Results from a Study Evaluating the Impact of Needle-free Intradermal Delivery of Inactivated Polio Vaccine in Nigeria's Routine Immunization Program

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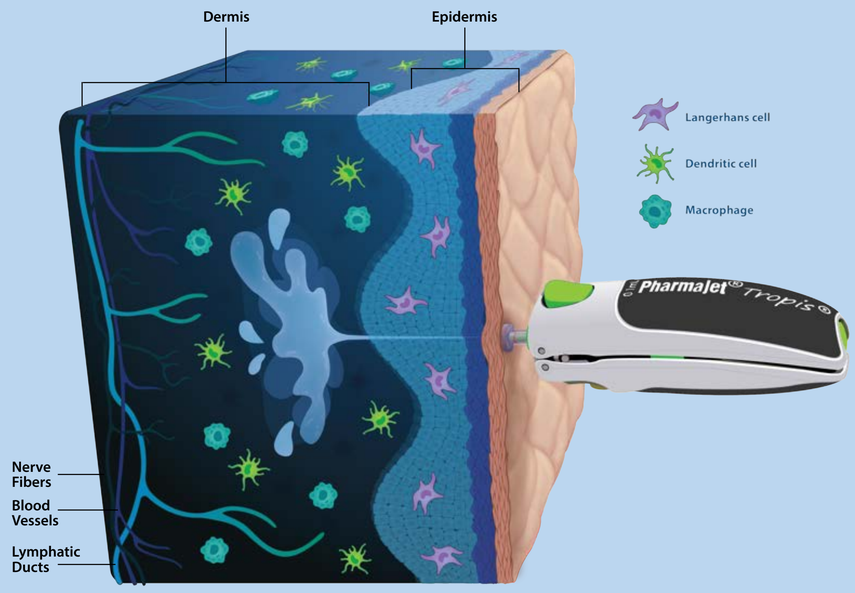
Overview:

Since 2018, intradermal (ID) delivery of fractional dose inactivated polio vaccine (fIPV) has played an important role in polio immunization campaigns in Nigeria, Pakistan, and Somalia by stretching limited vaccine stocks and improving immunization coverage.[1] To assess if these and other benefits, e.g., reduced cost, also apply to routine immunization programs, the study team conducted a cluster-randomized trial in Nigeria to evaluate the impact of ID vaccine administration using the Tropis® ID Needle-free Injection System. In this study, coverage was defined as the proportion of children, aged 14 weeks to 12 months, receiving two doses of IPV.



Benefits of ID delivery compared to intramuscular (IM) delivery

- Durable antibody response[2, 3, 4]
- Mucosal immunity[5]
- Cross-reactive antibodies[2, 5]
- T cell responses[3, 6]

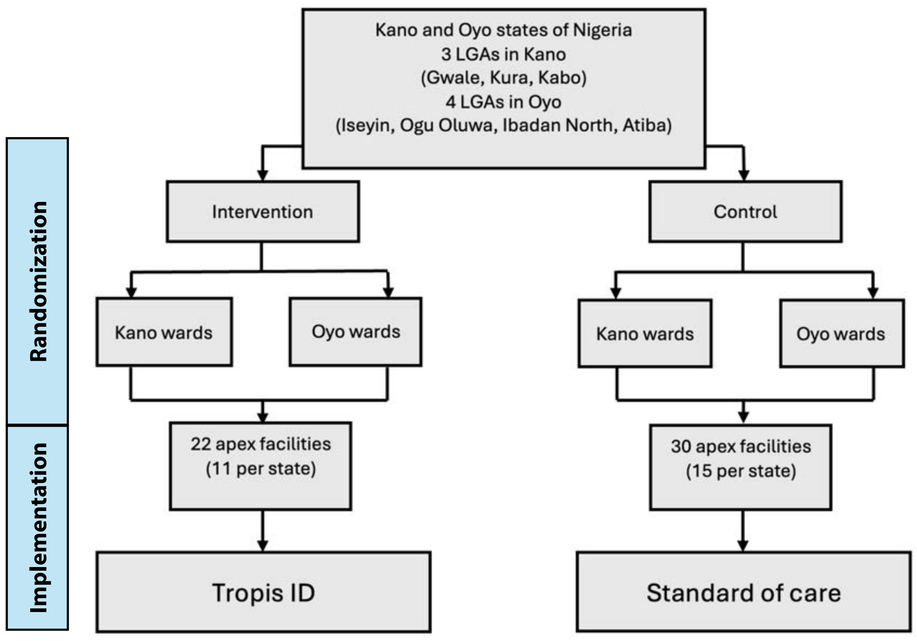
Study Aims:

Aim 1: To estimate the **effectiveness** of Tropis delivery of fIPV (0.1 mL) in improving **second-dose IPV coverage (IPV2)** in routine immunization services as compared to standard-of-care (SoC) vaccination practice (0.5 mL IM injection with traditional needle and syringe (NS)) among children aged less than one year.

Aim 2: To assess the **incremental cost** in regard to the immunization program of using Tropis for fIPV delivery as compared to standard vaccination practice.

Aim 3: To understand the **acceptability and feasibility** of fIPV Tropis delivery in routine immunization.

Study Design:



Cluster-randomized trial

- **Intervention units (Randomization):** 52 Apex facilities (22 intervention, 30 control to optimize resource use and study power). Randomization was stratified by state and urban/rural residence. The apex facility within each ward was the unit of randomization.
- **Intervention:** Tropis used for ID delivery at intervention sites (0.1 mL ID).
- **Control:** SoC delivered with NS (0.5 mL IM).
- **Data collection:** Surveys administered to caregivers of 3,433 eligible children (aged 14 weeks to 12 months) from 97,165 households screened.

Results:

Coverage: Tropis is an effective intervention for increasing coverage of IPV2.[7]

- Among those vaccinated with Tropis, IPV2 coverage was **11.2%** higher compared to the SoC (per-protocol analysis).*
- On a relative basis, the **odds of receiving 2 doses of IPV are doubled when Tropis is used.***

Costs: All intervention scenarios demonstrate cost savings compared to SoC.

- Incremental savings with needle-free could range from $0.07 to $1.00 per dose administered across evaluated scenarios** with **up to 47% total immunization cost savings** compared to SoC.
- Switching to needle-free delivered fIPV could **save the Nigeria immunization program ~$50M USD** over a 5-year period.

Acceptability and Feasibility: Needle-free was highly valued compared with SoC.

- Highly acceptable to caregivers **(94%)**.
- **97%** of healthcare workers **preferred Tropis** to NS for routine immunization, leading reasons included the belief it was **easier to use (95%)** and the perception **children experienced less discomfort or crying (94%).**
- **Non-disruptive:** Tropis reduced administration time by five seconds on average compared to SoC.
- **Zero device malfunctions** (6-month period).
- Tropis was **successfully integrated into routine immunization sessions** where other vaccines were being administered.

**The per-protocol compliance-adjusted treatment estimate was deemed a more relevant analysis than intention-to-treat analysis, because the intervention's theory of change rested on the client's experience of care.*

***The scenarios included assumptions on vaccine wastage rates with assumed incremental wastage rates of fIPV of 20% to 40% over wastage rates of SoC. In addition, the scenarios included varying prices of the Tropis devices and supplies and varying quantities of Tropis devices given to each facility.*

Conclusion:

The study results demonstrate increased IPV2 coverage among those receiving vaccination with Tropis. fIPV delivery with Tropis can also reduce program costs. High acceptability among healthcare workers and caregivers indicates scalability for routine immunization use.

For more info, please contact Paul.LaBarre@PharmaJet.com

1. Daly, C. et al. (2020). Needle-free injectors for mass administration of fractional dose inactivated poliovirus vaccine in Karachi, Pakistan: a survey of caregiver and vaccinator acceptability. Vaccine, 38(8), 1893-1898. 2. Kumar, D. et al. (2025). Cellular immune breadth of an Omicron-specific, self-amplifying monovalent mRNA vaccine booster for COVID-19. NPJ Vaccines 10, 42. 3. Alberer, M. et al. (2017). Safety and immunogenicity of a mRNA rabies vaccine in healthy adults: an open-label, non-randomised, prospective, first-in-human phase 1 clinical trial. Lancet 390, 1511-1520. 4. West, H. C. & Bennett, C. L. (2017) Redefining the Role of Langerhans Cells As Immune Regulators within the Skin. Front Immunol 8, 1941. 5. Hernandez-Franco, J. F. et al. (2023). Intradermal Vaccination against Influenza with a STING-Targeted Nanoparticle Combination Adjuvant Induces Superior Cross-Protective Humoral Immunity in Swine Compared with Intranasal and Intramuscular Immunization. Vaccines (Basel) 11. 6. Peng, S. et al. (2023). Immune responses, therapeutic anti-tumor effects, and tolerability upon therapeutic HPV16/18 E6/E7 DNA vaccination via needle-free biojector. mBio 14, e0212123. 7. Mohan D. et al. (2025). Evaluating the impact of needle-free delivery of inactivated polio vaccine on Nigeria's routine immunization program: an implementation hybrid trial. Vaccines (Basel) 13, 533.

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