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4 **Economic costs and health-related quality of life outcomes of HIV**  
5 **treatment following self- and facility-based HIV testing in a cluster**  
6 **randomised trial.**

7

8 Hendramoorthy Maheswaran<sup>1,2</sup>; Stavros Petrou<sup>1</sup>; Peter MacPherson<sup>3,4</sup>; Felistas  
9 Kumwenda<sup>2</sup>; David G Lalloo<sup>2,4</sup>; Elizabeth L. Corbett<sup>2,5</sup>; Aileen Clarke<sup>1</sup>;

10

- 11 1. Division of Health Sciences, University of Warwick Medical School, Coventry, UK  
12 2. Malawi-Liverpool-Wellcome Trust Clinical Research Programme, Blantyre, Malawi  
13 3. Department of Public Health and Policy, University of Liverpool, UK  
14 4. Department of Clinical Sciences, Liverpool School of Tropical Medicine, UK  
15 5. London School of Hygiene and Tropical Medicine, London, UK

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17 **Address for correspondence and request for reprints:**

18 Hendramoorthy Maheswaran  
19 Division of Health Sciences  
20 University of Warwick Medical School  
21 Gibbet Hill Campus  
22 Coventry CV4 7AL (UK)  
23 Tel: + 44 (0) 2476150220  
24 Email: H.Maheswaran@warwick.ac.uk

25

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47

48 **Abstract:**

49 **Background:** HIV self-testing (HIVST) is recommended in Africa, but little is known  
50 about how this approach influences economic outcomes following subsequent  
51 antiretroviral treatment (ART) compared to facility-based HIV testing and counselling  
52 (HTC).

53

54 **Methods:** HIV-positive participants attending HIV clinics, diagnosed by HIVST or  
55 facility-based HTC as part of a community cluster-randomised trial  
56 (ISRCTN02004005), were followed from initial assessment for ART until one-year  
57 postinitiation. Healthcare resource use was measured, and costing studies estimated  
58 total health provider costs. Participants were interviewed to establish direct non-  
59 medical and indirect costs over the first-year of ART. Costs were adjusted to 2014  
60 US\$ and INT\$. Health-related quality of life was measured using EuroQol EQ-5D.  
61 Multivariable analyses estimated predictors of economic outcomes.

62

63 **Results:** Of 325 participants attending HIV clinics for assessment for ART, 265 were  
64 identified through facility-based HTC, and 60 through HIVST; 168/265 (69.2%) and  
65 36/60 (60.0%), respectively, initiated ART. Mean total health provider assessment  
66 costs for ART initiation were US\$22.79 (SE:0.56) and US\$19.92 (SE:0.77) for  
67 facilitybased HTC and HIVST participants, respectively, and was US\$2.87  
68 (bootstrap95%CI:US\$1.01,US\$4.73) lower for the HIVST group. Mean health  
69 provider costs for first-year of ART were US\$168.65 (SE:2.02) and US\$164.66  
70 (SE:4.21) for facility-based HTC and HIVST participants, respectively, and were  
71 comparable (bootstrap95%CI:-US\$12.38,US\$4.39). EQ-5D utility scores were

72 comparable between the two groups, and one-year after ART initiation had increased  
73 by 0.129 (SE:0.011) and 0.139 (SE:0.027) for facility-based HTC and HIVST  
74 participants, respectively.

75  
76 Conclusions: Once HIV self-testers are linked into HIV services, their economic  
77 outcomes are comparable to those linking to services after facility-based HTC.  
78

79

## 80 **Introduction**

81 There are now over 10 million Africans receiving anti-retroviral treatment (ART), the  
82 majority living in Eastern and Southern Africa.<sup>1</sup> Despite this impressive achievement,  
83 over one half of HIV-positive individuals are still in need of treatment, and over one  
84 million people become infected every year.<sup>1</sup> Meeting HIV elimination targets set by  
85 UNAIDS (“90-90-90”) will require novel approaches and significant investment in  
86 HIV testing and treatment services. HIV self-testing (HIVST), defined as an  
87 individual performing and interpreting their own HIV test,<sup>2</sup> is one potential solution,  
88 and its scale-up in Africa is recommended.<sup>3</sup>

89

90 HIVST offers an opportunity for early engagement of individuals in HIV services.<sup>4,5</sup>  
91 However, there is limited research around the cost implications and health-related  
92 quality of life (HRQoL) outcomes of HIV-positive individuals, identified through  
93 HIVST, after entering HIV care, to inform potential users and providers on the  
94 benefits of HIVST. The cost of providing HIVST is comparable to standard facility-  
95 based HIV testing and counselling (HTC), but the lower yield of positive individuals,  
96 makes it more costly for identifying those who are HIV-positive.<sup>6</sup> In contrast to  
97 HIVST, facility HTC services are more commonly accessed by those with advanced  
98 HIV disease,<sup>4,7</sup> with individuals needing additional medical care to manage  
99 comorbidities.<sup>8,9</sup> Engaging individuals early within HIV care and treatment through

100 HIVST may yield later cost savings. Improvements in HRQoL amongst those  
101 initiating ART after testing HIV-positive through facility HTC services have been  
102 demonstrated;<sup>10</sup> this has yet to be shown for those identified through HIVST.  
103 Accurate and contemporaneous understanding of these economic outcomes will be  
104 essential to inform policy on scale-up.

105

106 We recruited a cohort of adults attending HIV treatment clinics in Blantyre, Malawi,  
107 after they had undergone HIVST or facility-based HTC. Our primary aim was to  
108 compare the economic costs incurred by health providers and patients, and to compare  
109 health-related quality of life outcomes for adults diagnosed through HIVST or  
110 facility-based HTC.

111

## 112 **Methods**

### 113 **Study design and participants**

114 We undertook a prospective cohort study in Blantyre, Malawi, between March 2013  
115 and January 2015. We recruited HIV-positive adults identified through either HIVST  
116 or facility-based HTC who were participants of a cluster-randomised trial  
117 investigating health outcomes of offering HIVST (ISRCTN02004005).<sup>4,5</sup> Ethical  
118 approval was obtained from the College of Medicine Ethics Review Committee,  
119 University of Malawi, and the University of Warwick Biomedical Research Ethics  
120 Committee. All participants provided informed consent.

121

122 The cluster-randomised trial comprised a population of approximately 34,000  
123 residents<sup>4-6</sup> where adult HIV prevalence was approximately 18%.<sup>11</sup> Participants in  
124 control clusters had access to routine facility-based HTC, and those in intervention

125 clusters were offered HIVST through resident community counsellors in addition to  
126 facility-based HTC. Participants who self-tested did not have to disclose their HIV  
127 test result to community counsellors but were offered post-test counselling, advice on  
128 where to seek care and a “self-referral card” for HIV clinics. HIVST was provided in  
129 the intervention clusters for a two-year period, starting in February 2012.

130

131 We recruited participants from three HIV clinics located in the study areas: Queen  
132 Elizabeth Central Hospital (QECH), Ndirande Health Centre and Chilomoni Health  
133 Centre. At the start of this study, these clinics had initiated 19,929, 6,656 and 4,485  
134 individuals onto ART, respectively.<sup>12</sup> Eligible participants were HIV-positive adults  
135 (aged  $\geq 18$  years) attending for first assessment for ART initiation and resident within  
136 trial clusters (verified using global position system-based “Map Book”<sup>13</sup>). Participants  
137 who had not accessed either HIVST or facility-based HTC, or who had been assessed  
138 for ART initiation or started ART at another location, were excluded.

139

140 All care was provided by the routine health system. HIV-positive individuals  
141 underwent CD4 count measurements, tuberculosis (TB) screening, provision of  
142 cotrimoxazole, and ART adherence counselling. Multiple visits may have been  
143 required to complete this assessment. Those who met Malawi national ART eligibility  
144 criteria (CD4 count  $< 350$  cells/mm<sup>3</sup> or WHO stage 3 or 4, or breastfeeding or  
145 pregnant) were initiated onto ART.

146

147 Participants initiated onto ART returned to the HIV clinic at regular intervals for  
148 assessment by clinic nurses (or clinical officers [available at all clinics], or doctors  
149 [available at QECH only] if unwell). At clinic visits, ART medication was provided,

150 adherence and response to treatment was assessed, and other clinical problems (e.g.  
151 TB) managed. Visits varied in frequency, depending on response to ART.

152

153 We interviewed participants after each visit to the HIV clinic and if they were  
154 initiated onto ART, they were followed-up for one year. On recruitment, the study  
155 team administered structured questionnaires, recording age, sex, marital status,  
156 educational attainment, employment status, self-reported income, mode of HIV  
157 testing (HIVST, or facility HTC), WHO clinical stage, CD4 count prior to starting  
158 ART and tracing details. Participants were defined as lost to follow-up if they did not  
159 return for scheduled clinic visits and could not be traced.

160

#### 161 **Direct health provider costs**

162 After each visit to the HIV clinic the study team used structured questionnaires to  
163 record healthcare resources for each participant, including medical personnel seen,  
164 investigations performed, and ART and other medications prescribed. Resources  
165 related to hospitalisation were not available from participants' HIV clinic records.  
166 Primary resource-based costing was undertaken to estimate unit costs for each  
167 resource input, and consequently total direct health provider costs.<sup>14,15</sup> Appendix A  
168 <http://links.lww.com/QAI/A996> provides a detailed description of the costing process,  
169 and Appendix B <http://links.lww.com/QAI/A996> the estimated unit costs estimated  
170 for healthcare resources from the primary costing studies.

171

#### 172 **Direct non-medical and indirect costs**

173 An interviewer-administered questionnaire was also used after each clinic visit to  
174 record participants' direct non-medical and indirect costs and, where appropriate,

175 costs incurred by family member(s) or carer(s) who accompanied them to clinic.  
176 Development, language translations and pilot testing of questionnaires followed  
177 previous procedures.<sup>6</sup> Direct non-medical costs included costs of transportation, food,  
178 drinks, and other items bought as a consequence of health center visits. For indirect  
179 costs, we recorded whether participants or their carers had taken time off work, and  
180 multiplied time by self-reported income.<sup>16</sup> There are no formal payments to access  
181 public health services in Malawi.

182

### 183 **Health-related quality of life**

184 The Chichewa EuroQoL EQ-5D-3L<sup>17</sup> was used to measure HRQoL after each clinic  
185 visit. Participants completed both the descriptive EQ-5D-3L system and the  
186 accompanying visual analogue scale (VAS).<sup>18</sup> Responses to the five dimensions  
187 (mobility; self-care; usual activities; pain; anxiety) of the EQ-5D-3L descriptive  
188 system were converted into an EQ-5D utility score using a tariff. Tariff sets have been  
189 derived from national surveys of the general population, with a subset of the 243  
190 health states being valued, most commonly using the time trade-off method.<sup>18</sup> As  
191 there is no Malawian EQ-5D tariff, we used the Zimbabwean EQ-5D tariff set to  
192 derive an EQ-5D utility score for each study participant at each time point.<sup>19</sup> The  
193 VAS is similar to a thermometer, and ranges from 100 (best imaginable health state)  
194 to 0 (worst imaginable health state). Participants recorded how good or bad their  
195 health was on the day of the clinic visit by drawing a line on the scale.

196

### 197 **Statistical Analysis**

198 Analyses used Stata version 13.1 (Stata Corporation, Texas, USA). Costs were  
199 converted into 2014 US Dollars and International Dollars.<sup>20,21</sup> International dollars are

200 hypothetical units of currency that take into account differences in purchasing power  
201 across countries, thereby providing a means of comparing cost estimates across  
202 jurisdictions. Principal component analysis was used to generate wealth quintiles  
203 combining socioeconomic variables, which included nine household assets, and home  
204 environment variables.<sup>22</sup>

205

206 We undertook multiple imputation using chained equations to impute missing values  
207 for cost and HRQoL estimates for participants lost to follow-up.<sup>23</sup> Comparable to  
208 previous studies, our imputation models included mode of HIV testing received,  
209 baseline CD4 count, age, sex, and socio-economic variables.<sup>24,25</sup> We used predictive  
210 mean matching to impute missing values for cost and HRQoL outcomes as they were  
211 non-normally distributed, and to ensure imputed costs were non-negative.<sup>26</sup>

212

213 We estimated the total direct health provider cost, total direct non-medical and  
214 indirect cost, and total societal costs for each study participant. For direct health  
215 provider costs, we first estimated total cost for clinic consultations, total costs for  
216 investigations and total costs for treatments. These costs were summed to estimate  
217 total direct health provider costs. Health provider costs only included the costs of  
218 providing HIV and related medical care at the clinics. The total societal cost was  
219 estimated by summing all direct and indirect costs. .

220

221 We estimated costs for two time periods. The first was for the ART assessment period.  
222 This included all costs from first attendance to the HIV clinic, and continued until the  
223 clinic had decided whether a participant was eligible for ART initiation. The second  
224 was for the first year on ART, and included all costs from the first visit to be initiated

225 onto ART until the participant had been on ART for one year. We estimated mean  
226 differences in these costs by mode of HIV testing using bootstrap methods with 500  
227 replications to estimate bias-corrected 95% confidence intervals (CI).<sup>27</sup> We undertook  
228 multivariable analysis to investigate the independent effects of mode of HIV testing  
229 on costs. The multivariable model was adjusted for age, sex and other socio-  
230 demographic variables, in addition to baseline CD4 count.<sup>8</sup> We used generalized  
231 linear models (GLM), and ran model diagnostics to determine optimal choices for  
232 distributional family and link functions.<sup>28</sup>

233

234 For HRQoL assessments, we estimated EQ-5D utility and VAS scores immediately  
235 prior to ART initiation, and for those who initiated ART, after one-year of treatment.  
236 We estimated mean differences, and 95% bootstrapped CIs, in HRQoL outcomes by  
237 mode of HIV testing received. In addition, we undertook multivariable analysis to  
238 investigate the independent effects of mode of HIV testing and baseline CD4 count on  
239 the EQ-5D utility scores. The multivariable models were additionally adjusted for age,  
240 sex and other socio-demographic variables. As EQ-5D utility scores are non-normally  
241 distributed, negatively skewed and truncated at 1.0, we evaluated four commonly  
242 used estimators for our multivariable analyses: ordinary least squares (OLS)  
243 regression, Tobit regression, Fractional logit regression, and censored least absolute  
244 deviations (CLAD) regression.<sup>29-31</sup> We compared mean squared error (MSE) and  
245 mean absolute error (MAE) statistics between observed and estimated EQ-5D utility  
246 scores to determine the choice of estimator. We also undertook sensitivity analysis  
247 using the UK York A1 tariff<sup>32</sup> to investigate the impact of using an alternative tariff to  
248 determine EQ-5D utility scores.

249

250 **Results**

251 325 trial residents attended the HIV clinics for assessment for ART initiation over the  
252 study period: 265 after facility-based HTC and 60 after HIVST (Figure 1). Of the 265  
253 facility-based HTC participants, 20 (7.5%) did not complete ART assessment  
254 procedures, 77 (28.8%) completed ART assessment but did not meet Malawian  
255 eligibility criteria for initiating ART, and 168 (62.9%) completed ART assessment  
256 procedures and initiated ART. Of the 60 HIVST participants, 5 (8.3%) did not  
257 complete ART assessment procedures, 19 (31.7%) were not eligible to start ART and  
258 36 (60.0%) initiated ART. There was no significant difference in the characteristics of  
259 ART assessed participants across the two groups, except for WHO clinical stage,  
260 where there was a higher proportion of missing data for the HIVST group (Table 1).

261  
262 The mean total health provider costs during the assessment period for ART initiation  
263 were US\$22.79 for facility HTC participants, and US\$19.92 for HIVST participants  
264 (Table 2). During this period, the mean health provider costs for clinic consultations  
265 were US\$3.33 (bootstrap 95%CI: US\$2.17-US\$4.50) lower for the HIVST group.  
266 The mean health provider costs for drug and other medical treatments received were  
267 US\$0.74 (bootstrap 95%CI: US\$0.33-US\$1.16) lower for the HIVST group. The  
268 mean health provider costs for investigations performed were not significantly  
269 different between the two groups. The mean total health provider cost was US\$2.87  
270 (bootstrap 95%CI: US\$1.01-US\$4.73) lower for the HIVST group. During the  
271 assessment period for ART initiation, the mean total direct non-medical and indirect  
272 costs were US\$3.31 for facility HTC participants, and US\$2.65 for HIVST  
273 participants. The mean total direct non-medical and indirect costs were not  
274 significantly different between the two groups. The mean total societal cost over this

275 period was US\$3.54 (bootstrap 95%CI: US\$0.37-US\$6.71) lower for the HIVST  
276 group.

277

278 The mean total health provider costs during the first year following ART initiation  
279 were US\$168.65 for facility HTC participants, and US\$164.66 for HIVST  
280 participants (Table 3). There were no significant differences in mean health provider  
281 costs for clinic consultations, mean health provider costs for treatments and  
282 investigations, or for mean total health provider costs between the two groups. The  
283 mean total direct non-medical and indirect costs during the first year following ART  
284 initiation were US\$10.44 for facility HTC participants, and US\$12.03 for HIVST  
285 participants. The mean total direct non-medical and indirect costs were not  
286 significantly different between the two groups. The mean total societal costs during  
287 the first year following ART initiation were US\$178.46 for facility HTC participants,  
288 and US\$177.55 for HIVST participants. The mean total societal costs were not  
289 significantly different between the two groups.

290

291 In the multivariable analysis (Table 4), after adjusting for participants' socio-  
292 demographic characteristics and CD4 count on ART assessment, the mean total  
293 provider cost for ART assessment was US\$3.18 (95%CI: US\$1.77-US\$4.59) lower  
294 for the HIVST group. The mean total societal cost for ART assessment was US\$3.86  
295 (95%CI: US\$1.64-US\$6.08) lower for the HIVST group. There were no significant  
296 differences in mean total provider costs or mean total societal costs during the first  
297 year following ART initiation between facility HTC and HIVST participants.  
298 Appendix C <http://links.lww.com/QAI/A996> provides the results from the cost  
299 analysis in 2014 INT dollars.

300

301 The HRQoL outcomes for those who were assessed for ART, immediately prior to  
302 initiation and at one-year post ART initiation, and the change in HRQoL scores  
303 between these time points, are summarised in Table 5. There were no significant  
304 difference in EQ-5D utility and VAS scores immediately prior to or one year post  
305 ART initiation between the two groups. Participants who were initiated onto ART  
306 experienced improvements in EQ-5D utility and VAS scores. For facility HTC  
307 participants who started ART, EQ-5D utility scores increased by 0.129 (SE: 0.011)  
308 and VAS scores increased by 9.8 (SE: 1.7). For HIVST participants who started ART,  
309 EQ-5D utility scores increased by 0.139 (SE: 0.027) and VAS scores increased by  
310 10.4 (SE: 4.6). There were no significant differences between the two groups with  
311 regards to the change in EQ-5D utility and VAS scores after ART initiation.

312

313 In the multivariable analysis (Table 6), the model diagnostics showed that the OLS  
314 estimator performed as well or better than the other estimators (Appendix D  
315 <http://links.lww.com/QAI/A996>). In the fully adjusted OLS model, there was no  
316 significant difference in the mean EQ-5D utility score by mode of HIV testing. In the  
317 fully adjusted OLS model, the mean EQ-5D utility score was 0.043 (95%CI: 0.008-  
318 0.079) lower in individuals whose CD4 count was 50-200 cells/ul compared to those  
319 whose CD4 count was  $\geq 350$  cells/ul on assessment for ART. The mean EQ-5D  
320 utility score was 0.230 (95%CI: 0.163-0.296) lower in individuals whose CD4 count  
321 was below 50 cells/ul compared to those whose CD4 count was  $\geq 350$  cells/ul on  
322 assessment for ART.

323

324

325 **Discussion**

326 The main finding of this study was that the economic costs of providing HIV care and  
327 ART to HIV-positive individuals identified through HIVST were comparable to those  
328 identified through standard facility-based HTC services. Health-related quality of life  
329 was worse amongst those with lower CD4 counts, with improvements seen after ART  
330 initiation, irrespective of mode of HIV testing. These findings emphasise that once  
331 HIV self-testers are linked into HIV services, their economic outcomes are  
332 comparable to those linked to services after facility-based HTC.

333  
334 Health provider costs for assessing HIV-positive individuals for ART initiation were  
335 lower for HIV self-testers. This difference was due to lower health provider costs  
336 associated with clinic consultations and from provision of medical treatments.  
337 Additionally, fewer HIV self-testers were clinically assessed as WHO stage 3 or 4. In  
338 comparison to community-based HIV testing services, individuals accessing HIV  
339 testing at health facilities were often unwell for other reasons (e.g. TB), or have more  
340 advanced HIV clinical disease.<sup>33</sup> These individuals may need medical care for  
341 management for these other problems, or for investigation to exclude HIV associated  
342 illnesses prior to initiating ART. Although the cost savings demonstrated are small at  
343 the individual-level, at the population-level, these could be significant with increasing  
344 availability of HIVST.

345  
346 We estimated the annual health provider cost of managing a patient on ART to be  
347 approximately 2014 US\$170, comparable to previous estimates for Malawi (US\$136  
348 per person per year in 2011).<sup>34</sup> Health provider and societal costs were not affected by  
349 modality of HIV testing prior to entering HIV care services. Malawi has followed a

350 public health approach to scaling-up its HIV treatment services with less reliance on  
351 diagnostic tests for clinical assessment, and therefore the majority of individuals  
352 utilise comparable levels of healthcare resources.<sup>35</sup> We did not find differences in  
353 healthcare utilisation between the two groups. Although it is reassuring that these  
354 costs were comparable, the findings highlight opportunities to explore how HIV  
355 treatment should be provided as we move towards universal access to ART.<sup>36</sup>

356

357 The study demonstrates the relatively high costs incurred by patients when accessing  
358 HIV care. Individuals incurred a cost of approximately US\$3 during their assessment  
359 for ART eligibility, and US\$13 during the first year following ART initiation. The  
360 majority of Malawians live on less than \$2 a day.<sup>37</sup> Anti-retroviral therapy is provided  
361 free, but those accessing care incur costs of transport or because of taking time off  
362 work to attend clinics.<sup>38</sup> These costs can also have a negative impact on adherence to  
363 therapy.<sup>39,40</sup> ART can be effectively provided in people's homes through community  
364 distribution models.<sup>5,41</sup> Further work is needed to explore the risks and benefits of  
365 home provision of treatment.

366

367 HRQoL as measured by the EQ-5D has been shown to be responsive to change  
368 amongst HIV-positive patients in high-income settings,<sup>42</sup> but few studies have used  
369 this measure in sub-Saharan African settings.<sup>10</sup> The EQ-5D utility score provides an  
370 objective assessment of HRQoL for cost-utility analysis, with the VAS scores  
371 reflecting respondents' own assessments of their HRQoL. We found EQ-5D utility  
372 scores to be significantly associated with an HIV-positive individual's CD4 count,  
373 with improvements after initiation of ART. Participants also reported higher VAS  
374 scores after ART initiation. The findings support the beneficial impact of ART on

375 both quality and quantity of life and illustrate the importance of reaching those not in  
376 care before their disease advances. The mode of HIV testing had no independent  
377 impact on HRQoL outcomes.

378

379 This study is not without its limitations. The numbers recruited into the study were  
380 small, and many were lost to follow-up. Although we undertook multiple imputation  
381 to account for this, our findings may be limited because those lost to follow-up are  
382 potentially a sicker population, with poorer HRQoL, and, had they remained in care,  
383 higher healthcare resource use. We were not able to include healthcare resources  
384 utilized as a result of hospitalisation, as there was no routine medical record keeping  
385 or linking of records between community, outpatient and inpatient services.  
386 Furthermore, some of the unit costs estimated for the healthcare resource inputs, for  
387 example costs of consultations with a healthcare worker, represent average costs for  
388 average reported duration of consultations. These information system issues reduced  
389 our ability to detect differences in economic outcomes, but are unlikely to bias our  
390 findings.

391

392 A further limitation is that the EQ-5D tool only evaluates HRQoL across five health  
393 dimensions and may therefore not capture all relevant aspects of HRQoL. The lack of  
394 a Malawian tariff led us to use the Zimbabwean tariff to derive EQ-5D-3L utility  
395 scores. However, the EQ-5D tool is widely used for health economic analyses, and it  
396 is accepted practice to use tariffs from another country where none exists for the  
397 country of interest provided the two populations would value health comparably.<sup>15</sup> A  
398 final study limitation is that the recent change in ART initiation guidelines<sup>36</sup> means

399 that we are unable to comment on the economic outcomes of those who would in the  
400 future start treatment with early HIV disease.

401

402 In conclusion, we found that once HIV self-testers link into HIV treatment services,  
403 the costs of providing HIV care and improvements in HRQoL from ART are no  
404 different to those identified through facility-based HTC. The findings add to the  
405 growing literature supporting the scale-up of HIVST in the region. Full economic  
406 evaluations are needed to explore whether implementing HIVST is cost-effective. Our  
407 assessments of economic costs and preference-based HRQoL outcomes can help  
408 inform such analyses.

409

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415

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417 analysis and drafted the manuscript. SP, AC and ELC supported design of study and  
418 data collection tools. All authors interpreted the data, prepared report and approved  
419 final version.

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549 **Figure 1: Participant recruitment and follow-up**

550 \*Malawi national ART eligibility criteria during study period: CD4 count <350 cells/mm<sup>3</sup>; WHO stage  
551 3 or 4; breastfeeding; or pregnant

552 \*\*Loss to follow-up from this health economic study

553

1 **Table 1: Characteristics of ART assessed participants**

		Facility HTC	HIVST	p-value*
		participants	participants	
		n (%)	n (%)	
<b>All</b>		265	60	
<b>Sex</b>	Male	110 (41.5%)	20 (33.3%)	0.243
	Female	155 (58.5%)	40 (66.7%)	
<b>Age (years)</b>	18-24	32 (12.1%)	11 (18.3%)	0.430
	25-39	169 (63.8%)	36 (60.0%)	
	40+	64 (24.2%)	13 (21.7%)	
<b>Marital status</b>	Single (never-married)	19 (7.2%)	4 (6.7%)	0.884
	Married/Cohabiting	183 (69.1%)	39 (65.0%)	
	Separated/Divorced	42 (15.85%)	12 (20.0%)	
	Widower/Widow	21 (7.9%)	5 (8.3%)	
<b>Educational attainment</b>	Up to standard 8	166 (62.6%)	44 (73.3%)	0.122
	Up to form 6	98 (37.0%)	15 (25.0%)	
	University or training college	1 (0.4%)	1 (1.7%)	
<b>Income</b>	0 Kwacha/week	89 (33.6%)	20 (33.3%)	0.296
	Up to 4,000 Kwacha/week	75 (28.3%)	16 (26.7%)	
	4,000 to 8,000 kwacha/week	42 (15.85%)	10 (16.7%)	
	8,000 to 12,000 kwacha/week	27 (10.2%)	2 (3.3%)	
	Over 12,000 kwacha/week	32 (12.1%)	12 (20.0%)	
<b>Employment status</b>	Formal employment	74 (27.9%)	9 (15.0%)	0.358
	Informal employment/Unemployed	106 (40.5%)	29 (48.3%)	
	School/University	7 (2.6%)	2 (3.3%)	
	Retired	2 (0.8%)	0 (0.0%)	
	Housework	74 (27.9%)	20 (33.3%)	
	Sick leave	2 (0.75%)	0 (0.0%)	
<b>Socio-economic position<sup>¶</sup></b>	Highest quintile	55 (20.75%)	10 (16.7%)	0.106
	2nd highest quintile	53 (20.0%)	17 (28.3%)	
	Middle quintile	57 (21.5%)	9 (15.0%)	
	2nd lowest quintile	53 (20.0%)	7 (11.7%)	
	Lowest quintile	47 (17.7%)	17 (28.3%)	
<b>CD4 Count</b>	CD4 count >=350	89 (33.6%)	23 (38.3%)	0.943
	CD4 count 200-350	68 (25.7%)	14 (23.3%)	
	CD4 count 50-200	76 (26.7%)	17 (28.3%)	
	CD4 count <50	13 (4.9%)	3 (5.0%)	
	Not done or missing	19 (7.2%)	3 (5.0%)	
<b>WHO clinical stage</b>	Stage 1	64 (24.2%)	16 (26.7%)	0.031
	Stage 2	48 (18.1%)	10 (16.7%)	
	Stage 3	45 (17.0%)	3 (5.0%)	
	Stage 4	6 (2.3%)	0 (0%)	
	Not done or missing	102 (38.5%)	31 (51.7%)	

2 <sup>¶</sup>Socio-economic position estimated through undertaking principal component analysis of responses to assets and housing  
3 environment  
4 \*Chi squared  
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9 **Table 2: ART assessment costs by mode of HIV testing (2014 US Dollars)**

				Mean differences (95% CI)*		
				N	Mean (SE)	HIVST v Facility HTC
<b>Direct health provider cost (2014 US\$)</b>	Clinic consultations <sup>1</sup>	Facility HTC	265	8.65 (0.32)	-3.33	
		HIVST	60	5.32 (0.49)	(-4.50, -2.17)	
	Investigations <sup>2</sup>	Facility HTC	265	15.05 (0.41)	-0.25	
		HIVST	60	14.80 (0.45)	(-1.37, 0.87)	
	Treatments <sup>3</sup>	Facility HTC	265	1.71 (0.12)	-0.74	
		HIVST	60	0.96 (0.17)	(-1.16, -0.33)	
	<b>Total</b>	Facility HTC	265	22.79 (0.56)	-2.87	
		HIVST	60	19.92 (0.77)	(-4.73, -1.01)	
<b>Total direct non-medical and indirect cost (2014 US\$)</b>		Facility HTC	265	3.31 (0.41)	-0.67	
		HIVST	60	2.65 (0.93)	(-2.65, 1.31)	
<b>Total societal cost (2014 US\$)</b>		Facility HTC	265	26.10 (0.75)	-3.54	
		HIVST	60	22.57 (1.44)	(-6.71, -0.37)	

10 ART: Anti-retroviral treatment  
 11 \*Bootstrapped 95%CI  
 12 1: includes cost of clinic visit and consultation with health professional  
 13 2: includes cost of CD4 count and TB diagnostics  
 14 3: includes cost for cotrimoxazole, condoms and other medications  
 15

16 **Table 3: First year ART costs by mode of HIV testing (2014 US Dollars)**

				Mean differences (95% CI)*		
				N	Mean (SE)	HIVST v Facility HTC
<b>Direct health provider cost (2014 US\$)</b>	Clinic consultations <sup>1</sup>	Facility HTC	165	23.91 (1.04)	-4.04	
		HIVST	36	19.88 (2.28)	(-8.68, 0.60)	
	Investigations <sup>2</sup> + Treatments <sup>3</sup>	Facility HTC	165	144.74 (1.29)	-0.04	
		HIVST	36	144.78 (2.74)	(-5.71, 5.79)	
	<b>Total</b>	Facility HTC	165	168.65 (2.02)	-4.00	
		HIVST	36	164.66 (4.21)	(-12.38, 4.39)	
<b>Total direct non-medical and indirect cost (2014 US\$)</b>		Facility HTC	165	13.26 (2.13)	1.46	
		HIVST	36	14.72 (4.81)	(-7.99, 10.91)	
<b>Total societal cost (2014 US\$)</b>		Facility HTC	165	181.91 (3.34)	-2.54	
		HIVST	36	179.38 (7.70)	(-17.74, 12.67)	

17 ART: Anti-retroviral treatment  
 18 \*Bootstrapped 95%CI  
 19 1: includes cost of clinic visit and consultation with health professional

20 2: costs of investigations combined with costs for treatments, as Malawi HIV guidelines at time of study were for clinical  
21 monitoring and hence few participants had investigations performed during study period.  
22 3: includes cost for anti-retroviral drugs, cotrimoxazole, condoms and other medications  
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24 **Table 4: Multivariable analysis exploring relationship between CD4 count and mode of HIV testing, and ART assessment and first year ART**  
 25 **costs (2014 US Dollars)\***

		Total health provider cost (2014 US Dollars)		Total societal cost (2014 US Dollars)	
		ART assessment (n=325) Coef (95% CI)	Frist year on ART (n=201) Coef (95% CI)**	ART assessment (n=325) Coef (95% CI)	Frist year on ART (n=201) Coef (95% CI)**
Mode of HIV testing	Facility HTC	Ref	Ref	Ref	Ref
	HIVST	-3.18 (-4.59, -1.77)	-5.28 (-11.67, 1.11)	-3.86 (-6.08, -1.64)	-4.72 (-14.89, 5.45)
	CD4 count >350 cells/ $\mu$ l	Ref	Ref	Ref	Ref
	CD4 count 200-350 cells/ $\mu$ l	1.19 (-1.43, 3.82)	-2.15 (-9.74, 5.45)	2.58 (-1.11, 6.27)	-3.56 (-7.71, 14.84)
	CD4 count 50-200 cells/ $\mu$ l	0.57 (-1.00, 2.14)	-4.60 (-12.56, 3.35)	1.64 (-0.81, 4.09)	0.98 (-7.78, 9.74)
Baseline CD4 count	CD4 count <50 cells/ $\mu$ l	-0.45 (-3.31, 2.40)	-3.47 (-17.57, 10.62)	1.00 (-3.60, 5.60)	-6.68 (-25.74, 12.38)
	Not done or missing	-16.01 (-17.76, -14.25)	-4.91 (-18.15, 8.34)	-16.41 (-18.81, -14.01)	-3.53 (-24.23, 17.17)
Constant		23.00 (19.46, 26.52)	178.19 (163.99, 192.38)	22.82 (18.32, 27.32)	189.18 (175.49, 202.88)

26 Model adjusted for modality of HTC, CD4 count, age, sex, marital status, educational attainment, income and wealth quintile  
 27 Total cost = constant +  $\beta$ (Modality of HIV testing) +  $\beta$ (Baseline CD4 count) +  $\beta$ (age) +  $\beta$ (sex) +  $\beta$ (marital status) +  $\beta$ (educational attainment) +  $\beta$ (income) +  $\beta$ (wealth quintile) +  $\epsilon$   
 28 \*Findings from Generalized Linear Model with Poisson distribution and Identity link function. Distributional family (Poisson) describes the distribution of the data, whilst the link function describes the relationship  
 29 between the linear predictor and the mean of the response (cost).  
 30 \*\*Findings from ten imputed datasets with coefficients calculated using Rubin's rules<sup>23</sup>  
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36 **Table 5: Health-related quality of life outcomes immediately prior to and one-year after ART initiation by mode of HIV testing**

				Mean differences (95% CI)*		
				N	Mean (SE)	HIVST v Facility HTC
EQ-5D utility score	Facility HTC	ART assessment – all	264	0.836 (0.008)	0.018 (-0.020, 0.056)	
	HIVST	ART assessment – all	60	0.854 (0.018)		
	Facility HTC	ART assessment – initiated ART	164	0.837 (0.010)	-0.001 (-0.055, 0.054)	
	HIVST	ART assessment – initiated ART	36	0.836 (0.025)		
	Facility HTC	One year post-ART**	165	0.965 (0.006)	0.010 (-0.017, 0.037)	
	HIVST	One year post-ART**	36	0.975 (0.011)		
	Facility HTC	Change on ART**	165	0.129 (0.011)	0.011 (-0.047, 0.068)	
	HIVST	Change on ART**	36	0.139 (0.027)		
VAS score	Facility HTC	ART assessment	264	73.0 (1.0)	0.5 (-4.7, 5.7)	
	HIVST	ART assessment	60	73.5 (2.4)		
	Facility HTC	ART assessment – initiated ART	164	70.9 (1.3)	3.2 (-4.2, 10.6)	
	HIVST	ART assessment – initiated ART	36	74.1 (3.4)		
	Facility HTC	One year post-ART**	165	80.8 (1.4)	3.7 (-3.8, 11.3)	
	HIVST	One year post-ART**	36	84.5 (3.6)		
	Facility HTC	Change on ART**	165	9.8 (1.7)	0.6 (-8.9, 10.0)	

	HIVST	Change on ART**	36	10.4 (4.6)	
<b>EQ-5D utility score (UK tariff)</b>	Facility HTC	ART assessment	264	0.793 (0.012)	0.020 (-0.037, 0.077)
	HIVST	ART assessment	60	0.813 (0.028)	
	Facility HTC	ART assessment – initiated ART	164	0.793 (0.015)	-0.009 (-0.093, 0.076)
	HIVST	ART assessment – initiated ART	36	0.785 (0.039)	
	Facility HTC	One year post-ART**	165	0.961 (0.007)	0.013 (-0.018, 0.044)
	HIVST	One year post-ART**	36	0.973 (0.013)	
	Facility HTC	Change on ART**	165	0.167 (0.016)	0.022 (-0.062, 0.105)
	HIVST	Change on ART**	36	0.189 (0.040)	

ART: Anti-retroviral treatment

\*Bootstrapped 95%CI

\*\*Findings from ten imputed datasets with overall differences in mean costs calculated using Rubin's rules<sup>23</sup>

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41 **Table 6: Multivariable analysis exploring relationship between CD4 count, mode of**  
 42 **HIV testing and pre-ART EQ-5D utility score\***

		EQ-5D utility score (Zimbabwean Tariff)	EQ-5D Utility Score (UK Tariff)**
		Coef (95% CI)	Coef (95% CI)
<b>Modality of HIV testing</b>	Facility HTC	Ref	Ref
	HIVST	0.022 (-0.015, 0.058)	0.026 (-0.028, 0.080)
<b>Baseline CD4 count</b>	CD4 count >=350	Ref	Ref
	CD4 count 200-350	-0.011 (-0.048, 0.026)	-0.021 (-0.075, 0.033)
	CD4 count 50-200	-0.043 (-0.079, -0.008)	-0.057 (-0.110, -0.004)
	CD4 count <50	-0.230 (-0.296, -0.163)	-0.371 (-0.469, -0.272)
	Not done or missing	-0.019 (-0.079, 0.040)	-0.035 (-0.122, 0.053)
<b>Constant</b>	0.878 (0.801, 0.956)	0.834 (0.719, 0.948)	

43 Model adjusted for modality of HTC, CD4 count, age, sex, marital status, educational attainment, income and wealth quintile  
 44 \*Findings from OLS estimator  
 45 Utility score = constant +  $\beta$ (Modality of HIV testing) +  $\beta$ (Baseline CD4 count) +  $\beta$ (age) +  $\beta$ (sex) +  $\beta$ (marital status) +  
 46  $\beta$ (educational attainment) +  $\beta$ (income) +  $\beta$ (wealth quintile) +  $\epsilon$   
 47 \*\*Findings from sensitivity analysis

