1 **Effectiveness of a mobile antiretroviral pharmacy and HIV care intervention on the**
2 **continuum of HIV care in rural Uganda**
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Abstract

Introduction: Adherence to antiretroviral therapy (ART) is critical in order to achieve viral suppression, one of three UNAIDS targets set for achievement before 2020. One of the main barriers to adherence is the long distance between patient residences and healthcare facilities. We designed an intervention, Mobile Antiretroviral Therapy and HIV care (MAP-HC) in rural southwestern Uganda aimed to reduce travel distance and hypothesized that MAP-HC would improve ART adherence and rates of viral load suppression.

Methods The study was conducted at two sites, Kitagata and Itojo Hospitals, and these are public health facilities located in rural southwestern Uganda. Patients who lived >5km from the hospital were provided the option to participate. For each hospital, we identified 4 health centres in the catchment area to serve as site for the mobile pharmacy. Each site was visited once a month to provide ART refills, adherence counseling and treatment of other illnesses. We measured patient waiting time, adherence and viral load suppression before and after the intervention.

Results: We conducted baseline assessment among 292 patients at the two hospitals. The mean waiting time at Kitagata Hospital changed from 4.48 hours before the intervention but increased to 4.76 hours after the intervention (p=0.13). The proportion of patients who missed an ART dose in the last 30 days dropped from 20% at baseline to 8.5% at 12 months after the intervention (p=0.009). The proportion of patients with detectable viral load from 19.9% to 7.4% after the intervention (p=0.001).

Conclusions: Our study has showed that a mobile pharmacy intervention in rural Uganda is feasible and resulted in improvement in adherence and viral load suppression. Although it did not reduce patient waiting time at the clinic, we recommend a scale-up of this intervention in rural areas where patients face challenges of transportation to the clinic.

Introduction

Adherence to antiretroviral therapy (ART) is critical in order to achieve viral suppression [1] or the third 90, one of three UNAIDS targets set for achievement before 2020. In order to achieve viral load suppression, patients should take at least 95% of their medications [2-4]. Although adherence levels in sub Saharan Africa are on average higher than estimates in North America [5], patients in countries such as Uganda face structural barriers to achieve high level adherence.

One of the main barriers to adherence is the long distance between one's place of residence and healthcare facilities. [6, 7] Specifically, patients seeking HIV care and treatment travel longer distances compared to their HIV negative counterparts. [8] Several studies have examined geographical factors as barriers and systematic analysis has shown that travel distance is a barrier across the continuum of HIV care from testing to treatment and retention in care [9]. Patients narrate how they struggle to raise the monthly transportation fee to the clinics to collect their medicines [10, 11]. Some patients devised innovative ways such as pooling resources in order to secure their monthly pills, with some patients making two-day arduous journeys to an HIV clinic. Long waiting times because clinics are crowded [12] cause patients to view their monthly visits as burdensome, competing with time needed to tend to gardens and other income generating activities.

The World Health Organization now recommends the testing and initiation of ART for all persons infected with HIV regardless of CD4 count or HIV stage [13], referred to the "test and treat approach." Uganda, along with other HIV-affected countries across the globe, is now implementing this strategy. The expected result is that HIV treatment clinics will experience rising numbers of patients needing treatment, worsening crowding and waiting times at these facilities. Such unintended effects of ART expansion are barriers to maintaining HIV care continuation, leading to poor retention and or non-adherence.

There is now a need for interventions that not only reduce distance to HIV treatment clinics, but also have potential to decongest them. These may result in better adherence to clinic visits, medications and improve viral load suppression. There is very limited interventions of this nature that have been tested in resource-limited settings. The few experiences with decentralized and community-based models in Africa have been successful [14, 15] including more recently from Nigeria where a community-based model increased adherence and retention in care [16]. More examples of such interventions are needed in this era of "test and treat."

With funding from the Doris Duke Charitable Foundation's Operations Research on AIDS Care and Treatment in Africa program, between 2009 and 2013, we developed and operated an intervention, Mobile Antiretroviral Therapy and HIV care (MAP-HC) in rural southwestern Uganda. Our intervention aimed to reduce travel distance and patient cost associated with travel to collect medicines and, indirectly, reduce wait time and crowding at the HIV clinic. We also hypothesized that MAP-HC would improve ART

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114 adherence and rates of viral load suppression. We report the results of our program
115 evaluation.
116
117 **Methodology**
118
119 *Study setting*
120 The study was conducted at two sites, Kitagata and Itojo Hospitals, and these are public
121 health facilities located in rural southwestern Uganda. They were selected because they
122 were among the first district-level ART clinics serving a rural population. Kitagata
123 Hospital is located in Sheema District, Uganda, which is predominantly a rural
124 population of subsistence farmers. The area has a difficult terrain and transportation
125 around the district is mainly by motorcycle taxis or *boda bodas.* Itojo Hospital is located
126 just south in Ntungamo District with mixed subsistence farming and livestock as the
127 major sources of livelihood. At both hospitals, majority of patients travel several hours to
128 the hospital to receive their monthly ART refills. By the beginning of 2009, the
129 cumulative number of patients receiving ART was over 520 for Kitagata Hospital and
130 632 for Itojo Hospital.
131
132 *Development and Implementation of MAP-HC*
133
134 The implementation of the MAP-HC was done in three phases, the Preparation,
135 Identification, and Implementation phases. We engaged health workers and patients at
136 both ART clinics to ensure the process was participatory, but began the development of
137 MAP-HC at Kitagata Hospital where we had already established working relationships
138 with healthcare workers and hospital administration. Once MAP-HC was developed and
139 operational at Kitagata, we repeated our implementation steps at Itojo Hospital.
140
141 In the *preparation phase*, which began in March 2009 at Kitagata Hospital and October
142 2009 at Itojo Hospital, our team began to sensitize ART clients about the intervention.
143 We conducted a baseline survey at the hospital to measure patient demographics, place of
144 residence, distance travelled to the clinic, pre-intervention adherence to ART and viral
145 load suppression. We also defined the catchment area of the clinic and mapped patients'
146 places of residence by parish and village. We used this information to identify the
147 clusters or zones where majority of patients resided. The catchment area of residence was
148 then divided into 4 zones based on clustering of the patient population. Within each zone,
149 we identified a county- or sub-county- (Health Centre III) or parish-level (Health Centre
150 II) healthcare facilities, which was closer in distance than the district-level hospital
151 (Health Centre IV) to the majority of patients in that zone, to serve as a distribution point
152 to dispense antiretroviral therapy.
153
154 In the *identification phase*, clinicians at the hospital interacted with patients and informed
155 them about our proposed intervention. At Kitagata Hospital, where we first began to
156 work, patients were asked to choose whether they would wish to receive their refills at
157 our proposed ART dispensing sites or continue receiving their medications at the
158 hospital. Patients were enthusiastic for our proposed intervention, but expressed a desire
159 for healthcare services in addition to ART refills. We then worked with hospital

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160 administration to determine the feasibility and logistics of adding healthcare delivery
161 elements to our intervention. Ultimately, we revised our intervention from being ART
162 dispensing alone (MAP) to one that also provides basic healthcare services (MAP-HC),
163 which is described further below.
164
165 Patients were offered MAP-HC services if they had been taking ART for at least 6
166 months, were considered stable on treatment by the physician, and lived further than five
167 kilometers from the district hospital, a distance determined by the Ministry of Health as
168 being excessive when traveling for one's healthcare. [17] In making their decision,
169 patients were asked to consider other issues such as privacy and whether the MAP-HC
170 site would be convenient to them.
171
172 In the *implementation phase*, we reviewed the appointment dates for all patients that
173 consented to participate in MAP-HC and synchronized appointment and ART refill dates
174 by zone. We obtained buy in from the district-level health service team, local government
175 and the healthcare facility where MAP-HC would be stationed. HIV care providers
176 selected a non-HIV clinic day during the week to operate MAP-HC and chose a day that
177 was also typically lighter at the hospital to allow the team be away.
178
179 *MAP-HC intervention*
180
181 The MAP-HC team consisted of five members: two nurses trained in dispensing ART
182 and monitoring adverse events, a trained medication dispenser, an ART adherence
183 counselor, a driver. The mobile team provided ART refills, adherence counseling, and
184 treatment of concomitant illnesses such as malaria, respiratory tract infections and other
185 conditions that did not require an admission. The physician who ordinarily runs the HIV
186 clinic was required to remain back at the hospital to serve other non-HIV care seeking
187 patients.
188 The MAP-HC team used the hospital's own vehicle and the research project investigators
189 provided reimbursement for fuel expenses and field day allowance at government
190 approved rates for health care staff. Patients received ART and basic care at MAP-HC
191 sites for three consecutive visits, but were required to return to the district hospital for the
192 fourth visit in order to be seen by the physician.
193
194 Data collection
195 We compared measurements before and after the MAP. First, we conducted a baseline
196 assessment at the two district hospitals to measure baseline features such as waiting time,
197 adherence and viral load. Next, we implemented the project, and then collected post
198 intervention measurements. We measured waiting time at the hospitals and sampled
199 patients for viral load and adherence measurement at the MAP sites. We repeated
200 measurements of patient waiting time, adherence and viral load 12 months after the MAP
201 was implemented.
202
203 Study outcomes
204 The primary outcome for this evaluation was viral load suppression. The secondary
205 outcomes were attendance at MAP sites, adherence to antiretroviral medication, and

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206   waiting time at the hospital. We hypothesized that adherence and viral load suppression
207   would improve among patients attending MAP and that MAP would decongest the ART
208   clinic at the hospital resulting in reduced waiting time.
209
210   To measure patient waiting time at the hospital, we positioned 4 research assistants at the
211   ART Clinic following the order of flow at the clinic. The research assistants were
212   positioned at the entrance/registration area, adherence officer room, clinician consultation
213   rooms, and dispensary. Patients followed this natural order and collected their
214   medications at the dispensary before departure. On arrival at the entrance of the ART
215   clinic, the research assistant wrote the arrival time on a small script of paper, which they
216   handed to the patient. The research assistant at the next stationed wrote the time when the
217   patient completed the visit at each station, and the final research assistant at the
218   dispensary wrote the time and collected the script from the patient before their departure.
219   The typical layout for the clinic at Kitagata Hospital is shown in Figure 1 below.
220
221   --------------------------- Insert Figure 1 here --
222
223   The circled numbers in Figure 1 represent the positions where the research assistants
224   were positioned to collect the waiting time data.
225
226   Adherence was measured using self-report. Blood samples were drawn from the patients
227   and sent to a regional testing laboratory in Mbarara for viral load testing. VL were
228   measured using Amplicor system® from Roche. Results were relayed back to the health
229   care providers 4 weeks after sample collection.
230
231   Sampling, sample size and data analysis
232   We used consecutive sampling to collect baseline data. We aimed to interview 300 study
233   participants at baseline to determine the proportion of participants that were living
234   outside of 5km from the hospital. At the follow up for evaluation, we did not calculate
235   sample size. The number was determined by the resources available to conduct viral load
236   testing, as this was the primary outcome for the evaluation.
237   We summarized the baseline characteristics using 5km as the cut off. This is because the
238   Ministry of Health recommends that persons should reside within a radius of 5km from a
239   health facility [18]. We compared continuous baseline variables using non-parametric
240   tests and categorical outcomes using Chi square tests. We compared the pre- and post-
241   intervention proportions of patients who were adherence or had viral load suppression
242   using Chi square test and a t-test to compare waiting time. Paired tests were not used
243   since the sampling process did not necessarily include the same patients before and after
244   the intervention.
245
246   Human subjects' issues
247   The proposal was approved by the Research Ethics Committee at Mbarara University of
248   Science and Technology and by the Uganda National Council of Science and
249   Technology. Study procedures were explained to the clients at the HIV clinic. Individual
250   written informed consent was obtained and all study participants signed a consent form
251   once they understood study procedures and accepted to participate. Participants were

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252 made aware they were free to decline participation in the MAP but continue to receive
253 their medications at the hospital. Confidentiality was maintained by using number
254 identifications for the patients on study materials and questionnaires.
255

256 **Results**
257 We conducted baseline assessment interviews among 292 patients at both Kitagata and
258 Itojo Hospital. Almost two thirds were women, with a median age of 37 years. Majority
259 lived more than 5km away from the hospital and the results are shown in Table 1. As
260 expected, those who lived nearer were more likely to walk compared to those who lived
261 further. Participants who lived further than 5 km also had significantly lowed median
262 monthly incomes compared to those who lived near the health facility (p=0.021). Those
263 who lived further than 5km also spent more time and money in travel to the hospital.
264

265 ------------------Insert Table 1 here ---
266

267 Table 1: Baseline characteristics of rural patients attending ART clinic at Kitagata and
268 Itojo Hospital, south western Uganda, 2009
269

Characteristic	Overall n=292	Less than 5km n=79	More than 5km n=213	p value
Gender				
Male	104 (36%)	39 (49%)	65 (31%)	0.003
Female	188 (64%)	40 (51%)	148 (69%)	
Age (median, IQR)	37 (32, 43)	36 (32, 42)	38 (33, 44)	0.041
Has job income	183 (63%)	54 (68%)	129 (61%)	0.221
Monthly income USD (median, IQR)	15 (10, 50)	25 (12.5, 62)	15 (10, 45)	0.021
Transport to clinic:				
Walking	91 (31%)	44 (56%)	47 (22%)	
Rode a bicycle	20 (7%)	6 (8%)	14 (7%)	<0.001
Took a bodaboda	88 (30%)	24 (30%)	64 (30%)	
Took a minibus	93 (32%)	5 (6%)	88 (41%)	
Travel time to clinic (minutes median, IQR)	90 (60, 140)	60 (30, 90)	120 (100, 150)	<0.001
Travel cost USD (median, IQR)	2.5 (1.5, 3.0)	1.5 (1.0, 2.0)	3.0 (2.0, 4.0)	<0.001

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273
274 Participants had comparable 3 and 30 day self-report adherence regardless of whether
275 they lived within or outside 5km from the hospital (p=0.577) and these results are shown
276 in Table 2 below. However, participants who lived further than 5km were more likely to
277 report having ever missed a pill compared to those who lived near (p=0.013). The

7

278 participants that lived further than 5km were also more likely to report distance as a
279 barrier to their travel to the clinic.
280
281 -------------------------------Insert Table 2 here --
282 Table 2: Characteristics related to antiretroviral treatment among rural patients at
283 Kitagata Hospital, southwestern Uganda

Characteristic	Overall n=292	Less than 5km n=79	More than 5km n=213	p value
Months on ART (median, IQR)	25 (14, 36)	29 (14, 39)	24 (14, 36)	0.57
Missed appointment	47 (16%)	9 (11%)	38 (18%)	0.134
Distance affects coming to clinic:				
All of the time	64 (22%)	5 (6%)	59 (28%)	
Most of the time	44 (15%)	6 (8%)	38 (18%)	<0.001
Rarely	112 (38%)	29 (37%)	83 (39%)	
Never	72 (25%)	39 (49%)	33 (15%)	
Missed ART dose:				
In last 3 days	4 (1%)	0 (0%)	4 (2%)	0.577
In last 30 days	57 (20%)	16 (20%)	41 (19%)	0.847
Missed an entire day of ART in last 30 days	35 (12%)	8 (10%)	27 (13%)	0.551
Ever missed ART dose	123 (42%)	24 (30%)	99 (45%)	0.013

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287
288 Post intervention results
289 Figure 2 shows a bar graph with attendance at the MAP, with numbers of participants
290 expected at each month visit versus those who actually turned up. The graph shows that
291 consistently, the attendance was nearly 100% and in some instances, exceeded the
292 expected numbers.
293
294 The mean waiting time at the hospital was 4.48 hours before the intervention and
295 increased to 4.76 hours after the intervention, however this change was not statistically
296 significant (p=0.13) and these results are shown in Table 3. The proportion of patients
297 who missed an ART dose in the last 30 days dropped from 20% at baseline to 8.5% at 12
298 months after the intervention and this drop was statistically significant (p=0.009).
299 Similarly, the proportion of patients with detectable viral load significantly dropped from
300 19.9% to 7.4% after the intervention (p=0.001).
301
302 ------------------------------Insert Table 3 here --

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303 Table 3: Changes in the treatment outcomes before and after implementation of the
304 Mobile antiretroviral therapy program, southwestern Uganda
305

Characteristic	Before intervention March 2009	After intervention March 2010	p value
Waiting time (in hours) at the main hospital (mean, standard deviation)	4.48 (1.7)	4.76 (1.7)	0.13
Proportion of patients who missed ART dose in the last 30 days	57/292 (19.5%)	9/106 (8.5%)	<0.009
Proportion of patients with detectable viral load	58/292 (19.8%)	9/122 (7.4%)	0.001

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311 **Discussion**
312
313 In this mobile pharmacy intervention for ART in rural western Uganda, there was
314 significant reduction in the proportion of patients who missed an ART dose in the last 30
315 days and a significant decrease in the proportion of patients with detectable viral load.
316 However, the intervention had no impact on the waiting time at the district hospital.
317
318
319 Our intervention targeted participants that lived more than 5km from the hospital and our
320 data indicate this was the right target population. Not only did they take more time to
321 travel to the hospital, they also paid more to reach the facility and reported more
322 difficulty trying to reach it. Yet, these participants who lived further away were more
323 likely to earn less per month compared to those who lived nearer, placing more burden on
324 their meager resources to meet their transportation fee to the hospital per month. Those
325 who lived further than 5km were more likely to reside in more rural remote
326 establishments. Although majority of the districts are predominantly rural, the hospital
327 was located in a semi-urban setting. This more rural population needed the intervention.
328
329 The hospital ART clinics were overcrowded pre-intervention. We hypothesized that
330 MAP would decongest them by taking away a large proportion who needed refills.
331 Despite the intervention, there was no significant decrease in waiting time at the hospital.
332 On closer scrutiny, the lack of decrease in waiting time came as no surprise because the
333 overall ART clinic population for instance at Kitagata grew from 500 patients to almost
334 1000 patients within a year following the implementation of the MAP. The potential
335 impact of the intervention was washed away by the exponential growth in the clinic size.
336 This is an important challenge to anticipate as clinic populations are expected to grow
337 even more as Uganda is now implementing the 'test and treat' approach to achieve 90-90-
338 90 UNAIDS targets. As efforts to identify and treat more people grow, the burden on

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339   health centers grows, and without other approaches to providing treatment, the increased
340   burden could eventually stall or reverse gains made.
341
342   Our results agree with other studies in sub Saharan Africa and elsewhere where results
343   show that programs to get patients to receive treatment at lower level health facilities are
344   successful [19] or even have better treatment outcomes compared to those at higher level
345   facilities [20, 21]. Our study did not perform a direct comparison between higher and
346   lower level facilities but instead compared a pre-intervention (district hospital) versus a
347   post-intervention (lower level facility) outcome outcomes. In our evaluation, the better
348   outcomes following the MAP intervention may be attributed to the elimination of
349   distance, a structural barrier to adherence. The results agree with our hypothesis that
350   removal of distance barrier would result in improvement in adherence and viral load
351   suppression. In the United States and other resource rich countries, a related kind of
352   intervention designed to improve adherence and involved the referral of patients who
353   were stable on ART to HIV-focused community pharmacies [22, 23] also showed
354   significant success.
355
356   Our results and others elsewhere, suggest that ART programs should consider scale up of
357   ART to proximal health facilities or community pharmacies in rural areas and where
358   patients have to travel long distances and or difficult terrain such as that here in rural
359   western Uganda where our study was based. However, there may be concerns about the
360   long term sustainability of this kind of program, especially where additional financial
361   support is required as was the case in our program. To ensure sustainability, the mobile
362   pharmacies should embrace the concept of decentralization of HIV services and based on
363   a recent review [24] should be considered for integration with other well-known
364   successful interventions such as short messaging services, adherence clubs and peer
365   counseling, or even merge with other outreach programs such as vaccinations.
366
367   Our evaluation has important strengths. First, the evaluation was conducted in a rural
368   population. This is important because majority of populations in sub Saharan Africa and
369   Uganda live in rural areas but also because patients in rural areas are more likely to
370   experience distance as a barrier to health care seeking. Second, we measured several
371   markers of impact of the MAP including crowding, adherence and viral load suppression.
372   Although self-reported adherence may be influenced by social desirability bias, viral load
373   suppression is insulated from subjective reporting.
374
375   Our study has some limitations. In our sampling, some of the patients involved in the pre-
376   intervention assessment were not necessarily involved in the post intervention VL and
377   adherence measurement. In the post-intervention assessment, we randomly sampled MAP
378   patients for viral load measurement, regardless of whether they had been involved in the
379   baseline assessment or not. Although this sampling approach partly engages components
380   of convenience in the sampling, it is unlikely to have influenced the results because all
381   patients receiving care at a MAP site lived more than 5 km from the hospital and reported
382   distance as a barrier to adherence. The sampling approach is consistent with other
383   pseudo-experimental study designs that involve a pre- and post-evaluation comparison.

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384   Lastly, we did not conduct a cost-effectiveness analysis for this intervention and future
385   evaluations should incorporate data collection to support this analysis.
386
387
388   In conclusion, our study has showed that a mobile pharmacy intervention in rural Uganda
389   is feasible and resulted in improvement in adherence and viral load suppression.
390   Although it did not reduce patient waiting time at the clinic, we recommend a scale-up of
391   this intervention in rural areas where patients face challenges of transportation to the
392   clinic.
393
394
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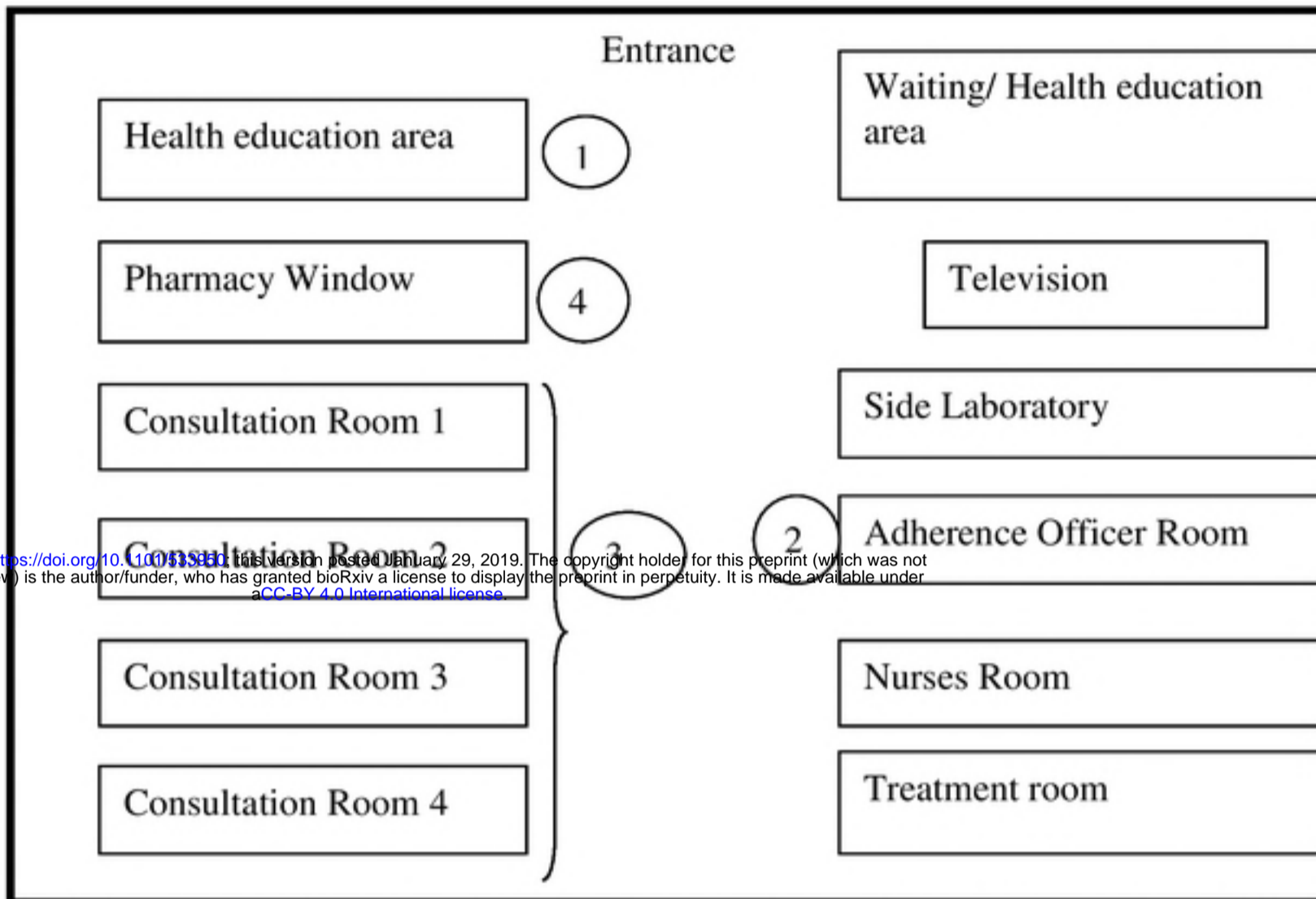402   (2007012) from the Doris Duke Charitable Foundation.
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Figure 1: Lay out for the ART clinic at Kitagata Hospital and location of research assistants to measure patient waiting time

The circled numbers indicate the position of the research assistants who were tracking patient waiting time.

Figure 1

Figure 2: Number of patients attending at the Mobile Antiretroviral therapy program, southwestern Uganda, January – December 2010

Figure 2