



DENGUE VACCINE IMPLEMENTATION (Screen & Vaccinate) SCREEN AND VACCINATE SESSIONS

INFORMATION FOR SKATEHOLDERS

The purpose of this document is to help decision makers and program planners focus on key questions regarding the organization and management of Screen and Vaccinate sessions with Dengvaxia®, the dengue tetravalent vaccine (live, attenuated).



1. CONTEXT FOR DENGUE VACCINATION

1.1. The Dengue Screen and Vaccinate strategy

- Dengvaxia®, also referred to as CYD-TDV, developed by Sanofi Pasteur, is a live recombinant tetravalent dengue vaccine given as a 3-dose series with 6 months between each dose. The vaccine is indicated for use in individuals 9-16, 12-45 or 9-45/60 years of age (depending on the license) with evidence of prior dengue infection and living in endemic areas. Vaccine indication is subject to change (e.g., from 6 years of age, EMA 2022). Previous infection by dengue virus can be evaluated through serotesting prior to vaccination or through a medical record of previous laboratory-confirmed dengue infection. This novel strategy is referred to as the Screen and Vaccinate (S&V) strategy.
- Note: Another WHO recommended – although less preferred – option, is vaccinating without individual pre-screening in highly endemic settings (seroprevalence $\geq 80\%$ at 9 years of age). This option will not be considered in this module.
- To reach the population targeted by the intervention, and adapt to national and sub-national contexts, the Screen and Vaccinate intervention can be conducted in different types of settings, and either in one-go on the same day (One-step approach) or conducting the screening and the vaccination on different days (Two-step approach). The dengue vaccine Toolkit Module IMPLEMENTATION STRATEGIES, describes various possible S&V implementation scenarios.

1.2. The dengue vaccine

- Dengvaxia® is formulated as a freeze-dried / lyophilized powder and solvent. The vaccine has a shelf life of 36 months, should be stored at a temperature between 2°C and 8°C and should NOT be frozen.
- Doses of vaccine are administered subcutaneously above the deltoid, promptly after reconstitution in solvent. Recent studies show that in baseline dengue seropositive participants, Dengvaxia® elicits comparable immunogenicity and safety profiles when administered concomitantly or sequentially with a human papilloma virus (HPV) vaccine or with a diphtheria toxoid and acellular pertussis (Tdap) vaccine.
- Dengue vaccination is contraindicated in: (1) individuals with a history of severe allergic reaction to any component of the dengue vaccine or after prior administration of the dengue vaccine or a vaccine containing the same components; (2) individuals with congenital or acquired immune deficiency that impairs cell-mediated immunity; (3) individuals with symptomatic HIV infection or with asymptomatic HIV infection when accompanied by evidence of impaired immune function; (4) pregnant or breastfeeding women. That vaccination should be postponed in individuals with moderate to severe febrile or acute disease.
- Until data become available from forthcoming studies in HIV-infected individuals or other persons with immune deficiency, there is no recommendation concerning the use of Dengvaxia® in HIV-infected or immune compromised individuals.



- The age indication starts at 9 years of age and the expected vaccine impact may often be optimal when vaccinating younger age groups – provided a large proportion is seropositive for dengue and they bear a large burden of disease.

1.3. Dengue diagnostic tests

- A Rapid Diagnostic Test, the *OnSite®* Dengue IgG RDT has been specially designed to identify individuals in the age range for vaccination who have had a past dengue infection. This test has achieved performance characteristics within the expected range to enable safe and efficient implementation of pre-vaccination screening and dengue vaccination. It is CE-marked and already registered for use in certain countries.
- The characteristics of other dengue RDTs for dengue are not optimal for use in the S&V dengue strategy as they are designed to detect acute infections only. Serological testing using IgG enzyme-linked immunosorbent assay (ELISA) is a less preferred option and is not fully considered in this module which focuses on the WHO-recommended use of point of care Rapid Diagnostic Tests (RDTs). Intervention teams should be trained with the testing procedure and if the test is invalid, a new one should be performed. The vaccination is triggered by a positive RDT read by the health staff or proven by a nominal previous test result. The team should never extrapolate on an invalid test result or medical form.
- Vaccination can be proposed without testing if there is a documented history of dengue with a nominal proof of a positive laboratory test.
- The operational test reading procedure should be organized in advance in order to ensure clear identification of the individual on the test. It is recommended to use an electronic application ensuring that test identifiers are associated to participant name or identifier, and that test results are entered in the database as soon as they are read.

Dengue IgG RDT Target Product Profile includes:



- High specificity (minimum 90%) and no cross-reactivity with other flaviviruses antibodies to ensure safety (avoid vaccinating false positives)
- High sensitivity (minimum 90%) to maximize public health benefit (identify majority of seropositives)
- Used by minimally trained Health Care Professional
- Implementable at point of care
- Finger prick, whole blood $\leq 100 \mu\text{l}$
- Simple to use, visual qualitative interpretation
- Results within 30 min
- Storage temperature: $10-30^{\circ}\text{C}$ and 80% relative humidity ≥ 12 -month shelf life

1.4. Scope of the Module

- A range of scenarios can be considered with various settings for each step of the intervention. The choice for a scenario depends on the age groups targeted by the vaccination, and on national and local experiences, capacities and constraints [See Module IMPLEMENTA-

TION STRATEGIES]. For this module, we consider the following most probable scenarios (FIGURE 1):




- > One-step scenarios:
 - Screening and Vaccination are both conducted on the same day at school
 - Screening and Vaccination are both conducted on the same day in community centers



- Screening and Vaccination are both conducted on the same day at health care facilities (HCF)
- > Two-step scenarios:
 - Screening is conducted in schools and vaccination is given on another day to seropositives at health care facilities
 - Screening is conducted in community settings and vaccination is given on another day to seropositives at health care facilities

FIGURE 1.

Selected implementation scenarios for the S&V strategy

		 School	 Community	 Health care facilities
One-step	Screen & Vaccinate	✓	✓	✓
Two-step	Screen only	✓	✓	✗
	Vaccinate only	✗	✗	✓

2. PLANNING, PREPARATION AND CONDUCT OF DENGUE SCREEN AND VACCINATE SESSIONS

- Whatever approach is chosen, it is essential to ensure adequate funding for tests and vaccines, technical assistance from relevant bodies, advocacy, and communication, engagement and training of relevant personnel, monitoring and reporting. In any case, strong support should be guaranteed from professional societies and responsive national and local partners.
- Countries should be evaluating their own current and required capacities with regards to human resources, stock, cold chain, waste management, and transport. It will take into consideration vaccines currently delivered through their immunization program, number of doses needed for dengue vaccination, requirement for testing before proposing vaccination, timing chosen for implementation, vaccination plans in terms of target, areas, and Screen and Vaccinate strategies. The number of tests should be higher than the number of individuals to be tested, in order to account for duplicative testing in the event of invalid test results or possible multiple rounds of testing over the time.
- Three doses of vaccine should be secured per vaccinee. The total number of tests and vaccines will depend on various factors including dengue seroprevalence, compliance rate, or adherence in the target population [See Module LOGISTICS].
- Electronic information systems (registries and databases) should be reinforced and linked together. Real-time data entry would be an asset.
- Community surveys may be planned to document anticipated reasons for the new dengue Screen and Vaccinate intervention acceptance / hesitancy / refusal in the target population and inform on the best way to implement activities.
- It is strongly recommended to conduct pilot studies for evaluation of intervention team size, tests and vaccines quantities, patient flow, logistical constraints, staff and population compliance and acceptancy, etc.
- Vaccination dose visits can be used as dose catch-up visits and as entry points for participants who were negative at last screening or who had missed the



previous screening. Two types of routine campaign roll-out may be considered, depending on program targets and capacities (FIGURE 2.):

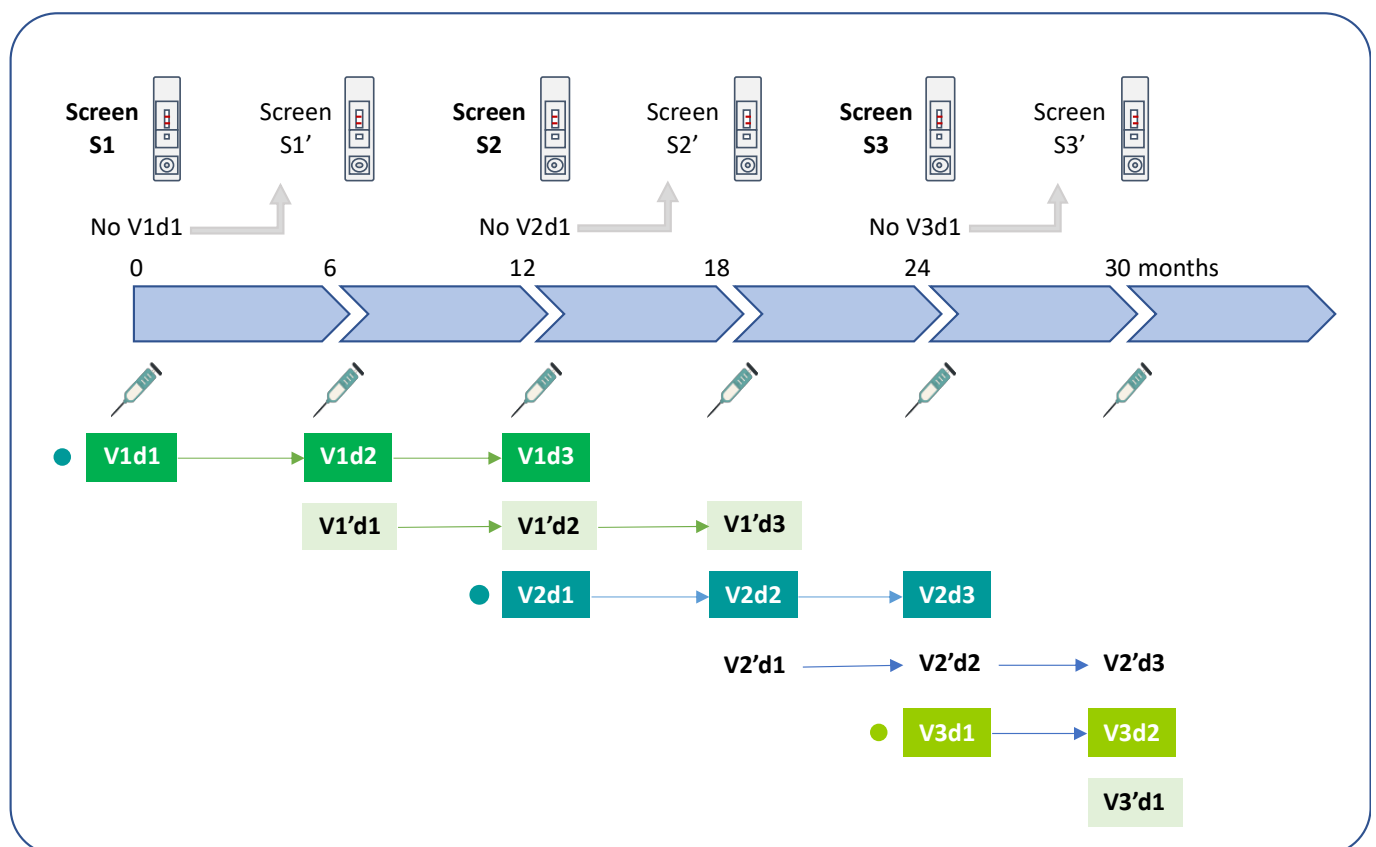
- > Annual cohort: first vaccine dose of the next cohort (V2d1) is given during the same visit as the third vaccine dose of the previous cohort (V1d3)
- > Bi-annual cohort: first vaccine dose of the next cohort (V1'd1) is given during the same visit as the second vaccine dose of the previous cohort (V1d2);

then each vaccination visit allows the delivery of 3 doses: d1 for the new cohort enrolled, d2 for the latest cohort, and d3 for the vaccinees receiving their last vaccination (one year after first one). Although this strategy may be more challenging to organize in terms of logistics and costs, it is also likely to help achieving the best vaccine coverage by vaccinating those who have become seropositive since the last screening, or those who were unable to attend the previous S&V intervention

FIGURE 2.

Roll-out of S&V routine campaigns.

New rounds of screening and vaccination can be implemented at the time of administration of the 2nd and/or 3rd dose of vaccine to allow starting routine intervention campaigns on new cohorts. S: screening cohort (3 cohorts in the example); V: vaccination cohort (3 cohorts in the example); d: dose of vaccine (1 to 3);



- The 2nd and 3rd dose of vaccine are administered 6 months and 12 months after the first dose, respectively, within a window of ± 20 days around the theoretical vaccination dates. (For example, if the theoretical date for the administration of the next dose is June 30, the vaccination can take place between June 10 and July 20).
- Specificities that need to be considered for the selected S&V interventions are described below.



2.1. Interventions in health care facilities (HCF)

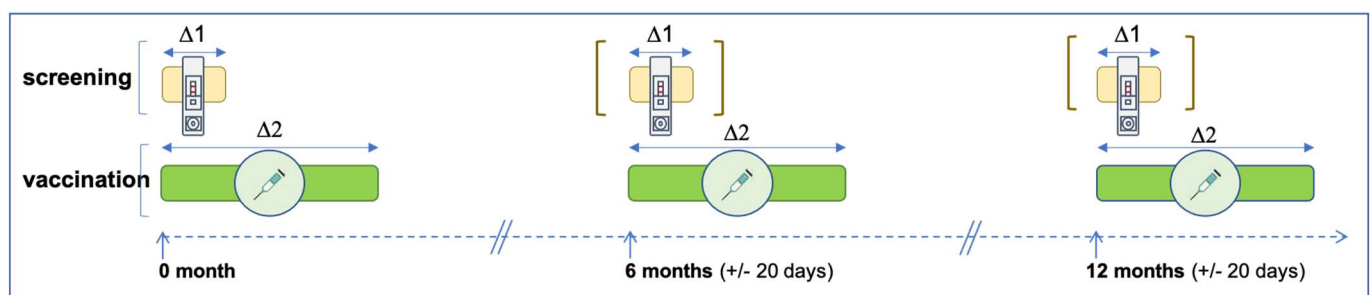
2.1.1. PLANNING HCF INTERVENTION

- Regardless of where the intervention takes place, all programs are based in HCF, including mobile teams and materials.
- Intervention in HCF can be either:
 - Organized in campaigns for people targeted by the intervention - During defined days of intervention, occurring over a fixed time period, either the full S&V intervention or the vaccination of identified seropositives is offered in designated and well-prepared HCF.
 - Integrated into routine health services - Throughout the year, people targeted by the intervention can present to their HCF to receive either the full S&V intervention, or the vaccination only if they already had a positive test result during previous screening in schools or community.
- In the case of an intervention organized in campaigns, scheduling is essential. It should take into account the seasonality of dengue, if any, to maximize the impact from the first vaccine dose, but also other planned health care interventions (e.g. vaccination campaigns), and anticipated disease burden (e.g. infection disease season) to reduce the risk of overwhelming already busy HCF. Scheduling of activities should be done considering each of the 3 doses of the vaccine. When a Two-step intervention is implemented, planning must be optimized to also allow best timing for the first step of screening in schools or in the community,
- The health care facilities participating into the dengue S&V intervention need extra support in terms of human resources for laboratory and vaccination, data management, communication, and logistics.
- In all cases, but even more if a full S&V intervention is implemented in HCF, Information, Education and Communication (IEC) materials must be carefully designed. Communication campaigns are organized to reach the target population and make them willing to participate. They will need to be reiterated every 6 months (for each dose) in case of S&V intervention through campaigns or implemented regularly throughout the year in the event of routine intervention.

FIGURE 3.

Planning of a Two-step S&V strategy where vaccination is given in health care facilities (HCF).

Screening campaigns to detect seropositives can take place in schools or communities. $\Delta 1$ represents the period during which screening campaigns are deployed (e.g. 1-day intervention in a school, 2-weeks intervention in the community). Vaccination should be offered as soon as the test result is known. $\Delta 2$ represents the period during which vaccination is offered at the HCF for those tested positive for dengue infection (e.g. vaccination available as soon as the screening campaign begins and lasts for a month). Every 6 months, recurrent campaigns are organized in HCF for each dose delivery.



2.1.2. PREPARING HCF INTERVENTION

- The S&V is a new type of intervention, consequently, appropriate training needs to be organized and conducted for all medical personnel involved. Additional health staff should be mobilized and trained in advance in order to increase vaccine coverage, avoid any disruption of other vaccination program, and manage any adverse effect following vaccination
- Communication is essential as going to the health care facility to enter the S&V program is a proactive process and the population needs to be educated



before participating [See Module COMMUNICATION]. IEC materials need to be displayed ahead and during the intervention, in the HCF, medical practices and various health structures, and in all places where the target population may be exposed to it in the community (e.g. banners in the streets, leaflets and posters in medical practices and schools, etc). Adequate information and mobilization campaigns should be conducted using information channels identified as being the most influent in the target group.

- An appointment booking system can be put in place to avoid long waiting times and better organize the flow of participants on intervention days. If vaccination is proposed based on a positive test result following screening in community or in schools, the closest HCF hosting the vaccination intervention should be clearly identified and communicated to the participant, and vaccination appointments should be given with an indication of address, date and hours. For the 1st and 2nd doses, appointment must be made for the next dose injection 6 months after. Reminders (SMS, emails, post mails, etc) should be sent to vaccinees before each dose.

2.1.3. CONDUCTING HCF INTERVENTION

- Especially if both screening and vaccination are conducted on same days, patient flow is organized during sessions to minimize disruptions of others care services
- A regular monitoring helps adjusting the intervention and maintaining a constant and manageable flow of participants
 - In case of low participant attendance, there is a risk for the intervention to be unsuccessful. Solutions include increasing social mobilization and communication campaigns, sending reminders to identified target population, working with schools where the screenings were conducted and from where students have low vaccination attendance, etc
 - In the event of overloaded flow and congestion of services, there is a risk of losing participants and affecting other healthcare services provided. Solutions include increasing human resources capacities during identified peak hours, increase inter-

vention rooms capacity, spread patient flow by setting up an intervention appointment system, etc

2.2. School-based interventions

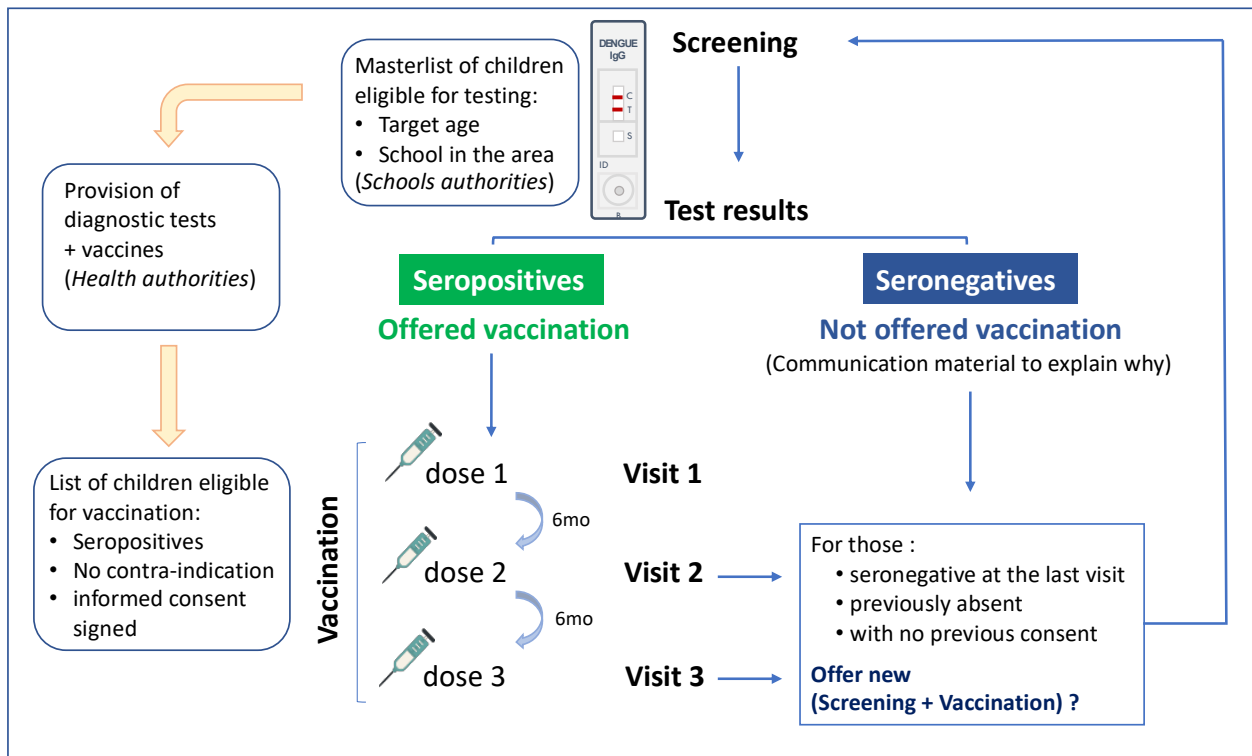
2.2.1. PLANNING SCHOOL-BASED INTERVENTIONS

- School-based health interventions require early joint planning and coordination of activities between the national immunization program and education sectors (public and private), both at national and local levels. Private schools' associations should be closely involved and engaged. Strong advocacy and education should be maintained towards the school staff during the whole intervention.
- Vaccination days for the three doses of Dengvaxia® take place twice a year, 6 months apart, over at least 2 school grades in each participating school. Therefore, scheduling should take into account in advance and as much as possible, school exams, holiday periods, and other planned school activities (special days, festival, elections, etc). Specific school calendars need to be taken into account in the planning of interventions.
- If the S&V program targets a specific age-group, e.g. 9 years old, vaccinees will be age 9 years old at screening and first injection, 9 to 10 years old at second injection, 10 years old at third injection. This may be difficult to implement when children of a same age are found in different grades.
- If the S&V program targets a specific school grade (e.g. grade 4), children of potentially very different ages will receive the intervention.
- Implementation of a Screen and Vaccinate strategy in schools may take different forms. FIGURE 3. summarizes one possibility. An initial screening is organized and those screened seropositives are offered vaccination on the same day. Six and 12 months later the second and third doses are given to the first cohort and during these visits, those previously tested seronegatives could be offered another screen and enter the vaccination program if they have turned positive.



FIGURE 4.

Example of planning a One-step Screen and Vaccinate strategy in schools



2.2.2. PREPARING FOR THE SCHOOL-BASED INTERVENTIONS

- A clear description of roles and responsibilities of both health and education staff should be developed. Teachers and administrative staff may be recruited to assist with session organization, helping with records, and monitoring for adverse events following immunization if vaccination is given in schools. Human resources should include psychosocial workers able to respond to people concerns including anxiety, fear or hostility. Key and popular school leaders should be identified to advocate for the vaccination campaign
- Schools should provide with a list of children and/or adolescents eligible for Dengvaxia® vaccination (routine and catch-up sessions if applies). Based on school census, estimates can be established for the number of diagnostic tests required to screen the target population and the number of vaccine doses, diluents vials, auto disable (AD) syringes, and other materials in the case of a One-step strategy.
- Parental informed consent forms (and children assent, when requested) should be collected beforehand in order to convene only children with a valid consent.
- Screening and vaccination areas should be clearly identified with adequate sign such as “dengue screening room” or “dengue vaccination room”. The area should include a waiting area with chairs and visible IEC materials, a registration space, a screening test table, vaccine preparation and injection tables, a check point, and a recording area.
- Immunization areas should be designed for efficient flow and avoid “bottle necks”, excess crowding, long waiting times, and confusion. This may be helped by establishing designated entry and exit points and one-way flow to prevent backtracking through the crowd following vaccination.
- Material and equipment should be prepared in advance, including ice packs and safety boxes. Vaccines safety should be checked beforehand with labels attached, expiry dates, vaccine vial monitors, and freeze indicators in the refrigerator. Adequate quantity of diluents, syringes and needles should be ensured, and vaccine carrier should be prepared [See Module LOGISTICS].



2.2.3. CONDUCTING SCHOOL-BASED INTERVENTIONS

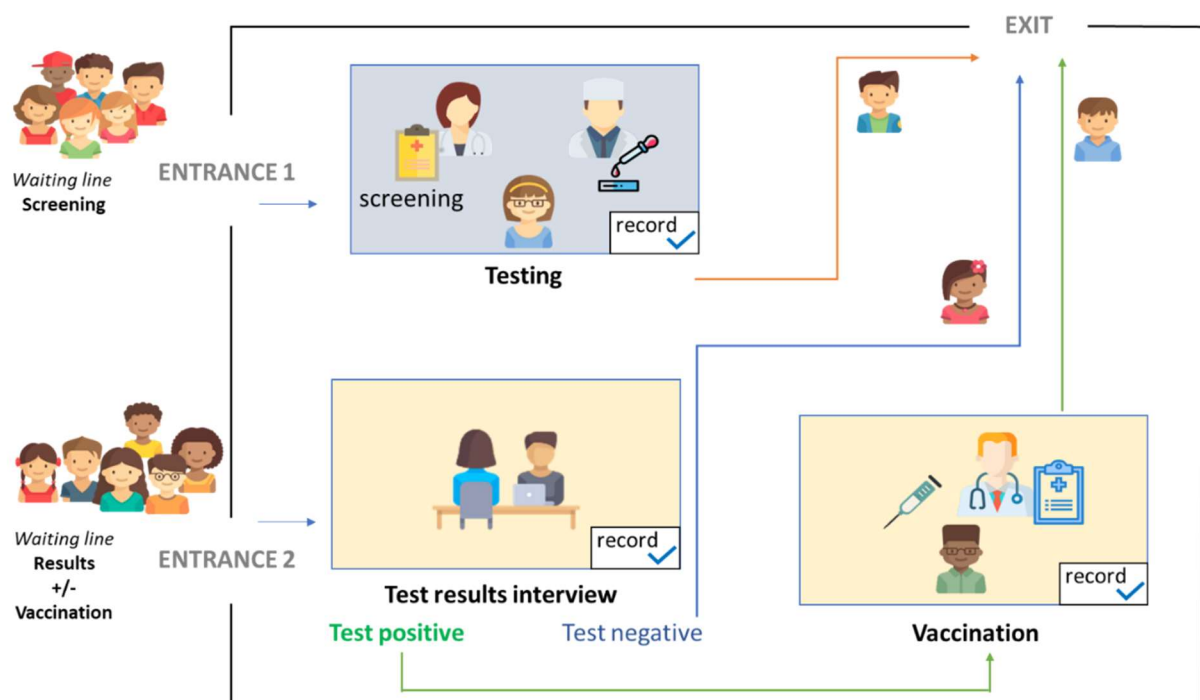
- The Screen and Vaccinate areas should be staffed appropriately. FIGURE 5. gives an example of a S&V setting: one mobiliser helps with the setting up, welcomes participants, screens the children, controls the crowd, gives health advices. Two health staff ensure quality and safe injections, correct storage and handling of the vaccine, monitor any reactions, give health advice to the vaccinees about dengue vaccine and possible side effects, and respond to questions. It is strongly recommended that a member of the vaccination team interacts with children in the waiting lines in order to be available to inform students and offer to dispel any wrong or inappropriate information
- In the screening area, health staff verifies if the adolescent is eligible, based on vaccine contra indications. Vaccination should be postponed in individuals with moderate to severe febrile or acute disease. One teacher or administrative staff can assist in organizing the sessions, helping with recording and Adverse Event Following Immunization (AEFI) monitoring.
- If screening and vaccination are offered on the same day, they should take place at two different times and students should leave their classrooms in small

groups. Flow must be adapted to the time to result period of the RDT used. Once they are called for the test results, children with a negative test should leave the room without entering the vaccination room. They should receive precise information on why they do not receive the vaccine, and the possibility to receive it later if tested positive in the future. Children with a positive test go to the vaccination room.

- If the Two-step S&V strategy is implemented, a first screening and testing session is organized where only the registration & screening, sampling and diagnostic area are set up. Subsequently, the children having test positive results will be invited to attend vaccination sessions at the designated health care facility, on specific days or as a pro-active approach. Vaccination invitation cards and/or text messaging system can be used as proof of seropositivity and reminders for the participants.
- Remaining doses of reconstituted vaccine should be discarded at the end of the immunization session, or within six hours of reconstitution. Immunization waste should be adequately managed: used syringe and needles should be discarded in a safety box together with the empty vaccine vials and brought back to the health facility. Safety boxes should be disposed like other immunization waste [See Module LOGISTICS].

FIGURE 5.

Example of children flow in the school-based strategy





- Management of contraindication:
 - > Contraindication for dengue vaccination should be addressed during individual and private interviews, as it is usually done for other vaccines (see chapter 1.2.).
 - > If there is a doubt on the child condition regarding contraindications, the participant should not be vaccinated.
 - > Vaccinators should be trained to address the issue of pregnancy with adolescent girls.
 - > The list of contraindications should be included in the letter to caregivers.
 - > A child should be able to withdraw his/her participation to the campaign at any time and without justification.

2.3. Community interventions

2.3.1. PLANNING COMMUNITY-BASED INTERVENTIONS

- Once the targeted population is defined, strategies and field activities are planned and coordinated between partners (health authorities, national and local government bodies) and organized with stakeholders and supporters such as community organizations, local social mobilisers, identified “S&V champions”, merchant associations, religious leaders, organizers of sporting or cultural events, etc.
- Whether they implement screening alone or the full S&V, teams need offering the intervention where and when they have the best chance of meeting the target population and delivering a quality service in an appropriate environment. Community surveys may be necessary to understand the daily habits, movements of the target population, possible interfering community events, as well as any behavioral barriers that could impede the intervention.
- Social mobilization and community information campaigns need to be planned in advance. This will include securing devoted human resources including social mobilizers and renowned “champions” trusted by the intervention targets, developing staff training and producing appropriate communication tools such as leaflets, banners, TV and radio spots, social media campaigns, posters, etc.

2.3.2. PREPARING COMMUNITY-BASED INTERVENTIONS

- The dengue screening only or the One-step S&V campaigns can be offered for fixed period of time

in a range of appropriate places in the community, such as schools, colleges, universities, private companies, gymnasium, churches, pharmacies, supermarkets, restaurants and shopping malls.

- Depending on the “where and when” parameters, for the campaign period, mobile S&V teams may need to be available 7 days a week, mornings, days, and evenings.
- Social mobilizers should be deployed to advocate for and inform on the intervention. They should be trained and use appropriate information materials such as leaflets.
- The mobile team should include psychosocial agents to respond to any participant anxiety during the intervention, to monitor for psychological side effects that may arise as a result of the intervention, and any aggressive behavior that may occur on the fringes of the intervention.
- The organization of the S&V out-reach post could be the same as the one described for the school-based strategy (FIGURE 5.). Here again it is essential to organize in advance patient flow and avoid bottlenecks and reverse flows.
- Other community health interventions may be offered during the community intervention to increase attendance and potentialize the intervention (counselling on smoking/alcohol/diet/sport, body mass index measurement, blood pressure, disease prevention, etc).

2.3.3. CONDUCTING COMMUNITY-BASED INTERVENTIONS

- Once participants have their screening test done, they get information on dengue, the dengue vaccine and the S&V intervention while waiting for the test results (see FIGURE 6.).
- If the test result is negative, they are not eligible for vaccination and they should get information on why they cannot be vaccinated, dengue prevention, and future opportunities to get screened to enter the program. It is important that the health care professional do not administer the vaccine without a valid proof of previous dengue infection.
- If the test result is positive, they are eligible for vaccination. Similar information should be given that helps them to take a decision on whether they accept the vaccination or not (informed consent). If an informed consent is signed, a questionnaire should be given to check for contra-indications. If no contraindication is identified, the vaccination can take place on-site in the event of a One-step S&V strategy, or an appointment can be made to get vaccinated in HCF



if a Two-step strategy is implemented. The participant can be either invited to present during specific vaccination days (in the case of vaccination campaigns) or receive a free individual appointment with defined days and hours (routine vaccination).

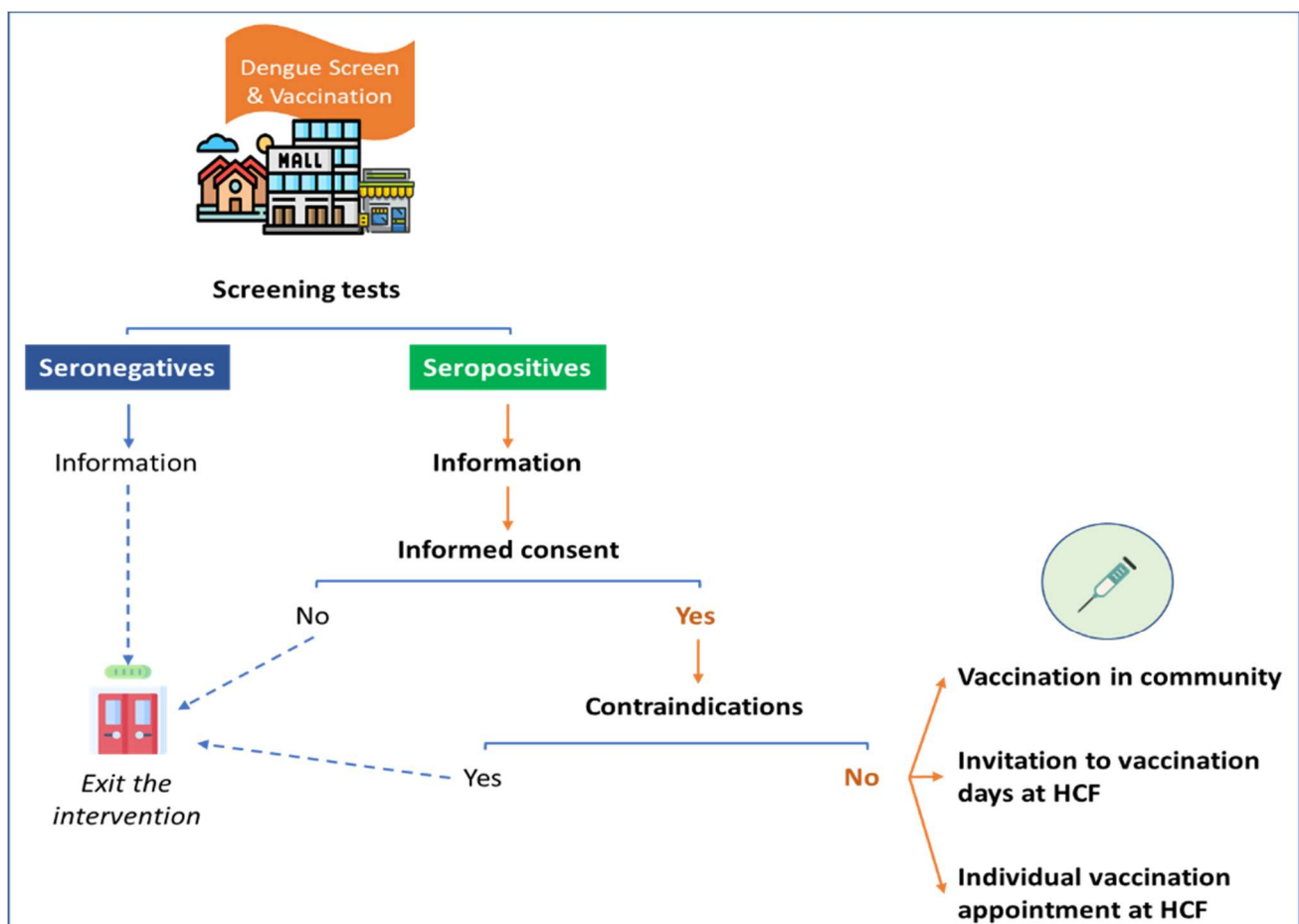
- A regular monitoring ensures a successful intervention and maintain a constant and manageable flow of participants:

- > In case of low attendance, there is a risk for the intervention to be unsuccessful. Solutions include increasing social mobilization and communication campaigns, sending reminders to identify target population

- > If there are too many participants at the same time, congestion can occur, which can prevent a quick, efficient and safe intervention and discourage people from participating. 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.

FIGURE 6.

Example of planning a community-based S&V intervention



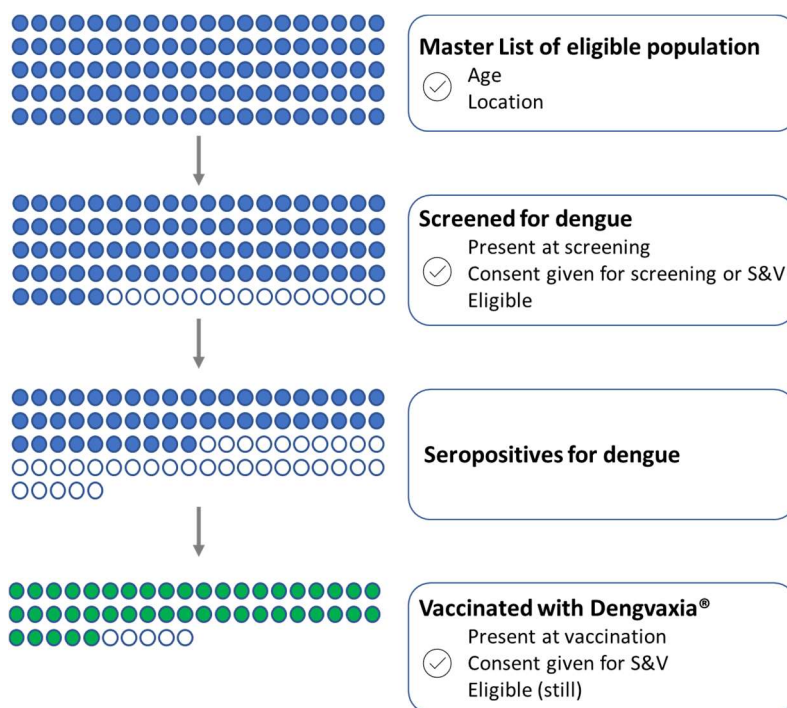


3. DOCUMENTING SEROSTATUS AND VACCINATION STATUS

- Starting from a master list of students or employees, or a population census of the target population, data will be collected at each step (see FIGURE 7).

FIGURE 7.

S&V database: from master list to vaccinated individuals



- Specific data needs to be obtained. At the minimum, this includes:
 - > Before the test:
 - Full name, date of birth, city of residence,
 - Name of school or vaccination center or out-reach post
 - Date of vaccination session
 - Name of staff
 - Previous documented history of dengue
 - Informed consent given: yes/no (if no, record stops here)
 - Presence of contra-indication: yes/no (if yes specify and record stops here)
 - Vaccination against Yellow fever or Japanese encephalitis: yes/no (if yes, vaccination date)
 - Diagnostic of Yellow fever / Chikungunya / Zika / Japanese encephalitis
 - > Screening test:
 - Type of test
 - Lot number of RDT
 - Expiry date
 - > Vaccination:
 - For each dose, verify or repeat steps 1 to 7 (even for dose 1 when a Two-step intervention is given)
 - For each dose, vaccination refused by participant: yes/no (if yes, record stops here)
 - Dose 1: date and lot number
 - Dose 2: date and lot number
 - Dose 3: date and lot number
 - Side effects and AEFIs after each dose (nature; category; date; investigation; etc)
- Until the country EPI documents are updated to include screening and vaccination against dengue, it may be necessary to organize separate records and monitoring tools for the intervention. The reporting systems should be designed in compliance with al-



ready existing systems to avoid additional work burden and confusion among vaccination staff.

- It is of utmost importance to organize efficient and accurate records on the individual results of the screening test. They will serve developing the vaccination master list for those tested seropositive and will also provide valuable data for dengue surveillance; This list of participants with dated history of serostatus will also serve developing a list of seronegatives individual who could be offered new testing at the next vaccination visit. Vaccination registers must include details on individual seropositive test (date, lot number, result) prior to the first dose of the vaccine.
 - Preferably, the data should be entered directly into an electronic application. However, it is recommended to develop and print paper versions of the data collecting forms to remedy any technical problem. Functionality of any electronic application should be verified before each session.
 - Constant monitoring of activities is essential to identify problems and adapt the intervention. In particular, the program should monitor screen test results and vaccine uptake (3 doses) at the individual level, round testing and defaulters to engage targeted actions for both testing and vaccination through information, reminders, and catch-up.
 - Electronic registers should be linked together so that individual data under the same identifier number is available on: serostatus history, vaccination history, AEFI history and disease history. Ideally, the following information should be linked:
 - > Individual serostatus for dengue virus infection
 - > Individual vaccination status (Dengvaxia (dose nb), YFV, JEV)
 - > Individualized dengue surveillance data (clinical, lab-conf, severe, hospitalized)
 - > Individualized pharmacovigilance data (AEFI)
 - Collected data will be used for calculation of dengue seroprevalence, dengue vaccine coverage, wastage and drop out after each round.
 - Specific documents should be developed for the dengue S&V program, and consistently completed. These include:
 - > Monitoring and recording tools: a dengue serostatus register, a dengue vaccination register,
- Screen and Vaccinate cards, a tracking file, reminder cards or electronic systems for reminders and tracking, tally sheets, etc
 - > Summary reporting tools for district, provincial and national levels
 - > Performance monitoring tools, such as immunization monitoring charts
 - > A dengue Screen and Vaccinate field guide
 - > Dengue Adverse Events Following Immunization forms and registers
- If it is national policy to allocate vaccination cards, dengue S&V cards should be designed and distributed to vaccinees during the screening session. The S&V cards should include:
 - > Details on vaccinee (date of birth, name, intervention setting, area of residence)
 - > Date of screening (positive) and date of scheduled vaccination visits
 - > Lot numbers of RDT and vaccines
 - > Hotline number / website address where information is available on dengue, the dengue vaccine and the S&V strategy in the countryThey will systematically be completed during the dengue S&V sessions.
- S&V registers should be kept at a referring health care facility or centralized and brought to each vaccination sessions. Once data are summarized, the information on coverage by age and areas, and vaccine adverse events can be used for recordkeeping purposes, for the assessment of program performance and the implementation of corrective actions.
- The establishment of a robust records system from the first dose implementation, including a defaulter tracking list, will ensure the quality and accuracy of future target group calculations and tracking of participants, ensuring completion of vaccine doses.



4. COMMUNICATION DURING DENGUE S&V SESSIONS

- The Module COMMUNICATION summarizes communication strategies and messages for the dengue Screen & Vaccinate program.
- Considering the novelty of the intervention, coordinated teams and committees including Communication Rapid Response Teams should be set up in advance, as well as systems to track and monitor rumours, issues, AEFI and raising concerns, with a major focus on social media.
- The Screen and Vaccinate session is a contact point where vaccinees and caregivers may get information and advice on dengue vaccination but also dengue transmission and clinical presentation.
- Outside of and during the S&V sessions, key messages may be delivered using a range of channels, materials and tools, such as:
 - > Discussions with health staff, information conference and meetings, information hotlines, etc.
 - > IEC posters in the vaccination session waiting room, health facilities, town halls, and school halls.
 - > IEC flyers
 - > Social media posts, websites blogs, etc
 - > Conventional information media: television, radio, newspapers
- Key messages should include the following ideas (to be adapted depending on the audience):
 - > Dengue is transmitted by mosquitoes, is a growing concern, causes outbreak and there is no specific treatment.
 - > Most infected people (75%) do not develop symptoms; however, they can transmit the disease via mosquito bites.
 - > Dengue virus can strike anyone – regardless of age or socioeconomic status
 - > Children and adults can be infected up to four times because there are four different dengue serotypes
 - > Dengue can be a serious disease, often requiring hospitalization, and may need intensive care; it can occur with any infection but is more common upon second infection with a different serotype,
 - > A vaccine exists that can protect those at greatest risk of severe and hospitalized dengue.
 - > The vaccine is indicated for people aged 9 through 45 or 60 years (depending on country), who have had a past dengue infection.
 - > A past dengue infection should be determined by a documented laboratory confirmed dengue infection or serotesting.
 - > In those who have not had a past dengue infection, there is a small risk that they develop more severe dengue when vaccinated with the dengue vaccine and if subsequently infected by the natural virus. Therefore, they cannot be offered vaccination. However, they can receive new testing in a near future to assess if they have turned seropositive for dengue hence becoming eligible to vaccination.
 - > Even though protection starts from the first dose, the three doses of vaccine, spaced 6 months apart, are necessary to ensure the protective effect of the vaccine.
 - > The vaccine greatly reduces symptomatic dengue of any severity but does not eliminate all disease risk. Therefore, in addition to vaccination, it is essential for the population to continue previous dengue prevention measures (e.g. avoiding mosquito breeding sites and bites), and to seek medical help if fever or other sign of illness develop.
 - > The vaccine is safe, but as with all vaccines, side effects may occur after vaccination, and should be reported immediately to the health services.
 - > It is scientifically proven that the vaccine does not cause dengue disease, and the dengue cases that may arise when vaccinated are generated by the wild-type circulating virus.

5. CHALLENGES

Implementing dengue S&V sessions includes specific challenges related to the novelty and complexity of such an intervention. Among those, the followings can be highlighted:

- **Communication challenge:** [see Module COMMUNICATION]
 - > Only vaccinating those who had a previous infection for dengue is counterintuitive for most participants, so this notion has to be clearly explained before and during sessions



- > When implementing the intervention in the community, the vaccination intervention may trigger hostile reactions in public places. Risk communication plans, rumour tracking and responding system, and trained psychosocial workers are essential for the success of the intervention
- > Clear, accurate and adapted communication messages and strategies should be developed to explain the targeted age group and geography if vaccine distribution is limited for epidemiologic or economic reasons
- > As with any vaccine, vaccination with Dengvaxia® may not protect 100% of vaccinated individuals. It is recommended to continue personal protection measures against mosquito bites after vaccination. This information should be included in training provided to vaccinators and other stakeholders, and clear communication messages should be delivered to the community. The introduction of the dengue vaccine may be an opportunity to reinforce dengue prevention and good health practices.
- > For dengue vaccination consent, EPI personnel should make decisions on the type of agreement or authorization needed; the selected strategy should be in line with the country policy. A separate consent may be needed to perform the dengue diagnostic test. It is a possibility that parents, or participants may agree to the testing, while they disagree on the vaccination. It is the country decision to admit that testing is performed even if authorization to vaccinate is not granted by parental authority.
- **Training challenge:**
 - > All staff involved in the new intervention should be trained, including health and vaccination staff. This is a new intervention and new specific aspects (e.g. vaccine characteristics, S&V strategy, communication challenges, etc) need to be addressed.
 - > Training programmes should ensure that the correct target group is vaccinated.
 - > Regular videoconferencing to discuss implementation learnings may help readjusting the training during refreshing sessions, especially in the early stages of implementation
 - > In a school-based strategy, teachers, school administrators and parents may be useful resource for monitoring, reporting and for the management of AEFI. Standardized national guidelines and training procedures should be available or developed for them.
- **Coordination challenge:**
 - > For school-based strategies, close coordination of efforts between the public education system, the private sector of education, the health systems and municipalities is essential.
- > Planning of activities and responsibilities should be done well in advance and regularly consolidated through joint meetings and workshops before and during the intervention
- **Drop-outs challenge:**
 - > Dengue vaccination requires 3-doses given 6 months apart; completing all 3 doses is essential to achieve maximum protection. As for HPV vaccination, common strategies for the follow up out-of-school children and children who might have missed doses may include directing children/adolescents to the nearest health care facilities, organising catch-up vaccination sessions at schools or administering missing doses at the next scheduled dose. The choice is driven by country specificities and policies (school absenteeism, target coverage levels, available resources, etc.). Having a coverage threshold may help in identifying beneficial follow-up activities.
 - > In the case of school-based vaccination, high drop-outs may be observed between doses, due to children changing of schools. A system for tracking children with incomplete vaccination should be developed.
 - > Should a vaccine dose be delayed for any reason, it is not necessary to restart the course and the next dose in the series should be administered.
- **Challenge of reaching the targets:**
 - > If school-based programs are the main strategy in a region, complementary strategies may be considered for reaching out-of-school children/adolescents, such as exist in mobile population and populations living in remote areas. Some children may be absent on the school vaccination day, which should be addressed in terms of provisions for missed doses, and strategies for catch up.
 - > Catch up visits at the health care facility need to be organized and clearly communicated to the family of a child/adolescent with moderate to severe febrile or acute disease. Tracked records of catch up vaccination must be in place and linked with the school vaccination registers.
 - > Out of school children and children in private schools should be part of the denominator for the vaccination strategies. Private schools have however different agenda and vaccine acceptance compared to public schools. It is important to communicate with the private sector and to align with the dengue vaccination program implemented in the public sector.



- > In the case of school-based vaccination, countries should determine whether birthdate or any other indicators works best for identifying targeted children.
 - Implementing vaccination by age (e.g. 9 years old) may be challenging in countries where birthdates are not recorded and may lead to greater disruption in schools by vaccinating children across multiple grades. However, having a target age group may be easier to present vaccination plans to communities, is aligned with routine EPI and allows for vaccine coverage measurement
 - In a school-based strategy, vaccinating by school grade is logistically easier and has proven to be efficient for HPV vaccination. However, a given classroom may include children of different ages, which could have implications for reporting systems, communication, and evaluation of vaccination coverage.
- > Dengvaxia® is indicated for persons aged 9 years to 45 or 60 years, which is not an usual age group for countries EPI. Immunization programs might need to be adapted to reach all age groups, especially older children, adolescents and young adults. This, in turn can provide an opportunity for additional adolescent health interventions and guidance
- **Screening test challenge:**
 - > An S&V optimized rapid diagnostic test, the OnSite® Dengue IgG RDT, is now available for the identification of individuals who have had a past dengue infection.
 - > Using other rapid diagnostic tests is not recommended as they have been designed to identify acute infection and do not comply to the same TPP. They may lead to:
 - false positive results due to cross reactions with other flaviviruses antibodies. In this case, individual serostatus regarding other circulating flaviviruses and vaccination programs for JE (Japanese encephalitis) and YF (Yellow Fever) must be reported and considered in interpreting screening test results. The date of vaccination against yellow fever (YF) or Japanese encephalitis (JE) should be collected to assess the probability of false positive through cross reaction of vaccine derived antibodies with the dengue serological test component. YF vaccination card should be brought on the S&V day, or access to YF vaccination status should be made available through the national immunization system. If the participant had recently received YF or JE vaccination, the S&V intervention should be postponed for a pre-defined period. Similarly documented previous or current infection with a flavivirus (yellow fever, Japanese encephalitis, St Louis encephalitis, Zika, West Nile) should be reported and possibility of cross reactions with the dengue screening test evaluated.
- **Data challenge:**
 - > It will be important to establish a robust records system during implementation of the first dose for future target group calculations and for tracking subsequent doses.
 - > Data collection may be challenging due to the unusual target population, the need to track multiple doses for each child/adolescent, the possible lack of standardized and harmonized routine vaccination forms, difficulties in accurately recording age, and discrepancies between data collection in different settings (community out-reach posts, public or private schools and health facilities).
 - > Databases usually monitored by different programs must be linked together to ensure proper monitoring of the intervention and analyses of outcomes. This includes laboratory database for dengue individual serostatus, dengue vaccination database including AEFI database, dengue surveillance database including case severity, and ideally YFV and JEV databases. Integration and links between electronic system must be organized before the program is launched.
- **Session organization challenge:**
 - > It is important to evaluate how many teams are required to screen and/or to vaccinate the target population in a given period: e.g. one vaccinator can vaccinate 75 to 100 persons in one day
 - > If a simultaneous test-and-vaccinate strategy is implemented, it is critical to include the time to sampling, time to testing and time-to-result of the test in those calculations. Participants flow and waiting time needs to be carefully organized and monitored. Solutions for adjustments need to be thought in advance to respond to any bottleneck and confusion.
 - > In some settings, schools may be reluctant to adding a school-based intervention, due to work overload, with a multi-dose intervention causing extra-burden on their staff and program disruptions. Strong advocacy and information may be



needed to help those schools understanding the public health value of the intervention and enhanced training and support may be needed to help them organizing sessions.

- **Logistic challenge:**

- > Countries should ensure that they have adequate supply chain capacity at national level and in the targeted dengue endemic areas.

- > Adding testing equipment and procedures to the immunization supply chain requires careful consideration when planning and preparing for the intervention. It will have a strong impact on stocks, and cold chain management, transport, intervention time, staffing and of course, budget.

NOTE: The S&V implementation in the context of the COVID-19 pandemic.

All the interventions and activities described can be conducted in the context of pandemic COVID-19, however, it is essential to strictly comply to prevention measures including: the organization of safe patient flow allowing for physical distancing, wearing masks, frequent hand washing, and isolating individuals with Covid-19 suspicious symptoms.

6. READ MORE

CONTEXT FOR DENGUE VACCINATION

- Sanofi Pasteur update of product label published November 29, 2017, is available at: <http://mediaroom.sanofi.com/sanofi-updates-information-on-dengue-vaccine/>
- Arredondo et al. "Immunogenicity and safety of a tetravalent dengue vaccine and a bivalent HPV vaccine given concomitantly or sequentially in girls aged 9 to 14 years in Mexico". *Vaccine*. 2021 Jun 8;39(25):3388-3396. doi: 10.1016/j.vaccine.2021.04.064. Epub 2021 May 13.
- Santos et al. "Immunogenicity and Safety of a Tetravalent Dengue Vaccine Administered Concomitantly or Sequentially With Tdap Vaccine: Randomized Phase IIIb Trial in Healthy Participants 9-60 Years of Age in the Philippines". *Pediatr Infect Dis J*. 2021 Jun 10. doi: 10.1097/INF.0000000000003220.
- Human medicine European public assessment report (EPAR): Dengvaxia, last updated Jan 21, 2022, available at: <https://www.ema.europa.eu/en/medicines/human/EPAR/dengvaxia>

PLANNING, PREPARATION AND CONDUCT OF DENGUE SCREEN AND VACCINATE SESSIONS

As dengue vaccine is an innovation and the Screen and Vaccinate strategy has never been implemented before, no documents exist on session management. However, many similarities exist between human papillomavirus vaccine delivery and Dengvaxia® delivery, especially in adolescent target group, potential delivery through school immunization programs, and need for multiple doses over a prolonged period. Consequently, a panel of resources are suggested, available at the World Health Organization (WHO), and PATH. In addition, workshops bringing together national and international experts led to the development of recommendations and considerations related to the implementation of the dengue S&V.

- 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. PMID: 34253416. This article summarizes the discussions and outcomes of the Partnership for Dengue Control (PDC) expert meeting held in January 2020 at the Mérieux Foundation, Veyrier du Lac, France.
- The WHO "Vaccine introduction guidelines. Adding a vaccine to a national immunization program: decision and implementation"; WHO, 2005, is a good source of information for new vaccination logistics. This publication is available at: www.who.int/vaccines-documents/
- The WHO multi-modules guide "Immunization in Practice, a Practical Resource Guide for Health Workers" (2004), is available at: <http://www.who.int/immunization/documents/training/en/>



- WHO has developed a “School Vaccination Readiness Assessment Tool” (WHO/IVB/13.02; July 2013), that can be downloaded at www.who.int/vaccines-documents/
- A Uganda publication “Bridging phase for the delivery of human papillomavirus (HPV) vaccine to prevent cervical cancer” provides with detailed information on HPV vaccination session. This publication is available at: [http://www.rho.org/files/rb3/Bridging Phase HPV Vaccine Field Guide Managers Uganda MoH 2010.pdf](http://www.rho.org/files/rb3/Bridging_Phase_HP_Vaccine_Field_Guide_Managers_Uganda_MoH_2010.pdf)

DOCUMENTING SEROSTATUS AND VACCINATION

- The PATH publication “Implementing HPV Vaccination Programs: Practical Experience from PATH”. PATH; 2011 is available online at: www.rho.org/HPV-vaccine-mplementation.htm
- The “HPV Vaccination Monitoring Tool for PATH Demonstration Projects”, is available at: [http://www.rho.org/files/rb3/HPV Vaccination Monitoring Tool PATH 2008.pdf](http://www.rho.org/files/rb3/HPV_Vaccination_Monitoring_Tool_PATH_2008.pdf) contains a comprehensive checklist for HPV vaccination activities and could serve as an example for Dengvaxia® vaccination.
- Similarly, the publication “Sample Vaccination Cards and Registers” from PATH, 2008, provides examples that could be adapted to Dengvaxia® vaccination and is available at: [http://www.rho.org/files/rb3/Sample Vaccination Cards Registers PATH 2008.pdf](http://www.rho.org/files/rb3/Sample_Vaccination_Cards_Registers_PATH_2008.pdf).
- The PAHO Immunization toolkit provides a range of technical resources for vaccine implementation, including organization of immunization programs or cold chain management: <http://www.paho.org/immunization/toolkit/technical-resources.html>

CHALLENGES

- The London School of Hygiene & Tropical Medicine and PATH edited a series of brief highlights findings and key lessons and recommendations. The “HPV Vaccine Lessons Learnt & Recommendations : delivery” and “HPV Vaccine: achievements” are relevant to this factsheet and can be downloaded at: [www.rho.org/files/PATH-LSHTM HPVvacll brief delivery 2015.pdf](http://www.rho.org/files/PATH-LSHTM_HP_Vvacll_brief_delivery_2015.pdf) and at: [www.rho.org/files/PATH-LSHTM HPVvacll brief achievements 2015.pdf](http://www.rho.org/files/PATH-LSHTM_HP_Vvacll_brief_achievements_2015.pdf)

