

Framework for the Initial Use of nOPV2 Under the EUL

This framework will determine the location and method of the initial uses of nOPV2 under the EUL. It has been endorsed by the WHO Strategic Advisory Group of Experts on Immunization (SAGE).¹

Why an Initial Use Period?

WHO Emergency Use Listing (EUL) grants the use of nOPV2 under specific guidance and with requirements for post-deployment monitoring, which will be applicable for the duration that nOPV2 is used under the EUL. This will be important to ensure close monitoring for any unanticipated events so that these can be quickly and effectively addressed to minimize risk and impact on broader immunization activities, including polio.

Essential Criteria for Use under EUL

1. VDPV2 detection (*as per current Standard Operating Procedures*)
2. Capacity to acquire and distribute the vaccine in a timely manner (*e.g. suitable country vaccine approval and import processes*)
3. Capacity to conduct post-deployment surveillance (*in addition to any post-deployment monitoring requirements from EUL*) including:
 - a. AFP surveillance
 - b. Environmental Surveillance (established or the capacity to deploy before use)
 - c. AEFI surveillance (and ability to determine if AEFIs are related to the vaccine)
4. Country capacity to respond to an unanticipated finding
5. A time period of at least 12 weeks from mOPV2 use in the area

Other Considerations for Use under EUL

- A time period of at least 6 weeks from OPV1/3 campaigns in the area
- Understanding of vaccine acceptance amongst the population in the country/area
- Known access or security issues that would prevent adequate coverage

Method for first use under EUL:

- The first uses under EUL should be an outbreak response with nOPV2 alone
- There must be sufficient vaccine to conduct the full required number of rounds with nOPV2 alone

¹ World Health Organization. Weekly Epidem Rec. 29 May 2020; 95(22):241-256 (<https://www.who.int/wer/2020/wer9522/en>, accessed 1 December 2020). Note: the first (April 2020) draft of the framework mentioned that IPV could be considered for outbreak response following two rounds with nOPV2 alone; this was removed following the October 2020 SAGE recommendation that IPV not be used in outbreak response. See: World Health Organization. Highlights from the Meeting of the Strategic Advisory Group of Experts (SAGE) on Immunization 5-7 October 2020 (<https://www.who.int/docs/default-source/immunization/sage/2020/october/highlights-sage-october-2020-meeting-final>, accessed 2 December 2020).