



Oral cholera vaccination strategy: Self-administration of the second dose in urban Dhaka, Bangladesh



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ABSTRACT

Cholera remains a major public health problem in many developing countries including Bangladesh. The oral cholera vaccine (OCV) is now considered a key component of the public health response to cholera. Although maintaining cold chain and organizing human resource are the major challenges of vaccine delivery to the community. Here we applied an innovative approach to second dose OCV delivery to minimize financial and logistic burdens. The purpose of this study was to assess the feasibility and compliance of second dose self-administration when the second dose was provided in a plastic bag to first dose vaccine recipients as OCV is stable for up to 42 days at ambient temperatures. We aimed to deploy vaccines (N = 112,000) left over from other studies to 56,000 people aged \geq one year living in Mirpur, Dhaka to see the feasibility of self-administration strategy. During vaccination, the first OCV dose (OCV1) was given from fixed sites and the second dose (OCV2) was provided in a plastic zip-lock bag for the participant to take the vaccine two weeks later at home. Participants were instructed to keep the vaccine away from light and in a dry cool place. Empty vials were collected following the end date of the scheduled second vaccination. Of the targeted population, 41,694 (74%) received the first OCV dose whereas an estimated 38,852 (93% of those receiving the first dose) received the second dose which represents a 7% drop out rate from OCV1 to OCV2. However the average two dose coverage was 69%. A survey of a subsample 2990 (from 8551) randomly selected households revealed that almost all respondents (98.75%) appreciated this new self-administration strategy and considered the strategy to be more practical and convenient than the usual method. This simplified, self-administered delivery strategy provides an ideal alternative for second-dose OCV delivery in hard-to-reach populations and resource-poor settings.

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1. Background

Cholera remains a major public health problem in Bangladesh, with seasonal outbreaks occurring every year. Globally, 1.3 billion people are at risk of cholera, with an estimated 2.9 million cholera cases each year and 95,000 deaths in 69 endemic countries per annum [1]. Due to poor hygiene, limited access to sanitation and inadequate safe drinking water supplies, and overcrowding due to rapid urbanization, cholera outbreaks frequently occur. Cholera cases have especially increased in urban settings, not least in Dhaka, Bangladesh, where many patients are admitted to the International Centre for Diarrheal Disease Research, Bangladesh (icddr, b) facilities [2]. On an average, 400–500 patients per day admitted to icddr,b and the number has been increase during peaks [3].

Provision of safe water and food, adequate sanitation, and personal and community hygiene are the main public health interventions against cholera. In addition, the oral cholera vaccine (OCV) is a newer preventative tool to control and prevent cholera [4]. According to the World Health Organization (WHO), vaccines should complement other cholera prevention and control strategies, especially in high-risk areas [5]. Moreover, it has been shown that a WHO-prequalified cholera vaccine provides 65% protection for 3–5 years [6,7] and that large-scale vaccination campaigns are feasible and acceptable with high coverage in both urban and rural settings [8–12].

The usual recommended OCV (Shanchol) schedule is two doses at least 14 days apart in a maintained cold chain (at 2–8 °C), the main challenges being maintaining the cold chain and having adequate human resources for vaccine delivery [12,13]. Earlier study revealed that 2nd dose OCV coverage was 87% which represent the demand for OCV 2nd dose and understanding the importance of the vaccine [14]. This two-round vaccine delivery system

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requires huge manpower and financial investment. Moreover, due to uncertainty in first-dose recipients receiving the second dose, field workers must continue interpersonal communication (IPC) with vaccinees. However, there is evidence that the OCV is stable for up to 42 days at ambient temperatures, which may facilitate vaccine delivery [13]. According to WHO, “Shanchol vaccine can be used in a controlled temperature chain (CTC), for up to fourteen days at ambient temperatures not exceeding 40 °C. A CTC is initiated immediately prior to administration, provided that the vaccine has not reached its expiry date and the vaccine vial monitor is still valid. Unopened vaccine vials should be discarded at the end of the fourteen days at 40 °C”. However, OCV, Shanchol is being the only prequalified oral cholera vaccine that WHO has approved for CTC use [15].

Therefore, to minimize economic burden, human resource involvement, and to evaluate the compliance of second-dose OCV, innovative vaccine delivery approaches for second-dose vaccination are needed. For instance, in Malawi, fishermen were provided with and self-administered a second OCV dose, with promising results [16]. We have been vaccinating people in urban Mirpur, Dhaka, a cholera-prone low-socioeconomic area of Bangladesh [17]. Here we describe our experience of a second-dose self-administration strategy and compliance with OCV administration when the second dose was provided in a plastic bag to first-dose vaccine recipients with the instruction to keep it at home in a cool place and self-administer it two weeks later.

2. Methods

2.1. Study sites and population

This study was conducted in Mirpur (ward 2 and part of ward 5), Dhaka, a densely populated city (~18 million) with a large population at high risk of cholera and other diarrheal diseases [2]. From 2011, large-scale vaccination studies have been conducted in high-risk urban areas of Dhaka with the whole cell OCV Shanchol™ [12,17]. Among these studies, the Gavi Vaccine Alliance-funded Cholera Vaccine Investment Strategy was conducted in Kamrangirchar, and the Gates Foundation-funded single dose OCV study was conducted in Mirpur. Shanchol OCV was used in both studies. However, around 112,000 doses of Shanchol were left over after vaccine delivery under the scope of these two studies, so that 56,000 individuals were selected for OCV vaccination using the unused OCV dose availability. A census was carried out in the study area between March 25 and April 13, 2017 to register the vaccine eligible population. Geographical information of the population was collected for preparing map for further participant's location identification. Participants with high risk for cholera and low socioeconomic condition were targeted for the vaccination. At the time of final listing, pregnant women, individuals who had already received the OCV, and children aged <1 year were excluded. Based on information obtained from the census, master list and session report forms were prepared for the study population.

2.2. Implementation of mass vaccination with OCV

2.2.1. Communication strategy and social mobilization

The OCV campaign was carried out in coordination with Dhaka North City Corporation (DNCC) and the Expanded Program of Immunization (EPI). The communication strategy involved planning and advocacy meetings and interpersonal communication by trained field workers. People from different sectors including EPI managers, city corporation staff, local school teachers, community members, public representatives, religious leaders, local key

people, and local journalists attended these meetings. In addition to interpersonal communication, other communication materials including banners and local announcements (miking) were used to increase awareness and encourage participation. During vaccination, a reminder was given to parents via cell phones and local announcements. Informed consent was taken from participants (aged ≥ 18 years) and from guardians (of children aged 1–10 years) during home visits by field workers. Moreover, assent was taken from children aged 11–17 years. Vaccination cards were prepared that included the name, personal identification number (PID), and other necessary information of participants. Card distribution was completed by house-to-house visits prior to vaccination by field workers, and communities were reminded about their vaccination date and time and to bring the ID card to the vaccination site.

2.2.2. Vaccination site and team

Forty vaccination centers were established in the vaccination area to account for accessibility for the maximum number of target individuals. Seven vaccination centers were run by NGOs routinely providing EPI services. One vaccination team was assigned to each site. The team included two vaccinators, one mobilizer, and two record keepers. The mobilizers informed people about vaccination on the vaccination days and checked eligibility for vaccination in the center. Record keepers completed session report forms and vaccination cards. Vaccinators also taught participants how to open vaccine vials and interpret the vaccine vial monitor (VVM; Fig. 1). There was one first-line supervisor for every two teams and a total of four second-line supervisors supervising all forty teams. Moreover, physicians were available at the vaccination sites during the vaccination period to manage any adverse events following immunization.



Fig. 1. Zip-lock bag containing the vaccine and immunization card.

2.2.3. Vaccine transportation to the site

The OCV was stored in the EPI cold room at 2–8 °C. Around 20,000 OCV vials were supplied from the EPI cold room for approximately 18,000 target participants per day. Forty OCV containers and 40 icepack-containing cold boxes were supplied every day from the EPI cold room to the vaccination centers in ten vehicles. At the end of the day after completing the session, all cold boxes were returned to EPI headquarters along with an accountability log.

2.2.4. Vaccine delivery following different strategies

Seven days of batch-wise training including theoretical and practical sessions were organized for the census team. One day of training on vaccine delivery was organized for supervisors, vaccinators, mobilizers, record keepers, and electronic data recorders. Before organizing training, a one-day orientation session was organized for managers and second-line supervisors. Physicians were trained on monitoring and preparing reports for adverse events following immunization (AEFIs) and serious adverse events (SAEs). Basic training on AEFIs was given to all vaccinators, mobilizers, record keepers, and supervisors.

Two different strategies were adopted to complete the vaccination program. The first-dose OCV was given to eligible participants at fixed sites, and intact vaccine vials were given to the first-dose recipients for self-administration for taking the second dose at home. This campaign was conducted from June 6–10, 2017. The campaign was extended to a non-working day, as many of the working target population could not receive the vaccine on workdays. Sites were kept open from 7:30 am to 5:00 pm each day. The vaccine was administered after ensuring a proper consent process that was obtained during census, and the date of first dose was recorded and written on the vaccination card. Then, the second OCV dose of the same vaccine vial monitor (VVM) stage was given to participants in a zip-lock bag (Fig. 1) for self-administration after 14 days at home. During handover, vaccinees were instructed to keep second dose vials in a cool place in their houses and, if available, in a non-deep chamber of their household fridge. Written instructions with some pictures regarding the VVM were provided with the second dose vial, which included the stages when the vaccine should or should not be taken. Participants were told to write the date of taking the second dose on the vaccination card and to return all materials, i.e., zip-lock bags with empty vials, aluminum foil, rubber caps, and VVM indicator cards to the study staff. Study staffs visited the participant's home after 14 days, at which point the staff also interviewed participants to collect information regarding the second vaccine dose. Individuals unable to take vaccine due to VVM changes (stage three or four) were told to return intact vials and cards to the field worker during home visit after 14 days. Those participants were offered a second dose from a fresh vial if they were interested.

Proper safety precautions were taken and continued throughout the campaign. Two hospitals were selected for managing AEFIs if needed. Nurses and doctors in the selected hospitals were oriented before vaccination. Participants were also advised to go the selected hospital for seeking treatment for any kind of health event. Four trained doctors were assigned to oversee AEFIs during the vaccination period, and doctors were assigned to 24 h of on-call duty from the vaccination start date to 14 days after the last date vaccination.

2.2.5. Cross-sectional coverage survey

A cross-sectional coverage survey was conducted in vaccine recipients during household visits by the study staff to collect the used vials. Systematic random sampling was used for this surveillance, where the first household was selected randomly and then every 5th household was included. Only participants aged

18 years or older were interviewed in this survey, and information was collected on all household members.

3. Data management and statistical analysis

All data were checked by a well-trained data management team. The statistical analysis was conducted using the StataSE v13, and results were presented in Microsoft Excel v13. Descriptive statistics (estimated percentages and 95% confidence intervals; CI) were calculated to find age- and sex-wise vaccine coverage, and the χ^2 test was used to draw inferences about differences in proportions. Differences were considered significant at a 5% significance level ($p < 0.05$). However, we also documented perceptions about the vaccine delivery strategy, information about any adverse events, places of vial storage, VVM colors, and reasons for not taking the vaccine.

4. Ethical statement

The icddr,b institutional review board approved the study, which was monitored by a data safety monitoring board. Written informed consent for was obtained from all participants or their parents or guardians (for participants <18 years of age), and assent was also obtained from all subjects 11–17 years of age. The study was registered with ClinicalTrials.gov, number NCT02727855.

5. Results

A total of 112,000 vaccine doses were left over from earlier studies. Considering this number of doses, 56,000 participants were selected for vaccination from 83,449 high-risk individuals residing in the study area where 64% shared toilet and 73% shared kitchen with other households. Of the target vaccination population, 41,694 (74%) received the first dose and an estimated 38,852 (93%) received the second dose (Fig. 2). Overall coverage with two complete doses was 69%. An age-sex pyramid based on two-dose vaccine recipients is shown in Fig. 3. First dose administration was highest (19%) in the 20–29 years age group, followed by in the 30–39 years age group and 14% in the 5–9 years age group. However, over 10% vaccine recipients were from <5 years age group during first and also second dose vaccine delivery. (Table 1). 8551 coverage surveys were conducted from 2990

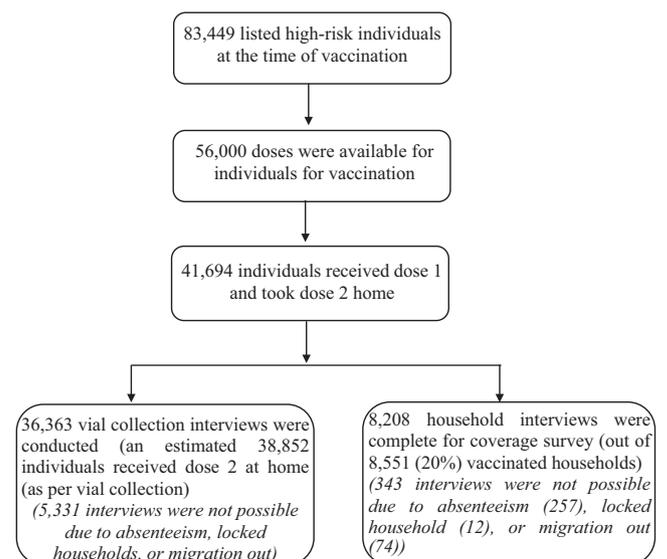


Fig. 2. Consort chart of OCV doses administered applying our alternative strategy.

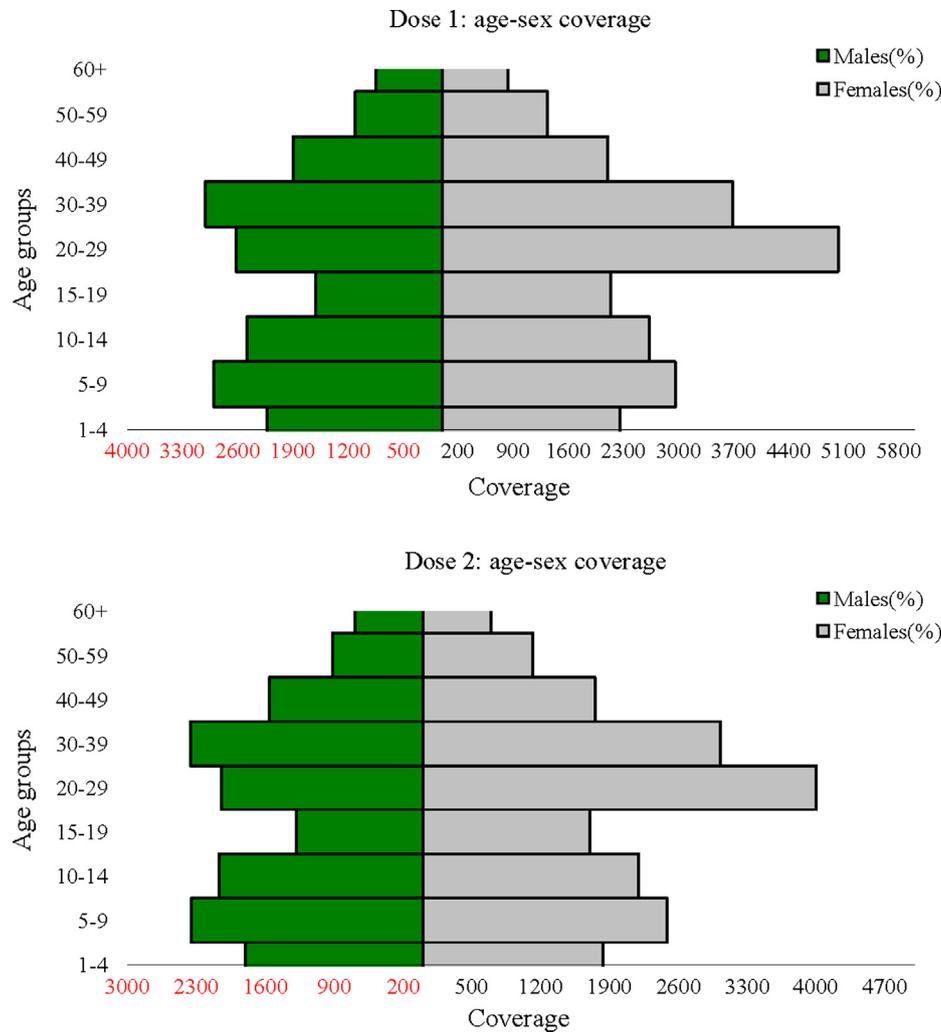


Fig. 3. Age-Sex pyramids based on doses administered.

Table 1
Doses administered by age group and sex against total target population.

Age (in years)	Dose 1 coverage, N (%)			Dose 2 coverage, N (%)		
	Male	Female	Total	Male	Female	Total
Age group						
1–4	2224 (11.87)	2250 (9.80)	4474 (10.73)	1808 (11.98)	1830 (9.74)	3638 (10.74)
5–9	2907 (15.52)	2957 (12.88)	5864 (14.06)	2352 (15.58)	2480 (13.20)	4832 (14.26)
10–14	2490 (13.29)	2632 (11.46)	5122 (12.28)	2071 (13.72)	2193 (11.67)	4264 (12.58)
15–19	1616 (8.63)	2132 (9.29)	3748 (8.99)	1289 (8.54)	1699 (9.04)	2988 (8.82)
20–29	2622 (14.00)	5035 (21.93)	7657 (18.36)	2047 (13.56)	4001 (21.30)	6048 (17.85)
30–39	3012 (16.08)	3678 (16.02)	6690 (16.05)	2362 (15.65)	3024 (16.10)	5386 (15.90)
40–49	1901 (10.15)	2103 (9.16)	4004 (9.60)	1558 (10.32)	1748 (9.30)	3306 (9.76)
50–59	1113 (5.94)	1336 (5.82)	2449 (5.87)	916 (6.07)	1117 (5.95)	2033 (6.00)
60+	850 (4.54)	836 (3.64)	1686 (4.04)	693 (4.59)	696 (3.70)	1389 (4.10)
All	18,735 (100)	22,959 (100)	41,694 (100)	15,096 (100)	18,788 (100)	33,884 (100)

randomly assigned households. However, 8208 samples were analyzed since 343 were not completed. The survey revealed that majority of the respondents (98.75%) appreciated this new alternative vaccine delivery strategy, considering it to be practical and convenient compared to the routine method. However, 29.13% said that it was difficult to take the vaccine responsibility themselves, 28.16% said that they were afraid of losing the vial, 26.21% were afraid of forgetting to take the vial, but only 14.56% said that the process of empty vial collection was complicated (Table 2). About

7% percent (of first dose recipients) did not take the second dose. Reasons for not taking the second dose were: not interested in receiving the vaccine, fear of AEFIs, sickness, and not liking the taste of the vaccine. Over 96% of beneficiaries kept the second-dose vial away from sunlight. Of these, 95% kept the vial in the household refrigerator. In maximum cases (99.3%), the VVM color of the second dose was completely white or slightly purple (stage 1 and 2 –considered as good color), since most vials were kept in the refrigerator, and only 0.6% (n = 47) of vials were dark purple

Table 2
Recipients' perceptions on alternative vaccine delivery strategy (N = 8208).

Variables	n	%
<i>Recipients' opinions on alternative delivery strategy (n = 8208)</i>		
<i>I think it is practical/convenient</i>	8105	98.75
<i>I think it is complicated</i>	70	0.85
<i>I do not appreciate it</i>	24	0.29
<i>Don't know</i>	9	0.11
<i>Reasons for considering complicated/not appreciated (n = 103)</i>		
<i>Because of taking responsibility of taking the vaccine myself</i>	30	29.13
<i>I was afraid of losing vial</i>	29	28.16
<i>I was afraid of forgetting to take vial</i>	27	26.21
<i>The process of empty vial collection is complicated</i>	15	14.56
<i>Because vial opening is complicated</i>	2	1.94
<i>Reasons for not taking second dose (multiple answers considered) (n = 459)</i>		
<i>Sickness</i>	68	–
<i>Did not want to receive vaccine</i>	108	–
<i>Did not like the taste of vaccine</i>	65	–
<i>Fear of AEFI</i>	65	–
<i>Neglected to be vaccinated</i>	13	–
<i>Forgot about vaccination</i>	35	–
<i>Box color of VVM was purple as like as purple within circle (Stage 3)</i>	48	–
<i>Box color of VVM was dark purple more than purple within circle (Stage 4)</i>	19	–
<i>Pregnant</i>	7	–
<i>Lost</i>	22	–
<i>Others (e.g., absent, receiving antibiotic)</i>	9	–
<i>Would you like to take vaccine now (who missed the second doses) (n = 382)</i>		
<i>Yes</i>	77	20.16
<i>No</i>	305	79.84
<i>Reasons for not taking second dose vaccine who like to take now (multiple answers considered) (n = 78)</i>		
<i>Sickness</i>	5	–
<i>Did not want to receive vaccine</i>	3	–
<i>Neglected to be vaccinated</i>	3	–
<i>Forgot about vaccination</i>	21	–
<i>Box color of VVM was purple as like as purple within circle (Stage 3)</i>	29	–
<i>Box color of VVM was dark purple more than purple within circle (Stage 4)</i>	12	–
<i>Lost</i>	5	–

Table 3
Storage and VVM color of second dose vaccine.

Place where vial was kept	Color of VVM during taking second-dose vaccine		Total
	Good color	Bad color	
<i>Kept in refrigerator</i>	7462 (99.51)	37 (0.49)	7499 (100.00)
<i>Kept in almirah</i>	86 (96.63)	3 (3.37)	89 (100.00)
<i>Kept in shelf</i>	164 (95.91)	7 (4.09)	171 (100.00)
<i>Kept in trunk</i>	1 (100.00)	0 (0.00)	1 (100.00)
<i>Kept in elsewhere</i>	3 (100.00)	0 (0.00)	3 (100.00)
Total	7716 (99.39)	47 (0.61)	7763 (100.00)

(stage 3 and 4- considered as bad color) that kept in other place at home (Table 3). Of the surveyed sample, 7826 received the second dose and 98.99% reported feeling good, while only 79 (1.01%) of recipients felt unwell after taking the second dose and reported fever, diarrhea, general weakness, and/or nausea.

AEFIs were monitored for 14 days after each vaccination dose. A total of 40 AEFI cases were identified over the reporting period. All complaints were very mild and included vomiting, fever, abdominal cramps, and loose motions. No SAE was recorded.

6. Discussion

The structure and strength of the local healthcare system is a key consideration when developing strategies for vaccination,

and many strategies have been implemented [18]. This study shows that self-administration is an acceptable and innovative vaccine delivery strategy to allow beneficiaries to take their second OCV dose at home. Moreover, the dropout rate between first and second doses was 6.8%. The OCV is usually delivered via two vaccination rounds at least two weeks apart and requires cold chain maintenance [19]. Mass vaccination campaigns with two OCV doses are proven effective for the prevention and control of cholera in urban settings [12], but these campaigns require complex logistics and are expensive. Self-administration of the second dose was implemented in order to decrease the logistical burden of second rounds. In this alternative service delivery model, responsibility for an expensive cold chain management system has been shifted to the vaccine recipients. The data also revealed that 90% of households had functioning refrigerators and less than 2% reported VVMs that progressed to stage 3 or 4. The novel delivery strategy for the second dose was well accepted and efficiently delivered the cholera vaccine to an at-risk population in urban Mirpur.

The main objective of this study was to test self-administration of a second OCV dose. Second dose coverage was high (~93%) in first-dose recipients. This coverage is comparable to a previous study following the same strategy [16,20]. Compliance with the self-administration strategy was good in this high-risk population. An interview survey revealed that 99% of vaccine recipients appreciated the new vaccine delivery strategy. Major reasons for inconvenience were fear of self-administration, forgetting to take the vaccine, preservation problems, and losing the vial. However, most people had no problems opening the vial or after taking the vaccine in their own homes. Moreover, no serious adverse event was identified over the reporting period, but 40 adverse events were reported that were unrelated to the vaccine. Overall, the vaccine was found to be safe in this campaign and the self-administration strategy was feasible to deliver the OCV.

People in Bangladesh have a very positive attitude towards vaccination, and most people know about vaccination programs and parents are well aware that their children can be vaccinated. EPI vaccine coverage was 82.5% according to the EPI coverage survey 2015 where eleven antigens were given [21]. This awareness has a positive impact on other vaccination campaigns. There was also cooperation from public representatives, political and religious leaders, NGO workers, and other key local people. A similar method was also applied successfully in Malawi to deliver the OCV to fishermen living in remote areas [16]. In that study, three different strategies were followed for delivering the vaccine, and the self-administration strategy showed similar results. This new vaccine delivery strategy is convenient for delivering the second dose of OCV, and the approach can be applied in other resource poor settings where cold chain and logistics management is critical.

6.1. Study limitations

This study had some limitations. The vaccination period was during a time of extreme weather (heavy rain frequently interrupting normal activities) and temperatures of up to 35–36 °C, which is relatively normal in Dhaka [22]. Moreover, we have time constraint to complete the campaign before fasting month of Ramadan. Proper planning and the effort made by all staff ensured that the campaign was completed in time. Most adult participants were factory workers who left for work early in the morning and returned home late at night, so it was difficult to provide vaccine to these working people. Interpersonal communication was done during card distribution due to the time constraints. We also used a purposive sampling technique for selecting the population for vaccination, as total doses were insufficient to cover the entire study area. In this study, most participants kept the vaccine in the refrigerator and the VVM remained at good stages. Although

the entire household do not have refrigerator. People kept in their neighbor's as well as nearby shop's refrigerator. However, this may not be representative of all resource-poor settings. Moreover, the study was not comprehensive enough to determine the importance of other important issues and outcomes like effectiveness and cost analysis.

7. Conclusions

This innovative self-administration strategy was successfully used to deliver the second dose of OCV in urban Mirpur, a low-resource urban setting particularly vulnerable to cholera. This approach allows the provision of two doses with a small dropout rate, permits longer protection than a single dose, and demands fewer logistics and human resources. The process and results of the campaign should form the basis for similar campaigns. This novel vaccination strategy may be considered in the future as an alternative delivery strategy in situations where there is confidence that households are able to properly store an OCV product that is approved for CTC use. The model described in this study can be an effective alternative to facility-based services for providing a second dose of OCV in a campaign in an urban setting as well as in difficult-to-reach populations or low-resource settings to reduce logistical constraints and costs of vaccination.

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Conflicts of interest

The authors have no conflicts of interest to disclose.

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