

1 **Title**

2 Development, feasibility and potential effectiveness of community-based
3 continuous mass dog vaccination delivery strategies: lessons for optimization
4 and replication

5 **Authors**

6 Christian Tetteh Duamor^{1,2*}, Katie Hampson³, Felix Lankester^{4,5}, Ahmed
7 Lugelo⁶, Emmanuel Mpolya¹, Katharina Kreppel¹, Sarah Cleaveland³, and Sally
8 Wyke⁷.

9 **Author Affiliations**

10 ¹Department of Global Health, Nelson Mandela African Institute of Science and
11 Technology, Arusha – Tanzania

12 ²Environmental Health and Ecological Sciences Thematic Group, Ifakara Health
13 Institute – Tanzania

14 ³Institute of Biodiversity, Animal Health & Comparative Medicine, College of
15 Medical, Veterinary and Life Sciences, University of Glasgow, Glasgow, G12 8QQ
16 – UK

17 ⁴Paul G. Allen School for Global Animal Health, Washington State University, 240
18 SE Ott Road, Pullman, WA 99164-7090 – USA

19 ⁵Serengeti Health Initiative, Serengeti – Tanzania

20 ⁶Sokoine University of Agriculture, Morongoro – Tanzania

21 ⁷Institute of Health and Wellbeing, College of Social Sciences, University of
22 Glasgow, Glasgow, G12 8QQ – UK

23 ***Corresponding author**

24 E-mail: ctetteh@ihi.or.tz (CTD)

33 **Abstract**

34 **Objectives:** Dog vaccination can eliminate rabies, but annual delivery strategies
35 do not sustain vaccination coverage between campaigns. We describe the
36 development of a community-based continuous mass dog vaccination (CBC-
37 MDV) approach designed to improve and maintain vaccination coverage in
38 Tanzania and examine the feasibility of delivering this approach as well as
39 lessons for its optimization.

40 **Methods:** We developed three delivery strategies of CBC-MDV and tested them
41 against the current annual vaccination strategy following the UK MRC's
42 guidance: i) developing an evidence-based theoretical framework of intervention
43 pathways and ii) piloting to test feasibility and inform optimization. For our
44 process evaluation of CBC-MDV we collected data using non-participant
45 observations, meeting reports and implementation audits and in-depth
46 interviews, as well as household surveys of vaccination coverage to assess
47 potential effectiveness. We analyzed qualitative data thematically and
48 quantitative data descriptively.

49 **Results:** The final design included delivery by veterinary teams supported by
50 village-level one health champions. In terms of feasibility, we found that less
51 than half of CBC-MDV's components were implemented as planned. Fidelity of
52 delivery was influenced by the strategy design, implementer availability and
53 appreciation of value intervention components, and local environmental and
54 socioeconomic events (e.g. elections, funerals, school cycles). CBC-MDV
55 activities decreased sharply after initial campaigns, partly due to lack of
56 supervision. Community engagement and involvement was not strong.
57 Nonetheless, the CBC-MDV approaches achieved vaccination coverage above the

58 critical threshold (40%) all-year-round. CBC-MDV components such as
59 identifying vaccinated dogs, which village members work as one health
60 champions and how provision of continuous vaccination is implemented need
61 further optimization prior to scale up.

62 **Interpretation:** CBC-MDV is feasible to deliver and can achieve good vaccination
63 coverage. Community involvement in the development of CBC-MDV, to better
64 tailor components to contextual situations, and improved supervision of
65 activities are likely to improve vaccination coverage in future.

66

67 **Key words:** community-based, dog vaccination, process evaluation, rabies.

68

69 **AUTHOR SUMMARY**

70 Annual mass dog vaccination campaigns that reach at least 70% of the dog
71 population, should maintain sufficient herd immunity between campaigns to
72 interrupt rabies transmission. However, it is often challenging to reach 70% of
73 the dog population with annual vaccination campaigns. We hypothesized that a
74 community-based continuous approach to dog vaccination could better
75 maintain high levels of vaccination coverage all-year-round. We describe the
76 development of a community-based continuous approach to dog vaccination in
77 Tanzania, and assessed the feasibility of delivering its components, its potential
78 effectiveness and lessons for its optimization. We found that the approach was
79 well accepted, as its development involved key stakeholders. Although less than
80 half of the components of the community-based continuous approach were
81 delivered exactly as planned, over 70% of dogs were vaccinated and the
82 approach maintained coverage above the critical vaccination threshold
83 throughout the year. We conclude that it is feasible to deliver a community-
84 based continuous approach to dog vaccination, but that some components
85 need further improvement; more supervision and community involvement
86 should lead to better outcomes.

87 INTRODUCTION

88 Rabies is a central nervous system infection that can infect all mammals. The
89 disease has a case fatality rate approaching 100% [1,2]. Globally, human deaths
90 are estimated at about 59,000 per annum, with 99% due to domestic dog-
91 mediated transmission [3]. The burden of rabies is highest in endemic regions
92 where both human and animal rabies vaccines are not reliably accessible [3].

93 Rabies is controllable for several reasons: domestic dogs are the primary source
94 of infections to humans and rabies has a consistently low basic reproductive
95 number ($R_0 < 2$) across a wide range of settings [1]; dogs in endemic regions are
96 typically accessible for vaccination [4,5]; and the low R_0 means that the critical
97 vaccination threshold required to achieve herd immunity is relatively low
98 (approximately 40%). Despite these reasons, rabies remains endemic in many
99 settings and only limited dog vaccination is undertaken. A possible concern
100 should mass dog vaccination be scaled up is that, despite the critical
101 vaccination threshold being low, to sustain vaccination coverage *above* this
102 level over the course of the year, annual vaccination campaigns must reach a
103 higher proportion of dogs, of around 70% [1,6,7].

104 Most endemic countries where some mass dog vaccination (MDV) has been
105 initiated, including Tanzania, use annual team-delivered approaches in which
106 government vaccination teams use cold-chain stored vaccines to conduct
107 annual vaccination clinics in targeted villages. However, annual team-delivered
108 campaigns (subsequently referred to in this study as the pulse approach) are
109 affected by several factors that limit their ability to achieve and sustain
110 vaccination coverages above the critical threshold to control rabies. These
111 include: high rates of dog population turnover in most endemic countries,
112 which results in rapid declines in population immunity in the interval between
113 annual campaigns [8,9]; teams needing to travel long distances on dirt roads
114 from cold chain facilities, which is sometimes possible only at certain times of
115 the year; campaign day(s) being negatively affected by agricultural cycles,

116 inclement weather, school days, funerals, and local festivals [7]; high fixed
117 vehicle and personnel costs, with the cost-per-dog vaccinated reaching as high
118 as \$7.36 [10-12].

119 Recent research has shown that Nobivac Canine Rabies Vaccine, a widely used
120 vaccine for dogs [13], is thermostable and can induce equivalent immune
121 responses following non cold chain storage at temperatures up to 30°C for
122 three months. Thermotolerance remained when the vaccines were stored in
123 rural Tanzania in locally made passive cooling devices, within which
124 temperatures were kept relatively cool despite ambient temperatures reaching
125 37°C [14]. This research has created opportunities for new approaches to rabies
126 vaccine distribution and delivery, including options for the storage of vaccines
127 in remote communities which would allow all year-round routine vaccination of
128 dogs by community-based personnel. A community-based continuous mass dog
129 vaccination (CBC-MDV) approach has the potential to sustain population
130 immunity above the critical threshold, as new puppies and other susceptible
131 dogs (for example, newly acquired dogs or those that missed previous
132 vaccination campaigns) can be vaccinated without having to wait for the annual
133 campaign. Through empowering communities to own and sustain local dog
134 vaccination efforts, it has been hypothesized that a CBC-MDV model could also
135 result in more dogs being reached at less cost per animal vaccinated
136 [13,15,16].

137 CBC-MDV is a complex intervention, with several interacting components such
138 as the involvement of local veterinary authorities and communities, local
139 storage of dog rabies vaccines outside of the cold chain system and a
140 continuous approach to dog vaccine delivery. Consequently, the intervention
141 could operate differently in different settings. The UK Medical Research Council
142 Guidance on developing and evaluating complex interventions prior to full scale
143 evaluation recommends a systematic approach to intervention development
144 [17]. This approach should include the development of the intervention with
145 stakeholders, a theoretical understanding of how it is likely to operate, and

146 piloting of its delivery with a view to evaluating the feasibility of its delivery in
147 the long term, prior to full scale evaluation. The study describes formative work
148 that took place to design a model of CBC-MDV and the development and testing
149 of three different delivery strategies for CBC-MDV. Following the UK Medical
150 Research Council Guidance, we describe the development and evaluation of the
151 feasibility of delivering CBC-MDV. We also assess the potential of CBC-MDV to
152 sustain vaccination levels above the critical threshold for rabies elimination and
153 lessons for its optimization and replication.

154

155 **METHODS**

156 The research was conducted in two stages, Figure 1 provides a schematic
157 overview of the processes involved.

158

159 **Phase 1: Developing components of CBC-MDV**

160 CBC-MDV was developed to be delivered in rural Tanzania and piloted in three
161 districts of Ranya, Tarime and Butiama of the Mara region, north-west Tanzania
162 between Lake Victoria and Kenya. This area is home to several ethnic groups
163 who are primarily engaged in agro-pastoral and fishing activities. Dog
164 ownership is common with larger households and those having livestock
165 tending to own more dogs [18-20]. The pilot phase included 12 wards drawn
166 from each district: wards are a cluster of 3-4 villages; villages are divided into
167 subvillages; the number of subvillages per village ranged from 2 to 13 in our
168 study area.

169 Evidence on barriers to a centralized, team-delivered dog vaccination approach
170 (as laid out in the introduction), the feasibility of storing the Nobivac Rabies
171 Vaccine in locally made passive cooling devices [13,14] and the ability of
172 community-based persons to vaccinate dogs [21] provided the context for
173 developing initial components of CBC-MDV.

174 The initial design was discussed with potential stakeholders in the Mara region
175 (where a large-scale randomized controlled trial (RCT) is proposed to take place
176 following on from this pilot study) and subsequently with national level
177 veterinary officials and international experts, with workshops taking place
178 between May 2018 and May 2019. Table 1 describes the stakeholder groups
179 involved and aim of each workshop.

180

181 Table 1. Stakeholder group, purpose and date of engagement workshops

Stakeholder Group	Purpose of Workshop	Dates; Venue
1 National Level Veterinary Officials, Mara Regional Medical and Veterinary Officers, District Medical and Veterinary Officers, Nurses and Livestock Field Officers plus research staff	To introduce national veterinary officials and Mara region stakeholders to potential CBC-MDV strategies	23-26 May, 2018; Mugumu – Serengeti
2 Veterinary technical staff from Ministry of Livestock and Fisheries Development, community health specialist from World Health Organization – Tanzania country office, the Mara Regional Medical Officer, representatives from Ministry of Health and Tanzanian One Health Coordination Unit plus research staff.	To share evidence for the safety of use of locally made passive cooling devices to store vaccines & non-animal health professionals to vaccinate dogs and to demonstrate that the research evidence was strong enough for local use.	17- 18 July, 2018; The Prime Minister's Office – Dar es Salaam
3 Three Rabies Researchers from Global Animal Health – Tanzania, Director of Veterinary Services and Registrar of Tanzanian Veterinary Council	To provide the outcome of Workshop 2, and to share evidence of use of locally made passive cooling devices to store vaccines & non-animal health professionals to vaccinate dogs	17th November, 2018; Office of Director of Veterinary Services – Dodoma
4 Researchers from Washington State University (5), University of Glasgow (5), Global Animal Health – Tanzania (6), Director of Veterinary Services, Chairman and Registrar of Tanzania Veterinary Council, President of Tanzania Veterinary Association, representatives from Ministry of Health and One Health Coordination Unit	To finalize design of CBC-MDV for the pilot study, define roles of district, ward and village level implementers and to launch the research project	22nd – 23rd Mar, 2019; Arusha.
5 Mara Regional Commissioner and Administrative Secretary, Researchers from Global Animal Health – Tanzania (6), Director of Veterinary Services, Chairman and Registrar of Tanzania Veterinary Council, President of Tanzania Veterinary Association, Mara Regional Medical and Veterinary Officers, District Medical and Veterinary Officers, Nurses and Livestock Field Officers	To bring the research team and human and animal health staff of the Mara region together, to outline logistical needs for implementing CBC-MDV and to declare the research as a national learning project to inform national mass dog vaccination strategies for Tanzania	7th – 8th May, 2019; Office of the Mara Regional Commissioner

182

183 The first author participated in and made notes (11 observation days) of all the
 184 workshops, and documented stakeholders' opinions and concerns of CBC-MDV,
 185 specifically: how vaccines will be stored outside of the cold chain system in

186 wards using locally made passive cooling devices, the level of training required
187 to vaccinate dogs, local involvement in implementation and roles at district,
188 ward and village levels. The research team met after each workshop to revise
189 the components of CBC-MDV.

190 Following the final workshop, the research team developed a theory of change
191 model and a manual to guide implementers (district livestock field officers,
192 ward-based rabies coordinators – RCs and village-based one-health champions –
193 OHCs) in delivering the CBC-MDV components. To identify the most efficient
194 approach to delivering the components, three delivery strategies of CBC-MDV
195 were designed to be piloted.

196

197 **Phase 2: Feasibility of delivering CBC-MDV, potential effectiveness and** 198 **lessons learned**

199 The three delivery strategies of CBC-MDV were piloted over a 12-month period
200 and evaluated using mixed methods and the outcomes compared to that of the
201 pulse (annual team-delivered) approach which was also undertaken as part of
202 the pilot study. Table 2 summarizes which methods were used to assess the
203 feasibility and potential effectiveness of the delivery strategies as well as to
204 formulate lessons learned.

205

206 Table 2. Summary of research methods used to assess the feasibility of
207 delivering community based continuous mass dog vaccination (CBC-MDV),
208 potential effectiveness and formulate lessons learnt

Aspect of CBC-MDV delivery assessed	Method	Data
Feasibility of delivery	Observation of advertising of vaccination clinics and delivery of CBC-MDV components to assess which were delivered as intended or varied	36 days of observation (6/55 advertising days, 30/235 delivery days)
i) Fidelity to protocol		
ii) Reasons for resultant variation in the delivery of CBC-MDV	Interviews with those responsible for aspects of the delivery of CBC-MDV to	All 47 implementers at month 1 and repeated at

iii)	Efforts required to deliver each strategy	audit the implementation process and to capture what was delivered and reasons for variation	month 6
Potential effectiveness			
i)	Vaccination coverage of the CBC-MDV delivery strategies compared with pulsed delivery	Household surveys	1,386 and 1,445 households from 47 villages surveyed at month 1 and 11 respectively
Lessons for optimization and replication		Feedback and appraisal meetings of the research team examining the delivery processes and exploring feasible and effective alternative approaches	24, fortnightly meetings; from July 2019 to June 2020

209

210 *Assessing Fidelity, Variation and Efforts*

211 To assess the fidelity of the implementation process during phase 2 and the
212 reasons for variation in delivering CBC-MDV, we conducted observations on
213 advertising campaigns (6/55 days) and delivery of vaccination activities (30/235
214 days) noting whether implementers delivered components of CBC-MDV as
215 planned and factors responsible for variation.

216 We audited delivery of CBC-MDV using semi-structured interviews with
217 implementers (one with each of the 47 implementers) about aspects of delivery,
218 record review, inspection of how vaccines were managed at district veterinary
219 offices and wards, and installation and maintenance of locally made passive
220 cooling devices and their temperature loggers within wards. Notes were taken
221 on which components of CBC-MDV were delivered as planned and on potential
222 reasons for variation. The audits were carried out early in the delivery of CBC-
223 MDV at month 1 and repeated at month 6.

224 We used observation and audit data to assess and compare efforts required for
225 each of the CBC-MDV strategies and the fidelity of their delivery.

226 *Assessing potential effectiveness*

227 When dogs were vaccinated owners were given a vaccination certificate and
228 dogs were microchipped. To assess how the strategies performed with respect

229 to vaccination coverage, random samples of households (Table 2) were
230 surveyed in each village, scanning dogs for a microchip and inspecting
231 vaccination certificates. If neither the dog nor the certificate could be found, we
232 asked household members whether their dog(s) had been vaccinated. The
233 surveys were conducted at month 1 and 11 after roll out of CBC-MDV. Detailed
234 reports of outcome measurement are presented in an outcome evaluation paper
235 (Lugelo et al. preprint) and are summarized in this manuscript to provide
236 informative context to the process evaluation.

237 *Lessons for optimization and replication*

238 To optimize CBC-MDV, the research team reviewed the observation and audit
239 data on the delivery process through fortnightly feedback and appraisal
240 meetings to identify components of CBC-MDV that were not working and
241 designed alternative approaches. The team also identified best practices by
242 implementers and components of CBC-MDV that were context sensitive. The
243 first author participated in these meetings and made detailed reports.

244

245 **Data analysis**

246 *Fidelity, Variation and Effort*

247 To assess the extent to which the components were delivered as intended, field
248 notes from observations of advertising and from the audits of the
249 implementation process were read and summarized as either 'delivered as
250 planned', 'delivery modified', 'not delivered as planned' or 'delivered in excess
251 of what was planned'. To assess the reasons for variation from what was
252 planned, qualitative notes from observation of the advertising process and
253 audits were thematically analysed as follows. The first author developed the
254 initial coding frame using a combination of deductive and inductive approaches
255 [22,23]. Two authors independently applied the coding frame to a sample of
256 the data (2 observation and 1 audit notes), and the coding frame was discussed

257 and amended over three iterations. The first author then applied the coding
258 frame to the whole data set. The main themes were: community engagement,
259 estimation of dog population, advertising of campaigns, starting and closing
260 time of vaccination clinics, delivery of continuous vaccination and choice of
261 approaches for clinics. The coded texts were used in complementing,
262 expanding and elaborating on understanding of the manner in which CBC-MDV
263 was delivered and factors that influenced feasibility of delivering the different
264 components. Qualitative data analysis was done using QSR NVIVO version
265 12.5.0 (NVivo qualitative data analysis software; QSR International Pty Ltd.
266 Version 12, 2018).

267 To assess the effort that was required to implement each of the three CBC-MDV
268 strategies data were collected on the number of times and hours spent
269 advertising, and number of campaigns delivered. These data were examined to
270 determine whether the efforts varied by strategy after plotting in Excel version
271 16.

272 *Assessing potential effectiveness*

273 Vaccination coverage achieved by each delivery strategy was calculated as the
274 proportion of the dog population surveyed that had either i) a microchip, ii) a
275 vaccination certificate or iii) owner recall that the dog had been vaccinated. We
276 summarized the coverage estimates at month 1 and month 11, annual averages
277 achieved by each CBC-MDV strategy and the pulse strategy.

278 *Lessons for optimization and replication*

279 To ensure successful replication of CBC-MDV in other settings, the research
280 team, through the appraisal meetings, identified components of CBC-MDV that
281 were appreciably influenced by contextual factors. Reference was made to the
282 literature on how certain barriers to implementing community-based
283 interventions were overcome and considered in optimizing CBC-MDV. Based on
284 the conclusions reached by the research team, alternative approaches were

285 designed for the CBC-MDV components that were not working as planned. Best
286 practices among implementers were identified and incorporated into the CBC-
287 MDV design for implementation in the full-scale trial planned for the Mara
288 region.

289 **Ethics statement**

290 The study was approved by the Institutional Animal Care and Use Committee,
291 Washington State University [Approval No. 04577 – 001], the Tanzania National
292 Medical Research Institute [NIMR/HQ/R.8a/Vol.IX/2788] and Ifakara Health
293 Institute [IHI/IRB/No:024-2018].

294 **RESULTS**

295 **Phase 1: Development of CBC-MDV intervention**

296 Table 3 summarizes the essential components of CBC-MDV, the rationale for
297 their inclusion, the views on each component expressed by stakeholders during
298 meetings and adaptations made to the design of the components to address
299 concerns. The detailed components of each ingredient are outlined in
300 Supplementary Table 1. The development process of CBC-MDV was iterative and
301 participation in the workshops was multisectoral and included participants who
302 both work in either the public health or animal health sector and are members
303 of local communities, but did not specifically include community leaders/
304 decision-makers.

305 **Table 3. Essential components of CBC-MDV and responses to stakeholder**
306 **concerns.**

Essential ingredient	Rationale	Stakeholder views	Adaptation
i. Local delivery of CBC-MDV to be led by district level veterinary authorities	A new service is more likely to be adopted and sustained if it has buy-in and fits within existing systems	Stakeholders agreed district level veterinary authorities should lead implementation and suggested specific adaptations	Each district would have a district livestock field officer or a district veterinary officer who should oversee the delivery
ii. Involvement of village level leadership in roll out of CBC-MDV	Support from village leadership is essential for high dog owner participation and local support for sustainability	Stakeholders expected village leaders to ensure members send their dogs for vaccination	Village leadership should enforce local laws to ensure community members vaccinate their dogs
iii. Use of village-based people, trained prior to implementation and called One Health Champions (OHCs), to support ward-level livestock field officers to carry out vaccination activities	Local knowledge will facilitate organization and greater reach; employment of local people also provides key additional human resource	Because vaccination is professionally regulated within Tanzanian law, stakeholders would not allow people without an animal health certificate to vaccinate dogs	Each ward would have a ward-based livestock field officer Trained village-based persons (OHCs) to be allowed to register dogs and issue certificates A village-based assistant could be employed as well

iv. Widespread communication at village level about CBC-MDV and advertising of campaigns using multiple forms of communication and venues	Widespread communication would be essential to achieve high coverage/reach	Use of village-based OHCs would facilitate local mobilization	Each village will have an OHC who will coordinate dog vaccination activities in the village
v. Use of locally made passive cooling devices to store rabies vaccine in wards	Local storage will improve operationalization of continuous dog vaccination by reducing time and travel costs thus improving access	Stakeholders agreed to storage of vaccines in locally made, locally made passive cooling devices	Livestock field officers should ensure conducive places are prepared for installation of cooling devices and their temperature monitors
vi. A continuous approach to MDV activities which will be delivered on a quarterly basis and also available on demand by dog owners all year round	All year-round access to dog vaccination will support maintaining sufficient coverage necessary to interrupt transmission	Stakeholders agreed livestock field officers can devote time to organizing four rounds of vaccination campaigns in a year and to delivering vaccination on demand	Livestock field officers should collaborate with OHCs to identify dogs that missed previous rounds of quarterly vaccination
vii. Delivery of dog vaccination must be free of charge to the dog owners	Fees have been documented to discourage owner participation	Stakeholders agreed vaccination of dogs and cats on this project will be free of charges to owners	To assist with the cost of implementation, local government authorities of Mara region agree to contribute US\$2,000 annually to dog vaccination
viii. Monitoring and feedback on vaccination coverage among research team, district veterinary authorities, vaccinators and communities.	Frequent feedback among implementers and district authorities will enable local actions to maximize CBC-MDV activities	Stakeholders agreed to monitor processes and outcomes through a joint steering committee and reporting via the district veterinary offices	Livestock field officers must submit weekly reports to district office and research team, and provide feedback to communities

307

308 **The strategies of CBC-MDV tested**

309 Stakeholders determined that the essential components of CBC-MDV could be
 310 delivered slightly differently and used the pilot (phase 2) to assess the three
 311 forms of delivery (Table 4), each of which included the essential components. A
 312 ward from each district was allocated to each of the three CBC-MDV delivery
 313 strategies. An additional ward from each district was then allocated to the pulse
 314 (once annual) strategy.

315

316 **Table 4. Strategies for delivering components of CBC-MDV in the pilot study**

Strategy	Frequency	Rationale
One: Village level temporal static point clinics in month 1 for all villages in the ward	Campaigns repeated at months 3, 6, and 9 using either the same approach or house-to-house, plus on-demand vaccination, i.e. responding to alerts from owners of dogs needing vaccination	Within three months enough puppies and new dogs would have arrived in villages in manageable numbers for efficient vaccination
Two: Subvillage level temporal static point clinics in month 1 for all villages in the ward.	Campaigns repeated at months 3, 6, and 9 using same approach or house-to-house, plus on-demand.	Bringing clinic centers closer to more people should increase owner participation
Three: Implementers will deliver mass dog vaccinations using whichever of the above methods they consider to be best.	Continuous quarterly campaigns (at months 1, 3, 6, and 9)	Discretion to implementers and their knowledge of local terrain and context will influence their choices of vaccination approach and improve performance.

317

318 Figure 2 presents the logic model agreed between research team members and
319 the stakeholder groups as to how CBC-MDV in general is expected to work.

320 **Phase 2: Assessment of feasibility and potential effectiveness**

321 *Fidelity and Reasons for Variation*

322 Table 1 (supplementary file) presents an expanded form of the essential (45)
323 components of CBC-MDV and summary analysis of fidelity of delivery: 20
324 components (44%) were delivered as planned, 14 (31%) were not delivered at all,
325 nine (20%) were modified and two (5%) were delivered in excess of what was
326 planned. The components were broadly categorized into eight groups (as
327 detailed in Table 3) and their fidelity described as follows:

328 **i. Local delivery of CBC-MDV to be led by district level veterinary
329 authorities to foster buy-in:** Of the four components relating to district
330 veterinary authority roles, two were modified in delivery. To foster community
331 acceptance of the one health champions and rabies coordinators, the district
332 livestock field officers were to write letters to introduce the vaccinators to their

333 villages. All the district officers wrote letters after the training workshop. The
334 district officers took stocks of vaccines received from the research project and
335 distributed them to wards as planned. However, vaccines returned from two
336 wards to district offices were not labeled and stored as planned. The district
337 officials reported only supervising and monitoring campaigns as part of routine
338 district veterinary functions. They cited lack of vehicle and fuel as key
339 challenges to supervision. All the RCs reported they were not supervised by
340 district officials as planned.

341 **ii. Involvement of village level leadership in roll out of CBC-MDV to foster**
342 **owner participation and local support:** There were five components of CBC-
343 MDV to be implemented to bring community leadership on-board with delivery
344 of dog vaccination. Of these, four were modified or partly delivered as planned
345 and one was not delivered. Of 35 OHCs, the majority received letters
346 introducing them to their villages (31, 89%). However, most of them received
347 the letters just a few days before or after the process had started and there
348 were very few or no opportunities to introduce them at village meetings. Of the
349 19 (54%) introduced, 17 were introduced only in a leaders' meeting; while in the
350 cases of those not introduced (16, 46%), the RCs or OHCs only informed ward
351 or village executive officers about the programme. Hence, most villagers did
352 not have the opportunity to link the RCs and OHCs with the vaccination
353 campaigns before they started.

354 The protocol also required RCs to discuss vaccination timetables with village
355 leaders; only four out of nine RCs reported directly informing a community
356 leader about their timetables. Again, OHCs were to work with 'mabalozi'
357 (leaders of a cluster of ten houses) to estimate the village dog population.
358 These were partly implemented; only a few (3, 9%) OHCs reported working with
359 'mabalozi'; the rest either went to houses directly (19, 54%) or instead worked
360 with subvillage chairpersons (13, 37%). The frequently cited reasons for not
361 working with 'mabalozi' included: 'mabalozi' perceived OHCs as not belonging
362 to their political party or seen the project as not a community agenda and

363 hence requested money (15, 43%); “*one ‘balozi’ said, you went to the workshop*
364 *and received big allowances and you have come to tell us to go and work*” [OHC,
365 Implementation Audit, Strategy 1-Tarime]. Also, the concept of ‘mabalozi’ is not
366 practiced uniformly across all jurisdictions (11, 31%). Other reasons were OHCs
367 thought they were to work instead with subvillage chairpersons (6, 17%) or they
368 did not trust ‘mabalozi’ to produce accurate figures on the dog population (4,
369 11%).

370 **iii. Use of trained village-based One Health Champions to support ward-
371 level rabies coordinators with local knowledge to carry out vaccination
372 activities:** There were six essential ingredients relating to village-based
373 personnel supporting delivery of CBC-MDV at village levels. Out of these six,
374 two were delivered as planned, one was partly delivered, two were not
375 implemented and one was implemented in excess of what was planned. To
376 ensure that only the required number of vaccines for a round were requested,
377 all OHCs (35, 100%) provided estimates of the village dog population to RCs for
378 request of vaccination materials. All OHCs also advertised vaccination clinics as
379 planned. On the other hand, only two out of 35 OHCs conducted sensitization
380 in village meetings. The opportunities for OHCs were likely limited as most of
381 the villages did not hold meetings before the start of campaigns. Over the
382 course of the year none of the OHCs documented dogs that missed the
383 previous rounds as planned. All OHCs supported vaccination clinics in other
384 villages of the ward in addition to theirs, as the workload at a center is ideally
385 for three people. Not all of OHCs had cooperation from their village leadership,
386 possibly because most of the OHCs were not persons with influential village
387 positions.

388 **iv. Widespread communication at village level about CBC-MDV and
389 advertising of campaigns using multiple forms of communication and
390 venues to promote high reach:** Advertising of campaigns was largely carried
391 out as planned. Of three components relating to advertising, one was delivered
392 as planned, one modified and one delivered in excess of what was planned. All

393 OHCs (35, 100%) delivered the complete contents of the adverts as designed,
394 which included: date, time, location of clinic, specified animals to be vaccinated
395 as dogs and cats, and vaccination being free-of-charge, using mega phones and
396 posters at vantage points as prescribed. However, instead of the night before,
397 announcements started two to three days before, likely occasioned by perceived
398 workload (nature of settlement and size of villages – need to cover long
399 distances). Out of a total of 55 announcements of the first round of campaigns,
400 only 24 (44%) were carried out in the evenings; the rest were carried out in
401 mornings (20, 36%) or afternoons (11, 20%) in variation with the protocol, and
402 was probably when the vaccinators presumed most people were at home.

403 **v. Use of locally made passive cooling devices to store rabies vaccine in**
404 **wards to support provision of continuous vaccination:** To ensure vaccines do
405 not remain outside of the cold chain for more than six months, eight CBC-MDV
406 components were to help to deliver the vaccines to wards in batches. Six out of
407 these were implemented as planned including: coordinated requests and
408 transport systems; basing requests on ward dog population; returning unused
409 vaccines after six months; installation of cooling pots away from sunlight; and
410 monitoring daily temperature in pots. However, labeling of unused vaccines was
411 not carried out as planned; only two out of nine RCs reported having ever
412 returned unused vaccines to the district office and these were given to wards
413 which were not part of the studies for use. Four out of nine pots were not in full
414 use because they developed cracks and leaked when water is added to the
415 cooling sand layer.

416 The prescribed waste management plans were partially implemented. The
417 different kinds of waste were mostly separated during vaccination clinics (7/9),
418 but instead of returning metallic and biohazard wastes to district offices or
419 nearest health centers for incineration, most teams burnt everything at the
420 location of clinics (6/9), indicating it was safe to do so.

421 **vi. A continuous approach to MDV activities; quarterly basis and available**
422 **on demand by dog owners all year round thereby providing continuous**
423 **access to dog vaccine:** Of the five components of CBC-MDV targeted at
424 supporting provision of continuous dog vaccination, two were implemented as
425 planned, one was modified and two were not implemented as planned. The
426 CBC-MDV protocol prescribed that each strategy team conducts four rounds of
427 campaigns in a year. However, only three out of the nine teams conducted four
428 rounds of campaigns. The frequently cited reasons for variation in vaccination
429 schedules included: farming/ rainy seasons, national activities such as
430 elections, counting of poor households and mass animal vaccination campaigns
431 (in which some RCs participated), social events such as cattle auction days,
432 funerals, puberty rites celebrations and school cycles, with campaigns more
433 patronized on weekends during school terms. For example, some dog owners
434 indicated that during the farming season, either they or their dogs were
435 required in the farms during the day time to guard against monkeys destroying
436 their crops. It was also noted in one district that campaigns were halted during
437 the month-long puberty rites celebrations.

438 The activity of finding unvaccinated dogs that missed previous rounds was not
439 implemented as planned. The implementers cited that this activity was labor-
440 intensive and not feasible in the absence of an existing village register of dogs.
441 To ensure dog owners have easy and continuous access to vaccinators, the
442 protocol prescribed that OHCs give their mobile numbers out during first round
443 of campaigns. None of OHCs reported giving their numbers out directly as
444 planned (0, 100%) but most (32, 91%) wrote them on the 5-10 posters per
445 village they pasted. The research team observed giving numbers out was
446 practically difficult to do during advertising or vaccination given how busy they
447 were at the centers. However, more than half of OHCs (20, 57%) reported having
448 received calls from dog owners to visit their homes to vaccinate their dogs.

449 **vii. Delivery of free dog vaccination clinics using suitable approaches to**
450 **encourage owner participation:** Out of the eight components related to

451 organizing vaccination clinics, five were implemented as planned, one was
452 modified and two were not implemented as planned. The CBC-MDV protocol
453 prescribed that vaccination should take place between 08:00 - 14:00; in
454 practice clinics started as early as 07:00 and as late as 12:00; and closed as
455 early as 11:00 and as late as 18:00. The length of clinics was dependent on
456 turnout at centers. House-to-house campaigns took longer where houses were
457 further apart. The starting time for clinics depended on when farmers had
458 returned home, whether RCs had to perform other duties on the same day (e.g.
459 having to inspect meat) before clinics or whether RCs had to attend to personal
460 business. Vaccinators also cited that microchipping dogs (during which a
461 number of dogs struggled) and entering data into the digital data collection
462 device was time-consuming.

463 To ensure safe vaccination of dogs by reducing dog aggression, the
464 implementation manual prescribes separation of registration and inoculation
465 points with at least a 20-meter distance and muzzling of potentially aggressive
466 dogs. However, none of the vaccination teams (0/9) implemented these. Dog
467 aggression was associated with poor dog handling techniques by vaccinators. It
468 was observed that vaccinators may not have had enough time to assimilate the
469 benefits of separating dogs being registered and those being inoculated to
470 reduce aggression. Dog aggression was observed to increase the time-per-dog
471 vaccinated and on rare occasions resulted in injury, especially of dog owners.

472 Muzzles were not used out of fear of being bitten or the muzzles could tear in
473 the process. One rabies coordinator said: "*is too difficult to use muzzles, dogs*
474 *are too fierce to use it on them, it will get loose, we are afraid, we use the Y-*
475 *stick*" [RC, Implementation Audit, Strategy 2-Tarime]. Others recommended
476 muzzles of three different sizes, whilst others perceived use of muzzles as time
477 consuming. Consequently, implementers in Butiama and Ranya Districts
478 restrained aggressive dogs by tying the rope or chain on the neck of dogs
479 closely to a tree, and holding the hind legs firmly whilst inoculating the dog.

480 While those in Tarime District used a 'Y-stick' to pin down the dog at the neck
481 region with the help of the rope or chain.

482 The vaccination teams varied the delivery strategies that were prescribed for
483 them, citing the following reasons: villagers saying it was difficult to bring dogs
484 over long distance to centers, large dog populations in their villages, and their
485 own perception of which strategy was likely to reach more dogs. Remarks by
486 implementers indicated they thought subvillage level temporal static point
487 clinics was the most effective approach, with the following quotes exemplifying
488 this, "*subvillage level is very good at reaching more dogs*" [RC, Implementation
489 Audit, Strategy 1-Rorya]; "*the Strategy (subvillage level temporal static point
490 approach) is good because we had time to educate the dog owners*" [RCs, FGD,
491 Strategy 2-Butiama]; "*I think Strategy 3 is good, it covers a lot of places because
492 we use sub-village level (temporal static point approach), house to house and on
493 demand*" [RC, Implementation Audit, Strategy 3-Tarime].

494 **viii. Monitoring and feedback on vaccination coverage among stakeholders
495 to promote collaborative local action:** Of the six components relating to
496 monitoring, reporting and providing feedback on CBC-MDV, only two (RCs
497 reporting on dogs vaccinated, daily temperature recording of the low-tech
498 cooling devices and rabies events) were delivered as planned. Supervision of
499 campaigns by district veterinary officers was not carried out; the district
500 veterinary officers cited lack of transportation to carry out this task and they
501 expected per diem payment while supervising. OHCs also did not provide
502 weekly reports on dogs needing vaccination and considered the weekly
503 reporting was too frequent to allow for completion. Communities' self-
504 monitoring of the campaigns and feedback to the research team and the district
505 veterinary office were also not carried out, largely due to weak community
506 involvement in the design of the CBC-MDV and sensitization on this role.

507 **Comparing efforts made at delivering CBC-MDV components by strategies**

508 **Involvement of village level leadership in roll out of CBC-MDV:** The strategy
509 teams delivered components relating to involving village leaders with varied
510 degrees of fidelity. For example, very few OHCs discussed their timetables with
511 a village leader to get their approval and support (0/12 for Strategy 1, 2/13 for
512 Strategy 2 and 2/10 for Strategy 3). OHCs largely did not work with ten-cell
513 leaders (Mabalozi) to estimate the dog population in their ward: Strategy 1
514 (3/12), Strategy 2 (0/13) and Strategy 3 (0/10). Further information about how
515 the delivery of the additional components were delivered is provided in
516 Supplementary Table 2.

517 All components relating to use of trained village-based OHCs to support
518 vaccination were delivered as planned by all strategies, except sensitization of
519 villagers about campaigns at village meetings which differed: Strategy 1 (2/12),
520 Strategy 2 (8/13) and Strategy 3 (9/10) (suppl table 2). All strategies delivered
521 advertising components as required, but the effort put into the advertising
522 differed: The number of times and hours per village advertised in the first
523 round, and total number of days of vaccination per village were all lowest in
524 Strategy 1 and highest in Strategy 3 respectively (Fig 3). The vaccinators
525 reported that having to walk for a long distance or personally pay for travel by
526 motorbike created challenges to advertising.

527 For all strategies, the number of days of campaign activities reduced
528 substantially after the first round. Over the one-year period, the three
529 strategies together used 237 days on campaigns: Strategy 1 (49, 21%), Strategy
530 2 (95, 40%) and Strategy 3 (91, 39%). The majority of days (189 days, 80%) were
531 spent during the first two rounds (Fig 4).

532 The strategy teams differed in terms of numbers of days spent finding dogs
533 that missed central point clinics, responding to on-demand vaccination by dog
534 owners and in organizing quarterly campaigns (suppl table 2).

535 **Waste management after vaccination clinic:** All teams installed and managed
536 vaccine batches as planned. However, there was discrepancy with regards to

537 how used needles and microchip units were disposed. Some teams either
538 incinerated or disposed of these items in pit toilets: Strategy 1 (2/3 teams),
539 Strategy 2 (2/3 teams) and Strategy 3 (1/3 teams), whilst the rest of the teams
540 burnt all waste at vaccination centers (suppl table 2).

541 **Delivery of free dog vaccination clinics using suitable approaches:** none of
542 the Strategy teams implemented separating registration and inoculation centers
543 with a distance of at least 20 meters and muzzling of potentially aggressive
544 dogs as planned. The Strategy teams partly followed CBC-MDV manual in
545 selecting approaches to deliver dog vaccination: All Strategy 3 wards opted for
546 subvillage level temporal static point approach, the same approach as was
547 prescribed for use in Strategy 2 wards in round 1 (6/6). In round 2, two of the
548 Strategy 3 wards avoided the lengthy campaign days that come with subvillage
549 level temporal static point approach by deciding to use village level temporal
550 static point. A remark by an RC exemplifies this: "*it (subvillage level temporal
551 static point approach) took long*" [RC, Implementation Audit, Strategy 3-Rorya].
552 Conversely, two out of the three Strategy 1 teams switched from village level in
553 round 1 to subvillage level temporal static point approach in round 2. The
554 reason given for this switch was that many dogs remained unvaccinated after
555 the round 1 village level temporal static point clinics and so they decided to
556 instead employ a subvillage level temporal static point approach to reach more
557 dogs. All teams employed some house-to-house and on-demand (9/9)
558 approaches. Subvillages were combined for single clinics where implementers
559 considered them to be smaller in size, had smaller dog populations or were
560 closer to each other (suppl Table 3).

561 Overall, subvillage level temporal static point and on-demand approaches were
562 the most (173 occasions) and least-used (20 occasions) respectively (Fig 5).

563 **Potential effectiveness of the CBC-MDV strategies**

564 To interrupt rabies transmission requires sustaining vaccination coverage above
565 the critical vaccination threshold (approximately 40%). Coverage estimations at

566 month 1 and 11 showed all continuous strategies did sustain coverage above
567 this level, whilst the pulsed approach did not achieve the $\geq 70\%$ target (Table 5).
568 Coverage at month 11 was slightly lower in Strategy 1 and 3 and slightly
569 increased in Strategy 2, but none were significantly different (Table 5). Strategy
570 3 which recorded the highest work inputs in terms of advertising and
571 vaccination days, recorded slightly higher annual average vaccination coverage:
572 Strategy 1, 2 & 3 (61.43%, 62.93% & 63.46%), respectively (Table 5).

573

574 Table 5. Vaccination coverage achieved by the delivery strategies at month 1
575 and 11

Vaccination coverage achieved by delivery strategies			
Strategies Arms	Month - 1 (%)	Month - 11 (%)	Annual Averages (%)
Pulse	35.86	32.10	33.98
Strategy 1	65.07	57.78	61.43
Strategy 2	60.97	64.88	62.93
Strategy 3	68.00	58.91	63.46

576

577 **Optimization of CBC-MDV for replication in the full-scale trial and**
578 **dissemination in other contexts**

579 Table 6 details optimization of some components of CBC-MDV for replication in
580 the full-scale trial and lessons for dissemination in other contexts.

581

582 Table 6. How CBC-MDV can be optimized for replication in the full-scale trial
583 and dissemination in other contexts

Finding from process evaluation	Modification in delivery of MDV-CBC for RCT and brief rationale	Further potential modifications and brief rationale
---------------------------------	---	---

Dog aggression showed potential to increase time-per-dog vaccinated: pain inflicted on dogs by microchip needles caused dog aggression	A facial recognition application will be used to scan the faces of vaccinated dogs, potentially faster and less irritating to dogs (reduce dog aggression)	*Knowledge of dog behavior and handling techniques to be incorporated into training curriculum of vaccinators
Scanning barcodes of microchips, microchipping dog and then scanning dog to check if microchip is firing was relatively time-consuming	Feasibility of scale up of use of the facial recognition is being studied	The sequence of procedures at clinic centers will be reordered to avert bites, so that painless procedures such as tying of collars are carried out before painful procedures such as inoculation
Dog aggression was also due to poor dog handling techniques by vaccinators		
OHCs were not very well received by village leaders (especially 'Mabalozi')	OHCs will be selected from village leadership, specifically village chairpersons: In doing so, OHCs will be able to use their authoritative positions to enhance community engagement and sensitization, hopefully leading to improved community acceptance, support and participation in vaccination campaigns	---
Delivery of CBC-MDV components were affected by community level physical, economic and sociocultural factors Such as elections, mass animal vaccination campaigns cattle auction days, funerals, puberty rites celebrations and school cycles	---	A bottom-up approach to design of CBC-MDV could lead to integration of CBC-MDV into village annual calendars (highly revered and largely adhered to) which considers local environmental and sociocultural events
		Village authorities will be more inclined to earmark resources towards CBC-MDV implementation:

		transport and launch allowances for vaccinators, volunteers to assist clinics, enforcing dog vaccination and community self-monitoring of campaigns
Identifying dogs that missed previous campaigns was not carried out by OHCs / RCs: vaccinators cited this activity was labor-intensive and not feasible in the absence of an existing village register of dogs	---	Ideally, campaigns will begin with a census of the entire village dog population linked to households, and will be ticked as dogs are vaccinated. Thus, dogs which missed a round of vaccination and where they live can easily be determined from the census data and targeted; facilitating effective logistics planning, accurate coverage estimation and delivery of continuous vaccination component of CBC-MDV
Because they were busy during clinics, implementers did not give their telephone numbers out for dog owners to call anytime they have dogs needing vaccination	---	Vaccination cards can be printed with the telephone number of the RC of ward on them. This would allow villagers ready access to vaccinators and potentially will promote on-demand/ continuous vaccination
RCs' routine duties and personal businesses influenced timing and frequency of vaccination schedules	---	Schedules composed of 3-rounds of vaccination (at the village / sub-village level) per year will be more manageable for RCs given their other duties. The campaign must include robust arrangements for on-demand to target new dogs and puppies that arrive in the village and dogs that missed previous vaccination rounds
OHCs participated in the campaigns for each village of the ward instead of just their own village: as such, the OHCs thought that they did more work than agreed upon	---	The work load at a vaccination center ideally requires three people. Hence provisions should be made to support OHCs/ volunteers to assist campaigns in other villages.
Supervision of vaccination campaigns by district veterinary	---	Frequent supervision and higher number of days spent vaccinating

officers was not carried out

The number of days during which vaccination campaigns took place reduced drastically after the first round

can be encouraged by a remuneration system that is based on performance: a portion of implementers' salaries can be paid as bonuses/ allowances upon delivery of certain indicators: e.g., for RCs - carrying out all rounds of campaigns of the year, complete & timely monthly reporting, achieving coverage above a minimum threshold at month 11, no animal rabies cases recorded in the ward; for district veterinary officers - number of verifiable supervision days.

584

585

586 **Discussion**

587 This paper provides formative insights into the development, feasibility,
588 potential effectiveness and optimization of CBC-MDV. Key findings were: *i.* the
589 development process of CBC-MDV was iterative and involved stakeholders from
590 multiple sectors but did not include direct involvement of community members;
591 *ii.* It was feasible to deliver about half of CBC-MDV components as planned
592 (about 50% fidelity to implementation manual); *iii.* variation of delivery from
593 what the implementation manual prescribed was because of factors inherent in
594 the design of the CBC-MDV strategies, implementers' understanding and
595 appreciation of the CBC-MDV components and moderating effects of contextual
596 (sociocultural, economic, political and environmental) elements such as
597 elections, mass cattle vaccination campaigns, cattle auction days, funerals,
598 puberty rites celebrations and school cycles; *iv.* all continuous delivery
599 strategies of CBC-MDV sustained vaccination coverage above the critical
600 threshold (approximately 40%), whilst the pulse (once annual) strategy failed to
601 achieve the required $\geq 70\%$ vaccination coverage; and *v.* because of the variation
602 to protocols a number of CBC-MDV components needed optimization prior to
603 replication in the planned full-scale trial.

604 The absence of community involvement in the design stage of CBC-MDV and
605 weak community sensitization at roll out may explain why some village leaders
606 perceived the project as an avenue for making money, questioned the identity
607 of OHCS or didn't fully corporate. More effective community entry processes
608 could have enhanced participation, strengthened collaborations between
609 implementers and community leaders in mobilizing towards vaccination
610 campaigns and increase community support and contributions to
611 implementation [24-28]. Globally, community participation in intervention

612 delivery has evolved from communities as passive recipients, through
613 communities as active participants in delivery to communities as co-designers
614 of interventions [16,25]. The performance of the community-based personnel in
615 the delivery of CBC-MDV components and outcomes of community-led
616 deliveries of interventions elsewhere show that communities can implement
617 intervention such as dog vaccination campaigns with effective engagement and
618 if supplied with logistics [25,29].

619 Implementation of CBC-MDV components that relate to managing vaccination
620 logistics, organizing clinics and information recording were carried out with
621 high fidelity. On the other hand, components aimed at ensuring vaccination
622 clinics proceeded smoothly such as community engagement and sensitization,
623 supervision and monitoring of campaigns, separation of registration and
624 inoculation points to minimize dog aggression were mostly omitted or
625 implemented with low fidelity. Certain components such as finding dogs that
626 missed previous rounds, vaccinators giving their telephone numbers out to dog
627 owners at centers and muzzling of potentially aggressive dogs appeared
628 practically challenging to implement. For instance, some implementers
629 expressed fear about muzzling a dog, others indicated the muzzles were too
630 small or could tear in the process. As documented by other process evaluation
631 studies, implementers not having ample time to assimilate the value of each
632 intervention component, to schedule activities, not feeling competent enough
633 to deliver certain components or having unusable equipment resulted in low
634 fidelity [30,31].

635 The marked decline in the number of vaccination days with each round of
636 vaccination may be an indication of implementation fatigue. RCs serve large
637 populations (3-4 villages / ward on average) providing many different extension
638 services such as dipping of large herds of domestic animals, meat inspection at
639 several different locations, animal levy collection at cattle auctions and other
640 routine duties. It is likely that conducting four rounds of dog vaccination
641 campaigns was a substantial additional work burden. It is also possible that the

642 RCs did not consider the *continuous* component of CBC-MDV as critical, and
643 rather assumed that they had vaccinated sufficient dogs in Round 1 without
644 consideration of arrival of new dogs and puppies in villages. This would be
645 consistent with other studies that found staff 'burn out' as a barrier to
646 implementing community-based interventions as intended [32,33].

647 Variation in work inputs by Strategy teams were explained primarily by the
648 nature of the specific approaches and offer insights into variation in the
649 coverage by each strategy. Strategy 1 required a larger effort occurring over a
650 shorter period of time for the implementers. However, because the vaccination
651 activity of Strategy 1 occurs at a central point of the village, for many owners
652 this Strategy likely posed a challenge of access as they will be required to travel
653 further to reach the central point where the clinic was hosted. Living far from
654 the point of the clinic is commonly cited as a reason for nonparticipation in
655 other studies [34–37]. In comparison, Strategy 2, being hosted at the subvillage
656 level, comes with a relatively lighter workload on each vaccination day for the
657 RC, but, with multiple subvillages for every village, requiring multiple days to
658 complete the campaign (reaching 35 consecutive days). However, subvillage
659 level clinics are easier for the owners to attend. It is noteworthy that, when
660 given the discretion to choose, all Strategy 3 teams adopted the subvillage
661 (Strategy 2) approach even though they reported it requires more time. This
662 suggests that empowering implementers with the ability to choose their own
663 Strategy fostered a stronger sense of ownership and desire to do what it takes
664 to achieve more. This notion is supported in previous research where social
665 motivation has been reported to enhance community participation in
666 community level development activities [38]. The discretion also may have
667 allowed Strategy 3 teams to be more flexible in their schedules around personal
668 and local events.

669 Strategy 3 teams also recorded higher number of times and hours advertised
670 per village and number of vaccination days per village, and possibly explain
671 why the annual average vaccination coverage achieved by Strategy 3 was

672 marginally higher (Lugelo et al., preprint). However, the discretion may have
673 caused strategy 3 team to relax after the first round of clinics, hence they
674 account for 3 out of the 7 missed rounds by all strategies and recording a lower
675 coverage at month 11. Given the differences in the prescribed activities, it
676 seems logical that Strategy 1 teams would need to work harder during
677 subsequent rounds to attain similar outputs as strategies 2 and 3.

678 Including communities in evaluating outcomes of CBC-MDV is likely to foster
679 ownership and sustained efforts at delivering components. Community
680 participation in evaluating local interventions has been gaining traction and, for
681 example, was a key component of the community-directed treatment with
682 ivermectin (CDTI) model introduced by the African Programme for
683 Onchocerciasis Control [16,25]. In the CDTI model, a 3-member committee
684 selected by each village carried out community self-monitoring of mass
685 distribution of ivermectin, thereby checking the performance of distributors
686 and compliance of community members. In the process, challenges were
687 identified and resolved with participation of community leaders. Lessons and
688 strategies such as those outlined above and those generated from this study
689 could be incorporated into CBC-MDV to ensure its successful replication.

690 Several local environmental, economic and sociocultural events affected
691 feasibility of delivering CBC-MDV components. Structural community
692 participation in initializing and implementing the intervention would clearly be
693 valuable in identifying these events and issues, and replication of CBC-MDV
694 across wider contexts would benefit from tailoring campaign schedules to local
695 environmental and social events [36,37,39,40] or calendars.

696 Process evaluation has been carried out for a wide range of complex
697 interventions, but this study represents the first process evaluation of mass dog
698 vaccination campaigns to our knowledge. The study revealed implementation
699 bottlenecks in their delivery, understanding of the impact pathways
700 underpinning these bottlenecks and also opportunities for addressing them.

701 These insights could be of value when designing national rabies elimination
702 strategies.

703 The study is likely slightly affected by recall bias where data collection
704 processes depended to a large extent on implementer reports. However, use of
705 mixed methods, including non-participant observations and following the
706 intervention prospectively through the design and implementation phases
707 provided first hand observations.

708 **Conclusions**

709 The development of CBC-MDV incorporated extensive stakeholder views and
710 hence fostered strong stakeholder acceptance so far. Including community level
711 decision makers/ leaders would be likely to have fostered ownership among
712 communities as well. It is possible to delivery CBC-MDV and achieve good
713 vaccination coverage although intervention-, implementer- and context-related
714 factors influenced delivery CBC-MDV components and effectiveness of the
715 strategies at reaching more dogs. These factors altogether occasioned
716 variations in implementation of about half of CBC-MDV components, resulting
717 in differences in choices and outputs made by strategy teams. The CBC-MDV
718 strategies sustained vaccination coverage well above the critical threshold
719 (approximately 40%) throughout the year whilst the pulse Strategy failed to
720 achieve the required vaccination coverage of $\geq 70\%$. The findings are being used
721 to optimize CBC-MDV components for dissemination in an RCT across the entire
722 Mara region. Overall, we conclude that improved supervision and monitoring, as
723 well as community participation in design, planning and execution of MDV
724 could result in higher fidelity, dose and reach of CBC-MDV strategies in a more
725 sustainable manner.

726

727 **Competing interests**

728 All authors declared that they have no competing interests.

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746 **Author contributions**

747 **Conceptualization:** Christian Tetteh Duamor, Katie Hampson, Felix Lankester,
748 Sally Wyke, Sarah Cleaveland.

749 **Data collection:** Christian Tetteh Duamor, Ahmed Lugelo.

750 **Formal analysis:** Christian Tetteh Duamor, Ahmed Lugelo.

751 **Funding acquisition:** Katie Hampson, Felix Lankester, Sally Wyke, Sarah
752 Cleaveland.

753 **Investigation:** Christian Tetteh Duamor.

754 **Methodology:** Christian Tetteh Duamor, Sally Wyke.

755 **Project administration:** Christian Tetteh Duamor, Ahmed Lugelo, Felix
756 Lankester.

757 **Supervision:** Katie Hampson, Felix Lankester, Katharina Kreppel, Emmanuel
758 Mpolya, Sally Wyke, Sarah Cleaveland.

759 **Validation:** Christian Tetteh Duamor, Katie Hampson, Felix Lankester, Katharina
760 Kreppel, Sally Wyke, Sarah Cleaveland.

761 **Visualization:** Christian Tetteh Duamor.

762 **Writing – original draft:** Christian Tetteh Duamor.

763 **Writing – review & editing:** Christian Tetteh Duamor, Katie Hampson, Felix
764 Lankester, Katharina Kreppel, Emmanuel Mpolya, Sally Wyke, Sarah Cleaveland.

765

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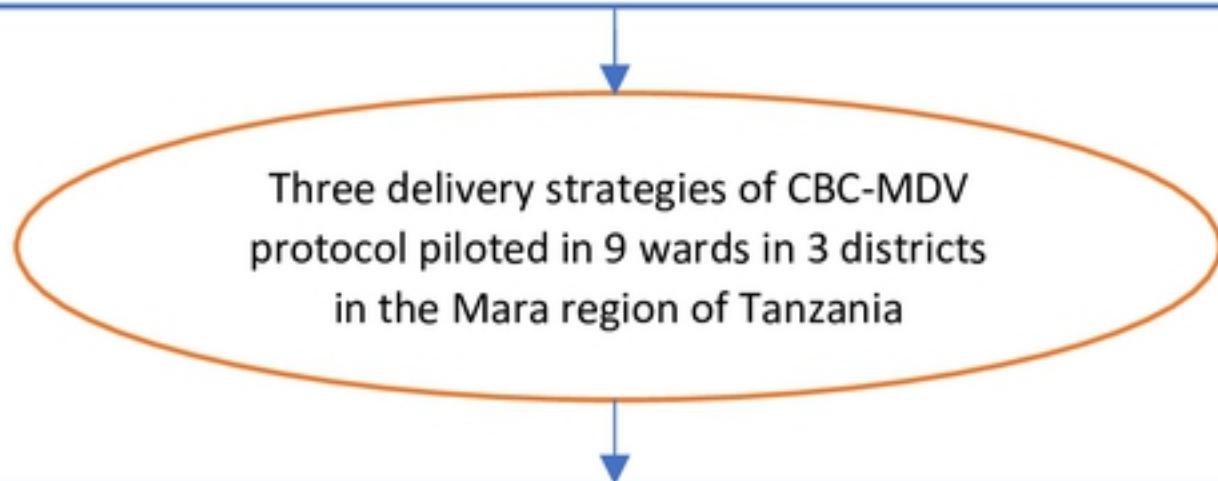
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PHASE 1 – Development of intervention(s)

- a) Initial development of components of CBC-MDV
- b) Five engagement workshops with stakeholders to adapt CBC-MDV and three delivery strategies of CBC-MDV developed for piloting, accompanied with detailed implementation manual



Feasibility assessed using mixed methods: observation and reviews/ audits of development, implementation processes, advertising and delivery of CBC-MDV

Data analyzed to assess: fidelity and reasons for variation; efforts by strategy delivery teams; potential effectiveness in achieving vaccination coverage and aspects of CBC-MDV needing optimization

Fig 1. Development and optimization process for Community-based Continuous Mass Dog Vaccination (CBC-MDV) prior to full-scale evaluation
Figure

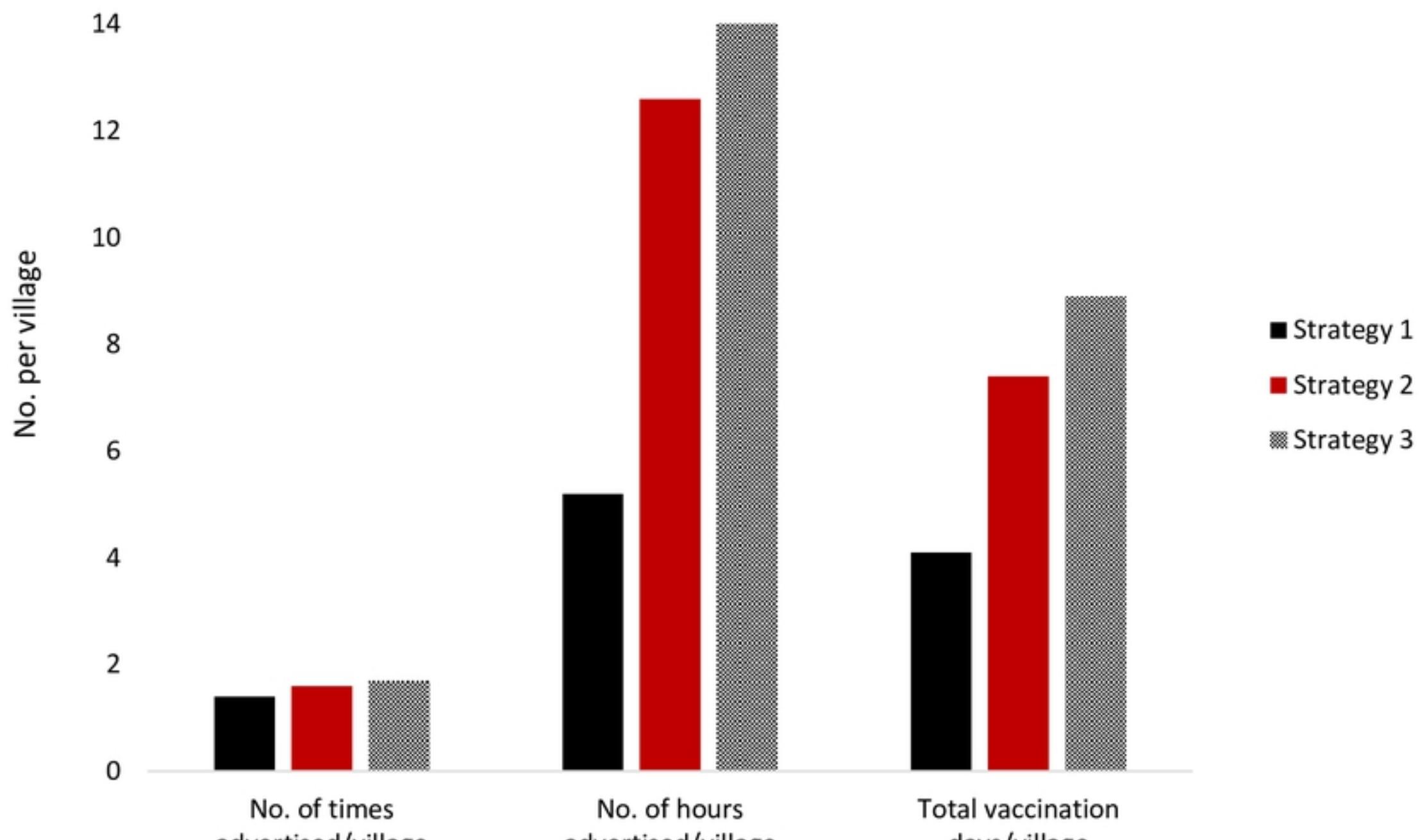


Fig 3. Effort at advertising and delivering vaccination campaigns by strategy
(totals for all three team per strategy)

Figure

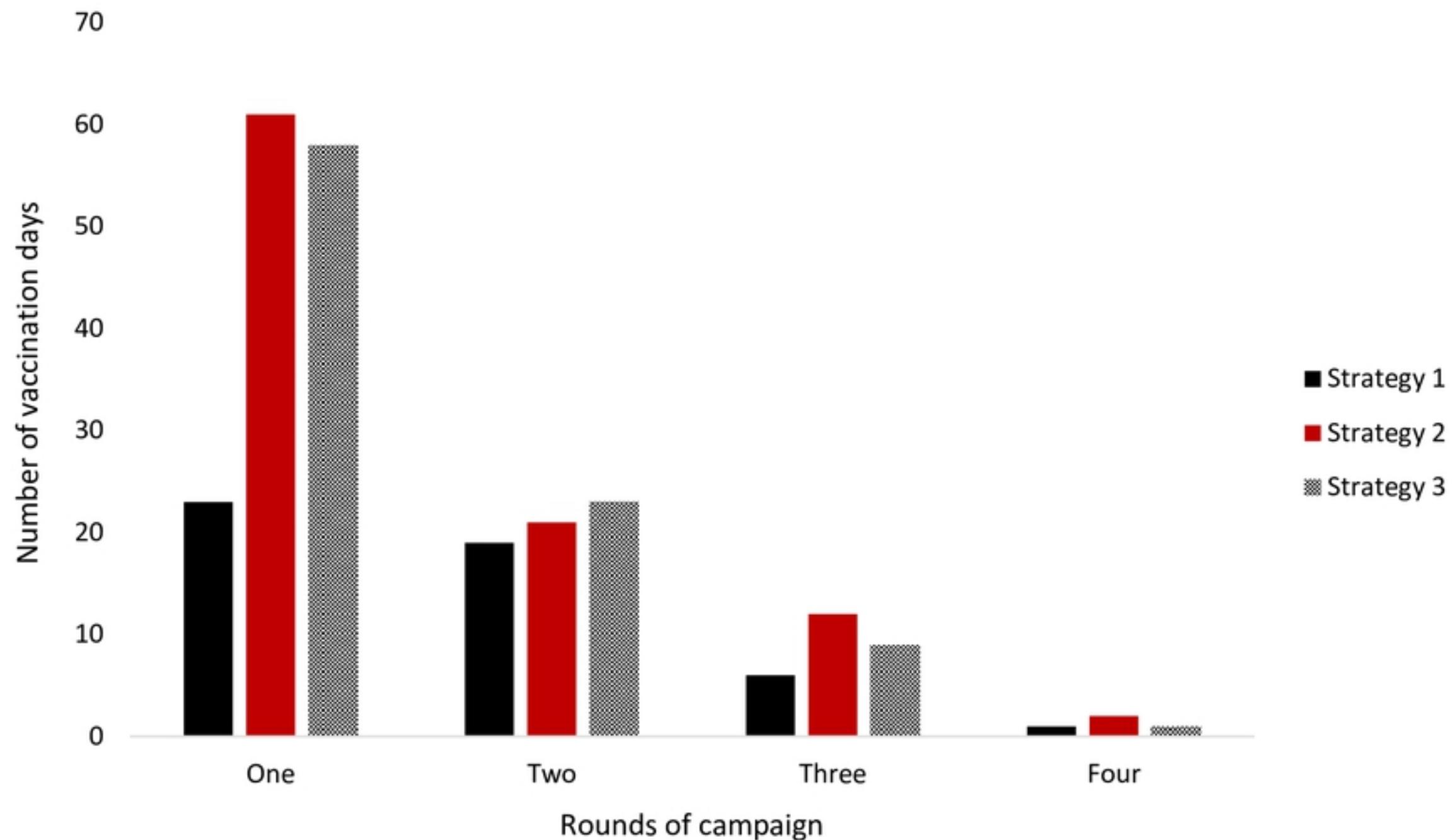


Fig 4. Number of days implementers conducted vaccination activities during each round (totals for all three team per strategy)
Figure

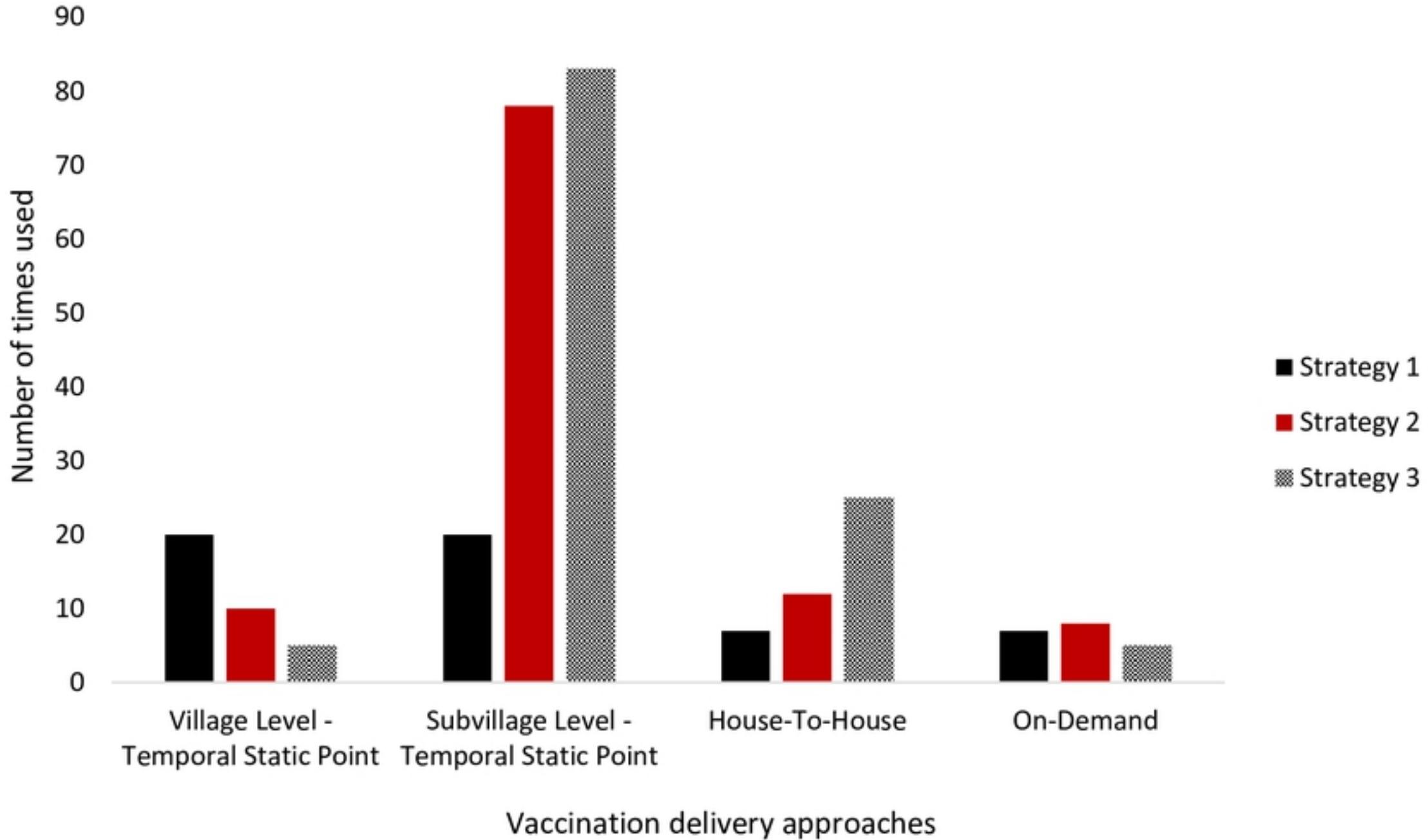
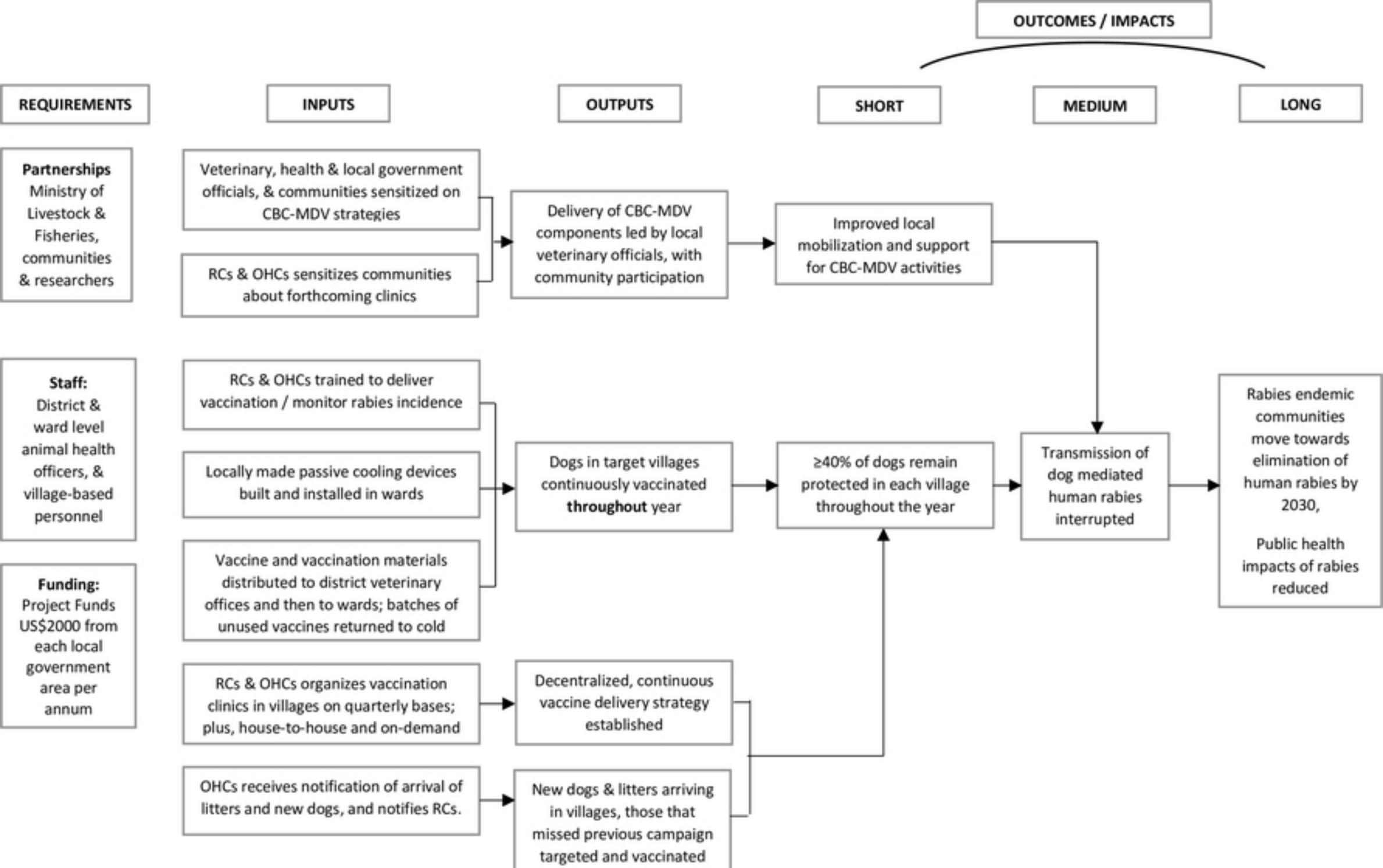


Fig 5. Use of vaccination delivery approaches by strategy team (totals for all three team per strategy)
Figure



Figure