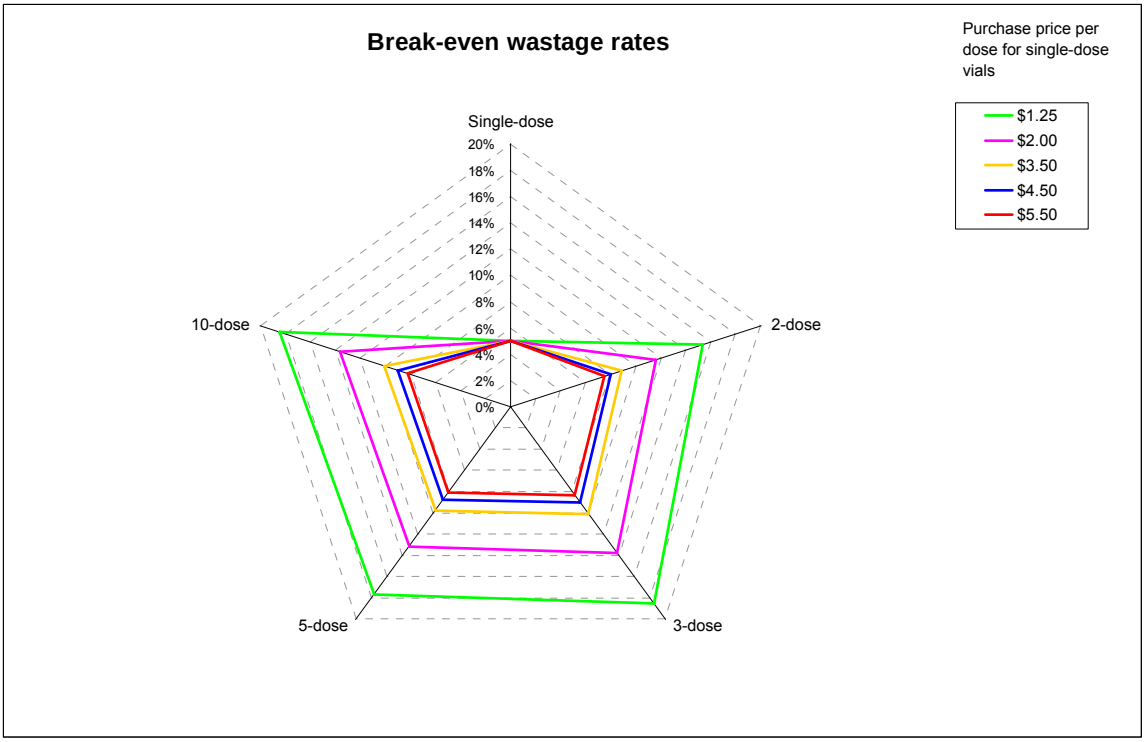
Output: The worksheet is formatted for printing (2 pages).

4.2.8 Vial charts worksheet

This chart is based uses the *Vial anal* worksheet data. It shows contour lines for each of the selected price points and indicates the break-even (or user set) wastage rates for each of the chosen presentations. All contour lines converge on the single-dose axis, at which point wastage rate is invariant, regardless of cost-per-dose. Figure 10 shows an example.

Figure 10 – *Vial anal* chart



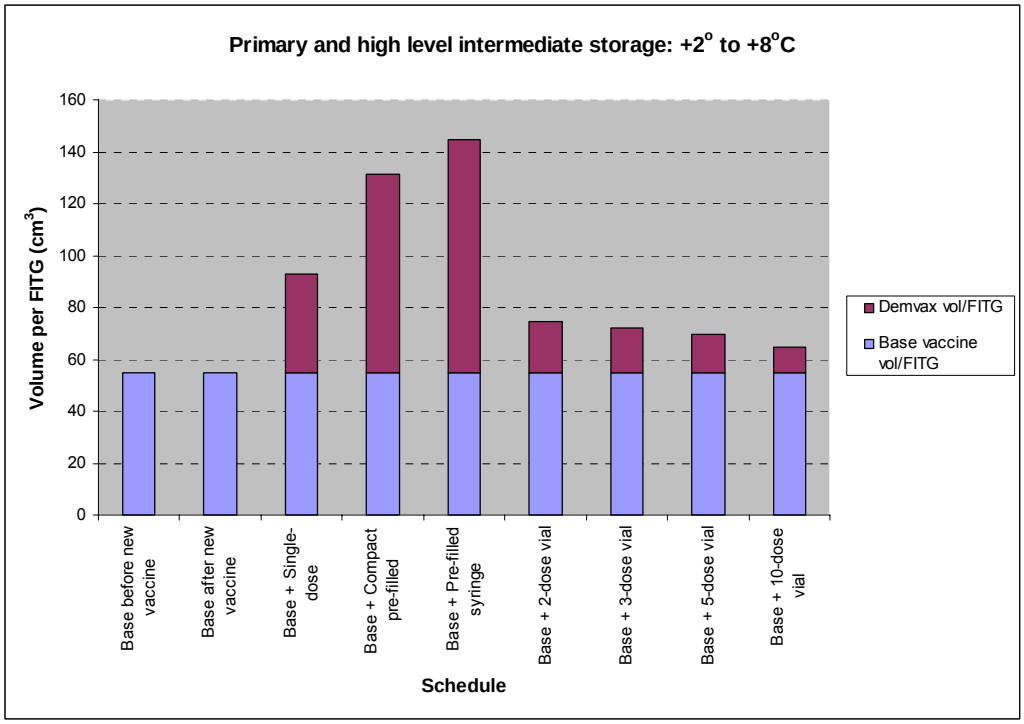
Output: The worksheet is formatted for printing.

4.2.9 FITG vol charts worksheet

There are a total of seven charts on this worksheet. The first one can be used to illustrate the main features shared by all of them – see Figure 11.

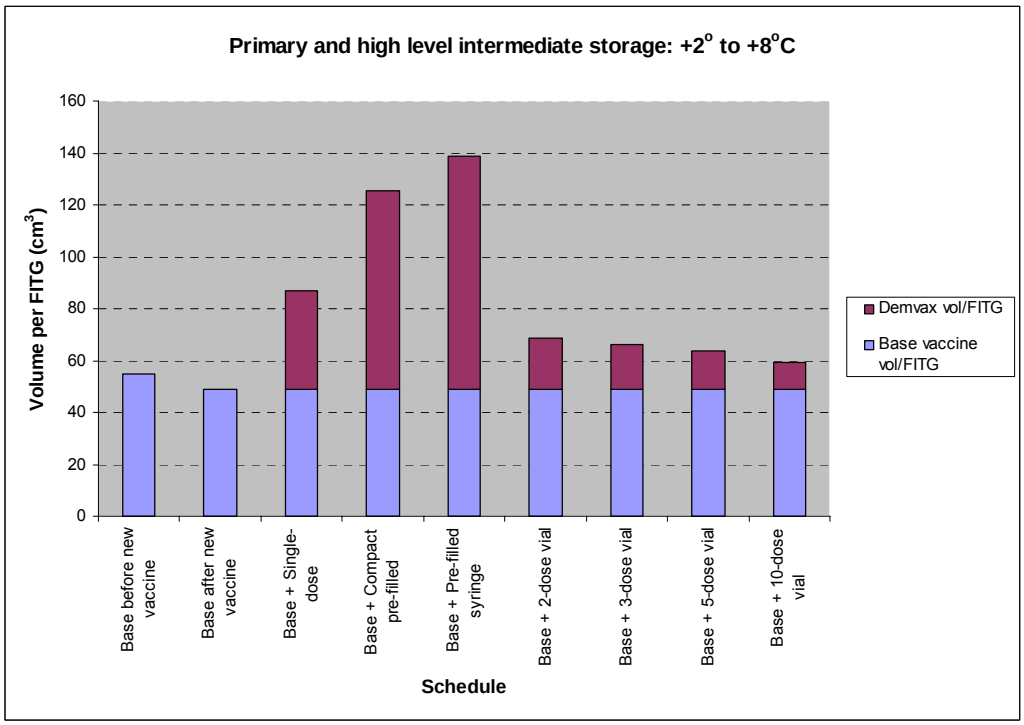
In this example, the blue bars represent the storage volume of the base schedule at a primary or high level intermediate store where vaccine that is to be kept at -20°C is stored separately. The purple bars show the additional volume of the new vaccine in five alternative presentations. In this example, the base schedule remains unchanged after the addition of the new vaccine.

Figure 11 – *FITG vol* chart – schedule addition



In Figure 12, the new vaccine is assumed to replace one of the existing ones (2-dose DTP-HepB+Hib, which is a bulky vaccine). Consequently the second and subsequent blue bars are much smaller than the original base schedule.

Figure 12 – *FITG vol* chart – schedule substitution



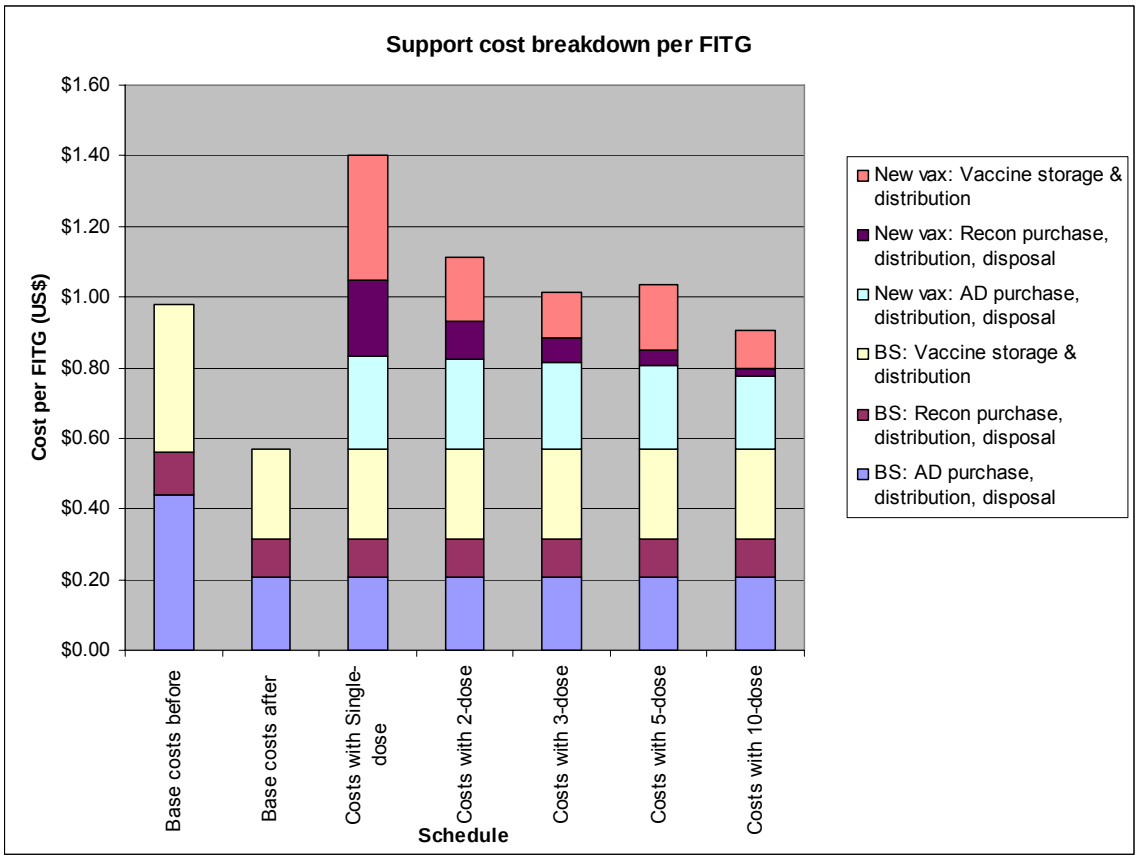
At the top of the worksheet there is a 'Filter' button and an 'Unfilter' button. Use these buttons to hide or reveal missing data points. In the examples above, there are seven columns. Clicking the 'unfilter' button would show a total of 11 columns. Two of these would be blank because two of the rows in Table 2 of the *New vax* worksheet contain no data – see Figure 3.

Output: The worksheet is formatted for printing (3 pages).

4.2.10 FITG cost charts worksheet

There are three charts on this worksheet showing vaccine purchase costs per FITG, total system costs per FITG and support cost breakdown per FITG. As shown below, the support costs chart summarises the logistical costs of storing and distributing the vaccine, the costs of purchasing syringes and safety boxes and the costs of distributing these and safely disposing of them after use. Figure 13 gives an example.

Figure 13 – *FITG cost* chart[17]



Output: The worksheet is formatted for printing.

4.2.11 Defaults worksheet

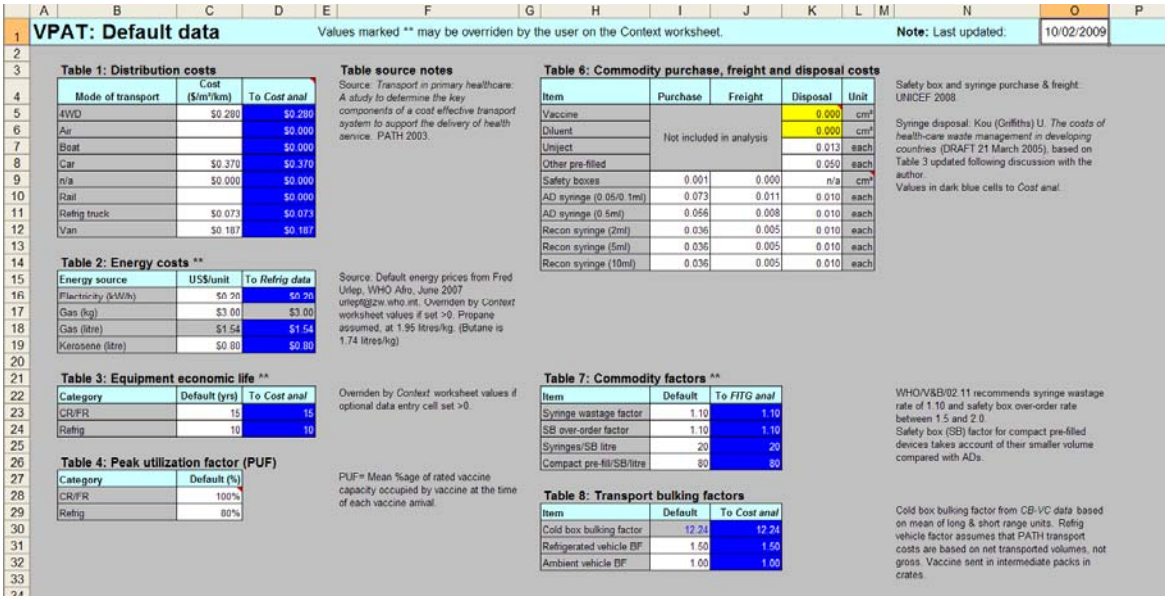
Use the seven tables on this worksheet to enter the default data settings for a range of cost and other factors used in the tool.

[17] The example shown demonstrates the effect of introducing a new lyophilized vaccine.

- Table 1 covers in-country distribution costs for seven modes of transport. (Refrigerated truck, van, car, 4WD, boat, rail and air).
- Table 2 covers energy costs for refrigeration equipment.
- Table 3 sets an economic life for refrigeration equipment.
- Table 4 defines the 'peak utilization factor' (PUF) for cold rooms, freezer rooms and refrigerators. The PUF represents the average percentage of the available vaccine storage volume within a piece of refrigeration equipment that is occupied at the time when a delivery is received. Thereafter, as vaccine is consumed, the utilization factor progressively declines up until the time of the next delivery, but the PUF establishes how efficiently the equipment is being used.
- Table 5 defines key commodity factors for syringes and safety boxes.
- Table 6 contains data on the cost of purchasing and disposing of vaccine vials, syringes and safety boxes. At present no data are available on vial and diluent ampoule disposal, which is why the relevant cells are highlighted in yellow.
- Table 7 defines key commodity factors for syringes and safety boxes.
- Table 8 defines the efficiency with which available storage space in road vehicles is used. For example, if vaccines are transported in cold boxes, the factor must take account of the volume of the insulated container and icepacks.

It is critically important that these data are checked to ensure that figures are valid in the context in which the tool is being used.

Figure 14 – *Defaults* worksheet



VPAT: Default data

Values marked ** may be overriden by the user on the Context worksheet.

Note: Last updated: 10/02/2009

Table 1: Distribution costs

Mode of transport	Cost ($/m³/km)	To *Cost anal*
4WD	$0.280	$0.280
Air		$0.000
Boat		$0.000
Car	$0.370	$0.370
n/a	$0.000	$0.000
Rail		$0.000
Refrig truck	$0.073	$0.073
Van	$0.187	$0.187

Table source notes

Source: *Transport in primary healthcare: A study to determine the key components of a cost effective transport system to support the delivery of health service.* PATH 2003.

Table 6: Commodity purchase, freight and disposal costs

Item	Purchase	Freight	Disposal	Unit
Vaccine	Not included in analysis		0.000	cm³
Diluent			0.000	cm³
Uniject			0.013	each
Other pre-filled			0.050	each
Safety boxes	0.001	0.000	n/a	cm³
AD syringe (0.05/0.1ml)	0.073	0.011	0.010	each
AD syringe (0.5ml)	0.056	0.008	0.010	each
Recon syringe (2ml)	0.036	0.005	0.010	each
Recon syringe (5ml)	0.036	0.005	0.010	each
Recon syringe (10ml)	0.036	0.005	0.010	each

Safety box and syringe purchase & freight: UNICEF 2008.

Syringe disposal: Kou (Griffiths) U. *The costs of health-care waste management in developing countries* (DRAFT 21 March 2005), based on Table 3 updated following discussion with the author.

Values in dark blue cells to *Cost anal*.

Table 2: Energy costs **

Energy source	US$/unit	To *Refrig data*
Electricity (kW/h)	$0.20	$0.20
Gas (kg)	$3.00	$3.00
Gas (litre)	$1.54	$1.54
Kerosene (litre)	$0.80	$0.80

Source: Default energy prices from Fred Unger, WHO Afro, June 2007 ungerf@afw.who.int. Overriden by *Context* worksheet values if set >0. Propane assumed, at 1.95 litres/kg. (Butane is 1.74 litres/kg)

Table 3: Equipment economic life **

Category	Default (yrs)	To *Cost anal*
CR/FR	15	15
Refrig	10	10

Overriden by *Context* worksheet values if optional data entry cell set >0.

Table 4: Peak utilization factor (PUF)

Category	Default (%)
CR/FR	100%
Refrig	80%

PUF= Mean %age of rated vaccine capacity occupied by vaccine at the time of each vaccine arrival.

Table 7: Commodity factors **

Item	Default	To *FITG anal*
Syringe wastage factor	1.10	1.10
SB over-order factor	1.10	1.10
Syringes/SB litre	20	20
Compact pre-fill/SB/litre	80	80

WHO/V&B/02.11 recommends syringe wastage rate of 1.10 and safety box over-order rate between 1.5 and 2.0.

Safety box (SB) factor for compact pre-filled devices takes account of their smaller volume compared with ADs.

Table 8: Transport bulking factors

Item	Default	To *Cost anal*
Cold box bulking factor	12.24	12.24
Refrigerated vehicle BF	1.50	1.50
Ambient vehicle BF	1.00	1.00

Cold box bulking factor from *CB-VC data* based on mean of long & short range units. Refrig vehicle factor assumes that PATH transport costs are based on net transported volumes, not gross. Vaccine sent in intermediate packs in crates.

4.2.12 Vax data worksheet

Use this table if it is necessary to update information on the standard range of vaccines and their associated commodity requirements. The current data are 'generic' and

derived from the WHO Shipping Guidelines[18]. Additional vaccines can be added to the table and instructions on how to do this are included at the bottom of the worksheet.

4.2.13 Refrig data worksheet

Use this table to update information on PIS/PQS pre-qualified refrigeration equipment and associated costs. There are tables for seven categories of refrigeration equipment: Cold rooms and freezer rooms; ice-lined refrigerators, compression freezers; domestic compression refrigerators[19]; gas absorption refrigerators; kerosene refrigerators and solar refrigerators. The cost data shown been obtained from UNICEF Supply Division and other cited sources.

4.2.14 CB-VC data worksheet

Use this table, if necessary, to update information on PIS/PQS pre-qualified cold boxes and vaccine carriers. These data are used to assess the suitability of vaccine manufacturers' proposed intermediate packaging. In order to economize on distribution costs, it is essential that this packaging fits in the widest possible range of cold boxes.

4.2.15 SB data worksheet

Use this table if it is necessary to update information of PIS/PQS pre-qualified safety boxes. Summaries of these data are used in the *FITG anal* and *Cost anal* worksheets to establish the volume of safety boxes required per FITG.

4.2.16 Syringe data worksheet

Use this table if it is necessary to update information on reconstitution syringes and PQS pre-qualified administration syringes. Summaries of these data are used in the *FITG anal* and *Cost anal* worksheets to establish the volume of syringes required per FITG.

[18] World Health Organization. *Guideline on the international packaging and shipping of vaccines. WHO*/IVB/05.23. Geneva, 2005.

[19] Currently no data are available for this commonly seen category of equipment.

Annex 1 – Underlying principles and methodology

A1.1 Vaccine wastage

Vaccine wastage is a key element in the economics of an immunization programme and this factor becomes ever more significant the cost-per-dose of purchasing vaccine rises.

VPAT currently treats all forms of wastage as a single percentage figure. In reality this figure is built up from a combination of all the component elements from the two distinct categories shown in Figure 2.

Figure A.1 – Types of wastage

Unopened vial wastage	Opened vial wastage
• Expiry • VVM indication • Heat exposure • Freezing • Breakage • Missing inventory • Theft • Discarding unused vials returned from an outreach session.	In addition to the types listed in the previous column: • Discarding remaining doses at the end of session • Not being able to draw up the number of doses indicated on the label of a vial • Poor reconstitution practices • Submergence of opened vials in water • Suspected contamination • Patient reaction requiring more than one dose

Source: Taken from Table 1 of WHO/V&B/O3.18: *Monitoring vaccine wastage at country level.*

There are a number of wastage rate studies in the literature, some based on the sentinel site approach[20] and others based on routine reports[21]. As new and much more expensive vaccines are introduced, the control of wastage of all types becomes a critical aspect of affordability. Moreover, these new vaccines tend to be supplied in single-dose or low multi-dose vials. Since much of the current wastage rate data[22] are based on vaccines in traditional large-format vials – typically 10 and 20-dose, there is a critical gap in our knowledge about the achievable minima for these low-dose number presentations. This gap is especially difficult to fill for presentations that are novel or currently uncommon – for example 3-dose or 5-dose vials. There is also an apparent absence of data discriminating between losses that are attributable to unopened vial wastage and losses that are attributable to wastage occurring after the vial has been opened. Thus the relative importance of these two categories of wastage is largely unknown.

The accuracy of a VPAT analysis would be significantly improved if it were based on context-specific field data; this is a data gap that needs to be filled. In the absence of such data, a reasonable starting point is to take GAVI (2008)[23] maximum wastage figures to calculate volumes per FITG for the baseline schedule.

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[20] Malawi: *Preliminary data analysis. Vaccine wastage, sentinel surveillance, Malawi, May-Aug 2004*. Dr Ümit Kartoğlu – personal communication.

WHO Ghana. *Guidelines for vaccine wastage monitoring. Sentinel project in Ghana.* January 2005. Cambodia: 2003 *study of vaccine wastage during outreach sessions: DTP-Hep B & Tetanus Toxoid: Kampong Chhnang Province Cambodia*.1 June 2004

[21] World Health Organization. *Spreadsheet analysis of vaccine wastage in Ghana, Niger, Senegal and Togo.* Dr Souleymane Kone – personal communication.

[22] There are some data on wastage rates for DTP-HepB+Hib which is typically supplied in 2-dose vials and some data on wastage rates for Uniject presentations.

[23] *GAVI Alliance Handbook: Country proposal and monitoring processes.* 2008. http://www.gavialliance.org/resources/Handbook_in_English.pdf

In order to establish whether a given wastage rate/presentation combination for the new target vaccine is realistically achievable; the user then must compare the break-even wastage rates, computed by the *Vial anal* worksheet, with these rates and/or with data from other sources.

A1.2 Cost categories

If we consider all the cost components associated with *purchasing* sufficient vaccine and associated commodities to deliver a given number of *administered* doses, we can break these elements down into three categories, as follows:

1. Costs that *increase* as vaccine wastage increases. As vaccine wastage rises, more vaccine must be processed through the supply chain to deliver the number of doses needed per FITG. Consequently, the costs of the vaccine purchase itself, its storage and distribution *increase* as vaccine wastage rises.
2. Costs that *reduce* with vaccine wastage. The required number of AD syringes and safety boxes, their purchase, storage, distribution and disposal costs depends on the number of doses *administered*, not on the number of doses *purchased*. In the limiting cases: at zero vaccine wastage one AD syringe is needed for every dose purchased and at 100% wastage, no AD syringes are required. Consequently, expressed as a cost per *purchased* dose, these costs *reduce* as vaccine wastage increases.
3. Costs that vary with the number of doses in the vial. These costs apply to lyophilized vaccines only. As the number of doses in a vial increases, the number of reconstitution syringes and safety boxes required per vial falls, as do the associated storage, distribution and disposal costs. However, the extent of this decline is moderated by the higher wastage associated with multi-dose vials. A single-dose presentation always requires one reconstitution syringe for every dose administered. The number of reconstitution syringes required per *administered* dose for a multi-dose presentation depends on the wastage rate achieved. In the case of a 20-dose vial with a 50% wastage rate for example, the figure is 0.1 syringes per administered dose. If there were no wastage, the figure would only be 0.05 syringes per administered dose.

VPAT uses these three cost categories to build up cost profiles for any chosen combination of vaccine presentation, and vaccine wastage. The three categories can also be expressed in another way: as a total cost per *administered* dose rather than per dose *purchased.* The former is always higher than the latter. Both methods are used in VPAT.

A1.3 Key algorithms

A1.3.1 FITG vol worksheet

Below are the principal algorithms expressed on a vaccine by vaccine basis:

a) Gross vaccine volume per FITG = ((volume per dose x no. of doses in schedule)) x 100/(100 - %wastage rate)

b) AD syringes per FITG = (no. of doses in schedule x syringe wastage factor)

c) Reconstitution syringes per FITG = (no. of doses in schedule x syringe wastage factor)/(no. of doses in vial x (100 - %wastage rate)/100))

d) Gross packed safety box volume for standard syringes = (total no. of syringes per FITG x packed safety box volume per standard syringe x safety box over-order factor)

e) Gross assembled safety box volume for standard syringes = (total no. of syringes per FITG x assembled safety box volume per standard syringe x safety box over-order factor)

f) Gross packed safety box volume for compact pre-filled syringes = (total no. of syringes per FITG x packed safety box volume per compact pre-fill x safety box over-order factor)

g) Gross assembled safety box volume for compact pre-filled syringes = (total no. of syringes per FITG x assembled safety box volume per compact pre-fill x safety box over-order factor)

A1.3.2 Cost anal worksheet

Tables 1 and 2 calculate purchase, international shipping, distribution, storage and disposal costs on a unit volume basis, taking account of the in-country distribution system delineated on the *Context* worksheet. Items [in yellow in square brackets] are relevant, but are not currently included for the reasons discussed in section A1.4. Below are the principal algorithms used in these tables.

Table 1

a) Vaccine purchase, distribution and disposal costs per cm^3 = [purchase + international airfreight costs per cm^3] + (($cost/cm^3$ per km for selected transport type at each level) x (round trip distance at each level) x (container bulking factor at each level) + (vial disposal costs per cm^3)

b) Diluent purchase, distribution and disposal costs per cm^3 = [purchase + international airfreight costs per cm^3] + (($cost/cm^3$ per km for selected transport type at each level) x (round trip distance at each level) x IF(diluent storage temperature = +5 OR -20 THEN (container bulking factor at each level)) + (vial disposal costs per cm^3)

c) Safety box purchase and distribution costs per cm^3 = (purchase cost per cm^3) + (international freight costs per cm^3) + (($cost/cm^3$ per km for selected transport type at each level) x (round trip distance at each level))

d) Syringe purchase, distribution and disposal costs per cm^3 = ((purchase cost per item + international freight cost per item)/item volume in cm^3) + (($cost/cm^3$ per km for selected transport type at each level) x (round trip distance at each level)) + (syringe disposal cost per cm^3)

Table 2

e) Refrigeration equipment life cost per cm^3 @ 1 arrival per annum = (equipment purchase cost + international freight cost + installation cost + fuel cost per annum + service cost per annum)/(nominal vaccine capacity in cm^3 x economic equipment life in years) [Footnote 24]

f) Vaccine/diluent cold storage costs per cm^3 = (refrigeration equipment life cost per cm^3 @ 1 arrival per annum) / (12/(arrival frequency in months at each level)/(equipment utilization factor at each level))

Tables 3 and *4* calculate the combined costs per *purchased* dose for the new target vaccine and for the existing schedule. These data are used in the *Vial anal* worksheet to carry out the break-even analysis. **Annex 2** shows the goal-seeking macro used to carry out this analysis.

Tables 5 and *6* calculate combined costs per FITG for the new target vaccine and for the existing schedule. These data are presented on the FITG cost charts.

[24] The principal here is that the total lifetime cost per unit volume for an item of refrigeration equipment is a function of the volume of vaccine it 'processes' over its economic life. As delivery frequency increases, so a larger volume of vaccine passes through the equipment, resulting in more efficient and a lower storage cost per unit volume of vacine. For example, if there are four deliveries per year this means that a 100 litre refrigerator can 'process' a maximum of 100 x 4 x 10 = 4,000 litres of vaccine over a 10 year life. If deliveries are increased to 12 times per year the amount the unit can process increases to 12,000 litres. Dividing the lifetime purchase and running costs by the lifetime processed volume gives the cost contribution of the equipment, per unit volume of vaccine.

A1. 4 Items excluded from the model

The warehousing costs associated with storing diluents, syringes and safety boxes at ambient temperature are not currently considered. These costs may be significant in primary and higher level intermediate stores, and they could be added to the model if good data become available. However storage costs for these items are unlikely to be worth considering in lower level stores and health facilities where essentially cost-free space is generally available[25].

Labour costs are also ignored. Adding a vaccine to an existing schedule will inevitably increase cold chain management costs (additional storekeeping activities, additional materials handling, etc) and, in many cases, will also increase health worker workload. However, at the present time it is difficult to see how these costs can accurately be assessed.

[25] Note that distribution costs for these items *are* included.

Annex 2 – *Vial anal* goal-seeking algorithm

```
Private Sub Goalseek2_Click()
' Goalseek2 Macro

With Application
        .Calculation = xlManual
        .MaxChange = 0.001
    End With
    ActiveWorkbook.PrecisionAsDisplayed = False

If Range("D6") = "" Then
Range("D10").ClearContents
Else
Range("D9").Goalseek Goal:=Range("C9"), ChangingCell:=Range("D10")
End If

If Range("E6") = "" Then
Range("E10").ClearContents
Else
Range("E9").Goalseek Goal:=Range("C9"), ChangingCell:=Range("E10")
End If

If Range("F6") = "" Then
Range("F10").ClearContents
Else
Range("F9").Goalseek Goal:=Range("C9"), ChangingCell:=Range("F10")
End If

If Range("G6") = "" Then
Range("G10").ClearContents
Else
Range("G9").Goalseek Goal:=Range("C9"), ChangingCell:=Range("G10")
End If

If Range("H6") = "" Then
Range("H10").ClearContents
Else
Range("H9").Goalseek Goal:=Range("C9"), ChangingCell:=Range("H10")
End If

If Range("I6") = "" Then
Range("I10").ClearContents
Else
Range("I9").Goalseek Goal:=Range("C9"), ChangingCell:=Range("I10")
End If

If Range("J6") = "" Then
Range("J10").ClearContents
Else
Range("J9").Goalseek Goal:=Range("C9"), ChangingCell:=Range("J10")
End If

If Range("K6") = "" Then
Range("K10").ClearContents
Else
Range("K9").Goalseek Goal:=Range("C9"), ChangingCell:=Range("K10")
End If
```

<Repeats a further four times for each price point>

```
With Application
        .Calculation = xlAutomatic
        .MaxChange = 0.001
    End With
    ActiveWorkbook.PrecisionAsDisplayed = False

End Sub
```