RESEARCH PAPER

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Uptake during an oral cholera vaccine pilot demonstration program, Odisha, India

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Abbreviations: DHS, Directorate of Health Services, Odisha India; ORC, Oral Cholera Vaccine; IVI, International Vaccine Institute; PHC, Primary Health Centers; RMRC, Regional Medical Research Center, Bhubaneswar India; WHO, World Health Organization.

Approximately 30% of reported global cholera cases occur in India. In 2011, a household survey was conducted 4 months after an oral cholera vaccine pilot demonstration project in Odisha India to assess factors associated with vaccine up-take and exposure to a communication and social mobilization campaign. Nine villages were purposefully selected based on socio-demographics and demonstration participation rates. Households were stratified by level of participation and randomly selected. Bivariate and ordered logistic regression analyses were conducted. 517/600 (86%) selected households were surveyed. At the household level, participant compared to non-participant households were more likely to use the local primary health centers for general healthcare ($P < 0.001$). Similarly, at the village level, higher participation was associated with use of the primary health centers ($P < 0.001$) and private clinics ($p = 0.032$). Also at the village level, lower participation was associated with greater perceived availability of effective treatment for cholera ($p = 0.013$) and higher participation was associated with respondents reporting spouse as the sole decision-maker for household participation in the study. In terms of pre-vaccination communication, at the household level verbal communication was reported to be more useful than written communication. However written communication was perceived to be more useful by respondents in low-participating villages compared to average-participating villages ($p = 0.007$) These data on participation in an oral cholera vaccine demonstration program are important in light of the World Health Organization's (WHO) recommendations for pre-emptive use of cholera vaccine among vulnerable populations in endemic settings. Continued research is needed to further delineate barriers to vaccine up-take within and across targeted communities in low- and middle-income countries.

Introduction

The global burden of disease for cholera is estimated to be 3 to 5 million cases and 100,000 to 130,000 deaths per year with recent outbreaks in the Caribbean, Africa, and Asia.[1-4] The World Health Organization (WHO) has recommended the pre-emptive use of oral cholera vaccines (OCV) with vulnerable populations in endemic settings as well as reactive implementation during epidemics.[5-7] Implementation of OCV campaigns in these settings is considered an opportunity to decrease morbidity and prevent the loss of thousands of lives.[8,9]

In India, a country with approximately 30% of reported global cholera cases, 18 out of 35 States and Union Territories were affected by cholera outbreaks between 2003 and 2006. Four states including Odisha accounted for 60% of these outbreaks.[10] Given the substantial burden of cholera in India and availability of an improved, low-cost oral cholera vaccine (OCV) (Shanchol^{TM}), national stakeholders of India gathered in 2009 to discuss strategies and plans for implementing the OCV within the country. The International Vaccine Institute (IVI) in Seoul South Korea collaborated with the Regional Medical Research Center (RMRC), Bhubaneswar and the Directorate of Health Services (DHS), Government of Odisha to implement a pilot demonstration to assess feasibility, acceptability, and costs associated with mass vaccination.

Through mixed methods socio-behavioral research conducted in Asia and Africa, we have identified multiple factors which affect participation in vaccine trials and pilot demonstration projects. These include perceptions of vulnerability to the targeted disease, previous disease experience, perceptions of risks associated with vaccines, engagement with health services and health-care utilization patterns, familial/household decision-making processes, and social constructs for roles and responsibilities (e.g. gender).[11-15] Socio-behavioral studies are important during pilot

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demonstration projects to assess barriers to vaccine up-take among various groups and ensure that national- and local-level stakeholders are engaged in dialog and informed about the target disease, prevention strategies, anticipated vaccination outcomes, as well as program logistics and procedures.

The State of Odisha includes 30 districts and a population of approximately 37 million. The pilot demonstration was conducted in 145 villages in Puri District. A total of 51,865 persons in 9,166 households were enumerated in a pre-vaccination census. Excluding children below one year, 51,488 persons were targeted for the vaccination. The mass vaccination took place in 2 phases between May and June 2011. Sixty-one percent of eligible recipients (31,552 persons) were vaccinated with at least one dose; 75% of those vaccinated (23,751 persons) received 2 doses.[16]

Prior to vaccination, focus group discussions and individual interviews were conducted with local residents, health providers, community health volunteers, and local leaders. These data contributed to development of communication and social mobilization campaigns to inform the public about cholera and the OCV demonstration project. A post-vaccination household survey was adapted to assess factors associated with participation and non-participation. The current paper utilizes data from the post-vaccination household survey. The research objectives of the current analysis are: (1) At the village level, what demographic and socio-cultural factors including healthcare utilization, disease knowledge, perceptions, and experience, and household decision-making are associated with higher and lower levels of OCV up-take; (2) At the household level, what demographic and socio-cultural factors are associated with vaccine up-take and completion (2 doses); (3) What attributes of the OCV pilot demonstration project contributed to non-participation and incomplete participation (one-dose); and, (4) Which social mobilization and communication activities were perceived as most informative and valuable?

Results

Demographics

Over 86% (517/600) of selected households participated in the survey. Sixty-7 percent (345/515) of respondents were female. Mean ages of female and male respondents were 39.3 (SD 13.1) and 44.7 y (SD 15.9) respectively [$F = 16.67$, df 1/507 $P < 0.001$]. Mean household size was 5.4 (SD 2.7) members. With the exception of one predominately Muslim village (93.7%), all respondents were Hindu. **Table 1** outlines village descriptors.

General healthcare utilization and access

Over 67% (351/517) respondents reported use of the local hospital for general healthcare followed by the primary health centers [PHC] (13.2%; 68/517), self-care or use of pharmacies/medicine shops (7.2%; 37/517), and private clinics (6.8%; 35/517). Mean travel time to the most often used healthcare facility was 34 (SD 26) minutes and to the local hospital 48 (SD 50) minutes. At the household level, participant households were less likely to use the hospital and more likely to use either self-care or the local PHC ($X^2 = 36.27$, df8: $P < 0.001$). Also at the household level, mean travel time to the local hospital for participant households was 57 (SD 62) minutes compared to 48 (SD 48) minutes for one-dose and 36 (SD 31) minutes for non-participant households ($F = 7.78$, df 2/499: $P < 0.001$). Similarly residents in low participating villages compared to high- and average- participating villages were more likely to use the hospital, while residents in high participating villages were more likely to use the public health clinics ($X^2 = 60.55$, df8: $P < 0.001$). Travel time to the most often used healthcare facility ($F = 3.97$, df 2/512: $p = 0.020$) and to the local hospital ($F = 18.43$, df 2/499: $P < 0.001$) were related to village level participation with low participation associated with shorter travel time (**Table 2**).

Knowledge and experience with cholera

Overall, 89.6% (458/511) participants had heard about cholera. However, from a list of 10 symptoms associated with the disease, the mean score for spontaneous identification of symptoms was only 2.6 (SD 1.1). Symptoms most often identified were 'watery stool' (98.5%: 453/460), 'vomiting' (88.9%: 409/460), and 'weakness' (25.9%: 119/459). There was no significant difference with regards to having heard about cholera by level of household ($X^2 = 0.11$, df 2: $p = 0.947$) or village participation ($X^2 = 4.28$, df 2: $p = 0.118$). Likewise, there was no difference in total number of identified symptoms by level of household ($F = 0.20$, df 2/457: $p = 0.821$) or village participation ($F = 0.58$, df 2/457: $p = 0.561$). The only significant relationship between specific symptoms and participation was at the village level. Over 11% (26/229) respondents from villages with average participation identified 'unconsciousness' as a symptom of cholera compared to 3.1% (2/65) and 4.8% (8/166) respondents from high and low participating villages ($X^2 = 8.06$, df 2: $p = 0.018$).

Compared to non-participant households, participant household respondents were more likely to report a case of cholera in their household in the past 6 months ($X^2 = 17.05$, df 2: $P < 0.001$); participant and one-dose household respondents were more likely to report knowing someone who had been quite sick from cholera ($X^2 = 10.71$, df2: $p = 0.005$). Respondents from villages with high and average participation were more likely to report a household member having had cholera in the past 6 months ($X^2 = 14.25$, df 4: $p = 0.007$) and knowing someone who had been quite sick ($X^2 = 32.71$, df4: $P < 0.001$) (**Table 2**).

Perceptions of cholera (severity, vulnerability, prevention, treatment)

Data indicate no relationship between perceived severity of cholera and participation either at the household ($F = 2.38$, df2/500: $p = 0.094$) or village levels ($F = 1.62$, df 2/500: $p = 0.200$). However in terms of vulnerability, respondents living in non-participant households and/or low-participating villages were less likely to perceive that someone in their household or village would contract cholera (see **Table 2**).

At the household level, respondents from participant households perceived prevention efforts as more efficacious than those

Table 1. Villages participating in the post-vaccination survey and population, demographic, and socio-economic information

Village	Total Population/Households	Number/Percentage[a] Households Surveyed	Vaccination Participation	% HH with Electricity	Primary Occupation [b]	Road Access
A	246/43	25/4.8%	High (80%)	83.7%	Farmer, laborer	Easy
B	325/60	32/6.2%	High (86%)	63.3%	Farmer, laborer	Average
C	244/48	21/4.1%	High (80%)	97.9%	Farmer	Average
D	1,211/192	95/18.4%	Average (47%)	78.6%	Trader, laborer	Easy
E	919/172	104/20.1%	Average (50%)	69.9%	Farmer	Average
F	627/118	61/11.8%	Average (67%)	60.2%	Farmer	Remote
G	929/204	120/23.2%	Low (31%)	96.6%	Government and service workers, trader	Easy
H	276/46	28/5.4%	Low (41%)	56.5%	Farmer, laborer	Remote
I	310/62	31/6.0%	Low (32%)	79.0%	Laborer	Average

[a] Percentage of total households interviewed.
[b] Occupation of household member who contributes most to the household economic base.

from non-participant households (F = 3.94, df 2/510: p = 0.020); alternatively, at the village level, those respondents from high-participating villages compared to low-participating villages perceived such efforts as less efficacious (F = 3.44, df 2/510: p = 0.033). In terms of treatment, respondents from non-participant households were more likely to perceive treatment costs as not expensive (X^2 = 15,65, df 4: p = 0.002) and respondents from low-participating villages perceived treatments as more efficacious (X^2 = 7.45, df 2: p = 0.024) (**Table 2**).

Household decision making

There were no significant differences at the household level in relation to level of participation and reported decision-making by self, spouse, self and spouse, or other household member for either male (X^2 = 10.53, df 6: p = 0.104) or female respondents (X^2 = 10.52, df 6: p = 0.104). At the village level, male respondents were more likely to report being the sole decision-maker about use of the vaccine in low-participating villages compared to average- and high-participating villages (X^2 = 16.15, df 6: p = 0.013). In these same analysis, both spouse only and joint decision making (self-spouse) were associated with higher participation. However, there were no significant differences at the village level in reported decision-making from female respondents (X^2 = 11.49, df 6: p = 0.074) (**Table 2**).

Household and village participation: ordered logistic regression

Utilizing findings from the bivariate analysis, ordered logistic regression analysis were conducted for both household level and village level participation. At the household level, participant households compared to one dose and non-participant households were more likely to use primary health centers [PHCs] for general healthcare (OR 3.55 [CI95 1.90–6.62]: $P < 0.001$). At the village level, respondents from high compared to low participating villages were more likely to use primary health centers [PHCs] (OR 3.39 [CI95 1.83–6.26]): $P < 0.001$). In addition, participants from average compared to low participating villages were more likely to use private clinics (OR 2.38 [CI95 1.08–5.25]; p = 0.032). Respondents from low compared to high participating villages were more likely to perceive availability of effective treatment for cholera (OR 7.85 [CI95 1.56–39.63]; p = 0.013). Analysis also indicates that spouses are more likely to be sole decision-makers in high compared to low participating villages (OR3.23 (CI95 1.55–6.76]; p = 0.002).Accessibility and acceptability of the OCV

The primary reason for non-participation of adults (55.7%; 201/361) and children (52.4%; 89/170), and for incomplete (one-dose) participation (45.7%; 63/138) was 'being away from the village' during vaccination. For one-dose households, characteristics of the vaccine including bad taste (32.4%; 45/139) and bad smell (25.4%; 35/138) were reasons for incomplete participation. Reasons for non-participation varied significantly between households with some members vaccinated and those household with no member vaccinated (non-participant households). For children, non-participant household respondents were more likely to state that 'the vaccine would not protect against cholera' (X^2 = 6.05, df 1: p = 0.014) and 'the vaccine was not important' (X^2 = 7.50, df 1: p = 0.006). They were also more likely to respond that their decision was affected by 'advice of other household members' (X^2 = 16.45, df 1: $P < 0.001$); 'not enough information' (X^2 = 4.27, df 1: p = 0.039); and, 'household decision-maker was not available' (X^2 = 8.96, df 1: p = 0.003). For adults, non-participant household respondents were also more likely to report 'the vaccine was not important' (X^2 = 4.87, df 1: p = 0.027); 'not enough information' (X^2 = 4.40, df 1: p = 0.036); and advice of other household members' (X^2 = 5.52, df 1: p = 0.022). In addition, they reported 'being sick during vaccination' (X^2 = 7.46, df 1: p = 0.006) and 'distance to the vaccine post' (X^2 = 6.36, df 1: p = 0.012).

Social mobilization and communication campaign

The multi-media social mobilization campaign prior to delivery of the first and second doses included posters, banners, leaflets, newspaper articles, public meetings with local leaders and community members, announcements via mobile loudspeakers ("miking"), and canvassing door-to-door by volunteer health

Table 2. Bivariate analysis for healthcare utilization, knowledge, experience, and perceptions of cholera, knowledge of prevention and treatment for cholera, and household decision-making by household level and village level participation

	Household Participation			Village Participation		
	Participant	**One-dose**	**Non-participant**	**High**	**Average**	**Low**
HEALTHCARE UTILIZATION						
Self/Pharmacy	9.3% (18/194)	5.0% (8/160)	6.7% [c]	2.6%	11.5% (30/260)	2.8% [c]
Public Health Centers	22.2% (43/194)	10.6% (17/160)	(11/163)	(2/78)	15.0% (39/260)	(5/179)
Hospital	58.8% (114/194)	71.3% (114/160)	4.9%	25.6% (20/78)	57.3% (149/260)	5.0%
Private Clinic	4.1%	10.6% (17/160)	(8/163)	59.0% (46/78)	10.0% (26/260)	(9/179)
	(8/194)		75.5% (123/163)	7.7%		87.2% (156/179)
			6.1%	(6/78)		1.7%
			(10/163)			(3/179)
Time to most used facility (*minutes*)	33 (SD 28)	36 (SD 23)	33 (SD 26)	36 (SD 29)	36 (SD 26)	29 (SD 24) [a]
Time to hospital (*minutes)*	57 (SD 62)	48 (SD 48)	36 (SD 31) [c]	49 (SD 40)	59 (SD 61)	30 (SD 28) [c]
KNOWLEDGE						
Heard of cholera	89.1% (171/192)	89.9% (142/158)	90.1% (145/161)	84.2% (64/76)	89.1% (229/257)	92.7% (165/178)
Symptom knowedge (scale: range 0–10)	2.7 (SD 1.1)	2.6 (SD 1.1)	2.6 (SD 1.0)	2.5 (SD 1.0)	2.7 (SD 1.1)	2.7 (SD 1.1)
EXPERIENCE						
Household case (past 6 mos.)	20.7% (40/193)	13.8% (22/160)	5.6% [c] (9/162)	15.6% (12/77)	18.1% (47/259)	6.7% [a] (12/179)
Know someone quite sick (past 6 mos.)	30.5%	30.0% (45/150)	16.5% [b]	35.6% (26/73)	32.7% (80/245)	12.4% [c]
	(57/187)		(26/158)			(22/117)
PERCEPTIONS (SEVERITY/VULNERABILITY)						
Severity by age categories (scale: range 4–12)	9.9 (SD 1.8)	9.7 (SD 1.8)	9.6 (SD 2.0)	9.4 (SD 2.1)	9.9 (SD 1.8)	9.7 SD (2.0)
Likely to have cholera in household	58.1% (97/167)	58.8% (76/131)	41.4% [a] (58/140)	60.0% (42/70)	61.7% (137/222)	36.3% [c] (53/146)
Likely to have cholera in village	73.2% (120/164)	74.6% (100/134)	58.6% [a] (82/140)	72.9% (51/70)	79.5% (178/224)	50.7% [c]
						(73/144)
PREVENTION & TREATMENT						
Prevention efficacy (scale: range 10–30)	27.0 (SD 4.0)	26.5 (SD 4.0)	25.8 (SD 4.6) [a]	26.2 (SD 4.6)	26.1 (SD 4.5)	27.2 (SD 3.5) [a]
Availability of effective treatment (*yes)*	96.7% (176/182)	97.3% (145/149)	98.6% (144/146)	93.5% (72/77)	97.4% (228/234)	99.4% [a]
						(165/166)
Cost of treatment (*expensive*)	92.7%	93.2% (137/147)	85.4% [b]	90.1% (64/71)	90.3% (215/238)	91.1% (153/168)
	(166/179)		(129/151)			
HOUSEHOLD DECISION-MAKING-MALE						
RESPONDENTS						
Self only	70.0% (35/50)	72.3% (34/47)	85.9% (61/71)	66.7% (10/15)	67.9% (55/81)	90.3% [a]
Spouse only	6.0%	0	1.4%	6.7%	3.7%	(65/72)
Self+Spouse	(3/50)	19.1%	(1/71)	(1/15)	(3/81)	0
Other (parents/in-laws/children)	20.0%	(9/47)	11.3%	13.3%	23.5%	8.3%
	(10/50)	8.5%	(8/71)	(2/15)	(19/81)	(6/72)
	4.0%	(4/47)	1.4%	13.3%	4.9%	1.4%
	(2/50)		(1/71)	(2/15)	(4/81)	(1/72)
HOUSEHOLD DECISION-MAKING-FEMALE						
RESPONDENTS						
Self only	54.6%	62.2%	69.0%	49.2%	59.9%	68.9%
Spouse only	(77/141)	(69/111)	(60/87)	(30/61)	(103/172)	(73/106)
Self+Spouse	18.4%	13.5%	8.0%	24.6%	14.0%	8.5%
Other	(26/141)	(15/111)	(7/87)	(15/61)	(24/172)	(9/106)
	19.9%	15.3%	20.7%	16.4%	19.9%	17.9%
	(28/141)	(17/111)	(18/87)	(10/61)	(34/172)	(19/106)
	7.1%	9.0%	2.3%	9.8%	6.4%	4.7%
	(10/141)	(10/111)	(2/87)	(6/61)	(11/172)	(5/106)

[a] $P < 0.05$.
[b] $P < 0.01$.
[c] $P < 0.001$ [significance based on Pearson's chi square for categorical variables and ANOVA for continuous variables]
Bold text indicates significant results
Table organized by independent variables (household participation and village participation) and independent variables including healthcare utilization, knowledge, experience, and perceptions of cholera and household decision-making in relation to participation in the OCV study.

workers (Accredited Social Health Activists-ASHA and Anganwadi Workers-AWW). These activities were conducted across all areas within the study catchment area. We also anticipated informal exchanges of information within families and communities. Only 2.3% (12/514) participants stated that they received no information about the campaign. For analysis, communication methods were categorized as 'public verbal' (canvassing, miking, community meetings), 'public written' (posters, newspapers,

leaflets, banners), and 'informal contact' (family, friends/neighbors, community leaders, health providers). At the household level, public verbal methods were more often perceived as useful by full participant and one-dose households compared to non-participant households ($F = 7.30$, df 2/511: $p = 0.001$). At the village level, written communication was perceived to be more useful by respondents in low-participating villages compared to average-participating villages ($F = 5.09$, df 2/511: $p = 0.007$) (**Table 3**).

Only 4.0% (20/497) of respondents reported being dissatisfied with information received. Full participant households were more likely to report being 'very satisfied' with information received (23.8%: 46/193) compared to one dose households (17.0%: 27/159) and non-participant households (8.3%: 12/145) ($X^2 = 28.61$; df 4: $P < 0.001$); respondents from high participating villages (26.9%: 21/78) were more likely to report being 'very satisfied' compared to both average (15.3%: 38/248) and low (15.2%: 26/171) participating villages ($X^2 = 10.55$; df 4: $p = 0.032$).

Discussion and Conclusions

Successful implementation of both vaccine trials and pilot demonstration projects are dependent on informed and engaged stakeholders within the local communities. Socio-behavioral research indicates that participation may be influenced by a range of factors including disease knowledge and perceptions, general experience and perceptions of vaccines, access to efficacious preventive measures and treatment, decision-making, and a host of cultural, political, and economic factors. Social mobilization and communication campaigns need to be designed to engage community members and to provide needed and salient information.

In this post-vaccination household survey for an OCV pilot demonstration project, we sampled and analyzed the data to enable the assessment of potentially different influences at the household level across intervention sites and at the village level. In general, these villages are small and self-contained and with familial ties between households. The research villages were located over a large area and often separated by difficult terrain and poor roads, thus minimizing cross-village contact and communication.

Through the bivariate analysis, we find no relationship between participation at either the household or village level by perceived disease severity or knowledge of cholera symptoms with the exception of more respondents from average-level participating villages identifying 'unconsciousness' as a symptom. After introduction of an OCV in Zanzibar, research identified respondents' association of 'unconsciousness' with dehydration increased likelihood of vaccine up-take.[17] And in research prior to an OCV demonstration project in Kenya, identification of non-specific symptoms for cholera were associated with non-participation.[18] In our analysis, there is a general perception of cholera as a 'serious' disease which decreases variability and likelihood of distinguishing differences across groups, e.g., participants and non-participants. While only 'unconsciousness' was associated with participation, future research should continue to determine if symptom specific knowledge of a disease is associated with vaccine up-take and explore more accurate tools for measuring such knowledge.

Bivariate analysis did indicate a relationship between levels of participation and experience with cholera and perceived vulnerability (likelihood of contracting cholera). While these relationships did not remain significant with ordered logistic regression analysis, other possible indicators of vulnerability were significant including less utilization of higher-level health facilities (e.g., district hospital) for high participating households and villages, and perceived lower availability of efficacious treatments in high participating villages. The latter issue of availability of treatment emphasizes the need in low-participating villages to promote the need for prevention, e.g., immunization, despite access to efficacious treatments. However, the utilization patterns for general healthcare may also be interpreted to indicate that those in higher participating households and villages were more engaged with the local public health centers and private clinics. Such engagement may have increased confidence in the information they received from the ASHAs and local providers in terms of study participation. Understanding healthcare utilization patterns is important for surveillance purposes to ensure that targeted populations are attending research surveillance sites, e.g., hospitals, clinics.[19] However, such patterns may also be useful in terms of outreach

Table 3. Perceived usefulness of forms of communication about vaccination by household and village participation (means/standard deviation; ANOVA) [N = 514]

		Public Verbal Communication[1]	Public Written Communication[2]	Informal Communication[3]
Household Participation	Participant	5.65 (1.95)	3.94 (2.96)	3.23 (2.70)
	One-dose	5.64 (1.82)	4.52 (3.07)	3.07 (2.38)
	Non-participant	4.91 (2.24)[b]	3.84 (3.40)	2.94 (3.22)
Village Participation	High	5.87 (1.43)	4.38 (2.62)	3.49 (2.65)
	Average	5.28 (2.30)	3.66 (3.14)	2.96 (2.55)
	Low	5.41 (1.82)	4.59 (3.29)[b]	3.10 (3.14)

[1]Public Verbal Communication includes door-to-door canvassing, 'miking', and community meetings.
[2]Public Written Communication includes newspapers, posters, banners, and leaflets.
[3] Informal Communication includes talking with family, friends/neighbors, community leaders, and healthcare providers.
[b] $P < 0.01$.

efforts for vaccine feasibility studies and public immunization campaigns. At the village level, higher levels of participation were associated with spouse being the sole decision-maker. Bivariate analysis by gender indicates that this association is confined to male respondents. During a typhoid fever trial in Kolkata, higher rates of participation were associated with joint spousal decision-making.[14] And in Hue Viet Nam, during a school-based typhoid fever trial, older children and adolescents were found to influence their parents' decision-making with regards to the child's participation.[11] Differences in household decision-making processes are dependent on socio-cultural factors, e.g., kinship patterns and gender roles, as well as the composition of specific households. Cultural factors however may also contribute to response bias-so that in the current data, male respondents may have been more likely to claim responsibility for a household decision compared to female respondents. Understanding decision-making patterns can be useful in terms of targeted messages for certain groups, (e.g., gender, age) as well as messages that take into account culturally specific household dynamics. Analysis of reasons for non-participation between households with some members participating compared to those with no members participating suggest a need to differentiate levels of acceptance and refusal.[20,21] Respondents from non-participant household were more likely to question the efficacy of the OCV and general need for the vaccine. These respondents were also more likely to report having insufficient information and being influenced by other household members. Thus, while increasing vaccination days may increase up-take for some portion of the non-participating population, other issues need to be addressed for those who might be less informed and/or more influenced by informal family and community communications.

In terms of social mobilization, written communication was preferred at the village level, whereas verbal communication was preferred at the household level. The greater value placed on written communication in low participating villages may reflect higher socio-economic status and higher literacy rates in at least one selected village and lower perceived vulnerability to cholera in this demographic stratum. These data are important for targeted communication planning and messaging to optimize limited resources for future vaccination campaigns in Odisha and/or other States in India. Utilization of effective messages and communication strategies are needed to ensure informed decision-making and decreased risk for negative misinformation and rumours.

The design and analysis strategy for our research contributes to a more refined understanding and ability to differentiate household- and village-level factors which can contribute to participation and non-participation in a vaccine demonstration project. However, there is need for more research on how local (village-level) social and cultural contexts compared to household dynamics effect participation in a vaccine program, and means to more adequately address these differences through targeted information campaigns. In addition, socio-behavioral scales need to be further developed and piloted to provide more sensitive measurement of such variables as perceived severity, vulnerability, household dynamics and decision-making processes and vaccine desirability.

With WHO recommendations to expand the delivery of OCV as well as typhoid fever vaccines to endemic and epidemic regions, there is need to maximize immunization coverage through a better understanding of universal and culturally specific facilitators and barriers to vaccine delivery and up-take.[7,22] It is only with such efforts that vaccine introduction can translate to a significant decrease in disease morbidity and mortality among the most vulnerable populations.

Materials and Methods

The reported data are from a cross-sectional survey conducted approximately 4 months after completion of vaccination delivery in 2011. Households were stratified and randomly selected from census and vaccine coverage data. Trained interviewers conducted the survey at the homes of respondents. Interviewers read the questions to respondents and marked their answers on a survey form. All data were double entered and analyzed using bivariate and ordered logistic regression analysis.

Research site

The post-vaccination household survey was conducted in 9 villages in the demonstration project catchment area. The villages were purposively selected based on: (1) location (more/less remote); (2) size (total number of households and village population); (3) socio-economic status (higher/lower-based on percent of households with electricity and primary occupation); and, (4) level of vaccine uptake. For level of vaccine up-take, villages were categorized as low, average, and high ($\leq$45%, 46–76%, $\geq$77%) based on the overall 61% participation rate for one dose plus/minus one standard deviation.

Household selection and sample size

Households within the research villages were stratified by all or some household members taking 2 doses (*participant*), at least one household member receiving only one dose (*one dose*), and no household members receiving the vaccine (*non-participant*). Within each household one individual was interviewed. Eligibility criteria included being a permanent member of the household and 18+ years. We collected data on the vaccine status of the respondent, but for logistical reasons we did not ask to interview any specific household member. Given villagers' work schedules and availability and data collection time restraints, we were not able to target individuals. Two hundred households were randomly selected from each level of participation (N = 600) across the 9 research villages. Based on socio-behavioral research on trial participation in Kolkata, a sample size of 414 was calculated using inference for proportions for comparing independent samples (*participant, one-dose, non-participant*) with $\alpha = 0.05$ and 0.80 power. We assumed a conservative estimate of 15% refusal and oversampled for a total of 600 randomly selected households [200/level of participation].

Table 4. Outcome Measures

Item/Scale	Response Options
Participation	
Household participation (*determined from vaccine log data)*	Non-Participant (1),participant (2), one dose (3)
Village participation (*determined from vaccine log data)*	Low (1), average (2), high (3)
Demographics	
Gender	Male, female
Age	Continuous
How many people live in your household?	Continuous
Does your household have electricity? [a]	Yes (1), no (0)
Occupation of the most important economic contributor to your family? [a]	Categorical
Healthcare Utilization	
Where do you and other family members usually go for healthcare? [b]	Self-medication, pharmacy, primary health center (PHC), private clinic, hospital, other
How long does it take to travel one way to the healthcare facility (you use most often)?	Continuous
How long does it take to travel one way to the district hospital?	Continuous
Knowledge	
Have you heard about cholera?	Yes (1), no (0), don't know/not sure (98)
What are the symptoms associated with cholera? [watery stool, vomiting, headache, abdominal pain, fever, weakness, thirsty dry mouth, wrinkling skin, unconscious, body cramping] (*spontaneous response)* [scale range 0–10]	Yes (1), no (0), don't know, not applicable (*not heard of cholera)* (98)
Experience	
Has anyone in your household had cholera in the past 6 months?	Yes (1), no (0), don't know (98)
Are you aware of anyone (know personally) who has been quite sick from cholera in the past 6 months?	Yes (1), no (0), don't know (98)
Perceptions	
How serious of a disease is cholera for the following groups [children less than one year; children ages 1 to 17; adults ages 18 to 50; adults 51 years+] [scale range 4–12]	Very serious (3), serious (2), not serious (1), don't know (98)
How likely is it that someone in your village would get cholera?	Very likely (3), likely (2), unlikely (1), don't know (98)
How likely is it that someone in your household would get cholera?	Very likely (3), likely (2), unlikely (1), don't know (98)
Prevention & Treatment	
How well can each of the following prevent cholera? [eating well-cooked foods, eating clean foods, drinking boiled water, wash hands before meals, avoid street food, maintaining clean house and surroundings, not using pond water for cooking, improving disposal of faeces, covering food and water, building health awareness] [scale range 10–30]	Little or no prevention (1), somewhat or partial prevention (2), good or full prevention (3), don't know (98)
Is there an effective treatment for cholera	Yes (1), no (0), don't know (98)
For your household, how expensive is this treatment?	Very expensive (3), expensive (2), not expensive (1), don't know, not applicable (*no treatment available)* (98)
Household Decision-making	
Who in the household made the decision to participate or not participate in the vaccination? [self, spouse, self and spouse, other [b]]	Yes (1), no (0)
Reasons for Non-participation	
Why did one or more adults not participate in the oral cholera vaccine program? (*spontaneous response)*	Categorical
Why did one or more household members take only one dose of the cholera vaccine? (*spontaneous response)*	Categorical
Communication & Social Mobilization	
How did you receive information about the cholera vaccination [door-to-door, newspaper, community meeting, banner, leaflet, poster, miking/loudspeaker, neighbors/friends, family members, community leaders, ASHA/AWW, healthcare providers [clinic or hospital staff], did not receive information, other (also recoded to verbal, written, and informal communication sources)	Yes (1), no (0)
How useful were the following in terms of providing the kind of information you needed to decide whether to use the cholera vaccine for yourself and your family? [same options as previous item]	Very useful (3), somewhat useful (2), not useful (1), not applicable (*did not use information source)* (98)
Overall, how satisfied were you with the information you received about the vaccination?	Very satisfied (3),satisfied (2), not satisfied (1)
[If not satisfied], why were you not satisfied with the information you received about the vaccination? [not enough information, information was too complicate/ technical, information was confusing, information was inconsistent, information made me anxious, I did not trust the information, I disagreed with the vaccination program, other]	Yes (1), no (0), not applicable (*satisfied with information)* (98)

[a] Items from the pre-vaccination census.
[b] Responses shown were result of post-data collection recoding of response items.

Instrument development and outcome measures

The research instrument was based on a socio-behavioral survey developed for a typhoid vaccine trial in Hue Viet Nam and adapted for an OCV trial in Kolkata India in 2006.[14,23] Items and responses were modified based on differences between conduct of a trial and a pilot demonstration project, and to measure responses to the specific social mobilization and communication activities during the demonstration project. Experienced bilingual staff translated the survey from English to Oriya. The survey included: (1) demographics; (2) general health care utilization and accessibility; (3) knowledge of cholera (symptoms, prevention, availability of treatment); (4) perceptions of cholera (prevalence, vulnerability, severity); (5) participation in the pilot demonstration and associated decision-making processes; (6) experience with the pilot demonstration logistics; (7) sources and types of information received about the pilot demonstration; (8) satisfaction and usefulness of information received; and, (9) readiness to pay for the vaccine in the future. For the current analysis, outcome measures are outlined in **Table 4**.

Data collection

Post-vaccination survey data were collected in August and September 2011. Trained data collectors were provided with lists of randomly selected households. Data collectors read the survey items and as instructed for the specific item either read responses or asked for a spontaneous answer. Responses were recorded on a survey form with a unique household identification number which corresponded to the pre-vaccination census. Each survey took approximately 30 minutes.

Data management and analysis

Data were double entered into Microsoft FoxPro 7.0 (Microsoft, Seattle, WA, USA). Raw data were reviewed, converted to and analyzed in SPSS (version 21.0). Variables for scales were developed for perceived severity, knowledge of cholera symptoms, and prevention efficacy. In addition, variables for healthcare utilization, household decision-making, household participation, and types of information resources were recoded to facilitate analyses (**Table 4**).

Descriptive analysis provided information on general demographics and healthcare utilization. Bivariate analysis included use of Pearson's chi square (categorical) and ANOVA (continuous) for testing significance. Ordered logistic regression analysis was used to determine independent association of factors identified as significant ($P < 0.05$) through the bivariate analysis by household participation (participant, one dose, non-participant) and village level participation (high, average, low). Odds ratios with 95% confidence intervals are presented. Independent variables for the household level regression analysis included general healthcare utilization, experience with cholera at the household and village level, likelihood of experiencing cholera at the household and village level, perceived treatment cost, and perceived prevention efficacy. Independent variables for the village level included general healthcare utilization, experience with cholera at the household and village level, likelihood of experiencing cholera at the household and village level, perceived availability of treatment, perceived prevention efficacy, and household decision-making for participating in the study.

Research ethics

The socio-behavioral research protocol was approved by the Health and Family Welfare Department, Government of Odisha, Human Ethical Committee of the Regional Medical Research Center, Bhubaneswar, Odisha, the Health Ministry Screening Committee of India, and the Institutional Review Board of the International Vaccine Institute, Seoul, Korea. All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation and with the Helsinki Declaration of 1975, as revised in 2000. Written consent was obtained. For participants unable to sign, a witness observed the consenting process and signed for the participant.

Disclosure of Potential Conflicts of Interest

No potential conflicts of interest were disclosed.

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References

1. World Health Organization. Immunizations, Vaccines and Biologicals: Cholera [Internet] 2012. Available from: "http://www.who.intimmunizationtopicsCholeraen
2. Chowdhury F, Rahman MA, Begum YA, Khan A, Farugue AS, Saha NC, Baby NI, Malek MA, Kumar AR, Svennerholm AM et al. Impact of rapid urbanization on rates of infection by *Vibrio Cholerae 01 and enterotoxigenic Escherichia Coli* in Dhaka, Bangladesh. PLoS Negl Trop Dis 2011; 5(14): e999; PMID: 21483709; http://dx.doi.org/10.1371/journal.pntd.0000999
3. Chao DL, Halloran ME, Longini IR. Vaccination strategies for epidemic cholera in Haiti with implications for the developing world. Proc Natl Acad Sci U S A 2011; 108(17):7081-5; PMID:21482756; http://dx.doi.org/10.1073/pnas.1102149108
4. Ryan ET. The cholera pandemic, still with us after half a century: time to rethink. PLoS Negl Trop Dis 2011; 5(1): e1003; http://dx.doi.org/10.1371/journal.pntd.0001003
5. Longini IM Jr, Nizam A, Ali M, Yunas M, Shenvi N, Clemens JD. Controlling endemic cholera with oral vaccines. PLoS Med 2007; 4(11): e336. PMID: 18044983; http://dx.doi.org/10.1371/journal.pmed.0040336
6. Sur D, Lopez AL, Kanungo S, Paisley A, Manna B, Ali M, Niyogi SK, Park JK, Sarkar B, Puri MK et al. Efficacy and safety of a modified killed-whole-cell oral cholera vaccine in India: an interim analysis of a cluster-randomized, double-blind, placebo-controlled trial. Lancet 2009; 374: 1694-701; PMID: 19819004; http://dx.doi.org/10.1016/S0140-6736(09)61297-6
7. World Health Organization. Cholera vaccines: WHO position paper. Wkly Epidemiol Rec 2010; 85: 117-28; PMID:20349546

8. Clemens JD. Vaccines in a time of cholera. Proc Natl Acad Sci 2011; 108(21): 8529-30; PMID: 21562216; http://dx.doi.org/10.1073/pnas.1105807108
9. Reyburn R, Deen JL, Grais RF, Bhattacharya SK, Sur D, Lopez AL, Jiddawi MS, Clemens JD, von Seidlein L. The Case for Reactive Mass Oral Cholera Vaccinations. PLoS Negl Trop Dis 2011; 5(1): e952; PMID: 21283614; http://dx.doi.org/10.1371/journal.pntd.0000952
10. Verma R, Khanna P, Chawla S. Cholera vaccine: new preventive tool for endemic countries. Hum Vaccin Immunother 2012; 8(5): 682-4; PMID:22634452; http://dx.doi.org/10.4161/hv.19083
11. Kaljee L, Pham V, Son ND, Hoa NT, Thiem VD, Canh do G, Thoa le TK, Ali M, Ochiai RL, Danovero-Holliday MC et al. Trial participation and vaccine desirability for Vi polysaccharide typhoid fever vaccine in Hue City, Viet Nam. Trop Med Int Health 2007; 12(1): 25-36. PMID:17207145; http://dx.doi.org/10.1111/j.1365-3156.2006.01751.x
12. Kaljee L, Pach A, Stanton B. Applied anthropology, vaccine trials and feasibility studies: intersections of local knowledge, biomedicine, and policy. Practicing Anthropol 2011; 33(4): 39–43
13. Kaljee L, Pach A, Thriemer K, Ley B, Jiddawi M, Puri M, Ochiai L, Wierzba T, Clemens J, Ali SM. Desirability for a typhoid fever vaccine among rural residents, Pemba Island Tanzania. Vaccine 2013; 24:2994-9; http://dx.doi.org/10.1016/j.vaccine.2013.04.058
14. Sur D, Manna B, Chakrabarty N, Kaljee LM, Riel R, Pach A, Kunungo S, Deen J, Ochiai RL, Clemens JD et al. Vaccine desirability during an effectiveness trial of the typhoid fever polysaccharide Vi vaccine, Kolkata India. Hum Vaccin Immunther 2009; 5(9): 614-20. PMID: 19652547; http://dx.doi.org/10.4161/hv.9313
15. Schaetti C, Hutubessy R, Ali SM, Pach A, Weiss MG, Chaignat CL, Khatib AM. Oral cholera vaccine use in Zanzibar: socio-economic and behavioral features affecting demand and acceptance. BMC Public Health 2009; 9:9; PMID:19351401; http://dx.doi.org/10.1186/1471-2458-9-99
16. Kar SK, Sah B, Patnaik B, Kim YH, Kerketaa AS, Shin S, Rath SB, Ali M, Mogasale V, Khuntia HK et al. Mass vaccination with a new, less expensive oral cholera vaccine using public health infrastructure in India: the Odisha model. PLoS Negl Trop Dis 2014; 8(2): e2629; PMID:24516675; http://dx.doi.org/10.1371/journal.pntd.0002629
17. Schaetti C, Ali SM, Hutubessy R, Khatib AM, Chaignat CL, Weiss MG. Social and cultural determinants of oral cholera vaccine up-take in Zanzibar. Hum Vaccin Immunther 2012; 8(9): 1223-9; http://dx.doi.org/10.4161/hv.20901
18. Sundaram N, Schaetti C, Chaignat CL, Hutubessy R, Nyambedha EO, Mbonga LA, Weiss MG. Socio-cultural determinants of anticipated acceptance of an oral cholera vaccine in Western Kenya. Epidemiol Infect 2013; 8: 1-12; http://dx.doi.org/10.1017/S0950268812000829
19. Kaljee L, Pach A, Thriemer K, Ley B, Ali S, Jiddawi M, Puri M, von Seidlein L, Deen J, Ochiai L, Wierzba T, Clemens J. Utilization and accessibility of health care on Pemba Island, Tanzania: implications for health outcomes and surveillance for typhoid fever. Am J Trop Med Hyg 2013; 88(1): 144-52; PMID: 23208887; http://dx.doi.org/10.4269/ajtmh.2012.12-0288
20. Nichter M. Vaccinations in the Third World: a consideration of community demand. In: Nichter M, Nichter M, editors. Anthropology and International Health. Amsterdam: Gorden and Breach Publishers, 1996; 329-66.
21. Streefland P, Chowdury AMR, Ramos-Jimenez P. Patterns of vaccination. Soc Sci Med 1999; 49: 1705-16; PMID:10574240; http://dx.doi.org/10.1016/S0277-9536(99)00239-7
22. World Health Organization. Typhoid vaccines: WHO position paper. Wkly Epidemiol Rec 2008; 83: 49-60; PMID:18260212
23. Kaljee, LM, Pack R, Pach A, Nyamete A, Stanton BF. Sociobehavioral research methods for the introduction of vaccines in the diseases of the most impoverished programme. J Health Popul Nutr 2004; 22(3): 293-303; PMID:15609782