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Feasibility of jet injector use during inactivated poliovirus vaccine house-to-house vaccination campaigns

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ABSTRACT

Background: To attain high coverage during polio vaccination campaigns, an outreach house-to-house strategy is used to administer oral poliovirus vaccine. Administering an injectable vaccine house-to-house requires a skilled work force and increases risks of needle stick injuries. Needle-free injection devices provide a safer alternative to needles and syringes for administering injectable vaccines. We evaluated the feasibility and acceptability of a needle-free injection device to administer injectable poliovirus vaccine during a house-to-house vaccination outreach activity.

Methods: Vaccination teams administered injectable poliovirus vaccine using the Pharmajet® needle-free intramuscular jet injector to children ages 6–59 months in 766 homes. Data on the feasibility of using the jet injector in an outreach campaign setting and the acceptability of the jet injector by caregivers and vaccinators were collected.

Results: A total of 993 injections were administered. Vaccinators faced challenges during device preparation in 16% (n = 158) of injections; challenges were related to problems loading the injector and not having a flat surface to use for setup of the injector. Among 32 vaccinators interviewed after the vaccination campaign, the main reported advantage of the device was absence of sharps disposal (91%) while the main reported disadvantage was unacceptability by parents (90%) which was related to the vaccine, not the device.

Conclusions: The needle-free jet injector was feasible for use in house-to-house campaigns. Acceptability by vaccinators was low as 81% stated that the jet injector was not easier to use than needle and syringe. Parental refusal related to frequent polio vaccination campaigns was the biggest challenge. In addition, novelty of the device posed a challenge to teams as they needed to reassure parents about safety of the device. To take full advantage of the ability to take injectable vaccines door-to-door during vaccination campaigns using a needle-free jet injector device, tailored social mobilization efforts are needed ahead of campaigns.

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1. Introduction

The Polio Eradication and Endgame Strategy Plan calls for sequential withdrawal of oral poliovirus vaccine (OPV) beginning with type 2 [1]. The last detected type 2 wild poliovirus (WPV2) was in 1999 from northern India and in September 2015, WPV2 was declared eradicated worldwide. The continued detection of type 2 circulating vaccine-derived poliovirus (cVDPV2) among under-immunized communities led to the decision to switch globally from trivalent OPV (poliovirus serotypes 1, 2 and 3) to bivalent OPV (poliovirus serotypes 1 and 3). Guidelines were developed for the control of potential outbreaks caused by waning immunity to type 2 virus. The Global Polio Eradication Initiative (GPEI) guidelines for outbreak response include the use of both monovalent OPV type 2 (mOPV2) and, in some circumstances, injectable inactivated poliovirus vaccine (IPV) to rapidly boost population immunity and prevent emergence of new cVDPV2 [2]. IPV is generally provided through fixed vaccination posts. In the WPV type 1 endemic countries (Nigeria, Afghanistan and Pakistan) IPV is administered at health facilities during vaccination campaigns to boost immunity

Abbreviations: OPV, oral poliovirus vaccine; mOPV2, monovalent oral poliovirus vaccine type 2; GPEI, Global Polio Eradication Initiative; IPV, injectable poliovirus vaccine; cVDPV, circulating vaccine derived poliovirus; SIA, supplementary vaccination activity; DSJI, Disposable syringe jet injector; MOH, Ministry of Health; SAS, Statistical Analysis Software.

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in high-risk and newly accessible areas. The house-to-house strategy has been the method of choice for administering OPV during vaccination campaigns because it has demonstrated improved vaccination coverage compared to vaccination at health facilities or in other types of fixed posts for vaccination [3]. However, the use of needles and syringes during house-to-house campaigns poses logistical challenges that are not faced in OPV house-to-house campaigns (e.g. the need for experienced health care workers who are trained to give injections, risks associated with handling sharps and the need to transport sharps containers). Therefore, alternative means of IPV administration are needed to facilitate its use during house-to-house campaigns conducted for outbreak response and in high risk areas (e.g. areas with problems such as inaccessibility, insecurity or other issues).

Available needle-free injection technologies offer a safe and efficient alternative to use of needles and syringes for vaccination [4–6]. They have been found to increase the ease and speed of vaccine administration during routine vaccination service delivery and in vaccination campaigns [5] and to eliminate the risks of needlestick injuries and biohazard waste/sharps disposal associated with use of needles and syringes [7]. Previous studies have demonstrated the non-inferiority of immune responses induced by IPV administered via needle and syringe compared with needle-free jet injectors [8–10].

Needle-free jet injectors were evaluated in a measles vaccination campaign among children ages 5–9 years in Cambodia [unpublished results; WHO communication]. The device was documented to be safe and easy to use for house-to-house vaccination and for vaccination in facilities during the campaign. However, the feasibility and acceptability for use in younger children (i.e., aged <5 years)) in house-to-house vaccination campaigns have not been evaluated. We assessed the feasibility and acceptability of needle- free jet injectors for IPV administration using a house-to-house vaccination campaign strategy in selected communities in Lebanon.

2. Materials and methods

Purposive sampling was used to select study areas representative of key criteria including country of origin (high number of Syrian displaced persons vs. a high number of native Lebanese persons), population density (high vs. low), geographic location (border vs. central), and reported vaccination coverage during prior vaccination campaigns (low vs. high). Comparisons by these criteria were not planned or conducted.

Eight vaccination teams worked in 31 localities of three governorates (Bekaa, Baalback-Hermel and North) in Lebanon during December 2016. Teams consisting of two nurses, a physician and a field worker who was knowledgeable about the communities visited every home in their assigned areas and offered vaccination to all children ages 6–59 months in the home. One supervisor was assigned to each team and was responsible for completing the observational checklist, monitoring and documenting adverse events, and responding on-site in case of fainting or any other unexpected adverse event during and immediately after injection. Teams were trained on the use of the disposable syringe jet injector (DSJI) (Pharmjet®) (Fig. 1) using didactic methods and hands-on exercises. Each team was given two DSJI devices in case one malfunctioned. Training was conducted over one and a half days in Lebanon three days before the planned campaign days. Pharmajet provided all the training materials and delivered a portion of the training via live video webinar. Team members were trained on the use of the device on the first day, then on the second day refresher exercises and question and answer sessions were conducted to ensure that all participants were comfortable using the device.

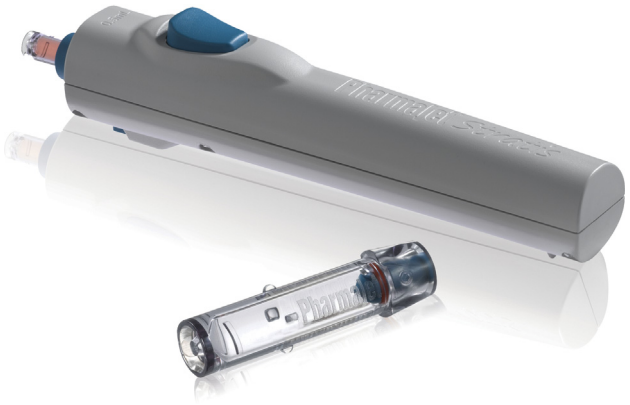

Fig. 1. Pharmajet® Intramuscular needle-free jet injector (Stratis).

Both IPV and OPV were offered to children in the selected households. When a parent provided written consent, IPV was administered intramuscularly using a DSJI The DSJI administered the vaccine intramuscularly without a needle; it was powered by a spring, required no external energy, and the waste generated was the plastic single use needle-free syringe and filling adaptor. Parents of participants were given the contact information of the supervising physician to report any adverse events. Outcomes related to acceptability included adverse events associated with DSJI use, pain/crying post injection, and preference of caregivers and vaccinators for use of DSJI vs. needle and syringe.

Feasibility outcomes included factors affecting ease of use of the DSJI device in field settings. Data on acceptability of the DSJI by caregivers and vaccinators were collected using observational checklists and questionnaires. Vaccinators were asked about acceptability after training but before using the device in the field and after using the device in the field during the vaccination campaign. Observational checklists and questionnaires for collection of acceptability data were administered to vaccinators and caregivers by members of the team from Connecting Research to Development (CRD) and by regional vaccination focal points from Ministry of Health. Focus group discussions to collect qualitative data on acceptability were conducted with vaccinators and supervisors after the campaign and were led by a member of the research team from CRD.

This study was approved by the institutional review board at Sagesse University. CDC deemed this study as research with reliance on local IRB at Sagesse University. SAS© (Version 9.4, SAS Institute Inc.) was used to perform descriptive analyses of variables related to the feasibility of use of DSJI in house-to-house campaigns and variables related to acceptability (experiences and perceptions of DSJI use by recipients, caregivers and vaccinators).

3. Results

Of 1628 homes approached for participation in the study, caregivers in 766 homes provided consent (47%). Reasons for refusal for the 862 caregivers declining participation included because their child had already received several doses of poliovirus vaccine (n = 592, 69%); fear of pain from injection (n = 122; 14%); fear of adverse events (n = 65; 8%); unfamiliarity with injection device (n = 60; 7%); ill child (n = 14; 2%) and concern that child would not be vaccinated properly with the device (n = 8; 1%). Possible interventions that could have changed their mind about participation among those who refused to participate included nothing (n = 635; 74%); information on safety and a description of what the injection feels like (n = 115; 13%)) watching other children receive vaccination from the device (n = 105; 12%), and

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