

Novel Polio Vaccine For Global Health

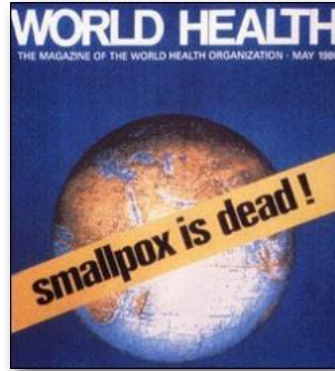
*DCVMN
September 2023*

*Erman Tritama
Senior Matter Expert in the production of nOPVs and other strategic project*

Disease Eradication

Smallpox is the only human disease to be eradicated?

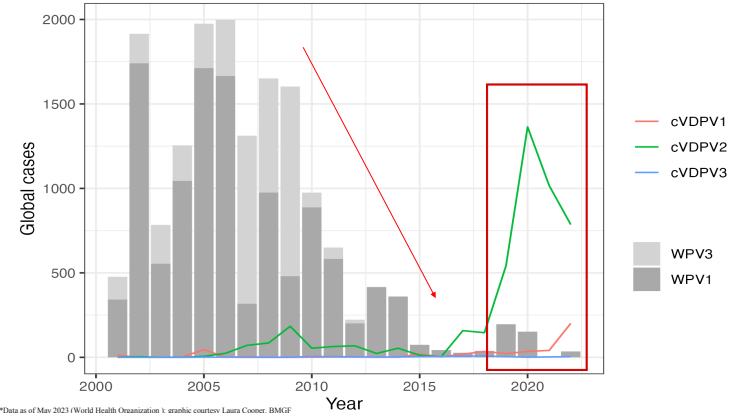
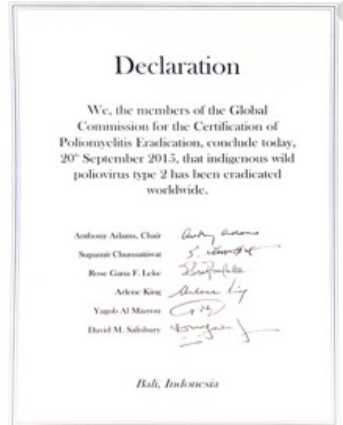
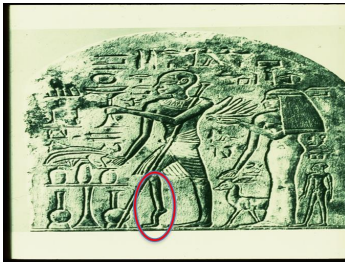
Permanent reduction to zero of
the worldwide incidence of
infection



Cochi SL, Dowdle WR eds., Disease Eradication in the 21st Century, Strungman Forum Reports, MIT Press, 2012, p5

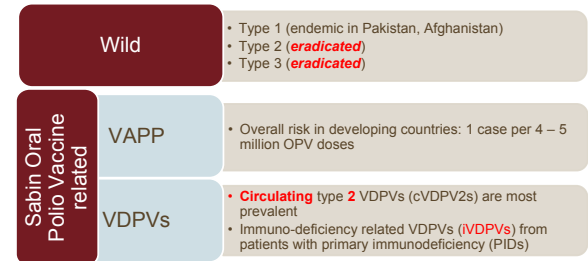


How about polio, Can polio be eradicated?



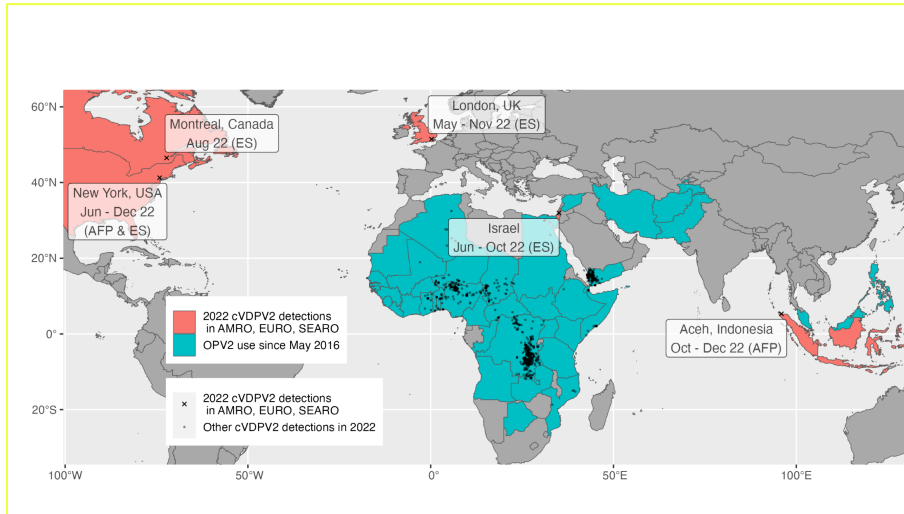
*Data as of May 2021 (World Health Organization); graphic courtesy Laura Cooper, BMGF

THE POLIOVIRUS SPECTRUM

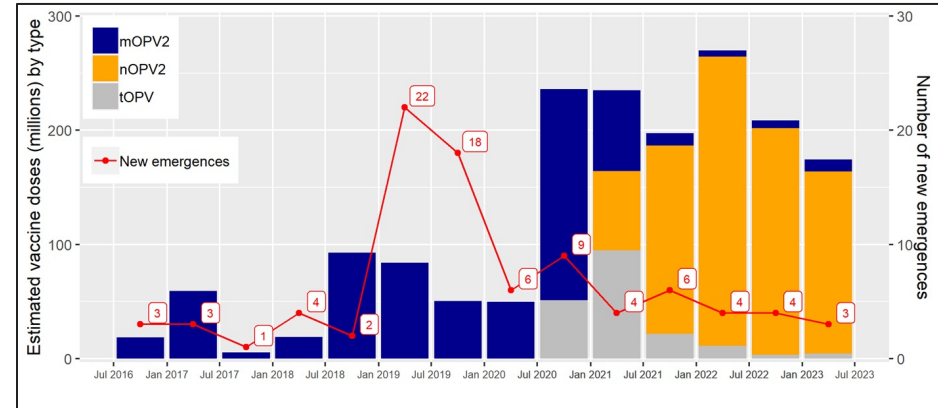


VAPP: Vaccine associated paralytic poliomyelitis
VDPV: Vaccine derived poliovirus

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

Bandyopadhyay A S. *PLOS Global Public Health*. “Why is polio making a “comeback” and what can we do about it?” <https://speakingofmedicine.plos.org/2023/03/17/why-is-polio-making-a-comeback-and-what-can-we-do-about-it/> ; Graphics Courtesy: Laura Cooper, BMGF (includes detections in the **year 2022**)

Novel Oral Polio Vaccine Type 2 (nOPV2)

Modification of Sabin mOPV2

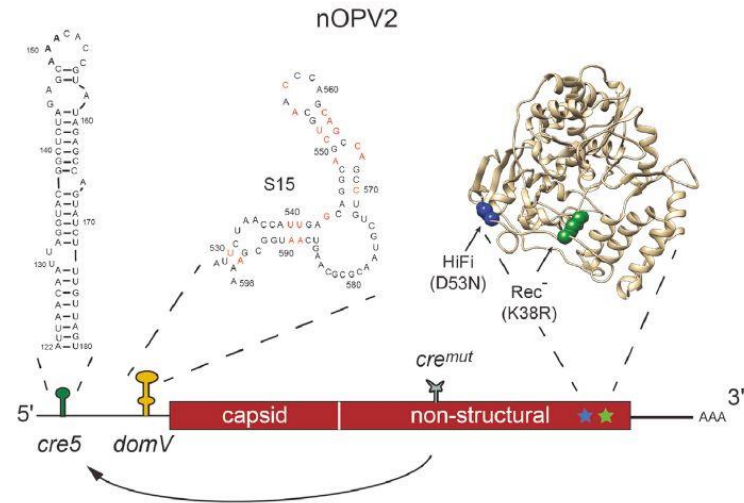
nOPV2 is a **next-generation version** of the existing cVDPV2 **outbreak response** vaccine, Sabin mOPV2.

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:

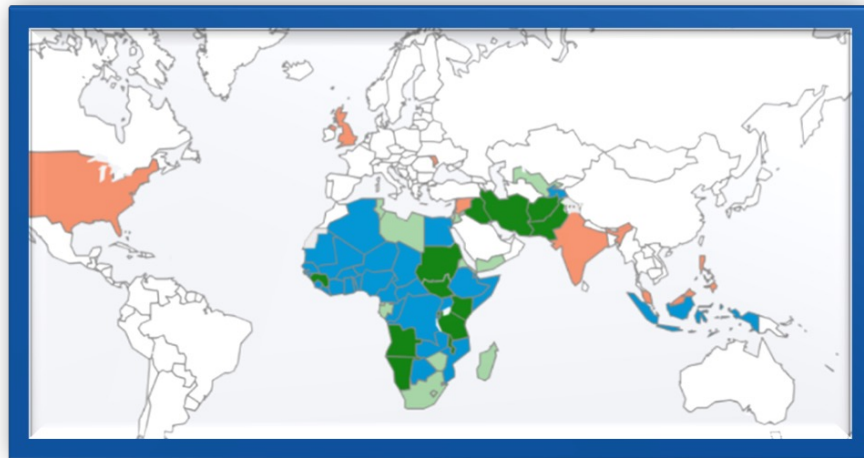
Ming Te Yeh, Erika Bujaki, Patrick T. Dolan, Matthew Smith, Rahnuma Wahid, John Konz, Amy J. Weiner, Ananda S. Bandyopadhyay, Pierre Van Damme, Ilse De Coster, Hilde Revets Andrew Macadam, and Raul Andino.

Engineering the Live-Attenuated Polio Vaccine to Prevent Reversion to Virulence. Cell Host and Microbe. 2020.



nOPV2 use under EUL

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



- Verified and nOPV2 campaigns conducted (31)
- Verified, but have not conducted campaigns (13)
- Verification in progress (19)
- Discussions ongoing (9)

- 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 | • Ethiopia | • Nigeria |
| • Algeria | • Ghana | • Senegal |
| • Benin | • Guinea | • Sierra Leone |
| • Botswana | • Guinea Bissau | • South Sudan |
| • Burkina Faso | • Kenya | • Tanzania |
| • Cameroon | • Liberia | • The Gambia |
| • CAR | • Malawi | • Togo |
| • Chad | • Mali | • Uganda |
| • Congo Brazzaville | • Mauritania | • Zambia |
| • Cote d'Ivoire | • Mozambique | |
| • DRC | • Niger | |

EURO

(1 country)

- Tajikistan

EMRO

(8 countries)

- Afghanistan
- Djibouti
- Egypt
- Iran
- Iraq
- Pakistan
- Somalia
- Sudan

SEARO

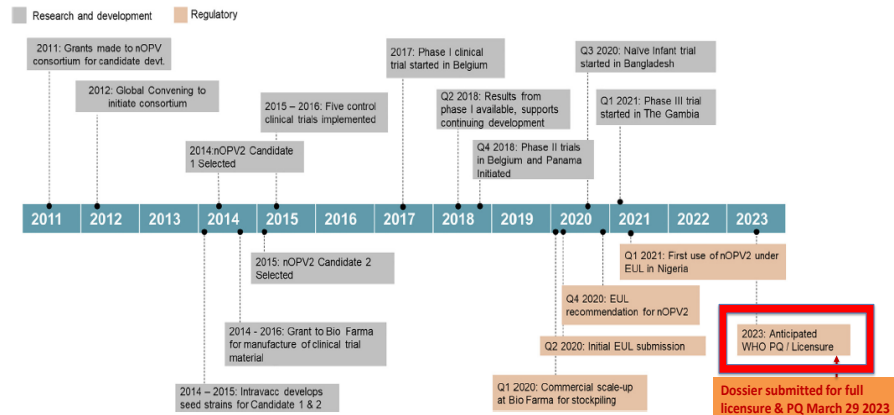
(1 country)

- Indonesia

nOPV2: From Idea Generation to Field Use

Tremendous progress has been made since 2011

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



Macklin, G., Peak, C., Eisenhawer, M., Kurji, F., Mach, O., Konz, J., Gast, C., Bachtiaar, N.S., Bandyopadhyay, A.S., Zipursky, S. and nOPV2 Working Group, 2022. Enabling accelerated vaccine roll-out for Public Health Emergencies of International Concern (PHEICs): Novel Oral Polio Vaccine type 2 (nOPV2) experience. Vaccine.

As of Jan 13, 2023

nOPV2 : Global Supply Commitment

BILL & MELINDA
GATES foundation



Donor



PATH
10::▲○◆//△□○

Technology Transfer DS and DP



Biological E. Limited
Celebrating Life Every Day

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

Acknowledgment

BILL & MELINDA
GATES foundation

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HUMANITY

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World Health
Organization

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