DENGUE VACCINE IMPLEMENTATION (Screen & Vaccinate) LOGISTICS

INFORMATION FOR SKATEHOLDERS

This module summarizes the logistical implications of introducing Dengvaxia®, the Sanofi Pasteur dengue vaccine, in the context of a Screen and Vaccinate (S&V) strategy. While the country can choose from a range of screening test options, this module focuses on the most optimal pre-vaccination screening approach, using a rapid diagnostic test (RDT) specially designed for the detection of dengue past infections. It describes the measures necessary for the availability and quality of tests and vaccines to ensure safe and effective vaccination. It aims to help countries plan, prepare, implement, and monitor the logistical aspects of dengue vaccine introduction. It refers to best practices defined by WHO, recommendations of expert committees, as well as country comments.

1. CONTEXT OF THE LOGISTICAL ASPECTS FOR DENGUE VACCINATION

- Dengvaxia® is the dengue tetravalent vaccine (recombinant, live-attenuated) developed by Sanofi Pasteur.
- For countries considering vaccination as part of their dengue control program, the World Health Organization (WHO) recommends a "Screen and Vaccinate" (S&V) strategy, in which only dengue-seropositive persons are vaccinated.
- The logistical aspects of implementing dengue screening and vaccination are essential to ensure optimal impact of the intervention and to accurately assess vaccine efficacy and safety. The quality and availability of screening tests, vaccines, and related supplies must be guaranteed throughout the supply chain. This includes the management of cold chain, transport, and storage capacities.
- The waste generated by dengue screening tests and vaccines must also be adequately managed to limit biohazard for the health workers, the population, and the environment.
- Although a range of tools already exists for vaccine introduction into vaccination programs, dengue vaccination presents a unique combination of characteristics that lead to specific challenges:
  - Pre-vaccination screening and vaccination of dengue seropositives only
  - 3-dose given 6 months apart
  - Adolescent and adult target population
  - Given through various S&V strategies (Figure 1)
- This module focuses on the logistics of implementing the dengue S&V strategy using rapid diagnostic tests (RDTs) for screening before vaccination.
- The module considers strategies for an implementation approach based on individual serostatus in a target population. Calculations can be adapted if the introduction targets individuals who are laboratory-confirmed clinical cases [see MODULE "Implementation strategies"].

2. LOGISTICS CHALLENGES

- Vaccination against dengue using the Screen and Vaccinate (S&V) approach, can be implemented in different ways, depending on the objectives that the country wishes to achieve in terms of reduction or control of dengue disease, and specificities and resources of the country and the region.
- Countries may choose to conduct:
  - > Mass vaccination campaigns to protect a large part of the population in a short period of time
  - > Routine immunization to systematically cover target groups and gradually achieve sustainable protection of the population
  - > A combination of both campaign and routine strategies
- The characteristics of the supply chain differ from one strategy to another (Table 1).

TABLE 1.

Supply chain characteristics

	LOGISTIC IMPLICATIONS	RECOMMENDED SUPPLY CHAIN
S&V through campaign	Large quantity of tests and vaccines and large quantity of hazardous waste within a short period of time, which can exceed the existing logistics capacity for safe transport, storage and elimination.	Flexible supply chain, based on routine supply chain for tests and vaccines and ad hoc measures
S&V through routine program	Needs for continuous availability of limited quantity of tests and vaccines. Slight increase in waste generated	Strengthened routine supply chain for tests and vaccines

- For both campaign or routine interventions, the S&V can be implemented in One-step or Two-step approaches [see MODULE "Implementation strategies"].
- In the One-step implementation, sampling, screening and vaccination of seropositives are performed on the same day and at the same place. When the One-step approach is not possible or desirable, a Two-step approach can be implemented, where the screening and the vaccination are dissociated. In this case, samples are collected and tested either on site if RDT is used or in a laboratory if ELISA testing is used. Seropositives subjects are offered vaccination on another day, either in the same setting or in health care facilities. Figure 1shows these two options for the S&V approach implementation.

FIGURE 1.

Examples of implementation scenarios for the S&V strategy

- The success of the mass campaign or the introduction into routine activities depends on the quality of planning, preparation, implementation and monitoring & evaluation. The campaign or introduction of dengue S&V should be based on the existing routine immunization (RI) program. In particular, it is important to collect RI program data such as target population, health facility session plans, maps of vaccination posts in catchment areas, risk factors for non-vaccination, cold-chain capacity, or waste management.
- Logistic planning, careful supervision and monitoring are essential for the success of the intervention and need to be adapted to the strategy selected by the country.

3. PLANNING OF LOGISTICS NEEDS

- The logistic plan of action is based on:
  - > Target population
  - > Geographical scope
  - > S&V strategy (campaign and/or introduction in the immunization program)
  - > S&V approach (One-step and/or Two-step)
  - > S&V site (school-based, community-based, health care facility-based)
- The objectives of the planning phase are i) to prepare a logistic plan of action and a budget estimate; ii) to secure high-level commitment; and iii) to plan an organizational structure for coordination of the campaign or the introduction into routine program, establish national/sub-national logistic coordinating committees and appoint national/sub-national coordinators. This chapter details estimations of logistics needs for the supply chains and the waste management.

3.1. Product specifications

- **Dengvaxia® vaccine**
  - > Dengvaxia® is found in single-dose and multi-dose vials, depending on local license and registration, each presentation meeting different needs. Countries can choose a mix of presentations to benefit from respective advantages and optimize cold chain capacity and vaccine wastage.

DENGVAXIA® VACCINE CHARACTERISTICS FOR LOGISTICS

	MONO-DOSE PRESENTATION	MULTI-DOSE PRESENTATION
FORMULATION	FREEZE-DRIED / LYOPHILIZED POWDER AND SOLVENT. NO ADJUVANT OR PRESERVATIVE	
STORAGE AND SHIPMENT CONDITIONS	2°C AND 8°C – DO NOT FREEZE PROTECT FROM LIGHT	
SHELF LIFE	36 MONTHS	
NUMBER OF DOSES PER VIAL	1	5

NUMBER OF DOSES PER BOX	1	25
BOX CONTENT	**ONE BOX CONTAINS:** - 1 vial of vaccine powder - 1 prefilled glass syringe of solvent (0.4% NaCl) - 2 sterile needles (1 of 23Gx1" for reconstitution and 1 of 25Gx5/8" for subcutaneous administration)	**ONE BOX CONTAINS:** - 5 vials of vaccine powder - 5 vials of 3mL-vials of solvent (0.9% NaCl)
VIAL	TYPE-1 GLASS VIAL	
VOLUME FOR 1 DOSE	153 cm^3	5,3 cm^3 *
COMPARATIVE ADVANTAGES	limit vaccine wastage → best appropriate for use in routine immunization	limit cold storage requirements → best appropriate for campaign strategy

* Volume to which must be added the necessary volume for the syringe and needles that are not included in the multidose box.

- **Screening tests**
  - > Diagnostic test results will determine whether an individual is eligible or not for vaccination. It is critical to use tests that are designed to detect prior dengue infection and are easy to use in a point-of-care approach, such as lateral flow immunoassay.
  - > A range of dengue rapid diagnostic tests (RDTs) are currently available or under development. However, the ***OnSite*® Dengue IgG rapid test**, co-developed by Sanofi Pasteur and CTK Biotech, is specifically designed to identify individuals in the age range for vaccination who have had a past dengue virus exposure. This test has achieved performance characteristics within the expected range to enable safe and efficient implementation of pre-vaccination screening and dengue vaccination.
  - > The ***OnSite*® Dengue IgG RDT:**
    - allows point-of-care screening of individuals on whole blood and fingerstick specimens
    - is a rapid test, giving results in 20 minutes
    - is designed for any health care personnel to run, including minimally trained personnel
    - does not require specific infrastructure or equipment and can be stored at room temperature

The test is CE-marked since September 2020 - check for registration in your country.

- > Other RDTs may be used, depending on local recommendations. However, current other RDTs are designed for the identification of acute dengue infection and are not optimal for pre-vaccination screening. The potential level of cross-reactivity especially with other related flaviviruses may affect the specificity of these tests, leading to the vaccination of false seropositives. An informed decision should be made by health staff, based on what is available and recommended locally.
- > Screening using the ELISA technology is also possible but is time-consuming and requires significant laboratory infrastructure, including instrumentation, trained staff and refrigeration for reagents tests. It may not be an ideal choice in the context of the dengue S&V strategy.
- > For these reasons, this module will focus on using CTK's *OnSite*® Dengue IgG RDT, or any similar RDT designed for detection of past dengue virus exposure.

CTK *OnSite*® Dengue IgG Rapid Test CHARACTERISTICS FOR LOGISTICS

FORMAT	**CASSETTE**	
SPECIMEN TYPE	**SERUM/PLASMA/WHOLE BLOOD**	
TIME TO RESULT	**1-25 min**	
STORAGE AND SHIPMENT CONDITIONS	**2°C - 30°C** (temporary excursions to up to 45°C allowed). **DO NOT FREEZE.** Once opened, the diluent must be used within 6 months and should be stored in conditions minimizing microbial exposure, at 2-8°C whenever possible	
USE CONDITIONS	**15°C - 30°C :** allow the cassette to reach room temperature if stored in a fridge.	
SHELF LIFE	**24 MONTHS**	
PACKAGING	2 PACKAGE SIZES:	- **30 tests/kit** - **10 tests/kit**
KIT CONTENT	1. Individually sealed foil pouches, containing one cassette device and one desiccant 2. Disposable capillary tubes, marked for 5 µL (10 or 30 depending on the packaging size) 3. Patient stickers (10 or 30 depending on the packaging size) 4. Sample diluent (REF SB-R0065, 2 bottles) Instructions for Use Sample diluent vial	
VOLUME/KIT	Pack of 10 kits: 124mm x 100mm x 70mm Pack of 30 kits: 205mm x 122mm x 70mm	

- **Other supplies**

OTHER MATERIAL REQUIRED FOR THE SCREENING	• Timing device • Sterile lancets for finger prick
OTHER MATERIAL REQUIRED FOR THE VACCINATION	• For the multidose presentation: 2 sterile needles (one of 23G x 1" for reconstitution and one of 25G x 5/8" for subcutaneous administration)
OTHER MATERIAL REQUIRED FOR BOTH THE SCREENING AND THE VACCINATION	• Sterile gauze or cotton • Alcohol or alcohol wipes • Bandages • Disposable gloves • Biohazard disposal containers • Documentation, stationery, and electronic devices (and chargers) related to screening and vaccination monitoring and safety • Informed consent forms • Information, Education and Communication (IEC) resources

3.2. Estimation of logistic needs

- Macroplanning at the national and sub-national levels leads to the development of a realistic action plan and budget estimate for logistics activities and helps to secure commitment from all parties involved.

TABLE 2.

Logistics requirements estimations:

CATEGORY	ITEMS
SUPPLIES	• SCREENING TESTS (RDTS) • STERILE LANCETS FOR FINGER PRICK • VACCINES • SYRINGES + NEEDLES • OTHER SUPPLIES (PLASTIC BAGS…)
COLD CHAIN EQUIPMENT	• REFRIGERATORS • FREEZERS FOR ICE PACKSCOLD ROOMS • VACCINE CARRIERS • COLD BOXES • COOLANT PACKS • GENERATORS • TEMPERATURE MONITORING DEVICES • SPARE PARTS
WASTE MANAGEMENT EQUIPMENT	• SAFETY BOXES • LOW-HEAT EQUIPMENT • INCINERATORS/BURNING PITS
TRANSPORT EQUIPMENT	• FOR SUPPLIES : TRUCKS AND PICK-UP (REFRIGERATED OR NOT) • FOR TEAMS : CARS, MOTORBIKES WHEN APPROPRIATE

3.3. Estimation of supply needs

- **Estimate numbers of tests, vaccines and related supplies must be adapted in the event the country decides to implement a strategy with multiple rounds of screening during the period of intervention** [see MODULE Screen and Vaccinate sessions]. In this case, individuals in the target age for the intervention but who were either previously tested dengue seronegative, or were absent, or did not give their consent at the previous visit, can be offered screening and possibly vaccination if they turned seropositive. The estimations for the screening and the vaccination material requirements will depend on a range of setting specific factors such as the transmission intensity (the chance to turn seropositive between 2 visits), the intervention compliance rate at the previous visit, epidemic situations, etc. Because this situation is highly dependent on country's choice and setting parameters, the following estimates consider one intervention including 1 screening visit and 3 vaccination visits for those seropositive. The numbers will need to be adapted as necessary.
- Safety stocks: When introducing the S&V strategy into the routine immunization program, countries should include a safety stock that acts as a buffer to protect against stockouts due to late deliveries, delays, or product shortages at the supplier level. The level of safety stock required should be established at each store based on past consumption data or country experience. Safety stock can represent 25% of the needs for a delivery. Safety stock is not applicable for implementation in campaign.
- The quantity of products to order depends on the following parameters.

3.3.1. TARGET POPULATION

- In the Screen and Vaccinate intervention:
  - The Screen target population is the population in the vaccination age range, living in the selected area. It is defined by the country based on vaccine indication, and impact on dengue burden.
  - The Vaccine target population corresponds to those who have been tested dengue-positive.

3.3.2. POPULATION ESTIMATES

- The Population estimates reflect the numbers of the target population expected to be served by the intervention.
- The Population estimate for Screening should only consider those, from the Screen target population, who gave their consent for vaccination, and who have no medical contraindication for the vaccination. It is based on:
  - Estimates of people adhering to the full S&V intervention (through surveys on acceptance/hesitancy/refusal)
  - Estimates of people with medical conditions leading to vaccine contraindications in the target population (from 5 to 10 % depending on the age range and population characteristics)
- The Population estimate for Vaccination is based on the proportion of dengue seropositives in the Population estimate for Screening. It uses recent age-stratified seroprevalence survey data (already available or obtained through new seroprevalence surveys), or clinical and hospitalization data from national and subnational health information system.

3.3.3. EXPECTED WASTAGE RATE / WASTAGE FACTOR (WF)

- The wastage rate is the proportion of wasted products used for the Screening and for the Vaccination. It needs to be estimated for the Screening tests and for the Vaccines independently.
- Reasons for wastage include loss, breakage, date expiration, exposure to out-of-range temperatures, etc.
  - The wastage rate for Screening tests also needs to consider the proportion of tests that will give invalid test result and that will need to be repeated.
  - The wastage rate for Vaccines also needs to consider remaining doses in the multidose vial.
  - The expected wastage rates for 1-dose vial and 5-dose vial vaccines are different.
- Wastage should be estimated based on past consumption data and country experience.
- The wastage factor (wf) is the number by which the estimated quantity of test or vaccine must be multiplied, to account for the wastage of some tests or doses.

The formula is: **wf = 100 ÷ (100 – wastage rate)**

3.3.4. NUMBER OF UNITS

- The number of Screening tests (RDTs) will be estimated based on:
  - The Population estimate for Screening
  - The number of test units per beneficiary (one or more if multiple rounds of screening organized)
  - The estimated test wastage factor for Screening tests
- The number of Vaccines will be estimated based on:
  - The Population estimate for vaccination
  - The number of vaccine doses per beneficiary (3 doses)

> The estimated vaccine wastage factor for Vaccines

3.3.5. INDICATIVE VALUES OF CALCULATION PARAMETERS AND CALCULATION METHOD FOR A SAME COHORT

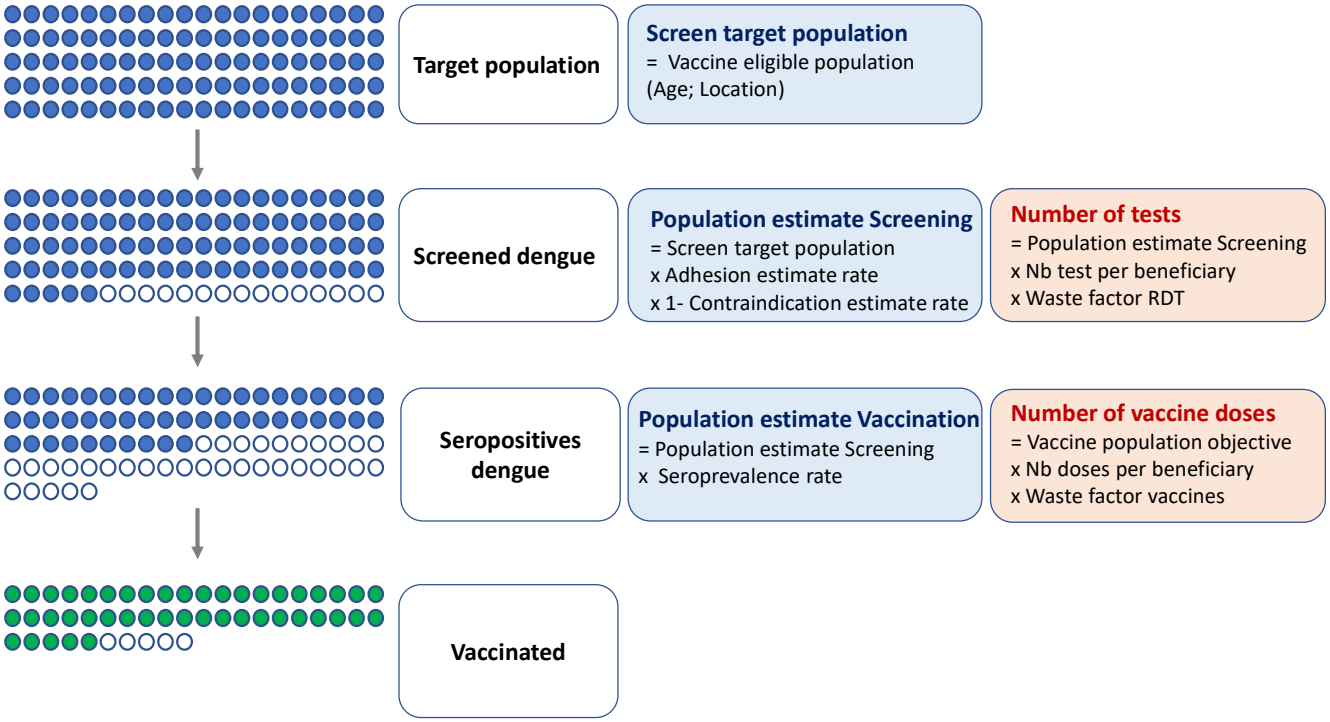
ITEM	TARGET POPULATION	POPULATION ESTIMATE	NUMBER OF UNITS PER BENEFICIARY	EXPECTED WASTAGE RATE	EXPECTED WASTAGE FACTOR (WF)	CALCULATION METHOD
RDTs	Screen target population (defined by the country	for Screening	1*	5%	1,05	Number of Screening tests = Population estimate for Screening x Number of units per beneficiary x Wf for RDTs
Sterile lancets and finger prickers		for Screening	1*	5%	1,05	Number sterile lancets and prickers = Number of Screening tests
Vaccines	Vaccine target: RDT positive	for Vaccination	3	5% for 1dose-vial 10% for 5-dose vial	1,05 for 1-dose vial 1,11 for 5-dose vial	Number of vaccine doses = Population estimate for Screening x Seroprevalence rate estimate x Number of doses per beneficiary x Wf. for vaccine** Number of 1dose-vials = Number of doses Number of 5 dose-vials = Number of doses ÷ **5** (rounded to the next unit) Number of vaccine boxes for 1dose-vial presentation = Number of vaccine doses Number of vaccine boxes for multi-dose presentation = Number of 5 dose-vials ÷ **5** (rounded to the next unit)
Syringes and needles for reconstitution (for multi-dose presentation only)	Vaccine target: RDT positive	for Vaccination	3/5 (3 doses and 1 syringe for 5 doses per vial)	5%	1,05	Number of syringes (reconstitution) = Number of vaccine doses ÷ 5 x Wf for syringe
Syringes and needles for injection (for multi-dose presentation only)	Vaccine target: RDT positive	for Vaccination	3	5%	1,05	Number of syringes (injection) = Number of vaccine doses x Wf for syringe
Safety boxes	S&V target for screening test wastage and vaccine target for vaccine wastage	for Screening and for Vaccination	1/100	0%		Screening: (number of finger prickers + number of test cassettes) ÷ 100 Vaccination: (number of syringes and needles + number of vaccine vials) ÷ 100

* This number can be refined if the country implements a vaccination program including several rounds of screening
** The wastage factors for 1-dose vial and 5-dose vial vaccines are different.

FIGURE 2

Number of screening tests and vaccine doses.

This figure is linked to Figure 7 "S&V database: from Master list to vaccinated individuals" in Module S&V SESSIONS.



- A case study for country calculation of supply needs is proposed below.

CASE STUDY

CONTEXT :

A dengue endemic country decides the introduction of Dengvaxia® to reduce dengue burden in a sub-region bearing high dengue seroprevalence and burden. The population identified as the target for vaccination are girls and boys aged 9 to 11 years at first date of vaccine injection, living in the sub-region. The total number of the identified population is 150 000.

The S&V intervention is implemented in campaign with a Two-step approach: children will be screened in schools and vaccinated in health care facilities.

Survey on S&V acceptability showed that 90% of this population and their parents are favorable to the full intervention. It is estimated that 5% of the children will not receive the vaccination due to medical conditions.

The program is implementing strategies to minimize drop-outs between doses.

The country plans procuring 30-tests/kit CTK *OnSite*® Dengue IgG rapid tests, and the multi-dose presentation of Dengvaxia®.

Regional age stratified data demonstrates a seroprevalence rate of 80% in the target age-group. The adherence rate for the vaccine 3-dose regimen is estimated to be 90%.

The coverage objective for the first dose is 100% among those who are tested seropositive. All efforts are undertaken to reduce vaccine drop-out between doses to a minimum.

TABLE 3 BELOW HELPS UNDERSTANDING RDTS UNITS AND VACCINE DOSES NEEDS DURING EACH SESSION OVER A PERIOD OF 5 YEARS.

ESTIMATE THE NEEDS FOR RDTs during the first year (one visit)		
S&V population target [9-11y]		150 000
Adherence Contraindication (1-)	0.90 0.95	
Population estimate for Screening	= 150 000 x 0.90 x 0.95	**128 250**
Number of RDT per beneficiary	1	
Wf for RDTs	1.05	
TOTAL RDTs for the first year : (T1(9-11A))	= 128 250 x 1 x 1.05	**134 663**

ESTIMATE THE NEEDS FOR VACCINES during the first year (2 doses included)		
Population estimate for Screening:		128 250
Seroprevalence rate estimate	0.80	
Population estimate for Vaccination	= 128 250 x 0,80	**102 600**
Number of doses per beneficiary in a year	x 2	
Wf for multi-dose vaccine	x 1.11	
TOTAL VACCINE DOSES for visits V1 and V2 in the first year : (V1(9-11A) + V2(9-12A))	= 102 600 x 2 x 1.11	**227 772**

CONTEXT (next):
After the initial screening of the eligible 9-11y population, other rounds of screening will be proposed during next annual school screening visit, for those who turned 9 years old meanwhile, and for those who, still in the age range, were seronegatives or absent during the previous screening visit. Those who have turned 12 will no longer be eligible to screening and first dose vaccination, but are still eligible to dose 2 and 3 of vaccine.

Annual cohorts are stable and estimated at 50 000 children for each year. There will be as many children leaving the age group because they have turned 12, as of children entering the age group because they have turned 9.

The adherence, absenteeism and seroprevalence rate are considered constant over the year but can be adjusted if new data arise.

ESTIMATE THE NEEDS FOR RDTs during the 2nd year (new cohort and 2nd round + catch-up)		
Cohort A : T2(10-11A) =10-to-11-year-olds not tested in the 1st year +10-to-11-year-olds tested seronegatives (1-0.8)	= [(150 000 – 128 250) x 2/3 + (128 250 x 0.20) x 2/3]	14 500 17 100
+ Cohort B : T1(9B) =new 9-year-olds eligible	+ (128 250/3)	42 750
Population estimate for Screening		**74 356**
Number of RDT per beneficiary	x 1	
Wf for RDTs	x 1.05	
TOTAL RDTs for the second year : (T1(9B) + T2(10-11A))	=74 356 x 1 x 1.05	**78 068**

ESTIMATE THE NEEDS FOR VACCINES during the 2nd year (new cohort and 2nd round + catch-up)		
Vaccine doses for V3(10-12A) =10-to-12-year-olds tested positive in the 1st year = population estimate for Vaccination in year 1 x 1 dose per beneficiary x Wf for vaccines	=102 600 x1 x 1.11	**113 886**
Vaccine doses for V1(10-11A),V2(10-12A, V1(9B) and V2(9B) =Population estimate for screening x Seroprevalence rate estimate x 2 doses per beneficiary x Wf for vaccines	=74 356 x 0.80 x 2 x 1,11	**132 057**
TOTAL VACCINE DOSES for year 2, including safety stocks to be reconstituted each year (routine intervention)	= (113 886 + 132 057) + 25%	**307 429**

TABLE 3.

Case study: A 5-year S&V eligibility table for children aged 9 to 11 years old at first S&V visit.

T for Test visit and V for Vaccine visit (1, 2 or 3)

	YEAR 1		YEAR 2		YEAR 3		YEAR 4		YEAR 5	
Cohort A	**T1** (9-11A) **V1** (9-11 A)	**V2** (9-12 A)	**V3** (10-12 A) T2 (10-11 A) * V1 (10-11	V2 (10-12A) *	V3 (11-12 A) T3 (11 A) ** V1 (11 A) **	V2 (11-12 A) **	V3 (12 A) **			
Cohort B			**T1** (9B) **V1** (9B)	**V2** (9-10B)	**V3** (10B) T2 (10B) * V1 (10B) *	V2 (10-11B) *	V3 (11-12B) * T3 (11B) ** V1 (11B) **	V2 (11-12B) **	V3 (12B) **	
Cohort C (up to year 5)					**T1** (9C) **V1** (9C)	**V2** (9-10C)	**V3** (10C) T2 (10C) * V1 (10C) *	V2 (10-11C) *	V3 (11-12C) * T3 (11C)** V1 (11C) **	V2 (11-12C) **
Cohort D (up to year 5)							**T1** (9D) **V1** (9D)	**V2** (9-10D)	**V3** (10D) T2 (10D) * V1 (10D) *	V2 (10-11D) *
Cohort E (up to year 5)									**T1** (9E) **V1** (9E)	V2 (9-10E)

Each year, a new cohort is offered the intervention.

In year 1, cohort A (children aged 9 to 11 at first injection) is the target of S&V. For the first visit they are tested (T1 (9-11A)) and some vaccinated (V1 (9-11A)). Six months later they receive the second dose of vaccine: some of them will still be 9 and other will have turn 12 (V2 (9-12A)).

In year 2, children of cohort A, now aged 10-12, are offered the third dose of vaccine (V3 (10-12 A)). A cohort B of children aged 9 (T1 and V1 (9B)) enters the intervention (note that those aged 10 to 11yo are already part of cohort A). Six months later, they receive the second dose of vaccine: some of them will be 10 years old (yo) (V2 (9-10B)). In addition, children in cohort A who have not been tested or have tested negative the previous year are offered a catch-up, i.e., additional screening, and vaccination if they are now positive (T1 and V1 (10-11A) *). Note that the youngest from cohort A are now 10yo, those who were 10yo are now 11yo, and those who were 11yo are now 12yo and therefore no longer eligible to enter the intervention. Six months later, they receive the second dose of vaccine: some of them are now 12yo (V2 (10-12A) *).

In year 3, children of cohort B, now aged 10yo, receive their third dose (V3 (10 B)). Children of cohort A* (catch-up), now aged 11 and 12, receive their third dose of vaccine (V3 (11-12A) *). A new cohort C of children aged 9 (T1 and V1 (9C)) enters the intervention. Six months later, they receive the second dose of vaccine: some of them are now 10yo (V2 (9-10C)). Children of cohort B* (catch-up) who are now 10 are offered screening and vaccination (T1 and V1 (10B) *). Six months later, they receive the second dose of vaccine: some of them are now 11yo (V2 (10-11B) *). The youngest children in cohort A are now 11yo. For those who have not yet been tested or tested seronegative, they are offered a last chance to enter the intervention in a second (**) catch-up (T1 and V1 (11A) **). Six months later, they receive the second dose of vaccine: some of them are now 12yo (V2 (11-12A) **).

In year 4, children of cohort C, now aged 10yo, receive their third dose (V3 (10 C)). Children of cohort B* (catch-up), now aged 11 and 12, receive their third dose of vaccine (V3 (11-12B) *). The youngest children of cohort A** (second catch-up) receive the third dose of vaccine (V3 (12A) **). A new cohort D of children aged 9 (T1 and V1 (9D)) enters the intervention. Six months later, they receive the second dose of vaccine: some of them are now 10yo (V2 (9-10D)). Children of cohort C* (catch-up) who are now 10 are offered screening and vaccination (T1 and V1 (10C) *). Six months later, they receive the second dose of vaccine (V2 (10-11C) *). The youngest children in cohort B are now 11yo. For those who have not yet been tested or tested seronegative, they are offered a last chance to enter the intervention in a second (**) catch-up (T1 and V1 (11B) **). Six months later, they receive the second dose of vaccine (V2 (11-12B) **).

For year 5 and beyond, a reasoning similar to that described for year 4 applies.

3.4. Estimation of storage and transport needs

3.4.1. CALCULATION OF STORAGE AND TRANSPORT CAPACITIES

a. Estimation of volumes

- The storage volume for tests and vaccines is estimated based on:
  - > Volume of packed test and vaccine
  - > Number of testing kits and vaccine doses needed
  - > Number of supply intervals between two deliveries of screening kits and/or vaccines to the stores or to service-delivery points
  - > Safety stock requirements, if applicable
- The storage volume should be calculated in liter. To convert the volume from cubic centimeters (cm^3) to liters (L), divide by 1000.

The packed volume is calculated by multiplying the three dimensions of the vaccine or testing kit box: length (l), width (w) and height (h), illustrated in Figure 1.

The box volume should then be divided by the number of units (testing kits, vaccines).

Example:
Dimensions of a box containing 5 vials of 5 doses of dengue vaccines and 5 vials of solvent:
l=13,25 cm; w= 5 cm ; h=2cm.
Volume of the box = 13,25x5x2=132,5 cm^3
Volume per dose = 132,5 ÷ 25 = 5,3 cm^3

(See in annex1: calculation tool for test, vaccines, and supplies volume)

b. Assessment of existing cold storage capacity

As per manufacturer recommendations, Dengvaxia® must be stored at temperature between 2°C to 8°C. A cold chain is required from the port of arrival of the vaccine till its point of use, for both transport and storage.

Temperature storage of dengue *OnSite*® Dengue IgG rapid test varies between 2 to 30°C, with temporary excursions to up to 45°C allowed. **In some countries, depending on climatic conditions, the tests may also require transport and storage in the cold chain.**

- By estimating the storage capacity in the cold chain equipment (i.e. cold rooms and refrigerators) and comparing it with the volumes needed, any storage gaps are highlighted, which must be filled to safely accommodate temperature sensitive products.
- Net storage capacity is the estimated volume available for temperature sensitive products inside cold chain equipment, which takes into account packaging efficiencies and airspace requirements. The net storage capacity is a fraction of the gross volume of the equipment; to estimate it, the gross volume (declared by the manufacturer or height x length x width of the internal refrigerated space) is multiplied by **0.67, the utilization factor recommended by the WHO**. The resulting value is converted to liters (L) by dividing the cm3 measurement by 1000.
- Net storage capacity values for WHO prequalified refrigerators and freezers are available in the WHO PQS catalog[1]. For cold rooms, an estimated net storage capacity is available for standard gross volumes of cold rooms and freezer rooms in the UNICEF Quick Reference Guide (shown in Table below).

APPROXIMATE NET STORAGE CAPACITY FOR COLD ROOMS	
Cold room size (m^3) (gross volume)	**Net storage capacity (L)**
10	2308
20	3765
30	4920
40	5817

c. Assessment of transport equipment capacity in the cold chain

- To determine the available capacity for transport of temperature sensitive product, it is necessary to determine net storage capacity in passive containers, refrigerated vehicles and traditional trucks.

Cold box

- Use the following procedure to calculate the net storage capacity of vaccine cold boxes and carriers:
  - Step 1: Load the vaccine cold box or carrier with the number of frozen coolant-packs designated by the manufacturer.
  - Step 2: Measure the gross volume in cm^3 ((length x width x height) and convert this volume in liters (divide by 1000).
  - Step 3: Multiply the gross volume by a utilization factor of 0.67 in order to estimate net storage capacity.

Vehicles

- For refrigerated vehicles, gross volume is usually provided by the manufacturer. Calculate net storage capacity by multiplying the gross volume (in L) by the standard utilization factor of 0.67.
- For conventional trucks and vans, the net storage capacity is calculated on the basis of the exterior dimensions of the coolers and the vehicle loading volume. Once these dimensions are known, an optimized load configuration can be calculated.

3.4.2. CALCULATION OF COLD CHAIN REQUIREMENTS

- Cold chain capacity requirements is measured for each storage point at each level, including the point of service.
- Cold storage capacity needed depends on:
  - The current cold storage capacity (as measured above).
  - The dengue vaccine volumes to be stored between 2 supply intervals (as measured above).
  - The dengue screening test to be stored between 2 supply intervals (as measured above), if the temperatures of the storage areas regularly exceed 30°C.
  - The volume of other temperature sensitive products stored in the cold chain (e.g., vaccines and diluent from the systematic immunization program)
- The volume of vaccines from the national immunization program is measured by summing the volume of each vaccine stored between 2 supply intervals. See details in ANNEX1.

[1] WHO PQS Catalogue, available at: https://apps.who.int/immunization_standards/vaccine_quality/pqs_catalogue/

- The gap in the cold storage capacity is calculated as follow:

Volume for dengue vaccines		
+ Volume for dengue screening test (if temperatures above 30°C)	-	Volume of cold storage capacity
+ Volume for temperature sensitive product already in cold chain		

- There should be sufficient freezing and net storage capacity to prepare and store coolant packs. The need to freeze, cool, or store coolant packs depends on the temperature-sensitive product distribution strategy and the Screen and Vaccinate strategies used by each point of service. It also depends on the type of container used for transport or storage during outreach activities.
- The quantity of cooler packs to be prepared is calculated based on a maximum number of cold box for a shipment or of tests and vaccine carriers used during outreach sessions.
- For implementation in campaigns, additional freezers may be required to meet the requirements of all S&V teams.

3.4.3. SOLUTIONS TO COVER THE COLD STORAGE GAP

- Identifying and addressing current and future cold chain capacity gaps is essential to ensure the quality and availability of rapid tests and dengue vaccines throughout the intervention.
- Capacity gaps may be reduced by:
  - > Choosing product presentations with a smaller packed volume per dose - The volume per dose for the mono-dose presentation of Dengvaxia® is 30 time larger than the multi-dose presentation. Similarly, the larger package size (30 tests per kit) reduces the volume per test.
  - > Increasing the utilization rate of the cold chain equipment gross volume - Check whether the utilization factor used to calculate net storage capacity is realistic. Explore changing shelving configurations or modifying storage racks or equipment packing protocols to use a larger percentage of the available gross volume.
  - > Shortening vaccine supply intervals - Reducing the supply interval will mean delivering a smaller quantity of product more often, thereby reducing screening tests and vaccines storage volumes for the receiving facility. Shorter supply intervals can reduce the cold chain capacity requirements and may also lower the risk of stockouts. However, they will increase transport and labor costs.
  - > Rehabilitating cold chain equipment - The available cold chain capacity can be increased by repairing cold chain equipment that is currently not functioning.
  - > Procure new cold chain equipment - When purchasing new equipment, give preference to WHO PQS-pre-qualified equipment[2] whose performance ensures better product quality. For the production or storage of ice packs, domestic freezers are suitable. Choice of cold chain equipment should be based on the performance history of equipment models already installed in facilities. Purchase should be planned in advance to allow for delivery time and adequate budget.
  - > Identify alternative cold chain equipment - When other solutions are unable to address cold chain capacity gaps, it may be possible to use existing equipment in public or private health structures. In this case, agreements must be made with these structures to ensure proper conservation of the products.
  - > Air conditioning can be an easier and cheaper alternative for storing screening tests where temperatures are above 30°C. provided that the air conditioners are working properly and the temperature is carefully monitored

3.4.4. DRY STORAGE CAPACITY FOR SUPPLIES

- Dry-storage capacity is needed to store several types of commodities, including finger prickers, diluents, syringes and needles used for reconstitution and injection, safety boxes, spare parts for cold chain equipment, and planned surpluses of cold boxes and carriers. The table below shows indicating packed volume for common supplies.

ESTIMATED PACKED VOLUME PER UNIT OF COMMON SAFE-INJECTION EQUIPMENT		
Safe-injection equipment	**Units per box**	**Packed volume (cm3) per unit**
AD syringes, 0.5 mL	100	56,7
Syringes, 5 mL for dilution	100	66,3
Safety boxes, 5 L	25	693,9
Safety boxes, 10 L	25	1094.4

3.5. Planning for waste management

[2] See https://apps.who.int/immunization_standards/vaccine_quality/pqs_catalogue/categorypage.aspx?id_cat=17

3.5.1. TYPES OF WASTE

- Dengue S&V generates waste for both the screening and the vaccination procedure. If implemented in campaigns, some extra waste is expected within a short period of time.
- Both hazardous and non-hazardous waste are produced:

	HAZARDOUS WASTE	NON-HAZARDOUS WASTE
Screening procedure	• Blood-contaminated cotton swabs • Lancets for finger pricking • Used RDT cassettes • Used Capillary tubes	• Used package boxes with sealed foil pouches containing desiccant • Sample diluent bottles • Instructions manuals • Disposable gloves • Gauze or cotton (not blood-contaminated) • Alcohol bottles or alcohol wipes
Vaccination procedure	• Vials of vaccine powder • Prefilled glass syringes of solvent (kit mono-dose) • Syringes for reconstitution (kit multi-dose) • Syringes for injection (kit multi-dose) • Needles for vaccine reconstitution (both kits) • Injection needles (both kits)	• Vials of solvent (kit multi-dose) • Used package boxes • Cotton swabs • Disposable gloves • Syringe caps

- Hazardous wastes are those at risk of transmission of HIV, HBV and other bloodborne pathogens (blood-contaminated or live vaccine) and those at risk of physical injury. Sharps and other hazardous waste should all be collected, whether or not they are blood-contaminated or have been in contact with the vaccine. Special attention must be given to their management to avoid damage to the health workers, the population, and the environment.
- Non-hazardous wastes are considered at low risk. They have not been in contact with blood or live vaccine. or do not pose a sharps hazard. They can be treated as other general waste.
- All specimens and materials used to perform the RDT are disposed as bio-hazardous waste.
- Personnel involved in hazardous waste handling (health personnel, technicians, drivers, …) should be vaccinated at least against hepatitis A and B, polio and tetanus and equipped with personnel protective equipment.

3.5.2. ESTIMATION OF WASTE NEEDS

- For waste management planning purpose, it is necessary to estimate the volume of waste to be treated for each testing and vaccination site.
  - > Step 1: calculate the number of hazardous waste produced based on the number of participants to be tested and/or vaccinated.

    A 10% safety margin should be included in the calculation for finger prickers, RDT cassettes/strips, lancets, syringes and needles.
  - > Step 2: calculate the total number of safety boxes necessary for the intervention. 5-liter safety boxes can be filled to the maximum fill line and can contain approximately 150 syringes with needles or 100 finger prickers with cassette and lancet (test kits).

    A 20% safety margin should be included in the number of syringes with needles or test kits per safety box.
  - > Step 3: calculate the daily production of safety boxes to be treated. The daily disposal of safety boxes must be ensured in each focal center. This number is based on the number of test or vaccines performed per day in each site.
  - > Step 4: estimate the cost for waste treatment and elimination for the intervention. Costs include:
    - Hazardous collection costs: safety boxes
    - Handling costs: personnel protective equipment, plastic bags, …
    - Minimal investment cost for waste treatment and elimination equipment; procurement/ rehabilitation of waste disposal equipment
    - Minimal recurrent costs: human resources, combustible/energy

CALCULATION TABLES ARE SHOWN IN ANNEX 2.

3.5.3. WASTE MANAGEMENT TREATMENT SOLUTIONS

- Hazardous waste management resulting from the screening or from the vaccination procedures is implemented in 4 steps: segregation, storage, transport and elimination. Procedures follow local laws governing the disposal of devices

  > **Segregation** - To reduce the risk to health, wastes should be segregated where they are produced, whether in community out-reach posts, schools or health centers. Containers need to be puncture-proof, rigid and waterproof to safely retain sharp objects and residual liquids from syringes. To discourage abuse, containers should be tamper-proof (difficult to open or break). When plastic or metal containers are unavailable or too costly, dense cardboard containers are recommended by WHO.

  > **Storage** - When possible, there should be secure storage rooms on site to keep hazardous wastes separate from general wastes. Safety boxes must be stored in an access-protected area, and should be kept dry especially if cardboard containers. The safety boxes should be stacked upright, standing on their bases, to prevent them from being damaged. Maximum storage times before treatment or disposal of infectious waste should not be longer than 72 hours.

  > **Transport** - In some cases, sharp waste cannot be disposed of on site. Transportation to a disposal site is necessary. Off-site transport of hazardous healthcare waste should comply with national regulations. Where there are no national regulations, responsible authorities may refer to recommendations on the transport of dangerous goods published by the United Nations[3]. The safety boxes should be stored in vehicles without direct contact with drugs, vaccines or other medical supplies. After each journey carrying safety boxes, the vehicle interior should be cleaned with surface disinfectant, such as 1/20 diluted household bleach.

  > **Elimination** - The most common sharp waste elimination methods are based on thermal processes such as low-heat steam sterilization in autoclaves and microwave treatment, or high-heat incineration. As for transport, waste elimination should strictly comply with national regulations. The WHO guidelines "Safe management of wastes from health care activities" (WHO 2014) and « Overview of technologies for the treatment of infectious and sharp waste from health care facilities » (WHO, 2019) [4, 5] detail WHO recommended elimination procedures. To reduce waste volume, a mechanical process such as a shredder or grinder can be used before or after low-heat treatment. Shredding reduces the volume of the treated waste by 60–80%. There are other methods of disposing of biomedical waste. These include the following: Frictional heat treatment, Chemical-based processes (Sodium Hypochlorite-based). Countries such India, Nepal, Senegal, Vietnam are using or have been using needle remover for immunization waste disposal.

4. LOGISTICS OF IMPLEMENTATION

Implementation of the S&V strategy requires specific logistics preparation depending on the selected approach (One-step or Two-step) and type of settings (facility based, school-based or community-based).

4.1. Logistics preparation for S&V session

- Logistics for tests and vaccines depends on country's choice of implementation.

4.1.1. LOGISTICS SPECIFICITIES: ONE-STEP VS. TWO-STEP

- In a One-step approach, both tests and vaccines need to be available on the same day.

  > Estimating the number of vaccines that are required per session is critical (see chapter 3). This determines the needs in human resources, in transport and storage of products and materials both in the dry and the cold chains, as well as in waste management.

3. See http://www.unece.org/trans/danger/publi/unrec/rev16/16files_e.html
4. Safe management of wastes from health-care activities. Geneva: World Health Organization; 2014
5. Overview of technologies for the treatment of infectious and sharp waste from health care facilities. Geneva: World Health Organization; 2014

- If the number of vaccine-eligible individuals is underestimated, possible consequences include:
  - Mitigation measures to quickly supply intervention settings in need of vaccines.
  - Optimal vaccination coverage not reached.
  - Needs to organize additional vaccination catch-up visits.
  - Loss of credibility and confidence of the population towards the intervention, which can ultimately lead to communication crisis situations.
- If the number of vaccine-eligible individuals is overestimated, possible consequences include:
  - Sub-optimal sizing of resources and supply chains placing unnecessary burden and costs on the system.
  - Possible loss and waste of vaccines products and materials due to unnecessary provision.

> A safety stock for vaccines should be planned in case the number of tested seropositives overruns the estimated number. Safety stock can represent 20% of the needs calculated for the session.

- In a Two-step approach, quantities of vaccines and related supplies can be adjusted to the real number of seropositives individuals.
  > The burden on human resources, on dry and cold chain storage and transport and on waste management is optimized to the real needs for vaccination.
  > There is no need for adding safety stocks for vaccines in the Two-step approach.
  > All information materials for the intervention need to be provided for the screening session, as participants need to consent for the full S&V intervention.

4.1.2. LOGISTICS SPECIFICITIES: TYPES OF SETTINGS

- Whatever the implementation approach (One-step vs Two-step; campaign and/or routine intervention), and regardless of where the intervention takes place, all programs are based in health care facilities (HCF). Staff, storage capacities and waste management are calculated and organized for each HCF participating in the S&V intervention.
- Transport is organized:
  > from country point of entry to national warehouse,
  > from national warehouse to participating HCF
  > from local HCF to schools or out-reach community posts when the intervention (S&V or screen only) is given in community settings.
- The supply chains for vaccines and for screening tests may be different (different national programs dealing with vaccines and diagnostics, different temperatures), but they need to be coordinated to ensure the concurrent availability of both when are where needed.
- Cold chain requirement and packaging of vaccines are arranged prior to out-reach sessions in community and schools. In the event of long local temperature excursion above 30°C, screening tests will require to be stored and transported in a cold chain.
- When full S&V intervention or vaccination only is implemented in health care facilities, logistical constraints are lowest as it uses health services, facilities, and staff.
  > Participating centers need to organize for the additional activity, ensuring sufficient storage room both in the cold and dry chains, spaces dedicated to the intervention and appropriate staffing.
  > The deployment of the S&V intervention should not come at the cost of disrupting other services routinely provided by the HCF.
  > The logistical constraint will be less if the intervention is conducted by appointment.
- When full S&V or screening only is conducted in schools, logistics is carefully planned and implemented with all partners and stakeholders involved.
  > Good coordination is necessary between heads of schools and managers at HCF level.
  > School settings provide a secured and closed environment for health interventions, although waste management and cold chain can be a challenge.
  > School interventions allow considering a "captive" target population, and consequently rather precise and non-fluctuating logistical needs can be estimated.
  > Each school will bring specific organizational challenges (estimated number of participating students, space available for the intervention, access routes, storage of heat-sensitive products, supervisory staff, etc.) which will have to be considered and resolved on a case-by-case basis.
- Community out-reach intervention is the option with the highest logistical constraints as it requires organization of out-reach posts in non-medical and open community settings.
  > An excellent logistical organization is essential to ensure effective and well accepted intervention in the community.
  > Attendance at screening or S&V sessions may vary greatly, depending on the availability and adherence of the target population to the intervention. Logistics need to adapt to these variations between out-reach posts and during the intervention period. A strong monitoring will help adjustment and corrective measures where and when needed. Materials and staff may be redirected to the busiest out-reach posts.
  > Logistics need also considering expected peak times for attendance to avoid congestion and product shortages. Solutions include increasing

human resources capacities during identified peak hours, increasing intervention rooms capacity, or spreading patient flow by setting up an intervention appointment system. Another option is to redirect participants to a nearby out-reach post that is less congested. In this case it may be good to have real-time connections between out-reach posts in the same area. Eventually, if the overcrowding of certain out-reach posts is confirmed, the network should be reorganized to move little-used out-reach posts to areas of high participation (see module S&V sessions).

A TABLE FOR CALCULATION OF MATERIAL NEEDED FOR A SESSION IS PRESENTED IN ANNEX 3.

A TABLE FOR CALCULATION OF SAFETY BOX IS PRESENTED IN ANNEX 3.

4.2. Handling of RDTs and vaccines

4.2.1. PACKING RDTS AND VACCINES FOR THE SESSIONS

- The RDTs and sample diluent are shipped and stored at room temperature, 2-30°C. Once opened, the diluent must be used within 6 months and be stored in conditions minimizing microbial exposure, at 2-8°C whenever possible.
- The vaccines are shipped and stored at 2-8°C and protected from light.
- Tests and vaccines must not be frozen.
- When packing the RDTs and vaccines, the integrity of the packaging, the expiry date and temperature and freeze indicators must be checked. If the packaging shows signs of damage, if the expiring date is passed, or if the indicator shows temperature excursions, the product must be discarded.
- For school and community interventions, tests and vaccines should be packed in dedicated carriers, ensuring that ice packs are not frozen to avoid product freezing. Ice packs may not be necessary in the event of sessions lasting less than a day, as the risk of freezing is greater than the risk of damage from heat for short temperature excursions.
- For schools and community-based interventions, the dispatching of products and materials are calculated per setting depending on the expected number of participants in each site.

4.2.2. PREPARING THE PRODUCTS AND THE WORKPLACE

- The place where the screening test is performed needs to be:
  - Appropriately lit as it can affect result interpretation
  - Friendly, clean and tidy as long waits and disorganized activities can frighten or discourage participants and prevent some from receiving these services
  - Without strong air flow, i.e., wind, electric fan or strong air-conditioning
- Intervention staff and participants should not smoke, drink or eat where specimens, tests and vaccines are being handled.
- RDTs and vaccines need to be brought to room temperature before use (15-30°C). Brief excursion to 45°C is allowed for the RDTs. For sessions in HCF and schools, the RDTs and / or vaccines needed are taken out of the refrigerator beforehand to reduce the number of refrigerator openings.
- The test device needs to be performed on a clean and flat surface.
- In the case of community-based intervention, the minimal requirements include the followings:
  - Easily accessible, clearly identified and located in the same place every day
  - Outside sheltered/shaded area with chairs when waiting rooms are not available inside
  - Sufficient space to accommodate separate stations for registration, screening, testing, vaccination and record keeping
  - Quiet area to allow health workers to deliver information and advice
  - Room for safe waste management
  - In a One-step approach, the screening posts must be well separated from the vaccination posts.
- Whatever the approach and the context, and particularly in the one-step approach, the flow of people must be carefully planned in advance to avoid long waits, confusion in instructions, loss of knowledge, and discouraged patients. Ideally, the intervention circuit should have a separate entrance and exit, and be well marked with signs, ropes and other visual aids through which community members or health workers can guide participants. (see Module "S&V sessions").

4.2.3. RDTS AND VACCINES HANDLING

- The manufacturer instructions' manuals give comprehensive indication for product handling and administration.
- Once the RDT pouch is opened, it should be used within 30 minutes to avoid possible failure caused by the absorption of moisture.
- RDTs device must be clearly labeled with the specimen's ID number, either by writing directly on the cassette device or by labeling a patient ID sticker.
- After interpreting the results, RDTs are discarded following local laws governing the disposal of devices.
- The handling of the vaccines will be different depending on whether it is a single or multi-dose presentation.

MONO-DOSE PRESENTATION (1DOSE VIAL)	MULTI-DOSE PRESENTATION (5 DOSE VIAL)
1. Fit the 23G dilution needle on the pre-filled glass syringe and after removing the flip off cap of the vial, transfer all the solvent into the vaccine vial. 2. Gently swirl the vial with the syringe until complete reconstitution of vaccine to obtain a clear and colorless liquid. 3. After complete dissolution, withdraw the total volume of reconstituted vaccine into the same syringe. 4. Change the dilution needle to the 25G injection needle and inject Dengvaxia® in the deltoid region of the arm. 5. Discard the injection syringe and needle and the used vaccine vial in a safety container.	1. Withdraw all the provided solvent with a sterile syringe and needle. 2. Transfer all the solvent into the vaccine vial. 3. Gently swirl the vial with the syringe until complete reconstitution of the vaccine to obtain a clear and colorless liquid, 4. Discard the reconstitution syringe and needle in a safety container. 5. After complete dissolution, 5 doses of Dengvaxia® vaccine are ready to use. 6. Withdraw one dose, 0.5 mL of the reconstituted vaccine into a new sterile syringe and needle and inject Dengvaxia® in the deltoid region of the arm. 7. Discard the injection syringe and needle in a safety container.

- For good injection practice, countries should follow their national guidelines. (Note: WHO does not recommend to swab clean skin with alcohol before injection).
- Once the multi-dose vial is reconstituted, all doses should be administered promptly using a new sterile syringe and needle. The opened multi-dose vial can be kept up to 6 hours if stored between 2 and 8°C.

4.2.4. CLOSING THE SESSION

- Materials must be stored safely or disposed of after the sessions. Equipment and sites must be cleaned and prepared for their next use.
- Open multi-dose vaccine vials are discarded at the end of the session.
- Vaccine carriers are packed with the remaining vaccine vials, and temperature is checked: if conditioned ice packs have completely melted and/or the thermometer in the vaccine carrier shows a temperature above +8°C, all vaccines inside the vaccine carrier should be discarded.
- Temperature-sensitive products are returned to the refrigerator.
- Dispose of wastes as described in chapter 3.5.

5. READ MORE

Implementation of Dengvaxia

- Fongwen et al. *"Implementation strategies for the first licensed dengue vaccine: A meeting report"*. Vaccine. 2021 Jul 9:S0264-410X(21)00845-8. doi: 10.1016/j.vaccine.2021.06.083
- Fongwen et al. *"Target product profile for a dengue pre-vaccination screening test"*. PLoS Negl Trop Dis. 2021 Jul 29;15(7):e0009557. doi: 10.1371/journal.pntd.0009557.

General Logistics

- Planning and implementing high-quality supplementary immunization activities for injectable vaccines using an example of measles and rubella vaccines: field guide. Geneva: WHO, 2016.
- How to calculate vaccine volumes and cold chain capacity requirements. Geneva: WHO, 2017.
- Safe management of wastes from health-care activities. Geneva: WHO, 2014.
- Management of waste from immunization campaign activities: practical guidelines for planners and managers. Geneva: WHO, 2004.
- Immunization in Practice - A practical guide for health staff. Module 5: Managing an immunization session; WHO, 201

ANNEX 1: VOLUME OF TEST KITS AND VACCINES

1. Volume of testing kits

TOTAL TESTS/YEAR (1)	A	
NUMBER OF SUPPLIES PER YEAR	B	
NUMBER OF TEST KITS PER SUPPLY	A/B	
PACKED TEST KIT VOLUME PER TEST (CM^3)	C	
STORAGE VOLUME OF TEST KITS (L)	$\frac{D=(A/B)xC}{1000}$	
VOL OF SAFETY STOCK	E	
COLD CHAIN CAPACITY REQUIREMENT	F	

NOTE 1: The total number of testing kit per year is calculated by applying the calculation method described in section 3.3 Estimation of supply needs.

2. Volume of vaccines

The volume of vaccines is measured by summing the volume of each vaccine in the vaccine store between 2 supply intervals. For each vaccine, the volume can be calculated as follow:

VACCINE	TOTAL DOSE/YEAR (1)	NUMBER OF SUPPLY PER YEAR	NUMBER OF DOSE PER SUPPLY	PACKED VACCINE VOLUME PER DOSE (CM^3)	PACKED DILUENT VOLUME PER DOSE (CM^3)	VACCINE STORAGE VOLUME OF VACCINE (L)	VACCINE STORAGE VOLUME OF DILUENT (L)
	A	B	A/B	C	D	$\frac{(A/B)xC}{1000}$	$\frac{(A/B)xD}{1000}$
DENGVAXIA® 1 DOSE-VIAL				153	na (2)		
DENGVAXIA® 5 DOSE VIAL				5,3	na (2)		
OTHER VACCINE 1							
OTHER VACCINE 2							
OTHER VACCINE 3							
TOTAL VACCINE VOLUME PER SUPPLY INTERVAL							
VOLUME OF SAFETY STOCK							
COLD CHAIN CAPACITY REQUIREMENT							

(1): The total number of dose per year is calculated by applying the calculation method described in section 3.3 Estimation of supply needs.

(2): Diluents for Dengvaxia® are packed with vaccines.

NOTE 1: the total vaccine storage volume should be calculated by storage temperature (ie. +2°C to +8°C, –25°C to –15°C)
NOTE 2: If the cold chain equipment stores other product than vaccines, then the cold chain capacity requirements should be expanded to include the appropriate packed volumes for those non-vaccine products.

ANNEX 2: WASTE MANAGEMENT REQUIREMENTS

1. Waste volume

TESTING KITS					
TESTING SITE	NUMBER OF PARTICIPANTS TO BE TESTED	NUMBER OF KITS USED	SAFETY MARGIN	TOTAL NUMBER OF KITS	NUMBER OF SAFETY BOX
	A	B	C= (10%)	D=B+(BxC)	D÷100
1					
2					
3					
				TOTAL	

IMMUNIZATION WASTE							
VACCINATION SITE	NUMBER OF PARTICIPANTS TO BE IMMUNIZED	NUMBER OF VACCINE SYRINGES WITH NEEDLES USED	VIAL SIZE	NUMBER OF DILUTION SYRINGES WITH NEEDLES	SAFETY MARGIN	TOTAL NUMBER OF SYRINGES WITH NEEDLES	NUMBER OF SAFETY BOX
	A	B	C	D=B÷C	E=10%	F=B+D+(B+DxE)	D÷150
1							
2							
3							
						TOTAL	

2. Number of safety boxes per day

TESTS				
TESTING SITE	NUMBER OF TECHNICIAN	NUMBER OF TESTS PERFORMED PER TECHNICIAN PER DAY	TOTAL NUMBER OF TEST PERFORMED PER DAY	NUMBER OF SAFETY BOX TO BE DISPOSED AT A FOCAL CENTER
	A	B	C=AxB	D=C÷100 + 10% SAFETY MARGIN
1				
2				
3				
TOTAL				

IMMUNIZATION WASTE				
VACCINATION SITE	NUMBER OF VACCINATORS	NUMBER OF VACCINES PERFORMED PER VACCINATOR PER DAY	TOTAL NUMBER OF VACCINES PERFORMED PER DAY	NUMBER OF SAFETY BOX TO BE DISPOSED AT A FOCAL CENTER
	A	B	C=AxB	D=C÷150 + 10% SAFETY MARGIN
1				
2				
3				
TOTAL				

3. Cost for waste treatment and disposal

CATEGORY	ITEM	UNIT COST	QUANTITY	TOTAL
SHARP COLLECTION	SAFETY BOX			
WASTE HANDLING	PROTECTIVE EQUIPMENT			
	PLASTIC BAG			
	ADHESIVE TAPE			
	OTHER …			
			TOTAL	

Investment cost: May vary greatly according to local conditions

RECURRENT COSTS				
HUMAN RESOURCE	NUMBER OF WORKER	DAILY RATE	NUMBER OF DAYS	SUBTOTAL
1				
2				
COMBUSTIBLE	QUANTITY USED/DAY	UNIT PRICE	NUMBER OF DAYS	SUBTOTAL
1				
2				
			TOTAL	

ANNEX 3: ESTIMATION OF MATERIAL NEEDS FOR A SESSION

1. Testing and vaccination

ITEM	TARGET POPULATION	EXPECTED COVERAGE	NUMBER OF UNIT/BENEFICIARY	WASTAGE FACTOR	TOTAL NEEDED
	A	B	C	D	E=(AxBxC)+D
RDT		100%	1	1,05	
VACCINE (1 DOSE VIAL)		100%	1	1,11	
VACCINE (5 DOSE VIAL)		100%	1	1,05	
FINGER PRICKERS (1)					
SYRINGES FOR INJECTION (0,5 ML) - (2)					
NEEDLES FOR INJECTION (2)					
SYRINGES FOR DILUTION (5 ML) - (3)					
NEEDLES FOR DILUTION (3)					

NOTES:

A : target population : RDT = defined by the country ; vaccine = RDT positives (from master list of seropositive subjects or country estimates)

B: Expected coverage of targeted population (usually 100%)

C: Number of test or dose per individual

D: Wastage factor = 100x(100-Wastage Rate) ------- Wastage rate for RDT and vaccine 1-dose vial = 5% ; wastage rate for vaccine 5-dose vial = 10%

E: Total of unit needed for the session

(1): Number of finger prickers = total number of test kits

(2): Number of syringes and needles for injection = total number of vaccine dose (5-dose vial presentation)

(3): Number of syringes and needles for dilution = number of 5-dose vials ÷ 5

2. Waste management (5L safety box)

	EXPECTED ATTENDANCE	STATIONS	SAFETY BOX/STATION	TOTAL
	A	B	C	D = B X C
TESTING				
VACCINATION				
			TOTAL	

A: based on population target

B: number of testing and/or vaccination stations for the session

C: For testing : C=A/B/100 (rounded up to the nearest whole number)
For vaccination : C=A/B/150 (rounded up to the nearest whole number)