Novel Polio Vaccine For Global Health

DCVMN
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Disease Eradication

Smallpox is the only human disease to be eradicated?

Permanent reduction to zero of the worldwide incidence of infection

How about polio, Can polio be eradicated?

THE POLIOVIRUS SPECTRUM

- Type 1 (endemic in Pakistan, Afghanistan)
- Type 2 (eradicated)
- Type 3 (eradicated)

Wild

Sabin Oral Polio Vaccine related

VAPP

VDPVs

- Overall risk in developing countries: 1 case per 4 – 5 million OPV doses
- Circulating type 2 VDPVs (cVDPV2s) are most prevalent
- Immuno-deficiency related VDPVs (VDPVs) from patients with primary immunodeficiency (PIDs)

VAPP: Vaccine associated acute flaccid paralysis
VDPV: Vaccine derived poliovirus

*As of May 2023 (World Health Organization’s graphics courtesy Laura Cooper, BMGF)
Circulating Vaccine-derived Poliovirus: a Public Health Emergency of International Concern

Interruption of cVDPV2 outbreaks and limiting its international spread remain a major challenge

Overall decline in trend of new emergence (and number of cases, countries infected) in recent past, especially following **wide-scale** use of nOPV2

Novel Oral Polio Vaccine Type 2 (nOPV2)

Modification of Sabin mOPV2

nOPV2 is a next-generation version of the existing cVDPV2 outbreak response vaccine, Sabin mOPV2.

Addresses cVDPV2

nOPV2 has the promise of enhanced genetic stability and has been developed to better address the risk of cVDPV2 and vaccine associated paralytic poliomyelitis (VAPP).

Rolled out under EUL, endorsed by SAGE for use policy

The Emergency Use Listing (EUL) is a regulatory pathway that involves careful and rigorous analysis of available data to enable early, targeted use of unlicensed products for a Public Health Emergency of International Concern (PHEIC) such as polio.

Relevant publication on the nOPV2 Modifications and Source of this photo:
nOPV2 use under EUL

Approx. 675 million doses of nOPV2 administered under EUL authorization to respond to outbreaks in 31 countries

- Field data on nOPV2 demonstrates its **safety, effectiveness** and **enhanced genetic stability**
- No safety concerns, based on review by GACVS and other agencies
- nOPV2 is performing comparably to mOPV2 for field effectiveness in stopping outbreaks: Over 65% of outbreak countries stopped detecting cVDPV2 after ≤2 nOPV2 vaccination campaigns (SIAs)
- Vast majority of isolates analyzed for Whole Genome Sequencing (WGS) indicate no/minimal changes in primary attenuation site of vaccine indicating enhanced genetic stability.
  - Five cVDPV2 emergences have been detected that are derived from nOPV2 in DRC (with detections in Burundi and Zambia), CAR, Nigeria
  - Sabin context: at this scale of use, we would expect ~57 emergences if nOPV2 seeded new emergences at the same rate as Sabin-2. We would expect ~38 of these to be detectable by Q2 2023 (due to surveillance lag)
- **SAGE in March 2023 recommended using** nOPV2 as the preferred option for cVDPV2 outbreak response except under exceptional conditions and called for an increase in nOPV2 supplier base
**nOPV2 readiness update**

56 countries have submitted documents towards confirming readiness for nOPV2 use

- Africa (41 countries)
- Europe (3 countries)
- Middle East (11 countries)
- Asia Pacific (1 country)

Of those, 41 countries are verified to use nOPV2

**AFRO** (31 countries)
- Angola
- Algeria
- Benin
- Botswana
- Burkina Faso
- Cameroon
- CAR
- Chad
- Congo Brazzaville
- Cote d’Ivoire
- DRC
- Ethiopia
- Ghana
- Guinea
- Guinea Bissau
- Kenya
- Liberia
- Malawi
- Mali
- Mauritania
- Mozambique
- Niger
- Nigeria
- Senegal
- Sierra Leone
- South Sudan
- Tanzania
- The Gambia
- Togo
- Uganda
- Zambia

**EURO** (1 country)
- Tajikistan

**EMRO** (8 countries)
- Afghanistan
- Djibouti
- Egypt
- Iran
- Iraq
- Pakistan
- Somalia
- Sudan

**SEARO** (1 country)
- Indonesia

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As of Jan 13, 2023

Tremendous progress has been made since 2011

Bio Farma was able to submit the dossier for full licensure and prequalification March 2023

nOPV2 : Global Supply Commitment

Technology Transfer DS and DP

Donor

Recipient
Conclusion

• The novel polio vaccine makes a significant contribution to the global health
• International collaborations contributed significantly to the development and production of the novel polio vaccine

Acknowledgement
Thank You

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