CENTER FOR PREPAREDNESS AND RESPONSE

United States Transfers of Poliovirus Infectious Materials, 2018-2022

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BACKGROUND

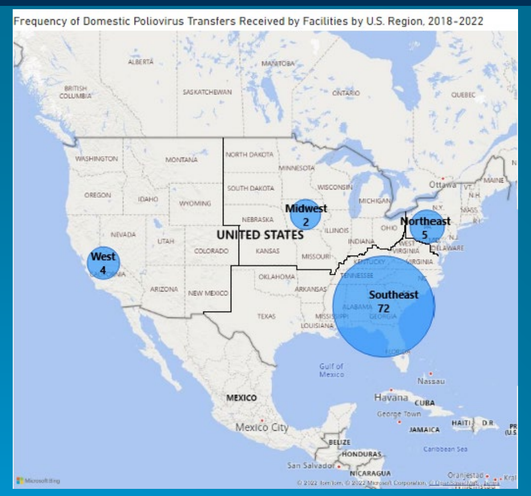
The United States National Authority for the Containment of Poliovirus (NAC), established in 2018, is implementing the World Health Organization (WHO) Global Action Plan IV (GAPIV) at NAC-certified poliovirus-essential facilities (PEFs) to prepare for global poliovirus (PV) final eradication. The NAC Transfer *Policy for U.S. Facilities to Transfer Poliovirus Materials* outlines processes, notifications, and applicable shipping and packaging regulations to ensure safe and secure U.S. transfers of PV infectious materials (IM) requiring GAPIV containment, including wild PV types 2 and 3 and oral polio vaccine (OPV)/Sabin type 2. The U.S. NAC policy also addressed PV potentially infectious materials (PIM). Only U.S. PEFs may possess or receive materials requiring GAPIV containment. As the NAC lacks authority to regulate PV transfers, a partnership with the Import Permit Program (IPP) is essential to ensure U.S. PV importations comply with applicable shipping regulations; IPP does not require import permits for FDA-approved vaccines (i.e., OPV2). Together, the NAC and IPP provide essential oversight of secure PV transfer. For importations, U.S. PEFs submit a request to Import Permit Program (IPP) who, before approval, consults with the NAC to ensure only PEFs receive eradicated material. U.S. PEFs submit a signed NAC GAPIV Poliovirus Transfer Report following the receipt of material. The report includes amounts of each material type received, which the NAC reports in aggregate format as part of the national inventory reported to WHO.

METHODS

Records of transfers occurring between March 2018 and September 2022 were extracted from NAC and IPP databases. Microsoft Power BI (version 2.98.1025.0 32-bit (October 2021)) was used to gather the date of transfer completion or request approval, and to generate figures and maps. Material types transferred include wild PV/vaccine-derived PV (WPV/VDPV), Sabin/OPV, novel OPV, and S19 (attenuated strain exempted from containment). Transfer notifications received by the NAC that have a duplicate IPP request, and requested non-related enteroviruses (e.g., Coxsackie B virus) were excluded. Serotype transfer statistics are based on each serotype included in transfers (n=140) as some transfers included multiple serotypes. No biosafety or security issues were reported with any transfer.

RESULTS

- 97 PV transfers were analyzed (83 domestic, 7 export and 7 import).
- More than half of all transfers, exports, and imports reported to NAC since 2018 occurred in 2022 (Figure 1).
- PV Type 1 was the most frequently transferred serotype (44%), followed by types 2 (29%) and 3 (22%) (Fig. 2A).
- All WVDPV IM types 2 and 3 transferred within and into the U.S. were received by a NAC-approved PEF (data not shown).
- Novel OPV and OPV/Sabin IM constitute 73% of material type transferred since 2018 (Fig. 2B).
- Over 60% of domestic transfers were sent by academic facilities (Fig. 3A) while almost 90% were received by federal government facilities (Fig. 3B).
- Over 50% of domestic transfers were sent by northeast facilities while 85% were received by southeast facilities (Maps).



CONCLUSIONS/FUTURE DIRECTIONS

- **The NAC has established an effective process to monitor and report transfers of PV materials by U.S. facilities.**
- **The number of transfers reported has increased since 2018 as NAC improves U.S. facility outreach and engagement (Fig. 1).**
- **Reduction in reported transfers in 2020 and 2021 is likely due to disruption of PV activities during the COVID-19 pandemic (Fig. 1).**
- **Attenuated PV strains including OPV/Sabin and novel OPV material for characterizing new vaccine candidates represents the majority of transferred material (Fig. 2).**
- **Transfers received by federal government facilities in the Southeast represent 1) material shipped for confirmatory testing and 2) final disposition from facilities no longer working or storing these materials (Maps and Fig. 3).**
- **The NAC is exploring regulatory mechanisms to improve oversight of all PV transfers, including importations not regulated by IPP.**
- **As the world prepares for final PV eradication, the NAC-IPP partnership will work together to strengthen oversight of PV transfers and importations to ensure safe and secure PV transfers to protect public health.**

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FIGURE 1

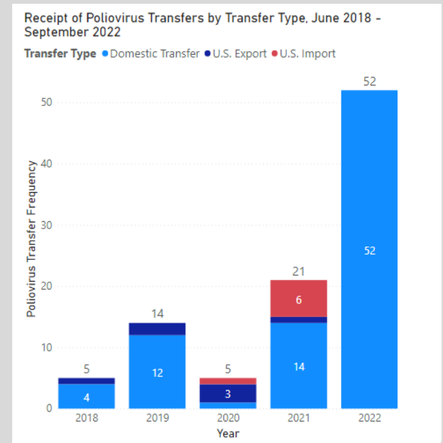

Figure 1. Receipt of Poliovirus transfers by transfer type, June 2018 – September 2022. Number of annual poliovirus domestic transfers, importations, and exportations.

FIGURE 2

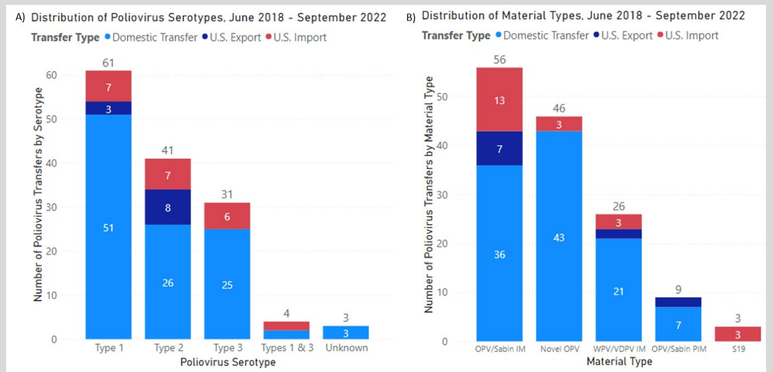

Figure 2. Distribution of Poliovirus Serotypes and Material Types, June 2018 – September 2022. A) Number of transfers, importations, and exportations by serotype. B) Number of transfers, importations, and exportations by material type.

FIGURE 3

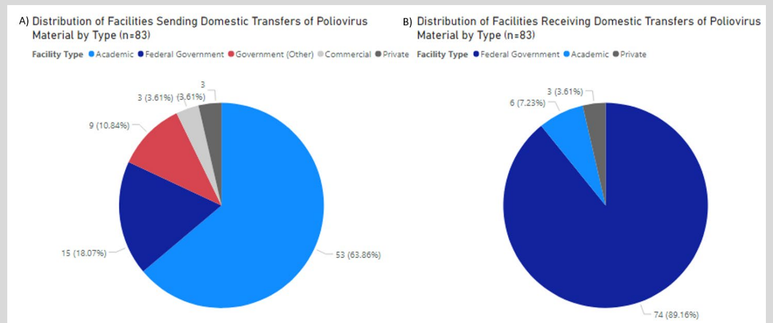

Figure 3. Distribution of Facilities Sending and Receiving Domestic Transfers of Polio Material. A) Number of poliovirus domestic transfers sent by facility type. B) Number of poliovirus domestic transfers received by facility type.

CONTACT INFO

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