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

Noha H. Farag<sup>a,\*</sup>, Ziad Mansour<sup>b</sup>, Lina Torossian<sup>b</sup>, Racha Said<sup>b</sup>, Cynthia J. Snider<sup>a</sup>, Derek Ehrhardt<sup>a</sup>

<sup>a</sup>Polio Eradication Branch, Global Immunization Division, Center for Global Health, Centers for Disease Control and Prevention, Atlanta, GA, USA

<sup>b</sup>Connecting Research to Development, Beirut Lebanon

### 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<sup>®</sup> 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.

\*Corresponding author at: Global Immunization Division, Centers for Disease Control and Prevention, 1600 Clifton Rd NE, Atlanta, GA 30333, USA. nfarag@cdc.gov (N.H. Farag).

Conflict of interest

The authors have no conflict of interest.

## Keywords

Needle-free injection; Injectable vaccine; Polio; Supplementary vaccination activities; Vaccination campaigns

## 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 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 needle-stick 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.

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 information on how well the injection works (effectiveness of immune response induced) (n = 31; 4%). All 862 caregivers who refused participation in the DSJI study also refused OPV vaccine.

Among the 766 participating homes, a total of 993 injections were administered to children ages 6–59 months (median = 29 months); 496 (50%) of vaccinated children were female. Of the 766 homes with children enrolled in this study, 551 (72%) had one child, 197 (26%) had two children and 18 (3%) had three children. Caregivers were majority female (98%), ages 15–49 years (median age = 29 years).

Thirty-two vaccinators were trained on the use of the DSJI device; 26 (81%) were female. Experience of vaccinators in the field of vaccination ranged from 2 to 20 years (median = 6.5 years). Of the 16 (50%) vaccinators, who experienced a needle stick injury previously; 10 (32%) had 2 needle sticks. None of the vaccinators had used a needle-free device before this study.

#### 3.1. Feasibility

During the campaign, the time needed for an injection (from opening the vaccine vial to disposing of the syringe) was 2.5–14 min (median = 5 min). There was no trend for increasing or decreasing time to give injections over the course of the day/days for each team. Vaccinators faced obstacles during the preparation of the DSJI device for 158 (16%) injections; 126 (80%) of these had challenges related to loading the device and 60 (40%) faced the problem of not having a flat surface to use for setup of the device. Injections took longer to administer; mean = 8.3 (95% CI: 8.0–8.6) minutes, when obstacles were reported compared to 5.2 (95% CI: 5.2–5.4) minutes when there were no obstacles. No issues were identified related to malfunctioning of any of the 16 devices used during the study.

### 3.2. Acceptability among caregivers

Of the 766 caregivers who consented, 349 (46%) liked the DSII device injector; reasons for liking it included, 287 (82%) because it was safe with no sharps, 93 (26%) because the child did not cry and 39 (11%) because it was quick to administer. Among caregivers, 303 (40%) would recommend the device to friends and family and would prefer the use of the injector over needle and syringe for future vaccinations and 5% “may recommend it” and “may prefer it” over needle and syringe.

### 3.3. Acceptability among vaccinators

Following the training but before the campaign 31 (97%) of the 32 vaccinators liked using the device and said injection with the device was safer for healthcare professionals, 30 (94%) found the device simple to use, 26 (81%) said injection was safer for the recipient, 11 (34%) said it would be easy to use during a house-to-house vaccination campaign, and 20 (63%) would recommend the use of the device to colleagues. After the campaign, 2 (6%) of vaccinators liked using the device; 26 (81%) said that compared to needle and syringe, the device was not easier to use during vaccination campaigns and 25 (78%) would not like the device to be used in future vaccination campaigns.

In the post-campaign interviews of 32 vaccinators, 29 (91%) noted that the main advantage of the device was the absence of sharps disposal; The main disadvantages were unacceptability by parents, cited by 28 (90%) vaccinators (unacceptability was related to the vaccine, not the device); loud noise made by the device and children’s reactions to the device, both cited by 22 (71%) of vaccinators. All the vaccinators said that the device did not hurt the hand/wrist and 31 (98%) said it was not difficult to use. 28 (87%) vaccinators said the training they received prior to the campaign prepared them moderately well and 26 (80%) said that the biggest challenge that they faced during the campaign for which they were not trained was social mobilization related to the device and vaccine among caregivers.

An overarching theme that arose during focus group discussions with vaccinators was that the use of the device was more cumbersome compared to needle and syringe (i.e., took more time to obtain informed consent and convince the caregiver to have the child receive the injection). Introduction of a new technology in a house-to-house campaign setting was seen as challenging by all vaccination team members and some members suggested that if a different vaccine had been offered other than IPV, acceptability by parents might have been higher. All team members agreed that social mobilization, including a media campaign to explain the usefulness and safety profile of the device, before a vaccination campaign would be the most optimal way of addressing concerns about the device and increasing acceptability among caregivers.

### 3.4. Reactions and adverse events among children

Of the 993 children, 178 (18%) did not cry at all, 412 (41%) cried before the injection was given and 403 (41%) cried during the injection. There was no difference in the prevalence of crying in households with one child (20%), two children (16%) and three children (17%). Vaccine fluid was present on the skin after 19 (2%) injections and a drop of blood was present at the injection site after 11 (1%) injections.

## 4. Discussion

The findings of this study indicate that use of the DSJI device was feasible to administer IPV in house-to-house campaigns. There were minimal technical issues (e.g., difficulty in filling the syringe even in absence of a flat surface) with the device despite its use in challenging field settings. In addition, vaccinations were injected properly with no reported adverse events after nominal training. However, we found that there was mixed acceptance of the DSJI device by the vaccinators and caregivers. During the training session for vaccinators, the DSJI device was well received by vaccinators; vaccinator opinions changed after challenges were faced during deployment of the device in the house-to-house campaign. After the campaign, 81% of vaccinators stated that the jet injector was not easier to use than needle and syringe and 78% felt it should not be used in future campaigns.

Parental refusal was the biggest limitation noted by vaccination teams, which was related to children receiving multiple polio vaccine doses in vaccination campaigns conducted during 2013–2016 in response to the polio outbreak in Syria and Iraq. All parents who refused participation in the study also refused to give their children OPV which was offered in the vaccination campaign. In addition, the novelty of the device posed a challenge to vaccination teams as they needed to spend a considerable amount of time reassuring parents about the safety of the device. To take full advantage of the ability to take vaccines door-to-door during campaigns using a device that is free of risk of sharps and does not need a highly skilled vaccinator, considerable social mobilization and educational efforts are needed to familiarize the community with the technology. In addition, training of the vaccinators should include effective communication and messaging strategies describing the device, its usefulness and safety profile. In this study, no social mobilization efforts were conducted ahead of the campaign to examine the acceptability of the technology in the absence of such interventions.

The DSJI used in this study was reported to be well accepted by vaccinators and caregivers during a measles vaccination campaign in Cambodia (unpublished WHO communication). The study in Cambodia used measles vaccine in an older age group (5–9 years) and children were able to watch others get vaccinated as vaccinations were given in a variety of locations including outside the homes in fixed posts and on boats. Our study was conducted in younger children (<5 years), all vaccinations took place inside the homes and poliovirus vaccines were offered in a setting where children had already received multiple polio vaccine doses. In addition, the findings of this study may not be representative of the entire population of Lebanon as sampling was purposive in nature. However, given that this assessment simulated a house-to-house immunization campaign, random sampling was not possible as vaccinators needed to go door to door to find and vaccinate children in the age range of the campaign. To obtain a sample that represents different population characteristics in Lebanon, we selected from areas having high number of Syrian displaced persons and areas with high number of native Lebanese persons, areas with high and others with low population density, border and central areas, and areas with high and others with low reported vaccination coverage during prior vaccination campaigns.



A sizable portion of the population in Lebanon receives vaccines through the private sector and only accept vaccines given by their private physician and refuse vaccine given through a campaign. A limitation of this study is that we could not effectively discern issues related to acceptance of the device from those of the injectable vaccine being used. The mixed acceptance by vaccinators was almost entirely related to the efforts they needed to exert to explain the injection process using the jet injector. Another limitation concerning feasibility was that vaccinators were already experienced in administering intramuscular injections using needle and syringe. Given the global shortage of IPV, WHO recommends dose sparing through the use of fractional IPV (fIPV) [11]. One of the constraints of using fIPV is the need for highly skilled vaccinators that are capable of performing quality intradermal injections. An intradermal DSJI makes intradermal injections easier and aids in ensuring injection quality. At the time of this study, the intradermal DSJI device was not yet prequalified by WHO, therefore we used the intramuscular DSJI. However, the intradermal DSJI is actually lighter and ergonomically easier to use than the intramuscular DSJI so any success seen with the intramuscular version can only be better with the intradermal DSJI.

To our knowledge this is the first field evaluation of needle-free injectors in which information on participation (the number approached vs. those who consented to participation) was collected. Finally, we collected information on proper administration of the injection as indicated by wetness and/or blood at the injection site. We found that only 2% of injections had any wetness and 1% had blood at the site of injection indicating that after minimal training and difficulties with administration, vaccinators were able to properly administer injections.

## 5. Conclusions

This study showed that jet injectors are feasible for intramuscular administration of vaccines in house to house campaigns. However, there was mixed acceptance of the device by vaccinators and caregivers. Further evaluation is needed in a setting where there have not been recent polio vaccination campaigns. Future evaluations of this technology must address two important issues: (1) include social mobilization and educational efforts ahead of the vaccination campaign; and (2) discern issues related to the vaccine vs. the device.

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## Abbreviations:

<b>OPV</b>	oral poliovirus vaccine
<b>mOPV2</b>	monovalent oral poliovirus vaccine type 2
<b>GPEI</b>	Global Polio Eradication Initiative

<b>IPV</b>	injectable poliovirus vaccine
<b>cVDPV</b>	circulating vaccine derived poliovirus
<b>SIA</b>	supplementary vaccination activity
<b>DSJI</b>	Disposable syringe jet injector
<b>MOH</b>	Ministry of Health
<b>SAS</b>	Statistical Analysis Software

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