Mass vaccination with a two-dose oral cholera vaccine in a long-standing refugee camp, Thailand

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A B S T R A C T

Background: During 2005–2012, surveillance in Maela refugee camp, Thailand, identified four cholera outbreaks, with rates up to 10.7 cases per 1000 refugees. In 2013, the Thailand Ministry of Public Health sponsored a two-dose oral cholera vaccine (OCV) campaign for the approximately 46,000 refugees living in Maela.
Methods: We enumerated the target population (refugees living in Maela who are ≥1 year old and not pregnant) in a census three months before the campaign and issued barcoded OCV cards to each individual. We conducted the campaign using a fixed-post strategy during two eight-day rounds plus one two-day round for persons who had missed their second dose and recorded vaccine status for each individual. To identify factors associated with no vaccination (versus at least one dose) and those associated with adverse events following immunization (AEFI), we used separate marginal log-binomial regression models with robust variance estimates to account for household clustering.
Results: A total of 63,057 OCV doses were administered to a target population of 43,485 refugees. An estimated 35,399 (81%) refugees received at least one dose and 27,658 (64%) received two doses. A total of 993 additional doses (1.5%) were wasted including 297 that were spat out. Only 0.05% of refugees, mostly children, could not be vaccinated due to repeated spitting. Characteristics associated with no vaccination (versus at least one dose) included age ≥15 years (versus 1–14 years), Karen ethnicity (versus any other ethnicity) and, only among adults 15–64 years old, male sex. Passive surveillance identified 84 refugees who experienced 108 AEFI including three serious but coincidental events. The most frequent AEFI were nausea (49%), dizziness (38%), and fever (30%). Overall, AEFI were more prevalent among young children and older adults.
Conclusions: Our results suggest that mass vaccination in refugee camps with a two-dose OCV is readily achievable and AEFI are few.

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1. Introduction

Exclusive use of clean drinking water and good sanitation and hygiene are the most effective means of preventing epidemic cholera and many other diseases, yet these basic measures are still deficient in many places. Some public health authorities have proposed the use of oral cholera vaccine (OCV) as a complementary measure in areas at risk for cholera [1,2]. A whole-cell killed OCV with recombinant cholera toxin B subunit, Dukoral® ( Crucell/SBL Vaccine, Sweden), has been available for more than two decades but at a prohibitive price for mass vaccination in resource-constrained...
settings. A less expensive, more easily administered, and similarly constituted OCV (minus the B subunit), Shan chol™ (Shantha Biotechnics, India), was licensed for the first time in India in 2009 and prequalified by the World Health Organization (WHO) in 2011, bringing at the time more attention and debate to the public health role of cholera vaccination [3].

Refugee camps, often overcrowded, are vulnerable to epidemic cholera when environmental conditions are unsanitary [4–6]. These conditions are more commonly seen in crisis situations but can also occur in established camps. Maela refugee camp, created in 1984 in northern Thailand, is one such long-standing yet vulnerable camp. Maela provides shelter for approximately 46,000 predominately Karen refugees from Burma and has experienced recurring cholera outbreaks since at least 2005 (data for prior years are not available). Maela is administered by the Royal Thai Government’s Ministry of Interior, while international non-governmental organizations (NGOs) provide essential services. The NGO Première Urgence—Aide Médicale Internationale (PU—AMI) has provided health services since 2005. In 2013, the Thailand Ministry of Public Health (MOPH) sponsored a two-dose Shan chol™ OCV campaign, partnering with PU—AMI and the U.S. Centers for Disease Control and Prevention (CDC) for implementation and evaluation. We review the history of cholera in Maela and describe the campaign including estimated coverage, factors associated with vaccine uptake, vaccine wastage, adverse events following immunization (AEFI), and factors associated with AEFI.

2. Methods

2.1. Cholera surveillance review

We reviewed PU—AMI cholera surveillance data from 2005 through 2012. From 2008 through 2012, all patients seeking care for acute watery diarrhea with moderate or severe dehydration during a confirmed outbreak received confirmatory testing (isolation of toxigenic Vibrio cholerae O1): before 2008, during a confirmed outbreak, some patients were presumptively diagnosed. Confirmatory testing was performed by a government hospital using Cary–Blair media for transport and thiosulfate citrate bile salts sucrose agar for isolation. Suspected V. cholerae colonies were tested by slide agglutination with specific monoclonal antibodies to identify the serogroup (O1 or O139) and serotype (Ogawa or Inaba).

2.2. Pre-campaign information, education, and communication activities

In the months leading up to the campaign, PU—AMI began providing information about cholera, prevention, and vaccination in meetings with camp-based governance committees, religious and civic leaders, and school principals and teachers. These leaders in turn informed their constituencies through town hall meetings, the camp newsletter, and informal communications. Social mobilization also included personal communications by PU—AMI community health workers during routine home visits. Other communications included classroom presentations, posters, and reminders via loudspeaker on the days leading up to the campaign.

2.3. Census and vaccine cards

PU—AMI conducted a pre-campaign census in October–November 2012, three months before the start of the vaccine campaign. Census workers, themselves refugees living in Maela, administered a standard questionnaire to one adult (≥ 18 years) member of each household and cross-checked demographic data with household food ration books. The census questionnaire collected individual-level data on name, sex, age, ethnicity, and length of residency in Maela and household-level information on environmental and behavioral characteristics related to water, sanitation, and hygiene. Upon completion, PU—AMI distributed barcoded OCV cards to each person identified in the census.

2.4. Campaign strategy

PU—AMI conducted the campaign in two rounds open to all eligible refugees plus a third, shorter round for refugees who had already received their first, but not their second, dose. The rounds took place two weeks apart in January, February, and March 2013, before the start of the rainy season. PU—AMI used a fixed-post strategy plus mobile teams (who offered vaccine to house-bound refugees, hospital inpatients, and children at some schools). The first two rounds lasted eight days each. The third round lasted two days.

Each post was staffed by 20–25 workers. Entry screeners obtained consent (verbally as illiteracy is high), screened for the excluded conditions of pregnancy (by self-report) or age <1 year, and scanned OCV cards or issued temporary cards. Vaccinators opened each vaccination vial, ensured the entire dose was consumed, and offered a second dose (but not a third dose) in the case of spitting or vomiting. Exit controllers marked the back of the hand of the vaccinated with indelible markers in order to avoid inadvertent revaccination during a single round. After ingesting the vaccine, water was offered for the vaccinees’ comfort and to reduce spitting. In response to frequent complaints about taste, PU—AMI flavored the water with syrup to help wash away the taste.

2.5. Vaccine registry

For refugees who sought vaccination and brought their barcoded OCV cards to the campaign, staff scanned the card to record date, time, and vaccine status for each refugee. For refugees who came without their OCV cards and refugees who were vaccinated off-site by mobile teams, staff issued temporary cards to capture this information. After the campaign, PU—AMI attempted to find each temporary cardholder in the census database, matching by name, date of birth or age, sex, address, and ration book number. Temporary cards that could not be matched were accounted for during statistical analysis as described below.

2.6. Adverse events following immunization

To detect AEFI on campaign days, staff encouraged refugees to wait in a designated area for 30 min immediately after ingesting the vaccine. Staff observed refugees and notified medics when AEFI occurred. Medics at camp clinics monitored inpatient and outpatient admissions for AEFI from the first day of each round through 14 days after the last day for a given round. All serious adverse events were investigated to assess a causal relationship with vaccination.

2.7. Statistical analysis

Because we determined first versus second dose according to the date of vaccination as recorded on OCV cards and temporary cards, the failure to identify some temporary cardholders in the census database introduced uncertainty into our estimate of vaccine coverage. For example, if a refugee was vaccinated during round two, received a temporary card, and could not be matched to a person in the census database, then we do not know whether that round two dose was a first dose (refugee did not attend round one) or a second dose (refugee brought an OCV card to round one but not round two). To account for this uncertainty, we calculated the minimum and maximum vaccine coverage statistics according to two different assumptions:
**Assumption A.** All refugees with only one documented dose truly received only that dose, regardless of the round during which it was received.

**Assumption B.** When refugees with only one documented dose received that dose during round two or three, the dose received was truly a second dose.

For the first dose coverage statistics, the maximum was calculated by including all those with at least one documented dose, regardless of round (Assumption A); the minimum was calculated by excluding those refugees with one documented dose when that dose was received during round two or three (Assumption B). For the second dose coverage statistics, the maximum was calculated by including all who received two documented doses plus all who received a single dose during round two or three, even when a first dose was not documented (Assumption B); the minimum was calculated by excluding those with only one documented dose, even when received during round two or three (Assumption A). We chose the midpoint as the best estimate of coverage.

To identify factors associated with no vaccination (versus receipt of at least one dose) and those associated with AEFI, we calculated prevalence ratios (PR) and 95% confidence intervals (CI) using separate marginal log-binomial regression models with robust variance estimates to account for clustering by household. We did not attempt to model full and partial vaccination separately because of the potential for misclassification as discussed above.

### 3. Results

#### 3.1. Cholera surveillance

From 2005 through 2012, surveillance identified 1540 suspected cholera cases. Testing was performed for 1161 (75%) of these cases, and V. cholerae O1 Ogawa or Inaba was isolated from 691 (60%) of those tested (Table 1). Cholera cases among camp residents were detected in 2005, 2007, 2008, and 2010, and the incidence ranged from 0.7 to 10.7 cholera cases per 1000 refugees (Table 1). On-going surveillance detected no cases in 2006, 2009, 2011, or 2012. The three largest outbreaks began in May (2010), June (2005), and July (2007), coinciding with the start of the rainy season, and lasted 17–26 weeks (Fig. 1). The age and sex distribution of cases in each of the three outbreaks followed a similar pattern: on average, adults 15–49 years old represented the largest proportion of cases (44%), followed by children 5–14 years old (27%), younger children 1–4 years old (18%), and finally adults ≥50 years old (10%); incidence rates were highest among younger children and older adults (Fig. 2). The majority of cases were male (58%, 57%, and 55% in 2005, 2007, and 2010, respectively) and incidence rates were higher among males of all ages with the exception of children 1–4 years old in 2010 (Fig. 3). The 2008 outbreak was smaller (26 confirmed cases), began in late October, and lasted just six weeks. Across all four outbreaks, 10 case-patients (two confirmed, eight presumed) were infants aged <1 year. Only one case (in 2010 in a pregnant woman) was fatal, for an overall case-fatality proportion of 0.1%.

#### 3.2. Camp population

At the time of the census, the camp population totaled 45,524 refugees, including 22,758 (50%) males, 1129 (2%) children <1 year old, and 4874 (11%) children 1–4 years old. Three-fourths of refugees were ethnic Karen. The population lived in 7831 households, including 7797 private houses (median: 5 people per house) and 34 boarding houses. Most (88%) houses had a private toilet, usually pour-flush pit latrines. Most (91%) toilet areas had water,

![Fig. 1. Seven-day moving average of cholera case (confirmed or presumed) counts for years when outbreaks occurred.](image1)

![Fig. 2. Cholera cases (confirmed or presumed) per 1000 refugees by age group for years when outbreaks occurred.](image2)

<table>
<thead>
<tr>
<th>Year</th>
<th>Tested by culture</th>
<th>Not tested</th>
<th>V. cholerae serogroup and serotype</th>
<th>Population</th>
<th>Cases* per 1000 refugees</th>
</tr>
</thead>
</table>
|      | Negative | Confirmed | Presumed      | O1 Ogawa  |                          | 48,174 | 10.7
| 2005 | 80       | 194       | 320           | O1 Ogawa  |                          | 47,731 | 7.3
| 2006 | 110      | 114       | 59            | O1 Inaba   |                          | 46,613 | 3.7
| 2007 | 81       | 26        | 0             | O1 Inaba   |                          | 38,724 | 0.7
| 2008 | 199      | 357       | 0             | O1 Ogawa  |                          | 43,459 | 8.2
| 2010 | 159      | 357       | 0             | O1 Ogawa  |                          | 47,078 | 8.2
| 2011 | 159      | 357       | 0             | O1 Ogawa  |                          | 48,283 | 8.2

* No cholera cases were detected in 2006, 2009, 2011, or 2012.

* Confirmed or presumed.

1 356 cases of V. cholerae O1 Ogawa and 1 case of O1 Inaba detected.
but half (48%) lacked soap. A third (31%) of households reported collecting drinking water from less safe sources (private wells and boreholes, water sellers, and natural springs, as opposed to chlorinated water supplied by an NGO).

3.3. Vaccine registry

Eighty percent (29,032 out of 36,325) of refugees who sought vaccination brought their OCV cards to the campaign, where the barcodes were scanned and their information updated with date, time, and vaccine status. The remaining 20% (7293) did not bring their OCV cards and were therefore issued temporary cards. Among these 7293 temporary cardholders, 68% (4927) could not be matched to people in the census database. Most of these unmatched temporary cardholders are likely represented in the census database but unidentifiable due to complicating factors such as the transliteration of names, unknown birthdates, lack of addresses, and lack of official identification numbers. Others are not in the database including those who were absent during the census, established residency after the census, or attended the campaign as visitors.

3.4. Vaccine campaign

Among 45,524 refugees living in Maesl, 1129 children aged <1 year and an estimated 910 pregnant women were not eligible for vaccination, leaving a target population of 43,485 refugees. During the 18 days of the campaign, 63,057 OCV doses were administered as intended to the target population. Only 0.05% of refugees, mostly children, spat out the vaccine on two consecutive attempts and thus could not be vaccinated. In addition, seven refugees unintentionally received a third dose. The screening process identified 358 pregnant women and 709 infants <1 year old in round one, 240 pregnant women and 469 infants in round two, and 12 pregnant women and 21 infants in round three. None of the women who reported a pregnancy received vaccine but 21 infants inadvertently received a single dose.

We estimated first dose coverage at 81% (minimum: 79%, maximum: 83%) and second dose coverage at 64% (minimum: 62%, maximum: 66%). Coverage was higher for children (1–14 years) and slightly higher for females; coverage was lowest among working-age (15–64 years) males. In multivariate models, remaining unvaccinated (versus receiving at least one dose) was associated with age ≥15 years, living in the camp for ≤5 years or >10 years, and Karen ethnicity (Table 2). Being unvaccinated was also associated with male sex (PR: 1.1; 95% CI: 1.1–1.2) but only among working-age adults. Factors not associated with vaccination status included household size, socioeconomic status, exclusive use of safe water, and markers of household hygiene.

### Table 2

Characteristics associated with no vaccination versus receipt of at least one dose.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Prevalence ratio (95% confidence interval)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td></td>
</tr>
<tr>
<td>1–14 years</td>
<td>1</td>
</tr>
<tr>
<td>15–64 years</td>
<td>1.5 (1.4–1.6)</td>
</tr>
<tr>
<td>≥65 years</td>
<td>2.0 (1.9–2.2)</td>
</tr>
<tr>
<td>Residency</td>
<td></td>
</tr>
<tr>
<td>≤5 years</td>
<td>1.1 (1.1–1.2)</td>
</tr>
<tr>
<td>6–10 years</td>
<td>1</td>
</tr>
<tr>
<td>≥10 years</td>
<td>1.3 (1.3–1.4)</td>
</tr>
<tr>
<td>Ethnicity</td>
<td></td>
</tr>
<tr>
<td>Karen</td>
<td>1.2 (1.1–1.3)</td>
</tr>
<tr>
<td>Other</td>
<td>1</td>
</tr>
</tbody>
</table>

* Adjusted for factors shown in the table plus sex and sex × age 15–64 years. Associations with age were constant by sex but association with sex varied by age group. In stratified analysis adjusted for residency and ethnicity, male sex was associated no vaccination among adults 15–64 years (prevalence ratio: 1.1; 95% confidence interval: 1.1–1.2) but sex was not associated with no vaccination among children 1–14 years or adults ≥65 years.

3.5. Unused vaccine and wasted vaccine

MOPH purchased 90,000 doses for this campaign. As indicated by vaccine vial monitors, all vials were maintained at an acceptable temperature prior to use. A total of 64,078 vials were opened, of which 993 (1.5%) were wasted. Among these 993 wasted doses, 297 were spit out. The remaining 696 vials cannot be accounted for precisely, but hundreds were wasted when workers, in preparation, pried the caps off vials that were then not consumed. Additional explanations include miscounts and theft. MOPH used remaining nearly 26,000 doses in other campaigns for migrant populations in Thailand.

3.6. Adverse events following immunization

PU–AMI documented 84 refugees with 108 AEFI, most frequently nausea (49%), dizziness (38%), and fever (30%), followed by itchiness/rash (5%) or other symptoms (7%). As compared with refugees 5–64 years old and adjusting for sex, AEFI were more prevalent among children 1–4 years old (PR: 2.7; 95% CI: 1.6–4.5) and adults ≥64 years old (PR: 2.9; 95% CI: 1.0–8.2, p < 0.05). No AEFI were documented among the 21 refugees <1 year old who were inadvertently vaccinated. Although not statistically significant, AEFI were more prevalent among females of all ages (PR: 1.6; 95% CI: 0.94–2.7; p < 0.09). Two serious adverse events required inpatient hospitalization. One patient, a 50 year old woman, was admitted for nausea, palpitations, and difficulty breathing the day after ingesting her first dose of vaccine. She was discharged 8 h later with a diagnosis of anxiety. The other patient, a 21 year old woman who was 3 weeks postpartum, was admitted for self-reported fever, cough, and tremor 2 days after ingesting her first dose of vaccine. She was treated with antibiotics and antiinflammatory medication and released after three days. The third serious event was a death in a 73 year old homebound man with a terminal illness. Although visibly ill, the patient’s terminal condition was not known to the mobile vaccination team at the time the vaccine was administered. Following this event, vaccinators were retrained to seek guidance from medical officers before administering vaccine to ill people. Upon investigation, none of the three serious adverse events were judged to be caused by vaccination.

4. Discussion

Recent years have seen a resurgence of interest in vaccination as a complement to traditional measures for cholera prevention. Our results suggest that mass vaccination with a two-dose OCV
in a refugee camp setting is feasible and AEFI are few. PU—AMI was critical to success as this organization was already a familiar and trusted source for health information and services for Maela refugees.

In deciding to conduct an OCV campaign in Maela, the MOPH considered surveillance data indicating that cholera causes significant morbidity for the approximately 46,000 refugees living there. Other factors included the perceived economic and political limitations to improved water and sanitation. An international NGO provides clean water in Maela in accordance with Sphere standards [7]. However, many water sources of questionable quality remain, including river water, boreholes and shallow wells, and commercial bottled water. Efforts to improve water and sanitation in Maela, such as distribution of covered water containers with taps and sand filters to treat turbid water sources, were undertaken after the 2007 and 2008 outbreaks. Although these measures likely reduced the risk of water-borne diseases, another cholera outbreak occurred in 2010. Additional improvements, such as construction of enduring sanitary infrastructure including a waste-treatment facility, were not permitted because the camp is not intended to be permanent.

Ultimately, the MOPH determined the burden of cholera was sufficiently high and the likelihood of imminent and adequate improvements to the sanitary environment sufficiently low to warrant a vaccine intervention. Shanchol™ was chosen in consideration of its affordability and ease of administration as compared with Dukoral®. Because surveillance data indicate a cholera season from May to November, the campaign was timed to occur in the off season. Because past cholera outbreaks affected all ages and both sexes, vaccination was offered to the entire camp population except for children <1 year and pregnant women. The manufacturer’s package insert does not recommend Shanchol™ for use in these two groups citing a lack of safety and efficacy data, although the insert goes on to state that Shanchol™ is, in theory, safe for the fetus and may be considered for use in pregnant women [8].

The resultant campaign achieved high (81%) first dose coverage, a proportion similar to that reported elsewhere [9–11], but relatively modest (64%) second dose coverage. Possible explanations for lower second dose coverage include: communications after the first round to dispel rumors that vaccination would improve opportunities for resettlement; an increase in competing activities during the second round; routine migration out of the camp for seasonal work between rounds; and, as suggested by frequent complaints during the first round, aversion to the taste. Working-age men were at greatest risk for remaining unvaccinated. As with other interventions and studies [12–14], we observed few AEFI. Better understanding of barriers to second-dose uptake in general and uptake among men in particular, including qualitative assessments, and strategies to overcome those obstacles are needed.

Field studies have observed vaccine effectiveness of 78–79% up to 14 months after vaccination [15,16] and a recent report suggests that Shanchol™ is 65% effective five years after vaccination [17]. We have not yet been able to directly measure the effectiveness of the 2013 Maela campaign because no cholera cases have since occurred as of November 2015. Further compounding an assessment of the impact of vaccination, surveillance data from PU—AMI outpatient clinics indicate that non-cholera watery diarrhea declined from 9.6 to 5.7 cases per 1000 refugees from 2009 to 2014 (unpublished data), which could indicate water, sanitation, or hygiene improvements during this period. In other words, it is not clear whether the absence of cases since the 2013 is due to the OCV intervention; general improvements in water, sanitation, or hygiene; other factors; or a combination of factors. Cholera surveillance, including weekly laboratory testing for a sample of watery diarrhea cases, has been continuously maintained since the campaign and will continue for the foreseeable future.

Two studies have observed an inverse relationship between cholera risk for unvaccinated people and neighborhood coverage [18,19], and simulated models of cholera transmission predict substantial indirect protection for unvaccinated people in highly endemic settings with just 50–70% coverage [20]. This phenomenon may provide indirect protection to unvaccinated pregnant women (and children <1 year); even so, excluding pregnant women from direct protection by vaccination, as was done here, is concerning. Cholera during pregnancy is associated with poor fetal outcomes, including fetal loss [21]. Indeed, in Maela, the only fatal case was a pregnant woman. Data to support the use of OCVs during pregnancy, or clearly establish a contraindication, are wanted.

Shanchol™ is only available in single-dose vials resulting in low wastage but large volume. Although PU—AMI had sufficient supplies for routine immunizations, the cold chain requirements of Shanchol™ during transport, storage, and administration necessitated procuring additional supplies and complicated campaign logistics. As other investigators have concluded [22], improved packaging and efforts to define the minimal cold chain requirements should be pursued. Other significant remaining questions included cost-effectiveness, length of protection (whether and when to offer a booster dose or conduct future campaigns), and the impact of population mobility on effectiveness.

More than a century ago, cholera was a major driver for the sanitary revolution that reduced the risk of many enteric diseases and overall mortality in many places [23,24] yet today many other places with fewer resources are still burdened by diseases caused by unsafe water and poor sanitation. Vaccination against cholera rouses debate because it draws attention to these unacceptable health disparities. OCVs address a small but highly visible part of the spectrum of waterborne diseases and are recommended as a complement to the traditional measures of safe water and adequate hygiene. The documentation of field experiences contributes to a better understanding of the life-saving potential of cholera vaccination while identifying features that need improvement to optimize delivery and impact.

Disclaimer

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of CDC.

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Conflict of interest statement

None.
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