

**Navigating vaccine introduction:** a guide for decision-makers  
**JAPANESE ENCEPHALITIS (JE)**

Module 4

**HOW SHOULD  
MY COUNTRY  
INTRODUCE JE  
VACCINES?**

**4**



## ABOUT THIS GUIDE

Japanese encephalitis (JE), a viral infection of the brain, is transmitted to humans by mosquitoes. Because these mosquitoes usually live in areas with standing water, such as rice fields, and the pigs and birds that are part of the JE transmission cycle are common in the countryside, people in rural areas are most at risk. It begins like the flu and can progress to a brain infection, killing up to 30 percent of its victims and leaving up to half of its survivors with permanent brain damage such as memory loss, impaired cognition, paralysis, seizures, the inability to speak, and other mental disorders. Providing lifelong care for survivors is a significant financial strain on families and on government health care systems. Although there is no treatment to cure JE, several safe and effective vaccines are available to prevent infection. In areas where JE is recognized as a public health priority, the World Health Organization (WHO) recommends implementing a one-time JE vaccination campaign focused on the at-risk population followed by incorporation of JE vaccine into routine immunization.<sup>1</sup>

The modules in this guide are designed to help country decision-makers understand the evidence around when to consider introducing JE vaccines, the potential benefits, how to incorporate JE vaccines into their country's immunization program, and how to monitor and evaluate the vaccines after introduction. The resources and evidence included focus on JE vaccines that are WHO-prequalified.



### KEY TAKEAWAYS • Module 4

- WHO recommends that JE-endemic countries conduct a one-time JE vaccination campaign in the primary target population and then incorporate JE vaccine into the national immunization program (NIP) as routine immunization.
- Routine immunization with any of the three WHO-prequalified JE vaccines can be done within existing NIP vaccination schedules without requiring additional visits.
- Determining and ordering the right number of vaccine doses and injection supplies is critical to prevent stockouts and wastage.
- Assessing and updating cold chain equipment and personnel, immunization cards, and data recording and reporting forms must be completed for all target areas and age groups before introducing JE vaccine.
- Health worker training is key to ensure proper administration, safety, and dissemination of accurate information about JE vaccination.
- Advocacy, communications, and social mobilization activities improve the reach and impact of JE vaccination programs by building demand and acceptance of JE vaccine from parents, community leaders, and policymakers.

## MODULE

## 4

**How should my country introduce JE vaccines?**

After your country decides which JE vaccine to introduce, the next step is to determine how JE vaccine will be integrated into your national immunization program (NIP). NIP managers need to develop a detailed vaccine introduction plan detailing all the activities and steps required for a successful and sustainable introduction. This module is based on WHO recommendations in *Principles and Considerations for Adding a Vaccine to a National Immunization Program*.<sup>2</sup> It provides guidance on strategies, logistic preparation, and other things that should be considered for JE vaccine introduction.

## Determining a target population for campaigns

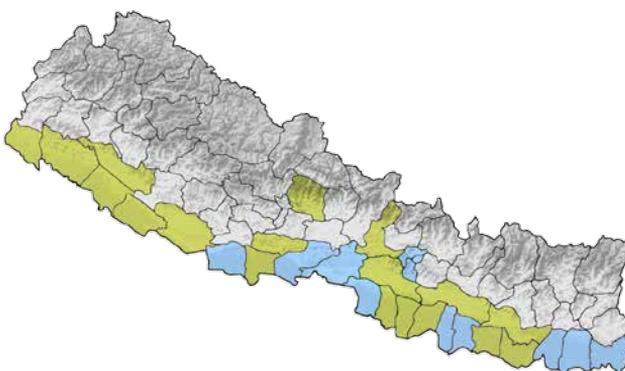
In JE-endemic settings, WHO recommends a one-time “catch-up” campaign in the primary target population followed by incorporation of JE vaccine into the NIP as part of routine immunization.<sup>1</sup> To conduct such campaigns, countries must specify the age groups and geographic locations that make up the target population which will impact the campaign strategy. Vaccination can occur nationally or only in selected areas within the country and can be school-based or community-based. Additionally, campaigns can be phased, adding new areas over time, or started simultaneously in all areas.

The age and location of a target population should be based on the burden of JE in your country (see *Module 1: Does my country need JE vaccine?*).<sup>2</sup> However, there are sometimes other considerations. For example, in Nepal, even though the highest JE rate is still in children less than 15 years old, the Nepal Ministry of Health and Population noted increasing JE rates in persons older than 15 years in some regions. To address this, Nepal conducted campaigns in new districts and allowed limited vaccination of adults (Figure 1).<sup>3</sup>

**FIGURE 1. NEPAL DISTRICTS COVERED IN JE VACCINATION CAMPAIGNS, 2006-2011**

Ages targeted in campaigns

- Whole population above 1 year
- 1-15 years



## Choosing a schedule and immunization strategy for JE vaccination in the NIP

When shifting from campaigns to routine immunization, your country will need to define the optimal JE vaccination schedule. Because routine JE immunization aims to secure early, lifelong protection, WHO recommends JE vaccination to start no earlier than at the youngest age recommended by each vaccine manufacturer:<sup>1</sup>

- 6 months of age for the inactivated Vero cell-derived JEEV vaccine;
- 8 months of age for the live attenuated CD-JEV vaccine; and
- 9 months of age for the live recombinant JE-CV vaccine.

Because many childhood vaccines are administered between 6 and 12 months of age, there are several already-planned clinic visits during which the three WHO-prequalified JE vaccines can be added without requiring an additional visit. No concerns over safety or immunogenicity have been identified for co-administration of any of the WHO-prequalified JE vaccines with other childhood vaccines.<sup>1</sup>

While simultaneous national rollouts will have faster public health impact, some countries choose to introduce in a phased or regional manner due to limited resources, logistical concerns, or disease burden data. In 2005, a large JE outbreak in India's eastern Uttar Pradesh led to a regional introduction of JE vaccines in 11 high-risk districts that has expanded to more states and districts as endemic JE is recognized in new areas.

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## Selecting the vaccine presentation and formulation

By this point in the planning process, your country has already chosen which JE vaccine to introduce (see *Module 3: Which JE vaccine should my country introduce?*). An additional decision is to select the specific presentation and formulation for that vaccine. In some cases, only one presentation and formulation may be available.

All of the WHO-prequalified JE vaccines come in vials. The WHO-prequalified presentation for JEEV is a one-dose vial only; for JE-CV, a four-dose vial only; and for CD-JEV, either a one- or five-dose vial. CD-JEV and JE-CV come in a two-vial set with the live virus in a lyophilized powder in one vial and the diluent to reconstitute the vaccine in the second vial. JEEV comes in a ready-to-use liquid formulation in one vial.

The price per dose should not be the only factor in decision-making. Different presentations and formulations may have different qualities that impact cost and public health benefit. Multi-dose vaccine vials are less expensive to purchase and take up less storage space than single-dose vials but can result in greater wastage. Lyophilized vaccines that must be reconstituted before use, such as CD-JEV and JE-CV, require additional steps before administration. WHO recommends selecting presentations and formulations based on safety, ease of use, vaccine wastage rates, and cold chain requirements.<sup>3</sup>

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## Procuring JE vaccine and injection supplies

Once your country determines which formulation and presentation to use, the next step will be procurement of vaccine and related supplies. A country may assume full ownership and responsibility for procurement. Alternatively, a country may delegate vaccine procurement to agencies such as UNICEF Supply

**FIND OUT MORE****What is pooled procurement?**

Pooled procurement is a method through which countries work together to improve vaccine procurement and NIP performance. It can range from sharing supplier and pricing information to having joint tenders and contracts with producers. When carefully considered and politically supported, pooled procurement can give countries sustainable access to affordable vaccines, achieve greater demand predictability, reduce transaction costs, and reduce the total price paid.<sup>5</sup>

Division. This was the primary method used by Laos and Cambodia to introduce JE vaccine in 2015 and 2016, respectively. A third option would be to collaborate with other countries to build a pooled procurement mechanism.<sup>2,4</sup> When planning for procurement, be mindful of the national regulatory approval processes and timelines, both in your country and the country of manufacture.

No matter which procurement method is chosen, accurately forecasting the needed number of vaccine doses and injection supplies is critical to prevent stockouts and wastage which can compromise the quality of your country's JE vaccination program. Additionally, to ensure matched quantities of vaccine and injection supplies and reduce costs and errors in procurement, WHO recommends procuring product bundles. For help in conducting multi-year forecasts of vaccine and injection supply needs, see the WHO Vaccine Forecasting Tool.<sup>5</sup>

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## Determining vaccine supply chain needs for JE vaccines

Your country's NIPs will also need to estimate, assess, and prepare JE vaccine storage and transportation requirements and current capacity. Requirements for JE vaccines should include cold storage, vaccine transport equipment and personnel, dry storage for syringes and safety boxes, and waste management equipment. The WHO Logistics Forecasting Tool can help NIPs determine the requirements per child.<sup>6</sup>

To assess your country's current cold and dry storage capacity, WHO recommends that NIPs conduct an up-to-date inventory of all equipment and personnel involved in the storage and transport of vaccines and related supplies at all levels of the system.<sup>2</sup> Various tools are available to inventory supply chain capacity, including the Cold Chain Equipment Manager<sup>7</sup> and the Effective Vaccine Management assessment.<sup>8</sup>

By comparing the inventory of storage capacity with the estimated additional needs for JE vaccine introduction, your country can identify gaps in storage and transport capacity that should be addressed before introduction.

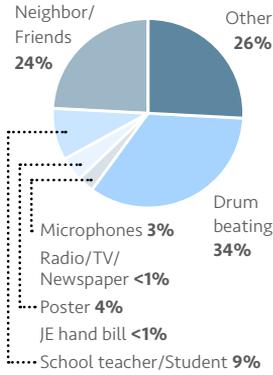
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## Training health personnel on JE vaccines

Training health workers, supervisors, and NIP staff about JE and the new vaccine is important to ensure proper administration and safety as well as dissemination of accurate information. Because two of three WHO-prequalified JE vaccines are reconstituted before administration, their use may present a challenge for health workers. For specific health worker training resources on JE vaccines, see WHO and PATH's CD-JEV Japanese Encephalitis Vaccine Introduction Training Modules for Health Care Workers.<sup>9</sup>

## Advocating for & communicating about JE vaccines

**FIGURE 2. SOURCE OF AWARENESS OF JE CAMPAIGN, MAHARAJGANJ**



A coordinated set of advocacy, communications, and social mobilization activities is a key element of JE vaccine introduction.<sup>2</sup> These are critical to building vaccine demand and acceptance among families, community leaders, and policymakers. During a JE campaign in the Maharajganj district of Uttar Pradesh, India, interviews with caregivers of immunized children revealed that many learned about the campaign from the NIP's information, education, and communications (IEC) materials and activities (Figure 2).

In JE-related communication, your country should emphasize that vaccination is the only effective way to prevent JE.<sup>1</sup> Additionally, if your country has used other JE vaccines in the past, IEC materials should explain why a new vaccine is being introduced and provide guidance for previously vaccinated children or adults. Sensitization meetings with community leaders, medical practitioners, and the media may be a good way to spread these messages.

## Developing a New Vaccine Introduction Plan

The final step in planning JE vaccine introduction is to summarize the strategies and components described in this module into a New Vaccine Introduction (NVI) Plan. The plan should build on broader plans, strategies, and activities, such as the National Immunization Plan, National Health Plan, or Comprehensive Multi-Year Plan. It should include required updates to information systems, such as child immunization or health cards and forms used to record and report vaccinations.<sup>2</sup> Additionally, countries should develop detailed microplans that translate goals and activities from the national strategic plan into ones more relevant for provincial- and district-level campaigns. For help developing and managing your country's plan, see WHO's NVI Checklist and NVI Activity List and Timeline.<sup>10</sup>

## References

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Developing a strategy and detailed plan for the successful and sustainable introduction of JE vaccines into your country's NIP requires many steps and considerations. Fortunately, WHO provides a range of recommendations, guides, tools, and templates to help countries through this process. In order to make evidence-based decisions about the most effective way to introduce JE vaccines, it is recommended to:

1. **Determine a target population for campaigns based on surveillance data, safety, and logistics.** High-quality JE surveillance data specific to your country is not necessary to conduct campaigns.
2. **Choose a schedule and immunization strategy for JE vaccination in the NIP.** Schedules should be chosen based on potential impact, safety, and simplicity.
3. **Select the vaccine presentation and formulation.** Presentation and formulation should be chosen based on safety, ease of use, vaccine wastage rates, and cold chain requirements.
4. **Procure JE vaccine and injection supplies based on supply forecasting.** For assistance in conducting multi-year forecasts of vaccine and injection supply needs, see the WHO Vaccine Forecasting Tool.
5. **Determine vaccine management, cold chain, logistics, and data recording and reporting needs for JE vaccines.** Your country should compare needs with capacity using tools such as the WHO Logistics Forecasting Tool and Cold Chain Equipment Manager. Based on these assessments, additional equipment or cold room expansion may be needed.
6. **Train health personnel on JE vaccines.** Health workers, medical officers, supply chain and logistics managers, and other health personnel need to be properly trained to ensure safe and effective vaccination.
7. **Develop an advocacy and communications plan for JE vaccines.** Your country should be sure to emphasize that vaccination is the only effective way to prevent JE.
8. **Summarize your country's JE vaccine introduction strategies and plans in a New Vaccine Introduction Plan.** Additionally, your country should translate national goals and activities into detailed microplans for provincial- and district-level campaigns. For help in developing and managing your country's plan, see the WHO NVI Checklist and NVI Activity List and Timeline.





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