Navigating vaccine introduction: a guide for decision-makers

JAPANESE ENCEPHALITIS (JE)

Module 6

IS MY COUNTRY'S JE VACCINATION PROGRAM WORKING?

6

PATH

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.[1]

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 6

- The success of a JE vaccination program can be measured by the number of children vaccinated, the overall proportion of eligible children vaccinated, and the subsequent reduction of JE and acute encephalitis syndrome (AES) cases.
- Monitoring and evaluating the success of a vaccination program is a process that should begin with monitoring before vaccination starts.
- Because JE is only one cause of encephalitis, other causes of AES will still be present after JE vaccine is introduced.
- Monitoring and evaluation are important to assess and communicate the health benefits, cost-effectiveness, and efficiency of your country's JE immunization program.

MODULE 6

Is my country's JE vaccination program working?

After your country has introduced JE vaccine, it is important to monitor and evaluate the progress and success of introduction. Monitoring is the systematic and continuous process of collecting and examining data, procedures, and practices. Once this information is collected, evaluation is performed to measure progress, identify problems, develop solutions, and guide policies and interventions. For JE vaccine programs, it is important to focus on the number and proportion of vaccine-eligible children actually immunized, the reduction of JE and AES cases, and a population-based estimate of adverse events following immunization. Through monitoring and evaluation, immunization program managers can improve the quality, safety, and benefits of your country's JE immunization program, maximize program efficiency and cost-effectiveness, and provide evidence of success to policymakers, donors, and the public.[2]

Monitoring coverage of JE vaccine

One primary method to evaluate JE immunization programs is to measure vaccination coverage.[2] Because JE burden is greatest among children, this requires tracking the total number of vaccine-eligible children in an area intended for vaccination (target population) as well as the number of children actually vaccinated by age, by gender, and by location. These data are used to determine the vaccine coverage by age, by gender, and by location. Coverage is often measured using administrative data from immunization registries, vaccination cards, and tally sheets collected at the local level and aggregated regionally and nationally to estimate the actual proportion immunized.[3] In situations where higher-quality vaccine coverage data are critically needed, population-based immunization coverage surveys should be used.

When possible, JE vaccine coverage data should always be reviewed in conjunction with JE disease surveillance data. In Uttar Pradesh, India, following a 2011 introduction campaign, JE surveillance data showed a less-than-expected decline in JE incidence. However, a cross-sectional coverage survey showed that only half of the eligible children had received one dose of JE vaccine.[4] Because the survey included questions about vaccine acceptance and vaccine administration, it was possible to identify factors that contributed to low community acceptance resulting in low vaccine coverage and lower vaccine impact than expected. Information from population-based coverage surveys such as this, which can include questions about community knowledge, attitudes, and practices in addition to coverage, not only result in accurate measures of vaccine coverage but also inform program improvements and future JE vaccination campaigns.

Comparing coverage with other vaccines in your country's Expanded Programme on Immunization (EPI) can identify potential problems with the introduction, such as low community acceptance, local vaccine stockouts, and other program issues needing corrective action.[2] By examining and comparing coverage rates of all EPI vaccines before and after JE vaccine is introduced, your country can identify trends, problems, and opportunities for improvement.[5]

Monitoring impact on JE disease

Conducting JE surveillance before and after vaccine introduction is the best way to measure the impact of JE vaccination programs on disease incidence, morbidity, and mortality.[2,6] A country's ability to measure JE vaccine impact generally depends on having an existing JE disease surveillance system with capacity for laboratory testing (see *Module 1: Does my country need JE vaccine?*). While some disease surveillance is necessary to measure impact, the absence of robust or perfect national surveillance does not have to impede measuring JE vaccine's impact in countries with limited resources. For example, your country could use secondary sources of information such as retrospective medical record reviews.[6]

Additionally, countries can use AES surveillance as a proxy for JE surveillance. WHO recommends that AES surveillance is important to identify all preventable causes of encephalitis and, in the absence of JE laboratory testing, may show JE vaccine impact with some limitations.[1] In Nepal, following the 2006-2009 JE vaccination campaigns, JE incidence was 72 percent lower than before the campaigns began. Additionally, AES incidence was 58 percent lower than before the campaigns began (Figure 1).[11] AES is a commonly reported disease syndrome, so the number of AES cases prevented was three times the number of laboratory-confirmed JE cases prevented. This finding strongly suggests that the JE burden was significantly underreported prior to JE vaccine introduction and that many AES cases were actually JE cases.[11] However, a drop in AES incidence may not always be seen following JE vaccine introduction because a significant proportion of AES cases may be due to agents other than JE virus.

Monitoring the impact of JE vaccination on JE incidence has numerous benefits. Evidence of the overall impact of a JE vaccination program may be critical to maintaining long-term political and financial support for the program. This may be especially true in low-income countries where, once external donor support ends, the country must cover vaccine procurement costs on its own. Disease surveillance can be used to monitor overall performance of the immunization program and identify program weaknesses. Evidence of ongoing JE after vaccine introduction may reveal new or pre-existing weaknesses in vaccine delivery systems, such as compromises in the cold chain or programmatic challenges that reduce coverage (e.g., inadequate microplanning or monitoring of campaigns). Finally, tracking changes in disease epidemiology can identify new at-risk groups, help anticipate future needs, and detect JE outbreaks.[6,13]

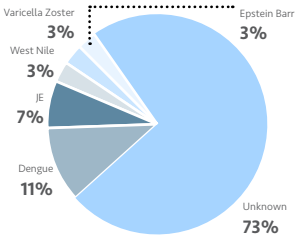
The costs of supporting JE and/or AES surveillance should be considered in the overall costs of the immunization program or another appropriate budget (See *Module 5: Can my country*

FIND OUT MORE

Why does my country still have encephalitis after JE vaccination?

JE virus is the most common vaccine-preventable cause of acute encephalitis syndrome (AES) in Asia. However, because many AES cases are not caused by JE, JE vaccination programs will not eliminate all AES cases. Estimated proportions of AES cases in Southeast Asian countries due to JE virus range from 4 to 37 percent, with countries using JE vaccine having a smaller percentage due to a decrease in JE after introduction.[7–12] Monitoring AES cases and doing laboratory testing to determine the proportion of AES due to JE is the best way to assess JE vaccine impact on JE and AES incidence.

Causes of AES in Colombo, Sri Lanka, 2012-2014 (all ages)[7]



Causes of AES in Uttar Pradesh, India, 2011-2012 (all ages)[8]

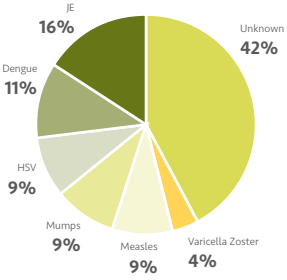
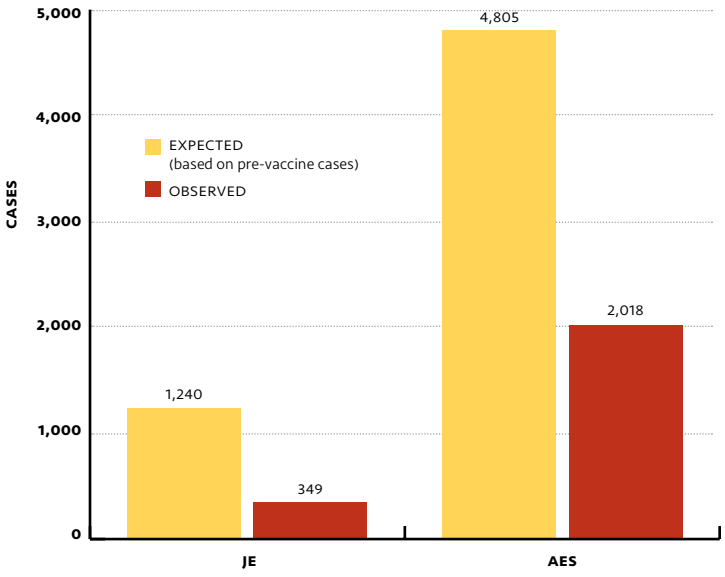


FIGURE 1. EXPECTED VERSUS OBSERVED CASES OF JE AND AES IN NEPAL FOLLOWING VACCINATION[11]



afford JE vaccination?). Once surveillance begins, the system and methods to find suspected JE cases, laboratory diagnostics, and other analyses should remain consistent. Otherwise, changes in surveillance methods could confuse the analysis of the impact of the vaccination program on JE incidence.

Monitoring JE vaccine safety

All WHO-prequalified JE vaccines are considered safe when the vaccine is shipped, stored, handled, and administered in a specified manner (see *Module 3: Which JE vaccine should my country use?*). These requirements should be thoroughly covered during logistics preparations and health worker training and supervision (see *Module 4: How should my country introduce JE vaccines?*). However, it is important for all countries to monitor vaccine safety, including detecting and investigating adverse events following immunization (AEFIs). In addition, safety is assessed during prequalification by reviewing data from clinical trials. Because these trials may not be large enough to capture rare AEFIs, ongoing monitoring of vaccine safety in a much larger population can be very valuable.

AEFIs may cause public concern. Early identification of AEFIs by the government and subsequent investigations may allow detection of problems with shipping, storing, handling, or administering the vaccine—mistakes that can be corrected through further health worker training and supervision.[2,14] Such transparency may inspire confidence in the JE vaccination program as well as other vaccination programs. In contrast, failure to identify such problems may result in suspicion of the national immunization program, reduce public confidence, and lead to low uptake of JE vaccine and other important vaccines.

Assessing program implementation and lessons learned

WHO recommends that all countries conduct post-introduction evaluations (PIEs) 6 to 12 months following new vaccine introductions and has prepared a PIE tool for country use.[15] PIEs use surveillance and monitoring data to provide a comprehensive assessment of the vaccine introduction's impact on the country's immunization program and to rapidly identify problems needing correction. The PIE may improve the overall quality of the JE vaccination program and may also provide valuable lessons for future new vaccine introductions. Additionally, evidence of the impact and success of the program can be shared with donors, policymakers, and the public to further strengthen support for JE immunization.

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RECOMMENDATIONS • Module 6

Planning and decision-making for JE vaccination will continue long after introduction. In order to ensure support for and success of your country's JE immunization program, it is important to:

1. Assess the reach of the program through coverage monitoring. Because the public health impact of JE disease is greatest among children, coverage data should focus on the number of children covered. By considering coverage and JE incidence together, you may identify potential programmatic or epidemiologic issues that necessitate adjustments.

2. Evaluate the public health impact of the program through JE or AES disease monitoring. While laboratory JE diagnostic testing provides the most accurate assessment of JE immunization program impact, AES monitoring may be useful if JE is not specifically monitored. Apart from evaluating the program's health impact, disease monitoring can provide information about potential changes in JE epidemiology and detect JE outbreaks.

3. Monitor the safety of JE vaccine through post-introduction safety monitoring. While all WHO-prequalified vaccines have acceptable safety profiles, post-introduction safety surveillance helps identify rare adverse events and potential handling and administration errors.

4. Use observations from monitoring and surveillance to evaluate and make any needed adjustments. Conducting post-introduction evaluations of JE immunization programs can lead to improvements in the implementation of JE vaccination, strengthen the overall immunization program, and provide valuable lessons for future vaccine introductions. Evidence of the success, cost-effectiveness, and public health impact of the program helps maintain political and financial support as well as the public's confidence in vaccine programs.

MAILING ADDRESS
PO Box 900922
Seattle, WA 98109 USA

STREET ADDRESS
2201 Westlake Avenue, Suite 200
Seattle, WA 98121 USA

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