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Peer Review

Review of: "A Narrative Review and Perspective on Implementation Research on Intradermal Delivery Methods for Fractionated-Dose Inactivated Poliomyelitis Vaccine"

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The manuscript presents a timely narrative review focusing on implementation research for novel intradermal delivery methods of the fractional dose inactivated polio vaccine. Given the global push for polio eradication and the challenges associated with vaccine supply and costs, exploring alternatives to traditional intramuscular delivery is highly relevant. The authors successfully aggregate 14 implementation studies to compare various needle-free injectors, intradermal needle adapters, and microneedle devices. However, the manuscript requires significant revisions to improve its methodological rigor and to balance its scientific objectivity, particularly given the declared industry sponsorship by PharmaJet. The narrative frequently shifts from an objective academic review to a promotional tone for the Tropis device. The manuscript must be revised to ensure a balanced and critical appraisal of all technologies.

Broad Suggestions for Improvement: The primary concern with this manuscript is the inherent bias in the narrative structure. While the authors transparently declare their funding and affiliations, the discussion section disproportionately highlights the benefits of the Tropis device while minimizing its limitations or the potential of other devices. The authors must revise the manuscript to maintain a neutral academic tone. Secondly, the methodology for the literature search is insufficiently robust for a comprehensive review. Relying solely on a single database restricts the scope of the findings and introduces selection bias. A broader search strategy incorporating multiple databases is necessary. Finally, the manuscript lacks a formal quality assessment or risk of bias evaluation for the included

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studies. Without evaluating the methodological quality of the 14 included publications, the conclusions drawn regarding acceptability, coverage, and time to vaccinate lack a strong evidence base.

Specific Suggestions and Page References: Page 1, Abstract, Conclusion section: The conclusion in the abstract leans heavily into promoting commercially available needle-free intradermal delivery without adequately summarizing the limitations found in the literature. The authors must revise this section to include a balanced summary of the implementation challenges, such as training variations and measurement inconsistencies across studies.

Page 4, Section 2 Methods: The literature search was limited to PubMed using only two search terms. The authors state that reference lists and recommended publications were also used, which introduces subjective selection bias. The authors must expand their search to include Embase, Global Health, and Scopus, and clearly define the Boolean operators used.

Page 5, Figure 1: The flowchart provided does not conform to the standard Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines. Specifically, the step where 24 studies were excluded lacks a detailed breakdown of the exact reasons for exclusion. The authors must update this figure to specify how many studies were excluded for being non-original, preclinical, or lacking implementation research.

Page 9 and Page 10, Section 3 Results: The synthesis of the time to vaccinate and child distress metrics relies on highly heterogeneous and subjective reporting from the primary studies. The authors note that methods for measuring time varied substantially, yet they present the data sequentially without critical synthesis. The authors must add a paragraph critically evaluating how the lack of standardized measurement tools affects the reliability of these specific implementation metrics.

Page 12, Section 4 Discussion: The subsection titled Analysis of the Only WHO Prequalified Needle-Free ID Delivery Technology reads as an advertisement for the sponsor product. The authors must retitle this section to reflect a broader discussion on commercial viability and tone down the promotional language, focusing strictly on the scientific implementation metrics extracted from the literature.

Page 13, Section 4 Discussion: The authors introduce concepts regarding immuno-oncology and vaccines for rabies and mpox. Since these topics were not part of the primary literature search or the results section, their inclusion in the final discussion is inappropriate. The authors must remove these extrapolations or clearly frame them as brief future perspectives separated from the core findings of the polio vaccine review.

Ten Questions for the Authors

How do you justify limiting the primary literature search exclusively to the PubMed database, and how might this limitation have excluded relevant implementation studies from developing nations?

Given the declared sponsorship by PharmaJet, what specific methodological safeguards were implemented during the study selection and data extraction phases to prevent confirmation bias?

Why was a formal risk of bias assessment tool not utilized to evaluate the quality of the 14 included implementation studies?

Since the definition of time to vaccinate varied so widely among the included studies, how can policymakers reliably use this metric to plan campaign logistics?

The review highlights cost savings as a benefit of fractional dose delivery, but did any of the included implementation studies provide a comprehensive health economics evaluation comparing the total procurement and operational costs of the different devices?

How do you account for the fact that the microneedle device was evaluated exclusively in an adult population, whereas the other devices were evaluated in pediatric populations, making direct comparisons of acceptability impossible?

What specific standardized training protocols would you recommend for future campaigns to overcome the 20 percent failure rate in proper bleb formation noted with traditional needle and syringe methods?

In studies where the Tropis device increased campaign coverage, how did the primary authors control for confounding variables such as simultaneous social mobilization efforts or enhanced community engagement?

Why were the ergonomic features of the devices only evaluated in a single study, and how does this lack of data impact the overall conclusions regarding health worker preference?

How do you plan to revise the manuscript to ensure that the discussion section provides a balanced academic critique of all evaluated technologies rather than serving primarily to highlight the sponsor's product?

Declarations

Potential competing interests: No potential competing interests to declare.