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"It depends on how you tell": A diagnostic analysis of the implementation climate for community-wide mass drug administration for soil-transmitted helminths

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3 1 ***It depends on how you tell: A diagnostic analysis of the implementation climate for community-wide***
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42 ABSTRACT

43 **Objectives:** Current soil-transmitted helminth (STH) morbidity control guidelines primarily target
44 deworming of pre-school and school-age children. Emerging evidence suggests that community-wide
45 mass drug administration (cMDA) may interrupt STH transmission. However, the success of such programs
46 depends upon achieving high treatment coverage and uptake. This formative analysis was conducted to
47 evaluate the implementation climate for cMDA and to determine barriers and facilitators to launch.

48 **Settings:** Prior to the launch of a cMDA trial in Benin, India, and Malawi.

49 **Participants:** Community members (adult women and men, children, and local leaders), community drug
50 distributors (CDDs), and health facility workers.

51 **Design:** We conducted 48 focus group discussions (FGDs) with community members, 13 FGDs with CDDs,
52 and 5 FGDs with health facility workers in twelve randomly selected clusters across the three study
53 countries. We utilized the Consolidated Framework for Implementation Research (CFIR) to guide the
54 design of the interview guide and thematic analysis.

55 **Results:** Across all three sites, aspects of the implementation climate that were facilitators to cMDA
56 launch included: high community member demand for cMDA, integration of cMDA into existing
57 vaccination campaigns and/or health services, and engagement with familiar health workers. Barriers to
58 launching cMDA included mistrust toward medical interventions, fear of side effects, and limited
59 perceived need for interrupting STH transmission. We include specific recommendations from community
60 members regarding cMDA distribution sites, personnel requirements, delivery timing and incentives,
61 leaders to engage, and methods for mobilizing participants.

62 **Conclusions:** Prior to launching the cMDA program as an alternative to school-based MDA, cMDA was
63 found to be generally acceptable across diverse geographic and demographic settings. Community

64 members, CDDs, and health workers felt that engaging communities and tailoring programs to the local
65 context are critical for success. Potential barriers may be mitigated by identifying local concerns and
66 addressing them via targeted community sensitization prior to implementation.

68 **Strengths and limitations of this study**

- 69 • This study highlights opportunities and challenges to launching community-wide mass drug
70 administration (cMDA) for STH as an alternative to school-based MDA from the perspective of
71 community members and the health delivery workforce that will be responsible for delivery of future
72 cMDA programs.
- 73 • Findings from three diverse settings strengthens opportunities to understand similarities and
74 differences across geographic areas.
- 75 • Some participants may have heard about DeWorm3 before participating in focus-group discussions
76 (FGDs), which may pose threats to social desirability and response biases.
- 77 • Although a large number of FGDs were conducted across heterogeneous settings, the generalizability
78 of study findings may not be translatable to other STH-endemic areas.

80 **INTRODUCTION**

81 Neglected tropical diseases (NTDs) affect some of the world's most impoverished populations and
82 contribute to a variety of morbidities that exacerbate existing health and economic inequities (1).
83 Infections with one NTD, soil-transmitted helminths (STH), are associated with anemia, cognitive
84 development delay, growth stunting, pre-term birth, and other adverse outcomes (2). World Health

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3 85 Organization (WHO) guidelines recommend control of STH morbidities via annual or bi-annual deworming
4
5 86 of pre-school and school-age children and other high-risk groups, including pregnant women and
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7 87 adolescent girls (3). However, in many settings, the current STH strategy would likely need to be continued
8
9
10 88 until significant economic development and universal water, sanitation and hygiene (WASH) access are
11
12 89 broadly available to stop transmission of STH (4). Emerging evidence suggests that it may be possible to
13
14 90 interrupt transmission of STH by expanding deworming to treat individuals of all ages via community-wide
15
16 91 MDA (cMDA) (5, 6).

17
18
19 92 The current standard of care for STH is school-based MDA to reach pre-school and school-age children,
20
21 93 and many school-based deworming programs have been successfully implemented for decades.
22
23 94 Transitioning from school-based MDA to cMDA for community-level STH transmission interruption will
24
25 95 require adapting long withstanding programs or designing new platforms for reaching much larger target
26
27 96 populations. These transitions should be approached carefully, as they will likely affect community
28
29 97 member and health worker attitudes towards and engagement in new programs. The success of cMDA in
30
31 98 interrupting transmission of STH is indeed predicated upon programs attaining high treatment coverage
32
33 99 (drug receipt) and uptake (drug ingestion) (7, 8). Many STH-endemic communities have a long history of
34
35 100 participating in other community-based mass distribution programs, including campaigns for lymphatic
36
37 101 filariasis (LF), onchocerciasis, trachoma, malaria bed net distribution, and/or mass immunization programs
38
39 102 such as polio campaigns (9). Factors that influence participation in mass campaigns include recipient trust
40
41 103 in programs and efforts to tailor programs to local conditions (10). Negative campaign experiences or
42
43 104 perceptions can compromise the success of future programs, particularly those requiring high coverage
44
45 105 over multiple years to reach targeted transmission endpoints (11, 12).

46
47 106 Formative qualitative research can be used to understand community-member and implementer
48
49 107 perceptions of past, ongoing, or prospective community-based campaigns. Diagnostic analyses, an
50
51 108 application of formative evaluations, are particularly helpful in illuminating processes that can facilitate

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3 109 or impede implementation. In this study, we perform a diagnostic analysis of the implementation climate
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5 110 to proactively identify factors influencing the launch of cMDA for STH transmission interruption, including
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7 111 (1) perceptions of current deworming practice, (2) potential barriers and facilitators to transitioning from
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10 112 school-based MDA to cMDA delivery, and (3) perceived effectiveness and need for cMDA (13).
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113 **METHODS**

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16 114 This analysis was conducted at the outset of the DeWorm3 Project, a large hybrid type I community cluster
17
18 115 randomized trial in Benin, India, and Malawi (Table 1). DeWorm3 aims to determine the feasibility of
19
20 116 interrupting STH transmission using biannual cMDA, relative to standard-of-care school-based MDA (14-
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Table 1. Overview of study sites

	Benin	India	Malawi
Site	Commune of Comè	Vellore and Thiruvannamalai Districts, Tamil Nadu	Mangochi District
Geographic area of site (km²)	148	477	289
Total number of households	24,378	36,536	27,750
Population size	94,969	140,932	121,819
Standard of care	Annual school-based MDA targeting children 5-14 years of age	Biannual school-based MDA on National Deworming Days targeting children 1-19 years of age	Annual school-based MDA and Child Health Days targeting children 1-14 years of age
cMDA workforce	Community drug distributors (CDDs), coordinated by the Ministry of Health	CDDs and Accredited Social Health Activists (ASHA), women working as health educators and promoters in their communities	Community health workers (Health Surveillance Assistants) who also fill the rolls of CDDs, coordinating with teachers

120 Sampling strategy

121 Key stakeholders shaping the implementation climate for cMDA include community members and local
 122 health workers. Focus group discussions (FGDs) were conducted separately with groups of community
 123 members, including adult women and men (over 15 years), community leaders, and children (ages 12-15
 124 years of age), local health workers, including CDDs, and Ministry of Health (MOH) health facility workers
 125 who often serve as CDD supervisors.

126 Prior to trial randomization (e.g., before designations of intervention or control clusters were made), four
 127 clusters were randomly selected in each site to conduct community-level FGDs. In each cluster, one FGD
 128 was conducted within each community member strata (four total), two FGDs among drug distributors,
 129 and one FGD among local MOH health facility workers. The sampling strategy for identifying and recruiting
 130 community members for FGDs within each cluster differed slightly by site (Table 2). In India, purposive
 131 sampling was employed, in which village leaders/influencers identified potential participants. In Benin and
 132 Malawi, community members were randomly selected to participate from a pool of individuals who
 133 attended outreach meetings at the chiefs/headmen's residence. The first five randomly approached

134 individuals from each demographic strata who agreed to participate were invited to attend FGDs within
 135 the next week (except children, for whom parents/caregivers were approached). No more than one
 136 individual per household was selected to participate in an FGD in a given cluster. Transportation was
 137 offered to individuals who needed access to the FGD location. In Benin and India, local leaders were
 138 chosen using purposive quota sampling. Purposive quota sampling was used to invite CDDs and health
 139 workers from local health facilities in each cluster to participate in FGDs.

140 **Table 2: Sampling strategy by stakeholder group**

Stakeholder	Targeted sample size (per FGD)	Sampling strategy
Community members		
Adult women (15+ years of age)	5-10	Purposive sampling (India) Random sampling (Benin ¹ and Malawi)
Adult men (15+ years of age)	5-10	
Local leaders	5-10	
Children (12-15 years of age)	5-10	
Health center staff and CDD supervisors	5-10	Purposive quota sampling
CDDs	10-15	Purposive quota sampling

¹ Purposive quota sampling was used to sample local leaders in Benin and India

141

142 Data collection

143 This diagnostic analysis study design is informed by the Consolidated Framework for Implementation
 144 Research (CFIR), a meta-theoretical framework of 38 constructs that provides a typology of constructs for
 145 characterizing potential determinants (barriers and facilitators) to implementation from the perspective
 146 of individuals involved in implementation (17). CFIR constructs are organized according to five major
 147 domains influencing implementation and implementation effectiveness including (1) the intervention, (2)
 148 the inner setting, (3) the outer settings, (4) the individuals involved, and (5) the process for accomplishing
 149 the intervention. While the CFIR can be used at any stage of implementation, when applied pre-
 150 implementation, the CFIR can help proactively identify opportunities and challenges facing
 151 implementation and inform adaptations to implementation strategies for the local context (17, 18).

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2
3 152 We drew upon the CFIR to inform the design of four semi-structured interview guides with a mix of
4
5 153 respondent and informant style questions, tailored to each stakeholder group (one question guide was
6
7 154 used for all adult community members). In this study, we identified *a priori* 23 CFIR constructs across all
8
9 155 five domains that we hypothesized would influence the implementation climate for cMDA and which were
10
11 156 appropriate for use during formative research prior to implementation (Appendix 1) (18). The question
12
13 157 guides were piloted and adapted slightly as necessary within each site to ensure that the questions were
14
15 158 clear, meaningful, and culturally appropriate. Site adapted question guides were thereafter translated
16
17 159 into local languages including Yao (Malawi) and Tamil (India), and the official language (French) in Benin.
18
19 160 FGD facilitators in Benin adapted the French question guide to local languages, including Watchi and
20
21 161 Pédah when necessary, during FGD facilitation.

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25
26 162 All participants provided written consent prior to the start of the FGD. The parents or caregivers of
27
28 163 participating children similarly provided written consent and children ages 12-15 also provided written
29
30 164 assent. Consent and assent could also be provided by a thumbprint in the presence of a witness. FGDs
31
32 165 were conducted in private locations with both a facilitator and notetaker present and all FGDs were audio-
33
34 166 recorded with participant permission.

35 36 37 38 167 **Analysis**

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41 168 Audio files were transcribed verbatim in the local or official language. For each transcript, two one-minute
42
43 169 random spot checks were conducted on each audio file for quality assurance. All transcripts were then
44
45 170 translated into English. All transcriptions and their translations were reviewed by a second individual
46
47 171 fluent in both English and the local language for quality assurance.

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49
50
51 172 Coders were based in each DeWorm3 site as well as at the central level (University of Washington,
52
53 173 Seattle). For data collected in Benin and India, two primary coders were assigned to each transcript, with
54
55 174 a third coder designated as the “tie-breaker.” When possible, at least one coder was based at the site in

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2
3 175 which the data were collected, and the other coder was a member of the DeWorm3 central team. For
4
5 176 data collected in Malawi, a single primary coder from the central level coded the data while a secondary
6
7 177 coder at the site reviewed and validated the findings, due to coder availability. Each primary coder
8
9
10 178 independently read and coded each transcript primarily using a deductive approach and a CFIR-based
11
12 179 codebook. Coding teams from each country and the central level met via conference calls to iteratively
13
14 180 refine code definitions and code inclusion/exclusion criteria until a final codebook was established. After
15
16 181 a transcript was coded, the coders assigned to the transcript met via conference call for consensus
17
18 182 meetings to discuss where applied codes diverged. When necessary, a third coder weighed in where
19
20
21 183 consensus between primary coders was not reached.

22
23
24 184 The final coded transcripts were used to create case memos that were grouped by stakeholder category
25
26 185 and site. The case memos included a summary of how the code was applied for a given stakeholder group,
27
28 186 a justification for the summary provided noting code patterns and latent messages, and specific quotes
29
30 187 highlighting how the code was applied. The summaries, patterns, and themes from the coded transcripts
31
32
33 188 and case memos were used to guide thematic analysis, an analytical method that is useful for summarizing
34
35 189 key features of large datasets using a clearly-structured approach (19, 20).

36 37 38 190 **Patient and public involvement**

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41 191 Community members and health workers living in the sampled STH endemic areas were not involved in
42
43 192 design, conduct, or reporting of this qualitative study. However, all feedback from community members
44
45 193 was used to shape a subsequent community-based intervention within a larger clinical trial.

46 47 48 194 **Ethical approval**

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50
51 195 This study has been reviewed and approved by the Institut de Recherche Clinique du Bénin (IRCB) through
52
53 196 the National Ethics Committee for Health Research (002-2017/CNERS-MS) from the Ministry of Health in
54
55 197 Benin, The London School of Hygiene and Tropical Medicine (12013), The College of Medicine Research

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3 198 Ethics Committee (P.04/17/2161) in Malawi, and Christian Medical College, Vellore, in India (10392). The
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5 199 study was also approved by The Human Subjects Division at the University of Washington
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7 200 (STUDY00000180).
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10 201 **RESULTS**

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14 202 In this study, 48 FGDs were conducted with community members – four FGDs (one per cluster) for each
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16 203 stakeholder group: adult women, adult men, children, and local leaders, totaling 16 in each site, 13 with
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18 204 CDDs (two each in Benin and Malawi, nine in India), and five with CDD supervisors (two in Benin and three
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20
21 205 in India).
22

23
24 206 Across FGDs and settings, key themes emerged within four CFIR domains: intervention characteristics,
25
26 207 inner settings, characteristics of individuals, and process. Factors positively influencing the
27
28 208 implementation climate for cMDA across sites included community member demand for community-wide
29
30 209 (versus school-based) MDA, integration of MDA into existing vaccination campaigns and/or health
31
32 210 services, and engagement with health workers (including trained CDDs) rather than community
33
34 211 volunteers. Factors negatively affecting the implementation climate across sites included mistrust and
35
36 212 resistance toward medical interventions, fear of side effects, and limited perceived need. Additional
37
38 213 process recommendations emerged as key themes that varied slightly across sites and included
39
40 214 suggestions regarding MDA distribution sites and distributors, treatment costs/financial incentives,
41
42 215 engaging leaders, and engaging participants through sensitization and mobilization efforts.
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45

46 216 **Intervention characteristics**

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49 217 *Relative advantage: cMDA is preferable to school-based MDA*

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52 218 The CFIR construct of *relative advantage* captures participant perceptions regarding the benefits of
53
54 219 implementing one intervention compared to an alternative (17). Across community member and health
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220 worker/CDD groups and sites, participants identified a preference for cMDA as compared to school-based
221 deworming programs for several reasons. Participants stressed that providing STH treatment to both
222 children and adults is the only way to prevent STH reinfection.

223 Across stakeholder groups, participants also highlighted that children who were not enrolled in school
224 would be able to receive treatment through cMDA. Adult community members in Benin and Malawi were
225 particularly concerned that school-based MDA campaigns do not always provide parents with treatment
226 information prior to distribution and often administer the medications without parental consent or trust.
227 Additionally, they thought uptake would be improved if parents are involved in treatment administration.

228 *It's better to go through the parents to reach the kids. Parents know how to approach their*
229 *children, manage them and make them understand the benefit of the thing [medicine]. The child*
230 *will easily take the medicine without any effect. (Cluster 26, Women, Benin)*

231 Across FGDs and sites, participants were enthusiastic that cMDA could interrupt STH transmission and
232 increase parental engagement with the intervention, particularly to enable parental consent, and allow
233 them to encourage and confirm their child's uptake.

234 *Design quality & packaging: Door-to-door MDA delivery by highly trained, familiar distributors is preferred*

235 *Design quality* describes stakeholder recommendations for how to bundle, present, and assemble the
236 intervention (17). Across sites and stakeholder groups, campaigns that delivered services door-to-door
237 were considered more desirable than those that used a central distribution site (Table 3). In India,
238 community participants reflected upon past experiences with LF MDA campaigns that were door-to-door
239 whereas participants in Benin reflected upon experiences with door-to-door vaccination campaigns and
240 bed net distributions at local health centers. Long waiting times, associated with lost income and
241 productivity, were identified as primary barriers to central distribution sites. One female participant in
242 Benin reported she would not wait around all day for someone to distribute MDA but instead would just

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2
3 243 purchase the medications herself, given their low costs. Additionally, participants stressed that door-to-
4
5 244 door campaigns improve equity by increasing the likelihood of reaching those unable to travel due to
6
7
8 245 financial or physical barriers.

9
10 246 *The HSAs should go door by door to give people the medicine as some people, for example old and*
11
12 247 *crippled, may not be able to go and access the drugs. But if they go door by door, then everyone*
13
14
15 248 *receives the drugs and not only those who walk. (Cluster 21, Women, Malawi)*

16
17
18 249 Community members and leaders across sites, participants preferred to receive treatment from
19
20 250 individuals perceived to be health professionals, especially a familiar health worker or CDD, or someone
21
22 251 working with a well-respected non-governmental organization (NGO). Participants believed that
23
24 252 increased health worker engagement could alleviate community mistrust linked with fear of adverse
25
26 253 events by medicalizing the distribution process and making community members feel safer, thereby
27
28
29 254 increase treatment coverage. Men in Malawi stressed that health volunteers are often poorly respected
30
31 255 and mistrusted, while clinically-trained health professionals are typically more respected. Of paramount
32
33 256 importance for adult community members and CDDs was that distributors are known members of the
34
35 257 community.

36
37
38 258 *When community members see new faces during a project, they tend to be resistant, so it is better*
39
40 259 *to use people from the area and not strangers. If not, this may not be successful. (Cluster 21, Local*
41
42
43 260 *leader, Malawi)*

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45
46 261 *But above all, it is necessary to involve health workers, who the population trusts....Many are afraid*
47
48 262 *because they do not see us, they do not see the health workers on the ground. (Health Center Staff,*
49
50
51 263 *Benin)*

52
53 264 In Benin, local leaders noted that when NGOs engage in CMDA, it is important they are well-respected and
54
55 265 have well-recognized logos that community members are familiar with and trust based on their prior

1
2
3 266 work. Regardless if cMDA is administered by a health professional, volunteer, or NGO, community
4
5 267 members across sites noted that their willingness to participate in cMDA is driven by their perception that
6
7
8 268 they have been fully and accurately informed about cMDA, and that they have had time to ask questions.
9

10 269 *Even if it [deworming medication] is given for free, they will not eat it unless it has been explained*
11
12 *and given. If they are told they will benefit...with awareness in the villages, they will eat it. (Cluster*
13 270
14
15 271 *12, CDD, India)*

16
17
18 272 Community members expressed that they wanted to be treated with dignity and that their participation
19
20 273 in community-wide public health campaigns of any kind should not be taken for granted.
21
22

23 274 *Whether they eat the tablet or not it depends on to what extent this information reaches the*
24
25 275 *people. It depends on how you tell. (Cluster 34, Men, India)*

26
27
28 276 *The messages about drugs should be given to us in good time and not just tell us like today that*
29
30 277 *tomorrow we will have a drug administration activity. Many people need time to ask questions*
31
32 278 *and clear their myths before they get treated. Some people tend to refuse medicine because of*
33
34 279 *fear of side effects, so when you sensitize them for a long time, they tend to listen and at the end*
35
36 280 *the program becomes successful. So avoid short notice messages, people are difficult. They need*
37
38 281 *enough time to understand what is happening. (Cluster 21, Men, Malawi)*

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41
42 282 In Malawi, local leaders reported that community members want to be followed up with after distribution
43
44 283 to monitor for adverse events or continued engagement with distribution programs to foster trust in
45
46 284 future campaigns. Without this, the leaders feared that negative rumors might proliferate, or
47
48 285 communities might feel as though they only received treatment for research purposes, rather than for
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50 286 their wellbeing.

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54 287 *Intervention complexity: cMDA is complex, but still feasible to implement*
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3 288 The CFIR construct of *complexity* is defined as the perceived difficulty of implementing an intervention
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5 289 (17). Across groups, participants were concerned about the timing of cMDA, the distance to distribution
6
7 290 sites if cMDA is centrally located as opposed to delivered door-to-door, and whether or not they would
8
9 291 have sufficient notice about cMDA before the campaign begins. Many community members suggested
10
11 292 optimal distribution times, which varied by site depending on common work schedules and holidays.
12
13 293 Concerns regarding health worker/CDD knowledge and accommodation of community members'
14
15 294 schedules were prevalent across FGDs but some participants stressed they would change their schedules
16
17 295 to be present for distribution if informed by community leaders.
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22 296 *Even if someone has a plan to go to the field or to the market, three days before the distribution*
23
24 297 *of the drug, they will cancel their plan and come and listen to what the village chief invited them*
25
26 298 *to do...if everyone is not informed, it [MDA] cannot succeed. (Cluster 10, Women, Benin)*
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28

29 299 Adults and children across sites recommended that distribution over multiple days within a community to
30
31 300 reach the greatest number of people.
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34 301 *The period of drug administration should be long so that everyone is able to receive treatment.*
35
36 302 *Some people may not be home during the time that you have set to administer the drugs and as*
37
38 303 *such if done for maybe only a day, it means those people will not receive the drugs. But if it is for*
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40 304 *some more days then everyone will be treated. (Cluster 21, Men, Malawi)*
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47 306 **Inner setting**

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49 307 *Implementation climate: Initial mistrust of MDA is likely, but demand and perceived need will counter this*
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52 308 The CFIR construct *implementation climate* captures comments related to the community member's
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54 309 receptivity to implementation, and the extent to which implementation is supported (17). The core
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3 310 component of implementation climate discussed across FGDs were factors that influence community
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5 311 member trust in treatment campaigns. Participants across the sites anticipated high levels of initial
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7 312 mistrust and potential resistance toward newly launched cMDA for STH. This initial mistrust is driven by
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10 313 personal and anecdotal evidence of adverse side-effects such as fatigue, stomachaches, and fever after
11
12 314 previous school-based deworming MDA campaigns.

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14
15 315 *Other pupils received the medical treatment before they ate a meal, hence they vomited. So those*
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17 316 *that did not receive the medical treatment were afraid of vomiting too if they took the medicine.*
18
19 317 (Cluster 19, Children, Malawi)

20
21
22 318 *They will eat [medication] based on the trust. They will eat [medication] based on your approach,*
23
24 319 *otherwise they may take and keep it aside somewhere....* (Cluster 17, Men, India)

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26
27 320 In Malawi, limited follow-up by transitory MDA programs and research projects was also noted as fueling
28
29 321 mistrust of community health programs. Similarly, in one CDD FGD in India, participants identified mistrust
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31 322 of government programs as a potential barrier to MDA campaigns where medications are provided for
32
33 323 free. CDDs explained that community members perceive government provided medications to be of
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35 324 poorer quality and therefore less effective with greater risks of side effects; therefore, those who can
36
37 325 afford to purchase their own medications from pharmacies will often do so.

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41 326 *For people who can, they will get it [deworming medicine] from the medical shop. Whatever is*
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43 327 *given through the government they will keep it aside and they will not use it.* (Cluster 15, CDD,
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45 328 India)

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49 329 In Benin, some participants from the men's, women's, and CDD FGDs shared concerns that drugs used in
50
51 330 such campaigns might be given by Westerners with malintent.

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3 331 *The majority of the population does not understand. They think that the drugs are poisoned in*
4
5 332 *order to reduce the African population. (Cluster 10, Men, Benin)*
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8 333 Similarly, in Malawi, CDDs identified rumors and misinformation as major barriers to delivering cMDA with
9
10 334 high coverage. Specific rumors include that stool collected for STH surveillance would be used for Satanist
11
12 335 practices, rather than medical purposes, and that school-based deworming programs provide
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14 336 contraceptives to young children to reduce population growth.
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18 337 While participants noted that mistrust and resistance might initially be high following a transition to cMDA
19
20 338 for STH, there was still a strong perceived demand for deworming of all ages, and a sentiment that
21
22 339 community sensitization could overcome these concerns.
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24

25 340 *...we are looking forward to this [community-based MDA] and we would like this to be a regular*
26
27 341 *treatment. People are suffering from intestinal worms and only children receive the treatment. So*
28
29 342 *this project [DeWorm3] will help all of us to receive treatment. (Cluster 21, Men, Malawi)*
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33 343 *Compatibility: Community-based MDA is highly compatible with existing health infrastructure*
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35 344 The CFIR construct *compatibility* is highly related to *implementation climate*, capturing the alignment
36
37 345 between the innovation and existing values and priorities (17). Health facility workers and CDDs across
38
39 346 sites noted cMDA should be integrated into existing community programs or, at a minimum, coordinate
40
41 347 with ongoing community-based activities to improve treatment coverage and mitigate risks of conflict
42
43 348 with ongoing local health programs. CDDs in India and community leaders in Benin identified community-
44
45 349 based vitamin A and iron distribution and childhood vaccination campaigns as ideal programs to integrate
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47 350 with cMDA. In India, CDDs also suggested integrating cMDA with existing indoor residual spraying
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49 351 programs for vector control.
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3 352 *The voluntary workers who go house to house to spray mosquitoes, we can make use of them to*
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5 353 *give the tablet...Earlier they were going once a month or once a week, but now they go daily house*
6
7 354 *to house. We can give through them. (Cluster 17, CDD, India)*
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9

10 355 *Available resources: Training, storage, and hygiene infrastructure are key resources for MDA*
11
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13 356 *implementation*
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16 357 The CFIR construct *available resources* describes the financial and material resources available (and
17
18 358 desired) for implementation, including training and education, space, time, and money (17). Health facility
19
20 359 workers and CDDs across sites stressed that existing resources may not be sufficient for delivery of cMDA.
21
22 360 CDDs in particular were concerned about receiving adequate training and access to resources to take
23
24 361 home for self-review. CDDs and health workers highlighted that they wanted more than a single one-day
25
26 362 training prior to MDA, in order to provide adequate time to practice and apply skills in a training
27
28 363 environment. Across sites, CDDs noted the importance of training before distribution.
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32 364 Other key resources identified by CDDs and health workers in Benin included medication storage in the
33
34 365 field, community education materials, shelter during inclement weather, as well as food, water, and
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36 366 financial incentives for CDDs. CDDs in Benin were particularly concerned with timely payment for their
37
38 367 work. In Malawi, local leaders noted that in the past villagers have felt burdened by volunteering for health
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40 368 program implementation without compensation. They also noted that villagers might expect payment for
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42 369 participating in MDA, given past experiences with research projects providing stipends. In India, health
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44 370 facility workers wanted to ensure they would have adequate staffing to assist during MDA.
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48 371 Lastly, CDDs and health center personnel across sites, women in Benin, and leaders in India stressed that
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50 372 hygiene infrastructure needs to be improved and that investing in WASH as part of a broader STH
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52 373 elimination program might, as a result, increase treatment coverage of cMDA by demonstrating long-term
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54 374 investments in community well-being.
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3 375 *The rules of hygiene are very important, very, very important. Without it, we cannot right away*
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5 376 *start distributing the drugs and say that we want to completely eradicate the transmission of*
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7 377 *worms, impossible. (CDD, Benin)*
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10 378 **Characteristics of individuals**

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13 379 *Knowledge & beliefs: Skepticism of the clinical rationale for MDA, fear of side effects, and limited perceived*
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15 380 *need for treatment will be barriers to cMDA*
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18 381 The *knowledge and beliefs* CFIR construct is defined as individuals' attitudes toward and value placed on
19
20 382 implementation and their familiarity with related facts, truths, and principles (17). While participants
21
22 383 strongly believed cMDA could eliminate STH transmission, some reservations about MDA rooted in
23
24 384 knowledge and perceptions about deworming medications remain. For example, adult men and children
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26 385 in Benin and local leaders in Malawi raised concerns about the effects of treating people who may not be
27
28 386 infected with STH.
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32 387 *When you get the drugs and you do not have the worms, the tablet can still damage your organs*
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34 388 *such as organs of digestion or breathing. (Cluster 1, Children, Benin)*
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38 389 In India and Malawi, participants in the men's FGDs thought individuals who feel healthy might perceive
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40 390 themselves to be at low risk of STH and thus choose not to participate in cMDA. Women in Malawi
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42 391 reported this occurred during prior cMDA campaigns while women in India also noted individuals with
43
44 392 limited literacy might not understand the need for treatment and be reluctant to participate in MDA
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46 393 campaigns.
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49 394 *Self-efficacy: Community members and CDDs will be key mobilizers for cMDA*

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52 395 The CFIR construct *self-efficacy* captures comments that reflect an individual's beliefs in their own abilities
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54 396 to achieve implementation goals (17). Women and community leaders in Benin identified themselves as
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397 important catalysts in influencing the acceptability of MDA by working together and influencing their
398 social networks.

399 *The process is simple as we have just understood, we will also explain to our brothers and sisters*
400 *who will not accept that treatment is a good thing. We will tell them they should not be*
401 *discouraged adding that there is good in it. It's up to us to explain to them. (Cluster 1, Women,*
402 *Benin)*

403 Health facility workers and CDDs also identified themselves as important contributors to ensuring
404 successful MDA implementation, given their existing relationships with communities.

405 *We worked with them and they know us on the ground to be able to do the job, so there are no*
406 *issues for community health workers. (CDD, Benin)*

408 **Process**

409 *Engaging: Local leaders and sensitization activities are essential for ensuring high treatment coverage*

410 The CFIR construct *engaging* is defined as approaches to attracting and involving individuals in
411 implementation, such as through social marketing or education campaigns (17). Adult participants across
412 sites, including local leaders, identified specific leaders as key facilitators of effective implementation
413 (Table 2). These leaders should be notified in advance of interventions taking place within their
414 communities to gain their support and promote the intervention prior to implementation. Advance
415 sensitization with information about the distribution time as well as potential intervention benefits and
416 risks were identified as critical pieces of information that influence the implementation climate and, in
417 effect, effective delivery of cMDA. Preferred engagement methods varied slightly across sites, however
418 community members suggested that a variety of information-sharing mechanisms be utilized in advance
419 of MDA to improve community member knowledge and buy-in (Table 3).

Table 3: Recommendations to optimize the implementation climate for newly launched cMDA

Recommendation category	Benin	India	Malawi
<i>MDA distribution mode</i>	Door-to-door distribution	Door-to-door distribution preferable; potential for 3-4 central distribution sites in some communities	Door-to-door distribution
<i>Intervention cost/financial incentives for participation</i>	Free, but need to address rumors about nefarious intentions behind free MDA distribution	Free treatment preferable to most participants; need to address fears of perceived poor-quality medications provided by government programs. Financial incentives should not be given for MDA participation, but incentives such as combs and soap were suggested	Free, but communities with past exposure to research studies might expect financial incentives for MDA participation
<i>Community drug distributor preferences</i>	Health workers (health facility workers or CDDs) who are familiar to community members	Trained health workers (nurses, doctors, ASHAs) who are familiar. Individuals without training should not be distributors	Health workers (including HSAs) who are familiar to community members. Volunteers are less respected and should not be distributors
<i>Duration and time of distribution</i>	Distribution over multiple days to accommodate different household schedules and reach the greatest number of people. Rainy season and market days should be avoided. Must consider work schedules and implement flexible distribution times	Distribution over multiple days. Evening or early morning preferred distribution time to accommodate work schedules	Distribution over multiple days to accommodate different household schedules and reach the greatest number of people
<i>Key leaders to engage prior to cMDA</i>	Village chiefs, religious leaders, and health workers	President and ward councilor of community (Panchayat), other health workers (Anganwadi workers), and teachers	Village chiefs, local leaders, religious leaders, local NGOs, HSAs, and teachers

<i>Community education topics to engage MDA participants</i>	Educate community about purpose and potential side effects of treatment	Educate community about purpose, advantages, and potential side effects of treatment, and proper dosage for different people (e.g., children, elders)	Educate community about purpose and potential side effects of treatment; sensitization must be done more than one day in advance to allow decision-making time
<i>Mechanisms for engaging community members</i>	Utilize radio, phones, community meetings, and word of mouth to share information. Ring gongs at distribution time	Utilize radio, loudspeaker announcements, flyers, health documentaries, TV news, community meetings (women's groups), and community dramas to share information. Beat drums at distribution time	Utilize radio, phones, loudspeaker announcements, dramas, community meetings, door-to-door outreach, to share information

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422 DISCUSSION

423 This diagnostic analysis highlights opportunities and challenges of launching cMDA for STH that are shared
 424 across geographic areas as well as important differences between them. Our findings build upon the
 425 existing literature and demonstrate strong acceptability of cMDA for STH interruption, particularly as an
 426 alternative to school-based distribution to provide more equitable access to deworming treatment. When
 427 considering a transition from school-based distribution to cMDA, participants highlighted opportunities
 428 to integrate cMDA into existing community health programs, such as vaccination campaigns, and the
 429 importance of engaging clinically trained, trusted drug distributors to mitigate fears of adverse events and
 430 increase treatment coverage. Utilizing local CDDs from the same area or are directly known to the
 431 recipients, is associated with high MDA coverage in other settings. (21, 22) While familiarity was important
 432 to participants in this study, they also stressed comprehensive clinical training for CDDs as essential for
 433 fostering trust during cMDA. While participants identified potential benefits of launching cMDA, they also

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3 434 noted key barriers that might limit implementation success. Similar to findings from studies exploring
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5 435 MDA barriers post-implementation, the primary barriers identified across sites included mistrust toward
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7 436 free drug distribution (especially those provided by community volunteers perceived to have no clinical
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9 437 training), fear of side effects, and limited perceived need for treatment without symptoms (12, 23-25).
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11 438 This information is essential for adapting interventions to fit the specific context and concerns of
12
13 439 communities prior to making a significant change to public health programs, such as changing from school-
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15 440 based delivery to community-wide delivery of deworming medicines.
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19 441 In this formative evaluation, we synthesized recommendations from community members to assist in
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21 442 intervention optimization at a site level, including preferred treatment time and distribution methods.
22
23 443 Site specific preferences and recommendations for implementation varied to small degrees across
24
25 444 settings, including preferred distribution times, campaign duration, location, distributor qualifications,
26
27 445 and procedures for engaging leaders and community participants. Other studies have found that
28
29 446 proactively identifying specific times when individuals are generally available to receive treatment is an
30
31 447 essential facilitator of effective campaign delivery (26-28), and when not completed can increase
32
33 448 frustration with community-based volunteer distributors (23) and the MDA campaign itself (29). Where
34
35 449 trial timeline and funding allow, formative evaluations such as this may facilitate proactive identification
36
37 450 of potential barriers and of implementation processes to optimize community acceptability and adapt
38
39 451 intervention delivery as needed. When timelines or funding are limited, like during cMDA implemented
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41 452 by national NTD programs in limited resources settings, brief surveys prior to MDA and interim analyses
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43 453 and may be conducted to tailor MDA implementation.
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49 454 Emerging themes from community member, local leader, CDD, and health worker FGDs were highly
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51 455 consistent. However, CDDs and health workers noted unique facilitators and barriers affecting their work,
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53 456 including time for training, resources in the field, and timely compensation, similar feedback from
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55 457 implementers in other settings (24). CDDs, health workers, and community leaders also uniquely stressed
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3 458 the importance of packaging WASH interventions with MDA for STH elimination. These sentiments reflect
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5 459 advanced knowledge of STH transmission but may also reflect doubt that transmission interruption
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7 460 programs predicated on broadly delivered MDA will interrupt transmission without also improving
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10 461 hygiene infrastructure. In fact, most of the benefits attributed to cMDA amongst these cadres was driven
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12 462 by beliefs that MDA will be more acceptable when delivered in the community, as opposed to its potential
13
14 463 for interrupt transmission. Although evidence regarding the effectiveness of WASH on STH transmission
15
16 464 interruption is still weak, it is also important to monitor how implementer and community enthusiasm for
17
18 465 cMDA changes over time, potentially driven by the absence of WASH interventions (30).

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22 466 Participants across all geographic areas noted that myths and rumors could pose serious challenges to
23
24 467 cMDA delivery, adding further to the literature documenting this obstacle in other settings (10, 24, 31,
25
26 468 32). Children in Benin and Malawi noted specific concerns about side effects of deworming treatment
27
28 469 circulating within schools prior to and post-MDA campaigns. While side effects for albendazole are
29
30 470 typically quite mild, albendazole is often co-administered to children with praziquantel as preventative
31
32 471 chemotherapy for schistosomiasis. Praziquantel can cause relatively more severe side effects, including
33
34 472 diarrhea and vomiting (33). Thus, prior experiences with MDA campaigns including other treatments
35
36 473 might influence future perceptions about albendazole specifically or MDA generally (34). Evidence
37
38 474 suggests that effective health workers can overcome these individual-level perceptions (29); addressing
39
40 475 myths and rumors will require targeted and pro-active community sensitization and CDD training that
41
42 476 openly discuss local myths and rumors pre-intervention.

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47 477 Mistrust toward public health campaigns and government-run health programs was prevalent across
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49 478 settings. These concerns were driven by prior negative experiences with medical interventions and
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51 479 programs in which limited information was provided in advance of treatment, parents were minimally
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53 480 engaged in school-based MDA, and there were perceived concerns about drug quality. Potential strategies
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55 481 for overcoming these barriers include engaging local leaders (27, 31, 35), targeted education campaigns

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3 482 (24, 36, 37), community mobilization (35, 38, 39), and engagement of trusted, trained personnel to
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5 483 administer preventive treatment.
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8 484 During the design of our initial question guide (Appendix 1), we drew from selected constructs across all
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10 485 CFIR domains. However, during data analysis no constructs within the outer setting emerged as major
11
12 486 facilitators or barriers to launch of cMDA campaigns. The outer setting domain is comprised of constructs
13
14 487 representing external influences on implementation and, perhaps because these data were collected at
15
16 488 the community-level, respondents were more focused on individuals involved in implementation and
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18 489 implementation processes (17). Additionally, while CFIR constructs should ideally be coupled to specific
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20 490 targeted outcomes, the formative nature of this study precludes linkage of implementation determinants
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22 491 to outcomes (18).
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27 492 **Conclusion**

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30 493 This study supports that cMDA, particularly as an alternative to school-based MDA, is generally acceptable
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32 494 across heterogenous settings and builds upon the existing literature exploring facilitators and barriers of
33
34 495 launching and implementing cMDA. Community engagement including STH education, understanding
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36 496 preferred distribution times and methods, involvement of local leaders and familiar health workers or
37
38 497 CDDs are critical for implementation success. Potential barriers, including mistrust of free drug
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40 498 distribution, fear of side effects, and limited perceived need of treatment can be addressed through
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42 499 community sensitization and engagement of local leaders and trusted health workers. Formative research
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44 500 exploring attitudes and community-derived recommendations should be conducted when possible to
45
46 501 improve community acceptability of new interventions.
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50 502 **Author contributions**

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52
53 503 ARM, JLW, MCGC, SSRA, KK, and MI conceived of the initial study design. EA, RR, SPK, FC, CIT, PN, MI, KK,
54
55 504 KA, AT, and YJ were involved in data collection and data processing. AR managed the data. AR, ABE, SL,
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3 505 and ARM contributed to data analysis. SL, EA, and AM led the writing of the paper. All authors read and
4
5 506 approved the final version of the manuscript.
6
7

8 507 **Competing Interests**

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10
11 508 None declared.
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13

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20
21 512 design, data collection and analysis, decision to publish, or preparation of the manuscript.
22
23

24 513 **Data availability**

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27 514 Data are available from the DeWorm3 Institutional Data Access Committee (contact dw3data@uw.edu)
28
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30
31

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Appendix 1. Qualitative interview guides

Interview guide #1: Health Centre & DeWorm3 Supervisory Teams

	Question
1	<p>What kind of information or evidence are you aware of that shows whether or not community-wide MDA for interrupting transmission of STH will work in your setting?</p> <p><i>Follow-up questions:</i></p> <ul style="list-style-type: none"> • <i>Is this evidence strong or weak?</i> • <i>What evidence are you aware of from your own research? Practice guidelines? Published literature? Other settings?</i> • <i>How does this knowledge affect your perception of the intervention?</i>
2	<p>What advantages does community-wide MDA for STH have compared to school-age targeted programs? What disadvantages?</p>
3	<p>When delivering community-wide MDA for STH, what local adaptations should be made so that the intervention is effective?</p> <p><i>Follow-up questions:</i></p> <ul style="list-style-type: none"> • <i>What aspects of the intervention should not be adapted?</i> • <i>Do you think you will be able to make these adaptations? Why or why not?</i>
4	<p>How complicated is delivery of the entire community-wide MDA for STH intervention? Please consider the following aspects of the intervention: duration of an MDA round, target population, and number of steps and sub-activities involved to fully implement.</p>
5	<p>What supportive materials or tools are needed to ensure effective implementation of community-wide MDA for STH?</p>
6	<p>What community-wide MDA for STH activities are built upon the previous LF MDA program infrastructure and experiences?</p> <p><i>Follow-up questions:</i></p> <ul style="list-style-type: none"> • <i>If none, what LF program activities could be leveraged for community-wide MDA for STH?</i>
7	<p>From your perspective, what are unique costs of implementing community-wide MDA for STH, relative to the standard of care of school-age targeted MDA?</p>
8	<p>What barriers might community members face in participating in community-wide MDA for STH?</p> <p><i>Follow-up question:</i></p> <ul style="list-style-type: none"> • <i>What could be done to overcome these barriers?</i>
9	<p>What kinds of infrastructure changes to the health system will be needed to accommodate community-wide MDA for STH?</p> <p><i>Follow-up questions:</i></p>

	Question
	<ul style="list-style-type: none"> <i>If community-wide MDA for STH is scaled-up after the DeWorm3 project, will there need to be any changes in formal policies? Changes in information systems or data reporting systems? Other?</i> <i>What kind of approvals do you think will be needed to transition the STH program entirely to community-wide MDA? Who will need to be involved?</i> <i>Can you describe the process that will be needed to make these changes?</i>
10	How accepting are your co-workers of implementing community-wide MDA for STH? Why?
11	<p>Do you think community-wide MDA for STH could be integrated into routine MOH programs?</p> <p><i>Follow-up questions:</i></p> <ul style="list-style-type: none"> <i>If yes, how? If no, why not?</i> <i>What would the effects of integration on routine programs be?</i>
12	How important do you think it is to implement community-wide MDA for STH compared to the other health priorities?
13	Do you feel incentivized to ensure that the DeWorm3 trial is successful in interrupting transmission of STH? What is the incentive?
14	<p>How supportive are government and non-governmental leadership of implementing community-wide MDA for STH?</p> <p><i>Follow-up question:</i></p> <ul style="list-style-type: none"> <i>How do you think it will affect uptake/implementation?</i>
15	<p>What kind of relevant training will you have during this intervention? Do you feel the training will prepare you to carry out the roles and responsibilities expected of you? How so?</p> <p><i>Follow-up questions:</i></p> <ul style="list-style-type: none"> <i>What are the positive aspects of the training?</i> <i>What is missing?</i> <i>What kind of continued training is necessary?</i>
16	Do you think that community-wide MDA could interrupt STH transmission (i.e. stop the spread of intestinal worms) in your setting? Why or why not?
17	How confident are you that you will be able to successfully carry out your DeWorm3 related duties? What gives you that level of confidence (or lack of confidence)?
18	<p>Can you describe your team's plan for implementing community-wide MDA for STH?</p> <p><i>Follow-up questions:</i></p> <ul style="list-style-type: none"> <i>Do you think everyone involved understands the plan well, or is it too complicated?</i> <i>What do you do if you have to modify or revise the plan due to challenges, errors, or mistakes?</i>
19	Who are the key influential individuals or organizations to get buy-in from during the DeWorm3 study?

	Question
20	How should community members be informed about community-wide MDA or other DeWorm3 interventions before they occur?
21	What are some strategies to achieve high MDA treatment coverage?
22	Is there any other information that you would like to share about community-wide MDA today?

Interview Guide #2: Community Drug Distributors & Community Health Workers

#	Question
1	What advantages does community-wide MDA for STH have compared to school-age targeted programs? What disadvantages?
2	When delivering community-wide MDA for STH, what local adaptations should be made so that the intervention is effective? <i>Follow-up questions:</i> <ul style="list-style-type: none"> • What aspects of the intervention should not be adapted? • Do you think you will be able to make these adaptations? Why or why not?
3	How complicated is delivery of the entire community-wide MDA for STH intervention? Please consider the following aspects of the intervention: duration of an MDA round, target population, and number of steps and sub-activities involved to fully implement.
4	What supportive materials or tools are needed to ensure effective implementation of community-wide MDA for STH?
5	From your perspective, what are unique costs of implementing community-wide MDA for STH, relative to the standard of care of school-age targeted MDA?
6	What barriers might community members face in participating in community-wide MDA for STH? <i>Follow-up question:</i> <ul style="list-style-type: none"> • What could be done to overcome these barriers?
10	How accepting are your co-workers of implementing community-wide MDA for STH? Why?
11	Do you think community-wide MDA for STH could be integrated into routine MOH programs? <i>Follow-up questions:</i> <ul style="list-style-type: none"> • If yes, how? If no, why not? • What would the effects of integration on routine programs be?
12	How important do you think it is to implement community-wide MDA for STH compared to the other health priorities?
13	Do you feel incentivized to ensure that the DeWorm3 trial is successful in interrupting transmission of STH? What is the incentive?
14	How supportive are government and non-governmental leadership of implementing community-wide MDA for STH?

#	Question
	<p><i>Follow-up question:</i></p> <ul style="list-style-type: none"> • <i>How do you think it will affect uptake/implementation?</i>
15	<p>What kind of relevant training will you have during this intervention? Do you feel the training will prepare you to carry out the roles and responsibilities expected of you? How so?</p> <p><i>Follow-up questions:</i></p> <ul style="list-style-type: none"> • <i>What are the positive aspects of the training?</i> • <i>What is missing?</i> • <i>What kind of continued training is necessary?</i>
16	Do you think that community-wide MDA could interrupt STH transmission (i.e. stop the spread of intestinal worms) in your setting? Why or why not?
17	How confident are you that you will be able to successfully carry out your DeWorm3 related duties? What gives you that level of confidence (or lack of confidence)?
18	<p>Can you describe your team's plan for implementing community-wide MDA for STH?</p> <p><i>Follow-up questions:</i></p> <ul style="list-style-type: none"> • <i>Do you think everyone involved understands the plan well, or is it too complicated?</i> • <i>What do you do if you have to modify or revise the plan due to challenges, errors, or mistakes?</i>
19	Who are the key influential individuals or organizations to get buy-in from during the DeWorm3 study?
20	How should community members be informed about community-wide MDA or other DeWorm3 interventions before they occur?
21	What are some strategies to achieve high MDA treatment coverage?
22	Is there any other information that you would like to share about community-wide MDA today?

Interview Guide #3: Community members

#	Question
1	<p>What advantages does community-wide MDA for STH have compared to school-age targeted programs?</p> <p><i>Follow-up question:</i></p> <ul style="list-style-type: none"> • <i>What disadvantages?</i>
2	<p>When delivering community-wide MDA for STH, what local adaptations should be made so that the intervention is effective?</p> <p><i>Follow-up question:</i></p> <ul style="list-style-type: none"> • <i>What aspects of the intervention should not be adapted?</i>

#	Question
3	<p>What barriers might community members face in participating in community-wide MDA for STH?</p> <p><i>Follow-up question:</i></p> <ul style="list-style-type: none"> • <i>What could be done to overcome these barriers?</i>
4	<p>Do you remember the lymphatic filariasis (LF) MDA programs that used to occur in this area? What do you remember about them?</p> <p><i>Follow-up questions:</i></p> <ul style="list-style-type: none"> • <i>What could be done to overcome these barriers?</i> • <i>Did you participate in those treatment days by swallowing the medicines given to you? Why or why not?</i> • <i>Has that affected your interest in participating in the current mass treatment days?</i>
5	<p>Do you think that community-wide MDA could interrupt STH transmission (i.e. stop the spread of intestinal worms) in your setting? Why or why not?</p>
6	<p>Who are the key influential individuals or organizations to get buy-in from during the DeWorm3 study?</p> <p><i>Follow-up questions:</i></p> <ul style="list-style-type: none"> • <i>Can you provide specific examples of why you think their buy-in is important?</i>
7	<p>How should community members be informed about community-wide MDA or other DeWorm3 interventions before they occur?</p>
8	<p>What are some strategies to achieve high MDA treatment coverage?</p>
9	<p>Is there any other information that you would like to share about community-wide MDA today?</p>

BMJ Open

"It depends on how you tell": A qualitative diagnostic analysis of the implementation climate for community-wide mass drug administration for soil-transmitted helminths

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42 ABSTRACT

43 **Objectives:** Current soil-transmitted helminth (STH) morbidity control guidelines primarily target
44 deworming of pre-school and school-age children. Emerging evidence suggests that community-wide
45 mass drug administration (cMDA) may interrupt STH transmission. However, the success of such programs
46 depends upon achieving high treatment coverage and uptake. This formative analysis was conducted to
47 evaluate the implementation climate for cMDA and to determine barriers and facilitators to launch.

48 **Settings:** Prior to the launch of a cMDA trial in Benin, India, and Malawi.

49 **Participants:** Community members (adult women and men, children, and local leaders), community drug
50 distributors (CDDs), and health facility workers.

51 **Design:** We conducted 48 focus group discussions (FGDs) with community members, 13 FGDs with CDDs,
52 and 5 FGDs with health facility workers in twelve randomly selected clusters across the three study
53 countries. We utilized the Consolidated Framework for Implementation Research (CFIR) to guide the
54 design of the interview guide and thematic analysis.

55 **Results:** Across all three sites, aspects of the implementation climate that were facilitators to cMDA
56 launch included: high community member demand for cMDA, integration of cMDA into existing
57 vaccination campaigns and/or health services, and engagement with familiar health workers. Barriers to
58 launching cMDA included mistrust toward medical interventions, fear of side effects, and limited
59 perceived need for interrupting STH transmission. We include specific recommendations from community
60 members regarding cMDA distribution sites, personnel requirements, delivery timing and incentives,
61 leaders to engage, and methods for mobilizing participants.

62 **Conclusions:** Prior to launching the cMDA program as an alternative to school-based MDA, cMDA was
63 found to be generally acceptable across diverse geographic and demographic settings. Community

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3 64 members, CDDs, and health workers felt that engaging communities and tailoring programs to the local
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5 65 context are critical for success. Potential barriers may be mitigated by identifying local concerns and
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7 66 addressing them via targeted community sensitization prior to implementation.
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14 68 **Strengths and limitations of this study**

- 17 69 • This study conducted focus group discussions across three diverse settings, creating the opportunity
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19 70 to understand similarities and differences in the implementation climate for community -wide mass
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21 71 drug administration (cMDA) and STH transmission interruption.
- 22 72 • Some participants may have heard about the intervention before participating in focus-group
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24 73 discussions (FGDs), which may pose threats to social desirability and response biases.
- 25 74 • Although a large number of FGDs were conducted across heterogeneous settings, the generalizability
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27 75 of study findings may not be translatable to other STH-endemic areas.
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37 77 **INTRODUCTION**

38 78 Neglected tropical diseases (NTDs) affect some of the world's most impoverished populations and
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41 79 contribute to a variety of morbidities that exacerbate existing health and economic inequities (1).
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44 80 Infections with one group of NTD, soil-transmitted helminths (STH), are associated with anemia, cognitive
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46 81 development delay, growth stunting, pre-term birth, and other adverse outcomes (2). World Health
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48 82 Organization (WHO) guidelines recommend control of STH morbidities via annual or bi-annual deworming
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50 83 of pre-school and school-age children and other high-risk groups, including pregnant women and
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52 84 adolescent girls (3). However, in many settings, the current STH strategy would likely need to be continued
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3 85 until significant economic development and universal water, sanitation and hygiene (WASH) access are
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5 86 broadly available to stop transmission of STH (4). Emerging evidence suggests that it may be possible to
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7 87 interrupt transmission of STH by expanding deworming to treat individuals of all ages via community-wide
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10 88 MDA (cMDA) (5, 6).

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13 89 The current standard of care for STH is school-based MDA to reach pre-school and school-age children,
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15 90 and many school-based deworming programs have been successfully implemented for decades.
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17 91 Transitioning from school-based MDA to cMDA for community-level STH transmission interruption will
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19 92 require adapting long withstanding programs or designing new platforms for reaching much larger target
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21 93 populations. These transitions should be approached carefully, as they will likely affect community
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23 94 member and health worker attitudes towards and engagement in new programs. The success of cMDA in
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25 95 interrupting transmission of STH is indeed predicated upon programs attaining high treatment coverage
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27 96 (drug receipt) and uptake (drug ingestion) (7, 8). Many STH-endemic communities have a long history of
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29 97 participating in other community-based mass distribution programs, including campaigns for lymphatic
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31 98 filariasis (LF), onchocerciasis, trachoma, malaria bed net distribution, and/or mass immunization programs
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33 99 such as polio campaigns (9). Factors that influence participation in mass campaigns include recipient trust
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35 100 in programs and efforts to tailor programs to local conditions (10). Negative campaign experiences or
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37 101 perceptions can compromise the success of future programs, particularly those requiring high coverage
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42 102 over multiple years to reach targeted transmission endpoints (11, 12).

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45 103 Formative qualitative research can be used to understand community-member and implementer
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47 104 perceptions of past, ongoing, or prospective community-based campaigns. Diagnostic analyses, an
48
49 105 application of formative evaluations, are particularly helpful in illuminating processes that can facilitate
50
51 106 or impede implementation. Diagnostic analyses help to identify determinants of current practices,
52
53 107 potential barriers and facilitators to implementing new interventions, and the perceived feasibility or
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55
56 108 utility of a new implementation strategy. This formative evidence can help researchers and implementers

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3 109 understand potential implementation challenges and, ideally, address them prior to intervention launch
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5 110 (13). In this study, we perform a diagnostic analysis of the implementation climate to proactively identify
6
7 111 factors influencing the launch of cMDA for STH transmission interruption, including (1) perceptions of
8
9 112 current deworming practice, (2) potential barriers and facilitators to transitioning from school-based MDA
10
11 113 to cMDA delivery, and (3) perceived effectiveness and need for cMDA (14).
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15 114 **METHODS**

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18 115 This analysis was conducted at the outset of the DeWorm3 Project, a large hybrid type I community cluster
19
20 116 randomized trial in Benin, India, and Malawi (Table 1). Launched in 2017, the currently underway
21
22 117 DeWorm3 Project aims to determine the feasibility of interrupting STH transmission using twice annual
23
24 118 cMDA treating eligible individuals of all ages, relative to standard-of-care school-based MDA. More
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26 119 information about the DeWorm3 cluster randomized trial design has been described in detail elsewhere
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28 120 (15-17).
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Table 1. Overview of study sites

	Benin	India	Malawi
Site	Commune of Comè	Vellore and Thiruvannamalai Districts, Tamil Nadu	Mangochi District
Geographic area of site (km²)	148	477	289
Total number of households	24,378	36,536	27,750
Population size	94,969	140,932	121,819
Standard of care	Annual school-based MDA targeting children 5-14 years of age	Biannual school-based MDA on National Deworming Days targeting children 1-19 years of age	Annual school-based MDA and Child Health Days targeting children 1-14 years of age
cMDA workforce	Community drug distributors (CDDs), coordinated by the Ministry of Health	CDDs and Accredited Social Health Activists (ASHA), women working as health educators and promoters in their communities	Community health workers (Health Surveillance Assistants) who also fill the rolls of CDDs, coordinating with teachers

123

124 **Sampling strategy**

125 Key stakeholders shaping the implementation climate for cMDA include community members and local
 126 health workers. Focus group discussions (FGDs) were conducted separately with groups of community
 127 members, including adult women and men (over 15 years), community leaders, and children (ages 12-15
 128 years of age), local health workers, including CDDs, and Ministry of Health (MOH) health facility workers
 129 who often serve as CDD supervisors.

130 Prior to trial randomization (e.g., before designations of intervention or control clusters were made), four
 131 clusters were randomly selected in each site to conduct community-level FGDs. In each cluster, one FGD
 132 was conducted within each community member strata (four total), two FGDs among drug distributors,
 133 and one FGD among local MOH health facility workers. The sampling strategy for identifying and recruiting
 134 community members for FGDs within each cluster differed slightly by site (Table 2). In India, purposive
 135 sampling was employed, in which village leaders/influencers identified potential participants. In Malawi,
 136 community members were selected to participate via pseudo-randomization from a pool of individuals

137 who attended outreach meetings at the chiefs/headmen's residence. The first five randomly approached
 138 individuals from each demographic strata who agreed to participate were invited to attend FGDs within
 139 the next week (except children, for whom parents/caregivers were approached). In Benin, community
 140 members were selected from a randomly generated list of potential participants from a baseline census
 141 database. The research team contacted the household heads by telephone and invited a specific individual
 142 (woman, man, or child) to participate in an FGD. No more than one individual per household was selected
 143 to participate in an FGD in a given cluster. Transportation was offered to individuals who needed access
 144 to the FGD location. In Benin and India, local leaders were chosen using purposive quota sampling, during
 145 which DeWorm3 study teams invited key leaders in each selected cluster. Leaders differ setting by setting,
 146 wherein in some countries key leaders primarily include village chiefs while in other areas key leaders are
 147 primarily religious leaders. Purposive quota sampling was also used to invite CDDs and health workers
 148 from local health facilities located in each cluster to participate in FGDs.

149 **Table 2: Sampling strategy by stakeholder group**

Stakeholder	Targeted sample size (per FGD)	Sampling strategy
Community members		
Adult women (15+ years of age)	5-10	Purposive sampling (India) Random sampling (Benin ¹ and Malawi)
Adult men (15+ years of age)	5-10	
Local leaders	5-10	
Children (12-15 years of age)	5-10	
Health center staff and CDD supervisors	5-10	Purposive quota sampling
Community drug distributors (CDDs)	10-15	Purposive quota sampling

¹Purposive quota sampling was used to sample local leaders in Benin and India

150

151 Data collection

152 This diagnostic analysis study design is informed by the Consolidated Framework for Implementation
 153 Research (CFIR), a meta-theoretical framework of 38 constructs that provides a typology of constructs for
 154 characterizing potential determinants (barriers and facilitators) to implementation from the perspective

1
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3 155 of individuals involved in implementation (18). The CFIR has been used widely in low-and-middle-income
4
5 156 countries to identify factors that could influence or are actively influencing successful implementation
6
7 157 (19). CFIR constructs are organized according to five major domains influencing implementation and
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10 158 implementation effectiveness including (1) the intervention, (2) the inner setting, (3) the outer settings,
11
12 159 (4) the individuals involved, and (5) the process for accomplishing the intervention. While the CFIR can be
13
14 160 used at any stage of implementation, when applied pre-implementation, the CFIR can help proactively
15
16 161 identify opportunities and challenges facing implementation and inform adaptations to implementation
17
18
19 162 strategies for the local context (18, 20).

20
21
22 163 We drew upon the CFIR to inform the design of four semi-structured interview guides with a mix of
23
24 164 respondent and informant style questions, tailored to each stakeholder group (one question guide was
25
26 165 used for all adult community members). In this study, we identified *a priori* 23 CFIR constructs across all
27
28 166 five domains that we hypothesized would influence the implementation climate for cMDA and which were
29
30
31 167 appropriate for use during formative diagnostic research prior to implementation (Appendix 1) (20). The
32
33 168 question guides were piloted and adapted slightly by changing word choice or sentence construction as
34
35 169 necessary within each site to ensure that the questions were clear, meaningful, and culturally appropriate.
36
37
38 170 Site adapted question guides were thereafter translated into local languages including Yao (Malawi) and
39
40 171 Tamil (India), and the official language (French) in Benin. FGD facilitators in Benin adapted the French
41
42 172 question guide to local languages, including Watchi and Pédah when necessary, during FGD facilitation.
43
44

45 173 All participants provided written consent prior to the start of the FGD. The parents or caregivers of
46
47 174 participating children similarly provided written consent and children ages 12-15 also provided written
48
49 175 assent. Consent and assent could also be provided by a thumbprint in the presence of a witness. FGDs
50
51 176 were conducted in private locations with both a facilitator and notetaker present and all FGDs were audio-
52
53
54 177 recorded with participant permission.
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178 **Analysis**

179 Audio files were transcribed verbatim in the local or official language. For each transcript, two one-minute
180 random spot checks were conducted on each audio file for quality assurance. All transcripts were then
181 translated into English. All transcriptions and their translations were reviewed by a second individual
182 fluent in both English and the local language for quality assurance. Transcripts were imported into ATLAS.ti
183 version 8 (Scientific Software Development GmbH, Berlin, Germany), which was used to manage data
184 analysis. Coders were based in each DeWorm3 site as well as at the central level (University of
185 Washington, Seattle). For data collected in Benin and India, two primary coders were assigned to each
186 transcript, with a third coder designated as the “tie-breaker.” When possible, at least one coder was based
187 at the site in which the data were collected, and the other coder was a member of the DeWorm3 central
188 team. For data collected in Malawi, a single primary coder from the central level coded the data while a
189 secondary coder at the site reviewed and validated the findings, due to coder availability. Each primary
190 coder independently read and coded each transcript primarily using a deductive approach and a CFIR-
191 based codebook. Coding teams from each country and the central level met via conference calls to
192 iteratively refine code definitions and code inclusion/exclusion criteria until a final codebook was
193 established. After a transcript was coded, the coders assigned to the transcript met via conference call for
194 consensus meetings to discuss where applied codes diverged. When necessary, a third coder weighed in
195 where consensus between primary coders was not reached. Data saturation was reached as no new
196 themes emerged during iterative review of the collected data.

197 The final coded transcripts were used to create case memos that were grouped by stakeholder category
198 and site. The case memos included a summary of how the code was applied for a given stakeholder group,
199 a justification for the summary provided noting code patterns and latent messages, and specific quotes
200 highlighting how the code was applied. The summaries, patterns, and themes from the coded transcripts

201 and case memos were used to guide thematic analysis, an analytical method that is useful for summarizing
202 key features of large datasets using a clearly-structured approach (21, 22).

203 **Patient and public involvement**

204 Community members and health workers living in the sampled STH endemic areas were not involved in
205 design, conduct, or reporting of this qualitative study. However, all feedback from community members
206 was used to shape a subsequent community-based intervention within a larger clinical trial.

207 **Ethical approval**

208 This study has been reviewed and approved by the Institut de Recherche Clinique du Bénin (IRCB) through
209 the National Ethics Committee for Health Research (002-2017/CNERS-MS) from the Ministry of Health in
210 Benin, The London School of Hygiene and Tropical Medicine (12013), The College of Medicine Research
211 Ethics Committee (P.04/17/2161) in Malawi, and Christian Medical College, Vellore, in India (10392). The
212 study was also approved by The Human Subjects Division at the University of Washington
213 (STUDY00000180).

214 **RESULTS**

215 In this study, 48 FGDs were conducted with community members – four FGDs (one per cluster) for each
216 stakeholder group: adult women, adult men, children, and local leaders, totaling 16 in each site, 13 with
217 CDDs (two each in Benin and Malawi, nine in India), and five with CDD supervisors (two in Benin and three
218 in India).

219 Across FGDs and settings, key themes emerged within four CFIR domains and are presented accordingly
220 below: intervention characteristics, inner settings, characteristics of individuals, and process. Factors
221 positively influencing the implementation climate for cMDA across sites included community member
222 demand for community-wide (versus school-based) MDA, integration of MDA into existing vaccination

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3 223 campaigns and/or health services, and engagement with health workers (including trained CDDs) rather
4
5 224 than community volunteers. Factors negatively affecting the implementation climate across sites included
6
7 225 mistrust and resistance toward medical interventions, fear of side effects, and limited perceived need.
8
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10 226 Additional process recommendations emerged as key themes that varied slightly across sites and included
11
12 227 suggestions regarding MDA distribution sites and distributors, treatment costs/financial incentives,
13
14 228 engaging leaders, and engaging participants through sensitization and mobilization efforts.
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16

17 229 **Intervention characteristics**

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20 230 *Relative advantage: cMDA is preferable to school-based MDA*

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22
23 231 The CFIR construct of *relative advantage* captures participant perceptions regarding the benefits of
24
25 232 implementing one intervention compared to an alternative (18). Across community member and health
26
27 233 worker/CDD groups and sites, participants identified a preference for cMDA as compared to school-based
28
29 234 deworming programs for several reasons. Participants stressed that providing STH treatment to both
30
31 235 children and adults is the only way to prevent STH reinfection.
32
33

34
35 236 Across stakeholder groups, participants also highlighted that children who were not enrolled in school
36
37 237 would be able to receive treatment through cMDA. Adult community members in Benin and Malawi were
38
39 238 particularly concerned that school-based MDA campaigns do not always provide parents with treatment
40
41 239 information prior to distribution and often administer the medications without parental consent or trust.
42
43 240 Additionally, they thought uptake would be improved if parents are involved in treatment administration.
44
45

46
47 241 *It's better to go through the parents to reach the kids. Parents know how to approach their*
48
49 242 *children, manage them and make them understand the benefit of the thing [medicine]. The child*
50
51 243 *will easily take the medicine without any effect. (Cluster 26, Women, Benin)*
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244 Across FGDs and sites, participants were enthusiastic that cMDA could interrupt STH transmission and
245 increase parental engagement with the intervention, particularly to enable parental consent, and allow
246 them to encourage and confirm their child's uptake.

247 *Design quality & packaging: Door-to-door MDA delivery by highly trained, familiar distributors is preferred*

248 *Design quality* describes stakeholder recommendations for how to bundle, present, and assemble the
249 intervention (18). Across sites and stakeholder groups, campaigns that delivered services door-to-door
250 were considered more desirable than those that used a central distribution site (Table 3). In India,
251 community participants reflected upon past experiences with LF MDA campaigns that were door-to-door
252 whereas participants in Benin reflected upon experiences with door-to-door vaccination campaigns and
253 bed net distributions at local health centers. Long waiting times, associated with lost income and
254 productivity, were identified as primary barriers to central distribution sites. One female participant in
255 Benin reported she would not wait around all day for someone to distribute MDA but instead would just
256 purchase the medications herself, given their low costs. Additionally, participants stressed that door-to-
257 door campaigns improve equity by increasing the likelihood of reaching those unable to travel due to
258 financial or physical barriers.

259 *The HSAs should go door by door to give people the medicine as some people, for example old and*
260 *crippled, may not be able to go and access the drugs. But if they go door by door, then everyone*
261 *receives the drugs and not only those who walk. (Cluster 21, Women, Malawi)*

262 Community members and leaders across sites, participants preferred to receive treatment from
263 individuals perceived to be health professionals, especially a familiar health worker or CDD, or someone
264 working with a well-respected non-governmental organization (NGO). Participants believed that
265 increased health worker engagement could alleviate community mistrust linked with fear of adverse
266 events by medicalizing the distribution process and making community members feel safer, thereby

1
2
3 267 increase treatment coverage. Men in Malawi stressed that health volunteers are often poorly respected
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5 268 and mistrusted, while clinically-trained health professionals are typically more respected. Of paramount
6
7 269 importance for adult community members and CDDs was that distributors are known members of the
8
9
10 270 community.

11
12
13 271 *When community members see new faces during a project, they tend to be resistant, so it is better*
14
15 272 *to use people from the area and not strangers. If not, this may not be successful. (Cluster 21, Local*
16
17 273 *leader, Malawi)*

18
19
20 274 *But above all, it is necessary to involve health workers, who the population trusts....Many are afraid*
21
22 275 *because they do not see us, they do not see the health workers on the ground. (Health Center Staff,*
23
24 276 *Benin)*

25
26
27 277 In Benin, local leaders noted that when NGOs engage in cMDA, it is important they are well-respected and
28
29 278 have well-recognized logos that community members are familiar with and trust based on their prior
30
31 279 work. Regardless if cMDA is administered by a health professional, volunteer, or NGO, community
32
33 280 members across sites noted that their willingness to participate in cMDA is driven by their perception that
34
35 281 they have been fully and accurately informed about cMDA, and that they have had time to ask questions.

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38
39 282 *Even if it [deworming medication] is given for free, they will not eat it unless it has been explained*
40
41 283 *and given. If they are told they will benefit...with awareness in the villages, they will eat it. (Cluster*
42
43 284 *12, CDD, India)*

44
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46
47 285 Community members expressed that they wanted to be treated with dignity and that their participation
48
49 286 in community-wide public health campaigns of any kind should not be taken for granted.

50
51
52 287 *Whether they eat the tablet or not it depends on to what extent this information reaches the*
53
54 288 *people. It depends on how you tell. (Cluster 34, Men, India)*

1
2
3 289 *The messages about drugs should be given to us in good time and not just tell us like today that*
4
5 290 *tomorrow we will have a drug administration activity. Many people need time to ask questions*
6
7 291 *and clear their myths before they get treated. Some people tend to refuse medicine because of*
8
9 292 *fear of side effects, so when you sensitize them for a long time, they tend to listen and at the end*
10
11 293 *the program becomes successful. So avoid short notice messages, people are difficult. They need*
12
13 294 *enough time to understand what is happening. (Cluster 21, Men, Malawi)*
14
15
16

17 295 In Malawi, local leaders reported that community members want to be followed up with after distribution
18
19 296 to monitor for adverse events or continued engagement with distribution programs to foster trust in
20
21 297 future campaigns. Without this, the leaders feared that negative rumors might proliferate, or
22
23 298 communities might feel as though they only received treatment for research purposes, rather than for
24
25 299 their wellbeing.
26
27
28

29 300 *Intervention complexity: cMDA is complex, but still feasible to implement*
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31

32 301 The CFIR construct of *complexity* is defined as the perceived difficulty of implementing an intervention
33
34 302 (18). Across groups, participants were concerned about the timing of cMDA, the distance to distribution
35
36 303 sites if cMDA is centrally located as opposed to delivered door-to-door, and whether or not they would
37
38 304 have sufficient notice about cMDA before the campaign begins. Many community members suggested
39
40 305 optimal distribution times, which varied by site depending on common work schedules and holidays.
41
42 306 Concerns regarding health worker/CDD knowledge and accommodation of community members'
43
44 307 schedules were prevalent across FGDs but some participants stressed they would change their schedules
45
46 308 to be present for distribution if informed by community leaders.
47
48
49

50 309 *Even if someone has a plan to go to the field or to the market, three days before the distribution*
51
52 310 *of the drug, they will cancel their plan and come and listen to what the village chief invited them*
53
54 311 *to do...if everyone is not informed, it [MDA] cannot succeed. (Cluster 10, Women, Benin)*
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1
2
3 312 Adults and children across sites recommended that distribution over multiple days within a community to
4
5 313 reach the greatest number of people.
6
7

8 314 *The period of drug administration should be long so that everyone is able to receive treatment.*

9
10 315 *Some people may not be home during the time that you have set to administer the drugs and as*

11
12 316 *such if done for maybe only a day, it means those people will not receive the drugs. But if it is for*

13
14
15 317 *some more days then everyone will be treated. (Cluster 21, Men, Malawi)*
16
17

18 318 **Inner setting**

19
20
21 319 *Implementation climate: Initial mistrust of MDA is likely, but demand and perceived need will counter this*

22
23
24 320 The CFIR construct *implementation climate* captures comments related to the community member's

25
26 321 receptivity to implementation, and the extent to which implementation is supported (18). The core

27
28 322 component of implementation climate discussed across FGDs were factors that influence community

29
30 323 member trust in treatment campaigns. Participants across the sites anticipated high levels of initial

31
32 324 mistrust and potential resistance toward newly launched cMDA for STH. This initial mistrust is driven by

33
34 325 personal and anecdotal evidence of adverse side-effects such as fatigue, stomachaches, and fever after

35
36 326 previous school-based deworming MDA campaigns.
37
38
39

40 327 *Other pupils received the medical treatment before they ate a meal, hence they vomited. So those*

41
42 328 *that did not receive the medical treatment were afraid of vomiting too if they took the medicine.*

43
44 329 (Cluster 19, Children, Malawi)
45
46

47 330 *They will eat [medication] based on the trust. They will eat [medication] based on your approach,*

48
49 331 *otherwise they may take and keep it aside somewhere.... (Cluster 17, Men, India)*
50
51

52 332 In Malawi, limited follow-up by transitory MDA programs and research projects was also noted as fueling

53
54 333 mistrust of community health programs. Similarly, in one CDD FGD in India, participants identified mistrust
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3 334 of government programs as a potential barrier to MDA campaigns where medications are provided for
4
5 335 free. CDDs explained that community members perceive government provided medications to be of
6
7 336 poorer quality and therefore less effective with greater risks of side effects; therefore, those who can
8
9 337 afford to purchase their own medications from pharmacies will often do so.

10
11
12
13 338 *For people who can, they will get it [deworming medicine] from the medical shop. Whatever is*
14
15 339 *given through the government they will keep it aside and they will not use it. (Cluster 15, CDD,*
16
17 340 *India)*

18
19
20 341 In Benin, some participants from the men's, women's, and CDD FGDs shared concerns that drugs used in
21
22 342 such campaigns might be given by Westerners with malintent.

23
24
25 343 *The majority of the population does not understand. They think that the drugs are poisoned in*
26
27 344 *order to reduce the African population. (Cluster 10, Men, Benin)*

28
29
30 345 Similarly, in Malawi, CDDs identified rumors and misinformation as major barriers to delivering cMDA with
31
32 346 high coverage. Specific rumors include that stool collected for STH surveillance would be used for Satanist
33
34 347 practices, rather than medical purposes, and that school-based deworming programs provide
35
36 348 contraceptives to young children to reduce population growth.

37
38
39
40 349 While participants noted that mistrust and resistance might initially be high following a transition to cMDA
41
42 350 for STH, there was still a strong perceived demand for deworming of all ages, and a sentiment that
43
44 351 community sensitization could overcome these concerns.

45
46
47 352 *...we are looking forward to this [community-based MDA] and we would like this to be a regular*
48
49 353 *treatment. People are suffering from intestinal worms and only children receive the treatment. So*
50
51 354 *this project [DeWorm3] will help all of us to receive treatment. (Cluster 21, Men, Malawi)*

52
53
54
55 355 *Compatibility: Community-based MDA is highly compatible with existing health infrastructure*

1
2
3 356 The CFIR construct *compatibility* is highly related to *implementation climate*, capturing the alignment
4
5 357 between the innovation and existing values and priorities (18). Health facility workers and CDDs across
6
7 358 sites noted cMDA should be integrated into existing community programs or, at a minimum, coordinate
8
9 359 with ongoing community-based activities to improve treatment coverage and mitigate risks of conflict
10
11 360 with ongoing local health programs. CDDs in India and community leaders in Benin identified community-
12
13 361 based vitamin A and iron distribution and childhood vaccination campaigns as ideal programs to integrate
14
15 362 with cMDA. In India, CDDs also suggested integrating cMDA with existing indoor residual spraying
16
17 363 programs for vector control.

18
19
20
21 364 *The voluntary workers who go house to house to spray mosquitoes, we can make use of them to*
22
23 365 *give the tablet...Earlier they were going once a month or once a week, but now they go daily house*
24
25 366 *to house. We can give through them. (Cluster 17, CDD, India)*

26
27
28
29 367 *Available resources: Training, storage, and hygiene infrastructure are key resources for MDA*
30
31 368 *implementation*

32
33
34 369 The CFIR construct *available resources* describes the financial and material resources available (and
35
36 370 desired) for implementation, including training and education, space, time, and money (18). Health facility
37
38 371 workers and CDDs across sites stressed that existing resources may not be sufficient for delivery of cMDA.
39
40 372 CDDs in particular were concerned about receiving adequate training and access to resources to take
41
42 373 home for self-review. CDDs and health workers highlighted that they wanted more than a single one-day
43
44 374 training prior to MDA, in order to provide adequate time to practice and apply skills in a training
45
46 375 environment. Across sites, CDDs noted the importance of training before distribution.

47
48
49
50 376 Other key resources identified by CDDs and health workers in Benin included medication storage in the
51
52 377 field, community education materials, shelter during inclement weather, as well as food, water, and
53
54 378 financial incentives for CDDs. CDDs in Benin were particularly concerned with timely payment for their

1
2
3 379 work. In Malawi, local leaders noted that in the past villagers have felt burdened by volunteering for health
4
5 380 program implementation without compensation. They also noted that villagers might expect payment for
6
7
8 381 participating in MDA, given past experiences with research projects providing stipends. In India, health
9
10 382 facility workers wanted to ensure they would have adequate staffing to assist during MDA.

11
12
13 383 Lastly, CDDs and health center personnel across sites, women in Benin, and leaders in India stressed that
14
15 384 hygiene infrastructure needs to be improved and that investing in WASH as part of a broader STH
16
17 385 elimination program might, as a result, increase treatment coverage of cMDA by demonstrating long-term
18
19 386 investments in community well-being.

20
21
22 387 *The rules of hygiene are very important, very, very important. Without it, we cannot right away*
23
24 388 *start distributing the drugs and say that we want to completely eradicate the transmission of*
25
26
27 389 *worms, impossible. (CDD, Benin)*

30 390 **Characteristics of individuals**

31
32
33 391 *Knowledge & beliefs: Skepticism of the clinical rationale for MDA, fear of side effects, and limited perceived*
34
35 392 *need for treatment will be barriers to cMDA*

36
37
38 393 The *knowledge and beliefs* CFIR construct is defined as individuals' attitudes toward and value placed on
39
40 394 implementation and their familiarity with related facts, truths, and principles (18). While participants
41
42 395 strongly believed cMDA could eliminate STH transmission, some reservations about MDA rooted in
43
44 396 knowledge and perceptions about deworming medications remain. For example, adult men and children
45
46
47 397 in Benin and local leaders in Malawi raised concerns about the effects of treating people who may not be
48
49 398 infected with STH.

50
51
52 399 *When you get the drugs and you do not have the worms, the tablet can still damage your organs*
53
54 400 *such as organs of digestion or breathing. (Cluster 1, Children, Benin)*

1
2
3 401 In India and Malawi, participants in the men's FGDs thought individuals who feel healthy might perceive
4
5 402 themselves to be at low risk of STH and thus choose not to participate in cMDA. Women in Malawi
6
7 403 reported this occurred during prior cMDA campaigns while women in India also noted individuals with
8
9 404 limited literacy might not understand the need for treatment and be reluctant to participate in MDA
10
11 405 campaigns.

12
13
14
15 406 *Self-efficacy: Community members and CDDs will be key mobilizers for cMDA*

16
17
18 407 The CFIR construct *self-efficacy* captures comments that reflect an individual's beliefs in their own abilities
19
20 408 to achieve implementation goals (18). Women and community leaders in Benin identified themselves as
21
22 409 important catalysts in influencing the acceptability of MDA by working together and influencing their
23
24 410 social networks.

25
26
27 411 *The process is simple as we have just understood, we will also explain to our brothers and sisters*
28
29 412 *who will not accept that treatment is a good thing. We will tell them they should not be*
30
31 413 *discouraged adding that there is good in it. It's up to us to explain to them. (Cluster 1, Women,*
32
33 414 *Benin)*

34
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36
37 415 Health facility workers and CDDs also identified themselves as important contributors to ensuring
38
39 416 successful MDA implementation, given their existing relationships with communities.

40
41
42 417 *We worked with them and they know us on the ground to be able to do the job, so there are no*
43
44 418 *issues for community health workers. (CDD, Benin)*

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49 420 **Process**

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52 421 *Engaging: Local leaders and sensitization activities are essential for ensuring high treatment coverage*
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422 The CFIR construct *engaging* is defined as approaches to attracting and involving individuals in
 423 implementation, such as through social marketing or education campaigns (18). Adult participants across
 424 sites, including local leaders, identified specific leaders as key facilitators of effective implementation
 425 (Table 2). These leaders should be notified in advance of interventions taking place within their
 426 communities to gain their support and promote the intervention prior to implementation. Advance
 427 sensitization with information about the distribution time as well as potential intervention benefits and
 428 risks were identified as critical pieces of information that influence the implementation climate and, in
 429 effect, effective delivery of cMDA. Preferred engagement methods varied slightly across sites, however
 430 community members suggested that a variety of information-sharing mechanisms be utilized in advance
 431 of MDA to improve community member knowledge and buy-in (Table 3).

Table 3: Recommendations to optimize the implementation climate for newly launched cMDA

Recommendation category	Benin	India	Malawi
<i>MDA distribution mode</i>	Door-to-door distribution	Door-to-door distribution preferable; potential for 3-4 central distribution sites in some communities	Door-to-door distribution
<i>Intervention cost/financial incentives for participation</i>	Free, but need to address rumors about nefarious intentions behind free MDA distribution	Free treatment preferable to most participants; need to address fears of perceived poor-quality medications provided by government programs. Financial incentives should not be given for MDA participation, but incentives such as combs and soap were suggested	Free, but communities with past exposure to research studies might expect financial incentives for MDA participation
<i>Community drug distributor preferences</i>	Health workers (health facility workers or CDDs) who are familiar to community members	Trained health workers (nurses, doctors, ASHAs) who are familiar. Individuals without training should not be distributors	Health workers (including HSAs) who are familiar to community members. Volunteers are less

<i>Duration and time of distribution</i>	Distribution over multiple days to accommodate different household schedules and reach the greatest number of people. Rainy season and market days should be avoided. Must consider work schedules and implement flexible distribution times	Distribution over multiple days. Evening or early morning preferred distribution time to accommodate work schedules	respected and should not be distributors	Distribution over multiple days to accommodate different household schedules and reach the greatest number of people
<i>Key leaders to engage prior to cMDA</i>	Village chiefs, religious leaders, and health workers	President and ward councilor of community (Panchayat), other health workers (Anganwadi workers), and teachers	Village chiefs, local leaders, religious leaders, local NGOs, HSAs, and teachers	
<i>Community education topics to engage MDA participants</i>	Educate community about purpose and potential side effects of treatment	Educate community about purpose, advantages, and potential side effects of treatment, and proper dosage for different people (e.g., children, elders)	Educate community about purpose and potential side effects of treatment; sensitization must be done more than one day in advance to allow decision-making time	
<i>Mechanisms for engaging community members</i>	Utilize radio, phones, community meetings, and word of mouth to share information. Ring gongs at distribution time	Utilize radio, loudspeaker announcements, flyers, health documentaries, TV news, community meetings (women's groups), and community dramas to share information. Beat drums at distribution time	Utilize radio, phones, loudspeaker announcements, dramas, community meetings, door-to-door outreach, to share information	

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434 **DISCUSSION**

435 This diagnostic analysis highlights opportunities and challenges of launching cMDA for STH that are shared
 436 across geographic areas as well as important differences between them. Our findings build upon the

1
2
3 437 existing literature and demonstrate strong acceptability of cMDA for STH interruption, particularly as an
4
5 438 alternative to school-based distribution to provide more equitable access to deworming treatment. When
6
7 439 considering a transition from school-based distribution to cMDA, participants highlighted opportunities
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9 440 to integrate cMDA into existing community health programs, such as vaccination campaigns, and the
10
11 441 importance of engaging clinically trained, trusted drug distributors to mitigate fears of adverse events and
12
13 442 increase treatment coverage. Utilizing local CDDs from the same area or are directly known to the
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15 443 recipients, is associated with high MDA coverage in other settings. (23, 24) While familiarity was important
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17 444 to participants in this study, they also stressed comprehensive clinical training for CDDs as essential for
18
19 445 fostering trust during cMDA. While participants identified potential benefits of launching cMDA, they also
20
21 446 noted key barriers that might limit implementation success. Similar to findings from studies exploring
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23 447 MDA barriers post-implementation, the primary barriers identified across sites included mistrust toward
24
25 448 free drug distribution (especially those provided by community volunteers perceived to have no clinical
26
27 449 training), fear of side effects, and limited perceived need for treatment without symptoms (12, 25-27).
28
29 450 This information is essential for adapting interventions to fit the specific context and concerns of
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31 451 communities prior to making a significant change to public health programs, such as changing from school-
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33 452 based delivery to community-wide delivery of deworming medicines.
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39 453 In this formative evaluation, we synthesized recommendations from community members to assist in
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41 454 intervention optimization at a site level, including preferred treatment time and distribution methods.
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43 455 Site specific preferences and recommendations for implementation varied to small degrees across
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45 456 settings, including preferred distribution times, campaign duration, location, distributor qualifications,
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47 457 and procedures for engaging leaders and community participants. Other studies have found that
48
49 458 proactively identifying specific times when individuals are generally available to receive treatment is an
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51 459 essential facilitator of effective campaign delivery (28-30), and when not completed can increase
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53 460 frustration with community-based volunteer distributors (25) and the MDA campaign itself (31). Where
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3 461 trial timeline and funding allow, formative evaluations such as this may facilitate proactive identification
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5 462 of potential barriers and of implementation processes to optimize community acceptability and adapt
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7 463 intervention delivery as needed. When timelines or funding are limited, like during cMDA implemented
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10 464 by national NTD programs in limited resources settings, brief surveys prior to MDA and interim analyses
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12 465 and may be conducted to tailor MDA implementation.

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15 466 Emerging themes from community member, local leader, CDD, and health worker FGDs were highly
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17 467 consistent. However, CDDs and health workers noted unique facilitators and barriers affecting their work,
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19 468 including time for training, resources in the field, and timely compensation, similar feedback from
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21 469 implementers in other settings (26). CDDs, health workers, and community leaders also uniquely stressed
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23 470 the importance of packaging WASH interventions with MDA for STH elimination. These sentiments reflect
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25 471 advanced knowledge of STH transmission but may also reflect doubt that transmission interruption
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27 472 programs predicated on broadly delivered MDA will interrupt transmission without also improving
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29 473 hygiene infrastructure. In fact, most of the benefits attributed to cMDA amongst these cadres was driven
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31 474 by beliefs that MDA will be more acceptable when delivered in the community, as opposed to its potential
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33 475 for interrupt transmission. Although evidence regarding the effectiveness of WASH on STH transmission
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35 476 interruption is still weak, it is also important to monitor how implementer and community enthusiasm for
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37 477 cMDA changes over time, potentially driven by the absence of WASH interventions (32).

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40 478 Participants across all geographic areas noted that myths and rumors could pose serious challenges to
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42 479 cMDA delivery, adding further to the literature documenting this obstacle in other settings (10, 26, 33,
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44 480 34). Children in Benin and Malawi noted specific concerns about side effects of deworming treatment
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46 481 circulating within schools prior to and post-MDA campaigns. While side effects for albendazole are
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48 482 typically quite mild, albendazole is often co-administered to children with praziquantel as preventative
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50 483 chemotherapy for schistosomiasis. Praziquantel can cause relatively more severe side effects, including
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52 484 diarrhea and vomiting (35). Thus, prior experiences with MDA campaigns including other treatments
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3 485 might influence future perceptions about albendazole specifically or MDA generally (36). Evidence
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5 486 suggests that effective health workers can overcome these individual-level perceptions (31); addressing
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7 487 myths and rumors will require targeted and pro-active community sensitization and CDD training that
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9 488 openly discuss local myths and rumors pre-intervention.

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12 489 Mistrust toward public health campaigns and government-run health programs was prevalent across
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14 490 settings. These concerns were driven by prior negative experiences with medical interventions and
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16 491 programs in which limited information was provided in advance of treatment, parents were minimally
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18 492 engaged in school-based MDA, and there were perceived concerns about drug quality. Potential strategies
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20 493 for overcoming these barriers include engaging local leaders (29, 33, 37), targeted education campaigns
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22 494 (26, 38, 39), community mobilization (37, 40, 41), and engagement of trusted, trained personnel to
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24 495 administer preventive treatment.

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29 496 During the design of our initial question guide (Appendix 1), we drew from selected constructs across all
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31 497 CFIR domains. However, during data analysis no constructs within the outer setting emerged as major
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33 498 facilitators or barriers to launch of cMDA campaigns. The outer setting domain is comprised of constructs
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35 499 representing external influences on implementation and, perhaps because these data were collected at
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37 500 the community-level, respondents were more focused on individuals involved in implementation and
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39 501 implementation processes (18). Additionally, because we conducted a formative study we did not link
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41 502 identified implementation determinants to observed implementation outcomes, however subsequent
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43 503 data collection activities in DeWorm3—once the trial is underway and outcome data are collected—will
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45 504 afford these opportunities (20).

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50 505 This study had several limitations. Some participants may have heard about DeWorm3 before
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52 506 participating in FGDs, which may have contributed to social desirability or response biases. While a large
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3 507 number of FGDs were conducted across heterogeneous settings, it is also possible that the study findings
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5 508 may not be generalizable to other STH-endemic areas.
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8 509 **Conclusion**

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11 510 This study supports that cMDA, particularly as an alternative to school-based MDA, is generally acceptable
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13 511 across heterogeneous settings and builds upon the existing literature exploring facilitators and barriers of
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15 512 launching and implementing cMDA. Community engagement including STH education, understanding
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17 513 preferred distribution times and methods, involvement of local leaders and familiar health workers or
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19 514 CDDs are critical for implementation success. Potential barriers, including mistrust of free drug
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21 515 distribution, fear of side effects, and limited perceived need of treatment can be addressed through
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23 516 community sensitization and engagement of local leaders and trusted health workers. These findings were
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25 517 used to shape implementation activities during the DeWorm3 trial, in order to ensure high acceptability
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27 518 of the intervention and high cMDA coverage from the onset of the trial. Formative research exploring
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29 519 attitudes and community-derived recommendations should be conducted when possible to improve
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31 520 community acceptability of new interventions.
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36 521 **Author contributions**

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39 522 ARM, JLW, MCGC, SSRA, KK, and MI conceived of the initial study design. EA, SPK, FC, CIT, PN, MI, KK, KA,
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41 523 AT, and YJ were involved in data collection and data processing. AR managed the data. AR, ABE, SL, and
42
43 524 ARM contributed to data analysis. SL, EA, and ARM led the writing of the paper. All authors read and
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45 525 approved the final version of the manuscript.
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49 526 **Competing Interests**

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51
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6
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9

10 532 **Data availability**

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13 533 Data are available from the DeWorm3 Institutional Data Access Committee (contact dw3data@uw.edu)
14
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17

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Appendix 1. Qualitative interview guides

Interview guide #1: Health Centre & DeWorm3 Supervisory Teams

	Question
1	<p>What kind of information or evidence are you aware of that shows whether or not community-wide MDA for interrupting transmission of STH will work in your setting?</p> <p><i>Follow-up questions:</i></p> <ul style="list-style-type: none"> • <i>Is this evidence strong or weak?</i> • <i>What evidence are you aware of from your own research? Practice guidelines? Published literature? Other settings?</i> • <i>How does this knowledge affect your perception of the intervention?</i>
2	<p>What advantages does community-wide MDA for STH have compared to school-age targeted programs? What disadvantages?</p>
3	<p>When delivering community-wide MDA for STH, what local adaptations should be made so that the intervention is effective?</p> <p><i>Follow-up questions:</i></p> <ul style="list-style-type: none"> • <i>What aspects of the intervention should not be adapted?</i> • <i>Do you think you will be able to make these adaptations? Why or why not?</i>
4	<p>How complicated is delivery of the entire community-wide MDA for STH intervention? Please consider the following aspects of the intervention: duration of an MDA round, target population, and number of steps and sub-activities involved to fully implement.</p>
5	<p>What supportive materials or tools are needed to ensure effective implementation of community-wide MDA for STH?</p>
6	<p>What community-wide MDA for STH activities are built upon the previous LF MDA program infrastructure and experiences?</p> <p><i>Follow-up questions:</i></p> <ul style="list-style-type: none"> • <i>If none, what LF program activities could be leveraged for community-wide MDA for STH?</i>
7	<p>From your perspective, what are unique costs of implementing community-wide MDA for STH, relative to the standard of care of school-age targeted MDA?</p>
8	<p>What barriers might community members face in participating in community-wide MDA for STH?</p> <p><i>Follow-up question:</i></p> <ul style="list-style-type: none"> • <i>What could be done to overcome these barriers?</i>
9	<p>What kinds of infrastructure changes to the health system will be needed to accommodate community-wide MDA for STH?</p> <p><i>Follow-up questions:</i></p>

	Question
	<ul style="list-style-type: none"> <i>If community-wide MDA for STH is scaled-up after the DeWorm3 project, will there need to be any changes in formal policies? Changes in information systems or data reporting systems? Other?</i> <i>What kind of approvals do you think will be needed to transition the STH program entirely to community-wide MDA? Who will need to be involved?</i> <i>Can you describe the process that will be needed to make these changes?</i>
10	How accepting are your co-workers of implementing community-wide MDA for STH? Why?
11	<p>Do you think community-wide MDA for STH could be integrated into routine MOH programs?</p> <p><i>Follow-up questions:</i></p> <ul style="list-style-type: none"> <i>If yes, how? If no, why not?</i> <i>What would the effects of integration on routine programs be?</i>
12	How important do you think it is to implement community-wide MDA for STH compared to the other health priorities?
13	Do you feel incentivized to ensure that the DeWorm3 trial is successful in interrupting transmission of STH? What is the incentive?
14	<p>How supportive are government and non-governmental leadership of implementing community-wide MDA for STH?</p> <p><i>Follow-up question:</i></p> <ul style="list-style-type: none"> <i>How do you think it will affect uptake/implementation?</i>
15	<p>What kind of relevant training will you have during this intervention? Do you feel the training will prepare you to carry out the roles and responsibilities expected of you? How so?</p> <p><i>Follow-up questions:</i></p> <ul style="list-style-type: none"> <i>What are the positive aspects of the training?</i> <i>What is missing?</i> <i>What kind of continued training is necessary?</i>
16	Do you think that community-wide MDA could interrupt STH transmission (i.e. stop the spread of intestinal worms) in your setting? Why or why not?
17	How confident are you that you will be able to successfully carry out your DeWorm3 related duties? What gives you that level of confidence (or lack of confidence)?
18	<p>Can you describe your team's plan for implementing community-wide MDA for STH?</p> <p><i>Follow-up questions:</i></p> <ul style="list-style-type: none"> <i>Do you think everyone involved understands the plan well, or is it too complicated?</i> <i>What do you do if you have to modify or revise the plan due to challenges, errors, or mistakes?</i>
19	Who are the key influential individuals or organizations to get buy-in from during the DeWorm3 study?

	Question
20	How should community members be informed about community-wide MDA or other DeWorm3 interventions before they occur?
21	What are some strategies to achieve high MDA treatment coverage?
22	Is there any other information that you would like to share about community-wide MDA today?

Interview Guide #2: Community Drug Distributors & Community Health Workers

#	Question
1	What advantages does community-wide MDA for STH have compared to school-age targeted programs? What disadvantages?
2	When delivering community-wide MDA for STH, what local adaptations should be made so that the intervention is effective? <i>Follow-up questions:</i> <ul style="list-style-type: none"> What aspects of the intervention should not be adapted? Do you think you will be able to make these adaptations? Why or why not?
3	How complicated is delivery of the entire community-wide MDA for STH intervention? Please consider the following aspects of the intervention: duration of an MDA round, target population, and number of steps and sub-activities involved to fully implement.
4	What supportive materials or tools are needed to ensure effective implementation of community-wide MDA for STH?
5	From your perspective, what are unique costs of implementing community-wide MDA for STH, relative to the standard of care of school-age targeted MDA?
6	What barriers might community members face in participating in community-wide MDA for STH? <i>Follow-up question:</i> <ul style="list-style-type: none"> What could be done to overcome these barriers?
10	How accepting are your co-workers of implementing community-wide MDA for STH? Why?
11	Do you think community-wide MDA for STH could be integrated into routine MOH programs? <i>Follow-up questions:</i> <ul style="list-style-type: none"> If yes, how? If no, why not? What would the effects of integration on routine programs be?
12	How important do you think it is to implement community-wide MDA for STH compared to the other health priorities?
13	Do you feel incentivized to ensure that the DeWorm3 trial is successful in interrupting transmission of STH? What is the incentive?
14	How supportive are government and non-governmental leadership of implementing community-wide MDA for STH?

#	Question
	<p><i>Follow-up question:</i></p> <ul style="list-style-type: none"> • <i>How do you think it will affect uptake/implementation?</i>
15	<p>What kind of relevant training will you have during this intervention? Do you feel the training will prepare you to carry out the roles and responsibilities expected of you? How so?</p> <p><i>Follow-up questions:</i></p> <ul style="list-style-type: none"> • <i>What are the positive aspects of the training?</i> • <i>What is missing?</i> • <i>What kind of continued training is necessary?</i>
16	Do you think that community-wide MDA could interrupt STH transmission (i.e. stop the spread of intestinal worms) in your setting? Why or why not?
17	How confident are you that you will be able to successfully carry out your DeWorm3 related duties? What gives you that level of confidence (or lack of confidence)?
18	<p>Can you describe your team's plan for implementing community-wide MDA for STH?</p> <p><i>Follow-up questions:</i></p> <ul style="list-style-type: none"> • <i>Do you think everyone involved understands the plan well, or is it too complicated?</i> • <i>What do you do if you have to modify or revise the plan due to challenges, errors, or mistakes?</i>
19	Who are the key influential individuals or organizations to get buy-in from during the DeWorm3 study?
20	How should community members be informed about community-wide MDA or other DeWorm3 interventions before they occur?
21	What are some strategies to achieve high MDA treatment coverage?
22	Is there any other information that you would like to share about community-wide MDA today?

Interview Guide #3: Community members

#	Question
1	<p>What advantages does community-wide MDA for STH have compared to school-age targeted programs?</p> <p><i>Follow-up question:</i></p> <ul style="list-style-type: none"> • <i>What disadvantages?</i>
2	<p>When delivering community-wide MDA for STH, what local adaptations should be made so that the intervention is effective?</p> <p><i>Follow-up question:</i></p> <ul style="list-style-type: none"> • <i>What aspects of the intervention should not be adapted?</i>

#	Question
3	<p>What barriers might community members face in participating in community-wide MDA for STH?</p> <p><i>Follow-up question:</i></p> <ul style="list-style-type: none"> • <i>What could be done to overcome these barriers?</i>
4	<p>Do you remember the lymphatic filariasis (LF) MDA programs that used to occur in this area? What do you remember about them?</p> <p><i>Follow-up questions:</i></p> <ul style="list-style-type: none"> • <i>What could be done to overcome these barriers?</i> • <i>Did you participate in those treatment days by swallowing the medicines given to you? Why or why not?</i> • <i>Has that affected your interest in participating in the current mass treatment days?</i>
5	<p>Do you think that community-wide MDA could interrupt STH transmission (i.e. stop the spread of intestinal worms) in your setting? Why or why not?</p>
6	<p>Who are the key influential individuals or organizations to get buy-in from during the DeWorm3 study?</p> <p><i>Follow-up questions:</i></p> <ul style="list-style-type: none"> • <i>Can you provide specific examples of why you think their buy-in is important?</i>
7	<p>How should community members be informed about community-wide MDA or other DeWorm3 interventions before they occur?</p>
8	<p>What are some strategies to achieve high MDA treatment coverage?</p>
9	<p>Is there any other information that you would like to share about community-wide MDA today?</p>