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A pre-emptive Oral Cholera Vaccine (OCV) mass vaccination campaign in Cuamba District, Niassa Province, Mozambique: feasibility, costs and vaccine coverage

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3 **1 A pre-emptive Oral Cholera Vaccine (OCV) mass vaccination campaign in Cuamba District, Niassa**
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5 **2 Province, Mozambique: feasibility, costs and vaccine coverage**
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2
3 **22 Abstract**
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8 **24 Objectives:** To evaluate the feasibility and costs of vaccination and vaccine coverage of a pre-emptive
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10 **25** Oral Cholera Vaccine (OCV) mass vaccination campaign in a rural, remote, and cholera endemic setting
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12 **26** in Cuamba District, Mozambique, generating evidence to guide future vaccination campaigns in similar
13
14 **27** settings.
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16 **28**

17
18 **29 Design:** World Health Organization (WHO) prequalified OCV (Euvichol-Plus), a killed whole-cell
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20 **30** bivalent vaccine containing *Vibrio cholerae* O1 (classical and El Tor) and O139, administered in two-
21
22 **31** doses with a 15-day interval in August 7-11 and August 27-31, 2018. Microplanning and community
23
24 **32** sensitization conducted prior to the campaign. Vaccine coverage rates and feasibility measured through
25
26 **33** coverage survey and vaccination registry, and vaccination costs using CholTool.
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31 **35 Setting:** Cuamba District located in Niassa province of Mozambique.
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35 **37 Participants:** Approximately 180,000 people aged above one year living in Cuamba District targeted for
36
37 **38** vaccination. Households in vaccination target area randomly selected for vaccine coverage survey.
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41 **40 Primary and secondary outcome measures:** Vaccine coverage estimates and costs of OCV mass
42
43 **41** vaccination campaign evaluated as primary outcome. Feasibility and barriers of vaccination measured as
44
45 **42** secondary outcome.
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49
50 **44 Results:** Administrative vaccine coverage of the first and second rounds of campaign were 98.9%
51
52 **45** (194,581) and 98.8% (194,325) respectively. Coverage survey exhibited 75.9% ($\pm 2.2\%$) and 68.5%
53
54 **46** ($\pm 3.3\%$) vaccine coverages for the first and second rounds, respectively. Overall, 60.4% ($\pm 3.4\%$) of the
55
56 **47** target population received full two-doses of OCV. No severe adverse events following immunization
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3 48 were notified. Financial cost per dose delivered was US\$0.60 without vaccine cost and US\$1.98 including
4
5 49 vaccine costs.
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7 50
8
9 51 **Conclusion:** The introduction of a pre-emptive OCV mass vaccination campaign in rural cholera endemic
10
11 52 setting in Mozambique was technically and programmatically feasible with reasonable full-dose vaccine
12
13 53 coverage to confer sufficient herd immunity for at least the next three to five years. The vaccination cost
14
15 54 estimate indicates affordability of OCV vaccination campaign, comparable to Gavi's operational support
16
17 55 for vaccination.
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20 56
21
22 57 **Key words:** Cholera, OCV, pre-emptive vaccination, Cuamba, Mozambique, coverage survey,
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24 58 feasibility, vaccination cost
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59 **Strengths and limitations of this study**

- 60 • This pre-emptive OCV mass vaccination campaign conducted in Cuamba District is the first and only
61 OCV (Euvichol-Plus) vaccination conducted in the Niassa Province of Mozambique until the date of
62 this manuscript submission, demonstrating its feasibility and acceptability in rural and remote setting
63 in Mozambique.
- 64 • Randomized survey of households in the community documented vaccine coverage in the target
65 population.
- 66 • Evaluation of barriers to OCV vaccination were communicated by the target population and
67 documented through the community survey.
- 68 • Community survey identified effective communication strategies for community engagement and
69 sensitization for each round of the OCV mass vaccination campaigns.
- 70 • Costs associated with conducting a mass vaccination campaign using a two-dose OCV (Euvichol-
71 Plus) documented through retrospective data collection and analysis.

73 **Introduction**

74 Cholera is a vaccine preventable disease that remains as a major public health concern in many parts of
75 low- and middle-income countries (LMICs). A comprehensive policy measure is warranted to control and
76 prevent cholera including investments in improving infrastructure and knowledge, attitude, and behavior
77 associated with water, sanitation, and hygiene (WaSH), strengthening health system, and adequate use of
78 oral cholera vaccine (OCV) (1). In Mozambique, cholera has been endemic since the early 1970's when
79 the first cholera outbreak was reported in the country. Several epidemics followed since then including
80 the outbreaks in 1997-1999 and 2012-2016 (2, 3). Cholera outbreaks are more frequent in the country's
81 northern provinces including Nampula, Cabo Delgado, Tete, and Niassa (4). Following the reinforcement
82 of cholera outbreak response strategies, the Ministry of Health (MOH) of Mozambique has carried out
83 several OCV mass vaccination campaigns, as recommended by the World Health Organization (WHO) as

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3 84 an integral part of a comprehensive strategy for cholera prevention and control in endemic setting along
4
5 85 with primary interventions of WaSH measures (5): Recent cholera outbreaks in these cholera endemic and
6
7 86 hotspot areas in December 2015 resulted in the use of global OCV emergency stockpile to vaccinate
8
9 87 approximately 212,745 people living in six neighborhoods of Nampula city in 2016 (4); and in April
10
11 88 2017, another 709,077 doses from the stockpile to vaccinate approximately 354,550 people in Tete City
12
13 89 and Moatize and Mutarara districts, in response to the cholera outbreak with over 3,592 cholera cases.
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18 91 In addition to these reactive vaccination campaigns supported by the WHO International Coordinating
19
20 92 Group (ICG) on vaccine provision for cholera, a growing need for a preventive public health intervention
21
22 93 using a targeted vaccination approach in cholera priority areas in-country was identified. The past records
23
24 94 of numerous episodes of cholera epidemics in Mozambique have spotted at-risk districts in the most
25
26 95 cholera endemic provinces such as Nampula (particularly Nampula City), Niassa (Lichinga city and
27
28 96 Cuamba and Lago Districts), and Cabo Delgado (Pemba City and Ancuabe District), and to a lesser
29
30 97 degree, other provinces and districts with limited sanitary conditions (5). Niassa province, one of the
31
32 98 cholera endemic regions with annual cholera outbreaks affecting largely the Lichinga City and Lago and
33
34 99 Cuamba Districts, was identified for a planned pre-emptive vaccine introduction to prevent subsequent
35
36 100 cholera outbreaks. Cuamba District with an estimated population of 264,572 (6), reports over 200
37
38 101 suspected cholera and 2,000 diarrheal cases almost every year, with an exception of 2014 and 2016 (7).
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40 102 Here, we describe the feasibility, costs, and coverage estimates associated with a pre-emptive OCV mass
41
42 103 vaccination campaign conducted in Cuamba District using two-dose OCVs (Euvichol-Plus) administered
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44 104 to approximately 180,000 people with a 15-day interval between the doses, as well as challenges of
45
46 105 delivering healthcare in resource limited rural setting in Mozambique.
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51 107 **Methods**

52 108 53 54 109 *Study site and population*

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3 110 The Cuamba District is located in Niassa Province with a population size of around 264,572 (6). The site
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5 111 was selected for a pre-emptive OCV mass vaccination campaign as the district includes the Cuamba
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7 112 Municipality area where cholera is found to be endemic with periodic outbreaks. The area was also
8
9 113 highlighted by the WHO as one of the priority sites to consider for a potential OCV intervention during a
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11 114 needs-assessment performed in September 2015 (1). The District of Cuamba is composed of a total 36
12
13 115 bairros and povoados with population size of approximately 264,572 (6), which includes 21 bairros in the
14
15 116 Cuamba Municipality area with around 137,640 residents (8). In total, approximately 180,000 individuals
16
17 117 living in Cuamba District was targeted initially, and ultimately around 196,652 people living in Cuamba
18
19 118 District were targeted, which included 20 Bairros in the Municipality area and 10 Povoados in the
20
21 119 outskirts of the Municipality area (Figure 1). Selection of bairros and povoados in the outskirts of
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23 120 Cuamba Municipality within the District was made not only based on the high number of doses destined
24
25 121 for the target population in the municipality area, but also the records of cholera cases during the
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27 122 outbreaks. Everyone above one year of age were eligible for the two-dose OCV administration.
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33 124 ***Vaccine delivery, storage, and handling***

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35 125 Approximately 360,000 doses of WHO pre-qualified Euvichol-Plus, a killed whole-cell bivalent OCV
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37 126 containing *Vibrio cholerae* O1 (classical and El Tor) and O139, were procured from the manufacturer
38
39 127 (EuBiologics) and shipped to the entry port in Pemba, Mozambique in cold-chain. Upon arrival in
40
41 128 Mozambique, the vaccines were delivered to Lichinga by airfreight and transported to a central vaccine
42
43 129 storage room in Cuamba project site, and kept in refrigerators with temperature maintained within range
44
45 130 between 2-8°C until and throughout the campaign. The vaccine vial monitor (VVM) and electronic
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47 131 shipping indicators (Q-Tag) were used to monitor the temperature of the vaccines during delivery,
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49 132 storage, and handling. During the vaccination campaign, cool boxes with dry ice maintained within 2-8°C
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52 133 were used to carry the vaccines to the vaccination posts.
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135 ***Cost of vaccine delivery***

136 An openly available, standardized and validated Excel-based tool known as the CholTool was used for
137 estimating vaccine delivery costs (9). This tool comprehensively estimates programmatic costs such as
138 microplanning, communication and training materials development, sensitization/social mobilization, and
139 personnel training, as well as costs related to vaccine delivery such as vaccine procurement, handling,
140 storage, and transport, vaccination administration, monitoring supervision, and field support. The
141 CholTool has the ability to estimate both financial and economic costs. Financial costs refer to the
142 monetary costs to the payer (e.g. allowances, supplies, transport and resources used in micro-planning,
143 training, and sensitization/social mobilization) while economic costs include financial costs along with
144 non-monetary costs of donated goods and resources already available (e.g., health personnel time).
145 Key informant interviews were conducted at various administrative levels before, during and after the
146 vaccination campaign in order to identify the resources necessary for each vaccination related activity and
147 costs of respective resources for each of the two rounds of vaccination. The resource and cost data were
148 entered in CholTool which auto-calculates OCV delivery costs. The costs were reported in 2018 in United
149 States Dollars (US\$) based on government and payer perspective.

150

151 ***Vaccination Strategy and microplanning***

152 A fixed-post vaccination strategy with additional mobile teams was adapted for the microplanning of the
153 vaccination campaign. The vaccination teams for 15 fixed posts (healthcare facilities) and 33 mobile
154 teams were identified and trained prior to the campaign. This adopted mixed vaccination strategy aimed
155 to improve quality, accessibility, and coverage. Each post was staffed with around 5 field workers
156 including 2 health workers and 3 community engagement workers. Five days prior to the vaccination
157 campaign, micro-plans for each cluster were prepared with postal addresses, target populations,
158 vaccination dates, teams, and other site-specific resources. The health workers obtained verbal informed
159 consents from the individuals visiting the vaccination posts for the OCV administration. Pregnant women
160 by self-report or infants below one year old were excluded from the vaccination. Vaccination cards and

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3 161 vaccination registry book were developed and deployed, specific to this vaccination that included
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5 162 variables such as name, age, address, and vaccination date. The collected data in the vaccine registry book
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7 163 were entered in an excel-based database. The number of doses planned and administered were also
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9 164 recorded daily for each round of the vaccination campaign.
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14 166 *Vaccination, adverse event monitoring, and coverage estimate*

16 167 The vaccination campaign occurred in two rounds with a 15-day interval. The first round took place
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18 168 during August 7-11, followed by the second round during August 27–31, 2018. Provision was made for
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20 169 mop-up activities after the second round for those who missed the second dose. To detect any possible
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22 170 adverse events following immunization (AEFI) during and after the campaign, health workers were
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24 171 trained to monitor and notify any adverse events encountered in inpatient and outpatient admissions at
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26 172 Cuamba health facilities from the first day of each round throughout the 15 days after the last day of each
27
28 173 round. Coverage estimates were assessed in two-folds; administrative coverage and community vaccine
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30 174 coverage surveys. Community vaccine coverage surveys included daily monitoring of vaccine coverage
31
32 175 in relations to vaccine dose usage, conducted during each rounds of the campaign, and a final coverage
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34 176 survey conducted following the completion of the second-round campaign to measure the vaccine
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36 177 coverage of two full doses of OCV administration.
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41 179 The vaccine coverage survey was carried out by a team composed of 16 interviewers distributed across 5
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43 180 teams. Each team conducted 26 interviews daily, totaling 572 instead of 650 for the 5 days of the first
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45 181 phase of the campaign, as some data were excluded due to inconsistency. For the second phase of the
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47 182 coverage survey, 714 households were visited and interviewed for the final coverage monitoring and
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49 183 evaluation survey. Performance of the vaccination campaign was monitored through daily surveys using
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51 184 questionnaires to collect daily information on vaccine coverage, barriers against OCV, and source of
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53 185 information on the campaign. The survey results were communicated to the vaccination campaign field
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55 186 teams and the local government officials in real-time, allowing them to refine the outreach strategies
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3 187 during the campaign. For both the daily monitoring and final coverage surveys, a two-stage cluster
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5 188 random sampling was used, where each cluster (primary sampling unit) was selected from the list of
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7 189 villages in the Health Zones, according to the Probability Proportional to Population Size (PPS), and
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9 190 households (secondary sampling unit) were chosen by segmentation of the sectors resulting in maximum
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11 191 15 households, followed by numbering of households and random selection to start the survey interviews.
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13 192 The final vaccine coverage was also calculated after converting the daily coverages to that of the final day
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15 193 by multiplying the ratio of the final vaccine consumption to that of each day, based on an assumption that
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17 194 vaccine coverage is linearly correlated with vaccine use. For each variable, the prevalence was estimated
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19 195 with 95% confidence interval.
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23 24 197 ***Ethics statement***

25
26 198 The vaccination campaign was conducted as a part of the government's public health intervention,
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28 199 approved by the Ministry of Health. Institutional Ethical Committee of the National Institute of Health
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30 200 (Ref: 116/CNBS/19) and ethical review board of the International Vaccine Institute, Seoul, Korea (IRB
31
32 201 number 2017-006) approved the study protocol for the OCV mass vaccination campaign monitoring and
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34 202 coverage survey. Oral informed consent was obtained from eligible participants. For children, consents
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36 203 were obtained from parents/guardian and all adult participants provided their own consent. The study did
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38 204 not present any risk of harm to subjects. No biological samples were collected. Minimum data was
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40 205 collected from participants, whereby privacy and confidentiality of the data were ensured during the
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42 206 survey implementation and data entry and management.
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46 47 208 ***Patient and public involvement***

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49 209 The participants in this study were people living in the cholera endemic and hotspot area, targeted for
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51 210 OCV vaccination campaign as an integral part of the government's cholera prevention efforts. The
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53 211 vaccination target population living in Cuamba District were sensitized and engaged, prior to and during
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55 212 the vaccination campaign, by the district and provincial health officials, study team that included the
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3 213 Ministry of Health and National Institute of Health government officials, and local public health
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5 214 professionals at healthcare facilities. The participants were provided with information on the planned
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7 215 OCV mass vaccination such as the purpose of pre-emptive vaccination and detailed information on where
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9 216 and when the vaccination campaigns were to take place. The vaccination campaign was also announced
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11 217 through various press and social media in Mozambique for public awareness and involvement. The study
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13 218 was conducted in a transparent manner with open communication and information sharing in the
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15 219 community, and participants to the OCV vaccination and vaccine coverage survey were informed for oral
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17 220 consent. Stakeholder meetings were also conducted prior to, during, and after the vaccination campaign to
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19 221 further disseminate the campaign plan and results to the community members.
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23 24 223 **Results**

25 26 224 *OCV vaccine coverage*

27
28 225 The administrative coverage of the first and the second rounds of the campaign were 98.9% (194,581) and
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30 226 98.8% (194,325) respectively based on the available census data of vaccination target population in
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32 227 Cuamba Municipality and outskirts, estimated at around 196,652 (6) inhabitants (Table 1a). A total of
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34 228 194,581 people over one-year-old received the first dose, out of whom 99,275 were females and 122,592
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36 229 were children aged less than 15 years. For the second round, total 194,325 people were vaccinated,
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38 230 including 99,275 females and 120,169 children less than 15 years old. Notably, the vaccine coverage
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40 231 survey conducted in the target community during each round and post-vaccination exhibited an
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42 232 approximate coverage estimates of 75.9% (95 CI, 78.10 - 73.70%) for the first round and 68.5% (71.80 -
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44 233 65.20%) for the second round. The coverage rate for the full two-doses was estimated at 60.4% (63.80 -
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46 234 57.00%), whereby the coverage of children aged 1-5 years was around 64.4 % (57.10 – 71.10%) (Table
47
48 235 1b). No adverse events were reported during and after the vaccination activities, monitored up to 14 days
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50 236 post-vaccination campaign.
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55 56 238 *Source of Information and Acceptability*

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3 239 The source of information on the OCV vaccination campaign, identified by the populations living in the
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5 240 vaccination target areas, showed use of megaphone as the most effective tool in disseminating
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7 241 information on the vaccination plan and mobilizing the community to get immunized for both rounds:
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9 242 24% and 34% at the first and second rounds respectively (Table 2). Around 15% of the surveyed people
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11 243 in the target community indicated that they have learnt about the vaccination campaign through radio
12
13 244 broadcast for the first round, but its communication impact reduced in the second round (4%). This was
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15 245 different for the community leaders, whose contribution increased from 5% in the first round to 19% in
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17 246 the following round, reflecting their active engagement and communication efforts in close coordination
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19 247 with the vaccination teams on the ground.
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24 249 ***Reasons for not being vaccinated***

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26 250 The unavailability (absence) of the target population for vaccination and incompatibility between working
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28 251 hours and campaign schedule were commonly cited as barriers for vaccination in both the first (35%) and
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30 252 the second round (51%) (Table 3). Absence of vaccinators at the vaccination sites were also mentioned,
31
32 253 12% and 18% for the first and second round respectively, despite the pre-vaccination planning and
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34 254 programmatic organization. Notably, around 10% of the target population has indicated that they have not
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36 255 been informed about the vaccination campaign even in the second round, though this was a reduction
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38 256 compared to 18% in the first round. In order to address the most common barriers identified in the first
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40 257 round, the second round of the vaccination campaign was further extended for additional few days
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42 258 including the weekends, enabling more people to get vaccinated.
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47 260 ***OCV delivery costs***

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49 261 The total financial cost of campaign was US\$768,904 of which vaccine acquisition including vaccine
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51 262 shipment constituted 69% (US\$533,659) (Table 4). The vaccine delivery costs including, microplanning,
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53 263 training, communication, and social mobilization, vaccination implementation (Round 1 & 2) constituted
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55 264 rest 31% (US\$235,245). The total financial cost per dose delivered was US\$0.60 without the vaccine cost
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3 265 and US\$1.98 including the vaccine costs in 2018 price. The economic cost per dose delivered excluding
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5 266 vaccine costs was five times higher at US\$3.02. The total financial cost of delivery per fully immunized
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7 267 person excluding vaccine costs was US\$1.21.
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11 269 **Conclusion**

13 270 The OCV campaign in Cuamba District was organized without major logistical and programmatic
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15 271 challenges, and no adverse events were reported throughout the vaccination activities and up to 14 days
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17 272 after the campaign. Despite the similarity in the number of people vaccinated in the first and second
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19 273 rounds, the vaccine coverage survey of the second round showed lower coverage estimates than the first
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21 274 round. This may be due to possible cross border movement of people from untargeted districts to get
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23 275 vaccination during the second round. The vaccine coverage for the full two-doses was over 60% that may
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25 276 confer sufficient herd immunity for the following several years based on the existing literature on a
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27 277 cholera transmission model using the Matlab data from Bangladesh (10,11), which predicted 50%
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29 278 coverage with OCV in cholera endemic areas may result in 89% reduction in cholera cases in
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31 279 unvaccinated (12).
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37 281 In our study, children aged 5-14 years exhibited the highest coverage. This may be due to the vaccination
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39 282 posts in both schools (fixed vaccination post) and near homes (mobile vaccination posts), which
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41 283 facilitated the school-aged children to access the immunization health service more easily. The female
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43 284 group also presented higher vaccine coverage rate compared to the male group, likely associated with
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45 285 their routine boundaries of livelihood near their houses or their child/children's schools as they take care
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47 286 of children while the male group typically work outside. This assumption is supported by the fact that the
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49 287 absence during the campaign was identified as a significant barrier against vaccination during both rounds
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51 288 of the campaign. Similar pattern was consistently prevalent in the previous OCV campaigns in Beira (13)
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53 289 and Nampula (4), whereby absence was the main barrier for vaccination. The second round of the
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55 290 campaign coincided with the period of school holidays when most households move to farming and food
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3 291 production, resulting in higher absence rate in the second round (43.0%) than in first round (17.0%).
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5 292 Further, it is encouraging to observe more than 60% vaccine coverage rate among children aged 1-4
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7 293 years, the most at-risk population age-group concerning cholera outbreaks. Considering that caregivers
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9 294 for these younger children are mostly women, higher vaccine coverage for these toddlers and younger
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11 295 children and women is as anticipated in accordance with other studies published in similar settings (14).
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16 297 In order to enhance the vaccine coverage, it is paramount to better understand the effective means of
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18 298 communications for community sensitization and engagements, as well as barriers towards participating
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20 299 in a vaccination program such as this campaign. Here, we showed that the use of megaphone proved to be
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22 300 the most effective advocacy tool for disseminating information on the vaccination to our target
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24 301 community, which may have allowed the field workers to reach out to families without access to other
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26 302 sources of information. For those with missed opportunities to receive the OCV doses during the two
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28 303 rounds, a mop-up vaccination can be considered, though it is often more laborious and costly, requiring a
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30 304 complex management (13). Further, informing the public on the availability of a mop-up prior to or
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32 305 during the campaign may negatively affect their participation in the regular vaccination schedule set-up.
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34 306 Hence, a mop-up was not considered after the first round in our approach, but pursued after the second
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36 307 round in order to enhance the full two-dose vaccination and verify vaccination data records submitted
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38 308 during the regular program. Approximately 15.4% (32,775/212,824) of the delivered second doses were
39
40 309 through this mop-up campaign indicative of an effective strategy.
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45 311 The financial costs of OCV delivery per fully immunized person in this campaign was lower than delivery
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47 312 costs reported in other African countries using the same CholTool (US\$1.8 in Shashemene district of
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49 313 Ethiopia; US\$2.5 in Nsanje district of Malawi; and US\$3.5 in Machinga, Phalombe, and Zomba districts
50
51 314 of Malawi per the US\$ price value of 2016), but closer to that reported in Puri district of India (US\$1.14
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53 315 per the US\$ price value of 2016) (9). One reason could be that Mozambique has experience of conducting
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55 316 several OCV campaigns in recent years, and hence there were already resources and expertise available
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3 317 for micro-planning, communication, sensitization, trainings etc., which might have reduced the costs
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5 318 associated with introduction of vaccines in comparison to a vaccination programs in naïve setting. The
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7 319 financial cost of US\$0.60 per dose delivered (excluding vaccine procurement) is comparable to the
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9 320 operational support ranging between US\$0.30 and US\$0.80 per person targeted for vaccination
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11 321 campaigns, recommended by the Gavi, the Vaccine Alliance (15,16). This indicates the affordability of
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13 322 OCV campaign in the current setting.
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17
18 324 Overall, our study proved the feasibility of conducting a preemptive OCV mass vaccination campaign in a
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20 325 rural and semi-rural setting in Cuamba District and Cuamba Municipality areas respectively, with
21
22 326 sufficient coverage rate and relatively lower delivery cost. The success of vaccination was a result of
23
24 327 effective coordination and microplanning among stakeholders despite some field challenges. The
25
26 328 vaccination strategy utilizing both fixed and mobile posts, as well as the daily feedback to the
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28 329 coordination team on the preliminary coverage survey result and data related to barriers and source of
29
30 330 information on the vaccination campaign, proved valuable to prospectively refine the campaign and
31
32 331 mobilization strategy every day on a real-time basis.
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37 333 However, there are several limitations. First, the operational challenges concerning poor road conditions
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39 334 resulted in the accessibility to the target area difficult. Second, the programmatic support that required
40
41 335 sufficient and trained human resources and budget for a sustained field monitoring activity and close on-
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43 336 site supervision prior to and during the vaccination campaign and coverage survey activities. Third, the
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45 337 differences in the coverage rates of administrative data and survey result are due to the lack of accurate
46
47 338 up-to-date census data of local population. In addition, in order to avoid any conflict with the measles and
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49 339 rubella national immunization campaign that was taking place across the country at the time of this
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51 340 vaccination campaign, we had to delay our OCV vaccination campaign for about two months to obtain
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53 341 support from immunization-related stakeholders, particularly the expanded programme of immunization
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3 342 (EPI) for cold chain space and logistics. Any mass vaccination campaigns should also consider
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5 343 seasonality and other major community activities and/or any political issues.
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7 344

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17 349 support.
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22 351 **Contributors**

23
24 352 S.E.P conceptualized the overall study design of the Mozambique Cholera Prevention and Surveillance:
25
26 353 MOCA) project. N.S.B. conceptualized and supervised vaccination campaign and monitoring and
27
28 354 evaluation study component. J.C., N.L, and the project field team in Cuamba and Niassa contributed to
29
30 355 data acquisition on the community vaccine coverage survey, and interpretation of results under the
31
32 356 supervision of N.S.B. R.B.J.M., S.A., A.O., M.M., and others in the vaccination teams of Cuamba District
33
34 357 and Niassa Province contributed to acquisition on the administrative coverage data. J.C. drafted and
35
36 358 edited the paper under the scientific guidance from N.S.B and S.E.P. All authors read and approved the
37
38 359 final draft.
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41 360

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54 366 **Competing interests**

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56 367 The authors declare no competing interests.
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5 369 **Data sharing statement**

7 370 All data is presented in this manuscript. No additional data available.
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10 371

11 372 **Figure legends**

13 373

14 374 **Figure 1. Pre-emptive OCV mass vaccination site**

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17 376 Location of the pre-emptive OCV vaccination campaign site in Cuamba District, Mozambique, included

18 377 bairros and povoados in the municipality and district.
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Table 1. OCV vaccine coverage estimates, Cuamba District, 2018**a) Administrative vaccine coverage rates of OCV**

		Number of people vaccinated (No.)						Total
		Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	
1st Dose	Age (year)							
Individuals vaccinated per age group	1-4	6,493	9,283	12,394	12,506	7,691	-	48,367
	5-15	7,050	16,705	21,590	17,536	11,344	-	74,225
	≥15	10,136	12,400	18,835	18,798	11,820	-	71,989
Total no. of daily vaccinated		23,679	38,388	52,819	48,840	30,855	-	194,581
Cumulative no. of vaccinated		23,679	62,067	114,886	163,726	194,581	-	
Cumulative administrative coverage		12.04%	31.56%	58.42%	83.26%	98.95%	-	98.95%
2nd Dose								
Individuals vaccinated per age group	1-4	5,479	6,484	11,117	9,596	7,760	7,586	48,022
	5-15	9,355	8,796	15,679	13,208	14,444	10,665	72,147
	≥15	9,416	9,275	14,271	14,265	14,848	12,081	74,156
Total no. of daily vaccinated		24,250	24,555	41,067	37,069	37,052	30,332	194,325
Cumulative no. of vaccinated		24,250	48,805	89,872	126,941	163,993	194,325	
Cumulative administrative coverage		12.33%	24.82%	45.70%	64.55%	83.39%	98.82%	98.82%

b) OCV vaccine coverage rates through coverage survey

		First Round	Second Round	Full Two Doses
Age (years old)	1- 4	81.1±4.5%	72.2±6.9%	64.4±7.3%
	5-14	86.4±3.1%	71.3±5.8%	65.2±6.1%
	≥15	67.6±3.3%	65.2±4.8%	55.7±5.0%
Sex	Male	76.3±2.9%	77.8±3.9%	57.3±4.6%
	Female	75.4±3.2%	67.7±5.0%	64.4±5.1%
Total	-	75.9±2.2%	68.5±3.3%	60.4±3.4%

388 **Table 2. Source of information on OCV campaign, Cuamba District, 2018**

389

Source of information	1 st Round ¹ N= 646 n (%=n/N)	2 nd Round ² N= 578 n (%=n/N)
Megaphone	152 (24%)	195 (34%)
Family	60 (9%)	53 (9%)
Radio	96 (15%)	23 (4%)
Religious leader	82 (13%)	25 (4%)
Health workers	74 (11%)	120 (21%)
Activists	55 (9%)	9 (2%)
Community leader	33 (5%)	108 (19%)
TV	14 (2%)	11 (2%)
Others ³	78 (12%)	33 (6%)

390 Footnote:

391 ¹ 1st round: 646 households/or people were interviewed.

392 ² 2nd round: 578 households/or people were interviewed.

393 ³ Others included: list other source of info if such data were collected.

394 **Table 3. Reasons for non-vaccination during the OCV campaign, Cuamba District, 2018**

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Reasons for non-vaccination	1 st Dose		2 nd Dose	
	n=361	%	n=222	%
Unavailable	63	17%	96	43%
Incompatibility between working hours and campaign time	53	15%	18	8%
Vaccination post without vaccinator	40	11%	41	18%
Did not have information	66	18%	23	10%
Ill during the vaccination period	30	8%	10	5%
Does not believe in vaccine efficacy	24	7%	2	1%
Afraid of adverse events	8	2%	0	0%
Head of the family did not authorize	4	1%	2	1%
Religious leader forbid	2	1%	0	0%
Considered not safe for pregnant women	1	0%	2	1%
Other	70	19%	28	13%

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Table 4. Costs of OCV vaccine delivery and immunization in Cuamba District

Vaccine Delivery Costs	Financial Cost (Mzn)	Economic Cost (Mzn)	Financial Cost (USD)	Economic Cost (USD)
Vaccine Acquisition	32,179,644	42,081,073	533,659	697,862
Microplanning	640,415	7,596,625	10,620	125,981
Training	265,186	299,419	4,398	4,965
Communication and Social Mobilization	1,912,520	4,301,342	31,717	71,332
Vaccination Implementation (Round 1 &2)	11,367,160	58,510,806	188,510	970,328
Total	46,364,925	112,789,265	768,904	1,870,469
Immunization Costs	Financial Cost (Mzn)	Economic Cost (Mzn)	Financial Cost (USD)	Economic Cost (USD)
Cost per Vaccine Administered (including vaccine)	119	290	1.98	4.81
Cost per Vaccine Administered (without vaccine cost)	36	182	0.60	3.02
Cost per Partially Immunized Person	238	580	3.95	9.61
Cost per Fully Immunized Person (with vaccine)	239	580	3.96	9.63
Cost per Fully Immunized Person (without vaccine)	73	364	1.21	6.03

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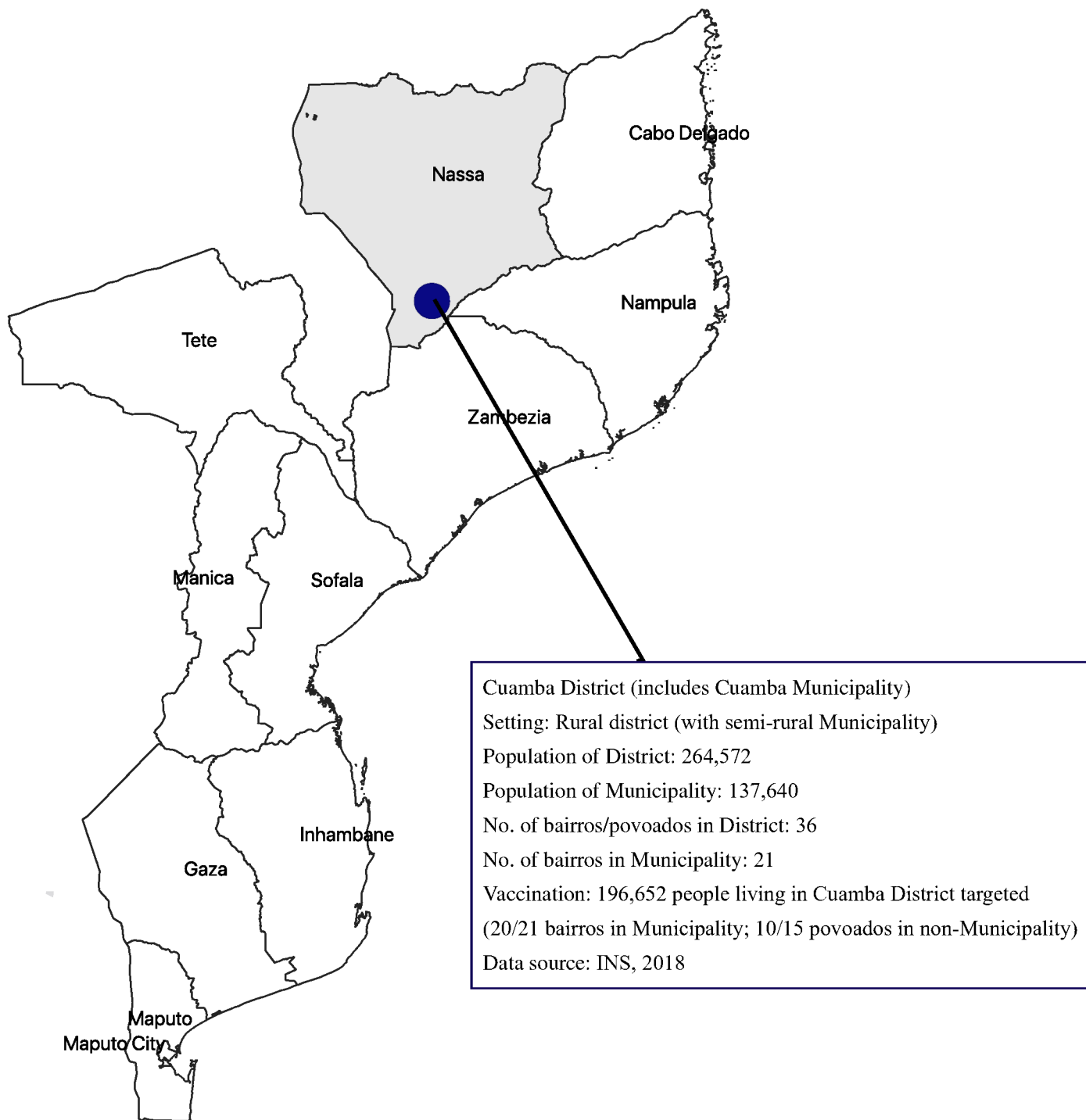


Figure 1. Pre-emptive OCV mass vaccination site

BMJ Open

A pre-emptive Oral Cholera Vaccine (OCV) mass vaccination campaign in Cuamba District, Niassa Province, Mozambique: feasibility, costs and vaccination coverage

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3 **1 A pre-emptive Oral Cholera Vaccine (OCV) mass vaccination campaign in Cuamba District, Niassa**
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5 **2 Province, Mozambique: feasibility, costs and vaccination coverage**
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3 **22 Abstract**
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5 **23**
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7 **24 Background:** Mozambique suffers from regular floods along its principal river basins and periodic
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9 **25** cyclones that resulted in several cholera epidemics during the last decades. Cholera outbreaks in the
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11 **26** recent five years affected particularly the northern provinces of the country including Nampula and
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13 **27** Niassa provinces. A pre-emptive Oral Cholera Vaccine (OCV) mass vaccination campaign was conducted
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15 **28** in Cuamba District, Niassa Province, and the feasibility, costs, and vaccination coverage assessed.
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20 **30 Method:** World Health Organization prequalified OCV (Euvichol-Plus), a killed whole-cell bivalent
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22 **31** vaccine containing *Vibrio cholerae* O1 (classical and El Tor) and O139, was administered in two-doses
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24 **32** with a 15-day interval during 7-31 August 2018, targeting around 180,000 people aged above one year in
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26 **33** Cuamba District. Microplanning, community sensitization, and trainings of local public health
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28 **34** professionals and field enumerators were conducted. Feasibility and costs of vaccination were assessed
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30 **35** using CholTool. Vaccination coverage and barriers were assessed through community surveys.
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35 **37 Findings:** The administrative coverage of the first and second rounds of the campaign were 98.9%
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37 **38** (194,581) and 98.8% (194,325) respectively based on the available population data that estimated total
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39 **39** 196,652 inhabitants in the target area. The vaccination coverage survey exhibited 75.9% ($\pm 2.2\%$) and
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41 **40** 68.5% ($\pm 3.3\%$) coverages for the first and second rounds, respectively. Overall, 60.4% ($\pm 3.4\%$) of the
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43 **41** target population received full two-doses of OCV. Barriers to vaccination included incompatibility
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45 **42** between working hours and campaign time. No severe adverse events were notified. The total financial
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47 **43** cost per dose delivered was US\$0.60 without vaccine cost and US\$1.98 including vaccine costs.
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52 **45 Conclusion:** The pre-emptive OCV mass vaccination campaign in remote setting in Mozambique was
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54 **46** feasible with reasonable full-dose vaccination coverage to confer sufficient herd immunity for at least the
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3 47 next three to five years. The delivery cost estimate indicates that the OCV campaign is affordable as it is
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5 48 comparable to Gavi's operational support for vaccination campaigns.
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9 50 **Key words:** Cholera, OCV, pre-emptive vaccination, Cuamba, Mozambique, vaccination coverage
11 51 survey, feasibility, vaccination cost
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For peer review only

52 **Strengths and limitations of this study**

- 53 • This study has successfully demonstrated the feasibility of an OCV mass vaccination campaign in a
54 remote setting in Mozambique.
- 55 • The cost of a mass vaccination campaign for the two-dose OCV administrations has been analysed for
56 the first time in Mozambique, which can serve as a reference cost estimate when planning for any
57 OCV vaccination programs in a similar setting in Mozambique or other countries.
- 58 • Vaccination coverage estimates may be affected if there are people movements in and out of the study
59 area. A sub-study on this and a focused community engagement strategy to reduce the identified
60 barriers to vaccination should be considered in future vaccination programs.

62 **Introduction**

63 Cholera is a vaccine preventable disease that remains as a major public health concern in many parts of
64 low- and middle-income countries (LMICs). A comprehensive policy measure is warranted to control and
65 prevent cholera including investments in improving infrastructure and knowledge, attitude, and behavior
66 associated with water, sanitation, and hygiene (WaSH), strengthening health system, and adequate use of
67 oral cholera vaccine (OCV) (1). In Mozambique, cholera has been endemic since the early 1970's when
68 the first cholera outbreak was reported in the country. Several epidemics followed since then including
69 the outbreaks in 1997-1999 and 2012-2016 (2, 3). Cholera outbreaks are more frequent in the country's
70 northern provinces including Nampula, Cabo Delgado, Tete, and Niassa (4). Following the reinforcement
71 of cholera outbreak response strategies, the Ministry of Health (MOH) of Mozambique has carried out
72 several OCV mass vaccination campaigns, as recommended by the World Health Organization (WHO) as
73 an integral part of a comprehensive strategy for cholera prevention and control in endemic setting along
74 with primary interventions of WaSH measures (5): Recent cholera outbreaks in these cholera endemic and
75 hotspot areas in December 2015 resulted in the use of global OCV emergency stockpile to vaccinate
76 approximately 212,745 people living in six neighborhoods of Nampula city in 2016 (4); and in April

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3 77 2017, another 709,077 doses from the stockpile to vaccinate approximately 354,550 people in Tete City
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5 78 and Moatize and Mutarara districts, in response to the cholera outbreak with over 3,592 cholera cases.
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9 80 In addition to these reactive vaccination campaigns supported by the WHO International Coordinating
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11 81 Group (ICG) on vaccine provision for cholera, a growing need for a preventive public health intervention
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13 82 using a targeted vaccination approach in cholera priority areas in-country was identified. The past records
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15 83 of numerous episodes of cholera epidemics in Mozambique have spotted at-risk districts in the most
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17 84 cholera endemic provinces such as Nampula (particularly Nampula City), Niassa (Lichinga city and
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19 85 Cuamba and Lago Districts), and Cabo Delgado (Pemba City and Ancuabe District), and to a lesser
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21 86 degree, other provinces and districts with limited sanitary conditions (5). Niassa province, one of the
22
23 87 cholera endemic regions with annual cholera outbreaks affecting largely the Lichinga City and Lago and
24
25 88 Cuamba Districts, was identified for a planned pre-emptive vaccine introduction to prevent subsequent
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27 89 cholera outbreaks. Cuamba District with an estimated population of 264,572 (6), reports over 200
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29 90 suspected cholera and 2,000 diarrheal cases almost every year, with an exception of 2014 and 2016 (7).
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31 91 Here, we describe the feasibility, costs, and coverage estimates associated with a pre-emptive OCV mass
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33 92 vaccination campaign conducted in Cuamba District using two-dose OCVs (Euvichol-Plus) administered
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35 93 to approximately 180,000 people with a 15-day interval between the doses, as well as challenges of
36
37 94 delivering healthcare in resource limited rural setting in Mozambique.
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43 96 **Methods**

47 98 *Study site and population*

49 99 The Cuamba District is located in Niassa Province with a population size of around 264,572 (6). The site
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51 100 was selected for a pre-emptive OCV mass vaccination campaign as the district includes the Cuamba
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53 101 Municipality area where cholera is found to be endemic with periodic outbreaks. The area was also
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55 102 highlighted by the WHO as one of the priority sites to consider for a potential OCV intervention during a
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3 103 needs-assessment performed in September 2015 (1). The District of Cuamba is composed of a total 36
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5 104 bairros and povoados with population size of approximately 264,572 (6), which includes 21 bairros in the
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7 105 Cuamba Municipality area with around 137,640 residents (8). In total, approximately 180,000 individuals
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9 106 living in Cuamba District was targeted initially, and ultimately around 196,652 people living in Cuamba
10
11 107 District were targeted, which included 20 Bairros in the Municipality area and 10 Povoados in the
12
13 108 outskirts of the Municipality area (Figure 1). Selection of bairros and povoados in the outskirts of
14
15 109 Cuamba Municipality within the District was made not only based on the high number of doses destined
16
17 110 for the target population in the municipality area, but also the records of cholera cases during the
18
19 111 outbreaks. Everyone above one year of age were eligible for the two-dose OCV administration.
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23 24 113 ***Vaccine delivery, storage, and handling***

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26 114 Approximately 360,000 doses of WHO pre-qualified Euvichol-Plus, a killed whole-cell bivalent OCV
27
28 115 containing *Vibrio cholerae* O1 (classical and El Tor) and O139, were procured from the manufacturer
29
30 116 (EuBiologics) and shipped to the entry port in Pemba, Mozambique in cold-chain. Upon arrival in
31
32 117 Mozambique, the vaccines were delivered to Lichinga by airfreight and transported to a central vaccine
33
34 118 storage room in Cuamba project site, and kept in refrigerators with temperature maintained within range
35
36 119 between 2-8°C until and throughout the campaign. The vaccine vial monitor (VVM) and electronic
37
38 120 shipping indicators (Q-Tag) were used to monitor the temperature of the vaccines during delivery,
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40 121 storage, and handling. During the vaccination campaign, cool boxes with dry ice maintained within 2-8°C
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42 122 were used to carry the vaccines to the vaccination posts.
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46 123 47 48 124 ***Cost of vaccine delivery***

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50 125 An openly available, standardized and validated Excel-based tool known as the CholTool was used for
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52 126 estimating vaccine delivery costs (9). This tool comprehensively estimates programmatic costs such as
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54 127 microplanning, communication and training materials development, sensitization/social mobilization, and
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3 128 personnel training, as well as costs related to vaccine delivery such as vaccine procurement, handling,
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5 129 storage, and transport, vaccination administration, adverse events following immunization (AEFI)
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7 130 management, monitoring supervision, and field support. The CholTool has the ability to estimate both
8
9 131 financial and economic costs. Financial costs refer to the monetary costs to the payer (e.g., allowances,
10
11 132 supplies, transport, and resources used in micro-planning, training, and sensitization/social mobilization)
12
13 133 while economic costs include financial costs along with non-monetary costs of donated goods and
14
15 134 resources already available (e.g., health personnel time). Key informant interviews were conducted at
16
17 135 various administrative levels before, during and after the vaccination campaign in order to identify the
18
19 136 resources necessary for each vaccination related activity and costs of respective resources for each of the
20
21 137 two rounds of vaccination. The resource and cost data were entered in CholTool which auto-calculates
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23 138 OCV delivery costs. The costs were reported in 2018 in United States Dollars (US\$) based on
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25 139 government and payer perspective.
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141 ***Vaccination Strategy and microplanning***

142 A fixed post vaccination strategy with additional mobile teams was adapted for the microplanning of the
143 vaccination campaign. The vaccination teams for 15 fixed posts and 33 mobile teams were identified and
144 trained prior to the campaign. The fixed posts included existing healthcare facilities such as primary
145 health centers and secondary and referral hospital, schools, market areas where many people have easy
146 access to. The mobile teams were deployed to households remotely located with limited access to these
147 fixed posts. This adopted mixed vaccination strategy aimed to improve quality, accessibility, and
148 coverage. Each post was staffed with around 5 field workers including 2 health workers and 3 community
149 engagement workers. Five days prior to the vaccination campaign, micro-plans for each cluster were
150 prepared with postal addresses, target populations, vaccination dates, teams, and other site-specific
151 resources. The health workers obtained verbal informed consents from the individuals visiting the
152 vaccination posts for the OCV administration. Pregnant women by self-report or infants below one year
153 old were excluded from the vaccination. Vaccination cards and vaccination registry book were developed

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3 154 and deployed, specific to this vaccination that included variables such as name, age, address, and
4
5 155 vaccination date. The collected data in the vaccine registry book were entered in an excel-based database.
6
7 156 The number of doses planned and administered were also recorded daily for each rounds of the
8
9 157 vaccination campaign.
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13 14 159 *Vaccination, adverse event monitoring, and coverage estimate*

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16 160 The vaccination campaign occurred in two rounds with a 15-day interval. The first round took place
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18 161 during August 7-11, followed by the second round during August 27–31, 2018. Provision was made for
19
20 162 mop-up activities after the second round for those who missed the second dose. To detect any possible
21
22 163 adverse events following immunization (AEFI) during and after the campaign, health workers were
23
24 164 trained to monitor and notify any adverse events encountered in inpatient and outpatient admissions at
25
26 165 Cuamba health facilities from the first day of each round throughout the 15 days after the last day of each
27
28 166 round.
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33 168 The vaccination coverage estimates were assessed in two-folds; administrative coverage and coverage
34
35 169 surveys. The administrative coverage was recorded by the local government health office in charge of the
36
37 170 vaccination campaign by tracking the number of vaccine doses administered compared to doses that had
38
39 171 been planned in the vaccination target areas, at the end of vaccination activities every day during the two
40
41 172 rounds of the OCV vaccination campaign. For the vaccination coverage surveys, around 520-650
42
43 173 households, subject to the vaccination schedule including the mop-up vaccination, were estimated to
44
45 174 ensure more than 550 samples for each age group (1-4 years, 5-14 years, 15 years and above) assuming
46
47 175 80% coverage with a design effect of 2 to achieve around 5% of prevision. Sampled households were
48
49 176 organized per cluster; total 20-25 clusters with 26 households per cluster. The households were selected
50
51 177 using a two-stage cluster random sampling methodology. Clusters (primary sampling unit) were selected
52
53 178 from the list of villages in the Health Zones, according to the Probability Proportional to Population Size
54
55 179 (PPS) and households (secondary sampling unit) were chosen randomly. For the household random
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3 180 sampling, the enumerators identified the center point and boundary of the survey target area and applied
4
5 181 random selection of households. The surveyors were recruited based on their knowledge on the local area
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7 182 and level of education to conduct the survey, and trained on household sampling methodology, structured
8
9 183 survey questionnaire, and process of conducting a survey interview, including verbal informed consent
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11 184 and data capturing on the paper-based survey questionnaires.
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16 186 Over the period of the OCV vaccination campaign, five survey teams were deployed to the predetermined
17
18 187 clusters for daily vaccination monitoring, where randomly identified 26 households per cluster (5 clusters
19
20 188 with total 130 households per day) were visited for 4-5 days (total 520-650 households) from the second
21
22 189 or third day of the campaign until one day after the last vaccination day. This was applied for each round
23
24 190 of the two-dose OCV vaccination campaigns. The information gathered through the survey on the vaccine
25
26 191 uptake in the previous day, barriers against the vaccination, and the information source on the campaign
27
28 192 were analyzed and fed daily to the vaccination campaign coordinators and supervisors in order to
29
30 193 facilitate overall vaccine uptakes. After the second round, the enumerators continued the household
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32 194 survey for additional three days to estimate the coverage of two full doses of vaccination.
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36 37 196 ***Patient and Public Involvement***

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39 197 The vaccination campaign was conducted as a part of the government's public health intervention,
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41 198 approved by the Ministry of Health (MOH) in Mozambique. The participants in this study were people
42
43 199 living in the cholera endemic and hotspot area, targeted for OCV vaccination campaign as an integral part
44
45 200 of the government's cholera prevention efforts. The vaccination target population living in Cuamba
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47 201 District were sensitized and engaged, prior to and during the vaccination campaign, by the district and
48
49 202 provincial health officials, study team that included the MOH and National Institute of Health
50
51 203 government officials, and local public health professionals at healthcare facilities. The participants were
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53 204 provided with information on the planned OCV mass vaccination such as the purpose of pre-emptive
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55 205 vaccination and detailed information on where and when the vaccination campaigns were to take place.
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3 206 The vaccination campaign was also announced through various press and social media in Mozambique
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5 207 for public awareness and involvement. The study was conducted in a transparent manner with open
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7 208 communication and information sharing in the community, and participants to the OCV vaccination and
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9 209 vaccination coverage surveys were informed for oral consent. For children, consents were obtained from
10
11 210 parents/guardian and all adult participants provided their own consent. The study did not present any risk
12
13 211 of harm to subjects. No biological samples were collected. Minimum data was collected from
14
15 212 participants, whereby privacy and confidentiality of the data were ensured during the survey
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17 213 implementation and data entry and management. Stakeholder meetings were conducted prior to, during,
18
19 214 and after the vaccination campaign to further disseminate the campaign plan and results to the community
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21 215 members.
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26 217 **Results**

28 218 *OCV vaccination coverage*

30 219 The administrative coverage of the first and the second rounds of the campaign were 98.9% (194,581) and
31
32 220 98.8% (194,325) respectively based on the available census data of vaccination target population in
33
34 221 Cuamba Municipality and outskirts, estimated at around 196,652 (6) inhabitants (Table 1). A total of
35
36 222 194,581 people over one-year-old received the first dose, out of whom 99,275 were females and 122,592
37
38 223 were children aged less than 15 years. For the second round, total 194,325 people were vaccinated,
39
40 224 including 99,275 females and 120,169 children less than 15 years old. Notably, the vaccination coverage
41
42 225 survey conducted in the target community during each round and post-vaccination exhibited an
43
44 226 approximate coverage estimates of 75.9% (95 CI, 78.10 - 73.70%) for the first round and 68.5% (71.80 -
45
46 227 65.20%) for the second round. The coverage rate for the full two-doses was estimated at 60.4% (63.80 -
47
48 228 57.00%), whereby the coverage of children aged 1-4 years was around 64.4 % (57.10 – 71.10%) (Table
49
50 229 1). The coverage rates in each round were higher in male (76.3% and 77.8%) than female (75.4% and
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52 230 67.7%), but coverage rate of full doses was higher in female (64.4%) than male (57.3%). No adverse
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3 231 events were reported during and after the vaccination activities, monitored up to 14 days post-vaccination
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234 **Table 1. OCV vaccination coverage estimates, Cuamba District, 2018**

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236 **a) Administrative vaccination coverage rates**

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		Number of people vaccinated (No.)						
		Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Total
1st Dose	Age (year)							
Individuals vaccinated per	1-4	6,493	9,283	12,394	12,506	7,691	-	48,367
age group	5-15	7,050	16,705	21,590	17,536	11,344	-	74,225
	≥15	10,136	12,400	18,835	18,798	11,820	-	71,989
Total no. of daily vaccinated		23,679	38,388	52,819	48,840	30,855	-	194,581
Cumulative no. of vaccinated		23,679	62,067	114,886	163,726	194,581	-	
Cumulative administrative coverage		12.04%	31.56%	58.42%	83.26%	98.95%	-	98.95%
2nd Dose								
Individuals vaccinated per	1-4	5,479	6,484	11,117	9,596	7,760	7,586	48,022
age group	5-15	9,355	8,796	15,679	13,208	14,444	10,665	72,147
	≥15	9,416	9,275	14,271	14,265	14,848	12,081	74,156
Total no. of daily vaccinated		24,250	24,555	41,067	37,069	37,052	30,332	194,325
Cumulative no. of vaccinated		24,250	48,805	89,872	126,941	163,993	194,325	
Cumulative administrative coverage		12.33%	24.82%	45.70%	64.55%	83.39%	98.82%	98.82%

238

239 **b) Vaccination coverage rates through coverage surveys**

240

		First Round	Second Round	Full Two Doses
Age (years old)	1- 4	81.1±4.5%	72.2±6.9%	64.4±7.3%
	5-14	86.4±3.1%	71.3±5.8%	65.2±6.1%
	≥15	67.6±3.3%	65.2±4.8%	55.7±5.0%
Sex	Male	76.3±2.9%	77.8±3.9%	57.3±4.6%
	Female	75.4±3.2%	67.7±5.0%	64.4±5.1%
Total	-	75.9±2.2%	68.5±3.3%	60.4±3.4%

241

242 *Source of Information and Acceptability*

243 The source of information on the OCV vaccination campaign, identified by the populations living in the
 244 vaccination target areas, showed use of megaphone as the most effective tool in disseminating
 245 information on the vaccination plan and mobilizing the community to get immunized for both rounds:
 246 24% and 34% at the first and second rounds respectively (Table 2). Around 15% of the surveyed people
 247 in the target community indicated that they have learnt about the vaccination campaign through radio
 248 broadcast for the first round, but its communication impact reduced in the second round (4%). This was
 249 different for the community leaders, whose contribution increased from 5% in the first round to 19% in
 250 the following round, reflecting their active engagement and communication efforts in close coordination
 251 with the vaccination teams on the ground.

252

253 **Table 2. Source of information on OCV campaign, Cuamba District, 2018**

254

Source of information	1 st Round ¹ N= 646 n (%=n/N)	2 nd Round ² N= 578 n (%=n/N)
Megaphone	152 (24%)	195 (34%)
Family	60 (9%)	53 (9%)
Radio	96 (15%)	23 (4%)
Religious leader	82 (13%)	25 (4%)
Health workers	74 (11%)	120 (21%)
Activists	55 (9%)	9 (2%)
Community leader	33 (5%)	108 (19%)
TV	14 (2%)	11 (2%)
Others ³	78 (12%)	33 (6%)

255 Footnote:

256 ¹ 1st round: 646 households/or people were interviewed.257 ² 2nd round: 578 households/or people were interviewed.258 ³ Others included: list other source of info if such data were collected.

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260

261 ***Reasons for not being vaccinated***

262 The unavailability (absence) of the target population for vaccination and incompatibility between working
 263 hours and campaign schedule were commonly cited as barriers for vaccination in both the first (35%) and
 264 the second round (51%) (Table 3). Absence of vaccinators at the vaccination sites were also mentioned,
 265 12% and 18% for the first and second round respectively, despite the pre-vaccination planning and
 266 programmatic organization. Notably, around 10% of the target population has indicated that they have not
 267 been informed about the vaccination campaign even in the second round, though this was a reduction
 268 compared to 18% in the first round. In order to address the most common barriers identified in the first
 269 round, the second round of the vaccination campaign was further extended for additional few days
 270 including the weekends, enabling more people to get vaccinated.

272 **Table 3. Reasons for non-vaccination during the OCV campaign, Cuamba District, 2018**

Reasons for non-vaccination	1 st Dose		2 nd Dose	
	n=361	%	n=222	%
Unavailable	63	17%	96	43%
Incompatibility between working hours and campaign time	53	15%	18	8%
Vaccination post without vaccinator	40	11%	41	18%
Did not have information	66	18%	23	10%
Ill during the vaccination period	30	8%	10	5%
Does not believe in vaccine efficacy	24	7%	2	1%
Afraid of adverse events	8	2%	0	0%
Head of the family did not authorize	4	1%	2	1%
Religious leader forbid	2	1%	0	0%
Considered not safe for pregnant women	1	0%	2	1%
Other	70	19%	28	13%

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3 275 ***OCV delivery costs***
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5 276 The total financial cost of campaign was US\$768,904 of which vaccine acquisition including vaccine
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7 277 shipment constituted 69% (US\$533,659) (Table 4). The vaccine delivery costs including, microplanning,
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9 278 training, communication, and social mobilization, vaccination implementation (Round 1 & 2) constituted
10
11 279 rest 31% (US\$235,245). The total financial cost per dose delivered was US\$0.60 without the vaccine cost
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13 280 and US\$1.98 including the vaccine costs in 2018 price. The economic cost per dose delivered excluding
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15 281 vaccine costs was five times higher at US\$3.02. The total financial cost of delivery per fully immunized
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17 282 person excluding vaccine costs was US\$1.21.
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284 **Table 4. Costs of OCV vaccine delivery and immunization in Cuamba District**

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Vaccine Delivery Costs	Financial Cost (Mzn)	Economic Cost (Mzn)	Financial Cost (USD)	Economic Cost (USD)
Vaccine Acquisition	32,179,644	42,081,073	533,659	697,862
Microplanning	640,415	7,596,625	10,620	125,981
Training	265,186	299,419	4,398	4,965
Communication and Social Mobilization	1,912,520	4,301,342	31,717	71,332
Vaccination Implementation (Round 1 &2)	11,367,160	58,510,806	188,510	970,328
Total	46,364,925	112,789,265	768,904	1,870,469
Immunization Costs	Financial Cost (Mzn)	Economic Cost (Mzn)	Financial Cost (USD)	Economic Cost (USD)
Cost per Vaccine Administered (including vaccine)	119	290	1.98	4.81
Cost per Vaccine Administered (without vaccine cost)	36	182	0.60	3.02
Cost per Partially Immunized Person	238	580	3.95	9.61
Cost per Fully Immunized Person (with vaccine)	239	580	3.96	9.63
Cost per Fully Immunized Person (without vaccine)	73	364	1.21	6.03

286

287 Discussion

288 The OCV campaign in Cuamba District was organized without major logistical and programmatic
289 challenges, and no adverse events were reported throughout the vaccination activities and up to 14 days
290 after the campaign. Despite the similarity in the number of people vaccinated in the first and second
291 rounds, the vaccination coverage survey of the second round showed lower coverage estimates than the
292 first round. This may be due to possible cross border movement of people from untargeted districts to get
293 vaccination during the second round. The vaccination coverage for the full two-doses was over 60% that
294 may confer sufficient herd immunity for the following several years based on the existing literature on a
295 cholera transmission model using the Matlab data from Bangladesh (10,11), which predicted 50%
296 coverage with OCV in cholera endemic areas may result in 89% reduction in cholera cases in
297 unvaccinated (12).

298
299 In our study, children aged 5-14 years exhibited the highest coverage. This may be due to the vaccination
300 posts in both schools (fixed vaccination post) and near homes (mobile vaccination posts), which
301 facilitated the school-aged children to access the immunization health service more easily. The female
302 group also presented higher full vaccination coverage rate compared to the male group, who showed
303 higher drop-out after first dose, likely associated with their routine boundaries of livelihood near their
304 houses or their child/children's schools as they take care of children while the male group typically work
305 outside. This assumption is supported by the fact that the absence during the campaign was identified as a
306 significant barrier against vaccination during both rounds of the campaign. Similar pattern was
307 consistently prevalent in the previous OCV campaigns in Beira (13) and Nampula (4), whereby absence
308 was the main barrier for vaccination. The second round of the campaign coincided with the period of
309 school holidays when most households move to farming and food production, resulting in higher absence
310 rate in the second round (43.0%) than in first round (17.0%). Further, it is encouraging to observe more
311 than 60% vaccination coverage rate among children aged 1-4 years, the most at-risk population age-group
312 concerning cholera outbreaks. Considering that caregivers for these younger children are mostly women,

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3 313 higher vaccination coverage for these toddlers and younger children and women is as anticipated in
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5 314 accordance with other studies published in similar settings (14).
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9 316 In order to enhance the vaccination coverage, it is paramount to better understand the effective means of
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11 317 communications for community sensitization and engagements, as well as barriers towards participating
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13 318 in a vaccination program such as this campaign. Here, we showed that the use of megaphone proved to be
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15 319 the most effective advocacy tool for disseminating information on the vaccination to our target
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17 320 community, which may have allowed the field workers to reach out to families without access to other
18
19 321 sources of information. This may also indicate the need to better understand the inter-personnel
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21 322 communication and community mobilization approach for future vaccination campaigns. For those with
22
23 323 missed opportunities to receive the OCV doses during the two rounds, a mop-up vaccination can be
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25 324 considered, though it is often more laborious and costly, requiring a complex management (13). Further,
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27 325 informing the public on the availability of a mop-up prior to or during the campaign may negatively affect
28
29 326 their participation in the regular vaccination schedule set-up. Hence, a mop-up was not considered after
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31 327 the first round in our approach but pursued after the second round in order to enhance the full two-dose
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33 328 vaccination and verify vaccination data records submitted during the regular program. Approximately
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35 329 15.4% (32,775/212,824) of the delivered second doses were through this mop-up campaign indicative of
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37 330 an effective strategy.
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43 332 The financial costs of OCV delivery per fully immunized person in this campaign was lower than delivery
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45 333 costs reported in other African countries using the same CholTool (US\$1.8 in Shashemene district of
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47 334 Ethiopia; US\$2.5 in Nsanje district of Malawi; and US\$3.5 in Machinga, Phalombe, and Zomba districts
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49 335 of Malawi per the US\$ price value of 2016), but closer to that reported in Puri district of India (US\$1.14
50
51 336 per the US\$ price value of 2016) (9). One reason could be that Mozambique has experience of conducting
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53 337 several OCV campaigns in recent years, and hence there were already resources and expertise available
54
55 338 for micro-planning, communication, sensitization, trainings etc., which might have reduced the costs
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3 339 associated with introduction of vaccines in comparison to a vaccination program in naïve setting. The
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5 340 financial cost of US\$0.60 per dose delivered (excluding vaccine procurement) is comparable to the
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7 341 operational support ranging between US\$0.30 and US\$0.80 per person targeted for vaccination
8
9 342 campaigns, recommended by the Gavi, the Vaccine Alliance (15,16). This indicates the affordability of
10
11 343 OCV campaign in the current setting. To economize the healthcare provider time and efforts and
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13 344 incentivize beneficiaries for greater uptake of vaccines, delivery of multiple products at vaccination posts
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15 345 or on household visits may potentially synergize the delivery cost associated with vaccination campaigns.
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20 347 Overall, our study proved the feasibility of conducting a preemptive OCV mass vaccination campaign in a
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22 348 rural and semi-rural setting in Cuamba District and Cuamba Municipality areas respectively, with
23
24 349 sufficient coverage rate and relatively lower delivery cost. The success of vaccination was a result of
25
26 350 effective coordination and microplanning among stakeholders despite some field challenges. The
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28 351 vaccination strategy utilizing both fixed and mobile posts, as well as the daily feedback to the
29
30 352 coordination team on the preliminary coverage survey result and data related to barriers and source of
31
32 353 information on the vaccination campaign, proved valuable to prospectively refine the campaign and
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34 354 mobilization strategy every day on a real-time basis.
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39 356 However, there are several limitations. First, the operational challenges concerning poor road conditions
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41 357 resulted in the accessibility to the target area difficult. Second, the programmatic support that required
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43 358 sufficient and trained human resources and budget for a sustained field monitoring activity and close on-
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45 359 site supervision prior to and during the vaccination campaign and coverage survey activities. Third, the
46
47 360 differences in the coverage rates of administrative data and survey result is due to the lack of accurate up-
48
49 361 to-date census data of local population. In addition, in order to avoid any conflict with the measles and
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51 362 rubella national immunization campaign that was taking place across the country at the time of this
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53 363 vaccination campaign, we had to delay our OCV vaccination campaign for about two months to obtain
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55 364 support from immunization-related stakeholders, particularly the expanded programme of immunization
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365 (EPI) for cold chain space and logistics. Any mass vaccination campaigns should also consider
366 seasonality and other major community activities and/or any political issues.

367

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371 and implementation period. Thanks are also extended to the people who consented and took part in the
372 coverage survey. We thank our research partners and staff at the MOCA sentinel site networks in
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374 Manjate for the project administrative support.

375

376 **Contributorship**

377 S.E.P conceptualized the overall study design of the Mozambique Cholera Prevention and Surveillance
378 (MOCA) project. C.S.B. supervised the MOCA project in Mozambique. N.S.B. supervised the overall
379 vaccination campaign and monitoring and evaluation. All authors participated in the vaccination
380 campaign. J.C., N.L., L.D.B., J.P.L., N.S.B., S.E.P., S.A., A.O., M.M., and the project field team in
381 Cuamba and Niassa contributed to data acquisition on the community vaccination coverage surveys, and
382 interpretation of results under the supervision of N.S.B. R.B.J.M., J.A.M., S.A., A.O., M.M., and others in
383 the vaccination teams of Cuamba District and Niassa Province contributed to acquisition, review, and
384 report of the administrative coverage data. I.C. contributed to data acquisition and analysis on vaccination
385 costs; and V.M. and C.V.R. reviewed the cost analysis. J.C. drafted and edited the paper under the
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387

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6

7 393

9 394 **Competing of Interests**

11 395 The authors declare no competing interests.
12

13 396

16 397 **Ethics approval**

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18 398 Institutional Ethical Committee of the National Institute of Health (Ref: 116/CNBS/19) and ethical review
19
20 399 board of the International Vaccine Institute, Seoul, Korea (IRB number 2017-006) approved the study
21
22 400 protocol for the OCV mass vaccination campaign monitoring and coverage survey.
23

24 401

26 402 **Data sharing**

28 403 All data relevant to the study are included in the article.
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30 404

32 405 **Figure legends**

34 406

37 407 **Figure 1. Pre-emptive OCV mass vaccination site**

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40 409 Location of the pre-emptive OCV vaccination campaign site in Cuamba District, Mozambique, included
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42 410 bairros and povoados in the municipality and district.
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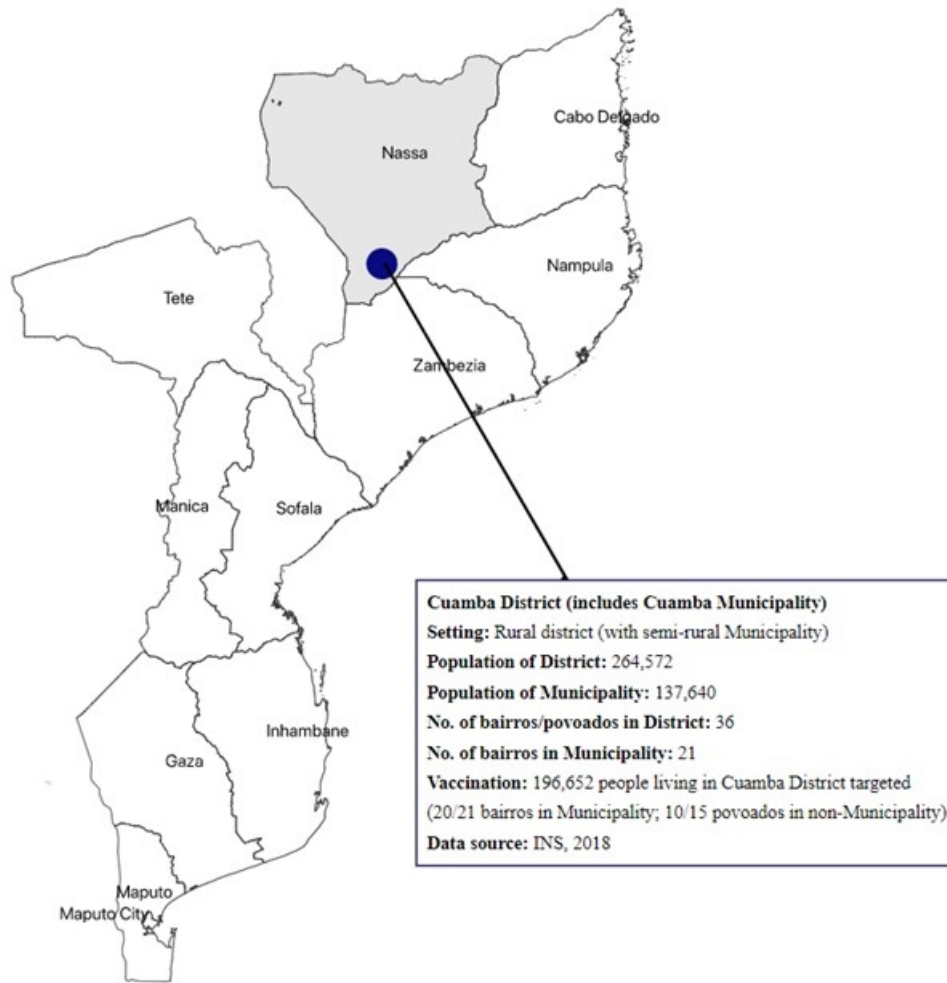


Figure 1. Pre-emptive OCV mass vaccination site

Figure 1. Pre-emptive OCV mass vaccination site

Location of the pre-emptive OCV vaccination campaign site in Cuamba District, Mozambique, included bairros and povoados in the municipality and district.

165x181mm (96 x 96 DPI)

BMJ Open

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3 1 **A pre-emptive Oral Cholera Vaccine (OCV) mass vaccination campaign in Cuamba District, Niassa**
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5 2 **Province, Mozambique: feasibility, vaccination coverage, and delivery costs using CholTool**
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9 4 Jucunú J. Elias Chitio¹, Cynthia Semá Baltazar¹, José Paulo Langa¹, Liliana Dengo Baloi¹, Ramos B. J.
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3 **22 Abstract**
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7 **24 Introduction:** Mozambique suffers from regular floods along its principal river basins and periodic
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25 cyclones that resulted in several cholera epidemics during the last decades. Cholera outbreaks in the
26 recent five years affected particularly the northern provinces of the country including Nampula and
27 Niassa provinces. A pre-emptive Oral Cholera Vaccine (OCV) mass vaccination campaign was conducted
28 in Cuamba District, Niassa Province, and the feasibility, costs, and vaccination coverage assessed.

30 Methods: World Health Organization prequalified OCV (Euvichol-Plus), a killed whole-cell bivalent
31 vaccine containing *Vibrio cholerae* O1 (classical and El Tor) and O139, was administered in two-doses
32 with a 15-day interval during 7-31 August 2018, targeting around 180,000 people aged above one year in
33 Cuamba District. Microplanning, community sensitization, and trainings of local public health
34 professionals and field enumerators were conducted. Feasibility and costs of vaccination were assessed
35 using CholTool. Vaccination coverage and barriers were assessed through community surveys.

37 Results: The administrative coverage of the first and second rounds of the campaign were 98.9%
38 (194,581) and 98.8% (194,325) respectively based on the available population data that estimated total
39 196,652 inhabitants in the target area. The vaccination coverage survey exhibited 75.9% ($\pm 2.2\%$) and
40 68.5% ($\pm 3.3\%$) coverages for the first and second rounds, respectively. Overall, 60.4% ($\pm 3.4\%$) of the
41 target population received full two-doses of OCV. Barriers to vaccination included incompatibility
42 between working hours and campaign time. No severe adverse events were notified. The total financial
43 cost per dose delivered was US\$0.60 without vaccine cost and US\$1.98 including vaccine costs.

45 Conclusion: The pre-emptive OCV mass vaccination campaign in remote setting in Mozambique was
46 feasible with reasonable full-dose vaccination coverage to confer sufficient herd immunity for at least the

1
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3 47 next three to five years. The delivery cost estimate indicates that the OCV campaign is affordable as it is
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5 48 comparable to Gavi's operational support for vaccination campaigns.
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7 49

9 50 **Key words:** Cholera, OCV, pre-emptive vaccination, Cuamba, Mozambique, vaccination coverage
11 51 survey, feasibility, vaccination cost
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For peer review only

52 **Strengths and limitations of this study**

- 53 • This study has successfully demonstrated the feasibility of an OCV mass vaccination campaign in a
54 remote setting in Mozambique.
- 55 • The cost of a mass vaccination campaign for the two-dose OCV administrations has been analysed for
56 the first time in Mozambique, which can serve as a reference cost estimate when planning for any
57 OCV vaccination programs in a similar setting in Mozambique or other countries.
- 58 • Vaccination coverage estimates may be affected if there are people movements in and out of the study
59 area. A sub-study on this and a focused community engagement strategy to reduce the identified
60 barriers to vaccination should be considered in future vaccination programs.
- 61 • Newly introduced vaccination monitoring/coverage survey engaging the same survey team enabled
62 quick availability of the vaccination coverage during or immediately after the campaign, but at the
63 same time the team could be overburdened.

65 **Introduction**

66 Cholera is a vaccine preventable disease that remains as a major public health concern in many parts of
67 low- and middle-income countries (LMICs). A comprehensive policy measure is warranted to control and
68 prevent cholera including investments in improving infrastructure and knowledge, attitude, and behavior
69 associated with water, sanitation, and hygiene (WASH), strengthening health system, and adequate use of
70 oral cholera vaccine (OCV) (1). In Mozambique, cholera has been endemic since the early 1970's when
71 the first cholera outbreak was reported in the country. Several epidemics followed since then including
72 the outbreaks in 1997-1999 and 2012-2016 (2, 3). Cholera outbreaks are more frequent in the country's
73 northern provinces including Nampula, Cabo Delgado, Tete, and Niassa (4). Following the reinforcement
74 of cholera outbreak response strategies, the Ministry of Health (MOH) of Mozambique has carried out
75 several OCV mass vaccination campaigns, as recommended by the World Health Organization (WHO) as
76 an integral part of a comprehensive strategy for cholera prevention and control in endemic setting along

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3 77 with primary interventions of WaSH measures (5): Recent cholera outbreaks in these cholera endemic and
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5 78 hotspot areas in December 2015 resulted in the use of global OCV emergency stockpile to vaccinate
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7 79 approximately 212,745 people living in six neighborhoods of Nampula city in 2016 (4); and in April
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9 80 2017, another 709,077 doses from the stockpile to vaccinate approximately 354,550 people in Tete City
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11 81 and Moatize and Mutarara districts, in response to the cholera outbreak with over 3,592 cholera cases.
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16 83 In addition to these reactive vaccination campaigns supported by the WHO International Coordinating
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18 84 Group (ICG) on vaccine provision for cholera, a growing need for a preventive public health intervention
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20 85 using a targeted vaccination approach in cholera priority areas in-country was identified. The past records
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22 86 of numerous episodes of cholera epidemics in Mozambique have spotted at-risk districts in the most
23
24 87 cholera endemic provinces such as Nampula (particularly Nampula City), Niassa (Lichinga city and
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26 88 Cuamba and Lago Districts), and Cabo Delgado (Pemba City and Ancuabe District), and to a lesser
27
28 89 degree, other provinces and districts with limited sanitary conditions (5). Niassa province, one of the
29
30 90 cholera endemic regions with annual cholera outbreaks affecting largely the Lichinga City and Lago and
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32 91 Cuamba Districts, was identified for a planned pre-emptive vaccine introduction to prevent subsequent
33
34 92 cholera outbreaks. Cuamba District with an estimated population of 264,572 (6), reports over 200
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36 93 suspected cholera and 2,000 diarrheal cases almost every year, with an exception of 2014 and 2016 (7).
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38 94 Here, we describe the feasibility, costs, and coverage estimates associated with a pre-emptive OCV mass
39
40 95 vaccination campaign conducted in Cuamba District using two-dose OCVs (Euvichol-Plus) administered
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42 96 to approximately 180,000 people with a 15-day interval between the doses, as well as challenges of
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44 97 delivering healthcare in resource limited rural setting in Mozambique.
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46 98

99 **Methods**

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101 ***Study site and population***

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3 102 The Cuamba District is located in Niassa Province with a population size of around 264,572 (6). The site
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5 103 was selected for a pre-emptive OCV mass vaccination campaign as the district includes the Cuamba
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7 104 Municipality area where cholera is found to be endemic with periodic outbreaks. The area was also
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9 105 highlighted by the WHO as one of the priority sites to consider for a potential OCV intervention during a
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11 106 needs-assessment performed in September 2015 (1). The District of Cuamba is composed of a total 36
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13 107 bairros and povoados with population size of approximately 264,572 (6), which includes 21 bairros in the
14
15 108 Cuamba Municipality area with around 137,640 residents (8). In total, approximately 180,000 individuals
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17 109 living in Cuamba District was targeted initially, and ultimately around 196,652 people living in Cuamba
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19 110 District were targeted, which included 20 Bairros in the Municipality area and 10 Povoados in the
20
21 111 outskirts of the Municipality area (Figure 1). Selection of bairros and povoados in the outskirts of
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23 112 Cuamba Municipality within the District was made not only based on the high number of doses destined
24
25 113 for the target population in the municipality area, but also the records of cholera cases during the
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27 114 outbreaks. Everyone above one year of age were eligible for the two-dose OCV administration.
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33 116 ***Vaccine delivery, storage, and handling***

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35 117 Approximately 360,000 doses of WHO pre-qualified Euvichol-Plus, a killed whole-cell bivalent OCV
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37 118 containing *Vibrio cholerae* O1 (classical and El Tor) and O139, were procured from the manufacturer
38
39 119 (EuBiologics) and shipped to the entry port in Pemba, Mozambique in cold-chain. Upon arrival in
40
41 120 Mozambique, the vaccines were delivered to Lichinga by airfreight and transported to a central vaccine
42
43 121 storage room in Cuamba project site, and kept in refrigerators with temperature maintained within range
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45 122 between 2-8°C until and throughout the campaign. The vaccine vial monitor (VVM) and electronic
46
47 123 shipping indicators (Q-Tag) were used to monitor the temperature of the vaccines during delivery,
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49 124 storage, and handling. During the vaccination campaign, cool boxes with dry ice maintained within 2-8°C
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52 125 were used to carry the vaccines to the vaccination posts.
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127 ***Cost of vaccine delivery***

128 An openly available, standardized and validated Excel-based tool known as the CholTool was used for
129 estimating vaccine delivery costs (9). This tool comprehensively estimates programmatic costs such as
130 microplanning, communication and training materials development, sensitization/social mobilization, and
131 personnel training, as well as costs related to vaccine delivery such as vaccine procurement, handling,
132 storage, and transport, vaccination administration, adverse events following immunization (AEFI)
133 management, monitoring supervision, and field support. The CholTool has the ability to estimate both
134 financial and economic costs. Financial costs refer to the monetary costs to the payer (e.g., allowances,
135 supplies, transport, and resources used in micro-planning, training, and sensitization/social mobilization)
136 while economic costs include financial costs along with non-monetary costs of donated goods and
137 resources already available (e.g., health personnel time). Key informant interviews were conducted at
138 various administrative levels before, during and after the vaccination campaign in order to identify the
139 resources necessary for each vaccination related activity and costs of respective resources for each of the
140 two rounds of vaccination. The resource and cost data were entered in CholTool which auto-calculates
141 OCV delivery costs. The costs were reported in 2018 in United States Dollars (US\$) based on
142 government and payer perspective.

144 ***Vaccination Strategy and microplanning***

145 A fixed post vaccination strategy with additional mobile teams was adapted for the microplanning of the
146 vaccination campaign. The vaccination teams for 15 fixed posts and 33 mobile teams were identified and
147 trained prior to the campaign. The fixed posts included existing healthcare facilities such as primary
148 health centers and secondary and referral hospital, schools, market areas where many people have easy
149 access to. The mobile teams were deployed to households remotely located with limited access to these
150 fixed posts. This adopted mixed vaccination strategy aimed to improve quality, accessibility, and
151 coverage. Each post was staffed with around 5 field workers including 2 health workers and 3 community
152 engagement workers. Five days prior to the vaccination campaign, micro-plans for each cluster were

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3 153 prepared with postal addresses, target populations, vaccination dates, teams, and other site-specific
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5 154 resources. The health workers obtained verbal informed consents from the individuals visiting the
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7 155 vaccination posts for the OCV administration. Pregnant women by self-report or infants below one year
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9 156 old were excluded from the vaccination. Vaccination cards and vaccination registry book were developed
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11 157 and deployed, specific to this vaccination that included variables such as name, age, address, and
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13 158 vaccination date. The collected data in the vaccine registry book were entered in an excel-based database.
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15 159 The number of doses planned and administered were also recorded daily for each rounds of the
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17 160 vaccination campaign.
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22 162 ***Vaccination, adverse event monitoring, and coverage estimate***

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24 163 The vaccination campaign occurred in two rounds with a 15-day interval. The first round took place
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26 164 during August 7-11, followed by the second round during August 27–31, 2018. Provision was made for
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28 165 mop-up activities after the second round for those who missed the second dose. To detect any possible
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30 166 adverse events following immunization (AEFI) during and after the campaign, health workers were
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32 167 trained to monitor and notify any adverse events encountered in inpatient and outpatient admissions at
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34 168 Cuamba health facilities from the first day of each round throughout the 15 days after the last day of each
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36 169 round.
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41 171 The vaccination coverage estimates were assessed in two-folds; administrative coverage and coverage
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43 172 surveys. The administrative coverage was recorded by the local government health office in charge of the
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45 173 vaccination campaign by tracking the number of vaccine doses administered compared to doses that had
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47 174 been planned in the vaccination target areas, at the end of vaccination activities every day during the two
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49 175 rounds of the OCV vaccination campaign. For the vaccination coverage surveys, around 520-650
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51 176 households, subject to the vaccination schedule including the mop-up vaccination, were estimated to
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53 177 ensure more than 550 samples for each age group (1-4 years, 5-14 years, 15 years and above) assuming
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55 178 80% coverage with a design effect of 2 to achieve around 5% of prevision. Sampled households were
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3 179 organized per cluster; total 20-25 clusters with 26 households per cluster. The households were selected
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5 180 using a two-stage cluster random sampling methodology. Clusters (primary sampling unit) were selected
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7 181 from the list of villages in the Health Zones, according to the Probability Proportional to Population Size
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9 182 (PPS) and households (secondary sampling unit) were chosen randomly. For the household random
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11 183 sampling, the enumerators identified the center point and boundary of the survey target area and applied
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13 184 random selection of households. The surveyors were recruited based on their knowledge on the local area
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15 185 and level of education to conduct the survey, and trained on household sampling methodology, structured
16
17 186 survey questionnaire, and process of conducting a survey interview, including verbal informed consent
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19
20 187 and data capturing on the paper-based survey questionnaires.
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23
24 189 Over the period of the OCV vaccination campaign, five survey teams were deployed to the predetermined
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26 190 clusters for daily vaccination monitoring, where randomly identified 26 households per cluster (5 clusters
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28 191 with total 130 households per day) were visited for 4-5 days (total 520-650 households) from the second
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30 192 or third day of the campaign until one day after the last vaccination day. This was applied for each round
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32 193 of the two-dose OCV vaccination campaigns. The information gathered through the survey on the vaccine
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34 194 uptake in the previous day, barriers against the vaccination, and the information source on the campaign
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36 195 were analyzed and fed daily to the vaccination campaign coordinators and supervisors in order to
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38 196 facilitate overall vaccine uptakes. During the second round of campaign, the survey team collected data
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40 197 for the first round coverage using the same questionnaire for monitoring, which enabled the first-round
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42 198 vaccine coverage available before the completion of the second round. After the second round, the
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44 199 enumerators continued the household survey for additional three days (total four days, including the last
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46 200 survey day for monitoring of the second round, which was one day after the mop-up campaign) to
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48 201 estimate the coverage for the second round and two full doses of vaccination.
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52 53 203 ***Patient and Public Involvement***

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3 204 The vaccination campaign was conducted as a part of the government's public health intervention,
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5 205 approved by the Ministry of Health (MOH) in Mozambique. The participants in this study were people
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7 206 living in the cholera endemic and hotspot area, targeted for OCV vaccination campaign as an integral part
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9 207 of the government's cholera prevention efforts. The vaccination target population living in Cuamba
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11 208 District were sensitized and engaged, prior to and during the vaccination campaign, by the district and
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13 209 provincial health officials, study team that included the MOH and National Institute of Health
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15 210 government officials, and local public health professionals at healthcare facilities. The participants were
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17 211 provided with information on the planned OCV mass vaccination such as the purpose of pre-emptive
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19 212 vaccination and detailed information on where and when the vaccination campaigns were to take place.
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21 213 The vaccination campaign was also announced through various press and social media in Mozambique
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23 214 for public awareness and involvement. The study was conducted in a transparent manner with open
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25 215 communication and information sharing in the community, and participants to the OCV vaccination and
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27 216 vaccination coverage surveys were informed for oral consent. For children, consents were obtained from
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29 217 parents/guardian and all adult participants provided their own consent. The study did not present any risk
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31 218 of harm to subjects. No biological samples were collected. Minimum data was collected from
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33 219 participants, whereby privacy and confidentiality of the data were ensured during the survey
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35 220 implementation and data entry and management. Stakeholder meetings were conducted prior to, during,
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37 221 and after the vaccination campaign to further disseminate the campaign plan and results to the community
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39 222 members.
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45 224 **Results**

46 225 *OCV vaccination coverage*

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49 226 The administrative coverage of the first and the second rounds of the campaign were 98.9% (194,581) and
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51 227 98.8% (194,325) respectively based on the available census data of vaccination target population in
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53 228 Cuamba Municipality and outskirts, estimated at around 196,652 (6) inhabitants (Table 1). A total of
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55 229 194,581 people over one-year-old received the first dose, out of whom 99,275 were females and 122,592
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3 230 were children aged less than 15 years. For the second round, total 194,325 people were vaccinated,
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5 231 including 99,275 females and 120,169 children less than 15 years old. Notably, the vaccination coverage
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7 232 survey conducted in the target community during each round and post-vaccination exhibited an
8
9 233 approximate coverage estimates of 75.9% (95 CI, 73.10 - 78.70%) for the first round and 68.5% (71.80 -
10
11 234 65.20%) for the second round. The coverage rate for the full two-doses was estimated at 60.4% (63.80 -
12
13 235 57.00%), whereby the coverage of children aged 1-4 years was around 64.4 % (57.10 – 71.10%) (Table
14
15 236 1). The coverage rates in each round were higher in male (76.3% and 77.8%) than female (75.4% and
16
17 237 67.7%), but coverage rate of full doses was higher in female (64.4%) than male (57.3%). No adverse
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19 238 events were reported during and after the vaccination activities, monitored up to 14 days post-vaccination
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21 239 campaign.
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241 **Table 1. OCV vaccination coverage estimates, Cuamba District, 2018**

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243 **a) Administrative vaccination coverage rates**

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		Number of people vaccinated (No.)						
		Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Total
1st Dose	Age (year)							
Individuals vaccinated per	1-4	6,493	9,283	12,394	12,506	7,691	-	48,367
age group	5-15	7,050	16,705	21,590	17,536	11,344	-	74,225
	≥15	10,136	12,400	18,835	18,798	11,820	-	71,989
Total no. of daily vaccinated		23,679	38,388	52,819	48,840	30,855	-	194,581
Cumulative no. of vaccinated		23,679	62,067	114,886	163,726	194,581	-	
Cumulative administrative coverage		12.04%	31.56%	58.42%	83.26%	98.95%	-	98.95%
2nd Dose								
Individuals vaccinated per	1-4	5,479	6,484	11,117	9,596	7,760	7,586	48,022
age group	5-15	9,355	8,796	15,679	13,208	14,444	10,665	72,147
	≥15	9,416	9,275	14,271	14,265	14,848	12,081	74,156
Total no. of daily vaccinated		24,250	24,555	41,067	37,069	37,052	30,332	194,325
Cumulative no. of vaccinated		24,250	48,805	89,872	126,941	163,993	194,325	
Cumulative administrative coverage		12.33%	24.82%	45.70%	64.55%	83.39%	98.82%	98.82%

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246 **b) Vaccination coverage rates through coverage surveys**

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		First Round	Second Round	Full Two Doses
Age (years old)	1- 4	81.1±4.5%	72.2±6.9%	64.4±7.3%
	5-14	86.4±3.1%	71.3±5.8%	65.2±6.1%
	≥15	67.6±3.3%	65.2±4.8%	55.7±5.0%
Sex	Male	76.3±2.9%	77.8±3.9%	57.3±4.6%
	Female	75.4±3.2%	67.7±5.0%	64.4±5.1%
Total	-	75.9±2.2%	68.5±3.3%	60.4±3.4%

248

249 *Source of Information and Acceptability*

250 The source of information on the OCV vaccination campaign, identified by the populations living in the
 251 vaccination target areas, showed use of megaphone as the most effective tool in disseminating
 252 information on the vaccination plan and mobilizing the community to get immunized for both rounds:
 253 24% and 34% at the first and second rounds respectively (Table 2). Around 15% of the surveyed people
 254 in the target community indicated that they have learnt about the vaccination campaign through radio
 255 broadcast for the first round, but its communication impact reduced in the second round (4%). This was
 256 different for the community leaders, whose contribution increased from 5% in the first round to 19% in
 257 the following round, reflecting their active engagement and communication efforts in close coordination
 258 with the vaccination teams on the ground.

260 **Table 2. Source of information on OCV campaign, Cuamba District, 2018**

Source of information	1 st Round ¹ N= 646 n (%=n/N)	2 nd Round ² N= 578 n (%=n/N)
Megaphone	152 (24%)	195 (34%)
Family	60 (9%)	53 (9%)
Radio	96 (15%)	23 (4%)
Religious leader	82 (13%)	25 (4%)
Health workers	74 (11%)	120 (21%)
Activists	55 (9%)	9 (2%)
Community leader	33 (5%)	108 (19%)
TV	14 (2%)	11 (2%)
Others ³	78 (12%)	33 (6%)

262 Footnote:

263 ¹ 1st round: 646 households/or people were interviewed.

264 ² 2nd round: 578 households/or people were interviewed.

265 ³ Others included: list other source of info if such data were collected.

268 ***Reasons for not being vaccinated***

269 The unavailability (absence) of the target population for vaccination and incompatibility between working
 270 hours and campaign schedule were commonly cited as barriers for vaccination in both the first (35%) and
 271 the second round (51%) (Table 3). Absence of vaccinators at the vaccination sites were also mentioned,
 272 12% and 18% for the first and second round respectively, despite the pre-vaccination planning and
 273 programmatic organization. Notably, around 10% of the target population has indicated that they have not
 274 been informed about the vaccination campaign even in the second round, though this was a reduction
 275 compared to 18% in the first round. In order to address the most common barriers identified in the first
 276 round, the second round of the vaccination campaign was further extended for additional few days
 277 including the weekends, enabling more people to get vaccinated.

279 **Table 3. Reasons for non-vaccination during the OCV campaign, Cuamba District, 2018**

Reasons for non-vaccination	1 st Dose		2 nd Dose	
	n=361	%	n=222	%
Unavailable	63	17%	96	43%
Incompatibility between working hours and campaign time	53	15%	18	8%
Vaccination post without vaccinator	40	11%	41	18%
Did not have information	66	18%	23	10%
Ill during the vaccination period	30	8%	10	5%
Does not believe in vaccine efficacy	24	7%	2	1%
Afraid of adverse events	8	2%	0	0%
Head of the family did not authorize	4	1%	2	1%
Religious leader forbid	2	1%	0	0%
Considered not safe for pregnant women	1	0%	2	1%
Other	70	19%	28	13%

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3 282 ***OCV delivery costs***
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5 283 The total financial cost of campaign was US\$768,904 of which vaccine acquisition including vaccine
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7 284 shipment constituted 69% (US\$533,659) (Table 4). The vaccine delivery costs including, microplanning,
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9 285 training, communication, and social mobilization, vaccination implementation (Round 1 & 2) constituted
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11 286 rest 31% (US\$235,245). The total financial cost per dose delivered was US\$0.60 without the vaccine cost
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14 287 and US\$1.98 including the vaccine costs in 2018 price. The economic cost per dose delivered excluding
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16 288 vaccine costs was five times higher at US\$3.02. The total financial cost of delivery per fully immunized
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18 289 person excluding vaccine costs was US\$1.21.
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291 **Table 4. Costs of OCV vaccine delivery and immunization in Cuamba District**

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Vaccine Delivery Costs	Financial Cost (Mzn)	Economic Cost (Mzn)	Financial Cost (USD)	Economic Cost (USD)
Vaccine Acquisition	32,179,644	42,081,073	533,659	697,862
Microplanning	640,415	7,596,625	10,620	125,981
Training	265,186	299,419	4,398	4,965
Communication and Social Mobilization	1,912,520	4,301,342	31,717	71,332
Vaccination Implementation (Round 1 &2)	11,367,160	58,510,806	188,510	970,328
Total	46,364,925	112,789,265	768,904	1,870,469

Immunization Costs	Financial Cost (Mzn)	Economic Cost (Mzn)	Financial Cost (USD)	Economic Cost (USD)
Cost per Vaccine Administered (including vaccine)	119	290	1.98	4.81
Cost per Vaccine Administered (without vaccine cost)	36	182	0.60	3.02
Cost per Partially Immunized Person	238	580	3.95	9.61
Cost per Fully Immunized Person (with vaccine)	239	580	3.96	9.63
Cost per Fully Immunized Person (without vaccine)	73	364	1.21	6.03

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294 Discussion

295 The OCV campaign in Cuamba District was organized without major logistical and programmatic
296 challenges, and no adverse events were reported throughout the vaccination activities and up to 14 days
297 after the campaign. Despite the similarity in the number of people vaccinated in the first and second
298 rounds, the vaccination coverage survey of the second round showed lower coverage estimates than the
299 first round. This may be due to possible cross border movement of people from untargeted districts to get
300 vaccination during the second round. The vaccination coverage for the full two-doses was over 60% that
301 may confer sufficient herd immunity for the following several years based on the existing literature on a
302 cholera transmission model using the Matlab data from Bangladesh (10,11), which predicted 50%
303 coverage with OCV in cholera endemic areas may result in 89% reduction in cholera cases in
304 unvaccinated (12).

305
306 In our study, children aged 5-14 years exhibited the highest coverage. This may be due to the vaccination
307 posts in both schools (fixed vaccination post) and near homes (mobile vaccination posts), which
308 facilitated the school-aged children to access the immunization health service more easily. The female
309 group also presented higher full vaccination coverage rate compared to the male group, who showed
310 higher drop-out after first dose, likely associated with their routine boundaries of livelihood near their
311 houses or their child/children's schools as they take care of children while the male group typically work
312 outside. This assumption is supported by the fact that the absence during the campaign was identified as a
313 significant barrier against vaccination during both rounds of the campaign. Similar pattern was
314 consistently prevalent in the previous OCV campaigns in Beira (13) and Nampula (4), whereby absence
315 was the main barrier for vaccination. The second round of the campaign coincided with the period of
316 school holidays when most households move to farming and food production, resulting in higher absence
317 rate in the second round (43.0%) than in first round (17.0%). Further, it is encouraging to observe more
318 than 60% vaccination coverage rate among children aged 1-4 years, the most at-risk population age-group
319 concerning cholera outbreaks. Considering that caregivers for these younger children are mostly women,

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3 320 higher vaccination coverage for these toddlers and younger children and women is as anticipated in
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5 321 accordance with other studies published in similar settings (14).
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9 323 For the monitoring of the campaign, the researchers used representative sampling with the same
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11 324 questionnaire for coverage, which resulted in representative daily coverage. The representative sampling
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13 325 enabled the first-round coverage available before completion of the second round and fed to the
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15 326 coordination team to fine-tune the mop-up campaign. Again, the second and full dose vaccination
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17 327 coverage were estimated within a week after the campaign by extension of the survey days by three more
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19 328 days. However, the survey extension and additional questions for the final coverages (the first, second and
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21 329 full) made some survey team members exhausted, which might have affected survey quality.
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26 331 In order to enhance the vaccination coverage, it is paramount to better understand the effective means of
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28 332 communications for community sensitization and engagements, as well as barriers towards participating
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30 333 in a vaccination program such as this campaign. Here, we showed that the use of megaphone proved to be
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32 334 the most effective advocacy tool for disseminating information on the vaccination to our target
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34 335 community, which may have allowed the field workers to reach out to families without access to other
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36 336 sources of information. This may also indicate the need to better understand the inter-personnel
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38 337 communication and community mobilization approach for future vaccination campaigns. For those with
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40 338 missed opportunities to receive the OCV doses during the two rounds, a mop-up vaccination can be
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42 339 considered, though it is often more laborious and costly, requiring a complex management (13). Further,
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44 340 informing the public on the availability of a mop-up prior to or during the campaign may negatively affect
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46 341 their participation in the regular vaccination schedule set-up. Hence, a mop-up was not considered after
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48 342 the first round in our approach but pursued after the second round in order to enhance the full two-dose
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50 343 vaccination and verify vaccination data records submitted during the regular program. Approximately
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52 344 15.4% (32,775/212,824) of the delivered second doses were through this mop-up campaign indicative of
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54 345 an effective strategy.
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5 347 The financial costs of OCV delivery per fully immunized person in this campaign was lower than delivery
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7 348 costs reported in other African countries using the same CholTool (US\$1.8 in Shashemene district of
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9 349 Ethiopia; US\$2.5 in Nsanje district of Malawi; and US\$3.5 in Machinga, Phalombe, and Zomba districts
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11 350 of Malawi per the US\$ price value of 2016), but closer to that reported in Puri district of India (US\$1.14
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13 351 per the US\$ price value of 2016) (9). One reason could be that Mozambique has experience of conducting
14
15 352 several OCV campaigns in recent years, and hence there were already resources and expertise available
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17 353 for micro-planning, communication, sensitization, trainings etc., which might have reduced the costs
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19 354 associated with introduction of vaccines in comparison to a vaccination program in naïve setting. The
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21 355 financial cost of US\$0.60 per dose delivered (excluding vaccine procurement) is comparable to the
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23 356 operational support ranging between US\$0.30 and US\$0.80 per person targeted for vaccination
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25 357 campaigns, recommended by the Gavi, the Vaccine Alliance (15,16). This indicates the affordability of
26
27 358 OCV campaign in the current setting. To economize the healthcare provider time and efforts and
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29 359 incentivize beneficiaries for greater uptake of vaccines, delivery of multiple products at vaccination posts
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31 360 or on household visits may potentially synergize the delivery cost associated with vaccination campaigns.
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36 362 Overall, our study proved the feasibility of conducting a preemptive OCV mass vaccination campaign in a
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38 363 rural and semi-rural setting in Cuamba District and Cuamba Municipality areas respectively, with
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40 364 sufficient coverage rate and relatively lower delivery cost. The success of vaccination was a result of
41
42 365 effective coordination and microplanning among stakeholders despite some field challenges. The
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44 366 vaccination strategy utilizing both fixed and mobile posts, as well as the daily feedback to the
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46 367 coordination team on the preliminary coverage survey result and data related to barriers and source of
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48 368 information on the vaccination campaign, proved valuable to prospectively refine the campaign and
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50 369 mobilization strategy every day on a real-time basis.
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3 371 However, there are several limitations. First, the operational challenges concerning poor road conditions
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5 372 resulted in the accessibility to the target area difficult. Second, the programmatic support that required
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7 373 sufficient and trained human resources and budget for a sustained field monitoring activity and close on-
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9 374 site supervision prior to and during the vaccination campaign and coverage survey activities. Third, the
10
11 375 differences in the coverage rates of administrative data and survey result is due to the lack of accurate up-
12
13 376 to-date census data of local population. In addition, in order to avoid any conflict with the measles and
14
15 377 rubella national immunization campaign that was taking place across the country at the time of this
16
17 378 vaccination campaign, we had to delay our OCV vaccination campaign for about two months to obtain
18
19 379 support from immunization-related stakeholders, particularly the expanded programme of immunization
20
21 380 (EPI) for cold chain space and logistics. Any mass vaccination campaigns should also consider
22
23 381 seasonality and other major community activities and/or any political issues.
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26 382

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31
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33
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35
36 387 coverage survey. We thank our research partners and staff at the MOCA sentinel site networks in
37
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39
40 389 Manjate for the project administrative support.
41
42

43 390

45 391 **Contributorship**

47 392 S.E.P conceptualized the overall study design of the Mozambique Cholera Prevention and Surveillance
48
49 393 (MOCA) project. C.S.B. supervised the MOCA project in Mozambique. N.S.B. supervised the overall
50
51 394 vaccination campaign and monitoring and evaluation. All authors participated in the vaccination
52
53 395 campaign. J.C., N.L, L.D.B., J.P.L., N.S.B., S.E.P., S.A., A.O., M.M., and the project field team in
54
55 396 Cuamba and Niassa contributed to data acquisition on the community vaccination coverage surveys, and
56
57
58

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3 397 interpretation of results under the supervision of N.S.B. R.B.J.M., J.A.M., S.A., A.O., M.M., and others in
4
5 398 the vaccination teams of Cuamba District and Niassa Province contributed to acquisition, review, and
6
7 399 report of the administrative coverage data. I.C. contributed to data acquisition and analysis on vaccination
8
9 400 costs; and V.M. and C.V.R. reviewed the cost analysis. J.C. drafted and edited the paper under the
10
11 401 scientific guidance from N.S.B. and S.E.P. All authors read and approved the final draft.
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13

14 402

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16
17
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27 28 409 **Competing of Interests**

29
30 410 The authors declare no competing interests.
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33 411

34 412 **Ethics approval**

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36
37 413 Institutional Ethical Committee of the National Institute of Health (Ref: 116/CNBS/19) and ethical review
38
39 414 board of the International Vaccine Institute, Seoul, Korea (IRB number 2017-006) approved the study
40
41 415 protocol for the OCV mass vaccination campaign monitoring and coverage survey.
42

43 416

44 417 **Data sharing**

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47 418 All data relevant to the study are included in the article.
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51 420 **Figure legends**

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53 54 55 422 **Figure 1. Pre-emptive OCV mass vaccination site**

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5 424 Location of the pre-emptive OCV vaccination campaign site in Cuamba District, Mozambique, included
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7 425 bairros and povoados in the municipality and district.
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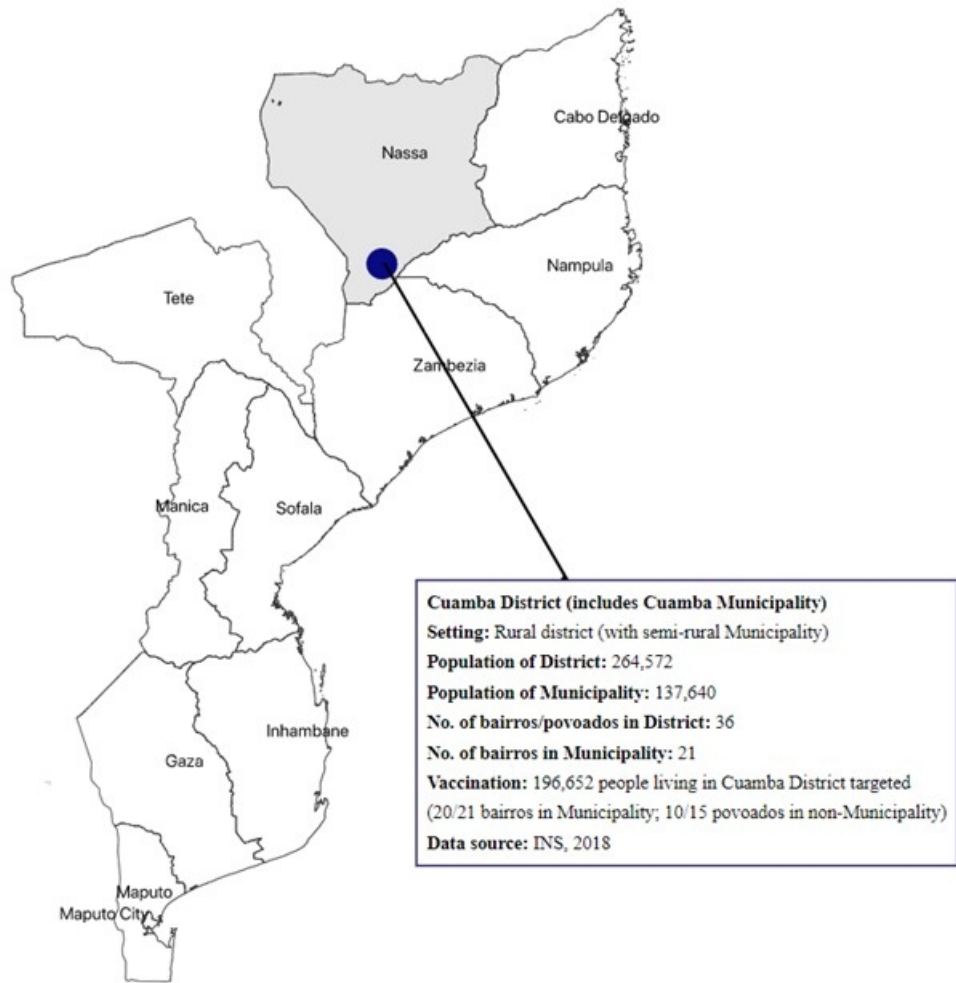


Figure 1. Pre-emptive OCV mass vaccination site

Figure 1. Pre-emptive OCV mass vaccination site

Location of the pre-emptive OCV vaccination campaign site in Cuamba District, Mozambique, included bairros and povoados in the municipality and district.

165x181mm (96 x 96 DPI)

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4 **The Final Vaccine Coverage Estimation by Five Series of Quick Household**
5 **Surveys for Monitoring of the Preventive Vaccination Campaign in Cuamba**
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Seoul, Korea
June 11, 2018

For peer review only

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Abbreviations

AE	Adverse Event
AEFI	Adverse Event Following Immunization
CFR	Case Fatality Rate
DRC	Democratic Republic of Congo
INS	Instituto Nacional de Saúde
IVI	the International Vaccine Institute
M&E	Monitoring and Evaluation
MOH	Ministry of Health
OCHA	the United Nations Office for the Coordination of Humanitarian Affairs
OCV	Oral Cholera Vaccine
PAHO	Pan American Health Organization
PPS	Probability Proportional to Population Size
PSU	Primary Sampling Unit
SAE	Serious Adverse Event (SAE).
SSU	Secondary Sampling Unit

2 Introduction

Mozambique suffers from regular floods along its principal rivers, especially the Zambezi and Limpopo river basins, and also cyclones almost annually. An outbreak of cholera was first reported in Mozambique in the early 1970s, followed by several epidemics in 1997-1999 and 2012-2014. [1] In December 2014, another cholera outbreak was reported in the country, with an official outbreak declaration by the government in January 2015. The situation worsened with extensive flooding, which led to over 8,835 cholera cases including 65 deaths in five months. [2] International humanitarian organizations and UN agencies responded with emergency cholera treatments and care service in the affected areas, but the need to address the gap in preparedness and response activities were identified by the United Nations Office for the Coordination of Humanitarian Affairs (OCHA).

In October 2016, a large scale OCV campaign was conducted in Nampula and neighborhoods regularly affected by cholera outbreaks. .

In 2017, the rainy season has been characterized by less frequent but heavier rains including the recent tropical cyclone, Dineo. Response to the cyclone together with other emergencies as well as a financial crisis has led to a dearth of human resources for response. Risk factors fueling cholera transmission include shortage of potable water, contamination of house water in cyclone-affected areas, and recurrent risk of flooding in high density populated areas, particularly in the most deprived areas. Between week 1 and 11, a total of 1,622 suspect cases and 3 deaths (CFR 0.2%) have been reported. Seventy five percent of cases came from Nampula and Tete provinces with 653 cases (40%) from Tete city during weeks 10 and 11 [3].

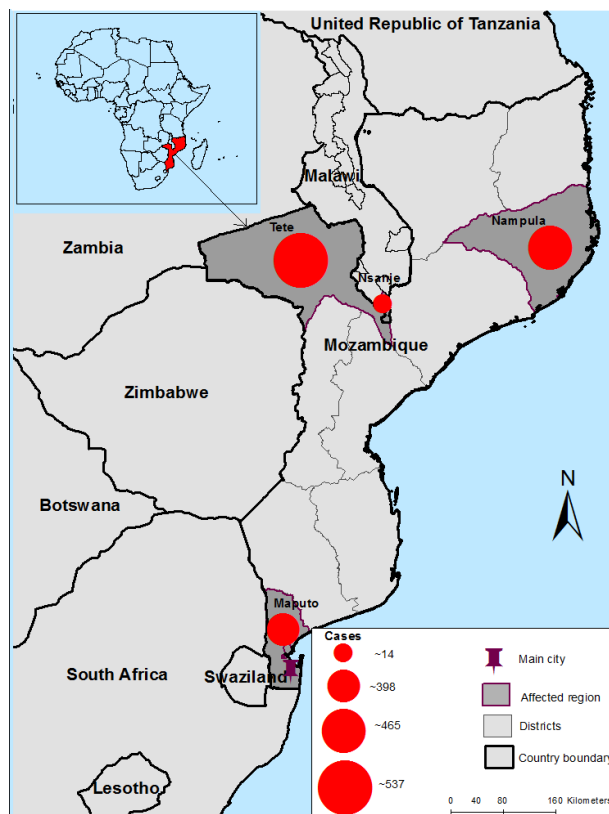
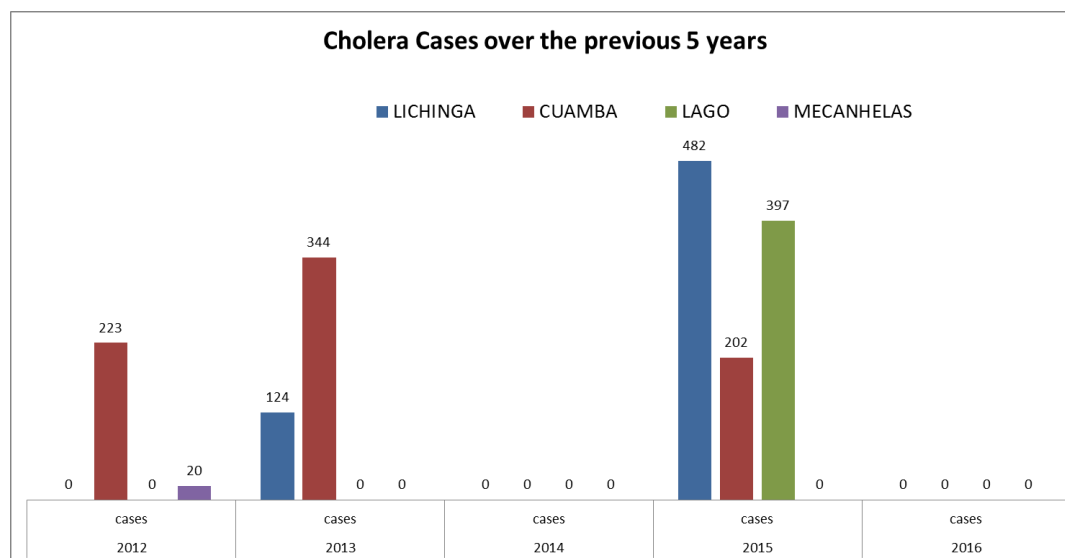


Figure 1. Geographical distribution of Cholera cases in Mozambique, 01 January - 15 March 2017 [4]

Coping with the outbreaks, the first round of reactive OCV campaign has been successfully conducted in Tete in June, 2017, which will be followed by the second dose immunization scheduled in Decembre.

Cuamba, an adjacent district to Nampula with an estimated population of over 300,000 inhabitants is considered as a cholera hot spot. As the district regularly experiences more than 200 suspect cholera cases per year except 2014 and 2016 the district will be targeted by IVI for a mass cholera vaccination campaign with supported by KOICA, followed by a cholera and diarrheal surveillance. With 180,000 individuals over the age of one year in the at-risk communities in the target area will benefit from receiving OCV (Euvichol[®]) hopefully before the rainy season.



The Rapid Coverage Monitoring strategy was designed by PAHO to provide local authorities with a quick impression of the completeness of vaccination [5,6]. Modifying the monitoring tool, Save the Children has invented a new monitoring tool which enables to estimate not only daily vaccination coverage and vaccination barriers, but also the final coverage. And its usefulness was proved during the period of preemptive 2016 yellow fever vaccination campaign in DRC [7].

3 Objectives

3.1 General Objective

- 1) To provide support to MOH Mozambique to ensure successful and quality national OCV campaign

3.2 Specific Objectives

- Evaluate the OCV vaccination campaign by estimation of final-day and post vaccination coverage
- Validate quick monitoring survey for estimation of final coverage
- Provide technical support to MOH Mozambique to ensure successful OCV campaign and quality data collection
- Build M&E capacity of MOH Mozambique ensuring quality vaccination campaign

- Increase vaccine coverage by feeding the vaccination team with daily vaccine coverage and barriers against cholera vaccination

4 Design

4.1 M&E activities during the Vaccination Campaign

During the vaccination campaigns, daily vaccine coverage and barriers against vaccination will be closely monitored employing a close monitoring tool described in the implementation section. The monitoring results will be fed to the vaccination team to address any identified challenges on real time bases. The final vaccine coverage will be estimated at the last day of the campaign for the three age groups including 'aged between 1 and 4 years', '5 to 14 years' and 'more than 15 years' using 'measurement error approach' [Annex 2] by analyzing the monitoring and administrative data. Mop-up vaccination shall be considered in case where the coverage rate indicates too low.

5 Sample Size Estimation

5.1 M&E activities for the vaccination campaign

In order to get the final vaccine coverage rate with reasonable precision (5%), we will conduct five series of independent assessment in the Cuamba district during the mass vaccination campaign day 1 to 5. Based on a confidence level of 95%, assuming 80% coverage and accounting for a design effect of 2, sample size requirements have been determined as follows in the table 1 for each of the three age groups: 1-4, 5-14 and 15+ years of age.

$$\text{Sample size} = \frac{t^2 P(1-P)d_{eff}}{d^2}$$

, where denotes $t = t$ score, $p =$ prevalence (or coverage), $d =$ precision, and $d_{eff} =$ design effect

Table 1. the number of households reached for each age group *

Age group	average household size	precision	Estimated coverage	Required sample size	Proportion among total population*	Average # of people / HH	required household	Household to be reached
1-4 years	6	0.05	0.8	535	14.0%	0.8	637	650
5-14 years	6	0.05	0.8	535	26.9%	1.6	332	650
15 years or more	6	0.05	0.8	535	55.9%	3.4	160	650

In conclusion, total 650 households will be reached to get 550 children aged between 1-4 years. However for the age group for 5-14 years and 15+, who are available more than 1 for average household, the enumerators will identify only one for the specific age group from each household for survey by randomization. Upon failure of acquisition of survey consent, the enumerators are advised to skip the household but continue to the nearest next household until reach all 26 households per cluster.

6 Consent Process

* UNICEF country profile 2016

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2
3 Data for the coverage survey will be obtained from an adult in the household, where adult is
4 defined as the person aged +18 years or the parents (aged 15 years or more) of a child(ren). As the
5 study is low risk, there will be no need for witness unless otherwise required by Institutional Review
6 Board (IRB). Consent for the vaccination survey will take place at the home of individuals living in
7 the target areas of the vaccination campaign before each survey. Residing in a target area for
8 vaccination will make an individual eligible for each survey. The age at the vaccination campaign is
9 considered for the eligibility for the survey by each age group. The consent and survey answers will
10 be obtained from the household heads or the adult who is most knowledgeable about the
11 household members' health whenever possible.
12

13 **7 Study Implementation**

14 **M&E activities for the vaccination campaign**

15 **7.1.1 Daily monitoring of vaccine coverage and barriers**

16
17 During the vaccination campaign, daily vaccine coverage, acceptability and barriers against the
18 campaign will be closely monitored employing a close monitoring tool described below. The
19 monitoring results will be fed to vaccination team to address any identified challenges on real time
20 bases. The final vaccine coverage will be estimated at the last day of the campaign using
21 'measurement error approach' (Annex 2) by analyzing the monitoring and administrative data.
22 Mop-up vaccination shall be considered in case where the coverage rate indicates too low.
23
24

25 **7.1.1.1 Daily Vaccine Coverage with precision of ~10%, and Barriers against vaccination:**

26
27 From Day 1 through Day 5, five community assessment teams are sent to the 5 clusters for each
28 vaccination group, where each team randomly identify 26 households and collect data for 'daily
29 vaccine coverage' and 'barriers' reaching daily total 130 households from 5 clusters households
30 involving more than 110 individuals for each of two age groups: 1-4, 5-14 and 15+ years. Based on
31 the collected data, the survey supervisor will estimate daily vaccine coverage rate and barriers from
32 D1 through 5 and share the results with the vaccination team and stakeholders to improve vaccine
33 coverage.
34
35

36 **Data Collection:**

37
38 Data for the community survey will be collected by trained surveyors and supervisors by direct
39 interview with a questionnaire (Annex 1). A pilot will be conducted to test the questionnaire before
40 the survey. Each questionnaire will collect information on a cluster of around 130 individuals for
41 each age group. The aim of the questionnaire is to obtain information on the vaccination status of
42 individuals, on the reasons for non-vaccination and on demographic characteristics that can be
43 associated with vaccination.
44
45

46 **Sampling Method for quick monitoring assessment:**

47
48 The sampling method will be two stage cluster sampling to select localities (primary sampling units
49 or PSUs) and households (secondary sampling units or SSUs). In each district 25 localities (villages or
50 neighborhoods) will be selected, in which clusters of 26 households will be accessed. PSUs will be
51 selected from the list of the villages in the districts (with information on the size of the target
52 population) according to probability proportional to population size (PPS). Each day for the
53 monitoring survey, 5 clusters are selected randomly out of the total 25 clusters identified by PPS so
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3 as not to reach the same cluster/household during the vaccination campaign. In this way the
4 number of clusters assigned to each locality will be based on the demographic weight of the village.
5 The first household (SSU) in each cluster will be selected according to geographic random sampling:
6 we will draft a map of the locality, divide it into smaller sectors according to existing divisions
7 (streets, rivers, etc), and select one sector according to simple random sampling (SRS). We will
8 continue dividing the selected sector until obtaining a sector with less than 20 households. In the
9 finally selected sector, we will number each household and selected one randomly to start the
10 survey. Once the interview will be completed in the household, we will move to the nearest the
11 household to select the subsequent households. Out of the eligible persons in the household
12 surveyed the enumerators are trained to select only one for each age group from each household
13 by randomization, and an adult will be identified for assess the barriers.
14

15
16 If the survey subjects (children aged 1-4 years, 5-14 years or 15 or more) are not available, the
17 enumerators are advised to move to the next households until reach 26 households.
18

19 The questionnaire is composed by three sections (Annex 1, survey questionnaire):

- 20 • Questions about vaccination status
 - 21 - How many eligible individuals (aged over one year) live in the household
 - 22 - Vaccinated: Yes/No for each eligible individuals
 - 23 - Vaccination card is available: Yes/No
 - 24 - Length of journey to the nearest health center:
 - 25 • Questions about reasons for non-vaccination: pre-coded multiple choice
 - 26 • Questions about the awareness of the campaign
- 27
28
29

30 Reason for non-vaccination:

31 Using the questionnaire the investigator will identify the major barriers against the mass
32 vaccination campaign and its delivery and administration strategies, and feed the result to the
33 vaccination coordination team.
34

35 7.1.1.2 Final Vaccine Coverage using monitoring and administrative data:

36
37 With the data of the daily vaccine coverage rate and cumulative vaccine consumption for each day,
38 the final vaccination coverage is estimated using 'measurement error approach' as described in
39 Annex 2 on assumption that the vaccine coverage rate is linearly correlated with the cumulative
40 number of vaccine consumption.
41

42 7.1.2 Post vaccination coverage survey

43
44 The post vaccination survey will employ the same sampling method and questionnaire used for the
45 daily monitoring while the post-vaccination survey will be conducted after the vaccination.
46
47

48 After the vaccination campaign has been completed, interview teams will be mobilized to visit
49 homes in the target areas. Two interviewers make up a team and administer the surveys with the
50 same questionnaire as used for daily monitoring survey. If the family is not home at the time when
51 the interview team approaches a selected house, the team would attempt to re-visit that house
52 later in the day.
53
54

55 A two-stage cluster sampling methods will be used to reach 650 households in which the clusters
56 are selected first using PPS, and in a second stage, households are selected from within those
57 clusters, which is used for the daily monitoring. Based on the collected data, the coverage rate is
58 estimated by disaggregation by age: 1-4 years, 5 years or more.
59
60

7.1.3 Monitoring of AEFI (Adverse Events Following Immunization)

Passive AEFI surveillance system will be set up for monitoring of adverse events following immunization at the health facilities up to 14 days after the vaccination campaign. However at the same time for the women with overt pregnant sign in their 2nd and 3rd trimester, and those reporting pregnancy during the vaccination period, the contact details (phone number) will be collected to reach them for active monitoring of adverse events both for the women and possible pregnancy outcomes up to 14 days after the campaign.

8 Ethical considerations

For household survey, data will be treated confidentially and no personal identifiers (names) will be collected from the interviewees. Verbal informed consent will be asked from the responsible adults in the household before starting the survey. Considering that the household survey described in this proposal is a programmatic activity undertaken in the frame of the already advised guideline by international community as a package of mass vaccination program, only verbal consent will be obtained for the data collection from the households surveyed.

If only children are available in the household selected, the questionnaires will not be administered and the household will be revisited or excluded.

For monitoring of AEFI, a verbal consent will be obtained from the pregnant women before acquisition of the contact details (Inform Consent Form) as well. While obtaining verbal consent the team will explain the purpose of the survey and AEFI surveillance to the parents or guardians of potential participants, and pregnant women and answer any questions that may arise. Considering illiteracy, the team uses a witness for the information by word of mouth. The adults or guardians of potential participants, or pregnant women will be provided the opportunity to ask questions prior to offer verbal consent. Before providing the verbal consent, parents or guardians of potential participants, or pregnant women will be asked to undergo an informed consent process validation to ensure that they fully understand the purpose of the study, procedures, AEFI surveillance and their rights. They are also informed to withdraw consent at any time.

9 Data management Plan

All source of documents and electronic records of participants in this study will be paper-based and double-entered into the study database by dedicated data entry staff. All data will be secured in locked cabinets at the INS office. The electronic database will be password protected and study computers will be locked. The database will automatically be backed up onto local hard disks and external drives. Access to the electronic database and hard-copy data will be restricted to authorized senior study personnel only. Data entry and cleaning will be conducted at local sites.

If resources allow, a digital platform for collection of study information on portable tablets may be developed and utilized in this study. Data will be uploaded from all devices at the end of each day to the central database and backed-up to compensate instability of electricity supply together with keeping paper based data until completion of all data installation. Paper-based data collection will be continued until the quality of digital collection is well established.

10 Potential Risk and Mitigation Plan

While there are no direct individual risks from participation in the study, information will be collected that could be used to identify the patient. Although the study takes care to keep this

1
2 information confidential, there is a risk that information could be stolen or accidentally released. All
3 data related to the study will be kept on password-locked computers and only specified study staff
4 will have access to the database where the information is stored.
5
6

7 The vaccination campaign might be delayed owing to slowness in acquisition of import permit,
8 registration, procurement, transportation of the vaccine as well as seasonal challenges. To mitigate
9 the expected challenges, the project team will work closely with the government officials with MOH
10 and WHO country and HQ IHM teams as well as Joint Cholera Initiative for Southern Africa for
11 expediting the vaccine registration and permission of utilization process. Also before
12 commencement of the project, IVI will work closely with the manufacture of the vaccine and
13 monitor the vaccine production and shipment.
14

15 **11 Benefits of the study**

16
17 Participation in the study will benefit the study population by being vaccinated against the V.
18 cholerae which effects will last at least three years with reasonable efficacy. However the results of
19 this study will benefit all populations at risk of cholera infection by improving the scientific
20 understanding of the protection offered by vaccination and directing both preventative and
21 reactive vaccine strategies. The pregnant women who provides contact details will be reached for
22 monitoring of adverse events and guided for appropriate care at nearest health facility for any
23 potential adverse events.
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26 **12 Fund**

27 This M&E is a part of the MOCA project.
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BMJ Open

A pre-emptive Oral Cholera Vaccine (OCV) mass vaccination campaign in Cuamba District, Niassa Province, Mozambique: feasibility, vaccination coverage, and delivery costs using CholTool

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Primary Subject Heading:	Global health
Secondary Subject Heading:	Infectious diseases, Health economics, Global health, Health policy
Keywords:	PUBLIC HEALTH, HEALTH ECONOMICS, INFECTIOUS DISEASES, PREVENTIVE MEDICINE, Infection control < INFECTIOUS DISEASES

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3 1 **A pre-emptive Oral Cholera Vaccine (OCV) mass vaccination campaign in Cuamba District, Niassa**
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5 2 **Province, Mozambique: feasibility, vaccination coverage, and delivery costs using CholTool**
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3 **22 Abstract**
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7 **24 Introduction:** Mozambique suffers from regular floods along its principal river basins and periodic
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10 **25** cyclones that resulted in several cholera epidemics during the last decades. Cholera outbreaks in the
11
12 **26** recent five years affected particularly the northern provinces of the country including Nampula and
13
14 **27** Niassa provinces. A pre-emptive Oral Cholera Vaccine (OCV) mass vaccination campaign was conducted
15
16 **28** in Cuamba District, Niassa Province, and the feasibility, costs, and vaccination coverage assessed.
17

18 **29**
19
20 **30 Methods:** World Health Organization prequalified OCV (Euvichol-Plus), a killed whole-cell bivalent
21
22 **31** vaccine containing *Vibrio cholerae* O1 (classical and El Tor) and O139, was administered in two-doses
23
24 **32** with a 15-day interval during 7-31 August 2018, targeting around 180,000 people aged above one year in
25
26 **33** Cuamba District. Microplanning, community sensitization, and trainings of local public health
27
28 **34** professionals and field enumerators were conducted. Feasibility and costs of vaccination were assessed
29
30 **35** using CholTool. Vaccination coverage and barriers were assessed through community surveys.
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33 **36**

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35 **37 Results:** The administrative coverage of the first and second rounds of the campaign were 98.9%
36
37 **38** (194,581) and 98.8% (194,325) respectively based on the available population data that estimated total
38
39 **39** 196,652 inhabitants in the target area. The vaccination coverage survey exhibited 75.9% ($\pm 2.2\%$) and
40
41 **40** 68.5% ($\pm 3.3\%$) coverages for the first and second rounds, respectively. Overall, 60.4% ($\pm 3.4\%$) of the
42
43 **41** target population received full two-doses of OCV. Barriers to vaccination included incompatibility
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45 **42** between working hours and campaign time. No severe adverse events were notified. The total financial
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47 **43** cost per dose delivered was US\$0.60 without vaccine cost and US\$1.98 including vaccine costs.
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52 **45 Conclusion:** The pre-emptive OCV mass vaccination campaign in remote setting in Mozambique was
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54 **46** feasible with reasonable full-dose vaccination coverage to confer sufficient herd immunity for at least the
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3 47 next three to five years. The delivery cost estimate indicates that the OCV campaign is affordable as it is
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5 48 comparable to Gavi's operational support for vaccination campaigns.
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9 50 **Key words:** Cholera, OCV, pre-emptive vaccination, Cuamba, Mozambique, vaccination coverage
11 51 survey, feasibility, vaccination cost
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For peer review only

52 **Strengths and limitations of this study**

- 53 • This study has successfully demonstrated the feasibility of an OCV mass vaccination campaign in a
54 remote setting in Mozambique.
- 55 • The cost of a mass vaccination campaign for the two-dose OCV administrations has been analysed for
56 the first time in Mozambique, which can serve as a reference cost estimate when planning for any
57 OCV vaccination programs in a similar setting in Mozambique or other countries.
- 58 • Vaccination coverage estimates may be affected if there are people movements in and out of the study
59 area. A sub-study on this and a focused community engagement strategy to reduce the identified
60 barriers to vaccination should be considered in future vaccination programs.
- 61 • Newly introduced vaccination monitoring/coverage survey engaging the same survey team enabled
62 quick availability of the vaccination coverage during or immediately after the campaign, but at the
63 same time the team could be overburdened.

65 **Introduction**

66 Cholera is a vaccine preventable disease that remains as a major public health concern in many parts of
67 low- and middle-income countries (LMICs). A comprehensive policy measure is warranted to control and
68 prevent cholera including investments in improving infrastructure and knowledge, attitude, and behavior
69 associated with water, sanitation, and hygiene (WASH), strengthening health system, and adequate use of
70 oral cholera vaccine (OCV) (1). In Mozambique, cholera has been endemic since the early 1970's when
71 the first cholera outbreak was reported in the country. Several epidemics followed since then including
72 the outbreaks in 1997-1999 and 2012-2016 (2, 3). Cholera outbreaks are more frequent in the country's
73 northern provinces including Nampula, Cabo Delgado, Tete, and Niassa (4). Following the reinforcement
74 of cholera outbreak response strategies, the Ministry of Health (MOH) of Mozambique has carried out
75 several OCV mass vaccination campaigns, as recommended by the World Health Organization (WHO) as
76 an integral part of a comprehensive strategy for cholera prevention and control in endemic setting along

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3 77 with primary interventions of WaSH measures (5): Recent cholera outbreaks in these cholera endemic and
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5 78 hotspot areas in December 2015 resulted in the use of global OCV emergency stockpile to vaccinate
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7 79 approximately 212,745 people living in six neighborhoods of Nampula city in 2016 (4); and in April
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9 80 2017, another 709,077 doses from the stockpile to vaccinate approximately 354,550 people in Tete City
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11 81 and Moatize and Mutarara districts, in response to the cholera outbreak with over 3,592 cholera cases.
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16 83 In addition to these reactive vaccination campaigns supported by the WHO International Coordinating
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18 84 Group (ICG) on vaccine provision for cholera, a growing need for a preventive public health intervention
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20 85 using a targeted vaccination approach in cholera priority areas in-country was identified. The past records
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22 86 of numerous episodes of cholera epidemics in Mozambique have spotted at-risk districts in the most
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24 87 cholera endemic provinces such as Nampula (particularly Nampula City), Niassa (Lichinga city and
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26 88 Cuamba and Lago Districts), and Cabo Delgado (Pemba City and Ancuabe District), and to a lesser
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28 89 degree, other provinces and districts with limited sanitary conditions (5). Niassa province, one of the
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30 90 cholera endemic regions with annual cholera outbreaks affecting largely the Lichinga City and Lago and
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32 91 Cuamba Districts, was identified for a planned pre-emptive vaccine introduction to prevent subsequent
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34 92 cholera outbreaks. Cuamba District with an estimated population of 264,572 (6), reports over 200
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36 93 suspected cholera and 2,000 diarrheal cases almost every year, with an exception of 2014 and 2016 (7).
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38 94 Here, we describe the feasibility, costs, and coverage estimates associated with a pre-emptive OCV mass
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40 95 vaccination campaign conducted in Cuamba District using two-dose OCVs (Euvichol-Plus) administered
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42 96 to approximately 180,000 people with a 15-day interval between the doses, as well as challenges of
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44 97 delivering healthcare in resource limited rural setting in Mozambique.
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49 99 **Methods**

51 52 100 53 54 101 ***Study site and population***

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3 102 The Cuamba District is located in Niassa Province with a population size of around 264,572 (6). The site
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5 103 was selected for a pre-emptive OCV mass vaccination campaign as the district includes the Cuamba
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7 104 Municipality area where cholera is found to be endemic with periodic outbreaks. The area was also
8
9 105 highlighted by the WHO as one of the priority sites to consider for a potential OCV intervention during a
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11 106 needs-assessment performed in September 2015 (1). The District of Cuamba is composed of a total 36
12
13 107 bairros and povoados with population size of approximately 264,572 (6), which includes 21 bairros in the
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15 108 Cuamba Municipality area with around 137,640 residents (8). In total, approximately 180,000 individuals
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17 109 living in Cuamba District was targeted initially, and ultimately around 196,652 people living in Cuamba
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19 110 District were targeted, which included 20 Bairros in the Municipality area and 10 Povoados in the
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21 111 outskirts of the Municipality area (Figure 1). Selection of bairros and povoados in the outskirts of
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23 112 Cuamba Municipality within the District was made not only based on the high number of doses destined
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25 113 for the target population in the municipality area, but also the records of cholera cases during the
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27 114 outbreaks. Everyone above one year of age were eligible for the two-dose OCV administration.
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33 116 ***Vaccine delivery, storage, and handling***

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35 117 Approximately 360,000 doses of WHO pre-qualified Euvichol-Plus, a killed whole-cell bivalent OCV
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37 118 containing *Vibrio cholerae* O1 (classical and El Tor) and O139, were procured from the manufacturer
38
39 119 (EuBiologics) and shipped to the entry port in Pemba, Mozambique in cold-chain. Upon arrival in
40
41 120 Mozambique, the vaccines were delivered to Lichinga by airfreight and transported to a central vaccine
42
43 121 storage room in Cuamba project site, and kept in refrigerators with temperature maintained within range
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45 122 between 2-8°C until and throughout the campaign. The vaccine vial monitor (VVM) and electronic
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47 123 shipping indicators (Q-Tag) were used to monitor the temperature of the vaccines during delivery,
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49 124 storage, and handling. During the vaccination campaign, cool boxes with dry ice maintained within 2-8°C
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52 125 were used to carry the vaccines to the vaccination posts.
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127 ***Cost of vaccine delivery***

128 An openly available, standardized and validated Excel-based tool known as the CholTool was used for
129 estimating vaccine delivery costs (9). This tool comprehensively estimates programmatic costs such as
130 microplanning, communication and training materials development, sensitization/social mobilization, and
131 personnel training, as well as costs related to vaccine delivery such as vaccine procurement, handling,
132 storage, and transport, vaccination administration, adverse events following immunization (AEFI)
133 management, monitoring supervision, and field support. The CholTool has the ability to estimate both
134 financial and economic costs. Financial costs refer to the monetary costs to the payer (e.g., allowances,
135 supplies, transport, and resources used in micro-planning, training, and sensitization/social mobilization)
136 while economic costs include financial costs along with non-monetary costs of donated goods and
137 resources already available (e.g., health personnel time). Key informant interviews were conducted at
138 various administrative levels before, during and after the vaccination campaign in order to identify the
139 resources necessary for each vaccination related activity and costs of respective resources for each of the
140 two rounds of vaccination. The resource and cost data were entered in CholTool which auto-calculates
141 OCV delivery costs. The costs were reported in 2018 in United States Dollars (US\$) based on
142 government and payer perspective.

144 ***Vaccination Strategy and microplanning***

145 A fixed post vaccination strategy with additional mobile teams was adapted for the microplanning of the
146 vaccination campaign. The vaccination teams for 15 fixed posts and 33 mobile teams were identified and
147 trained prior to the campaign. The fixed posts included existing healthcare facilities such as primary
148 health centers and secondary and referral hospital, schools, market areas where many people have easy
149 access to. The mobile teams were deployed to households remotely located with limited access to these
150 fixed posts. This adopted mixed vaccination strategy aimed to improve quality, accessibility, and
151 coverage. Each post was staffed with around 5 field workers including 2 health workers and 3 community
152 engagement workers. Five days prior to the vaccination campaign, micro-plans for each cluster were

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3 153 prepared with postal addresses, target populations, vaccination dates, teams, and other site-specific
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5 154 resources. The health workers obtained verbal informed consents from the individuals visiting the
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7 155 vaccination posts for the OCV administration. Pregnant women by self-report or infants below one year
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9 156 old were excluded from the vaccination. Vaccination cards and vaccination registry book were developed
10
11 157 and deployed, specific to this vaccination that included variables such as name, age, address, and
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13 158 vaccination date. The collected data in the vaccine registry book were entered in an excel-based database.
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15 159 The number of doses planned and administered were also recorded daily for each rounds of the
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17 160 vaccination campaign.
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22 162 ***Vaccination, adverse event monitoring, and coverage estimate***

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24 163 The vaccination campaign occurred in two rounds with a 15-day interval. The first round took place
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26 164 during August 7-11, followed by the second round during August 27–31, 2018. Provision was made for
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28 165 mop-up activities after the second round for those who missed the second dose. To detect any possible
29
30 166 adverse events following immunization (AEFI) during and after the campaign, health workers were
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32 167 trained to monitor and notify any adverse events encountered in inpatient and outpatient admissions at
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34 168 Cuamba health facilities from the first day of each round throughout the 15 days after the last day of each
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36 169 round.
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41 171 The vaccination coverage estimates were assessed in two-folds; administrative coverage and coverage
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43 172 surveys. The administrative coverage was recorded by the local government health office in charge of the
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45 173 vaccination campaign by tracking the number of vaccine doses administered compared to doses that had
46
47 174 been planned in the vaccination target areas, at the end of vaccination activities every day during the two
48
49 175 rounds of the OCV vaccination campaign. For the vaccination coverage surveys, around 520-650
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51 176 households, subject to the vaccination schedule including the mop-up vaccination, were estimated to
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53 177 ensure more than 550 samples for each age group (1-4 years, 5-14 years, 15 years and above) assuming
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55 178 80% coverage with a design effect of 2 to achieve around 5% of prevision. Sampled households were
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3 179 organized per cluster; total 20-25 clusters with 26 households per cluster. The households were selected
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5 180 using a two-stage cluster random sampling methodology. Clusters (primary sampling unit) were selected
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7 181 from the list of villages in the Health Zones, according to the Probability Proportional to Population Size
8
9 182 (PPS) and households (secondary sampling unit) were chosen randomly. For the household random
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11 183 sampling, the enumerators identified the center point and boundary of the survey target area and applied
12
13 184 random selection of households. The surveyors were recruited based on their knowledge on the local area
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15 185 and level of education to conduct the survey, and trained on household sampling methodology, structured
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17 186 survey questionnaire, and process of conducting a survey interview, including verbal informed consent
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20 187 and data capturing on the paper-based survey questionnaires.
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22 188 **F**

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24 189 **Five** survey teams were deployed to the predetermined clusters for daily vaccination monitoring, where
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26 190 randomly identified 26 households per cluster (5 clusters with total 130 households per day) were visited
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28 191 for 4-5 days (total 520-650 households) from the second or third day of the campaign until one day after
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30 192 the last vaccination day. This was applied for each round of the two-dose OCV vaccination campaigns.
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32 193 The information gathered through the survey on the vaccine uptake in the previous day, barriers against
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34 194 the vaccination, and the information source on the campaign were analyzed and fed daily to the
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36 195 vaccination campaign coordinators and supervisors in order to facilitate overall vaccine uptakes. During
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38 196 the second-round of campaign, the survey team collected data for the first-round coverage using the same
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40 197 questionnaire for monitoring, which enabled the first-round vaccine coverage available before the
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42 198 completion of the second round. After the second round, the enumerators continued the household survey
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44 199 for additional three days (total four days, including the last survey day for monitoring of the second
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46 200 round, which was one day after the mop-up campaign) to estimate the coverage for the second round and
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48 201 two full doses of vaccination.
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53 203 ***Patient and Public Involvement***
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3 204 The vaccination campaign was conducted as a part of the government's public health intervention,
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5 205 approved by the Ministry of Health (MOH) in Mozambique. The participants in this study were people
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7 206 living in the cholera endemic and hotspot area, targeted for OCV vaccination campaign as an integral part
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9 207 of the government's cholera prevention efforts. The vaccination target population living in Cuamba
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11 208 District were sensitized and engaged, prior to and during the vaccination campaign, by the district and
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13 209 provincial health officials, study team that included the MOH and National Institute of Health
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15 210 government officials, and local public health professionals at healthcare facilities. The participants were
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17 211 provided with information on the planned OCV mass vaccination such as the purpose of pre-emptive
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19 212 vaccination and detailed information on where and when the vaccination campaigns were to take place.
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21 213 The vaccination campaign was also announced through various press and social media in Mozambique
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23 214 for public awareness and involvement. The study was conducted in a transparent manner with open
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25 215 communication and information sharing in the community, and participants to the OCV vaccination and
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27 216 vaccination coverage surveys were informed for oral consent. For children, consents were obtained from
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29 217 parents/guardian and all adult participants provided their own consent. The study did not present any risk
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31 218 of harm to subjects. No biological samples were collected. Minimum data was collected from
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33 219 participants, whereby privacy and confidentiality of the data were ensured during the survey
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35 220 implementation and data entry and management. Stakeholder meetings were conducted prior to, during,
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37 221 and after the vaccination campaign to further disseminate the campaign plan and results to the community
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39 222 members.
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45 224 **Results**

46 225 *OCV vaccination coverage*

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49 226 The administrative coverage of the first and the second rounds of the campaign were 98.9% (194,581) and
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51 227 98.8% (194,325) respectively based on the available census data of vaccination target population in
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53 228 Cuamba Municipality and outskirts, estimated at around 196,652 (6) inhabitants (Table 1). A total of
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55 229 194,581 people over one-year-old received the first dose, out of whom 99,275 were females and 122,592
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3 230 were children aged less than 15 years. For the second round, total 194,325 people were vaccinated,
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5 231 including 99,275 females and 120,169 children less than 15 years old. Notably, the vaccination coverage
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7 232 survey conducted in the target community during each round and post-vaccination exhibited an
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9 233 approximate coverage estimates of 75.9% (95 CI, 73.10 - 78.70%) for the first round and 68.5% (71.80 -
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11 234 65.20%) for the second round. The coverage rate for the full two-doses was estimated at 60.4% (63.80 -
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13 235 57.00%), whereby the coverage of children aged 1-4 years was around 64.4 % (57.10 – 71.10%) (Table
14
15 236 1). The coverage rates in each round were higher in male (76.3% and 77.8%) than female (75.4% and
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17 237 67.7%), but coverage rate of full doses was higher in female (64.4%) than male (57.3%). No adverse
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19 238 events were reported during and after the vaccination activities, monitored up to 14 days post-vaccination
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21 239 campaign.
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241 **Table 1. OCV vaccination coverage estimates, Cuamba District, 2018**

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243 **a) Administrative vaccination coverage rates**

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		Number of people vaccinated (No.)						
		Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Total
1st Dose	Age (year)							
Individuals vaccinated per	1-4	6,493	9,283	12,394	12,506	7,691	-	48,367
age group	5-15	7,050	16,705	21,590	17,536	11,344	-	74,225
	≥15	10,136	12,400	18,835	18,798	11,820	-	71,989
Total no. of daily vaccinated		23,679	38,388	52,819	48,840	30,855	-	194,581
Cumulative no. of vaccinated		23,679	62,067	114,886	163,726	194,581	-	
Cumulative administrative coverage		12.04%	31.56%	58.42%	83.26%	98.95%	-	98.95%
2nd Dose								
Individuals vaccinated per	1-4	5,479	6,484	11,117	9,596	7,760	7,586	48,022
age group	5-15	9,355	8,796	15,679	13,208	14,444	10,665	72,147
	≥15	9,416	9,275	14,271	14,265	14,848	12,081	74,156
Total no. of daily vaccinated		24,250	24,555	41,067	37,069	37,052	30,332	194,325
Cumulative no. of vaccinated		24,250	48,805	89,872	126,941	163,993	194,325	
Cumulative administrative coverage		12.33%	24.82%	45.70%	64.55%	83.39%	98.82%	98.82%

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246 **b) Vaccination coverage rates through coverage surveys**

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		First Round	Second Round	Full Two Doses
Age (years old)	1- 4	81.1±4.5%	72.2±6.9%	64.4±7.3%
	5-14	86.4±3.1%	71.3±5.8%	65.2±6.1%
	≥15	67.6±3.3%	65.2±4.8%	55.7±5.0%
Sex	Male	76.3±2.9%	77.8±3.9%	57.3±4.6%
	Female	75.4±3.2%	67.7±5.0%	64.4±5.1%
Total	-	75.9±2.2%	68.5±3.3%	60.4±3.4%

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249 *Source of Information and Acceptability*

250 The source of information on the OCV vaccination campaign, identified by the populations living in the
 251 vaccination target areas, showed use of megaphone as the most effective tool in disseminating
 252 information on the vaccination plan and mobilizing the community to get immunized for both rounds:
 253 24% and 34% at the first and second rounds respectively (Table 2). Around 15% of the surveyed people
 254 in the target community indicated that they have learnt about the vaccination campaign through radio
 255 broadcast for the first round, but its communication impact reduced in the second round (4%). This was
 256 different for the community leaders, whose contribution increased from 5% in the first round to 19% in
 257 the following round, reflecting their active engagement and communication efforts in close coordination
 258 with the vaccination teams on the ground.

260 **Table 2. Source of information on OCV campaign, Cuamba District, 2018**

Source of information	1 st Round ¹ N= 646 n (%=n/N)	2 nd Round ² N= 578 n (%=n/N)
Megaphone	152 (24%)	195 (34%)
Family	60 (9%)	53 (9%)
Radio	96 (15%)	23 (4%)
Religious leader	82 (13%)	25 (4%)
Health workers	74 (11%)	120 (21%)
Activists	55 (9%)	9 (2%)
Community leader	33 (5%)	108 (19%)
TV	14 (2%)	11 (2%)
Others ³	78 (12%)	33 (6%)

262 Footnote:

263 ¹ 1st round: 646 households/or people were interviewed.

264 ² 2nd round: 578 households/or people were interviewed.

265 ³ Others included: list other source of info if such data were collected.

268 ***Reasons for not being vaccinated***

269 The unavailability (absence) of the target population for vaccination and incompatibility between working
 270 hours and campaign schedule were commonly cited as barriers for vaccination in both the first (35%) and
 271 the second round (51%) (Table 3). Absence of vaccinators at the vaccination sites were also mentioned,
 272 12% and 18% for the first and second round respectively, despite the pre-vaccination planning and
 273 programmatic organization. Notably, around 10% of the target population has indicated that they have not
 274 been informed about the vaccination campaign even in the second round, though this was a reduction
 275 compared to 18% in the first round. In order to address the most common barriers identified in the first
 276 round, the second round of the vaccination campaign was further extended for additional few days
 277 including the weekends, enabling more people to get vaccinated.

278

279 **Table 3. Reasons for non-vaccination during the OCV campaign, Cuamba District, 2018**

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Reasons for non-vaccination	1 st Dose		2 nd Dose	
	n=361	%	n=222	%
Unavailable	63	17%	96	43%
Incompatibility between working hours and campaign time	53	15%	18	8%
Vaccination post without vaccinator	40	11%	41	18%
Did not have information	66	18%	23	10%
Ill during the vaccination period	30	8%	10	5%
Does not believe in vaccine efficacy	24	7%	2	1%
Afraid of adverse events	8	2%	0	0%
Head of the family did not authorize	4	1%	2	1%
Religious leader forbid	2	1%	0	0%
Considered not safe for pregnant women	1	0%	2	1%
Other	70	19%	28	13%

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3 282 ***OCV delivery costs***
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5 283 The total financial cost of campaign was US\$768,904 of which vaccine acquisition including vaccine
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7 284 shipment constituted 69% (US\$533,659) (Table 4). The vaccine delivery costs including, microplanning,
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9 285 training, communication, and social mobilization, vaccination implementation (Round 1 & 2) constituted
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11 286 rest 31% (US\$235,245). The total financial cost per dose delivered was US\$0.60 without the vaccine cost
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14 287 and US\$1.98 including the vaccine costs in 2018 price. The economic cost per dose delivered excluding
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16 288 vaccine costs was five times higher at US\$3.02. The total financial cost of delivery per fully immunized
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18 289 person excluding vaccine costs was US\$1.21.
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291 **Table 4. Costs of OCV vaccine delivery and immunization in Cuamba District**

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Vaccine Delivery Costs	Financial Cost (Mzn)	Economic Cost (Mzn)	Financial Cost (USD)	Economic Cost (USD)
Vaccine Acquisition	32,179,644	42,081,073	533,659	697,862
Microplanning	640,415	7,596,625	10,620	125,981
Training	265,186	299,419	4,398	4,965
Communication and Social Mobilization	1,912,520	4,301,342	31,717	71,332
Vaccination Implementation (Round 1 &2)	11,367,160	58,510,806	188,510	970,328
Total	46,364,925	112,789,265	768,904	1,870,469
Immunization Costs	Financial Cost (Mzn)	Economic Cost (Mzn)	Financial Cost (USD)	Economic Cost (USD)
Cost per Vaccine Administered (including vaccine)	119	290	1.98	4.81
Cost per Vaccine Administered (without vaccine cost)	36	182	0.60	3.02
Cost per Partially Immunized Person	238	580	3.95	9.61
Cost per Fully Immunized Person (with vaccine)	239	580	3.96	9.63
Cost per Fully Immunized Person (without vaccine)	73	364	1.21	6.03

293

294 Discussion

295 The OCV campaign in Cuamba District was organized without major logistical and programmatic
296 challenges, and no adverse events were reported throughout the vaccination activities and up to 14 days
297 after the campaign. Despite the similarity in the number of people vaccinated in the first and second
298 rounds, the vaccination coverage survey of the second round showed lower coverage estimates than the
299 first round. This may be due to possible cross border movement of people from untargeted districts to get
300 vaccination during the second round. The vaccination coverage for the full two-doses was over 60% that
301 may confer sufficient herd immunity for the following several years based on the existing literature on a
302 cholera transmission model using the Matlab data from Bangladesh (10,11), which predicted 50%
303 coverage with OCV in cholera endemic areas may result in 89% reduction in cholera cases in
304 unvaccinated (12).

305
306 In our study, children aged 5-14 years exhibited the highest coverage. This may be due to the vaccination
307 posts in both schools (fixed vaccination post) and near homes (mobile vaccination posts), which
308 facilitated the school-aged children to access the immunization health service more easily. The female
309 group also presented higher full vaccination coverage rate compared to the male group, who showed
310 higher drop-out after first dose, likely associated with their routine boundaries of livelihood near their
311 houses or their child/children's schools as they take care of children while the male group typically work
312 outside. This assumption is supported by the fact that the absence during the campaign was identified as a
313 significant barrier against vaccination during both rounds of the campaign. Similar pattern was
314 consistently prevalent in the previous OCV campaigns in Beira (13) and Nampula (4), whereby absence
315 was the main barrier for vaccination. The second round of the campaign coincided with the period of
316 school holidays when most households move to farming and food production, resulting in higher absence
317 rate in the second round (43.0%) than in first round (17.0%). Further, it is encouraging to observe more
318 than 60% vaccination coverage rate among children aged 1-4 years, the most at-risk population age-group
319 concerning cholera outbreaks. Considering that caregivers for these younger children are mostly women,

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3 320 higher vaccination coverage for these toddlers and younger children and women is as anticipated in
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5 321 accordance with other studies published in similar settings (14).
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9 323 For real time monitoring of the OCV vaccination campaign, the researchers have employed a
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11 324 representative sampling (two stage cluster sampling) instead of conventional convenient sampling, where
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13 325 the new approach assessed only 1/5 of the predetermined households and demanding five days reaching
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15 326 full households for optimal precision. This new approach has several advantages including 1) availability
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17 327 of representative daily coverage, and barriers, which were fed to the coordination team on a real time
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19 328 bases despite limited precision, 2) the first round vaccine coverage became available before the end of the
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21 329 second round, and finally 3) the vaccine coverage was available immediately after each round without a
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23 330 separate post vaccination coverage survey using ‘measurement error approach (15)’ (the details have not
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25 331 been discussed here, but in a separate article currently under development). Again, the second and full
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27 332 dose vaccine coverage were estimated within a week after the campaign by extension of the survey days
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29 333 by three more days. However, the survey extension and additional questions for the final coverages (the
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31 334 first, second and full) made some survey team members exhausted, which might have affected survey
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33 335 quality.
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39 337 In order to enhance the vaccination coverage, it is paramount to better understand the effective means of
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41 338 communications for community sensitization and engagements, as well as barriers towards participating
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43 339 in a vaccination program such as this campaign. Here, we showed that the use of megaphone proved to be
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45 340 the most effective advocacy tool for disseminating information on the vaccination to our target
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47 341 community, which may have allowed the field workers to reach out to families without access to other
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49 342 sources of information. This may also indicate the need to better understand the inter-personnel
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51 343 communication and community mobilization approach for future vaccination campaigns. For those with
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53 344 missed opportunities to receive the OCV doses during the two rounds, a mop-up vaccination can be
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55 345 considered, though it is often more laborious and costly, requiring a complex management (13). Further,
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3 346 informing the public on the availability of a mop-up prior to or during the campaign may negatively affect
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5 347 their participation in the regular vaccination schedule set-up. Hence, a mop-up was not considered after
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7 348 the first round in our approach but pursued after the second round in order to enhance the full two-dose
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9 349 vaccination and verify vaccination data records submitted during the regular program. Approximately
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11 350 15.4% (32,775/212,824) of the delivered second doses were through this mop-up campaign indicative of
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13 351 an effective strategy.
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18 353 The financial costs of OCV delivery per fully immunized person in this campaign was lower than delivery
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20 354 costs reported in other African countries using the same CholTool (US\$1.8 in Shashemene district of
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22 355 Ethiopia; US\$2.5 in Nsanje district of Malawi; and US\$3.5 in Machinga, Phalombe, and Zomba districts
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24 356 of Malawi per the US\$ price value of 2016), but closer to that reported in Puri district of India (US\$1.14
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26 357 per the US\$ price value of 2016) (9). One reason could be that Mozambique has experience of conducting
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28 358 several OCV campaigns in recent years, and hence there were already resources and expertise available
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30 359 for micro-planning, communication, sensitization, trainings etc., which might have reduced the costs
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32 360 associated with introduction of vaccines in comparison to a vaccination program in naïve setting. The
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34 361 financial cost of US\$0.60 per dose delivered (excluding vaccine procurement) is comparable to the
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36 362 operational support ranging between US\$0.30 and US\$0.80 per person targeted for vaccination
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38 363 campaigns, recommended by the Gavi, the Vaccine Alliance (16,17). This indicates the affordability of
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40 364 OCV campaign in the current setting. To economize the healthcare provider time and efforts and
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42 365 incentivize beneficiaries for greater uptake of vaccines, delivery of multiple products at vaccination posts
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44 366 or on household visits may potentially synergize the delivery cost associated with vaccination campaigns.
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50 368 Overall, our study proved the feasibility of conducting a preemptive OCV mass vaccination campaign in a
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52 369 rural and semi-rural setting in Cuamba District and Cuamba Municipality areas respectively, with
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54 370 sufficient coverage rate and relatively lower delivery cost. The success of vaccination was a result of
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56 371 effective coordination and microplanning among stakeholders despite some field challenges. The
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3 372 vaccination strategy utilizing both fixed and mobile posts, as well as the daily feedback to the
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5 373 coordination team on the preliminary coverage survey result and data related to barriers and source of
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7 374 information on the vaccination campaign, proved valuable to prospectively refine the campaign and
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9 375 mobilization strategy every day on a real-time basis.
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13 377 However, there are several limitations. First, the operational challenges concerning poor road conditions
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15 378 resulted in the accessibility to the target area difficult. Second, the programmatic support that required
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17 379 sufficient and trained human resources and budget for a sustained field monitoring activity and close on-
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19 380 site supervision prior to and during the vaccination campaign and coverage survey activities. Third, the
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21 381 differences in the coverage rates of administrative data and survey result is due to the lack of accurate up-
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23 382 to-date census data of local population. In addition, in order to avoid any conflict with the measles and
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25 383 rubella national immunization campaign that was taking place across the country at the time of this
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27 384 vaccination campaign, we had to delay our OCV vaccination campaign for about two months to obtain
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29 385 support from immunization-related stakeholders, particularly the expanded programme of immunization
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31 386 (EPI) for cold chain space and logistics. Any mass vaccination campaigns should also consider
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33 387 seasonality and other major community activities and/or any political issues.
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40
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42
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53 397 **Contributorship**

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2
3 398 S.E.P conceptualized the overall study design of the Mozambique Cholera Prevention and Surveillance
4
5 399 (MOCA) project. C.S.B. supervised the MOCA project in Mozambique. N.S.B. supervised the overall
6
7 400 vaccination campaign and monitoring and evaluation. All authors participated in the vaccination
8
9 401 campaign. J.C., N.L., L.D.B., J.P.L., N.S.B., S.E.P., S.A., A.O., M.M., and the project field team in
10
11 402 Cuamba and Niassa contributed to data acquisition on the community vaccination coverage surveys, and
12
13 403 interpretation of results under the supervision of N.S.B. R.B.J.M., J.A.M., S.A., A.O., M.M., and others in
14
15 404 the vaccination teams of Cuamba District and Niassa Province contributed to acquisition, review, and
16
17 405 report of the administrative coverage data. I.C. contributed to data acquisition and analysis on vaccination
18
19 406 costs; and V.M. and C.V.R. reviewed the cost analysis. J.C. drafted and edited the paper under the
20
21 407 scientific guidance from N.S.B. and S.E.P. All authors read and approved the final draft.
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27
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39 415 **Competing of Interests**

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41 416 The authors declare no competing interests.
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45 418 **Ethics approval**

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47 419 Institutional Ethical Committee of the National Institute of Health (Ref: 116/CNBS/19) and ethical review
48
49 420 board of the International Vaccine Institute, Seoul, Korea (IRB number 2017-006) approved the study
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51 421 protocol for the OCV mass vaccination campaign monitoring and coverage survey.
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55 423 **Data sharing**

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3 424 All data relevant to the study are included in the article.
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7 426 **Figure legends**
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9 427
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11 428 **Figure 1. Pre-emptive OCV mass vaccination site**
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15 430 Location of the pre-emptive OCV vaccination campaign site in Cuamba District, Mozambique, included
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17 431 bairros and povoados in the municipality and district.
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21 433 **References**
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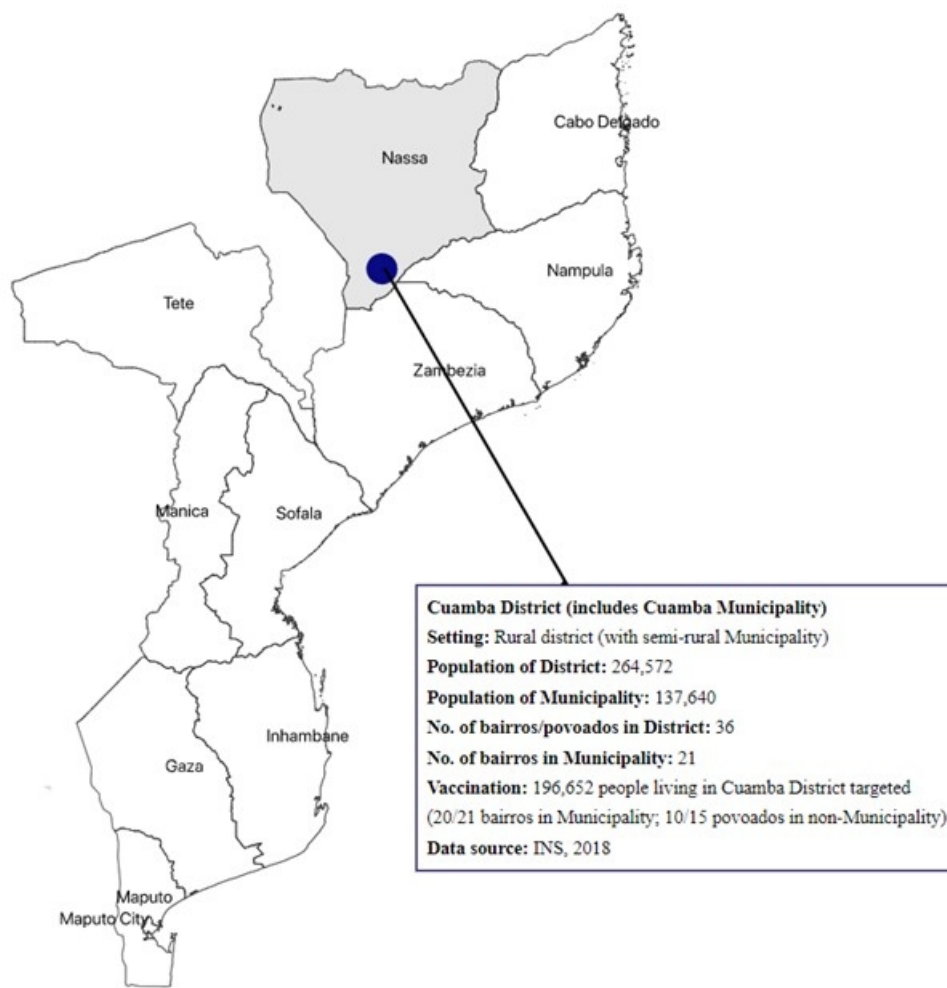


Figure 1. Pre-emptive OCV mass vaccination site

Figure 1. Pre-emptive OCV mass vaccination site

Location of the pre-emptive OCV vaccination campaign site in Cuamba District, Mozambique, included bairros and povoados in the municipality and district.

165x181mm (96 x 96 DPI)