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# BMJ Open

## Understanding the patient experience to improve HIV service delivery using an adapted standardised patient approach in 16 facilities in Zambia

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# Understanding the patient experience to improve HIV service delivery using an adapted standardised patient approach in 16 facilities in Zambia

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## ABSTRACT

**Objectives:** To evaluate sub-optimal patient experiences in HIV care (e.g., unfriendly interactions with health care workers [HCW], long-waiting times, and lost laboratory results) using an adapted standardised patient approach “mystery-clients” that addresses information and social desirability biases.

**Setting:** Cross-sectional surveys in 16 government-operated HIV primary care clinics in Lusaka, Zambia providing antiretroviral-therapy (ART).

**Participants:** 3526 participants  $\geq 18$  years of age receiving ART participated in the exit surveys between August 2019 and November 2021.

**Intervention:** Patients systematically sampled from the clinic waiting area willing to be trained received pre-visit training and post-visit interviews. HCWs were unaware of trained patients.

**Outcome measures:** We assessed patient experience among patients that received a brief training prior to their care visit (explaining each patient experience construct in the exit survey, being anonymous, not altering behaviour or manipulating interactions) with those who did not undergo training on the instrument prior to their visit.

**Results:** Among 3526 participants who participated in the exit surveys, 2415 were untrained (56% female, median age 40 (IQR:32-47)) and 1111 were trained (50% female, median age 37 (IQR:31-45)). Compared to untrained, trained patients were more likely to report a negative care experience overall (adjusted Prevalence Ratio aPR for aggregate sum score: 1.64 [95% CI:1.39-1.94]), with a greater proportion reporting feeling unwelcomed by providers ([aPR]: 1.71 [95% CI:1.20-2.44]) and witnessing providers behaving rudely (aPR: 2.28 [95% CI:1.63-3.19]).

**Conclusion:** Trained patients were more likely to identify instances of sub-optimal care. They may have had a better understanding of the items solicited or felt empowered to be more critical. Unlike studies where “standardised patients” are drawn from outside of the patient population, we trained existing patients. This low-cost strategy might be used in other settings to improve patient-centred service delivery.

**Trial registration:** Assessment was nested within a parent study. [www.pactr.org](http://www.pactr.org) registered the parent study (PACTR202101847907585).

## STRENGTHS AND LIMITATIONS OF THIS STUDY

- Patient experience is hard to measure rigorously and pragmatically. Approaches to assessing patient experience such as standardised patient (SP) surveys are often referred to as the golden standard. However, these methods are not feasible in HIV care settings with limited resources because they frequently require highly skilled personnel and are typically utilised for episodic care. The current procedure for SP calls for a trained individual to make one visit to many locations while acting as a simulated patient.
- We present a novel approach to measuring patient experience using an adapted version of the standardised patient approach. In our method, we trained actual patients to look out for certain facility characteristics, to evaluate key components of quality of care such as waiting times, communication, respectfulness of providers, and privacy and compared their responses to traditional exit survey responses in 16 health facilities in Zambia.
- Recipients of care who received a brief training provided more critical appraisal of care either because they were more alert to the items solicited or felt empowered to be more critical. Patient-centred care can be institutionalised further through the evaluation of what occurs at the point of contact between the patient, the healthcare facility, and the healthcare professional using this low-cost method.

## BACKGROUND

Retention in care remains a major obstacle to improving Human Immunodeficiency Virus (HIV) treatment outcomes, and health systems in low-income settings like Zambia, have sought to shift their public health response by designing and delivering high quality and patient-centred HIV care [1–6]. Efforts to improve service quality and patient experience require systematic measurement of the patient experience to guide facility responses as poor patient experience has been shown to lead to disengagement from care [7–11]. Health policymakers and donors, such as the President's Emergency Plan for AIDS Relief (PEPFAR), have invested in clinical metrics to assess care quality in Zambia and the wider region, but to a lesser extent in non-clinical metrics like patient experience [12]. These metrics can be critical for guiding efforts to improve retention in care by ensuring an informed response to improving quality of care and patient centredness.

Accurate and pragmatic measurement of the patient experience poses a range of challenges. Patient experience exit surveys are prone to social desirability bias because of power dynamics in health care. Empirical studies of satisfaction, for example, are widely believed to over-estimate patient satisfaction [13]. This may be particularly true where provider-patient relationships are traditional and hierarchical. Delaying surveys for some time after the encounter is theorised to ameliorate social desirability bias, but in turn may exacerbate bias due to simple inability to remember — thus creating recall bias [6]. Other methods such as direct clinical observations of care pose practical difficulties [13,14]. For example, direct observations may be intrusive and therefore may not reflect everyday functionality of a health facility. Care provided under direct observations may be of higher quality as behaviour may be influenced by observation, a phenomenon often known as the “Hawthorne effect” [13,14].



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3 161 Standardised patients (SP), also known as “mystery clients” or “simulated patients” have  
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6 162 largely been used to assess quality of care in developed countries, as well as in assessing customer  
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8 163 service in the retail industry[15]. SP can be resource-intensive and require training, but reduce  
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10 164 potential for recall bias, social desirability, bias, and Hawthorne effects, providing an opportunity  
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12 165 for optimal assessment of patient satisfaction among people receiving HIV care [6,16]. They have  
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15 166 largely been used for episodic care where a highly skilled and well-trained person poses as a client  
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17 167 by making one visit to multiple facilities. This approach holds promise for assessing the patient  
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19 168 experience in HIV care but poses pragmatic challenges when assessing the quality of chronic care  
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22 169 in which a patient makes multiple visits and may compromise efficiency at, already overburdened,  
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24 170 facilities [17–22]. In this study, we report on the development and evaluation of a modified SP  
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26 171 approach in which we trained real patients (trained exit clients - TEC) to report on certain  
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29 172 characteristics of encounters, and rate key components of care such as waiting times, communication,  
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31 173 respectfulness of providers, and privacy.  
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## 34 35 174 **METHODS**

### 36 37 175 **Study design & setting**

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40 176 This study seeks to compare two different methods for assessing patient experience: standard  
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42 177 exit survey and those reported by patients who had a brief training on the items before the clinical  
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44 178 encounter and to whom the clinic was blinded. The assessment was nested within a parent study:  
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47 179 the Leveraging Person-Centred Public Health (PCPH) to improve HIV outcomes in Zambia study  
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49 180 ([www.pactr.org](http://www.pactr.org) PACTR202101847907585), a Stepped Wedge Cluster Randomised Trial that  
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51 181 occurred between August 2019 and November 2021. The aim of the PCPH study was to assess the  
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54 182 impact of introducing health care workers (HCW) to a patient-centred care (PCC) curriculum and  
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56 183 mentoring them on PCC principles to improve retention and viral suppression in HIV care. The two  
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3 184 assessments we compare were conducted primarily to evaluate effects of the intervention. This  
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6 185 comparative analysis is secondary analysis of the experience endpoints.  
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## 8 186 9 10 187 **Population**

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12 188 The sub-study reported here included 16 health facilities in Lusaka, Zambia, operated by the  
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15 189 Ministry of Health (MOH) and receiving technical assistance from the Centre for Infectious  
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17 190 Diseases Research in Zambia (CIDRZ) - a Zambian non-governmental organisation (NGO) as well  
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19 191 as a part of the larger parent study. We surveyed adults aged 18 years and over who were accessing  
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22 192 antiretroviral therapy (ART) at study facilities. Exit survey patients were selected in a systematic  
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24 193 sample at the time of exit from the clinic. Trained patients were recruited in the waiting room for  
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26 194 their visit, underwent a brief training, and then answered survey questions on exit from their  
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28 195 encounter. Participants attending an HIV care visit on the day, able to recall events and comprehend  
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31 196 study participant recruitment details (as assessed using the comprehension assessment tool) and able  
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33 197 to read and write (assessed using literacy tool) were eligible for inclusion.  
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## 35 198 36 37 38 199 **Procedures and Measurements**

### 39 40 200 *Survey Instrument*

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42 201 For both survey methods, we developed a patient experience instrument based on a previously  
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45 202 validated tool developed and used in Kenya: The Wachira Physician-Patient Communication  
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47 203 Behaviours Scale [23–25]. This survey assessed elements of patient experience including how they  
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49 204 were greeted, communicated to, and overall experience. We included additional questions to capture  
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52 205 for example, patient reports of witnessing rude behaviour, receiving appropriate medications and  
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54 206 availability of lab results. Prior to use in this study, we performed cognitive interviews among  
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56 207 twenty participants to assess consistency in understanding questions in English, Bemba and Nyanja.  
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3 208 Surveys were forward and back translated to ensure consistency across the three languages. The  
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6 209 survey tools for trained and untrained clients were identical. For both trained and untrained clients,  
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8 210 all interviews and surveys were conducted in either English, Bemba or Nyanja depending on the  
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10 211 participant's preference.

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12 212 For the untrained exit surveys, among patients leaving the facility after attending the clinic on  
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15 213 the survey day, we took a systematic (every  $k^{th}$ , varied by facility size) sample of patients. Patients  
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17 214 were approached by study staff after the visit using a recruitment script to determine their eligibility  
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19 215 and were administered the survey after granting consent. Participants received a snack during the  
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22 216 survey administration, but no other financial incentive.

#### 23 24 217 Additional procedures for Trained Exit Client

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26 218 Efforts to “standardise” assessment of the quality and nature of care in HIV care differs from  
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29 219 most previously standardised patient or mystery client work in that HIV care is longitudinal as  
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31 220 opposed to episodic or acute care. Under these circumstances, the more conventional standardised  
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33 221 patient where a single trained actor can present to multiple different care facilities as a simulated  
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35 222 patient with a defined set of symptoms or complaints to assess a single episode of care is not feasible.  
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38 223 For example, a patient would have to either register as a new patient or have a false “file” introduced  
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40 224 into the paper and electronic medical records — which was deemed infeasible and undesirable.  
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42 225 Instead of simulated patients, we recruited existing patients already receiving care at a particular  
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45 226 facility and then subsequently trained them on the concepts of quality of care according to the MOH  
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47 227 manual on Quality Improvement for HCWs in Zambia. To avoid disclosing their trained status,  
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49 228 patients were recruited prior to them entering the triage area (i.e., the first point of contact with  
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52 229 HCWs). Those who consented underwent a single training session for 40 to 60 minutes where they  
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54 230 were sensitised to the study instrument (which was the same for both TEC and untrained exit clients  
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3 231 (UEC)), the MOH care standards, and strategies on being natural yet observant during their clinic  
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5 232 visit for that day according to the standard SP approach. These procedures were meant to ensure  
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8 233 patients had a clear and uniform understanding on what they should expect during a high-quality  
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10 234 patient visit and were attentive to these critical aspects relative to these standards. After this training,  
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12 235 the TEC presented themselves to their facility and completed their visit as they normally would.  
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15 236 After their clinic encounter, participants then completed the exit survey. Given the extra time  
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17 237 commitments required for the training, TEC participants were given K100 (~\$5) for the time spent  
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19 238 during training. Research assistants were trained by the first author and were available for  
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21 239 recruitment, training and administering of the TEC and UEC survey in all 16 facilities. The  
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24 240 provincial and district health management teams were informed about the unannounced TEC survey  
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26 241 as well as the UEC survey. The study team sensitised all facility staff at the start of the study, but  
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28 242 HCWs were not aware of who specific TECs were.  
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### 31 243 32 33 244 **Statistical Analysis**

34  
35 245 To assess the association between training and response for each question, we conducted  
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38 246 unadjusted and adjusted poisson regression for each question separately [26]. We then assessed the  
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40 247 overall association between training and total sum score. We used descriptive statistics to  
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42 248 characterise patient characteristics and report survey responses. In these analyses, most of the survey  
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45 249 responses were reverse coded to identify when respondents reported a negative experience. Results  
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47 250 for individual questions (binary response) represent prevalence ratios for reporting a lapse in care.  
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49 251 To assess the sum score (count data) we used Poisson regression, estimating the rate ratio for  
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51 252 reporting lapses in care. All models were adjusted, given potential differences in survey participants  
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54 253 related to different recruitment strategies using mixed-effects regression, adjusted for age, sex,  
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3 254 education, care status at the time (i.e., continuously retained in care versus returning to care after  
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6 255 disengagement/ lost to follow up [LTFU]), secular time (using cubic splines), allowing random  
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8 256 effects at the facility level. We present these results for the overall population as well as stratified  
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10 257 by different patient subgroups. Lastly, we used bubble plots to compare summary assessments of  
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12 258 the patient experience at the facility-level using TECs versus UECs. All analyses were performed  
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15 259 using STATA 14MP (StataCorp, College Station, TX, USA). This sub-study represents a secondary  
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17 260 analysis and no formal power calculations were performed for this outcome.  
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### 21 22 262 **Statement of Ethics Approval**

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24 264 Ethics approval to conduct this research was granted by the Zambian Ministry of Health,  
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26 265 National Health Research Authority, and the institutional review boards of the University of Zambia  
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28 266 (008-03-19), the University of Alabama at Birmingham (300003282) and the London School of  
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31 267 Hygiene and Tropical Medicine (21384).  
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### 33 268 34 35 36 269 **Patient and Public Involvement**

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38 270 Survey questions were developed through a cognitive process with recipients of care. Study  
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40 271 implementation guidance was conducted as part of routine CIDRZ partnership with the Zambian  
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42 272 MOH through a Human Centered Design workshop. CIDRZ engages with implementing partners  
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45 273 and affected communities in health facilities, including people living with HIV often represented by  
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47 274 neighbourhood health representatives. Although patients were not directly involved in the design of  
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49 275 the parent study intervention or the analysis presented here, all study activities were guided by a  
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52 276 Scientific Advisory Board with representation from the MOH and a representative of recipients of  
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54 277 HIV care. Dissemination of study results is ongoing.  
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## RESULTS

### Characteristics of health facilities and patients

We approached 4375 clients (2955 in the untrained and 1420 in the trained), and 3526 participated, of which 2415 (55.2%) completed experience surveys as untrained exit clients (UEC) (56% female, median age was 40 years (interquartile range [IQR]:32-47 years)) and 1111 (32%) completed experience surveys as trained exit clients (TEC) (50% female with a median age 37 years (IQR:31-45 years)). Reasons for non-participation included unavailability at the time due to other commitments. Sixteen percent (16%) of UECs and 40% of TECs who had been lost to care and were returning to care on the day of the survey. Education levels differed between UEC and TEC with 47% and 58% reporting completion of secondary level of education, respectively (Table 1). UEC and TEC were similar for HIV enrolment WHO stage with the largest proportion enrolling at WHO stage 1 and similar in terms of marital status.

**Table 1. Socio-demographic characteristics of untrained exit and trained exit clients**

Characteristics	Level	Untrained Exit Clients n=2415 (68%)	Trained Exit Clients n=1111 (32%)
<b>Sex, n (%)</b>	<b>Female</b>	1355 (56)	553 (50)
	<b>Male</b>	1060 (44)	558 (50)
<b>Age, Median (IQR)</b>		40 (32-47)	37 (31-45)
<b>Age category, n (%)</b>	<b>&lt;30 years</b>	453 (19)	258 (23)
	<b>30-40 years</b>	828 (34)	416 (37)
	<b>40-50 years</b>	815 (34)	304 (27)
	<b>&gt;50 years</b>	319 (13)	133 (12)
<b>Education category</b>	<b>None</b>	132 (5)	36 (3)
	<b>Primary</b>	654 (27)	166 (15)
	<b>Secondary</b>	1134 (47)	645 (58)
	<b>University</b>	150 (6)	100 (9)
	<b>Missing</b>	307 (13)	151 (14)

<b>HIV Enrollment Stage</b>			
	<b>WHO Stage 1</b>	1173 (49)	533 (48)
	<b>WHO Stage 2</b>	314 (13)	147 (13)
	<b>WHO Stage 3</b>	355 (15)	162 (15)
	<b>WHO Stage 4</b>	27 (1)	7 (1)
	<b>Missing</b>	546 (23)	262 (24)
<b>Care status at survey visit</b>			
	<b>In care</b>	2038 (84)	664 (60)
	<b>Returning to care</b>	377 (16)	447 (40)
<b>Marital Status</b>			
	<b>Single</b>	257 (11)	167 (15)
	<b>Married</b>	1361 (56)	575 (52)
	<b>Divorced</b>	248 (10)	108 (10)
	<b>Widowed</b>	173 (7)	81 (7)
	<b>Unknown</b>	41 (2)	20 (2)
	<b>Missing</b>	335 (14)	160 (14)
<b>Facility size</b>			
	<b>&lt; 1000 patients</b>	591 (25)	245 (22)
	<b>1000-5000 patients</b>	897 (37)	485 (44)
	<b>&gt; 5000 patients</b>	927 (38)	381 (34)

Table 2 shows the absolute responses for TEC and UEC. Although most patients reported a good experience, across the questions between 5% and 25% of patients reported poor experiences in care. For example, when asked if their HIV care provider gave them as much information about their health as they wanted, 13.4% (UEC) vs 24.6% (TEC) of patients reported not being provided with sufficient information about their health. Similarly, between 9.6% vs 18.8% patients reported that their HIV care provider was not spending the right amount of time with them at their visit, and 6.8% vs 16.4% reported witnessing rude behaviour.

**Table 2. Survey responses by training status**

Factor	Level	Untrained Exit Client n (%)	Trained Exit Client n (%)
<b>Did your HIV care provider greet you in a way that made you feel comfortable?</b>	Yes	2249 (93.1)	980 (88.2)
	No	166 (6.9)	131 (11.8)
<b>Did your HIV care provider listen to what you said?</b>	Yes	2328 (96.4)	1039 (93.5)
	No	79 (3.3)	64 (5.8)
	Refused	8 (0.3)	8 (0.7)
<b>Did your HIV care provider give you as much information about your health as you wanted?</b>	Yes	2092 (86.6)	838 (75.4)
	No	323 (13.4)	273 (24.6)
<b>Did your HIV care provider allow you to ask questions?</b>	Yes	2082 (86.2)	887 (79.8)
	No	326 (13.5)	222 (20)
	Refused	7 (0.3)	2 (0.2)
<b>Did your HIV care provider spend the right amount of time with you?</b>	Yes	2179 (90.2)	900 (81)
	No	232 (9.6)	209 (18.8)
	Refused	4 (0.2)	2 (0.2)
<b>Overall, how did you feel about the care you received today?</b>	Happy	2231 (92.4)	983 (88.5)
	Unhappy	178 (7.4)	123 (11.1)
	Refused	6 (0.2)	5 (0.4)
<b>Overall, were you satisfied with all your HIV care providers today?</b>	Yes	2206 (91.4)	906 (81.5)
	No	208 (8.6)	202 (18.2)
	Refused	1 (0.0)	3 (0.3)
<b>I witnessed HIV care providers behaving rudely during my visit today</b>	No	2251 (93.2)	928 (83.5)
	Yes	163 (6.8)	182 (16.4)
	Refused	1 (0.0)	1 (0.1)
<b>Were your lab results lost?</b>	No	2143 (88.7)	985 (88.7)
	Yes	268 (11.1)	126 (11.3)
	Not picking up	4 (0.2)	0 (0)
<b>Were you able to pick up your medicine today?</b>	Yes	2366 (98.0)	1087 (97.8)
	No	48 (2.0)	24 (2.2)
	Not Picking Up Meds	1 (0.0)	0 (0)

**Effects of training on response patterns: sum score and prevalence ratios**

In adjusted models, TECs overall reported poor experiences in care: 1.64 times as frequently as UEC respondents (Sum Score Rate Ratio [RR]: 1.64 [95% CI: 1.39-1.94] (Fig 1, Supplementary Table S1), and reported an increased prevalence of poor experiences in care quality compared to



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3 312 untrained across almost all questions. For example; among TECs compared to UECs, there was an  
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5 increased prevalence of reports of not being greeted in a way that made them feel welcome (adjusted  
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8 314 Prevalence Ratio [aPR]: 1.71 [95% CI: 1.20-2.44]), reporting being dissatisfied with all their HIV  
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10 315 care providers during their HIV care visit (aPR: 2.06 [95% CI: 1.61-2.63]) and witnessing any  
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12 316 providers behaving rudely during their visit (aPR: 2.28 [95% CI: 1.63-3.19]) (Fig 1, Supplementary  
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14 Table S1).

### 18 319 **Impact of training across age, sex, and gender to differences in responses**

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21 320 In stratified analysis of the impact of training on the sum score, training was consistently  
22  
23 321 associated with increased identification of poor experiences in care across all subgroups apart from  
24  
25 322 those aged 50 years or older and those with no education. We also observed that training had a larger  
26  
27 323 impact among females compared to males, those with a primary education only, and among  
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29 324 individuals presenting at smaller facilities (Fig 2). We observed similarities in responses on the  
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31 impact of training on different age categories, sex, care status and different levels of education when  
32 325  
33 we looked at individual questions except for the question on providers spending the right amount of  
34 326  
35 time where we found that females were twice as likely to report lapses with care compared to males  
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37 327 (Supplementary Figure 1). Using TECs gave worse assessments of patient experience at the facility-  
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39 328 level regardless of facility size compared to UECs (Fig 3, Supplementary Figure 2).

## 43 330 **DISCUSSION**

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49 333 Disengaged patients often express a disconnect between their care expectations and the  
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51 provider's style, hence experience is bound to vary across facilities [7]. This disconnect can lead to  
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53 dissatisfaction with HIV services which can often lead to patients dropping out of care[7,10,27]. A  
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3 336 brief training for patients living with HIV on how to evaluate the quality and experience of routine  
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6 337 care changed patient experience reports compared to untrained patients using the same instrument.  
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8 338 Patients who underwent a brief training identified more lapses in care across most questions. Women  
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10 339 and young people were more likely to report critical responses after training - consistent with the  
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12 340 idea that those who feel least empowered underwent the biggest change. Differences were also  
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15 341 bigger for questions in which social desirability is likely to operate. For example, larger differences  
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17 342 were observed for witnessing rude behaviour, while no differences were observed for more objective  
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19 343 questions such as whether lab results were lost.  
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23 344 Improving HIV health outcomes requires new strategies that minimise methodological biases  
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25 345 and includes everyone the patient encounters during their visit, including clinical officers, doctors,  
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27 346 nurses, data clerks, and lay HCWs. Our TEC approach could contribute to getting a true reflection  
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30 347 of how much value patients place on things such as effective communication, being greeted  
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32 348 appropriately, or being treated with care and respect at all these different touch points. Involving  
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34 349 patients in their own care and design of health services has been linked to improved HIV care  
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36 350 retention and patient outcomes, such as higher viral suppression rates [28–30]. As progress is being  
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39 351 made towards UNAIDS 95-95-95 targets, the global HIV sector is constantly reviewing priorities  
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41 352 and challenges for optimal engagement in care [31,32]. Patient experience is a key indicator of  
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43 353 healthcare quality for meeting the 95-95-95 targets: delivering services patients need, can access,  
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46 354 and address wider determinants of poor health. Clinicians and health systems must address HIV  
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48 355 patients' needs from diagnosis to death to ensure healthy ageing and viral suppression. Other  
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50 356 outcomes in Zambia [10,33,34] show that lifelong needs vary by facility, highlighting the  
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53 357 importance of metrics that measure patient experience accurately. We have shown that it is feasible  
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3 358 to involve patients in assessing the quality of care and this could potentially lead to involvement of  
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5 359 patients in the redesign of healthcare services.

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8 360 Because HIV care is longitudinal, SP, who are often used to evaluate episodic care, require  
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10 361 highly skilled people to pose as a simulated patient making one visit to multiple clinics, posing  
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12 362 practical implementation challenges in our setting[17–22]. Contrary to SP, we evaluated care quality  
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15 363 without using simulated patients and administered the survey once among people in long term care.  
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17 364 Using real patients instead of simulated ones drawn from outside the true patient population, we  
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19 365 would argue, made our TEC approach more applicable and reproducible in clinical settings. We  
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22 366 were able to record HCW behaviour in a typical HIV context using this concealment method,  
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24 367 potentially reducing the impact of the Hawthorne effect. Our TECs also consistently identified more  
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26 368 lapses in care, potentially reducing social desirability bias and ability to identify issues at the facility.  
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29 369 Even though training takes time, the increased quality of our measurement allows one to perform  
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31 370 fewer surveys. With traditional approaches like exit surveys, one would require a larger sample size,  
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33 371 but this does not address bias [35].

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35 372 Our findings are consistent with a study done in South Africa which found that non-clinical  
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38 373 dimensions of care play a bigger role in determining an overall satisfactory experience for  
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40 374 standardised patients when compared to untrained patients[35]. However, our findings may  
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42 375 contradict previous suggestions that tailoring support to individuals to build skills and confidence  
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45 376 through patient activation can lead to trained/informed patients reporting a better experience than  
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47 377 untrained/ uninformed [36]. TECs cared about the following non-clinical aspects of care: rude  
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49 378 providers, being satisfied with HIV care providers, and spending enough time with providers. This  
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52 379 finding is consistent with a previous study in Zambia, where patients reported rude HCWs deterring  
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54 380 HIV care engagement [7,9,10]. This could mean that studies assessing patient experience with TEC  
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3 381 could focus on a few questions to save time and resources. Questions like, "Did you pick up your  
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5 382 medicine or lab results at your visit?" may not add much to a TEC survey because they are definitive,  
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8 383 and training appears to influence subjective care dimensions.  
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10 384 Women TECs were generally more critical about the care they received and would likely  
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12 385 provide a more accurate reflection of the health system, possibly because they have better health-  
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15 386 seeking behaviour than men, which may be strongly influenced by local gender norms and health  
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17 387 service structures designed to engage women of reproductive age [37]. There is some consistency  
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19 388 with other findings that women may be more interested in their care than men, especially in facilities  
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22 389 that provide integrated services for women and their children [8,38]. Despite longer wait times,  
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24 390 women were more satisfied with integrated facilities [39]. In addition, middle-aged people between  
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26 391 40-50 benefited the most from training. Compared to older people over 50, younger people under  
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29 392 30 were less satisfied with the care they received and often felt they were not greeted by a HCW  
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31 393 during their visit. This finding is consistent with cultural norms where younger people are less  
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33 394 respected[40]. Given the current strategy of targeting young people, who account for most new  
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35 395 infections, these findings suggest an important new approach to identifying what young people value  
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38 396 most. Education level was among the strongest predictors of patient experience feedback. Well-  
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40 397 educated patients were found to have a less critical/better HIV care visit experience compared to  
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42 398 participants with lower levels of educational attainment. This difference in care experience report  
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45 399 may be associated, at least in part, with the HCW perception of the patient in the facility. Research  
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47 400 conducted in Nigeria discovered that people with higher levels of education are frequently given  
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49 401 better and more considerate treatment by HCW, hence limited by a form of discrimination/  
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52 402 socioeconomic status bias [41,42].  
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3 403 The observed effect of training on patient experience is likely multifaceted potentially  
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6 404 stemming from increased attention and recall to the exit survey items which solicited a feeling of  
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8 405 empowerment to be more critical of the care received. In future studies, patient activation should be  
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10 406 measured as an outcome to see how training changes the patient's engagement with their care over  
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12 407 time [36]. Further research is required into why women TECs reported poorer experiences with care  
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15 408 than men. Other studies that have used SP to assess medical students' performance showed that  
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17 409 women were more critical on certain aspects of care. These studies also recommend matching of  
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19 410 SPs to clinicians by sex [43], something we were not able to do given the nature of our study in  
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22 411 primary health facilities where we assessed interpersonal communication with HCWs at all levels.  
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24 412 Perhaps our findings call for more investigation into the integration of women's services, such as  
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26 413 family planning and children's services with HIV care given some studies have shown this can  
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29 414 improve patient satisfaction.

### 30 31 415 **Limitations**

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33 416 Our findings should be interpreted with caution due to the following limitations. Because this  
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35 417 was the first time such a study was done, we recruited educated participants who were able to read  
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38 418 and write, perceived to have good recall ability and were able to comprehend things. Our study was  
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40 419 only done in Lusaka province in facilities that were largely urban except for one facility which was  
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42 420 peri-urban hence it is hard to generalise these findings. Another limitation in our approach is the  
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45 421 one-time cross-sectional nature of our measurements among people in long term HIV care. If more  
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47 422 measures were collected from each TEC, we may well see them being activated in a way that results  
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49 423 in an improvement in their experience based on the skills they develop to seek better care from  
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52 424 providers which ultimately would improve their retention in care. Despite its limitations, the TEC  
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54 425 method provides valuable information about healthcare quality, even though it is limited to  
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3 426 situations where "walk-ins" are permitted. Our approach only focused on real patients accessing  
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6 427 care and we did not manipulate any patient files, so it is possible that some TECs were known to the  
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8 428 facility as patients accessing chronic care. Our approach does require a trained interviewer to speak  
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10 429 with TECs after their visits, but this is not any different to what already exists. In future, it may be  
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12 430 worth using the domains in the national HIV guidelines as the gold standard, but we did not do this  
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15 431 as our aim was to come up with a low-cost approach that can easily be rolled out. In addition, the  
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17 432 concept of patient centred care is still catching on in Zambia. Our TEC approach can be used to  
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19 433 further the knowledge in provider attitudes to other relatively new approaches to delivering quality  
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22 434 HIV care such as differentiated service delivery (DSD) for stable patients by assessing whether  
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24 435 HCWs follow guidelines when offering this [32]. We also see an opportunity to assess provider  
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26 436 patient communication of viral load laboratory results by use of a universal script for each TEC to  
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29 437 assess if they are communicated to and if unsuppressed but adherent, what procedures followed.

## 31 32 438 **Conclusion**

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35 439 TEC offers pragmatic methods for health systems in low-income countries to assess non-  
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38 440 clinical dimensions of care (communication, respect, and autonomy) which are grounded on the  
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40 441 concept of health-system responsiveness and could be critical to the transformation of low-quality  
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42 442 health systems to high quality ones[44]. Hawthorne effects and social desirability biases may be  
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45 443 mitigated using TECs. We were able to capture HCWs behaviour in a normal day to day setting  
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47 444 [45]. Our findings suggest that TECs provide a more critical appraisal of some aspects of the quality  
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49 445 of HIV care. It provides new insights in the Zambian context on what patients' value when they  
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52 446 interact with the health system. This could be important given the need to reduce loss to follow up  
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54 447 among new ART clients who disengage within the first 6 months of treatment due to a bad first  
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3 448 encounter with the health system. Our TEC approach could be used to assess reengagement  
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5 449 interventions. The fact that TECs had a better understanding of the items solicited or felt empowered  
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8 450 to be more critical shows that the training we provided worked. This low-cost method could be  
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10 451 reproduced in other routine settings and presents an opportunity to further institutionalise patient  
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12 452 centred care by evaluating what happens at the point of contact between the patient, the health  
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15 453 facility, and the health provider. The implications are that it provides an opportunity to improve HIV  
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17 454 care, meet patients' expectations and can serve as a monitoring tool for healthcare performance.  
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19 455 Coupled with the recent approaches to client led monitoring in HIV care, our approach can be used  
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22 456 to enhance decision making that considers patients' involvement.  
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### **Data Availability Statement**

The Government of Zambia allows data sharing when applicable local conditions are satisfied. In this case, the data from the study will be made available to any interested researchers upon request. The CIDRZ Ethics and Compliance Committee is responsible for approving such request. To request data access, one must write to the Secretary to the Committee/Head of Research Operations, Mrs. Hope Chinganya ([Hope.Chinganya@cidrz.org](mailto:Hope.Chinganya@cidrz.org)) mentioning the intended use for the data. The Committee will then facilitate review and authorization to release the data as requested. Data requests must include contact information, a research project title, and a description of the intended use.

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## Contributors

KS: guarantor, lead author, conducted all analyses, led data management activities, field  
coordination of activities and designed data collection tools. JMP: field coordination of data, assisted  
with analysis and revising it critically for important intellectual content, designed data collection  
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BR: final approval for publication, assisted with framing and revising it critically for important  
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drafted statistical analysis plan, assisted with conceptualisation and interpretation of data. JM:  
assisted with data acquisition and cleaning, field coordination of data quality processes. SS: led  
intervention implementation, project administration and data curation. LKB, NM, AS: cognitively  
tested data collection tools, assisted with conceptualization, underlying data processes, and assisted  
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conceptualisation and advised regarding intervention implementation details. IS: funding

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3 516 acquisition, assisted with conceptualisation and manuscript writing. EHG: funding acquisition, led  
4  
5 517 conceptualisation and advised on all analyses, final approval for publication.  
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9 519

10 520 Ethics approval to conduct this research was granted by the Zambian Ministry of Health,  
11  
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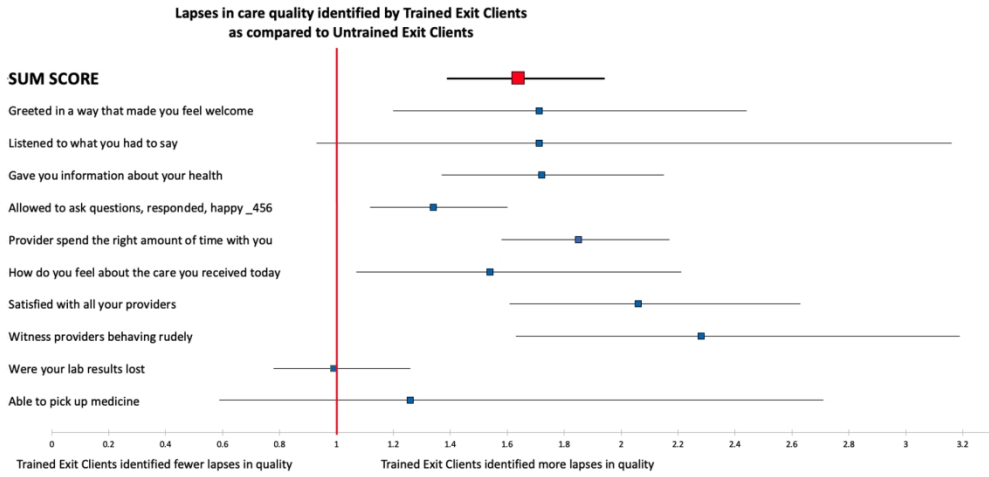
**Figure 1. Forest plot comparing responses from Trained Exit Clients (TEC) relative to Untrained Exit Clients (UEC) on 10 measures of clinic experience.** Points indicate the rate

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3 ratio (for sum score) or prevalence ratio (for all others) for identifying a lapse in care in TEC  
4 surveys as compared to UEC. The sum score represents the total number of binary responses (yes  
5 vs no) across all clients in one group shown as a rate ratio. The red line indicates a rate or  
6 prevalence ratio of 1 and values greater than this indicates more lapses in care identified in TECs.  
7 Results are based on mixed-effects models adjusted for age, sex, education with a random effect at  
8 the facility.  
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11 **Figure 2. Impact of Training on Identifying Care Lapses Stratified by Subgroups (N=3480).**  
12 When all questions were collapsed into a Sum score among TEC, females were more likely to report  
13 lapses in care quality than males. We observed some level of interaction for care status, age category,  
14 education category and facility size.  
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17 **Figure 3. Bubble plot showing Trained Exit Sum Score vs Untrained Exit Sum Score.** Each  
18 bubble represents a single facility's performance. Each bubble's size indicates the number of patients  
19 at each facility with larger bubbles corresponding to larger facilities. The horizontal position notes  
20 the Untrained Exit Sum Score for all questions against the facility, and the vertical position notes  
21 the Trained Exit sum score at the same facility.  
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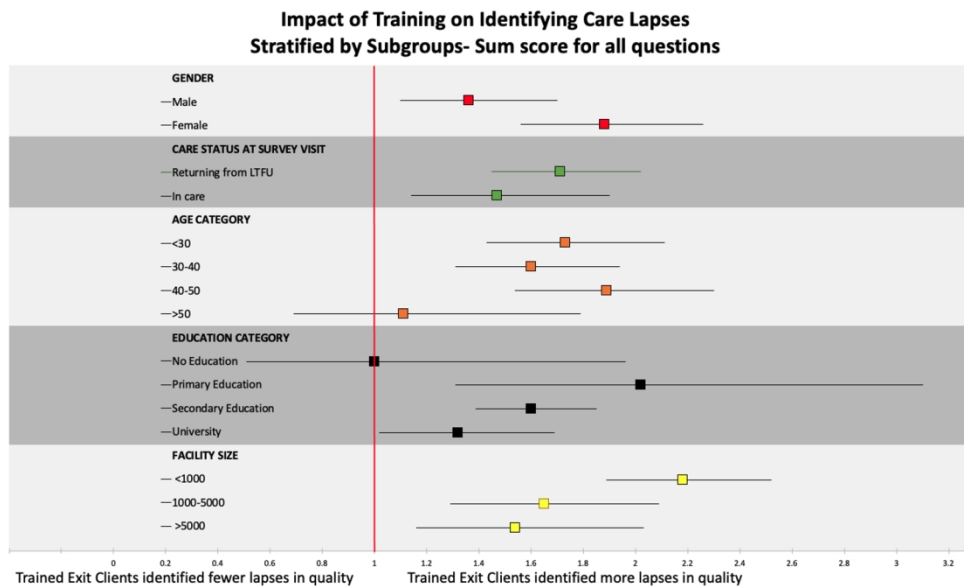
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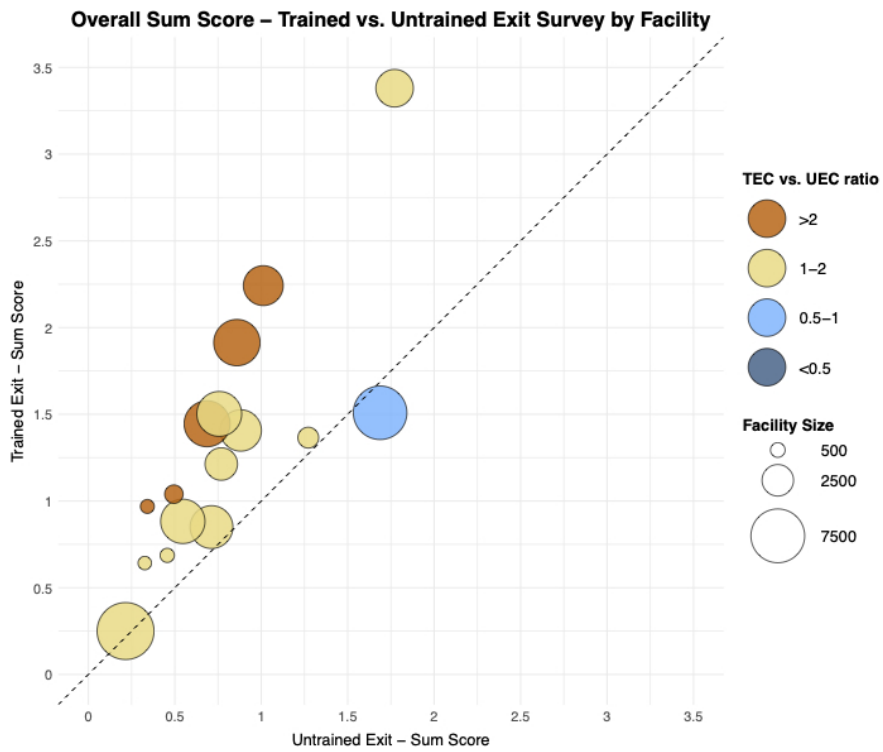
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## Supplementary Tables S1

**Supplementary Table S1. Mixed effect Poisson regression comparing 10 questions for Trained Exit Clients vs Untrained Exit Clients. Adjusted for age, sex, education, and study period.**

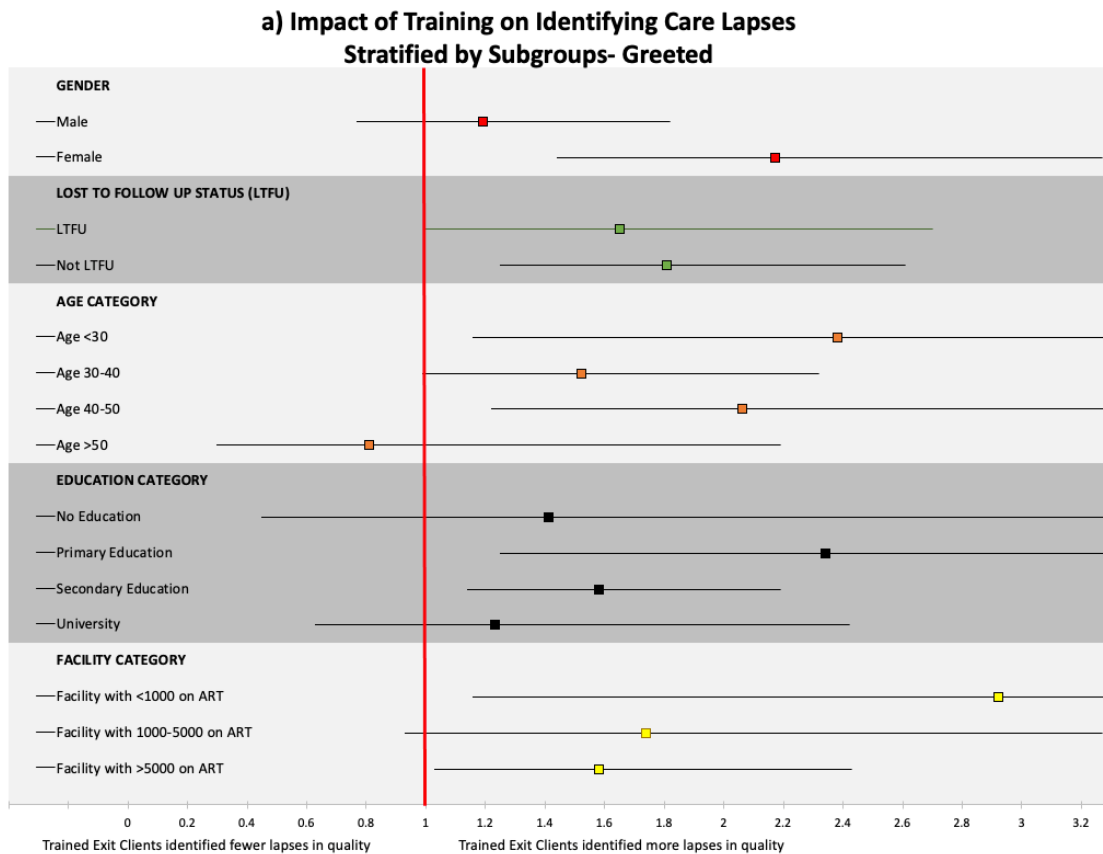
Trained Exit Clients	Prevalence ratio (PR) Unadjusted	P value	95% Confidence Interval (CI)	PR-Adjusted	P value	95% Confidence Interval (CI)	N
Sum score (Rate ratio)	1.73	<0.01	1.47-2.02	1.64	<0.01	1.39-1.94	3480
Did your HIV care provider greet you in a way that made you feel comfortable?	1.74	0.01	1.24-2.44	1.71	<0.01	1.20-2.44	3526
Did your HIV care provider listen to what you said?	1.77	0.09	0.91-3.45	1.71	0.09	0.93-3.16	3510
Did your HIV care provider give you as much information about your health as you wanted?	1.82	<0.01	1.43-2.33	1.72	<0.01	1.37-2.15	3526
Did your HIV care provider allow you to ask questions?	1.44	<0.01	1.20-1.73	1.34	<0.01	1.12-1.6	3517
Did your HIV care provider spend the right amount of time with you?	1.94	<0.01	1.66-2.27	1.85	<0.01	1.58-2.17	3520
Overall, how did you feel about the care you received today?	1.51	0.02	1.06-2.16	1.54	0.02	1.07-2.21	3515
Overall, were you satisfied with all your HIV care providers today?	2.12	<0.01	1.68-2.66	2.06	<0.01	1.61-2.63	3522
I witnessed HIV care providers behaving rudely during my visit today	2.39	<0.01	1.73-3.32	2.28	<0.01	1.63-3.19	3524
Were your lab results lost?	0.99	0.98	0.84-1.19	0.99	0.93	0.78-1.26	3522
Were you able to pick up your medicine today?	1.04	0.90	0.57-1.89	1.26	0.55	0.59-2.71	3525

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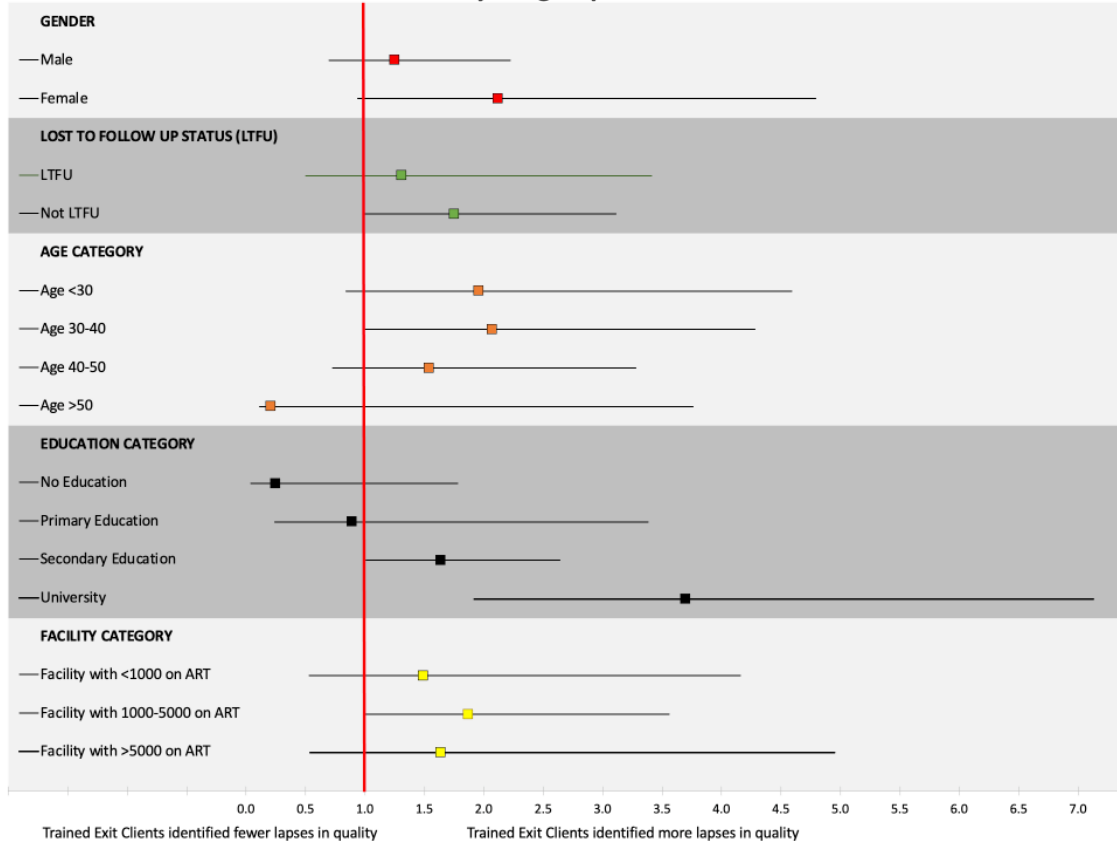
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Supplementary Figure 1.

**Impact of Training on Identifying Care Lapses Stratified by Subgroups for 10 questions.** We observed some level of interaction for care status, age category, education category and facility size. Panel **a)** Greet you in a way that made you feel comfortable **b)** Listen to what you said **c)** Give you as much information about your health as you wanted **d)** Allowed you to ask questions, responded, happy q456 **e)** spend the right amount of time with you **f)** feel about the care you received today **g)** satisfied with all your HIV care providers today **h)** witnessed HIV care providers behaving rudely during my visit today **i)** lost lab results **j)** pick up meds

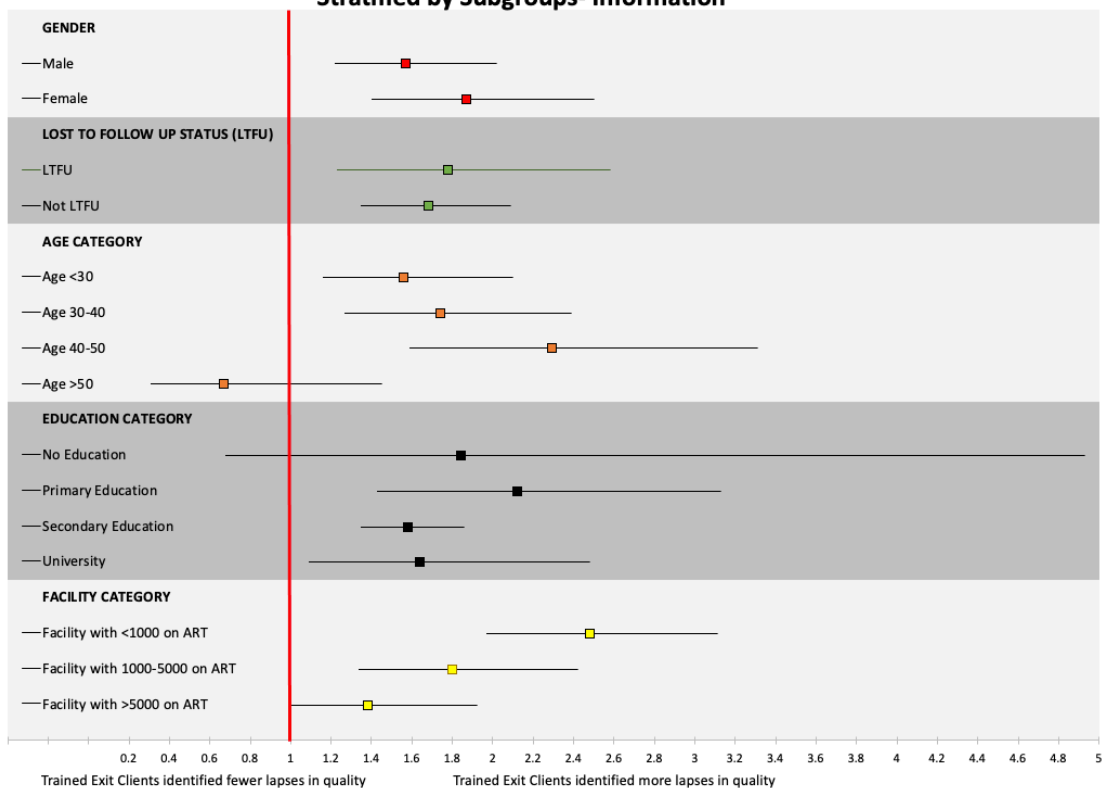


### b) Impact of Training on Identifying Care Lapses Stratified by Subgroups- Listened



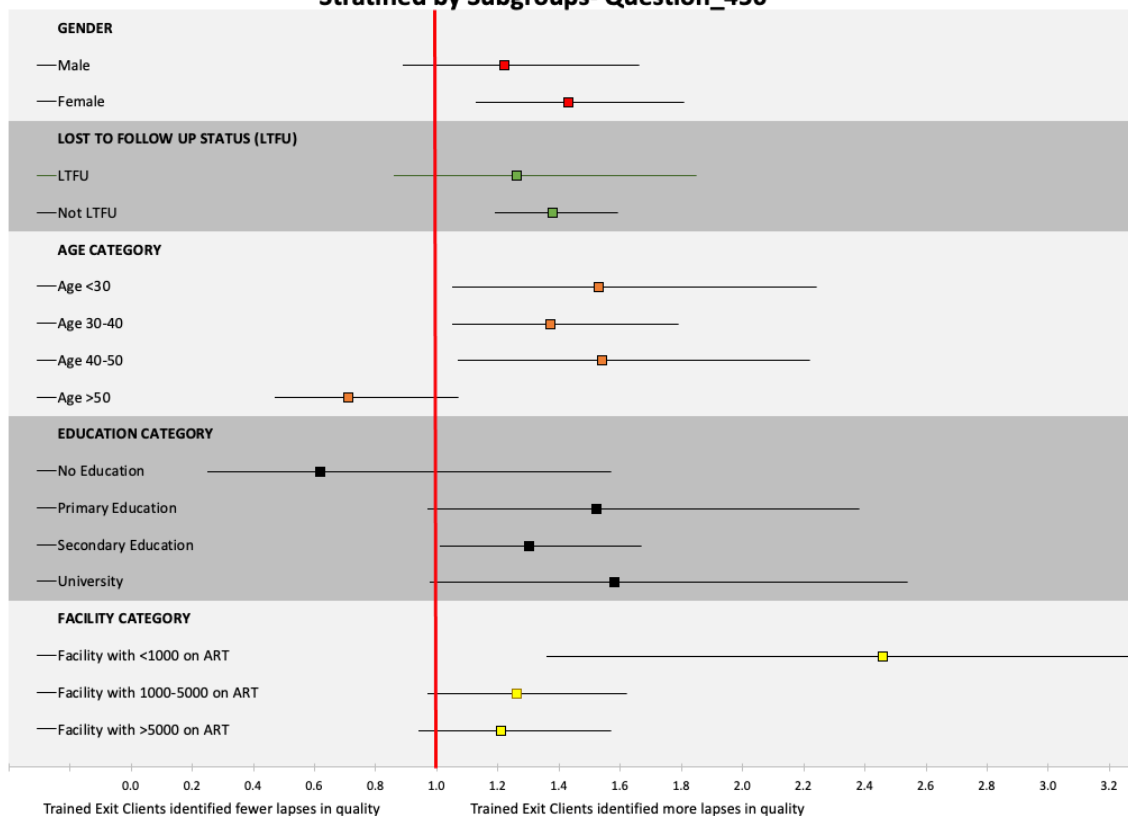
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**c) Impact of Training on Identifying Care Lapses  
Stratified by Subgroups- Information**



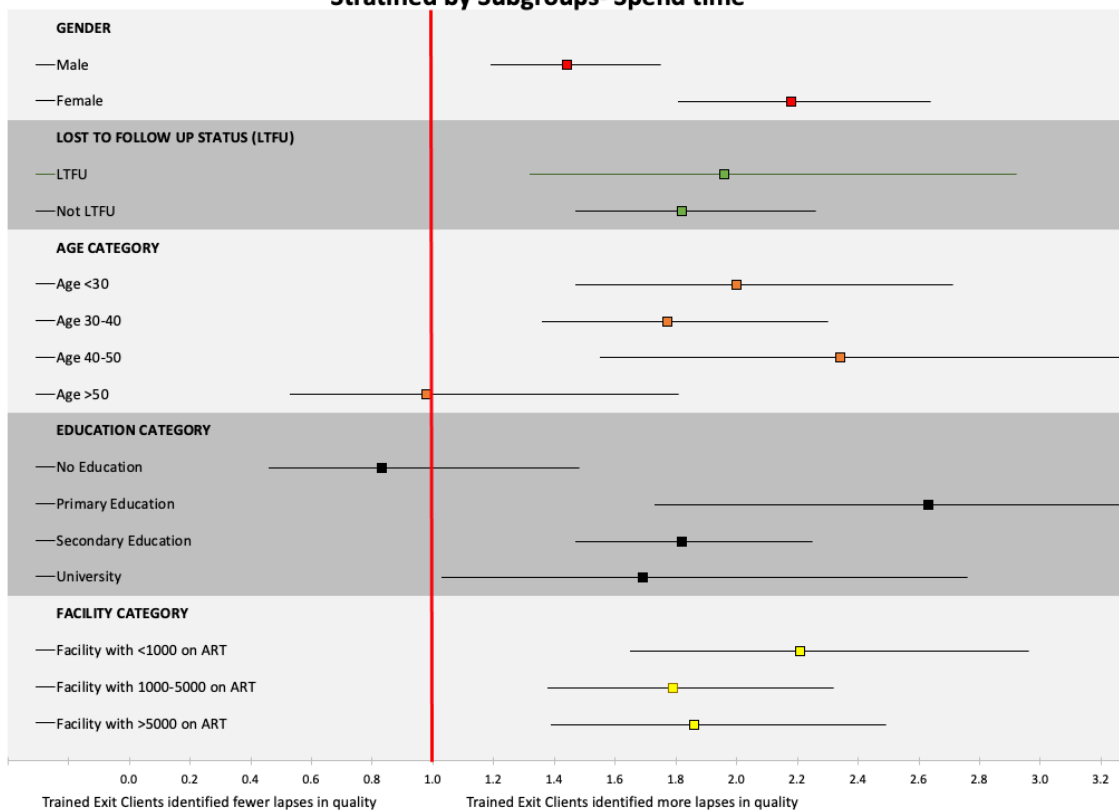
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**d) Impact of Training on Identifying Care Lapses  
Stratified by Subgroups- Question\_456**



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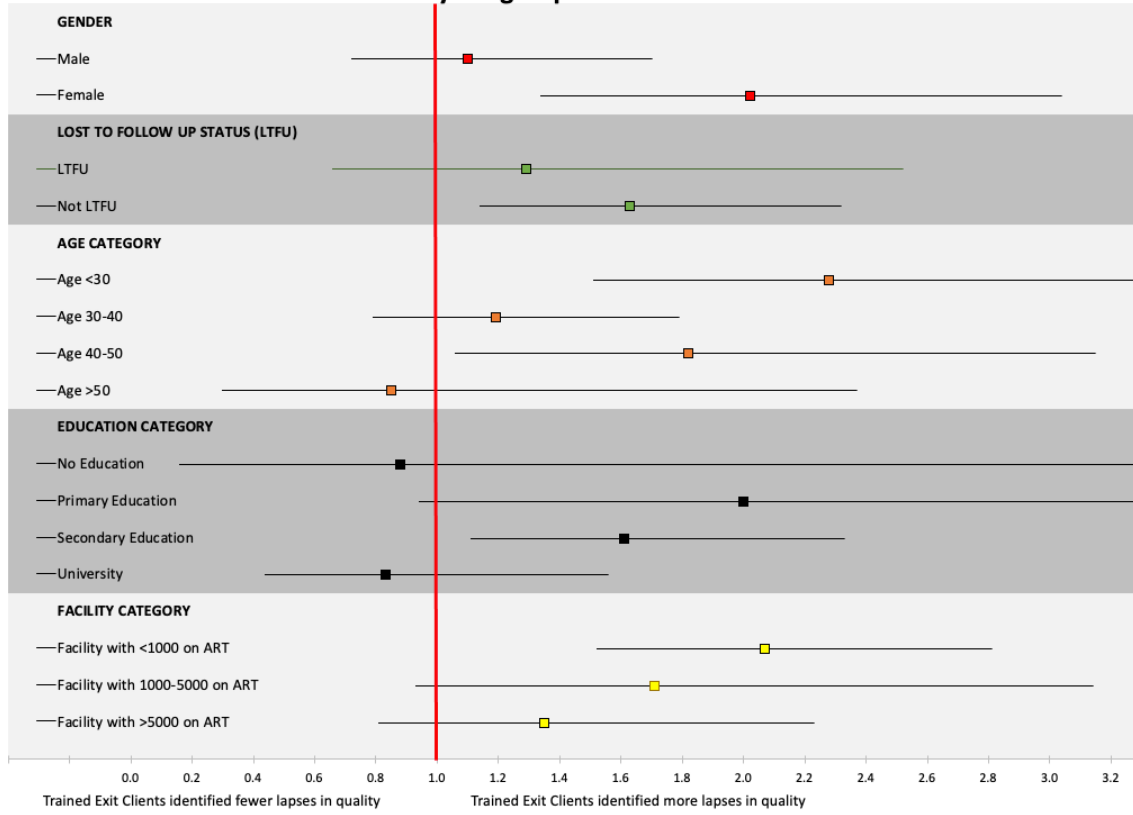
**e) Impact of Training on Identifying Care Lapses  
Stratified by Subgroups- Spend time**



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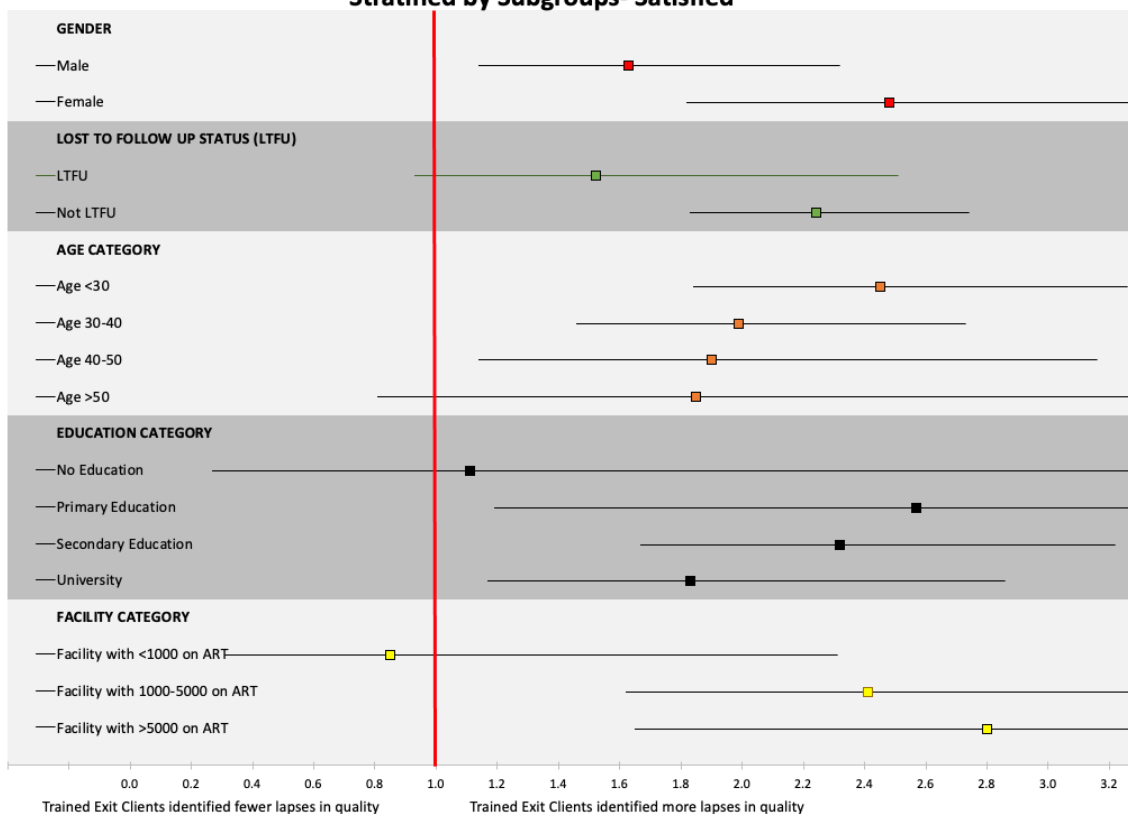


### f) Impact of Training on Identifying Care Lapses Stratified by Subgroups- Feel about care



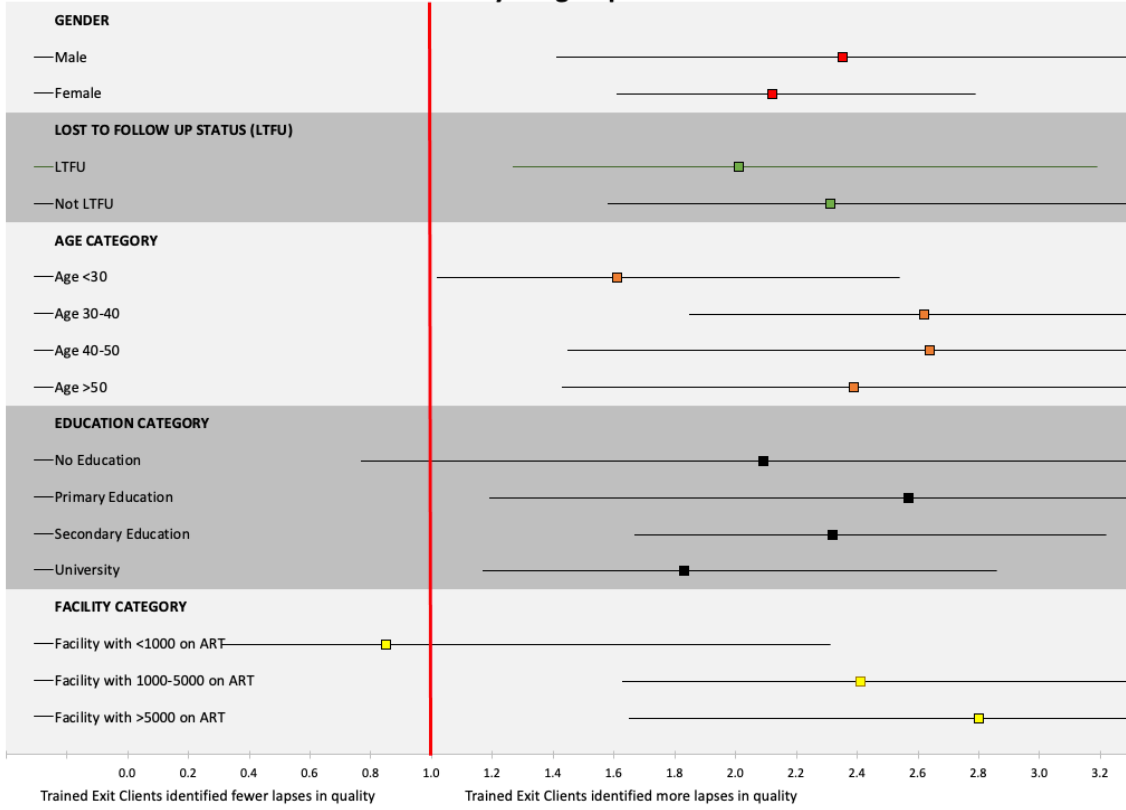
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**g) Impact of Training on Identifying Care Lapses  
Stratified by Subgroups- Satisfied**



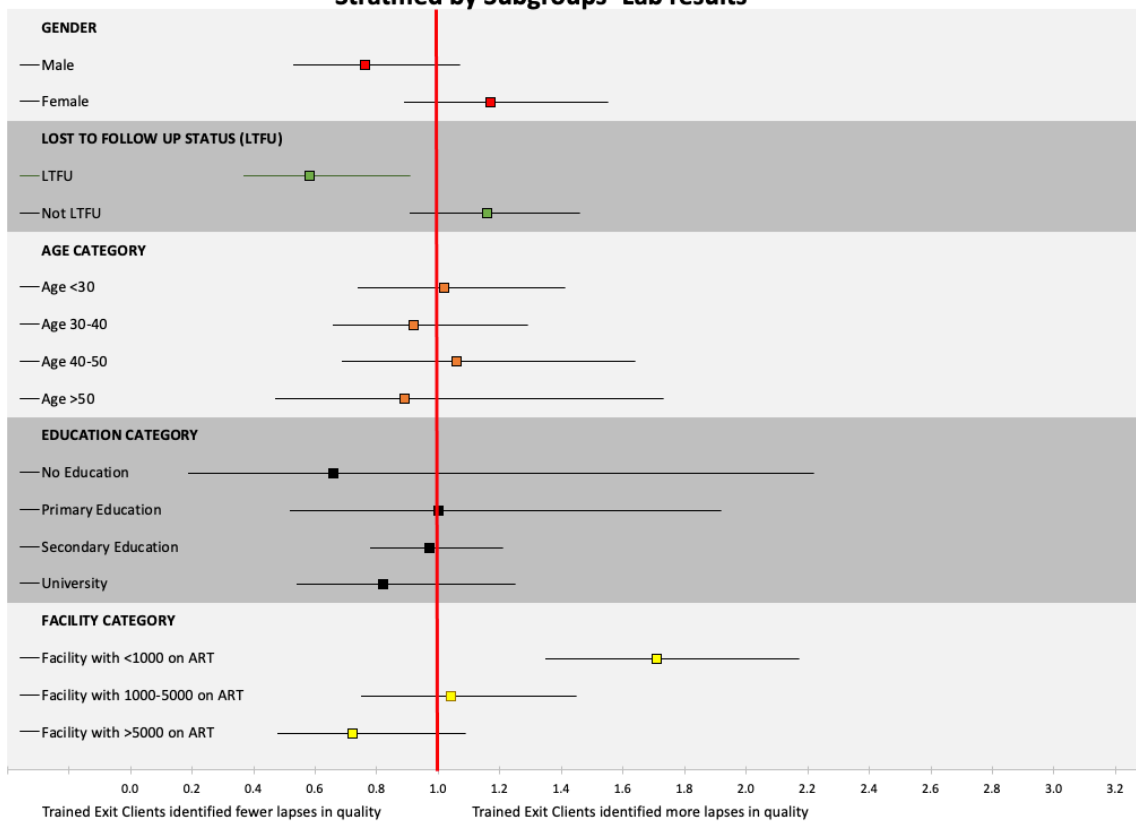
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### h) Impact of Training on Identifying Care Lapses Stratified by Subgroups- Rude



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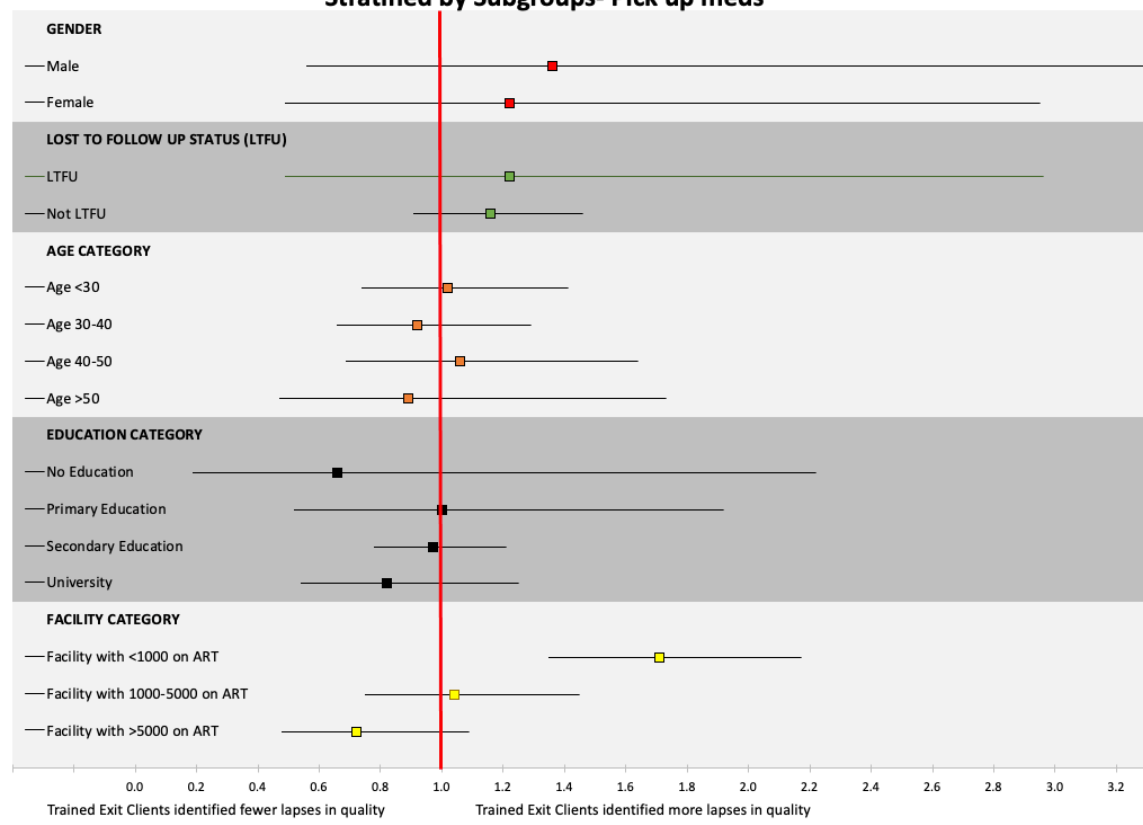
**i) Impact of Training on Identifying Care Lapses  
Stratified by Subgroups- Lab results**



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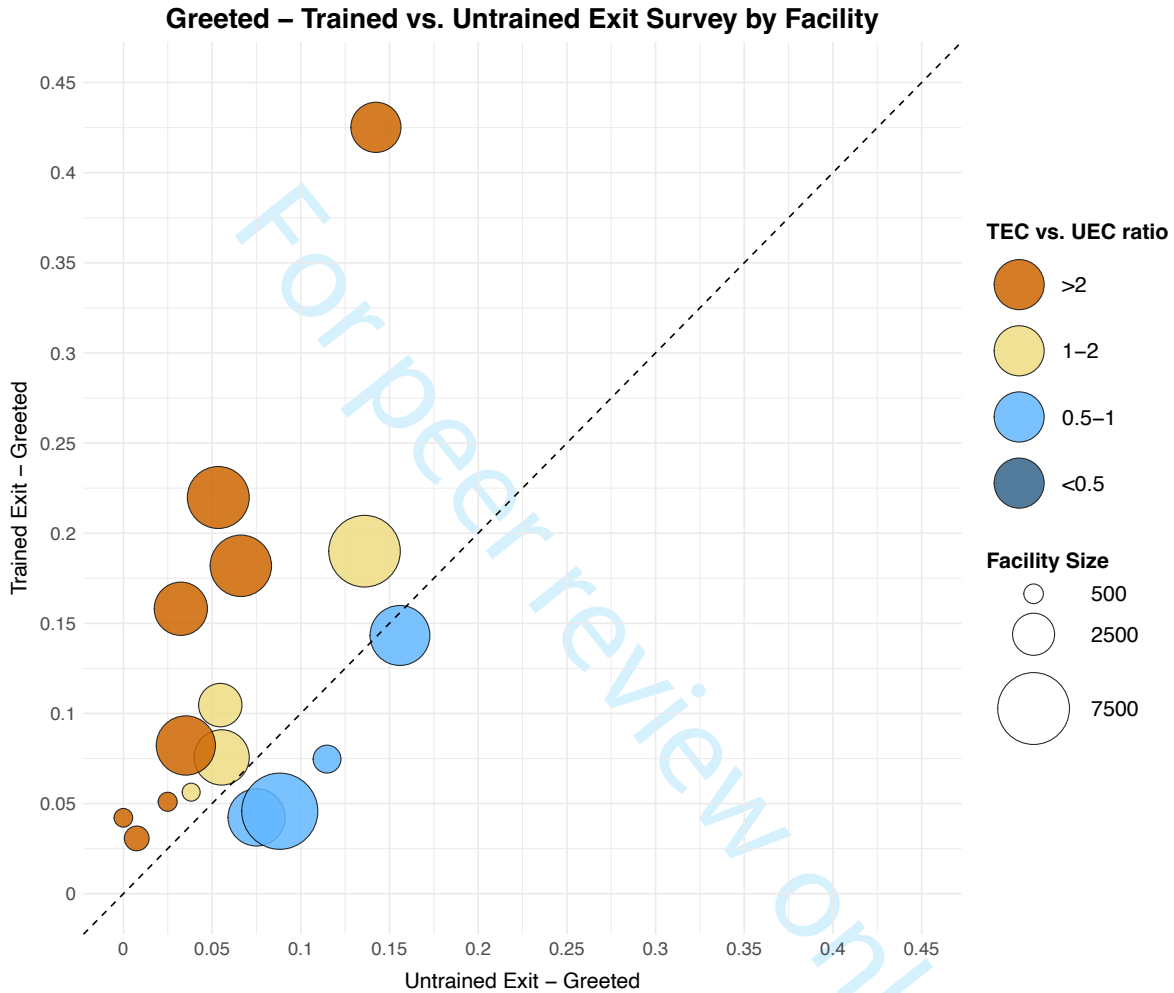
### j) Impact of Training on Identifying Care Lapses Stratified by Subgroups- Pick up meds

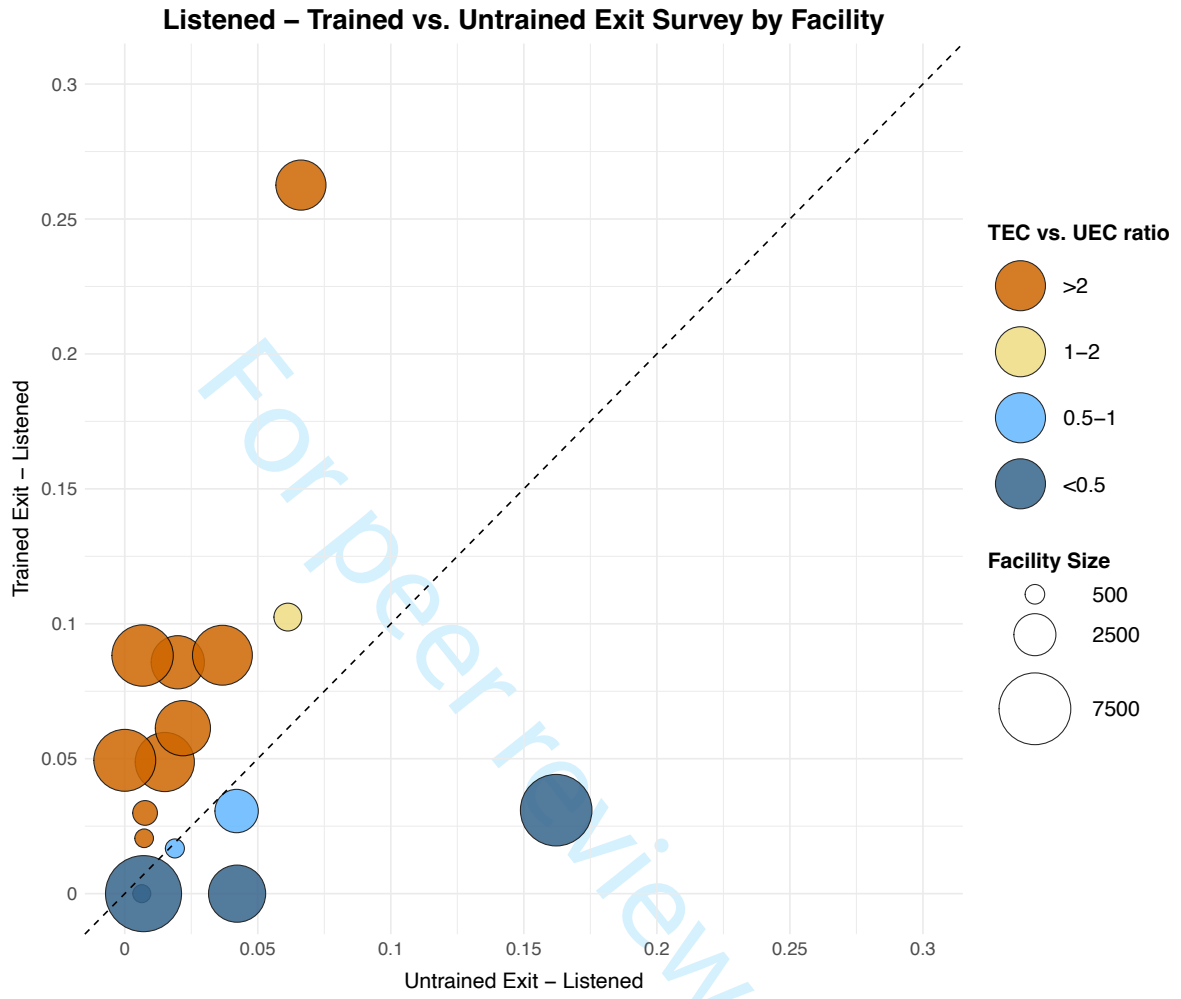


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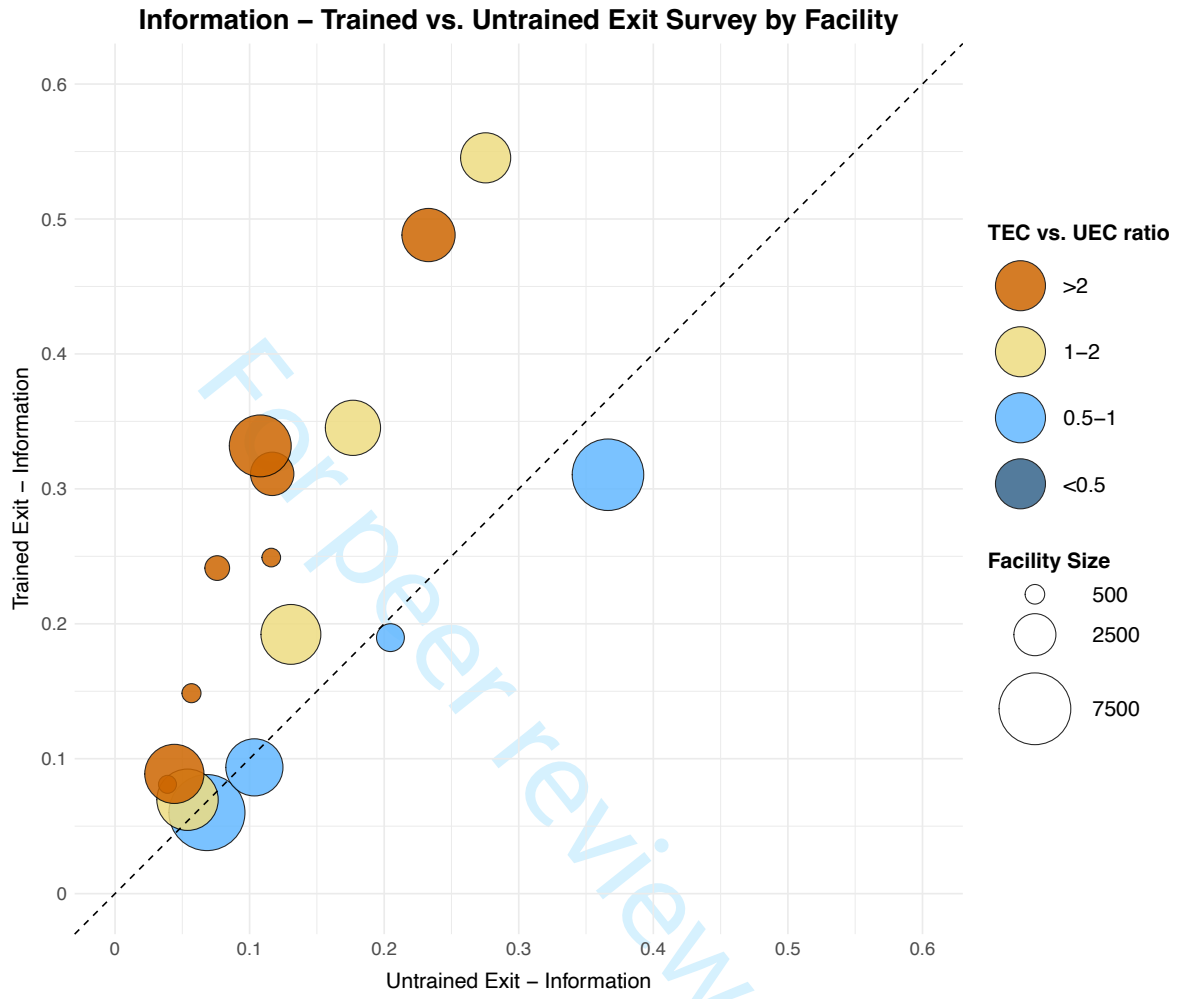
Supplementary Figure 2

**Supplementary Figure 2.** Bubble plot showing Trained Exit Sum Score vs Untrained Exit Sum Score. Each bubble represents a single facilities performance. Each bubble’s size indicates the number of patients at each facility with larger bubbles corresponding to larger facilities. The horizontal position notes the Untrained Exit Sum Score for all questions against the facility, and the vertical position notes the Trained Exit sum score at the same facility.



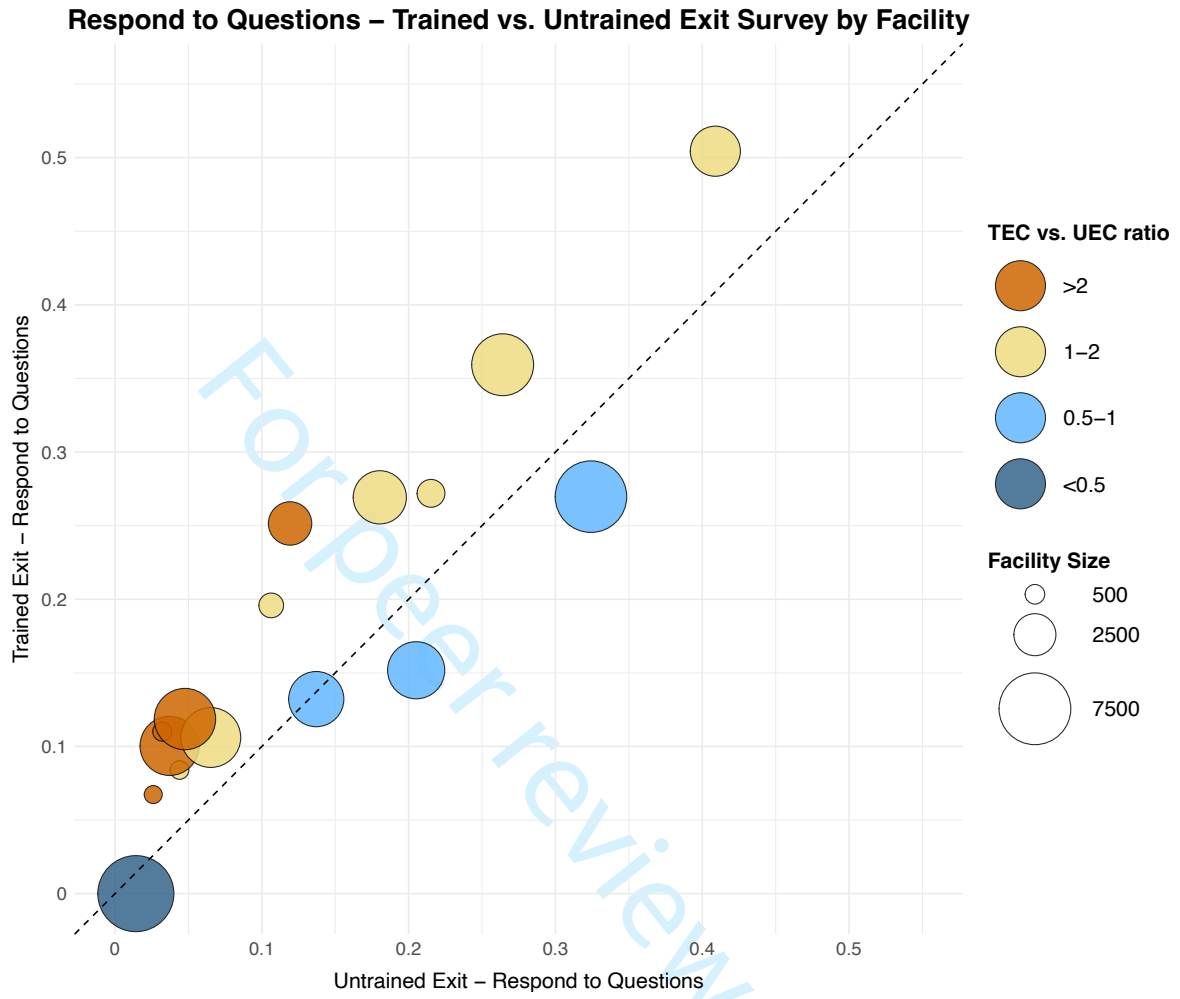


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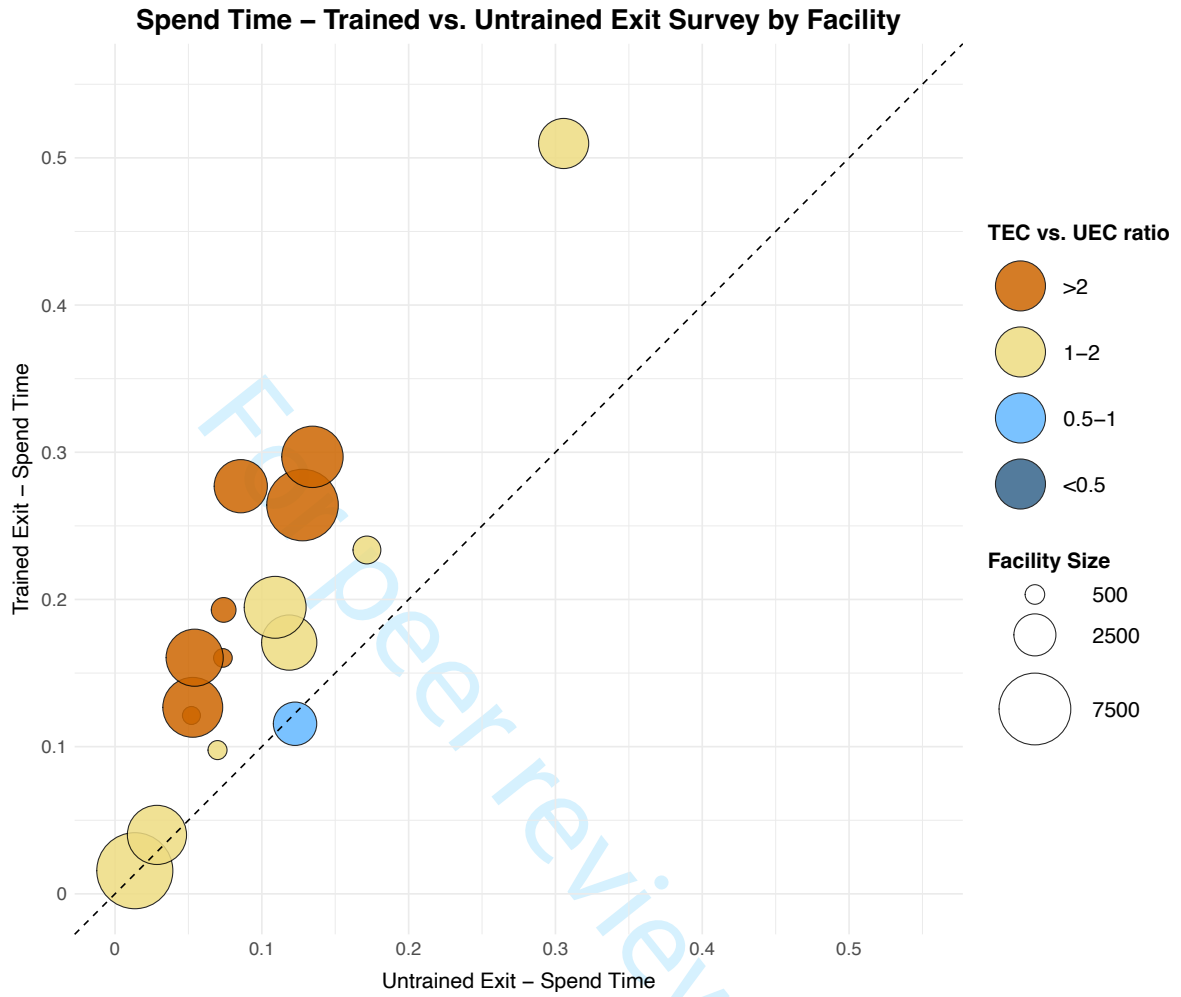


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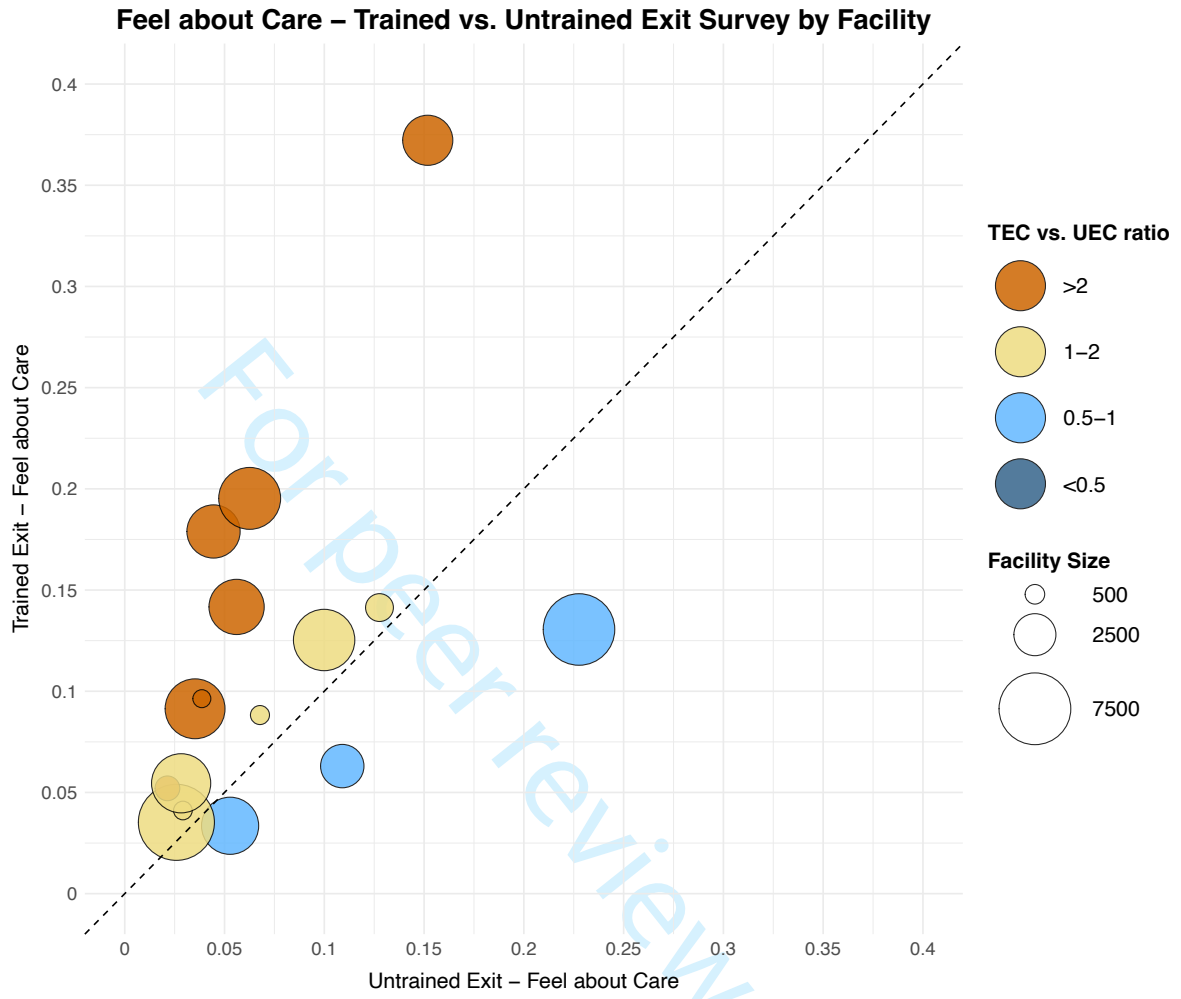


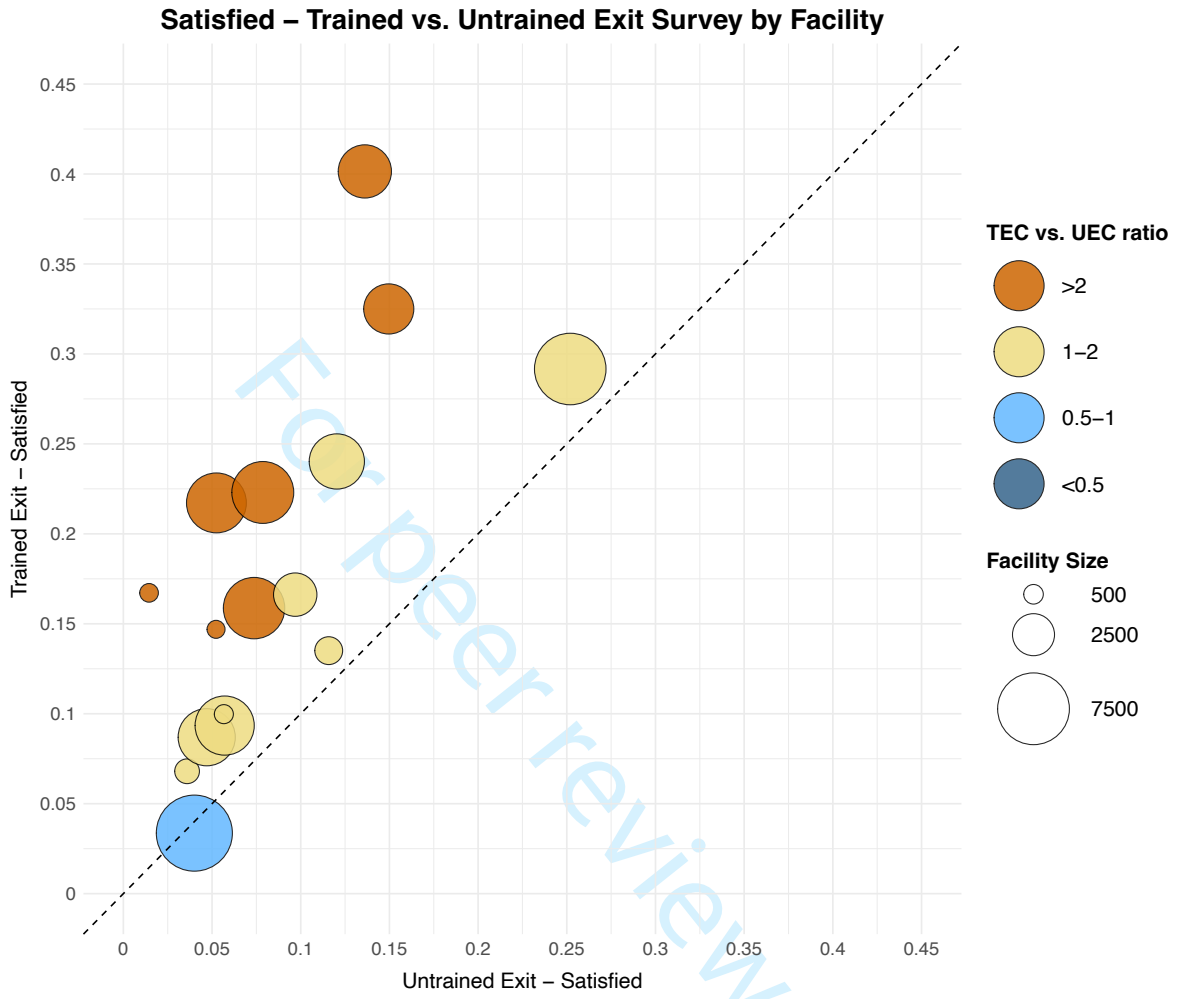


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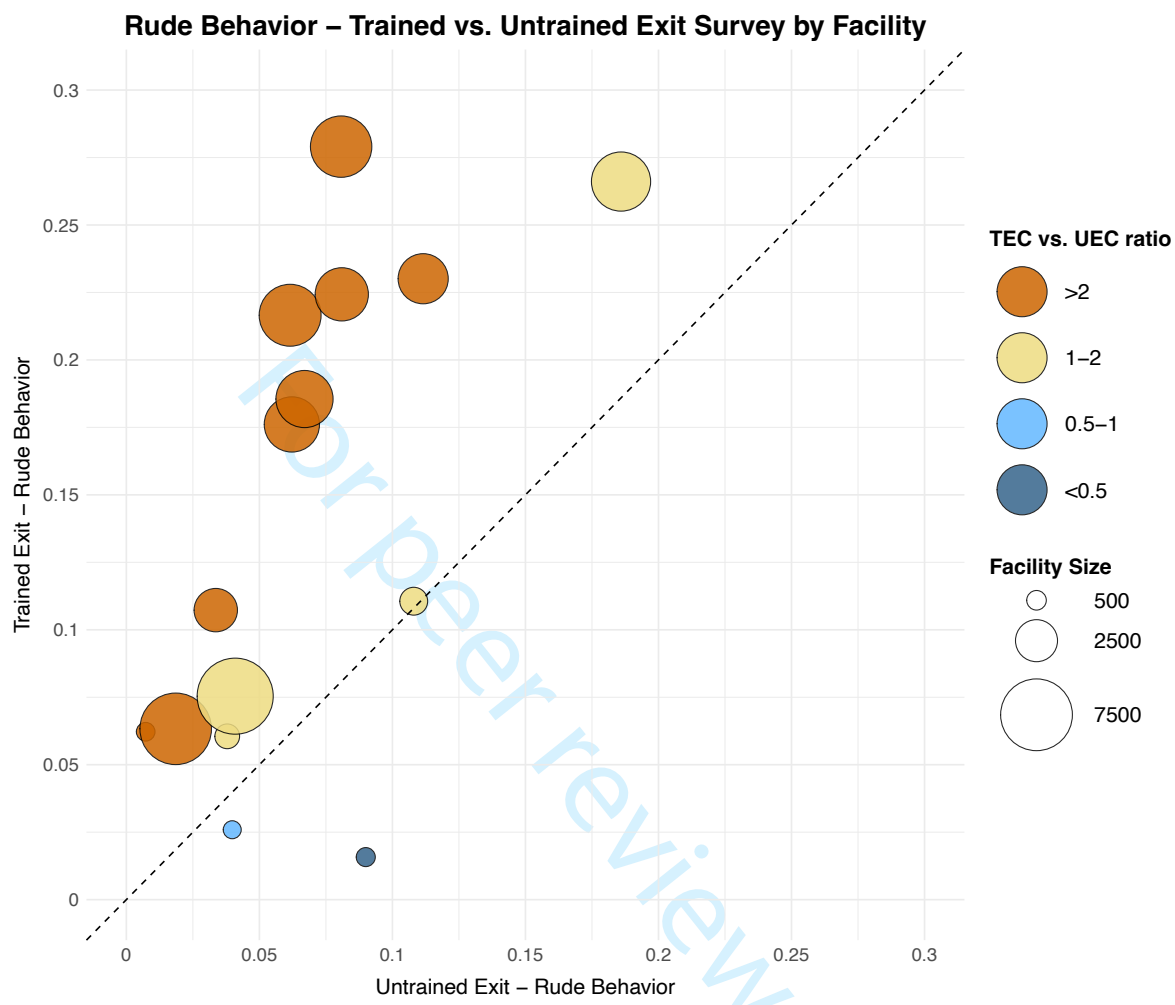


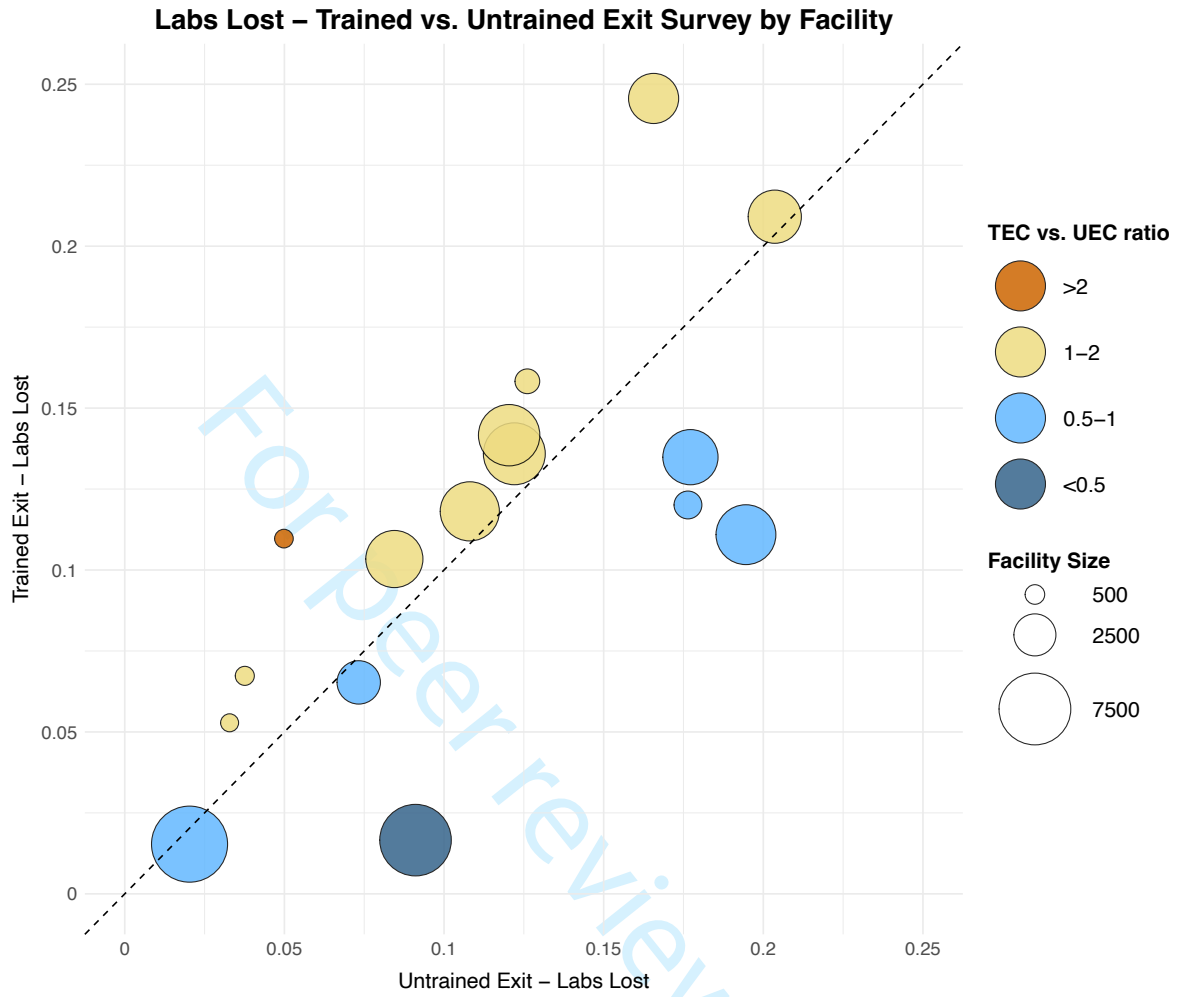
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## STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation	Page No
<b>Title and abstract</b>	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	1
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	1
<b>Introduction</b>			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	3,4
Objectives	3	State specific objectives, including any prespecified hypotheses	3
<b>Methods</b>			
Study design	4	Present key elements of study design early in the paper	4,5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	5
Participants	6	(a) <i>Cohort study</i> —Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up <i>Case-control study</i> —Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls <i>Cross-sectional study</i> —Give the eligibility criteria, and the sources and methods of selection of participants	5,6
		(b) <i>Cohort study</i> —For matched studies, give matching criteria and number of exposed and unexposed <i>Case-control study</i> —For matched studies, give matching criteria and the number of controls per case	N/A
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	5,7,8
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	5-7
Bias	9	Describe any efforts to address potential sources of bias	4
Study size	10	Explain how the study size was arrived at	8
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	7
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	7
		(b) Describe any methods used to examine subgroups and interactions	7
		(c) Explain how missing data were addressed	N/A
		(d) <i>Cohort study</i> —If applicable, explain how loss to follow-up was addressed <i>Case-control study</i> —If applicable, explain how matching of cases and controls was addressed <i>Cross-sectional study</i> —If applicable, describe analytical methods taking account of sampling strategy	N/A
		(e) Describe any sensitivity analyses	N/A

Continued on next page

<b>Results</b>			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	9
		(b) Give reasons for non-participation at each stage	9
		(c) Consider use of a flow diagram	N/A
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	9, 10
		(b) Indicate number of participants with missing data for each variable of interest	9,10
		(c) <i>Cohort study</i> —Summarise follow-up time (eg, average and total amount)	N/A
Outcome data	15*	<i>Cohort study</i> —Report numbers of outcome events or summary measures over time	N/A
		<i>Case-control study</i> —Report numbers in each exposure category, or summary measures of exposure	N/A
		<i>Cross-sectional study</i> —Report numbers of outcome events or summary measures	10
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	7,11
		(b) Report category boundaries when continuous variables were categorized	
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	12,14
<b>Discussion</b>			
Key results	18	Summarise key results with reference to study objectives	14,15
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	18
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	19,20
Generalisability	21	Discuss the generalisability (external validity) of the study results	18
<b>Other information</b>			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	20

\*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

**Note:** An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at [www.strobe-statement.org](http://www.strobe-statement.org).



# BMJ Open

## A Comparison of Patient Exit Interviews to Unannounced Standardised Patients for Assessing HIV Service Delivery in Zambia

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## A Comparison of Patient Exit Interviews to Unannounced Standardised Patients for Assessing HIV Service Delivery in Zambia

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## ABSTRACT

**Objectives:** To compare the use of an unannounced standardised patient approach (e.g., mystery clients) to typical exit interviews for assessing patient experiences in HIV care (e.g., unfriendly interactions with providers, long-waiting times). We hypothesize standardized patients would report more negative experiences than typical exit interviews affected by social desirability bias.

**Setting:** Cross-sectional surveys in 16 government-operated HIV primary care clinics in Lusaka, Zambia providing antiretroviral-therapy (ART).

**Participants:** 3526 participants aged  $\geq 18$  years receiving ART participated in the exit surveys between August 2019 and November 2021.

**Intervention:** Systematic sample (every  $k^{\text{th}}$  file) of patients in clinic waiting area willing to be trained received pre-visit training and post-visit interviews. Providers were unaware of trained patients.

**Outcome measures:** We compared patient experience among patients that received a brief training prior to their care visit (explaining each patient experience construct in the exit survey, being anonymous, without manipulating behaviour) with those who did not undergo training on the survey prior to their visit.

**Results:** Among 3526 participants who participated in exit surveys, 2415 were untrained (56% female, median age 40 (IQR:32-47)) and 1111 were trained (50% female, median age 37 (IQR:31-45)). Compared to untrained, trained patients were more likely to report a negative care experience overall (adjusted Prevalence Ratio aPR for aggregate sum score: 1.64 [95% CI:1.39-1.94]), with a greater proportion reporting feeling unwelcomed by providers ([aPR]: 1.71 [95% CI:1.20-2.44]) and witnessing providers behaving rude (aPR: 2.28 [95% CI:1.63-3.19]).

**Conclusion:** Trained patients were more likely to identify sub-optimal care. They may have understood the items solicited better or felt empowered to be more critical., We trained existing patients, unlike studies that use “standardised patients” drawn from outside the patient population. This low-cost strategy could improve patient-centred service delivery elsewhere.

**Trial registration:** Assessment was nested within a parent study. [www.pactr.org](http://www.pactr.org) registered the parent study (PACTR202101847907585).

## STRENGTHS AND LIMITATIONS OF THIS STUDY

- We demonstrate feasibility of a standardised patient (SP) approach designed to assess chronic care in which real, not simulated, patients are trained before their upcoming encounters.
- Traditional SP techniques require a trained simulated patient to visit multiple clinics, a strategy more appropriate for episodic care rather than chronic care.
- Modified SP approaches can address these rigorous and pragmatic challenges of integrating patient experience into chronic routine public health- a crucial indicator of quality for governments and funders.
- We trained patients to evaluate quality of care (e.g., waiting times, rude providers), and compared their responses to traditional untrained exit surveys in 16 facilities in Zambia.
- How to train remains a challenge as we did not recruit participants who were not able to read and write, perceived to have bad recall ability and potentially unable to comprehend.

## BACKGROUND

Because of improved testing, linkage, and treatment to meet the global 95-95-95 treatment targets (95% of HIV-positive patients know their status, 95% are on treatment, and 95% have suppressed viral loads) [1], retention in care have become a major obstacle to improving Human Immunodeficiency Virus (HIV) treatment outcomes, and health systems in low-income settings like Zambia, have sought to shift their public health response by designing and delivering high quality and patient-centred HIV care [2–7]. Efforts to improve service quality and patient experience require systematic measurement of the patient experience to guide facility responses as poor patient experience has been shown to lead to disengagement from care [8–12]. Health policymakers and donors, such as the President's Emergency Plan for AIDS Relief (PEPFAR), have invested in clinical metrics to assess care quality in Zambia and the wider region, but to a lesser extent in non-clinical metrics like patient experience [13]. These metrics can be critical for guiding efforts to improve retention in care by ensuring an informed response to improving quality of care and patient centredness.

Accurate and pragmatic measurement of the patient experience poses a range of challenges. Patient experience exit surveys are prone to social desirability bias because of power dynamics in health care. Empirical studies of satisfaction, for example, are widely believed to over-estimate patient satisfaction [14]. This may be particularly true where provider-patient relationships are traditional and hierarchical. Delaying surveys for some time after the encounter is theorised to ameliorate social desirability bias, but in turn may exacerbate bias due to simple inability to remember — thus creating recall bias [7,15]. Other methods such as direct clinical observations of care pose practical difficulties [14,16]. For example, direct observations may be intrusive and

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3 160 therefore may not reflect everyday functionality of a health facility. Care provided under direct  
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6 161 observations may be of higher quality as behaviour may be influenced by observation, a  
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8 162 phenomenon often known as the “Hawthorne effect” [14,16].  
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11 163 Standardised patients (SP), also known as “mystery clients” or “simulated patients” have  
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14 164 largely been used to assess quality of care in developed countries, as well as in assessing customer  
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16 165 service in the retail industry[17]. SP can be resource-intensive and require training, but reduce  
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18 166 potential for recall bias, social desirability, bias, and Hawthorne effects, providing an opportunity  
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21 167 for optimal assessment of patient satisfaction among people receiving HIV care [7,15,18]. They  
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23 168 have largely been used for episodic care where a highly skilled and well-trained person poses as a  
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25 169 client by making one visit to multiple facilities. This approach holds promise for assessing the  
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27 170 patient experience in HIV care but poses pragmatic challenges when assessing the quality of chronic  
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30 171 care in which a patient makes multiple visits and may compromise efficiency at, already  
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32 172 overburdened, facilities [19–24]. In this study, we report on the development and evaluation of a  
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34 173 modified SP approach in which we trained real patients (trained exit clients - TEC) to report on  
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37 174 certain characteristics of encounters, and rate key components of care such as waiting times,  
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39 175 communication, respectfulness of providers, and privacy.  
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## 42 43 176 **METHODS**

### 44 45 177 **Study design & setting**

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47  
48 178 This study seeks to compare two different methods for assessing patient experience: standard  
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50 179 exit survey and those reported by patients who had a brief training on the items before the clinical  
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52 180 encounter and to whom the clinic was blinded. The assessment was nested within a parent study:  
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55 181 the Leveraging Person-Centred Public Health (PCPH) to improve HIV outcomes in Zambia study  
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3 182 ([www.pactr.org](http://www.pactr.org) PACTR202101847907585), a Stepped Wedge Cluster Randomised Trial that  
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6 183 occurred between August 2019 and November 2021. The aim of the overall PCPH study was to  
7  
8 184 assess the impact of introducing health care workers (HCW) to a patient-centred care (PCC)  
9  
10 185 curriculum and mentoring them on PCC principles to improve retention and viral suppression in  
11  
12 186 HIV care. In this nested sub-study, we compared cross sectional surveys of patient experience using  
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15 187 two different survey methods: adapted standardised approach (Trained Exit Clients) vs traditional  
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17 188 exit surveys.  
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## 19 189 20 21 190 **Population**

22  
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24 191 The sub-study reported here included 16 health facilities in Lusaka, Zambia, operated by the  
25  
26 192 Ministry of Health (MOH) and receiving technical assistance from the Centre for Infectious  
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28 193 Diseases Research in Zambia (CIDRZ) - a Zambian non-governmental organisation (NGO) as well  
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30  
31 194 as a part of the larger parent study. We surveyed adults aged 18 years and over who were accessing  
32  
33 195 antiretroviral therapy (ART) at study facilities. Exit survey patients were selected in a systematic  
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35 196 sample (every  $k^{\text{th}}$  file varied by facility size) at the time of exit from the clinic. Trained patients were  
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38 197 recruited in the waiting room for their visit, underwent a brief training, and then answered survey  
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40 198 questions on exit from their encounter. Participants attending an HIV care visit on the day, able to  
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42 199 recall events and comprehend study participant recruitment details (as assessed using the  
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44  
45 200 comprehension assessment tool) and able to read and write (assessed using literacy tool) were  
46  
47 201 eligible for inclusion.  
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## 49 202 50 51 203 **Procedures and Measurements**

### 52 53 54 204 Survey Instrument

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3 205 For both survey methods, we developed a patient experience instrument based on a previously  
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6 206 validated tool developed and used in Kenya: The Wachira Physician-Patient Communication  
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8 207 Behaviours Scale [25–27]. This survey assessed elements of patient experience including how they  
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10 208 were greeted, communicated to, and overall experience. We included additional questions to capture  
11  
12 209 for example, patient reports of witnessing rude behaviour, receiving appropriate medications and  
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15 210 availability of lab results. Prior to use in this study, we performed cognitive interviews among  
16  
17 211 twenty participants to assess consistency in understanding questions in English, Bemba and Nyanja.  
18  
19 212 Surveys were forward and back translated to ensure consistency across the three languages. The  
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21  
22 213 survey tools for trained and untrained clients were identical. Research assistants were trained by the  
23  
24 214 first author in recruitment, training and administering of the TEC and UEC survey in all 16 facilities.  
25  
26 215 The provincial and district health management teams were informed about the unannounced TEC  
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29 216 survey as well as the UEC survey. The study team sensitised all facility staff at the start of the study,  
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31 217 but HCWs were not aware of who specific TECs were.  
32

### 33 218 Procedures for Trained and Untrained Exit Clients

34  
35 219  
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38 220 Efforts to “standardise” assessment of the quality and nature of care in HIV care differs from  
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40 221 most previously standardised patient or mystery client work in that HIV care is longitudinal as  
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42 222 opposed to episodic or acute care. Under these circumstances, the more conventional standardised  
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45 223 patient where a single trained actor can present to multiple different care facilities as a simulated  
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47 224 patient with a defined set of symptoms or complaints to assess a single episode of care is not feasible.  
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49 225 For example, a patient would have to either register as a new patient or have a false “file” introduced  
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52 226 into the paper and electronic medical records — which was deemed infeasible and undesirable.  
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3 227 Instead of simulated patients, we recruited existing patients already receiving care at a particular  
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5 228 facility and then subsequently trained them on the concepts of quality of care according to the MOH  
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7 manual on Quality Improvement for HCWs in Zambia. To avoid disclosing their trained status,  
8 229  
9 patients were recruited on the day of their visit prior to them entering the triage area (i.e., the first  
10 230  
11 point of contact with HCWs). Those who consented underwent a single one-on-one training session  
12 231  
13 for 40 to 60 minutes where they were sensitised to the study instrument (which was the same for  
14 232  
15 both TEC and untrained exit clients (UEC)), the MOH care standards, and strategies on being natural  
16 233  
17 yet observant during their clinic visit for that day according to the standard SP approach. These  
18 234  
19 procedures were meant to ensure patients had a clear and uniform understanding on what they should  
20 235  
21 expect during a high-quality patient visit and were attentive to these critical aspects relative to these  
22 236  
23 standards. Immediately after this training, the TEC presented themselves to their facility and  
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25 completed their visit as they normally would. After their clinic encounter, participants then  
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27 completed the exit survey in a private area.  
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33 240 For the untrained exit surveys, we took a systematic (every  $k^{th}$ , varied by facility size) sample  
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35 241 among the patients leaving the facility after attending the clinic on the survey day. Patients were  
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37 approached by study staff after the visit using a recruitment script to determine their eligibility and  
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39 were administered the survey after granting consent in a private area.  
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42 244 For both trained and untrained clients, all interviews and surveys were conducted in either  
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44 English, Bemba or Nyanja depending on the participant's preference. Given the extra time  
45 245  
46 commitments required for the training, TEC participants were given K100 (~\$5) for the time spent  
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48 during training as well as a light snack during the survey administration.  
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## 51 248 52 53 54 249 **Statistical Analysis**

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3 250 To assess the association between training and response for each question, we conducted  
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6 251 unadjusted and adjusted Poisson regression for each question separately [28]. We then assessed the  
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8 252 overall association between training and total sum score. We used descriptive statistics to  
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10 253 characterise patient characteristics and report survey responses. In these analyses, most of the survey  
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12 254 responses were reverse coded to identify when respondents reported a negative experience. Results  
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14  
15 255 for individual questions (binary response) represent prevalence ratios for reporting a lapse in care.  
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17 256 To assess the sum score (count data) we used Poisson regression, estimating the rate ratio for  
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19 257 reporting lapses in care. All models were adjusted, given potential differences in survey participants  
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21  
22 258 related to different recruitment strategies using mixed-effects regression, adjusted for age, sex,  
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24 259 education, care status at the time (i.e., continuously retained in care versus returning to care after  
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26 260 disengagement/ lost to follow up [LTFU]), secular time (using cubic splines), allowing random  
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29 261 effects at the facility level. We present these results for the overall population as well as stratified  
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31 262 by different pre-defined patient subgroups. Lastly, we used bubble plots to compare summary  
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33 263 assessments of the patient experience at the facility-level using TECs versus UECs. All analyses  
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35 264 were performed using STATA 14MP (StataCorp, College Station, TX, USA). This sub-study  
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38 265 represents a secondary analysis and no formal power calculations were performed for this outcome.  
39  
40 266

### 41 42 267 **Statement of Ethics Approval**

43 268  
44 269 Ethics approval to conduct this research was granted by the Zambian Ministry of Health,  
45  
46  
47 270 National Health Research Authority, and the institutional review boards of the University of Zambia  
48  
49 271 (008-03-19), the University of Alabama at Birmingham (300003282) and the London School of  
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51  
52 272 Hygiene and Tropical Medicine (21384).  
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54 273

## Patient and Public Involvement

Survey questions were developed through a cognitive process with recipients of care. Study implementation guidance was conducted as part of routine CIDRZ partnership with the Zambian MOH through a Human Centered Design workshop. CIDRZ engages with implementing partners and affected communities in health facilities, including people living with HIV often represented by neighbourhood health representatives. Although patients were not directly involved in the design of the parent study intervention or the analysis presented here, all study activities were guided by a Scientific Advisory Board with representation from the MOH and a representative of recipients of HIV care. Dissemination of study results is ongoing.

## RESULTS

### Characteristics of health facilities and patients

We approached 4375 clients (2955 in the untrained and 1420 in the trained), and 3526 participated, of which 2415 (55.2%) completed experience surveys as untrained exit clients (UEC) (56% female, median age was 40 years (interquartile range [IQR]:32-47 years)) and 1111 (32%) completed experience surveys as trained exit clients (TEC) (50% female with a median age 37 years (IQR:31-45 years). Reasons for non-participation included unavailability at the time due to other commitments. Sixteen percent (16%) of UECs and 40% of TECs who had been lost to care and were returning to care on the day of the survey. Education levels differed between UEC and TEC with 47% and 58% reporting completion of secondary level of education, respectively (Table 1). UEC and TEC were similar for HIV enrolment WHO stage with the largest proportion enrolling at WHO stage 1 and similar in terms of marital status.

**Table 1. Socio-demographic characteristics of untrained exit and trained exit clients**

<b>Characteristics</b>	<b>Level</b>	<b>Untrained Exit Clients n=2415 (68%)</b>	<b>Trained Exit Clients n=1111 (32%)</b>
<b>Sex, n (%)</b>			
	<b>Female</b>	1355 (56)	553 (50)
	<b>Male</b>	1060 (44)	558 (50)
<b>Age, Median (IQR)</b>			
		40 (32-47)	37 (31-45)
<b>Age category, n (%)</b>			
	<b>&lt;30 years</b>	453 (19)	258 (23)
	<b>30-40 years</b>	828 (34)	416 (37)
	<b>40-50 years</b>	815 (34)	304 (27)
	<b>&gt;50 years</b>	319 (13)	133 (12)
<b>Education category</b>			
	<b>None</b>	132 (5)	36 (3)
	<b>Primary</b>	654 (27)	166 (15)
	<b>Secondary</b>	1134 (47)	645 (58)
	<b>University</b>	150 (6)	100 (9)
	<b>Missing</b>	307 (13)	151 (14)
<b>HIV Enrollment Stage</b>			
	<b>WHO Stage 1</b>	1173 (49)	533 (48)
	<b>WHO Stage 2</b>	314 (13)	147 (13)
	<b>WHO Stage 3</b>	355 (15)	162 (15)
	<b>WHO Stage 4</b>	27 (1)	7 (1)
	<b>Missing</b>	546 (23)	262 (24)
<b>Care status at survey visit</b>			
	<b>In care</b>	2038 (84)	664 (60)
	<b>Returning to care</b>	377 (16)	447 (40)
<b>Marital Status</b>			
	<b>Single</b>	257 (11)	167 (15)
	<b>Married</b>	1361 (56)	575 (52)
	<b>Divorced</b>	248 (10)	108 (10)
	<b>Widowed</b>	173 (7)	81 (7)
	<b>Unknown</b>	41 (2)	20 (2)
	<b>Missing</b>	335 (14)	160 (14)
<b>Facility size</b>			
	<b>&lt; 1000 patients</b>	591 (25)	245 (22)
	<b>1000-5000 patients</b>	897 (37)	485 (44)
	<b>&gt; 5000 patients</b>	927 (38)	381 (34)

Table 2 shows the absolute responses for TEC and UEC. Although most patients reported a good experience, across the questions between 5% and 25% of patients reported poor experiences

in care. For example, when asked if their HIV care provider gave them as much information about their health as they wanted, 13.4% (UEC) vs 24.6% (TEC) of patients reported not being provided with sufficient information about their health. Similarly, between 9.6% vs 18.8% patients reported that their HIV care provider was not spending the right amount of time with them at their visit, and 6.8% vs 16.4% reported witnessing rude behaviour.

**Table 2. Survey responses by training status**

Factor	Level	Untrained Exit Client n (%)	Trained Exit Client n (%)
<b>Did your HIV care provider greet you in a way that made you feel comfortable?</b>	Yes	2249 (93.1)	980 (88.2)
	No	166 (6.9)	131 (11.8)
<b>Did your HIV care provider listen to what you said?</b>	Yes	2328 (96.4)	1039 (93.5)
	No	79 (3.3)	64 (5.8)
	Refused	8 (0.3)	8 (0.7)
<b>Did your HIV care provider give you as much information about your health as you wanted?</b>	Yes	2092 (86.6)	838 (75.4)
	No	323 (13.4)	273 (24.6)
<b>Did your HIV care provider allow you to ask questions?</b>	Yes	2082 (86.2)	887 (79.8)
	No	326 (13.5)	222 (20)
	Refused	7 (0.3)	2 (0.2)
<b>Did your HIV care provider spend the right amount of time with you?</b>	Yes	2179 (90.2)	900 (81)
	No	232 (9.6)	209 (18.8)
	Refused	4 (0.2)	2 (0.2)
<b>Overall, how did you feel about the care you received today?</b>	Happy	2231 (92.4)	983 (88.5)
	Unhappy	178 (7.4)	123 (11.1)
	Refused	6 (0.2)	5 (0.4)
<b>Overall, were you satisfied with all your HIV care providers today?</b>	Yes	2206 (91.4)	906 (81.5)
	No	208 (8.6)	202 (18.2)
	Refused	1 (0.0)	3 (0.3)
<b>I witnessed HIV care providers behaving rudely during my visit today</b>	No	2251 (93.2)	928 (83.5)
	Yes	163 (6.8)	182 (16.4)
	Refused	1 (0.0)	1 (0.1)
<b>Were your lab results lost?</b>	No	2143 (88.7)	985 (88.7)
	Yes	268 (11.1)	126 (11.3)
	Not picking up	4 (0.2)	0 (0)
<b>Were you able to pick up your</b>	Yes	2366 (98.0)	1087 (97.8)

<b>medicine today?</b>	No	48 (2.0)	24 (2.2)
	Not Picking Up Meds	1 (0.0)	0 (0)

### Effects of training on response patterns: sum score and prevalence ratios

In adjusted models, TECs overall reported poor experiences in care: 1.64 times as frequently as UEC respondents (Sum Score Rate Ratio [RR]: 1.64 [95% CI: 1.39-1.94] (Fig 1, Supplementary Table S1), and reported an increased prevalence of poor experiences in care quality compared to untrained across almost all questions. For example; among TECs compared to UECs, there was an increased prevalence of reports of not being greeted in a way that made them feel welcome (adjusted Prevalence Ratio [aPR]: 1.71 [95% CI: 1.20-2.44]), reporting being dissatisfied with all their HIV care providers during their HIV care visit (aPR: 2.06 [95% CI: 1.61-2.63]) and witnessing any providers behaving rudely during their visit (aPR: 2.28 [95% CI: 1.63-3.19]) (Fig 1, Supplementary Table S1).

### Impact of training across age, sex, and gender to differences in responses

In stratified analysis of the impact of training on the sum score, training was consistently associated with increased identification of poor experiences in care across all subgroups apart from those aged 50 years or older and those with no education. We also observed that training had a larger impact among females compared to males, those with a primary education only, and among individuals presenting at smaller facilities (Fig 2). We observed similarities in responses on the impact of training on different age categories, sex, care status and different levels of education when we looked at individual questions except for the question on providers spending the right amount of time where we found that females were twice as likely to report lapses with care compared to males (Supplementary Figure 1). Using TECs gave worse assessments of patient experience at the facility-level regardless of facility size compared to UECs (Fig 3, Supplementary Figure 2).



## DISCUSSION

Disengaged patients often express a disconnect between their care expectations and the provider's style, hence experience is bound to vary across facilities [8]. This disconnect can lead to dissatisfaction with HIV services which can often lead to patients dropping out of care[8,11,29]. A brief training for patients living with HIV on how to evaluate the quality and experience of routine care changed patient experience reports compared to untrained patients using the same instrument. Patients who underwent a brief training identified more lapses in care across most questions. Women and young people were more likely to report critical responses after training - consistent with the idea that those who feel least empowered underwent the biggest change. Differences were also bigger for questions in which social desirability is likely to operate. For example, larger differences were observed for witnessing rude behaviour, while no differences were observed for more objective questions such as whether lab results were lost.

Improving HIV health outcomes requires new strategies that minimise methodological biases and includes everyone the patient encounters during their visit, including clinical officers, doctors, nurses, data clerks, and lay HCWs. Our TEC approach could contribute to getting a true reflection of how much value patients place on things such as effective communication, being greeted appropriately, or being treated with care and respect at all these different touch points. Involving patients in their own care and design of health services has been linked to improved HIV care retention and patient outcomes, such as higher viral suppression rates [30–32]. As progress is being made towards UNAIDS 95-95-95 targets, the global HIV sector is constantly reviewing priorities and challenges for optimal engagement in care [33,34]. Patient experience is a key indicator of

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3 355 healthcare quality for meeting the 95-95-95 targets: delivering services patients need, can access,  
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6 356 and address wider determinants of poor health. Clinicians and health systems must address HIV  
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8 357 patients' needs from diagnosis to death to ensure healthy ageing and viral suppression. Other  
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10 358 outcomes in Zambia [11,35,36] show that lifelong needs vary by facility, highlighting the  
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12 359 importance of metrics that measure patient experience accurately. We have shown that it is feasible  
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15 360 to involve patients in assessing the quality of care and this could potentially lead to involvement of  
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17 361 patients in the redesign of healthcare services.  
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19 362 Because HIV care is longitudinal, SP, who are often used to evaluate episodic care, require  
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22 363 highly skilled people to pose as a simulated patient making one visit to multiple clinics, posing  
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24 364 practical implementation challenges in our setting[19–24]. Contrary to SP, we evaluated care quality  
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26 365 without using simulated patients and administered the survey once among people in long term care.  
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29 366 Using real patients instead of simulated ones drawn from outside the true patient population, we  
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31 367 would argue, made our TEC approach more applicable and reproducible in clinical settings. We  
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33 368 were able to record HCW behaviour in a typical HIV context using this concealment method,  
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35 369 potentially reducing the impact of the Hawthorne effect. Our TECs also consistently identified more  
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38 370 lapses in care, potentially reducing social desirability bias and ability to identify issues at the facility.  
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40 371 Even though training takes time, the increased quality of our measurement allows one to perform  
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42 372 fewer surveys. With traditional approaches like exit surveys, one would require a larger sample size,  
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45 373 but this does not address bias [37].  
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47 374 Our findings are consistent with a study done in South Africa which found that non-clinical  
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49 375 dimensions of care play a bigger role in determining an overall satisfactory experience for  
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52 376 standardised patients when compared to untrained patients[37]. However, our findings may  
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54 377 contradict previous suggestions that tailoring support to individuals to build skills and confidence  
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3 378 through patient activation can lead to trained/informed patients reporting a better experience than  
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6 379 untrained/ uninformed [38]. TECs cared about the following non-clinical aspects of care: rude  
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8 380 providers, being satisfied with HIV care providers, and spending enough time with providers. This  
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10 381 finding is consistent with a previous study in Zambia, where patients reported rude HCWs deterring  
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12 382 HIV care engagement [8,10,11]. This could mean that studies assessing patient experience with TEC  
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15 383 could focus on a few questions to save time and resources. Questions like, "Did you pick up your  
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17 384 medicine or lab results at your visit?" may not add much to a TEC survey because they are definitive,  
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19 385 and training appears to influence subjective care dimensions.

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22 386 Women TECs were generally more critical about the care they received and would likely  
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24 387 provide a more accurate reflection of the health system, possibly because they have better health-  
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26 388 seeking behaviour than men, which may be strongly influenced by local gender norms and health  
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29 389 service structures designed to engage women of reproductive age [39]. There is some consistency  
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31 390 with other findings that women may be more interested in their care than men, especially in facilities  
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33 391 that provide integrated services for women and their children [9,40]. Despite longer wait times,  
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35 392 women were more satisfied with integrated facilities [41]. In addition, middle-aged people between  
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38 393 40-50 benefited the most from training. Compared to older people over 50, younger people under  
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40 394 30 were less satisfied with the care they received and often felt they were not greeted by a HCW  
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42 395 during their visit. This finding is consistent with cultural norms where younger people are less  
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45 396 respected[42]. Given the current strategy of targeting young people, who account for most new  
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47 397 infections, these findings suggest an important new approach to identifying what young people value  
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49 398 most. Education level was among the strongest predictors of patient experience feedback. Well-  
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52 399 educated patients were found to have a less critical/better HIV care visit experience compared to  
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54 400 participants with lower levels of educational attainment. This difference in care experience report

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3 401 may be associated, at least in part, with the HCW perception of the patient in the facility. Research  
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5 402 conducted in Nigeria discovered that people with higher levels of education are frequently given  
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8 403 better and more considerate treatment by HCW, hence limited by a form of discrimination/  
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10 404 socioeconomic status bias [43,44].

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12 405 The observed effect of training on patient experience is likely multifaceted potentially  
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15 406 stemming from increased attention and recall to the exit survey items which solicited a feeling of  
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17 407 empowerment to be more critical of the care received. In future studies, patient activation should be  
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19 408 measured as an outcome to see how training changes the patient's engagement with their care over  
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22 409 time [38]. Further research is required into why women TECs reported poorer experiences with care  
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24 410 than men. Other studies that have used SP to assess medical students' performance showed that  
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26 411 women were more critical on certain aspects of care. These studies also recommend matching of  
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29 412 SPs to clinicians by sex [45], something we were not able to do given the nature of our study in  
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31 413 primary health facilities where we assessed interpersonal communication with HCWs at all levels.  
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33 414 Perhaps our findings call for more investigation into the integration of women's services, such as  
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35 415 family planning and children's services with HIV care given some studies have shown this can  
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38 416 improve patient satisfaction.

### 40 417 **Limitations**

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42 418 Our findings should be interpreted with caution due to the following limitations. Because this  
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45 419 was the first time such a study was done, we recruited educated participants who were able to read  
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47 420 and write, perceived to have good recall ability and were able to comprehend things. Our study was  
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49 421 only done in Lusaka province in facilities that were largely urban except for one facility which was  
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52 422 peri-urban hence it is hard to generalise these findings. Another limitation in our approach is the  
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54 423 one-time cross-sectional nature of our measurements among people in long term HIV care. If more  
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3 424 measures were collected from each TEC, we may well see them being activated in a way that results  
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6 425 in an improvement in their experience based on the skills they develop to seek better care from  
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8 426 providers which ultimately would improve their retention in care. Despite its limitations, the TEC  
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10 427 method provides valuable information about healthcare quality, even though it is limited to  
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12 428 situations where "walk-ins" are permitted. Our approach only focused on real patients accessing  
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15 429 care and we did not manipulate any patient files, so it is possible that some TECs were known to the  
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17 430 facility as patients accessing chronic care. Our approach does require a trained interviewer to speak  
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19 431 with TECs after their visits, but this is not any different to what already exists. In future, it may be  
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21  
22 432 worth using the domains in the national HIV guidelines as the gold standard, but we did not do this  
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24 433 as our aim was to come up with a low-cost approach that can easily be rolled out. In addition, the  
25  
26 434 concept of patient centred care is still catching on in Zambia. Our TEC approach can be used to  
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28  
29 435 further the knowledge in provider attitudes to other relatively new approaches to delivering quality  
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31 436 HIV care such as differentiated service delivery (DSD) for stable patients by assessing whether  
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33 437 HCWs follow guidelines when offering this [34]. We also see an opportunity to assess provider  
34  
35 438 patient communication of viral load laboratory results by use of a universal script for each TEC to  
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38 439 assess if they are communicated to and if unsuppressed but adherent, what procedures followed.

## 41 440 **Conclusion**

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45 441 TEC offers pragmatic methods for health systems in low-income countries to assess non-  
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47 442 clinical dimensions of care (communication, respect, and autonomy) which are grounded on the  
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49 443 concept of health-system responsiveness and could be critical to the transformation of low-quality  
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52 444 health systems to high quality ones[46]. Hawthorne effects and social desirability biases may be  
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54 445 mitigated using TECs. We were able to capture HCWs behaviour in a normal day to day low middle  
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3 446 income setting using similar approaches recommended by King and colleagues that minimise harm  
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6 447 to HCWs and SPs [15]. Our findings suggest that TECs provide a more critical appraisal of some  
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8 448 aspects of the quality of HIV care. It provides new insights in the Zambian context on what patients'  
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10 449 value when they interact with the health system. This could be important given the need to reduce  
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12 450 loss to follow up among new ART clients who disengage within the first 6 months of treatment due  
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15 451 to a bad first encounter with the health system. Our TEC approach could be used to assess  
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17 452 reengagement interventions. The fact that TECs had a better understanding of the items solicited or  
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19 453 felt empowered to be more critical shows that the training we provided worked. This low-cost  
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22 454 method could be reproduced in other routine settings and presents an opportunity to further  
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24 455 institutionalise patient centred care by evaluating what happens at the point of contact between the  
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26 456 patient, the health facility, and the health provider. The implications are that it provides an  
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29 457 opportunity to improve HIV care, meet patients' expectations and can serve as a monitoring tool for  
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31 458 healthcare performance. Coupled with the recent approaches to client led monitoring in HIV care,  
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33 459 our approach can be used to enhance decision making that considers patients' involvement.  
34

### **Data Availability Statement**

The Government of Zambia allows data sharing when applicable local conditions are satisfied. In this case, the data from the study will be made available to any interested researchers upon request. The CIDRZ Ethics and Compliance Committee is responsible for approving such request. To request data access, one must write to the Secretary to the Committee/Head of Research Operations, Mrs. Hope Chinganya ([Hope.Chinganya@cidrz.org](mailto:Hope.Chinganya@cidrz.org)) mentioning the intended use for the data. The Committee will then facilitate review and authorization to release the data as requested. Data requests must include contact information, a research project title, and a description of the intended use.

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## Contributors

KS: guarantor, lead author, conducted all analyses, led data management activities, field  
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with analysis and revising it critically for important intellectual content, designed data collection  
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BR: final approval for publication, assisted with framing and revising it critically for important  
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drafted statistical analysis plan, assisted with conceptualisation and interpretation of data. JM:  
assisted with data acquisition and cleaning, field coordination of data quality processes. SS: led  
intervention implementation, project administration and data curation. LKB, NM, AS: cognitively  
tested data collection tools, assisted with conceptualization, underlying data processes, and assisted  
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conceptualisation and advised regarding intervention implementation details. IS: funding



1  
2  
3 514 acquisition, assisted with conceptualisation and manuscript writing. EHG: funding acquisition, led  
4  
5 515 conceptualisation and advised on all analyses, final approval for publication.  
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### 8 516 **Statement of Ethics Approval**

9 517  
10 518 Ethics approval to conduct this research was granted by the Zambian Ministry of Health,  
11  
12 519 National Health Research Authority, and the institutional review boards of the University of Zambia  
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17 521 Hygiene and Tropical Medicine (21384).  
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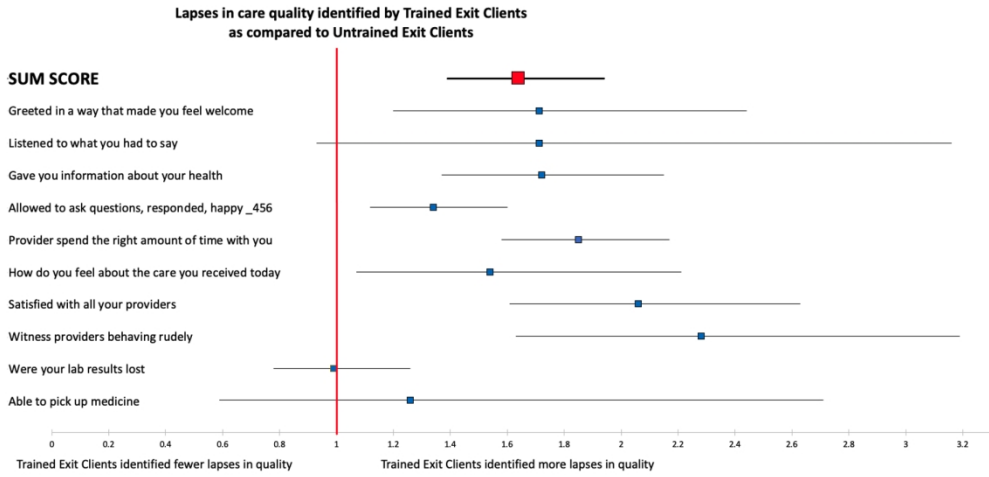
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6 **Figure 1. Forest plot comparing responses from Trained Exit Clients (TEC) relative to**  
7 **Untrained Exit Clients (UEC) on 10 measures of clinic experience.** Points indicate the rate  
8 ratio (for sum score) or prevalence ratio (for all others) for identifying a lapse in care in TEC  
9 surveys as compared to UEC. The sum score represents the total number of binary responses (yes  
10 vs no) across all clients in one group shown as a rate ratio. The red line indicates a rate or  
11 prevalence ratio of 1 and values greater than this indicates more lapses in care identified in TECs.  
12 Results are based on mixed-effects models adjusted for age, sex, education with a random effect at  
13 the facility.  
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16 **Figure 2. Impact of Training on Identifying Care Lapses Stratified by Subgroups (N=3480).**  
17 When all questions were collapsed into a Sum score among TEC, females were more likely to report  
18 lapses in care quality than males. We observed some level of interaction for care status, age category,  
19 education category and facility size.  
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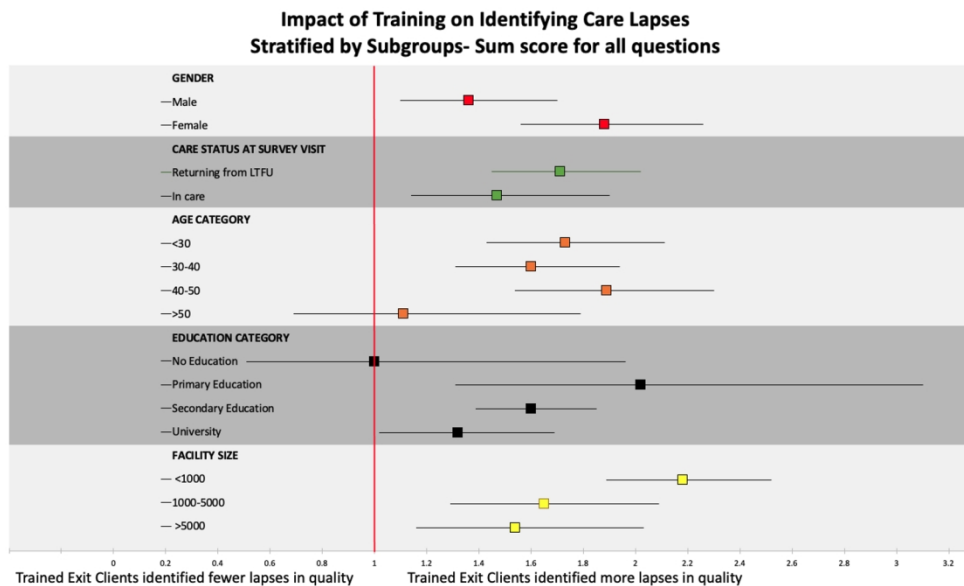
21 **Figure 3. Bubble plot showing Trained Exit Sum Score vs Untrained Exit Sum Score.** Each  
22 bubble represents a single facility's performance. Each bubble's size indicates the number of patients  
23 at each facility with larger bubbles corresponding to larger facilities. The horizontal position notes  
24 the Untrained Exit Sum Score for all questions against the facility, and the vertical position notes  
25 the Trained Exit sum score at the same facility.  
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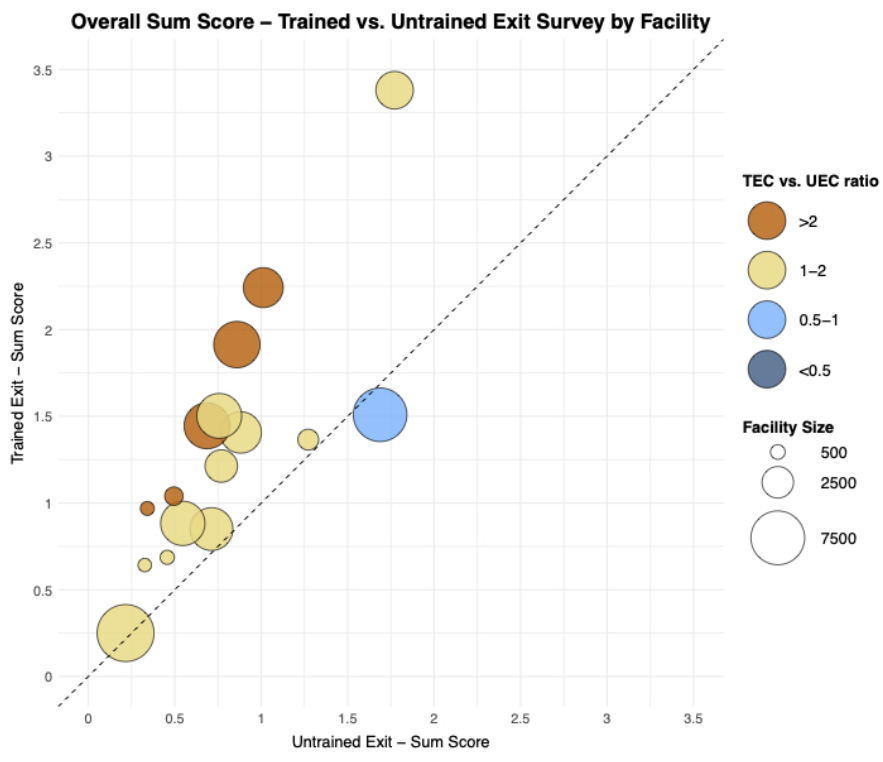
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## Supplementary Tables S1

**Supplementary Table S1. Mixed effect Poisson regression comparing 10 questions for Trained Exit Clients vs Untrained Exit Clients. Adjusted for age, sex, education, and study period.**

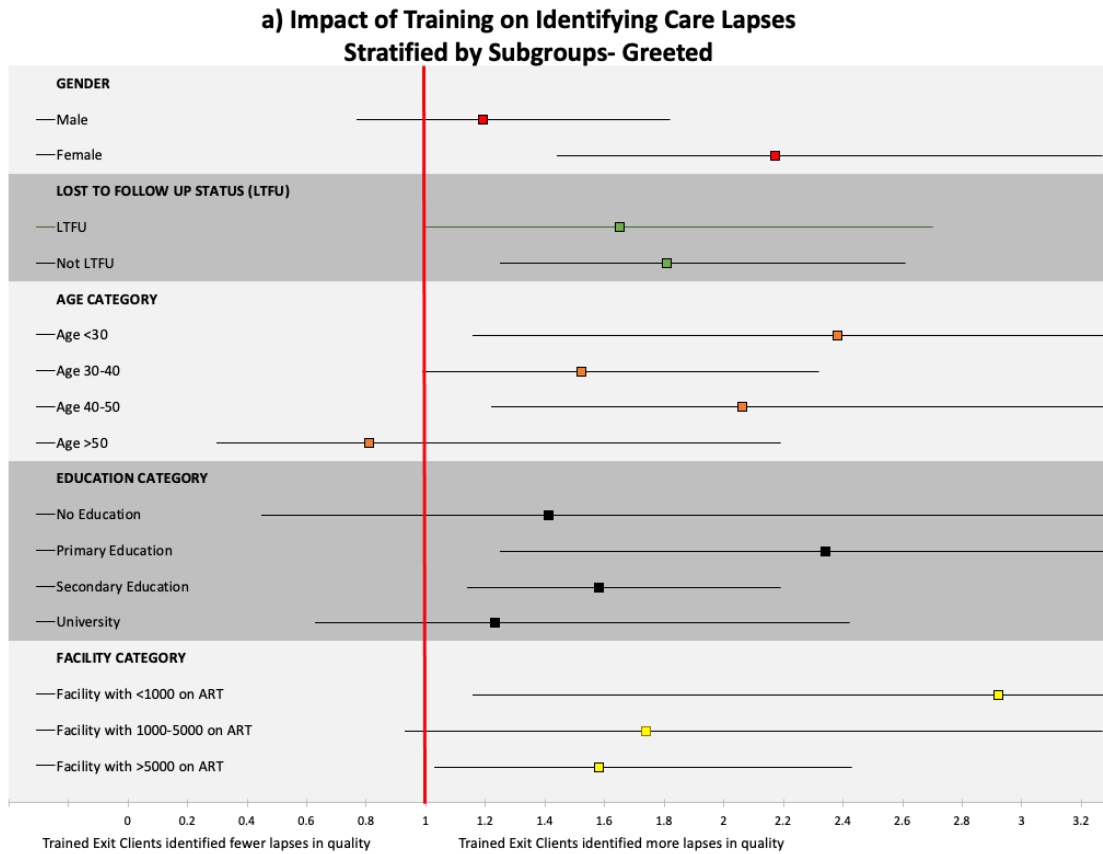
Trained Exit Clients	Prevalence ratio (PR) Unadjusted	P value	95% Confidence Interval (CI)	PR-Adjusted	P value	95% Confidence Interval (CI)	N
Sum score (Rate ratio)	1.73	<0.01	1.47-2.02	1.64	<0.01	1.39-1.94	3480
Did your HIV care provider greet you in a way that made you feel comfortable?	1.74	0.01	1.24-2.44	1.71	<0.01	1.20-2.44	3526
Did your HIV care provider listen to what you said?	1.77	0.09	0.91-3.45	1.71	0.09	0.93-3.16	3510
Did your HIV care provider give you as much information about your health as you wanted?	1.82	<0.01	1.43-2.33	1.72	<0.01	1.37-2.15	3526
Did your HIV care provider allow you to ask questions?	1.44	<0.01	1.20-1.73	1.34	<0.01	1.12-1.6	3517
Did your HIV care provider spend the right amount of time with you?	1.94	<0.01	1.66-2.27	1.85	<0.01	1.58-2.17	3520
Overall, how did you feel about the care you received today?	1.51	0.02	1.06-2.16	1.54	0.02	1.07-2.21	3515
Overall, were you satisfied with all your HIV care providers today?	2.12	<0.01	1.68-2.66	2.06	<0.01	1.61-2.63	3522
I witnessed HIV care providers behaving rudely during my visit today	2.39	<0.01	1.73-3.32	2.28	<0.01	1.63-3.19	3524
Were your lab results lost?	0.99	0.98	0.84-1.19	0.99	0.93	0.78-1.26	3522
Were you able to pick up your medicine today?	1.04	0.90	0.57-1.89	1.26	0.55	0.59-2.71	3525

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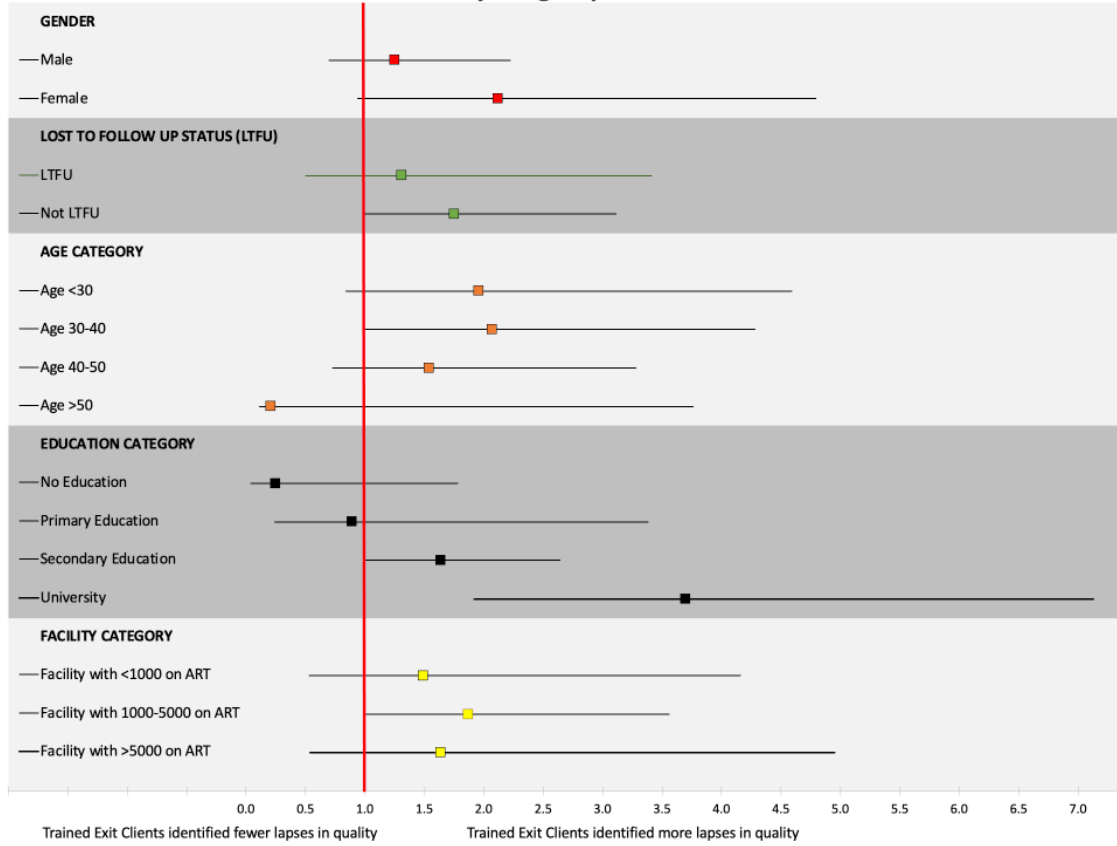
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Supplementary Figure 1.

**Impact of Training on Identifying Care Lapses Stratified by Subgroups for 10 questions.** We observed some level of interaction for care status, age category, education category and facility size. Panel **a)** Greet you in a way that made you feel comfortable **b)** Listen to what you said **c)** Give you as much information about your health as you wanted **d)** Allowed you to ask questions, responded, happy q456 **e)** spend the right amount of time with you **f)** feel about the care you received today **g)** satisfied with all your HIV care providers today **h)** witnessed HIV care providers behaving rudely during my visit today **i)** lost lab results **j)** pick up meds

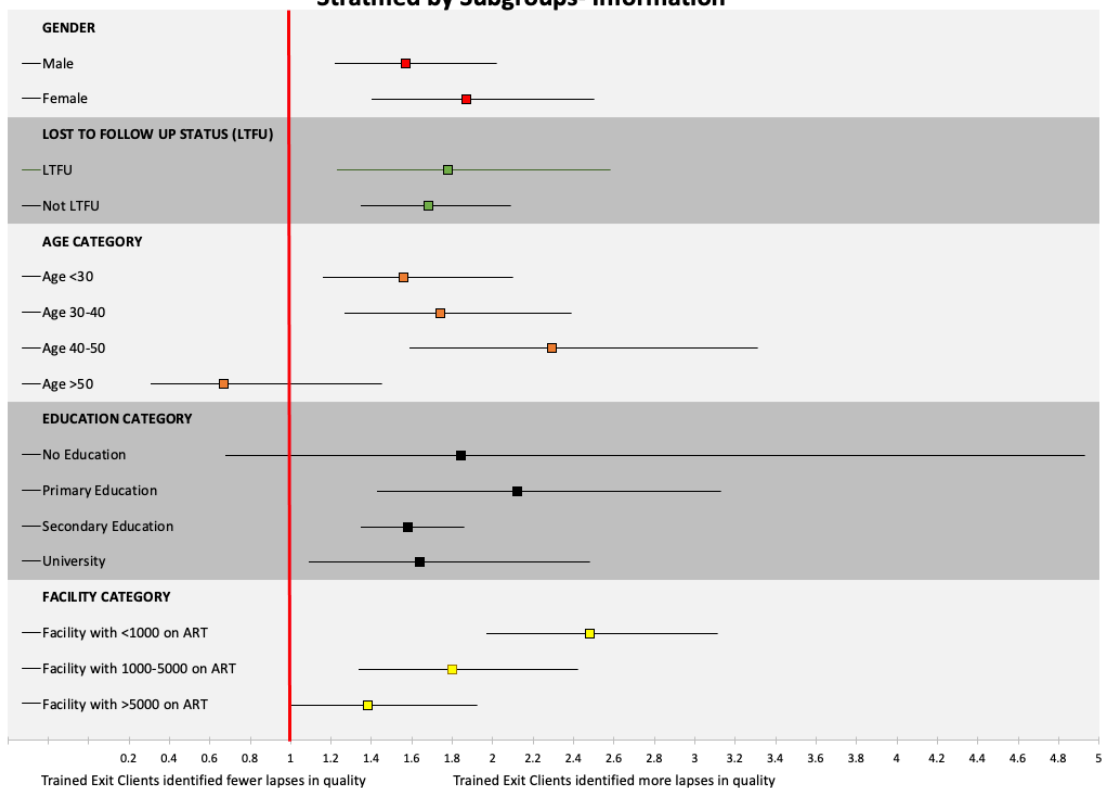


### b) Impact of Training on Identifying Care Lapses Stratified by Subgroups- Listened



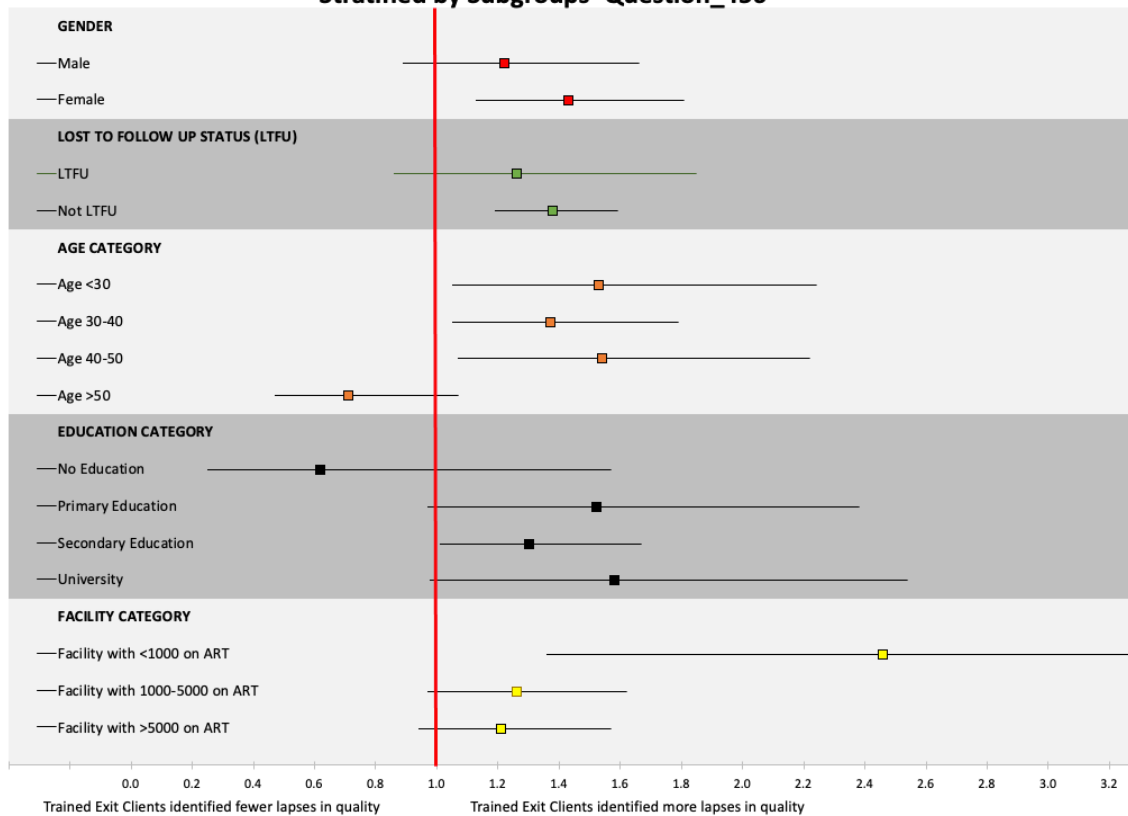
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**c) Impact of Training on Identifying Care Lapses  
Stratified by Subgroups- Information**



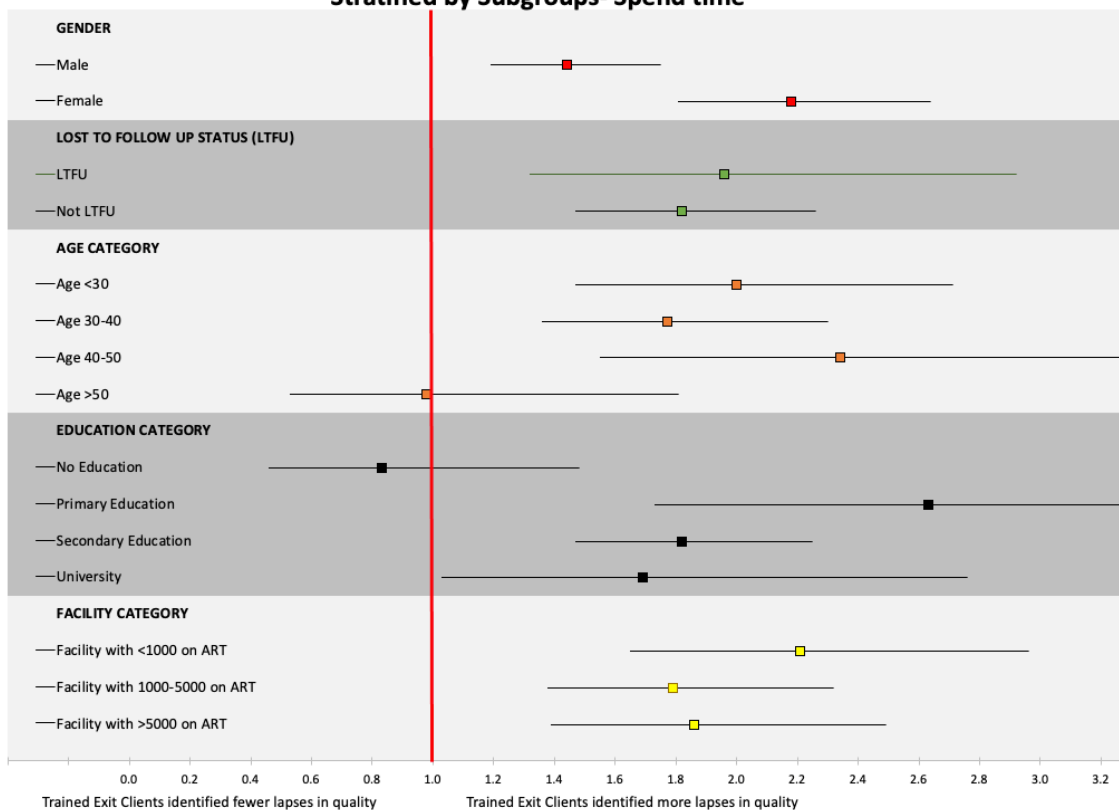
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**d) Impact of Training on Identifying Care Lapses  
Stratified by Subgroups- Question\_456**



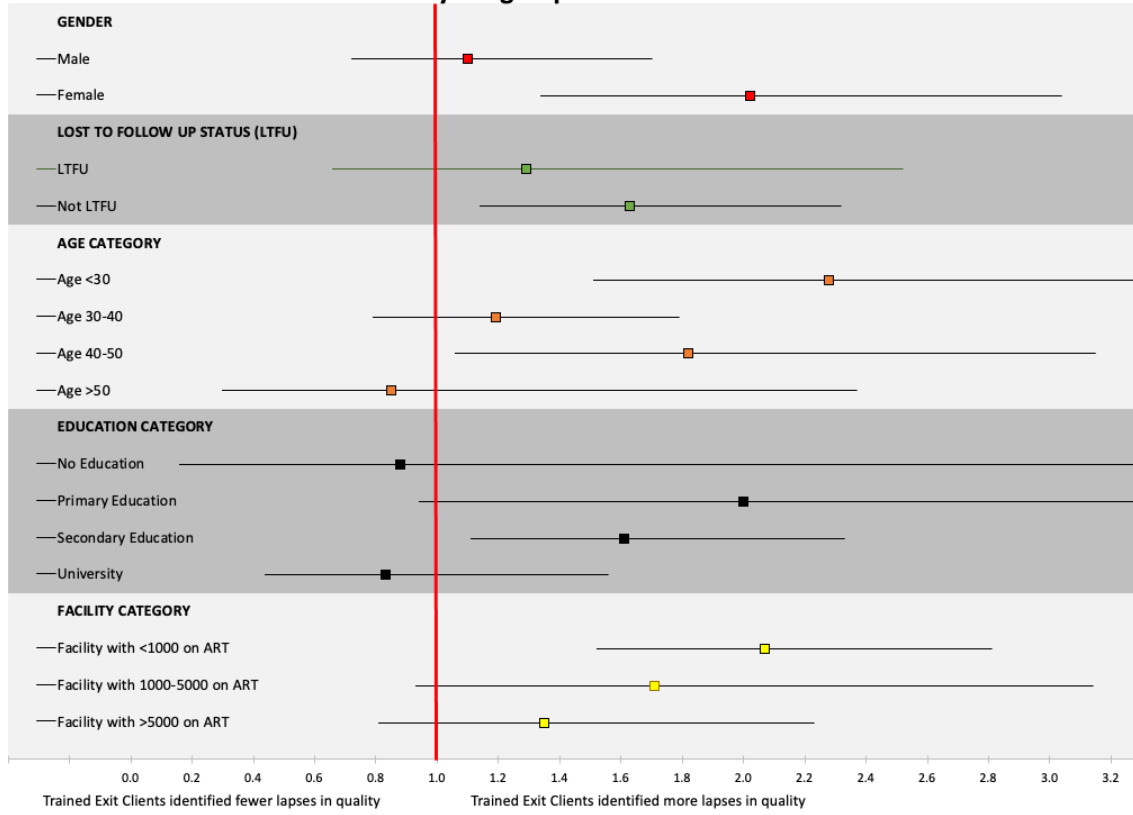
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**e) Impact of Training on Identifying Care Lapses  
Stratified by Subgroups- Spend time**



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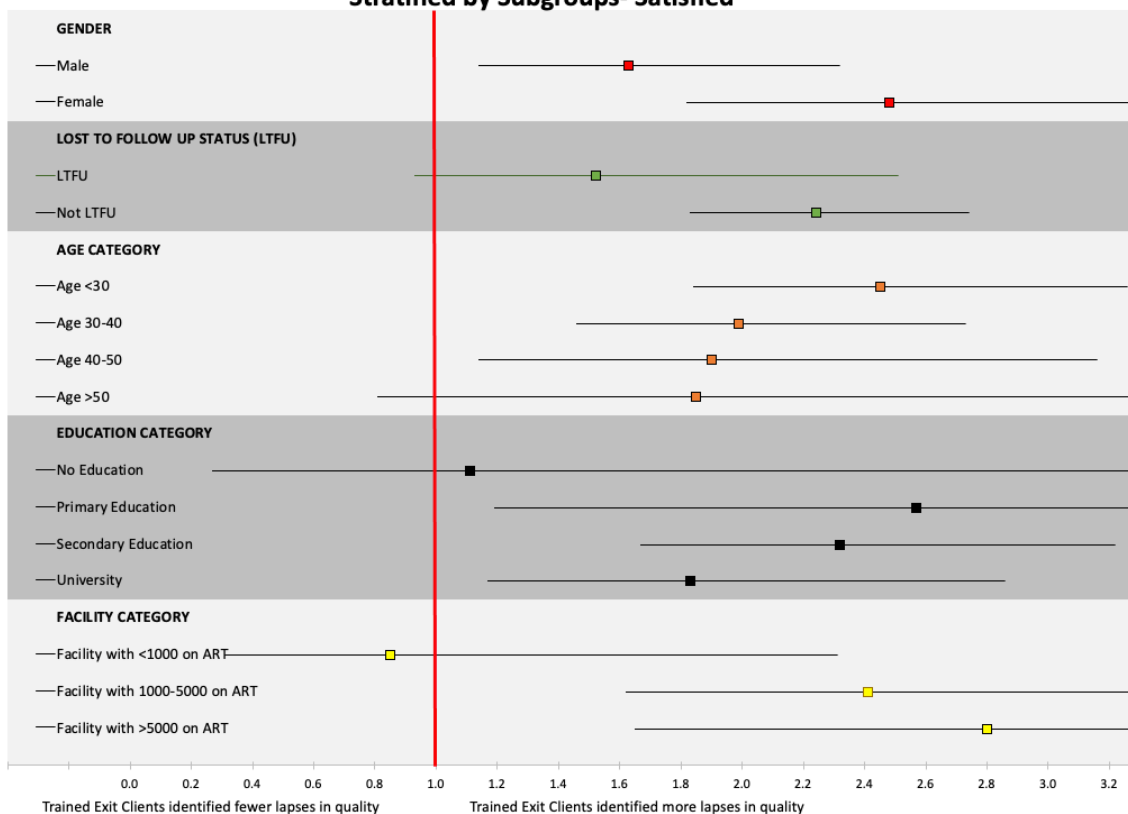
### f) Impact of Training on Identifying Care Lapses Stratified by Subgroups- Feel about care



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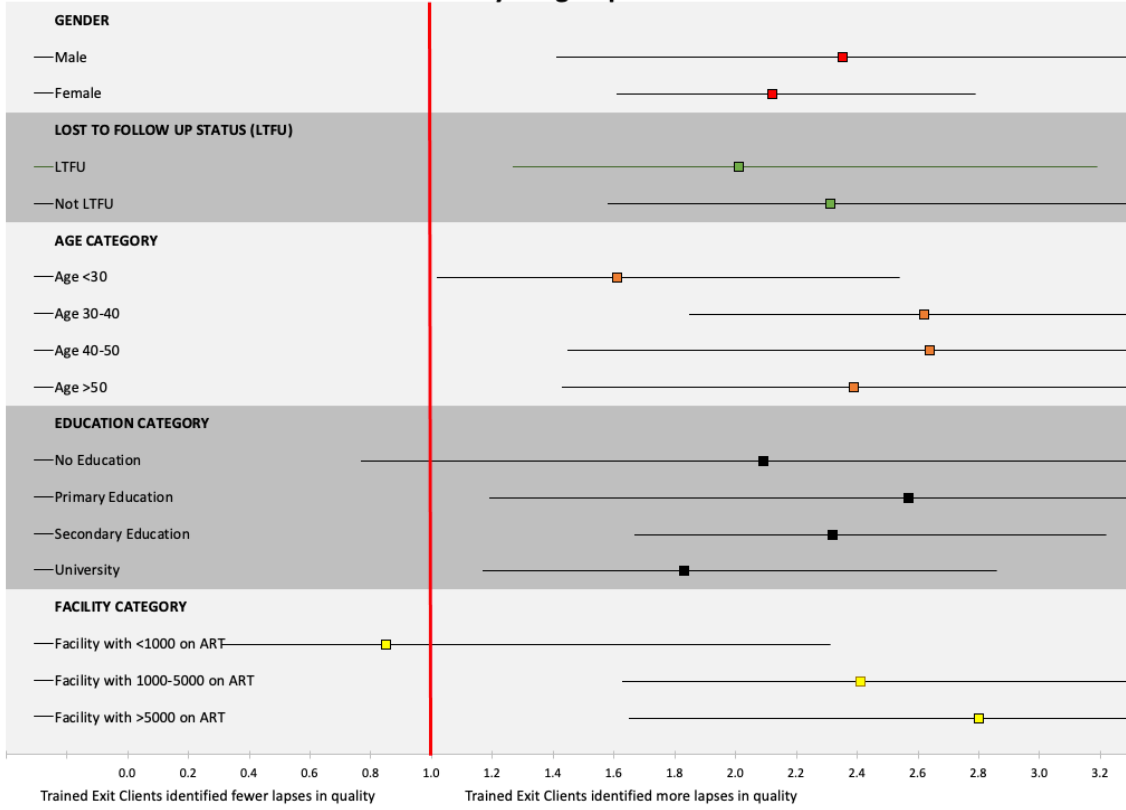


**g) Impact of Training on Identifying Care Lapses  
Stratified by Subgroups- Satisfied**



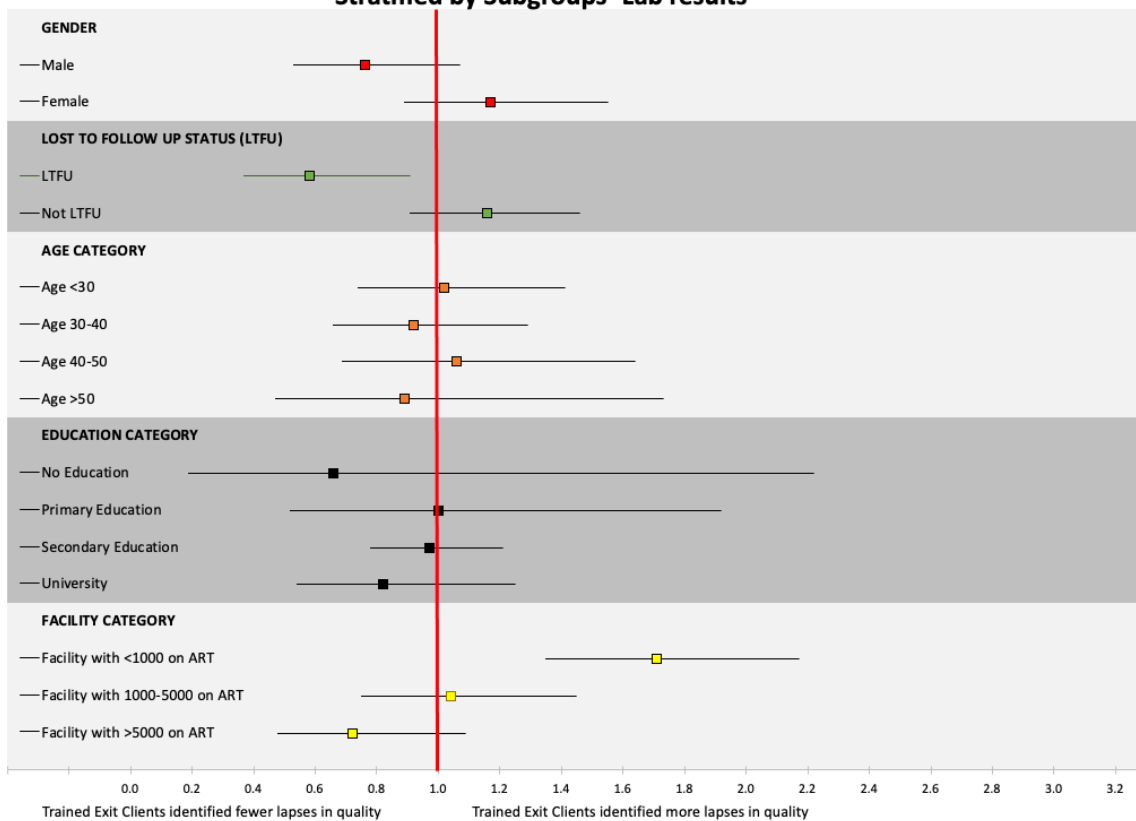
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### h) Impact of Training on Identifying Care Lapses Stratified by Subgroups- Rude



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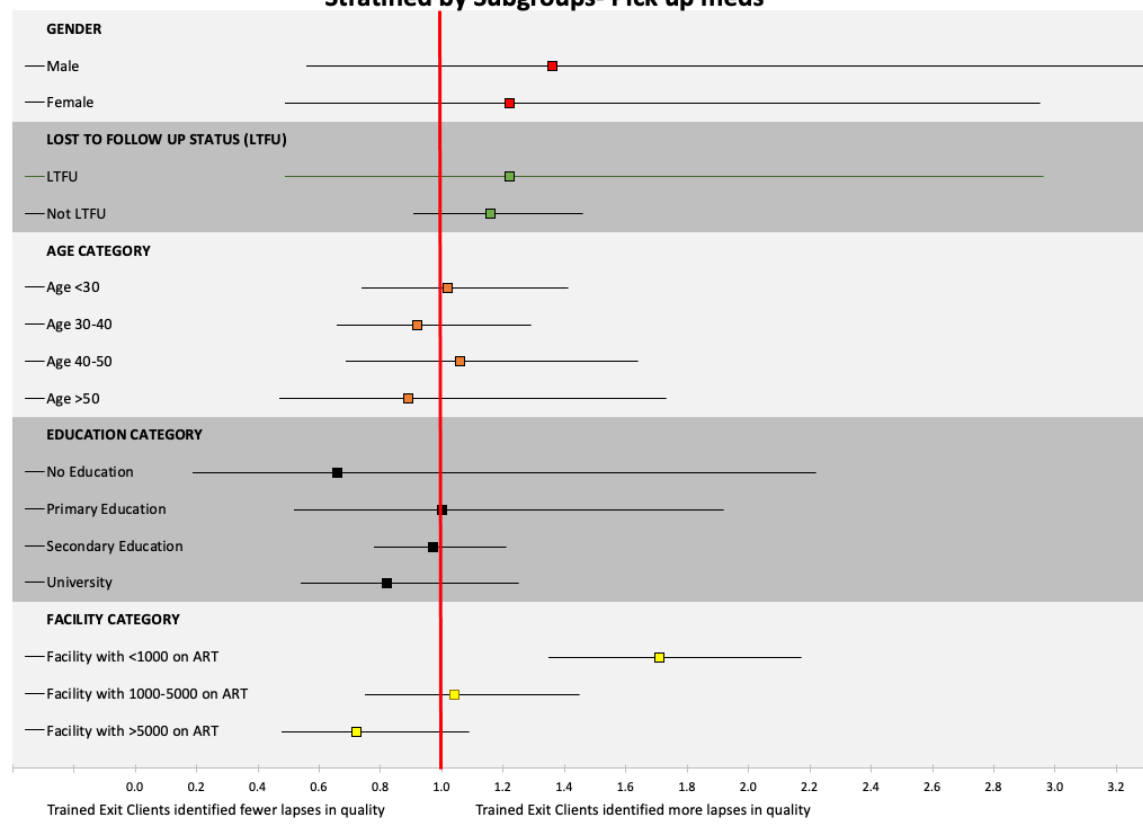
**i) Impact of Training on Identifying Care Lapses  
Stratified by Subgroups- Lab results**



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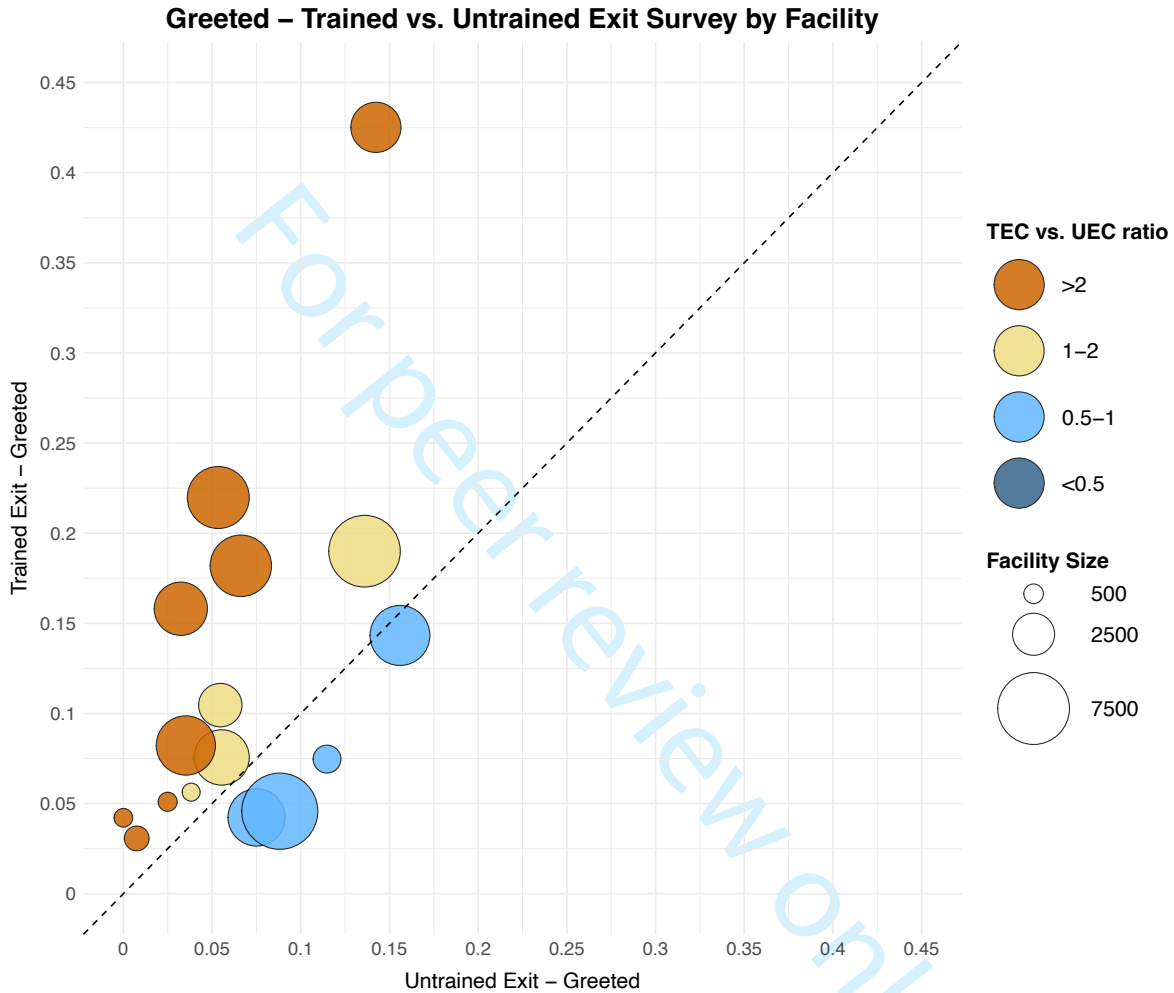
### j) Impact of Training on Identifying Care Lapses Stratified by Subgroups- Pick up meds

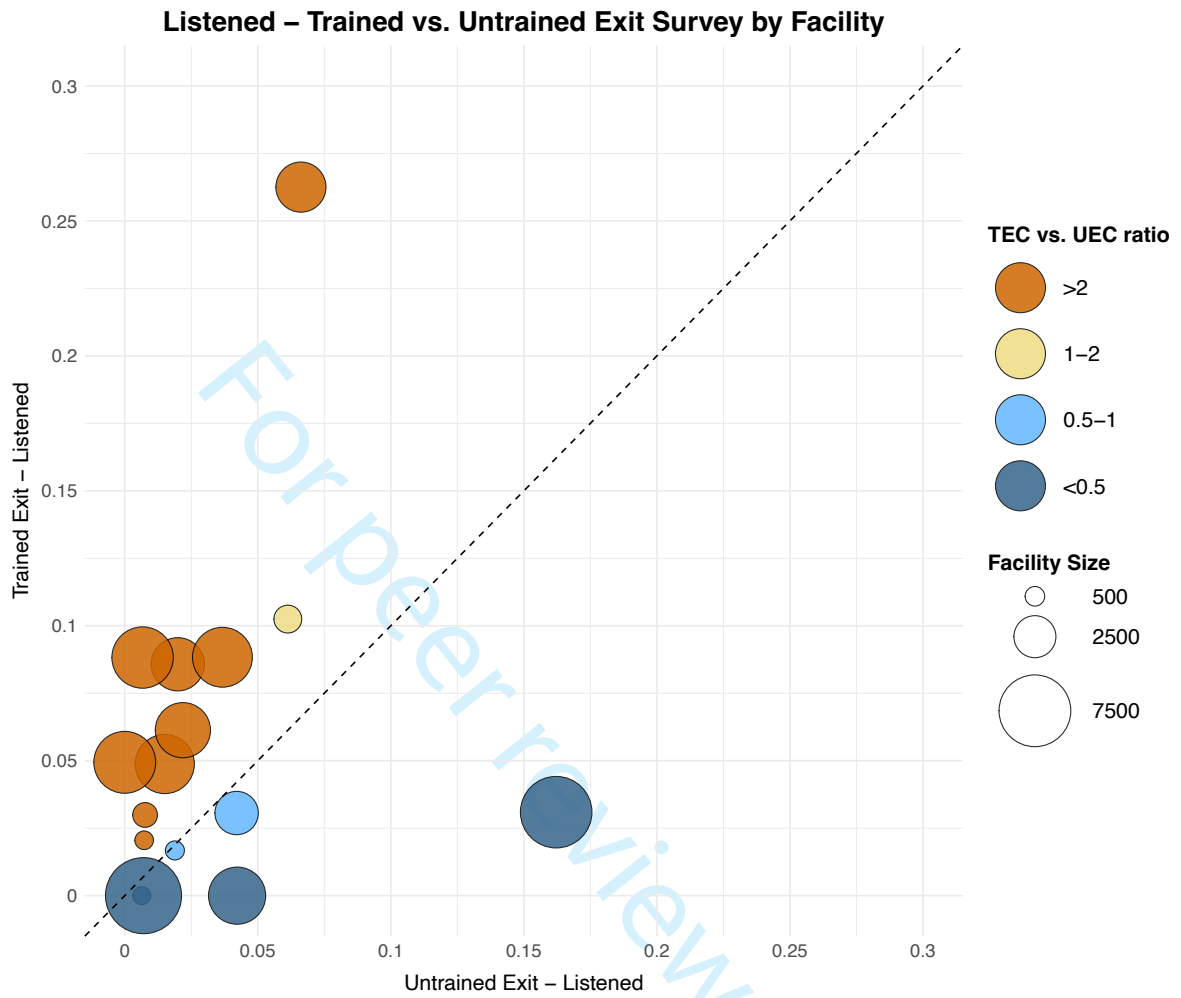


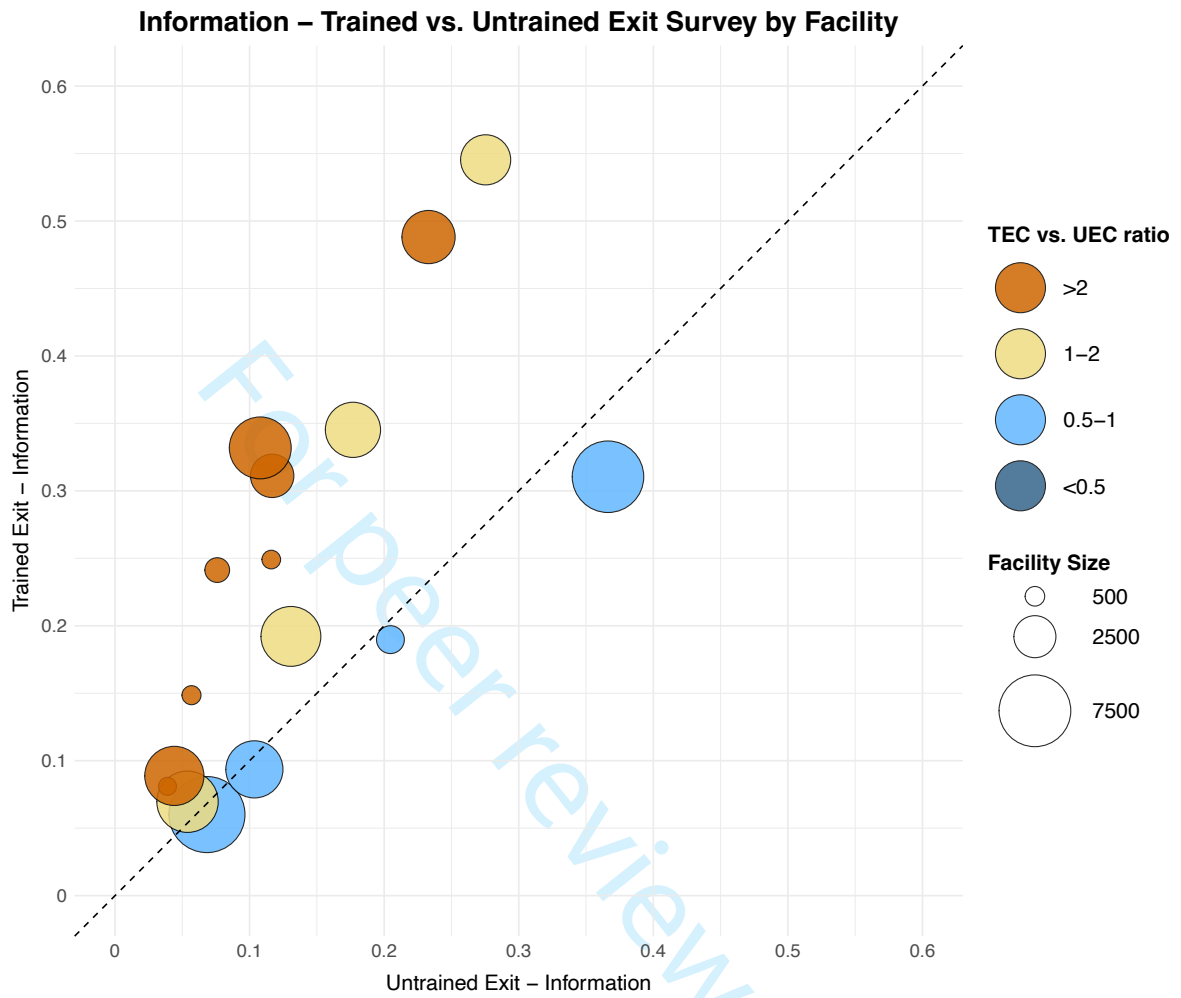
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Supplementary Figure 2

**Supplementary Figure 2.** Bubble plot showing Trained Exit Sum Score vs Untrained Exit Sum Score. Each bubble represents a single facilities performance. Each bubble's size indicates the number of patients at each facility with larger bubbles corresponding to larger facilities. The horizontal position notes the Untrained Exit Sum Score for all questions against the facility, and the vertical position notes the Trained Exit sum score at the same facility.

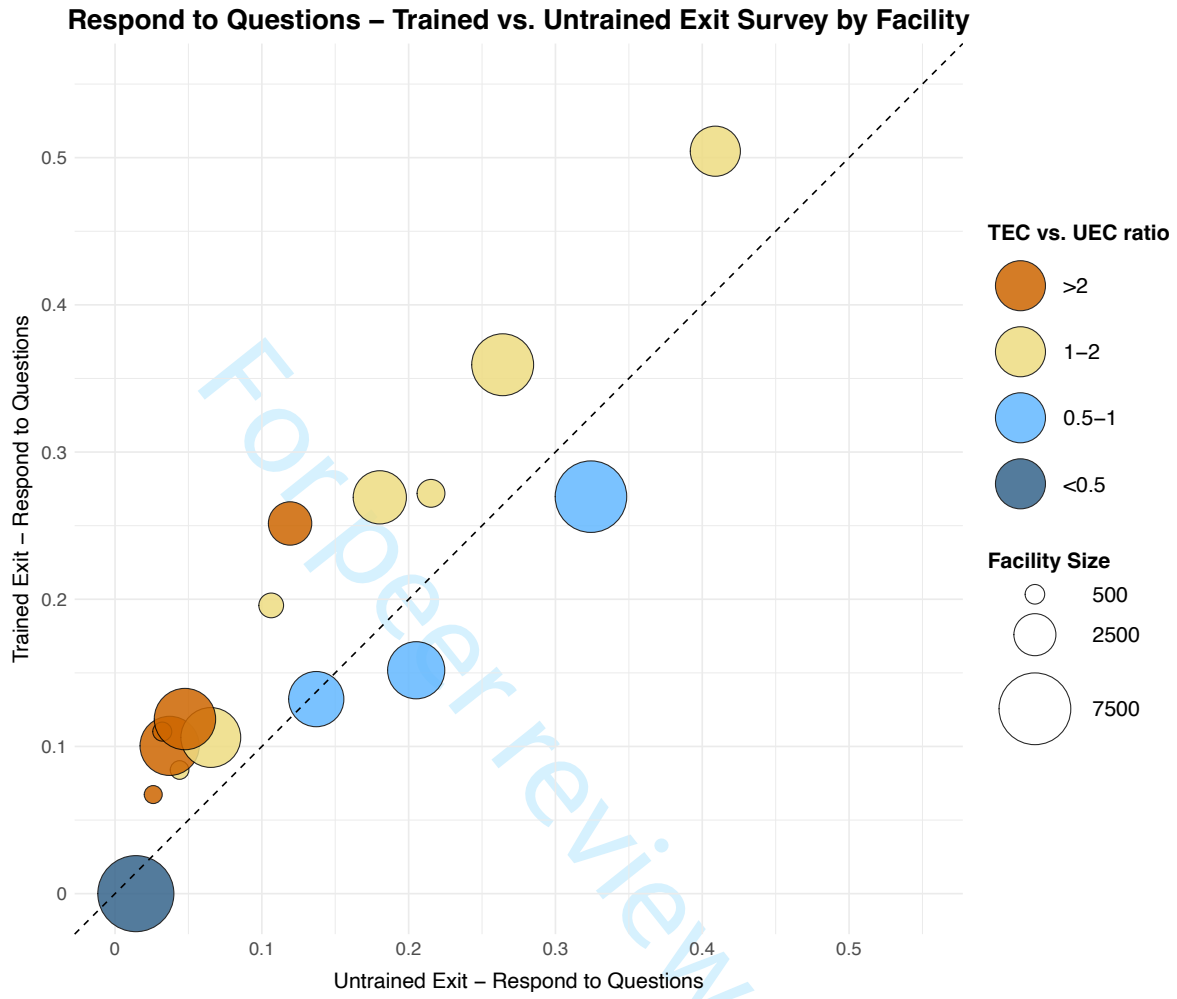




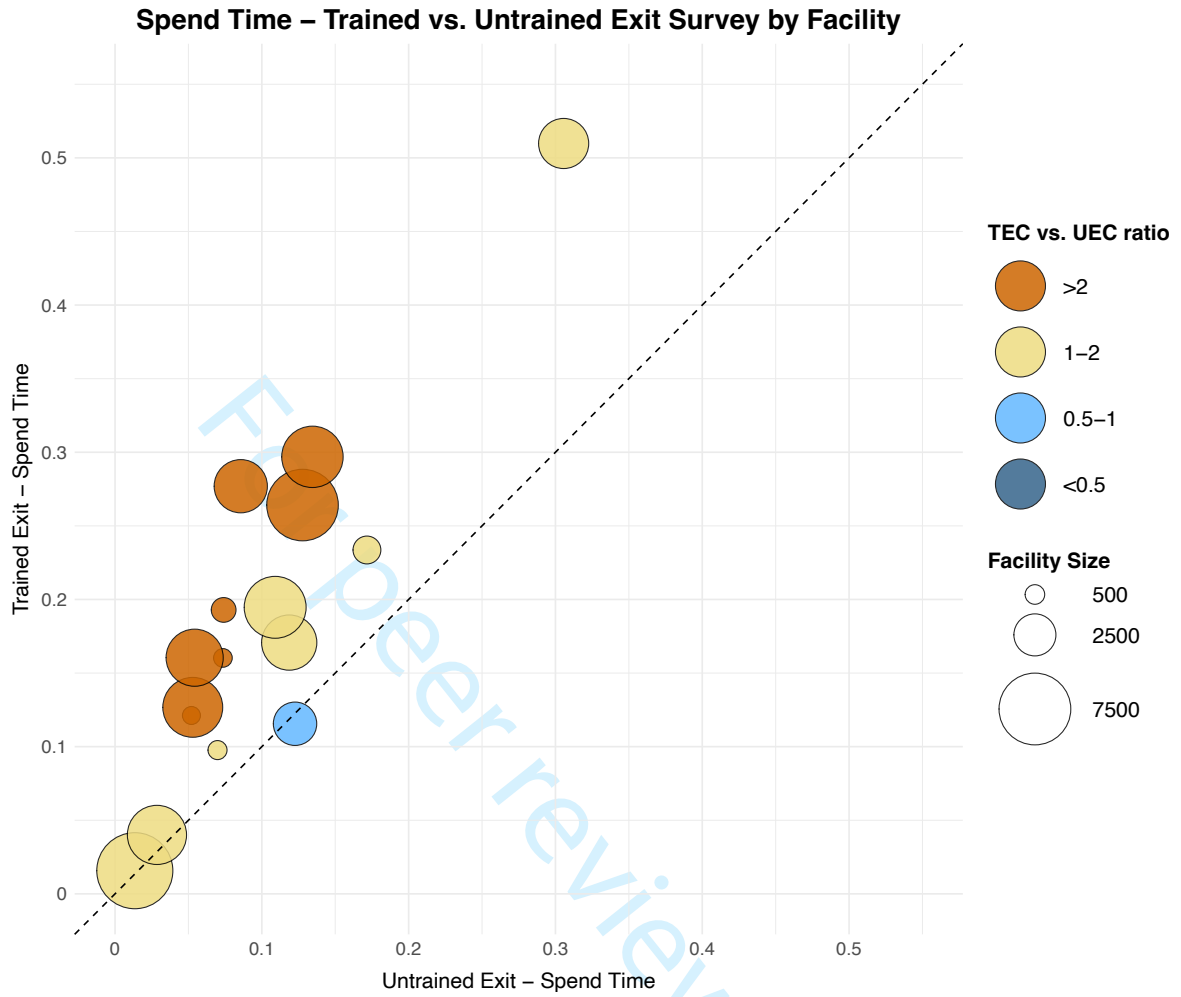


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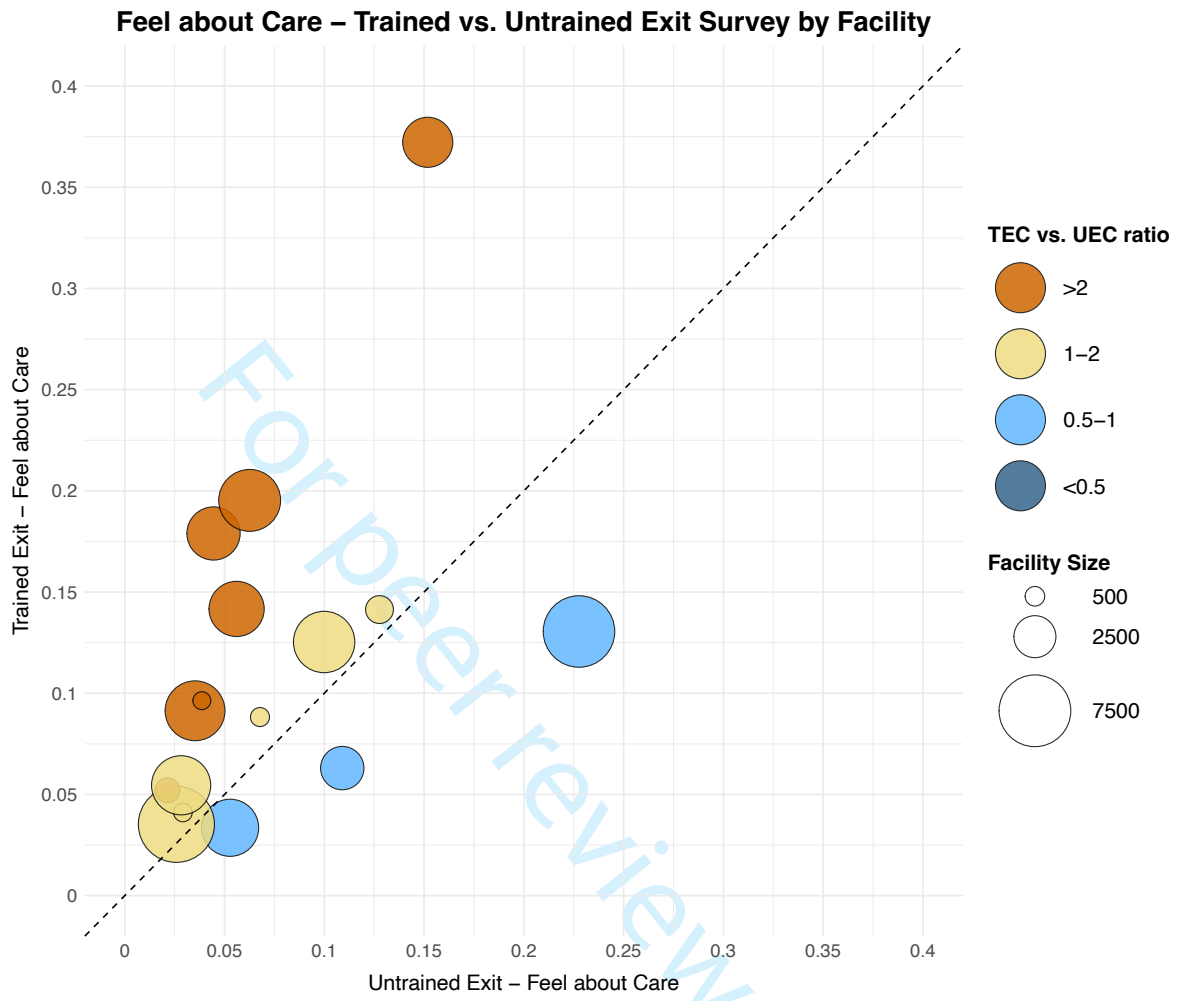
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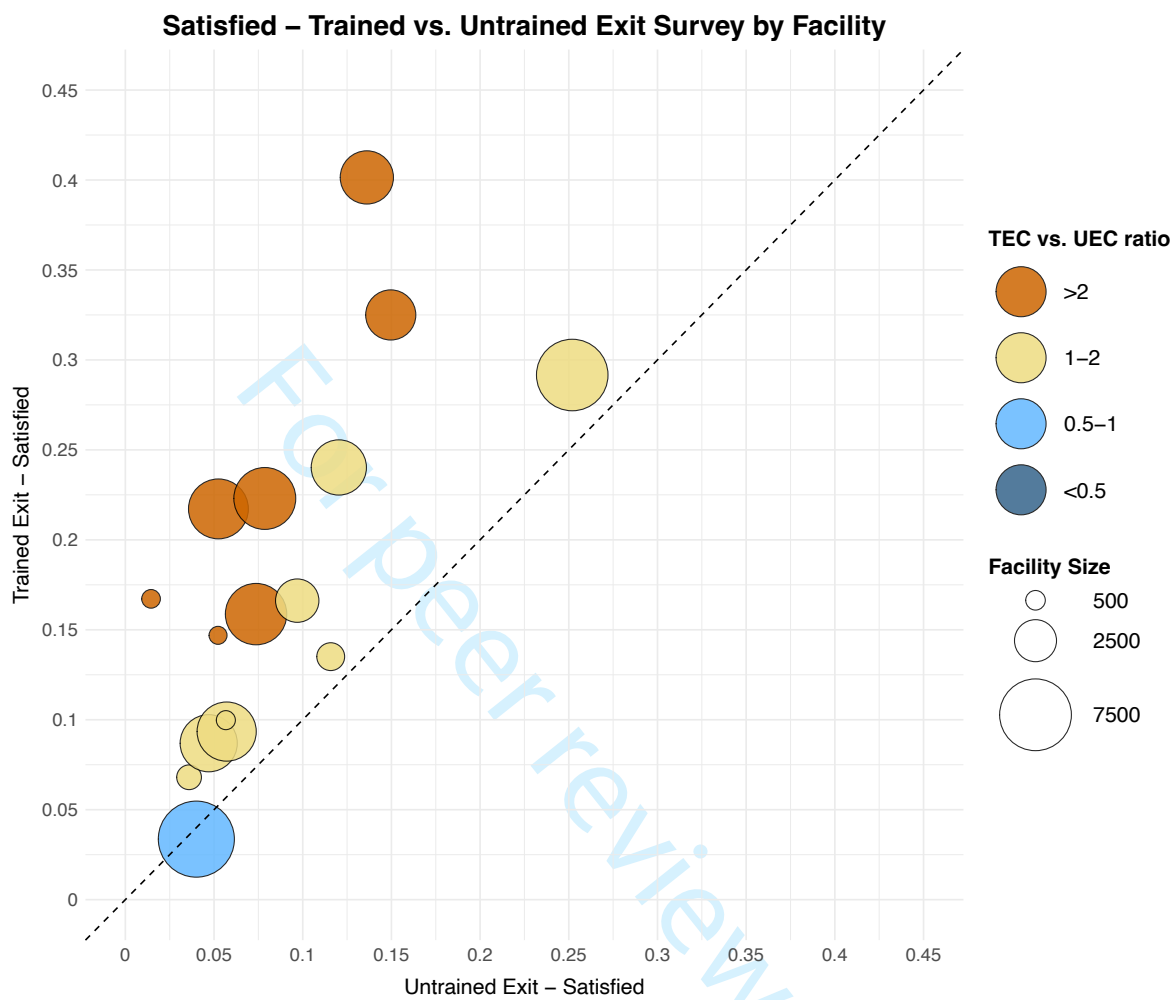




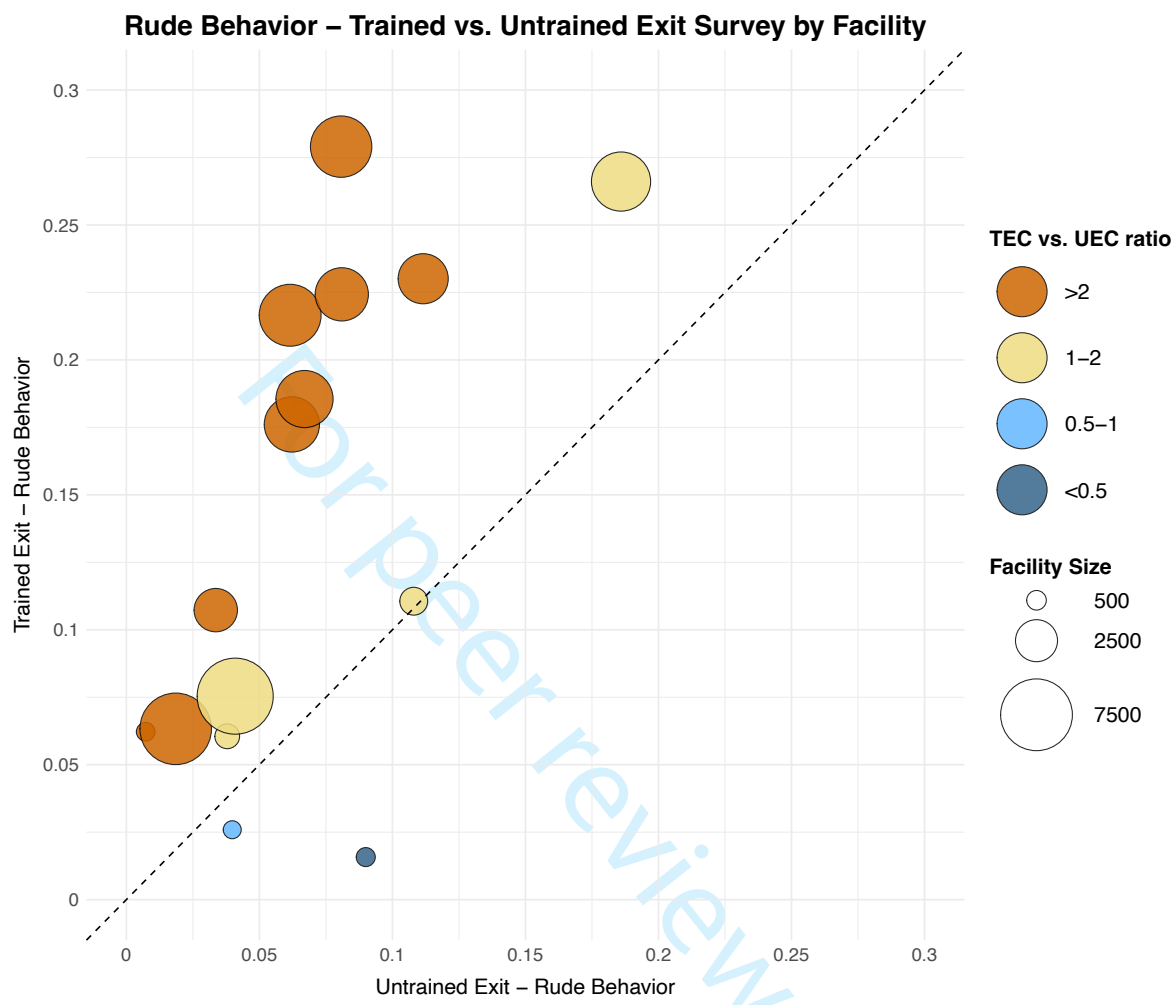


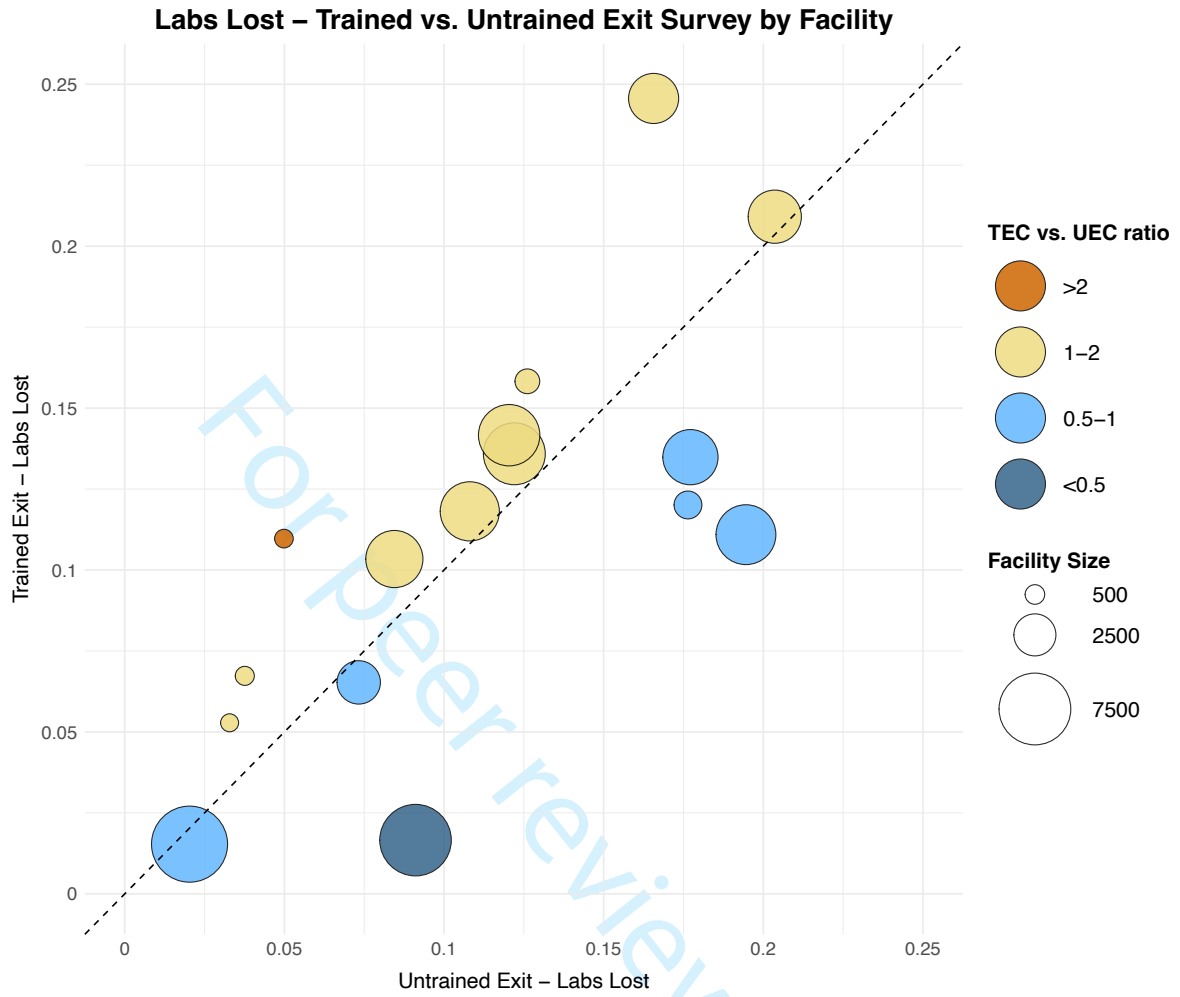
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## STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation	Page No
<b>Title and abstract</b>	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	1
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	1
<b>Introduction</b>			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	3,4
Objectives	3	State specific objectives, including any prespecified hypotheses	3
<b>Methods</b>			
Study design	4	Present key elements of study design early in the paper	4,5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	5
Participants	6	(a) <i>Cohort study</i> —Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up <i>Case-control study</i> —Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls <i>Cross-sectional study</i> —Give the eligibility criteria, and the sources and methods of selection of participants	5,6
		(b) <i>Cohort study</i> —For matched studies, give matching criteria and number of exposed and unexposed <i>Case-control study</i> —For matched studies, give matching criteria and the number of controls per case	N/A
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	5,7,8
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	5-7
Bias	9	Describe any efforts to address potential sources of bias	4
Study size	10	Explain how the study size was arrived at	8
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	7
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	7
		(b) Describe any methods used to examine subgroups and interactions	7
		(c) Explain how missing data were addressed	N/A
		(d) <i>Cohort study</i> —If applicable, explain how loss to follow-up was addressed <i>Case-control study</i> —If applicable, explain how matching of cases and controls was addressed <i>Cross-sectional study</i> —If applicable, describe analytical methods taking account of sampling strategy	N/A
		(e) Describe any sensitivity analyses	N/A

Continued on next page

<b>Results</b>			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	9
		(b) Give reasons for non-participation at each stage	9
		(c) Consider use of a flow diagram	N/A
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	9, 10
		(b) Indicate number of participants with missing data for each variable of interest	9,10
		(c) <i>Cohort study</i> —Summarise follow-up time (eg, average and total amount)	N/A
Outcome data	15*	<i>Cohort study</i> —Report numbers of outcome events or summary measures over time	N/A
		<i>Case-control study</i> —Report numbers in each exposure category, or summary measures of exposure	N/A
		<i>Cross-sectional study</i> —Report numbers of outcome events or summary measures	10
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	7,11
		(b) Report category boundaries when continuous variables were categorized	
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	12,14
<b>Discussion</b>			
Key results	18	Summarise key results with reference to study objectives	14,15
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	18
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	19,20
Generalisability	21	Discuss the generalisability (external validity) of the study results	18
<b>Other information</b>			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	20

\*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

**Note:** An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at [www.strobe-statement.org](http://www.strobe-statement.org).

# BMJ Open

## A Comparison of Patient Exit Interviews to Unannounced Standardised Patients for Assessing HIV Service Delivery in Zambia nested within a Cluster Randomised Trial

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2022-069086.R2
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# A Comparison of Patient Exit Interviews to Unannounced Standardised Patients for Assessing HIV Service Delivery in Zambia nested within a Cluster Randomised Trial

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## ABSTRACT

**Objectives:** To compare unannounced standardised patient approach (e.g., mystery clients) to typical exit interviews for assessing patient experiences in Human Immunodeficiency Virus (HIV) care (e.g., unfriendly providers, long-waiting times). We hypothesize standardized patients would report more negative experiences than typical exit interviews affected by social desirability bias.

**Setting:** Cross-sectional surveys in 16 government-operated HIV primary care clinics in Lusaka, Zambia providing antiretroviral-therapy (ART).

**Participants:** 3526 participants aged  $\geq 18$  years receiving ART participated in the exit surveys between August 2019 and November 2021.

**Intervention:** Systematic sample (every  $k^{\text{th}}$  file) of patients in clinic waiting area willing to be trained received pre-visit training and post-visit interviews. Providers were unaware of trained patients.

**Outcome measures:** We compared patient experience among patients that received a brief training prior to their care visit (explaining each patient experience construct in the exit survey, being anonymous, without manipulating behaviour) with those who did not undergo training on the survey prior to their visit.

**Results:** Among 3526 participants who participated in exit surveys, 2415 were untrained (56% female, median age 40 (inter quartile range [IQR]:32-47)) and 1111 were trained (50% female, median age 37 (IQR:31-45)). Compared to untrained, trained patients were more likely to report a negative care experience overall (adjusted Prevalence Ratio aPR for aggregate sum score: 1.64 [95% CI:1.39-1.94]), with a greater proportion reporting feeling unwelcomed by providers ([aPR]: 1.71 [95% CI:1.20-2.44]) and witnessing providers behaving rude (aPR: 2.28 [95% CI:1.63-3.19]).

**Conclusion:** Trained patients were more likely to identify sub-optimal care. They may have understood the items solicited better or felt empowered to be more critical., We trained existing patients, unlike studies that use “standardised patients” drawn from outside the patient population. This low-cost strategy could improve patient-centred service delivery elsewhere.

**Trial registration:** Assessment was nested within a parent study. [www.pactr.org](http://www.pactr.org) registered the parent study (PACTR202101847907585).

## STRENGTHS AND LIMITATIONS OF THIS STUDY

- This study utilised standardised patients (SP) to assess chronic care in which actual, rather than simulated patients were trained before their upcoming clinic visits.
- Traditional SP techniques require a trained simulated patient to visit multiple clinics, a strategy more appropriate for episodic care.
- Modified SP approaches can address the challenge of integrating patient experience into routine public health, a crucial quality indicator for governments and funders.
- We trained patients to assess care quality (e.g., waiting times, rude providers), and compared their responses to traditional untrained exit surveys in 16 facilities in Zambia.
- Training remains challenging as we did not include participants who were illiterate, had poor recall ability, or potentially struggled with comprehension.

## BACKGROUND

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6 138 Because of improved testing, linkage, and treatment to meet the global 95-95-95 treatment  
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8 139 targets (95% of HIV-positive patients know their status, 95% are on treatment, and 95% have  
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10 140 suppressed viral loads) [1], retention in care have become a major obstacle to improving Human  
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12 141 Immunodeficiency Virus (HIV) treatment outcomes, and health systems in low-income settings like  
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15 142 Zambia, have sought to shift their public health response by designing and delivering high quality  
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17 143 and patient-centred HIV care [2–7]. Efforts to improve service quality and patient experience require  
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19 144 systematic measurement of the patient experience to guide facility responses as poor patient  
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22 145 experience has been shown to lead to disengagement from care [8–12]. Health policymakers and  
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24 146 donors, such as the President's Emergency Plan for AIDS Relief (PEPFAR), have invested in clinical  
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26 147 metrics to assess care quality in Zambia and the wider region, but to a lesser extent in non-clinical  
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29 148 metrics like patient experience [13]. These metrics can be critical for guiding efforts to improve  
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31 149 retention in care by ensuring an informed response to improving quality of care and patient  
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33 150 centredness.

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37 151 Accurate and pragmatic measurement of the patient experience poses a range of challenges.  
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39 152 Patient experience exit surveys are prone to social desirability bias because of power dynamics in  
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41 153 health care. Empirical studies of satisfaction, for example, are widely believed to over-estimate  
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44 154 patient satisfaction [14]. This may be particularly true where provider-patient relationships are  
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46 155 traditional and hierarchical. Delaying surveys for some time after the encounter is theorised to  
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48 156 ameliorate social desirability bias, but in turn may exacerbate bias due to simple inability to  
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51 157 remember — thus creating recall bias [7,15]. Other methods such as direct clinical observations of  
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53 158 care pose practical difficulties [14,16]. For example, direct observations may be intrusive and  
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55 159 therefore may not reflect everyday functionality of a health facility. Care provided under direct  
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3 160 observations may be of higher quality as behaviour may be influenced by observation, a  
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5 161 phenomenon often known as the “Hawthorne effect” [14,16].  
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9 162 Standardised patients (SP), also known as “mystery clients” or “simulated patients” have  
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11 163 largely been used to assess quality of care in developed countries, as well as in assessing customer  
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13 164 service in the retail industry[17]. SP can be resource-intensive and require training, but reduce  
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16 165 potential for recall bias, social desirability, bias, and Hawthorne effects, providing an opportunity  
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18 166 for optimal assessment of patient satisfaction among people receiving HIV care [7,15,18]. They  
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20 167 have largely been used for episodic care where a highly skilled and well-trained person poses as a  
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23 168 client by making one visit to multiple facilities. This approach holds promise for assessing the  
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25 169 patient experience in HIV care but poses pragmatic challenges when assessing the quality of chronic  
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27 170 care in which a patient makes multiple visits and may compromise efficiency at, already  
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30 171 overburdened, facilities [19–24]. In this study, we report on the development and evaluation of a  
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32 172 modified SP approach in which we trained real patients (trained exit clients - TEC) to report on  
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34 173 certain characteristics of encounters, and rate key components of care such as waiting times,  
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37 174 communication, respectfulness of providers, and privacy.  
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## 40 175 **METHODS**

### 41 42 43 176 **Study design & setting**

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45 177 This study seeks to compare two different methods for assessing patient experience: standard  
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48 178 exit survey and those reported by patients who had a brief training on the items before the clinical  
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50 179 encounter and to whom the clinic was blinded. The assessment was nested within a parent study:  
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52 180 the Leveraging Person-Centred Public Health (PCPH) to improve HIV outcomes in Zambia study  
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55 181 ([www.pactr.org](http://www.pactr.org) PACTR202101847907585), a Stepped Wedge Cluster Randomised Trial that  
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3 182 occurred between August 2019 and November 2021. The aim of the overall PCPH study was to  
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6 183 assess the impact of introducing health care workers (HCW) to a patient-centred care (PCC)  
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8 184 curriculum and mentoring them on PCC principles to improve retention and viral suppression in  
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10 185 HIV care. In this nested sub-study, we compared cross sectional surveys of patient experience using  
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12 186 two different survey methods: adapted standardised approach (Trained Exit Clients) vs traditional  
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15 187 exit surveys.  
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## 17 188 18 19 189 **Population**

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22 190 The sub-study reported here included 16 health facilities in Lusaka, Zambia, operated by the  
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24 191 Ministry of Health (MOH) and receiving technical assistance from the Centre for Infectious  
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26 192 Diseases Research in Zambia (CIDRZ) - a Zambian non-governmental organisation (NGO) as well  
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28 193 as a part of the larger parent study. We surveyed adults aged 18 years and over who were accessing  
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31 194 antiretroviral therapy (ART) at study facilities. Exit survey patients were selected in a systematic  
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33 195 sample (every  $k^{\text{th}}$  file varied by facility size) at the time of exit from the clinic. Trained patients were  
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35 196 recruited in the waiting room for their visit, underwent a brief training, and then answered survey  
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38 197 questions on exit from their encounter. Participants attending an HIV care visit on the day, able to  
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40 198 recall events and comprehend study participant recruitment details (as assessed using the  
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42 199 comprehension assessment tool) and able to read and write (assessed using literacy tool) were  
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44  
45 200 eligible for inclusion.  
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## 47 201 48 49 202 **Procedures and Measurements**

### 50 51 203 *Survey Instrument*

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54 204 For both survey methods, we developed a patient experience instrument based on a previously  
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56 205 validated tool developed and used in Kenya: The Wachira Physician-Patient Communication  
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3 206 Behaviours Scale [25–27]. This survey assessed elements of patient experience including how they  
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5 207 were greeted, communicated to, and overall experience. We included additional questions to capture  
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8 208 for example, patient reports of witnessing rude behaviour, receiving appropriate medications and  
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10 209 availability of lab results. Prior to use in this study, we performed cognitive interviews among  
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12 210 twenty participants to assess consistency in understanding questions in English, Bemba and Nyanja.  
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15 211 Surveys were forward and back translated to ensure consistency across the three languages. The  
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17 212 survey tools for trained and untrained clients were identical. Research assistants were trained by the  
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19 213 first author in recruitment, training and administering of the TEC and UEC survey in all 16 facilities.  
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21 214 The provincial and district health management teams were informed about the unannounced TEC  
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24 215 survey as well as the UEC survey. The study team sensitised all facility staff at the start of the study,  
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26 216 but HCWs were not aware of who specific TECs were.  
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### 30 31 218 Procedures for Trained and Untrained Exit Clients

32  
33 219 Efforts to “standardise” assessment of the quality and nature of care in HIV care differs from  
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35 220 most previously standardised patient or mystery client work in that HIV care is longitudinal as  
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38 221 opposed to episodic or acute care. Under these circumstances, the more conventional standardised  
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40 222 patient where a single trained actor can present to multiple different care facilities as a simulated  
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42 223 patient with a defined set of symptoms or complaints to assess a single episode of care is not feasible.  
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45 224 For example, a patient would have to either register as a new patient or have a false “file” introduced  
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47 225 into the paper and electronic medical records — which was deemed infeasible and undesirable.  
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49 226 Instead of simulated patients, we recruited existing patients already receiving care at a particular  
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51 227 facility and then subsequently trained them on the concepts of quality of care according to the MOH  
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54 228 manual on Quality Improvement for HCWs in Zambia. To avoid disclosing their trained status,  
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3 229 patients were recruited on the day of their visit prior to them entering the triage area (i.e., the first  
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5 230 point of contact with HCWs). Those who consented underwent a single one-on-one training session  
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8 231 for 40 to 60 minutes where they were sensitised to the study instrument (which was the same for  
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10 232 both TEC and untrained exit clients (UEC)), the MOH care standards, and strategies on being natural  
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12 233 yet observant during their clinic visit for that day according to the standard SP approach. These  
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15 234 procedures were meant to ensure patients had a clear and uniform understanding on what they should  
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17 235 expect during a high-quality patient visit and were attentive to these critical aspects relative to these  
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19 236 standards. Immediately after this training, the TEC presented themselves to their facility and  
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22 237 completed their visit as they normally would. After their clinic encounter, participants then  
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24 238 completed the exit survey in a private area.

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26 239 For the untrained exit surveys, we took a systematic (every  $k^{th}$ , varied by facility size) sample  
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29 240 among the patients leaving the facility after attending the clinic on the survey day. Patients were  
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31 241 approached by study staff after the visit using a recruitment script to determine their eligibility and  
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33 242 were administered the survey after granting consent in a private area.

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35 243 For both trained and untrained clients, all interviews and surveys were conducted in either  
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38 244 English, Bemba or Nyanja depending on the participant's preference. Given the extra time  
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40 245 commitments required for the training, TEC participants were given K100 (~\$5) for the time spent  
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42 246 during training as well as a light snack during the survey administration.

## 46 47 248 **Statistical Analysis**

48  
49 249 To assess the association between training and response for each question, we conducted  
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52 250 unadjusted and adjusted Poisson regression for each question separately [28]. We then assessed the  
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54 251 overall association between training and total sum score. We used descriptive statistics to

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3 252 characterise patient characteristics and report survey responses. In these analyses, most of the survey  
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6 253 responses were reverse coded to identify when respondents reported a negative experience. Results  
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8 254 for individual questions (binary response) represent prevalence ratios for reporting a lapse in care.  
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10 255 To assess the sum score (count data) we used Poisson regression, estimating the rate ratio for  
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12 256 reporting lapses in care. All models were adjusted, given potential differences in survey participants  
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15 257 related to different recruitment strategies using mixed-effects regression, adjusted for age, sex,  
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17 258 education, care status at the time (i.e., continuously retained in care versus returning to care after  
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19 259 disengagement/ lost to follow up [LTFU]), secular time (using cubic splines), allowing random  
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22 260 effects at the facility level. We present these results for the overall population as well as stratified  
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24 261 by different pre-defined patient subgroups. Lastly, we used bubble plots to compare summary  
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26 262 assessments of the patient experience at the facility-level using TECs versus UECs. All analyses  
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29 263 were performed using STATA 14MP (StataCorp, College Station, TX, USA). This sub-study  
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31 264 represents a secondary analysis and no formal power calculations were performed for this outcome.  
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### 35 266 **Statement of Ethics Approval**

36 267  
37 267  
38 268 Ethics approval to conduct this research was granted by the Zambian Ministry of Health,  
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40 269 National Health Research Authority, and the institutional review boards of the University of Zambia  
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42 270 (008-03-19), the University of Alabama at Birmingham (300003282) and the London School of  
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45 271 Hygiene and Tropical Medicine (21384).  
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### 47 272 48 49 273 **Patient and Public Involvement**

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52 274 Survey questions were developed through a cognitive process with recipients of care. Study  
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54 275 implementation guidance was conducted as part of routine CIDRZ partnership with the Zambian  
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3 276 MOH through a Human Centered Design workshop. CIDRZ engages with implementing partners  
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6 277 and affected communities in health facilities, including people living with HIV often represented by  
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8 278 neighbourhood health representatives. Although patients were not directly involved in the design of  
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10 279 the parent study intervention or the analysis presented here, all study activities were guided by a  
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12 280 Scientific Advisory Board with representation from the MOH and a representative of recipients of  
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15 281 HIV care. Dissemination of study results is ongoing.  
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## 18 282 RESULTS

### 21 283 Characteristics of health facilities and patients

23 284 We approached 4375 clients (2955 in the untrained and 1420 in the trained), and 3526  
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25 participated, of which 2415 (55.2%) completed experience surveys as untrained exit clients (UEC)  
26 285 (56% female, median age was 40 years (interquartile range [IQR]:32-47 years)) and 1111 (32%)  
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28 286 completed experience surveys as trained exit clients (TEC) (50% female with a median age 37 years  
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30 287 (IQR:31-45 years). Reasons for non-participation included unavailability at the time due to other  
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32 288 commitments. Sixteen percent (16%) of UECs and 40% of TECs who had been lost to care and were  
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34 289 returning to care on the day of the survey. Education levels differed between UEC and TEC with 47%  
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36 290 and 58% reporting completion of secondary level of education, respectively (Table 1). UEC and  
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38 291 TEC were similar for HIV enrolment WHO stage with the largest proportion enrolling at WHO  
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40 292 stage 1 and similar in terms of marital status.  
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**Table 1. Socio-demographic characteristics of untrained exit and trained exit clients**

Characteristics	Level	Untrained Exit Clients n=2415 (68%)	Trained Exit Clients n=1111 (32%)
<b>Sex, n (%)</b>			
	<b>Female</b>	1355 (56)	553 (50)
	<b>Male</b>	1060 (44)	558 (50)

<b>Age, Median (IQR)</b>		40 (32-47)	37 (31-45)
<b>Age category, n (%)</b>			
	<b>&lt;30 years</b>	453 (19)	258 (23)
	<b>30-40 years</b>	828 (34)	416 (37)
	<b>40-50 years</b>	815 (34)	304 (27)
	<b>&gt;50 years</b>	319 (13)	133 (12)
<b>Education category</b>			
	<b>None</b>	132 (5)	36 (3)
	<b>Primary</b>	654 (27)	166 (15)
	<b>Secondary</b>	1134 (47)	645 (58)
	<b>University</b>	150 (6)	100 (9)
	<b>Missing</b>	307 (13)	151 (14)
<b>HIV Enrollment Stage</b>			
	<b>WHO Stage 1</b>	1173 (49)	533 (48)
	<b>WHO Stage 2</b>	314 (13)	147 (13)
	<b>WHO Stage 3</b>	355 (15)	162 (15)
	<b>WHO Stage 4</b>	27 (1)	7 (1)
	<b>Missing</b>	546 (23)	262 (24)
<b>Care status at survey visit</b>			
	<b>In care</b>	2038 (84)	664 (60)
	<b>Returning to care</b>	377 (16)	447 (40)
<b>Marital Status</b>			
	<b>Single</b>	257 (11)	167 (15)
	<b>Married</b>	1361 (56)	575 (52)
	<b>Divorced</b>	248 (10)	108 (10)
	<b>Widowed</b>	173 (7)	81 (7)
	<b>Unknown</b>	41 (2)	20 (2)
	<b>Missing</b>	335 (14)	160 (14)
<b>Facility size</b>			
	<b>&lt; 1000 patients</b>	591 (25)	245 (22)
	<b>1000-5000 patients</b>	897 (37)	485 (44)
	<b>&gt; 5000 patients</b>	927 (38)	381 (34)

Table 2 shows the absolute responses for TEC and UEC. Although most patients reported a good experience, across the questions between 5% and 25% of patients reported poor experiences in care. For example, when asked if their HIV care provider gave them as much information about their health as they wanted, 13.4% (UEC) vs 24.6% (TEC) of patients reported not being provided with sufficient information about their health. Similarly, between 9.6% vs 18.8% patients reported

that their HIV care provider was not spending the right amount of time with them at their visit, and 6.8% vs 16.4% reported witnessing rude behaviour.

**Table 2. Survey responses by training status**

Factor	Level	Untrained Exit Client n (%)	Trained Exit Client n (%)
Did your HIV care provider greet you in a way that made you feel comfortable?	Yes	2249 (93.1)	980 (88.2)
	No	166 (6.9)	131 (11.8)
Did your HIV care provider listen to what you said?	Yes	2328 (96.4)	1039 (93.5)
	No	79 (3.3)	64 (5.8)
	Refused	8 (0.3)	8 (0.7)
Did your HIV care provider give you as much information about your health as you wanted?	Yes	2092 (86.6)	838 (75.4)
	No	323 (13.4)	273 (24.6)
Did your HIV care provider allow you to ask questions?	Yes	2082 (86.2)	887 (79.8)
	No	326 (13.5)	222 (20)
	Refused	7 (0.3)	2 (0.2)
Did your HIV care provider spend the right amount of time with you?	Yes	2179 (90.2)	900 (81)
	No	232 (9.6)	209 (18.8)
	Refused	4 (0.2)	2 (0.2)
Overall, how did you feel about the care you received today?	Happy	2231 (92.4)	983 (88.5)
	Unhappy	178 (7.4)	123 (11.1)
	Refused	6 (0.2)	5 (0.4)
Overall, were you satisfied with all your HIV care providers today?	Yes	2206 (91.4)	906 (81.5)
	No	208 (8.6)	202 (18.2)
	Refused	1 (0.0)	3 (0.3)
I witnessed HIV care providers behaving rudely during my visit today	No	2251 (93.2)	928 (83.5)
	Yes	163 (6.8)	182 (16.4)
	Refused	1 (0.0)	1 (0.1)
Were your lab results lost?	No	2143 (88.7)	985 (88.7)
	Yes	268 (11.1)	126 (11.3)
	Not picking up	4 (0.2)	0 (0)
Were you able to pick up your medicine today?	Yes	2366 (98.0)	1087 (97.8)
	No	48 (2.0)	24 (2.2)
	Not Picking Up Meds	1 (0.0)	0 (0)

**Effects of training on response patterns: sum score and prevalence ratios**

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3 310 In adjusted models, TECs overall reported poor experiences in care: 1.64 times as frequently as  
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5 UEC respondents (Sum Score Rate Ratio [RR]: 1.64 [95% CI: 1.39-1.94] (Fig 1, Supplementary  
6 311  
7  
8 312 Table S1), and reported an increased prevalence of poor experiences in care quality compared to  
9  
10 313 untrained across almost all questions. For example; among TECs compared to UECs, there was an  
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12 314 increased prevalence of reports of not being greeted in a way that made them feel welcome (adjusted  
13  
14 Prevalence Ratio [aPR]: 1.71 [95% CI: 1.20-2.44]), reporting being dissatisfied with all their HIV  
15 315  
16 care providers during their HIV care visit (aPR: 2.06 [95% CI: 1.61-2.63]) and witnessing any  
17 316  
18 providers behaving rudely during their visit (aPR: 2.28 [95% CI: 1.63-3.19]) (Fig 1, Supplementary  
19 317  
20 Table S1).  
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### 25 320 **Impact of training across age, sex, and gender to differences in responses**

  
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27 321 In stratified analysis of the impact of training on the sum score, training was consistently  
28  
29 associated with increased identification of poor experiences in care across all subgroups apart from  
30 322  
31 those aged 50 years or older and those with no education. We also observed that training had a larger  
32 323  
33 impact among females compared to males, those with a primary education only, and among  
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35 individuals presenting at smaller facilities (Fig 2). We observed similarities in responses on the  
36 325  
37 impact of training on different age categories, sex, care status and different levels of education when  
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39 326 we looked at individual questions except for the question on providers spending the right amount of  
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41 327 time where we found that females were twice as likely to report lapses with care compared to males  
42  
43 328 (Supplementary Figure 1). Using TECs gave worse assessments of patient experience at the facility-  
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45 level regardless of facility size compared to UECs (Fig 3, Supplementary Figure 2).  
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## 54 55 56 57 58 59 60 **DISCUSSION**

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3 334 Disengaged patients often express a disconnect between their care expectations and the  
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6 335 provider's style, hence experience is bound to vary across facilities [8]. This disconnect can lead to  
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8 336 dissatisfaction with HIV services which can often lead to patients dropping out of care[8,11,29]. A  
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10 337 brief training for patients living with HIV on how to evaluate the quality and experience of routine  
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12 338 care changed patient experience reports compared to untrained patients using the same instrument.  
13  
14  
15 339 Patients who underwent a brief training identified more lapses in care across most questions. Women  
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17 340 and young people were more likely to report critical responses after training - consistent with the  
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19 341 idea that those who feel least empowered underwent the biggest change. Differences were also  
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21  
22 342 bigger for questions in which social desirability is likely to operate. For example, larger differences  
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24 343 were observed for witnessing rude behaviour, while no differences were observed for more objective  
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26 344 questions such as whether lab results were lost.  
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30 345 Improving HIV health outcomes requires new strategies that minimise methodological biases  
31  
32 346 and includes everyone the patient encounters during their visit, including clinical officers, doctors,  
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34 347 nurses, data clerks, and lay HCWs. Our TEC approach could contribute to getting a true reflection  
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37 348 of how much value patients place on things such as effective communication, being greeted  
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39 349 appropriately, or being treated with care and respect at all these different touch points. Involving  
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41 350 patients in their own care and design of health services has been linked to improved HIV care  
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44 351 retention and patient outcomes, such as higher viral suppression rates [30–32]. As progress is being  
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46 352 made towards UNAIDS 95-95-95 targets, the global HIV sector is constantly reviewing priorities  
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48 353 and challenges for optimal engagement in care [33,34]. Patient experience is a key indicator of  
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51 354 healthcare quality for meeting the 95-95-95 targets: delivering services patients need, can access,  
52  
53 355 and address wider determinants of poor health. Clinicians and health systems must address HIV  
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55 356 patients' needs from diagnosis to death to ensure healthy ageing and viral suppression. Other  
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3 357 outcomes in Zambia [11,35,36] show that lifelong needs vary by facility, highlighting the  
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5 importance of metrics that measure patient experience accurately. We have shown that it is feasible  
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8 359 to involve patients in assessing the quality of care and this could potentially lead to involvement of  
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10 360 patients in the redesign of healthcare services.

11  
12 361 Because HIV care is longitudinal, SP, who are often used to evaluate episodic care, require  
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14 highly skilled people to pose as a simulated patient making one visit to multiple clinics, posing  
15 362  
16 practical implementation challenges in our setting[19–24]. Contrary to SP, we evaluated care quality  
17 363  
18 without using simulated patients and administered the survey once among people in long term care.  
19 364  
20 Using real patients instead of simulated ones drawn from outside the true patient population, we  
21 365  
22 would argue, made our TEC approach more applicable and reproducible in clinical settings. We  
23  
24 366 were able to record HCW behaviour in a typical HIV context using this concealment method,  
25  
26 367 potentially reducing the impact of the Hawthorne effect. Our TECs also consistently identified more  
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28 368 lapses in care, potentially reducing social desirability bias and ability to identify issues at the facility.  
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31 369 Even though training takes time, the increased quality of our measurement allows one to perform  
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33 370 fewer surveys. With traditional approaches like exit surveys, one would require a larger sample size,  
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35 371 but this does not address bias [37].  
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40 373 Our findings are consistent with a study done in South Africa which found that non-clinical  
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42 374 dimensions of care play a bigger role in determining an overall satisfactory experience for  
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44 standardised patients when compared to untrained patients[37]. However, our findings may  
45 375  
46 contradict previous suggestions that tailoring support to individuals to build skills and confidence  
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48 through patient activation can lead to trained/informed patients reporting a better experience than  
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50 untrained/ uninformed [38]. TECs cared about the following non-clinical aspects of care: rude  
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52 providers, being satisfied with HIV care providers, and spending enough time with providers. This  
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3 380 finding is consistent with a previous study in Zambia, where patients reported rude HCWs deterring  
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5 381 HIV care engagement [8,10,11]. This could mean that studies assessing patient experience with TEC  
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8 382 could focus on a few questions to save time and resources. Questions like, "Did you pick up your  
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10 383 medicine or lab results at your visit?" may not add much to a TEC survey because they are definitive,  
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12 384 and training appears to influence subjective care dimensions.

14  
15 385 Women TECs were generally more critical about the care they received and would likely  
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17 386 provide a more accurate reflection of the health system, possibly because they have better health-  
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19 387 seeking behaviour than men, which may be strongly influenced by local gender norms and health  
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22 388 service structures designed to engage women of reproductive age [39]. There is some consistency  
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24 389 with other findings that women may be more interested in their care than men, especially in facilities  
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26 390 that provide integrated services for women and their children [9,40]. Despite longer wait times,  
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29 391 women were more satisfied with integrated facilities [41]. In addition, middle-aged people between  
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31 392 40-50 benefited the most from training. Compared to older people over 50, younger people under  
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33 393 30 were less satisfied with the care they received and often felt they were not greeted by a HCW  
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35 394 during their visit. This finding is consistent with cultural norms where younger people are less  
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38 395 respected[42]. Given the current strategy of targeting young people, who account for most new  
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40 396 infections, these findings suggest an important new approach to identifying what young people value  
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42 397 most. Education level was among the strongest predictors of patient experience feedback. Well-  
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45 398 educated patients were found to have a less critical/better HIV care visit experience compared to  
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47 399 participants with lower levels of educational attainment. This difference in care experience report  
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49 400 may be associated, at least in part, with the HCW perception of the patient in the facility. Research  
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51 401 conducted in Nigeria discovered that people with higher levels of education are frequently given

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3 402 better and more considerate treatment by HCW, hence limited by a form of discrimination/  
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5 403 socioeconomic status bias [43,44].  
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8 404 The observed effect of training on patient experience is likely multifaceted potentially  
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10 405 stemming from increased attention and recall to the exit survey items which solicited a feeling of  
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12 406 empowerment to be more critical of the care received. In future studies, patient activation should be  
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14  
15 407 measured as an outcome to see how training changes the patient's engagement with their care over  
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17 408 time [38]. Further research is required into why women TECs reported poorer experiences with care  
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19 409 than men. Other studies that have used SP to assess medical students' performance showed that  
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22 410 women were more critical on certain aspects of care. These studies also recommend matching of  
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24 411 SPs to clinicians by sex [45], something we were not able to do given the nature of our study in  
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26 412 primary health facilities where we assessed interpersonal communication with HCWs at all levels.  
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29 413 Perhaps our findings call for more investigation into the integration of women's services, such as  
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31 414 family planning and children's services with HIV care given some studies have shown this can  
32  
33 415 improve patient satisfaction.  
34

### 35 416 **Limitations**

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37  
38 417 Our findings should be interpreted with caution due to the following limitations. Because this  
39  
40 418 was the first time such a study was done, we recruited educated participants who were able to read  
41  
42 419 and write, perceived to have good recall ability and were able to comprehend things. Our study was  
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45 420 only done in Lusaka province in facilities that were largely urban except for one facility which was  
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47 421 peri-urban hence it is hard to generalise these findings. Another limitation in our approach is the  
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49 422 one-time cross-sectional nature of our measurements among people in long term HIV care. If more  
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52 423 measures were collected from each TEC, we may well see them being activated in a way that results  
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54 424 in an improvement in their experience based on the skills they develop to seek better care from  
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3 425 providers which ultimately would improve their retention in care. Despite its limitations, the TEC  
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6 426 method provides valuable information about healthcare quality, even though it is limited to  
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8 427 situations where "walk-ins" are permitted. Our approach only focused on real patients accessing  
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10 428 care and we did not manipulate any patient files, so it is possible that some TECs were known to the  
11  
12 429 facility as patients accessing chronic care. Our approach does require a trained interviewer to speak  
13  
14  
15 430 with TECs after their visits, but this is not any different to what already exists. In future, it may be  
16  
17 431 worth using the domains in the national HIV guidelines as the gold standard, but we did not do this  
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19 432 as our aim was to come up with a low-cost approach that can easily be rolled out. In addition, the  
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21  
22 433 concept of patient centred care is still catching on in Zambia. Our TEC approach can be used to  
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24 434 further the knowledge in provider attitudes to other relatively new approaches to delivering quality  
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26 435 HIV care such as differentiated service delivery (DSD) for stable patients by assessing whether  
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29 436 HCWs follow guidelines when offering this [34]. We also see an opportunity to assess provider  
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31 437 patient communication of viral load laboratory results by use of a universal script for each TEC to  
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33 438 assess if they are communicated to and if unsuppressed but adherent, what procedures followed.

## 34 35 36 37 439 **Conclusion**

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40 440 TEC offers pragmatic methods for health systems in low-income countries to assess non-  
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42 441 clinical dimensions of care (communication, respect, and autonomy) which are grounded on the  
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45 442 concept of health-system responsiveness and could be critical to the transformation of low-quality  
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47 443 health systems to high quality ones[46]. Hawthorne effects and social desirability biases may be  
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49 444 mitigated using TECs. We were able to capture HCWs behaviour in a normal day to day low middle  
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52 445 income setting using similar approaches recommended by King and colleagues that minimise harm  
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54 446 to HCWs and SPs [15]. Our findings suggest that TECs provide a more critical appraisal of some

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3 447 aspects of the quality of HIV care. It provides new insights in the Zambian context on what patients'  
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6 448 value when they interact with the health system. This could be important given the need to reduce  
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8 449 loss to follow up among new ART clients who disengage within the first 6 months of treatment due  
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10 450 to a bad first encounter with the health system. Our TEC approach could be used to assess  
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12 451 reengagement interventions. The fact that TECs had a better understanding of the items solicited or  
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14  
15 452 felt empowered to be more critical shows that the training we provided worked. This low-cost  
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17 453 method could be reproduced in other routine settings and presents an opportunity to further  
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19 454 institutionalise patient centred care by evaluating what happens at the point of contact between the  
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22 455 patient, the health facility, and the health provider. The implications are that it provides an  
23  
24 456 opportunity to improve HIV care, meet patients' expectations and can serve as a monitoring tool for  
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26 457 healthcare performance. Coupled with the recent approaches to client led monitoring in HIV care,  
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29 458 our approach can be used to enhance decision making that considers patients' involvement.  
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### **Data Availability Statement**

The Government of Zambia allows data sharing when applicable local conditions are satisfied. In this case, the data from the study will be made available to any interested researchers upon request. The CIDRZ Ethics and Compliance Committee is responsible for approving such requests. To request data access, one must write to the Secretary to the Committee/Head of Research Operations, Mrs. Hope Chinganya ([Hope.Chinganya@cidrz.org](mailto:Hope.Chinganya@cidrz.org)) mentioning the intended use for the data. The Committee will then facilitate review and authorization to release the data as requested. Data requests must include contact information, a research project title, and a description of the intended use.

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## Contributors

KS: guarantor, lead author, conducted all analyses, led data management activities, field  
coordination of activities and designed data collection tools. JMP: field coordination of data, assisted  
with analysis and revising it critically for important intellectual content, designed data collection  
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BR: final approval for publication, assisted with framing and revising it critically for important  
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drafted statistical analysis plan, assisted with conceptualisation and interpretation of data. JM:  
assisted with data acquisition and cleaning, field coordination of data quality processes. SS: led  
intervention implementation, project administration and data curation. LKB, NM, AS: cognitively  
tested data collection tools, assisted with conceptualization, underlying data processes, and assisted  
with writing and data interpretation. DM, MM-M: advised implementation details. AW, JH: assisted  
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conceptualisation and advised regarding intervention implementation details. IS: funding

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2  
3 515 acquisition, assisted with conceptualisation and manuscript writing. EHG: funding acquisition, led  
4  
5  
6 516 conceptualisation and advised on all analyses, final approval for publication.  
7

### 8 517 **Statement of Ethics Approval**

9 518  
10 519 Ethics approval to conduct this research was granted by the Zambian Ministry of Health,  
11  
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13  
14  
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16  
17 522 Hygiene and Tropical Medicine (21384).  
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22 524 **Figure 1. Forest plot comparing responses from Trained Exit Clients (TEC) relative to**  
23 525 **Untrained Exit Clients (UEC) on 10 measures of clinic experience.** Points indicate the rate  
24 526 ratio (for sum score) or prevalence ratio (for all others) for identifying a lapse in care in TEC  
25 527 surveys as compared to UEC. The sum score represents the total number of binary responses (yes  
26 528 vs no) across all clients in one group shown as a rate ratio. The red line indicates a rate or  
27 529 prevalence ratio of 1 and values greater than this indicates more lapses in care identified in TECs.  
28 529 Results are based on mixed-effects models adjusted for age, sex, education with a random effect at  
29 530 the facility.  
30 531  
31 532

32 533 **Figure 2. Impact of Training on Identifying Care Lapses Stratified by Subgroups (N=3480).**  
33 534 When all questions were collapsed into a Sum score among TEC, females were more likely to report  
34 535 lapses in care quality than males. We observed some level of interaction for care status, age category,  
35 536 education category and facility size.  
36 536  
37 537

38 538 **Figure 3. Bubble plot showing Trained Exit Sum Score vs Untrained Exit Sum Score.** Each  
39 539 bubble represents a single facility's performance. Each bubble's size indicates the number of patients  
40 540 at each facility with larger bubbles corresponding to larger facilities. The horizontal position notes  
41 541 the Untrained Exit Sum Score for all questions against the facility, and the vertical position notes  
42 542 the Trained Exit sum score at the same facility.  
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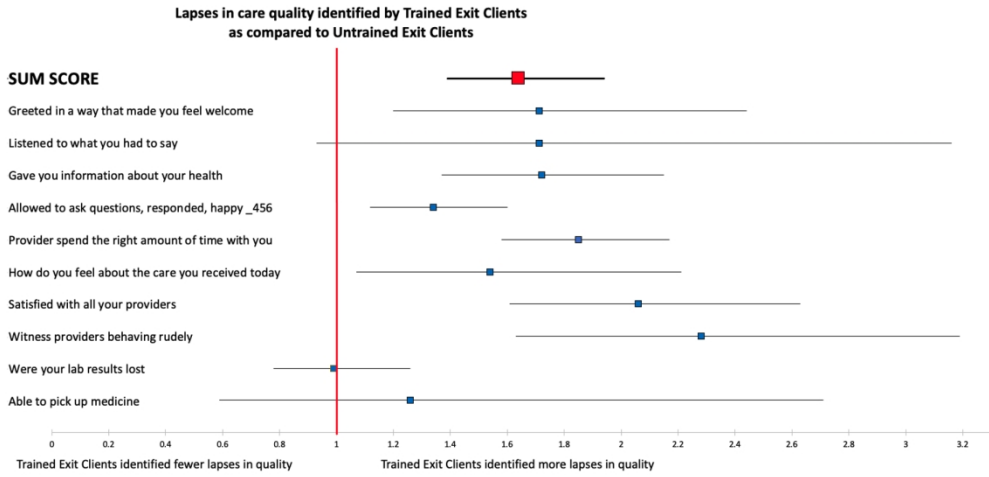
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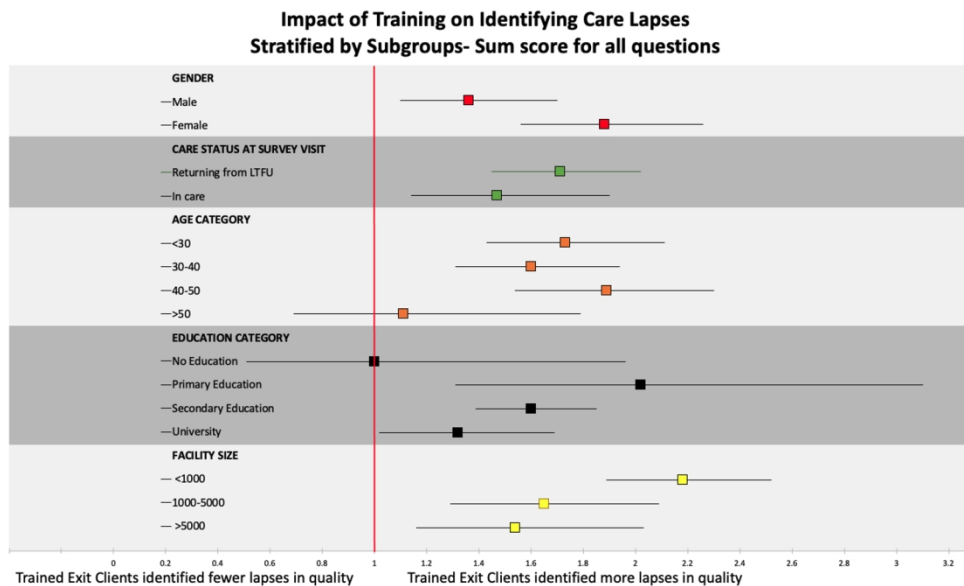
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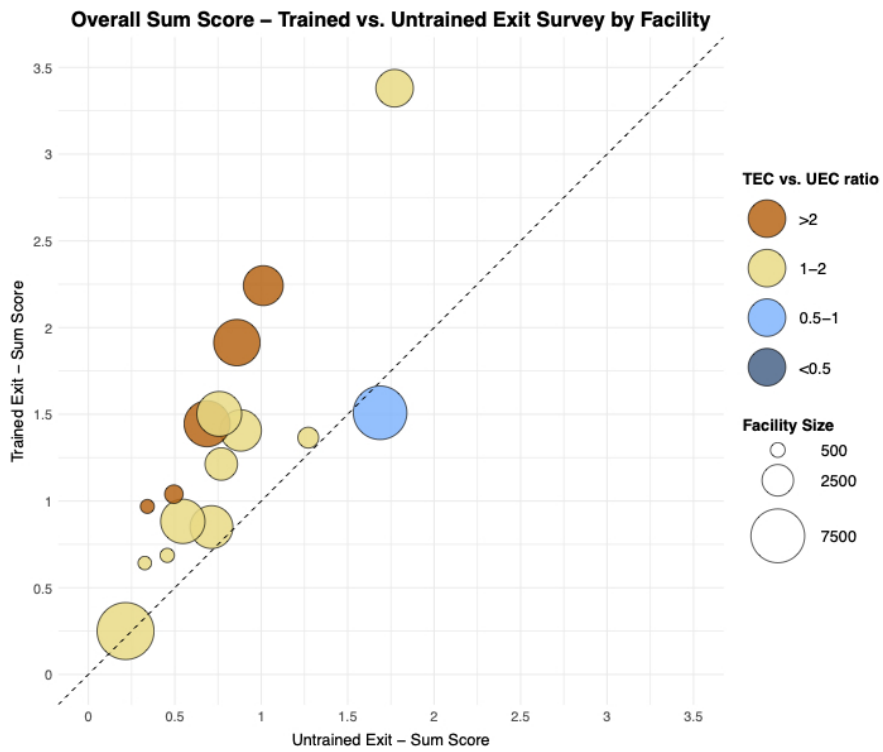
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## Supplementary Tables S1

**Supplementary Table S1. Mixed effect Poisson regression comparing 10 questions for Trained Exit Clients vs Untrained Exit Clients. Adjusted for age, sex, education, and study period.**

Trained Exit Clients	Prevalence ratio (PR) Unadjusted	P value	95% Confidence Interval (CI)	PR-Adjusted	P value	95% Confidence Interval (CI)	N
Sum score (Rate ratio)	1.73	<0.01	1.47-2.02	1.64	<0.01	1.39-1.94	3480
Did your HIV care provider greet you in a way that made you feel comfortable?	1.74	0.01	1.24-2.44	1.71	<0.01	1.20-2.44	3526
Did your HIV care provider listen to what you said?	1.77	0.09	0.91-3.45	1.71	0.09	0.93-3.16	3510
Did your HIV care provider give you as much information about your health as you wanted?	1.82	<0.01	1.43-2.33	1.72	<0.01	1.37-2.15	3526
Did your HIV care provider allow you to ask questions?	1.44	<0.01	1.20-1.73	1.34	<0.01	1.12-1.6	3517
Did your HIV care provider spend the right amount of time with you?	1.94	<0.01	1.66-2.27	1.85	<0.01	1.58-2.17	3520
Overall, how did you feel about the care you received today?	1.51	0.02	1.06-2.16	1.54	0.02	1.07-2.21	3515
Overall, were you satisfied with all your HIV care providers today?	2.12	<0.01	1.68-2.66	2.06	<0.01	1.61-2.63	3522
I witnessed HIV care providers behaving rudely during my visit today	2.39	<0.01	1.73-3.32	2.28	<0.01	1.63-3.19	3524
Were your lab results lost?	0.99	0.98	0.84-1.19	0.99	0.93	0.78-1.26	3522
Were you able to pick up your medicine today?	1.04	0.90	0.57-1.89	1.26	0.55	0.59-2.71	3525

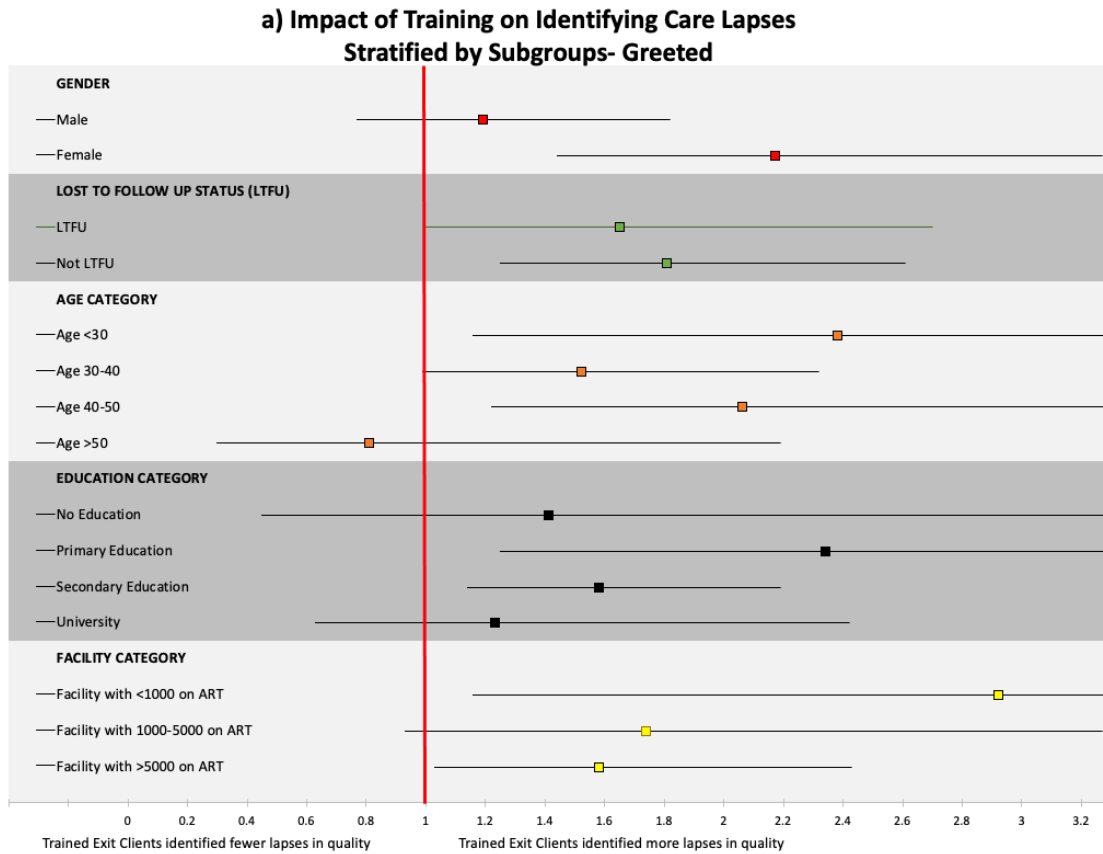


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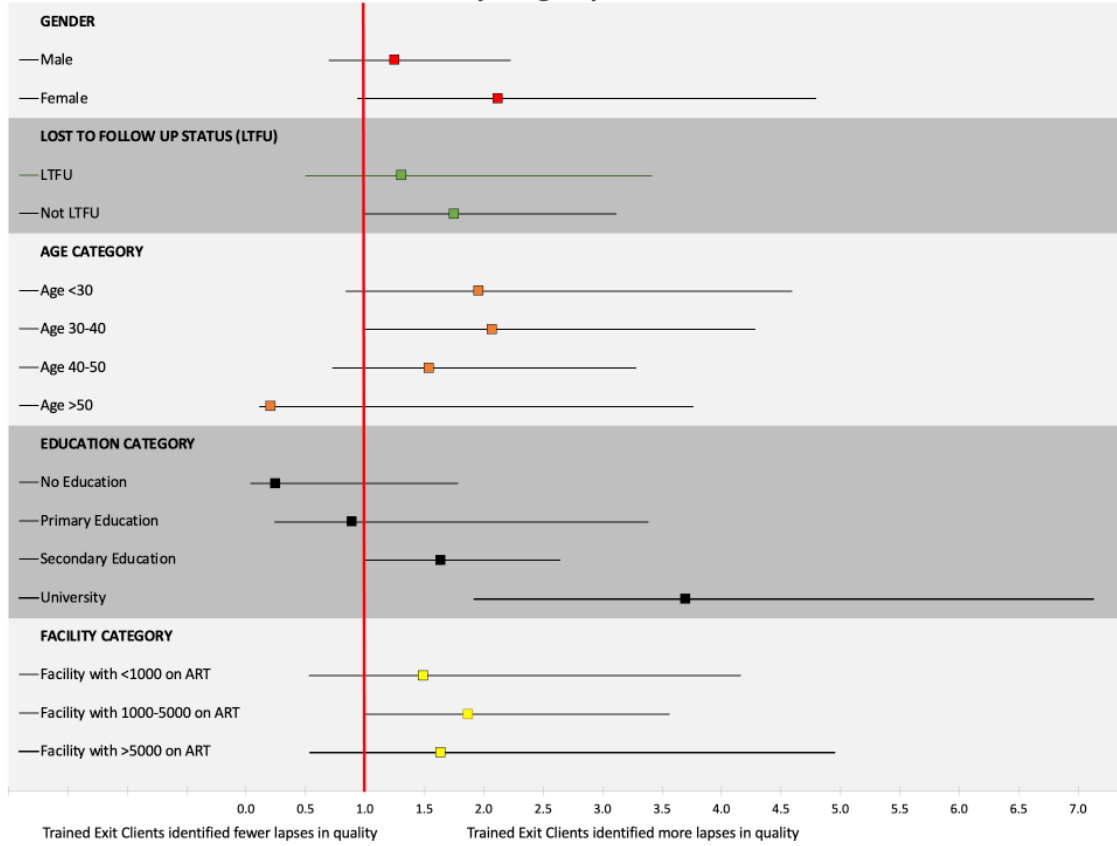
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Supplementary Figure 1.

**Impact of Training on Identifying Care Lapses Stratified by Subgroups for 10 questions.** We observed some level of interaction for care status, age category, education category and facility size. Panel **a)** Greet you in a way that made you feel comfortable **b)** Listen to what you said **c)** Give you as much information about your health as you wanted **d)** Allowed you to ask questions, responded, happy q456 **e)** spend the right amount of time with you **f)** feel about the care you received today **g)** satisfied with all your HIV care providers today **h)** witnessed HIV care providers behaving rudely during my visit today **i)** lost lab results **j)** pick up meds

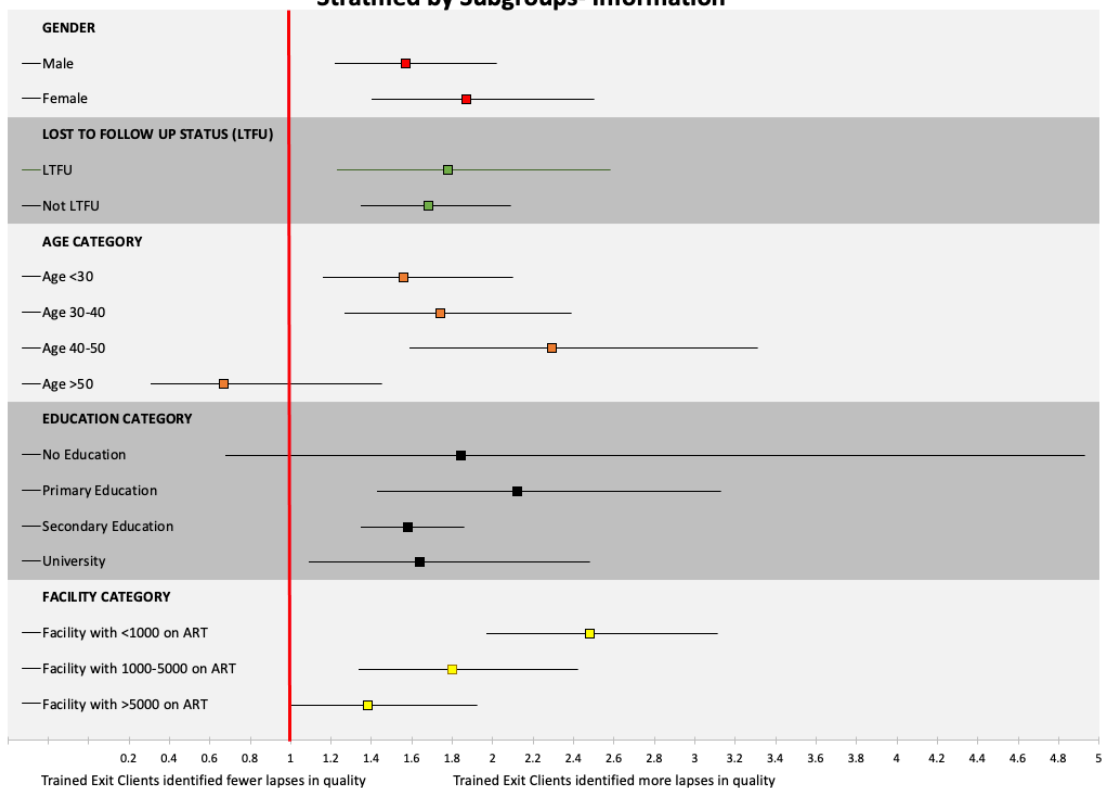


### b) Impact of Training on Identifying Care Lapses Stratified by Subgroups- Listened



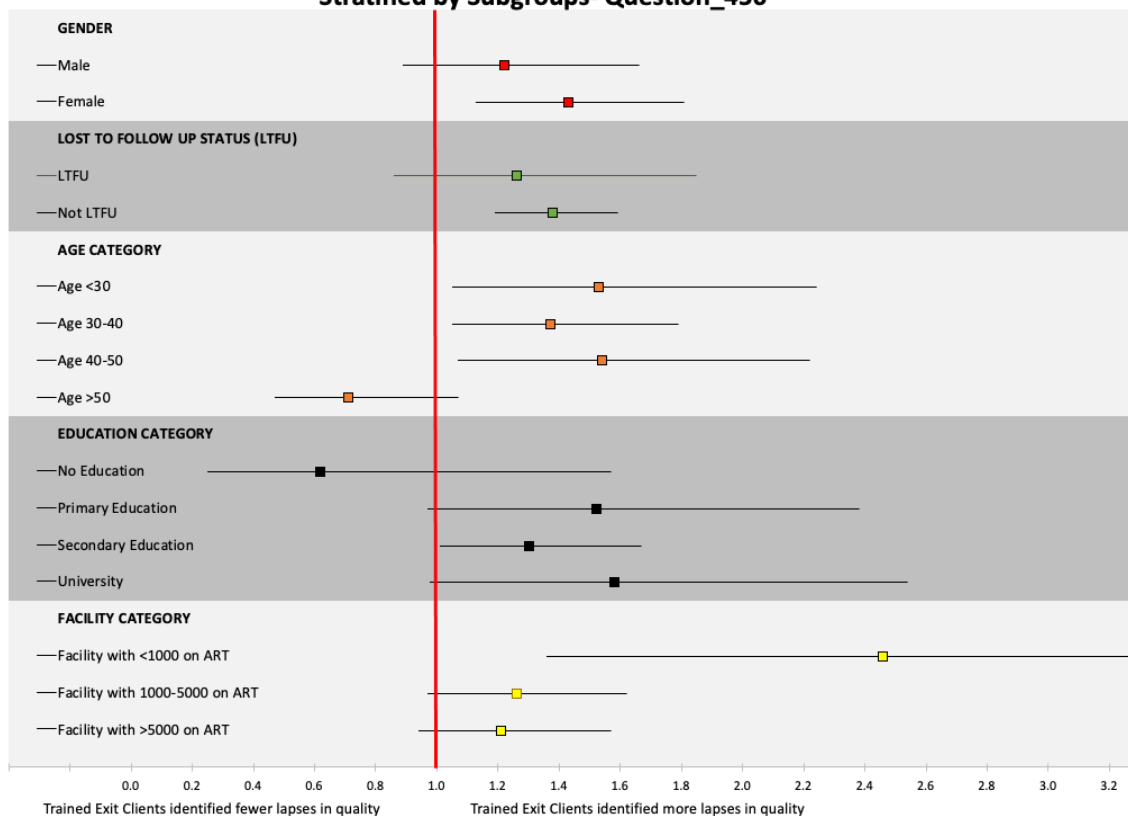
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**c) Impact of Training on Identifying Care Lapses  
Stratified by Subgroups- Information**



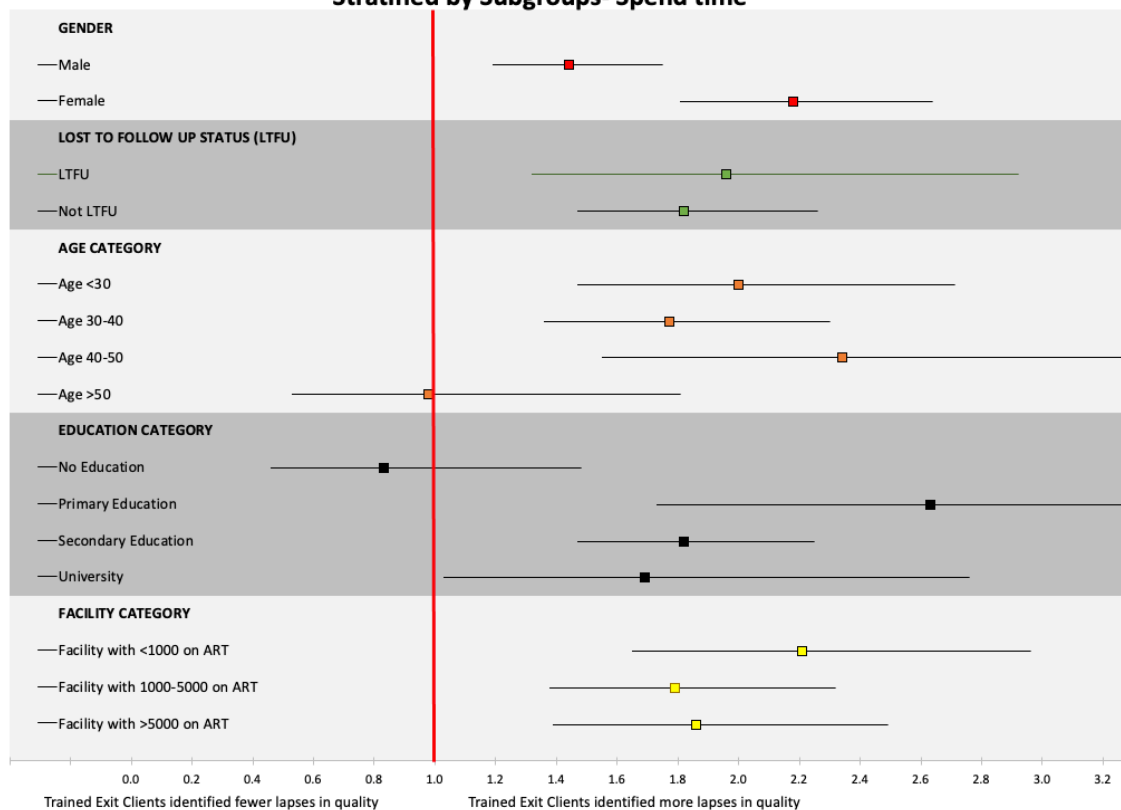
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**d) Impact of Training on Identifying Care Lapses  
Stratified by Subgroups- Question\_456**



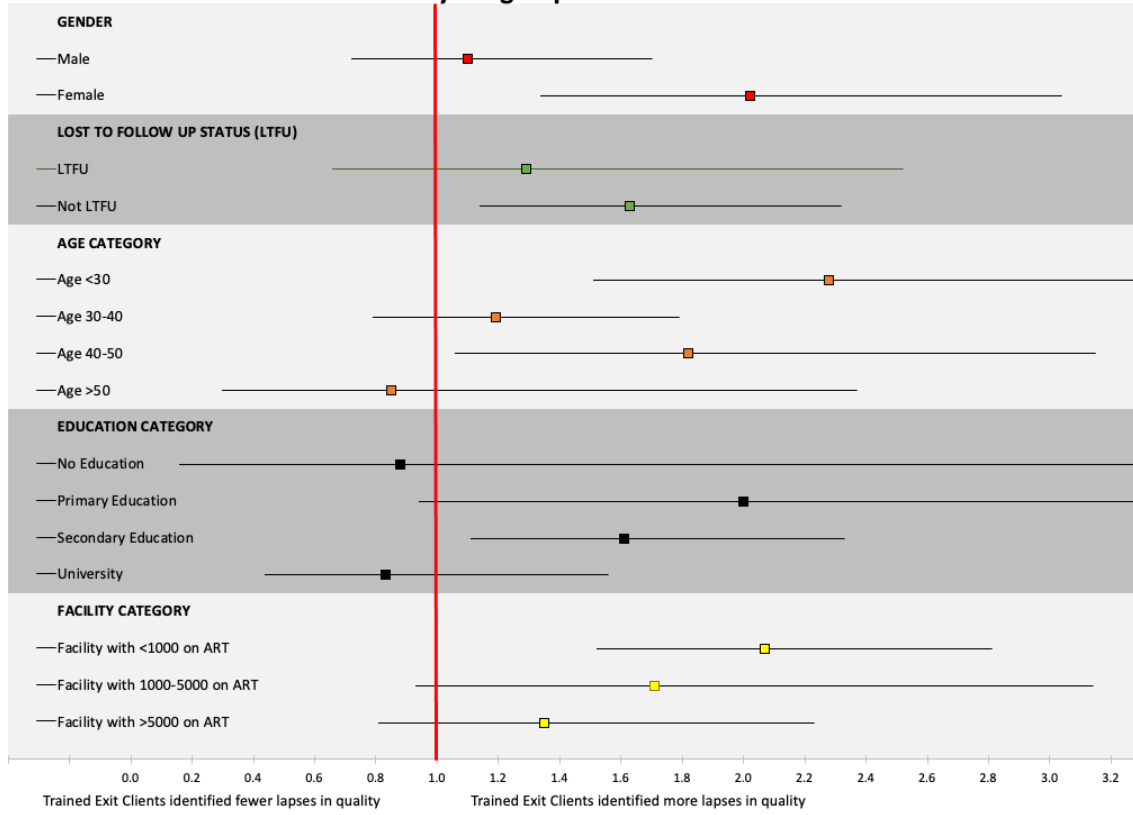
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**e) Impact of Training on Identifying Care Lapses  
Stratified by Subgroups- Spend time**



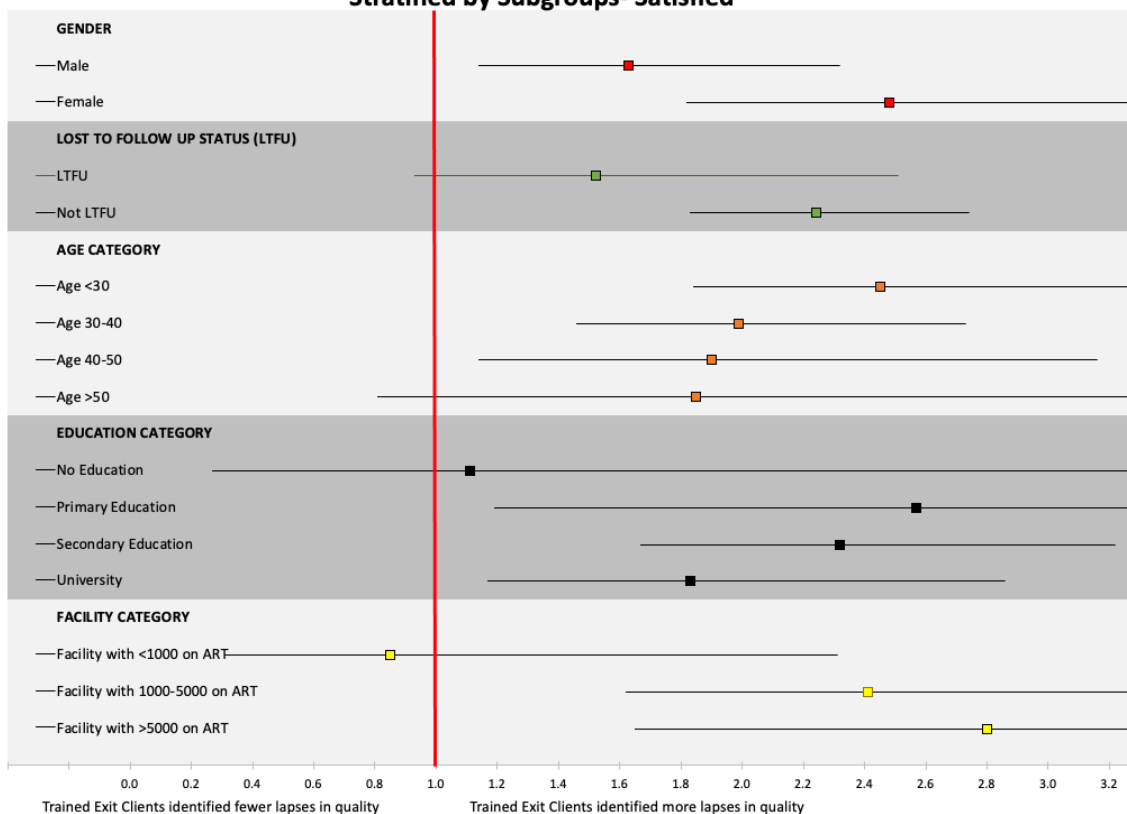
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### f) Impact of Training on Identifying Care Lapses Stratified by Subgroups- Feel about care



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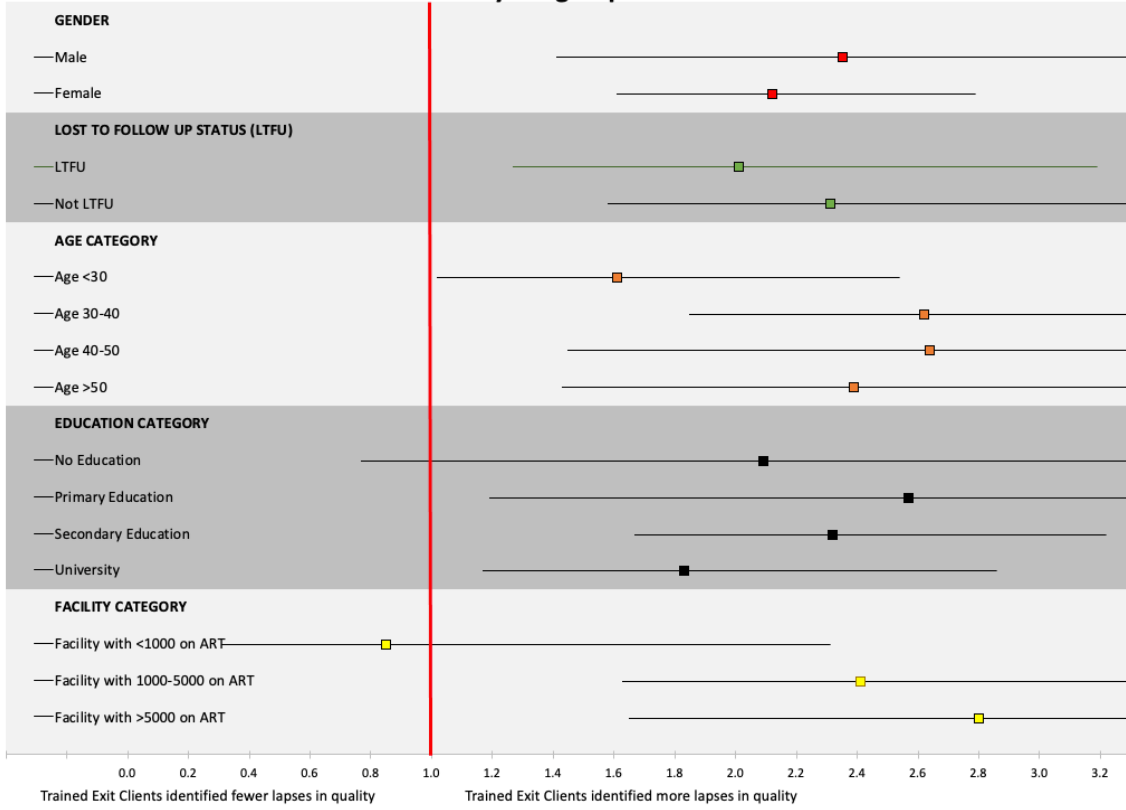
**g) Impact of Training on Identifying Care Lapses  
Stratified by Subgroups- Satisfied**



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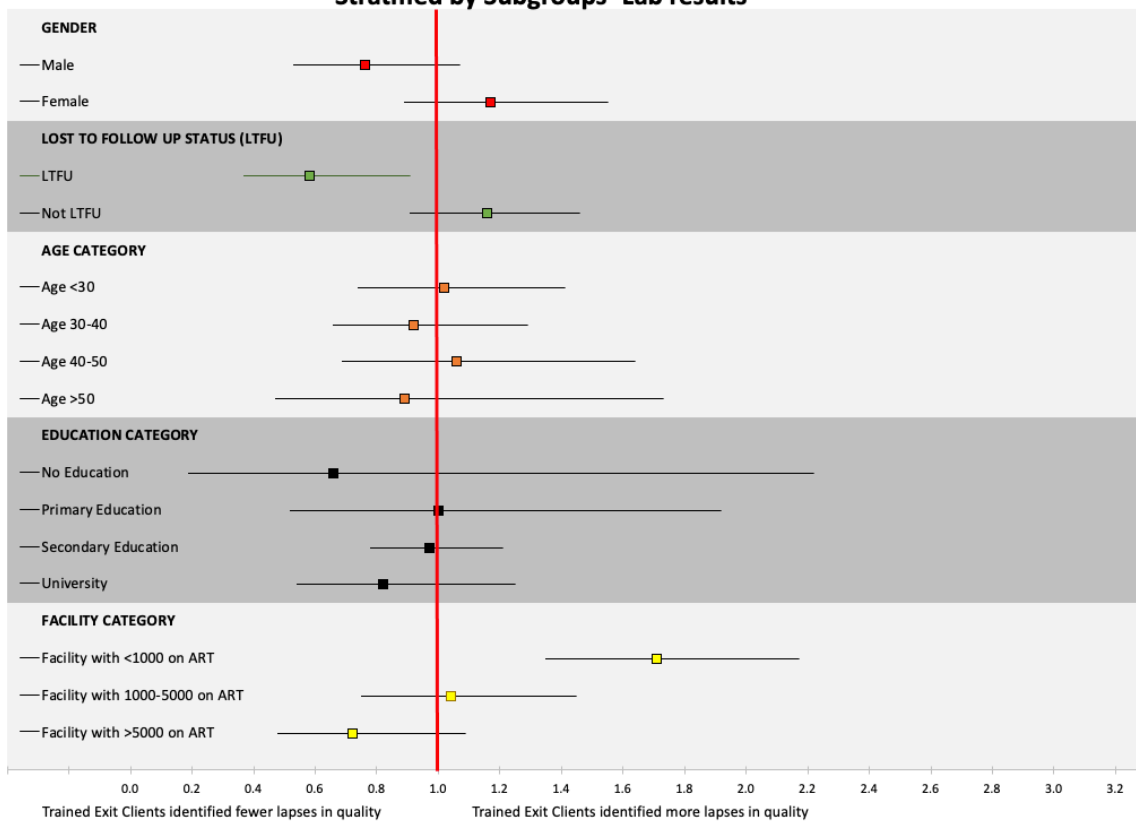


### h) Impact of Training on Identifying Care Lapses Stratified by Subgroups- Rude



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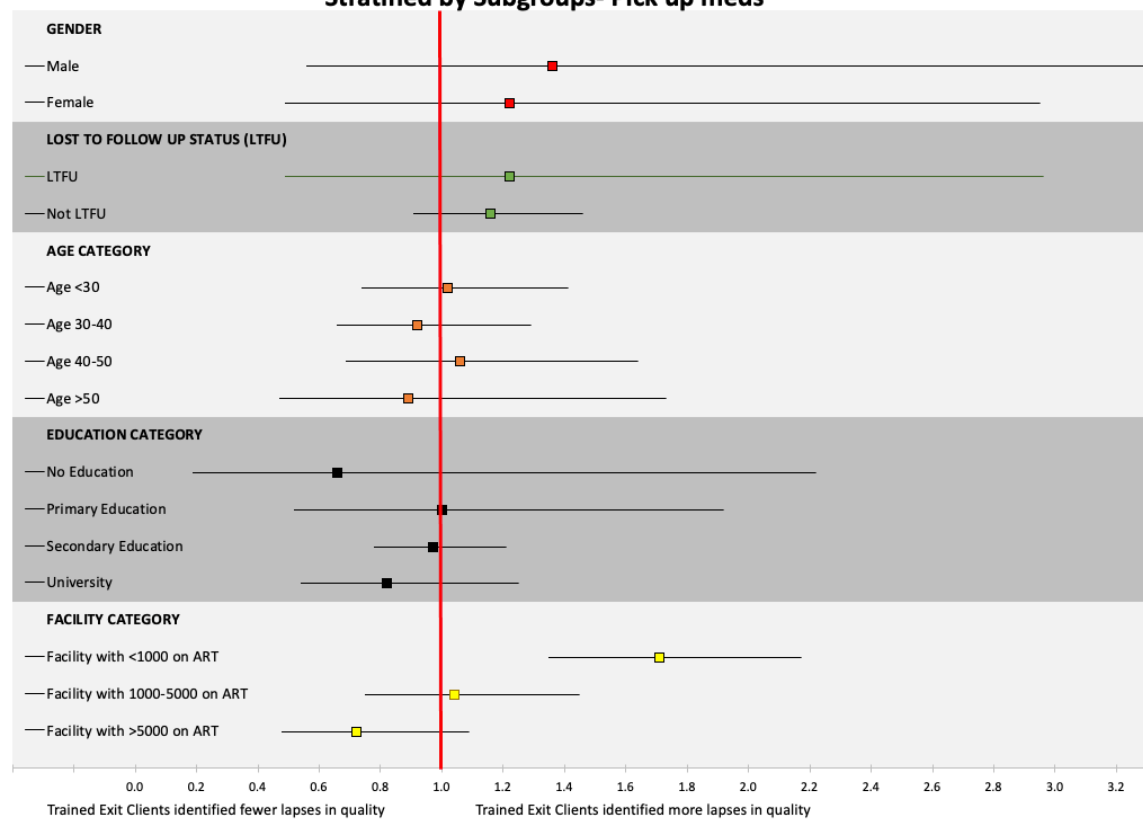
**i) Impact of Training on Identifying Care Lapses  
Stratified by Subgroups- Lab results**



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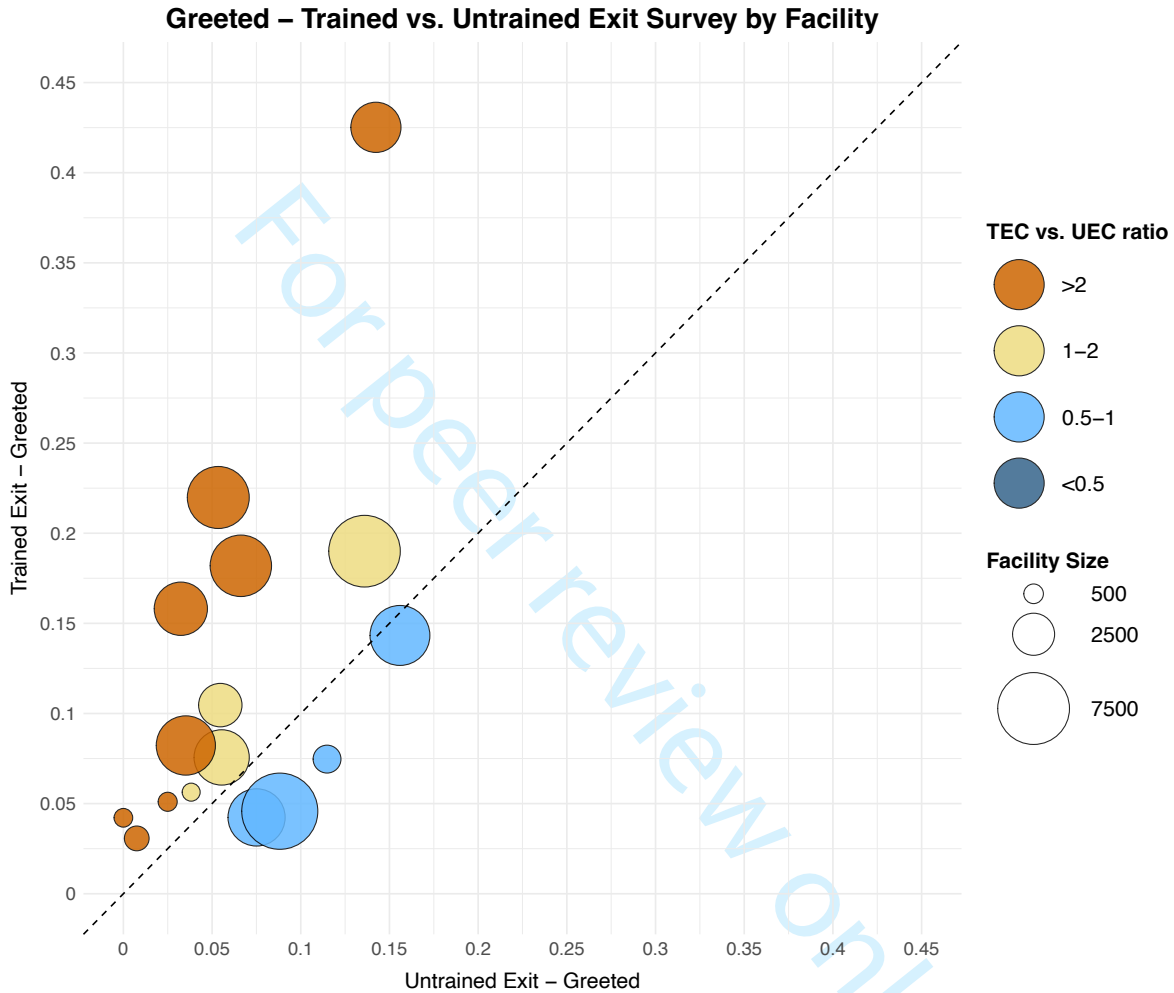
### j) Impact of Training on Identifying Care Lapses Stratified by Subgroups- Pick up meds



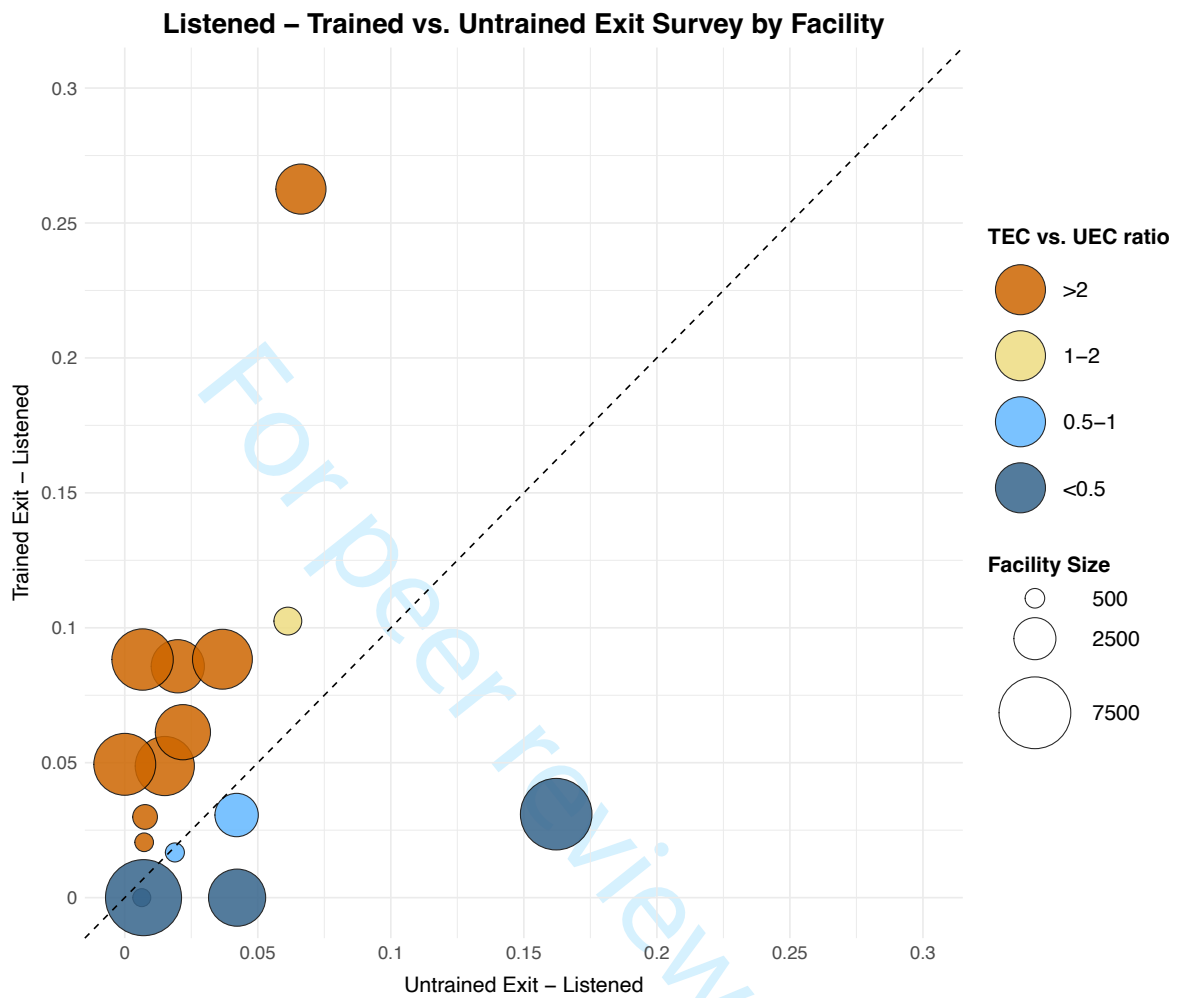
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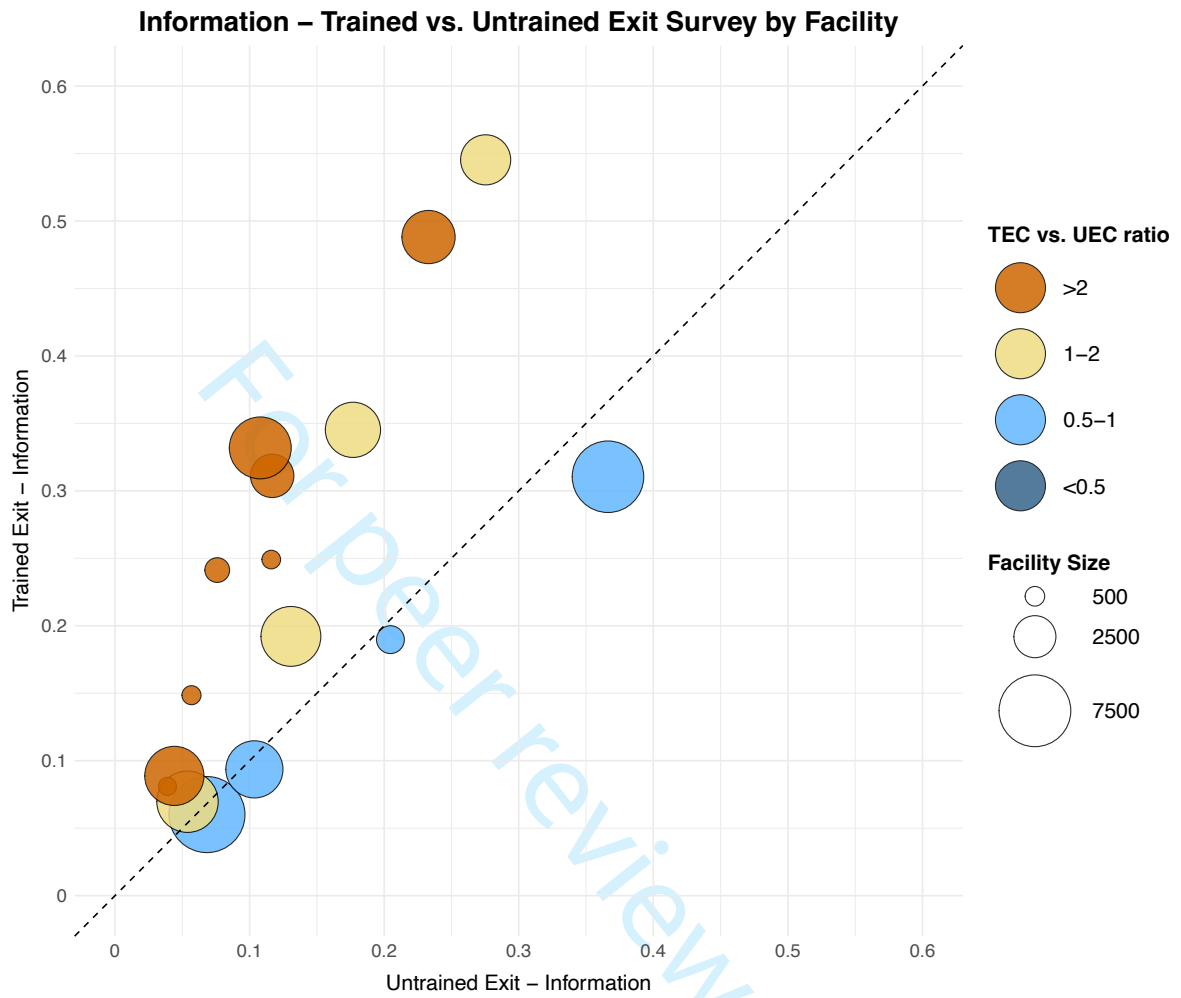
Supplementary Figure 2

**Supplementary Figure 2.** Bubble plot showing Trained Exit Sum Score vs Untrained Exit Sum Score. Each bubble represents a single facilities performance. Each bubble's size indicates the number of patients at each facility with larger bubbles corresponding to larger facilities. The horizontal position notes the Untrained Exit Sum Score for all questions against the facility, and the vertical position notes the Trained Exit sum score at the same facility.



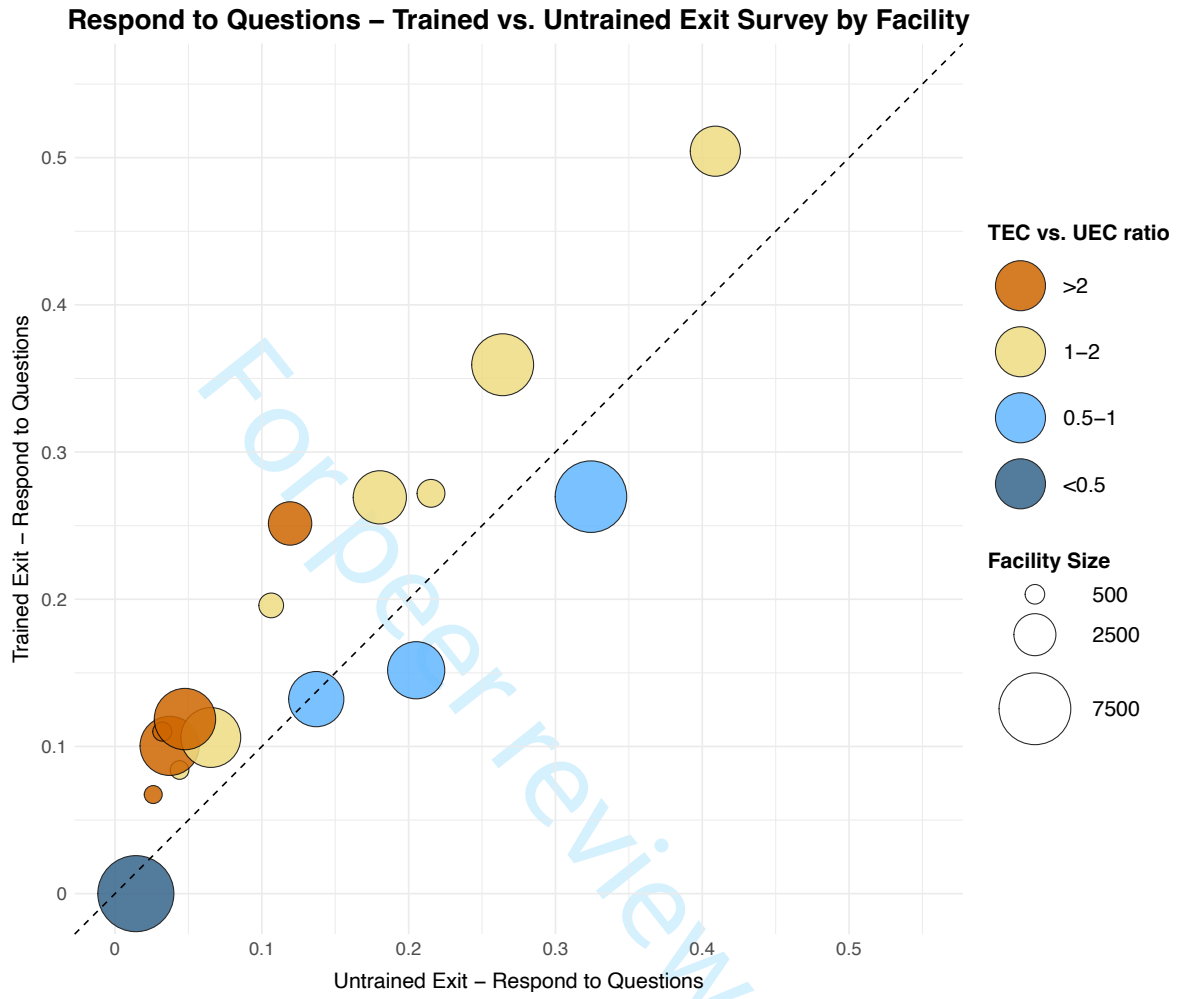
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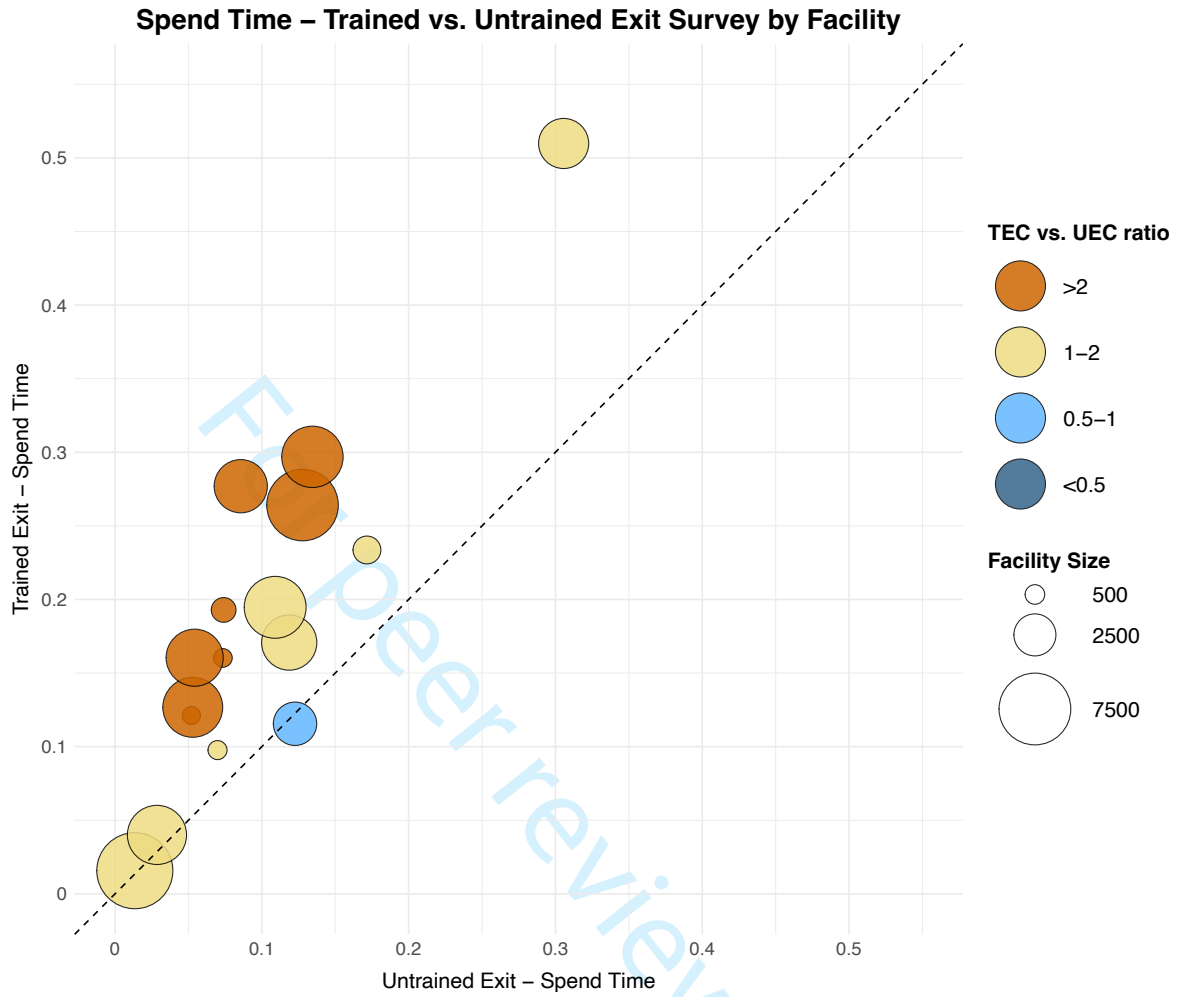




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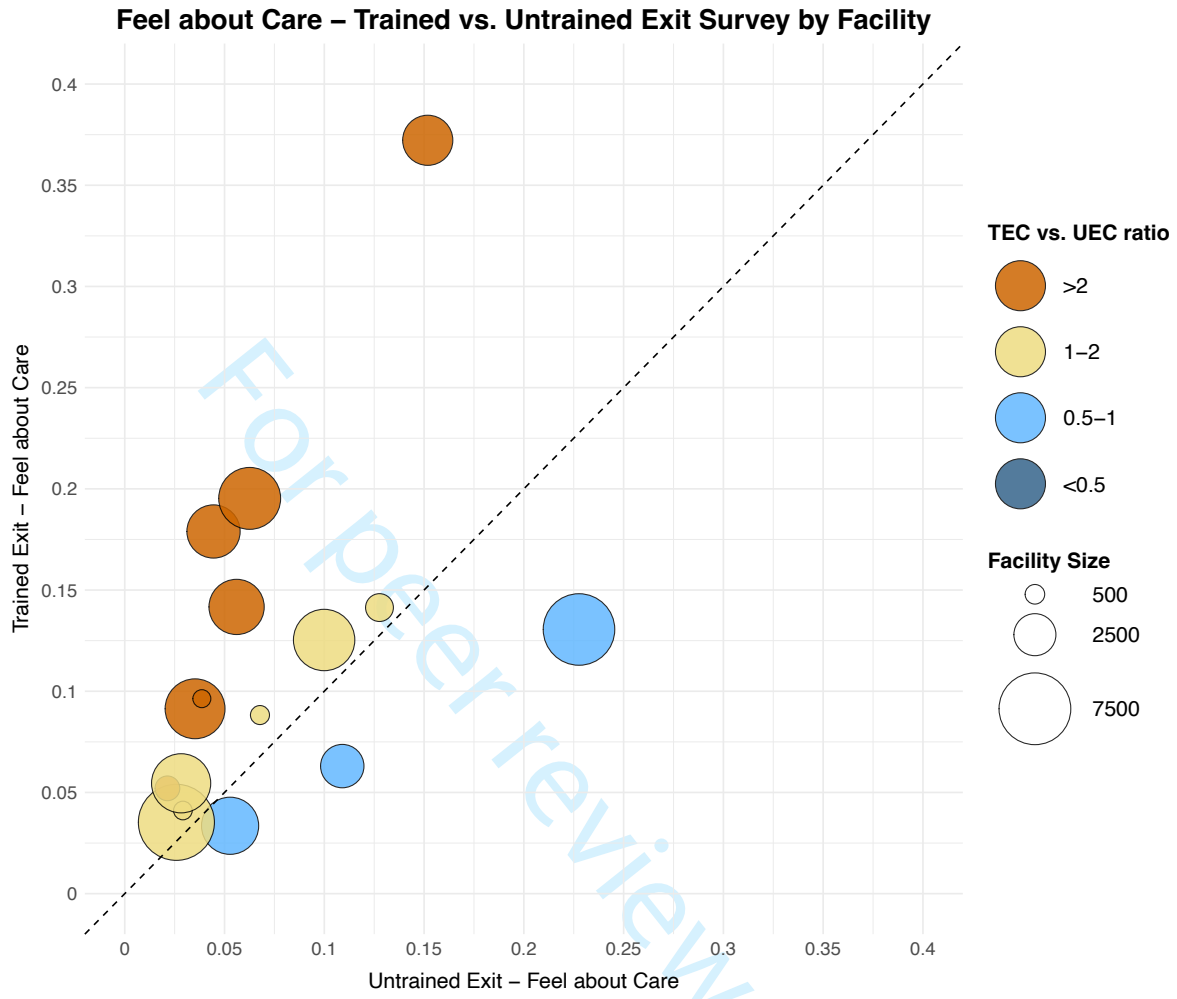
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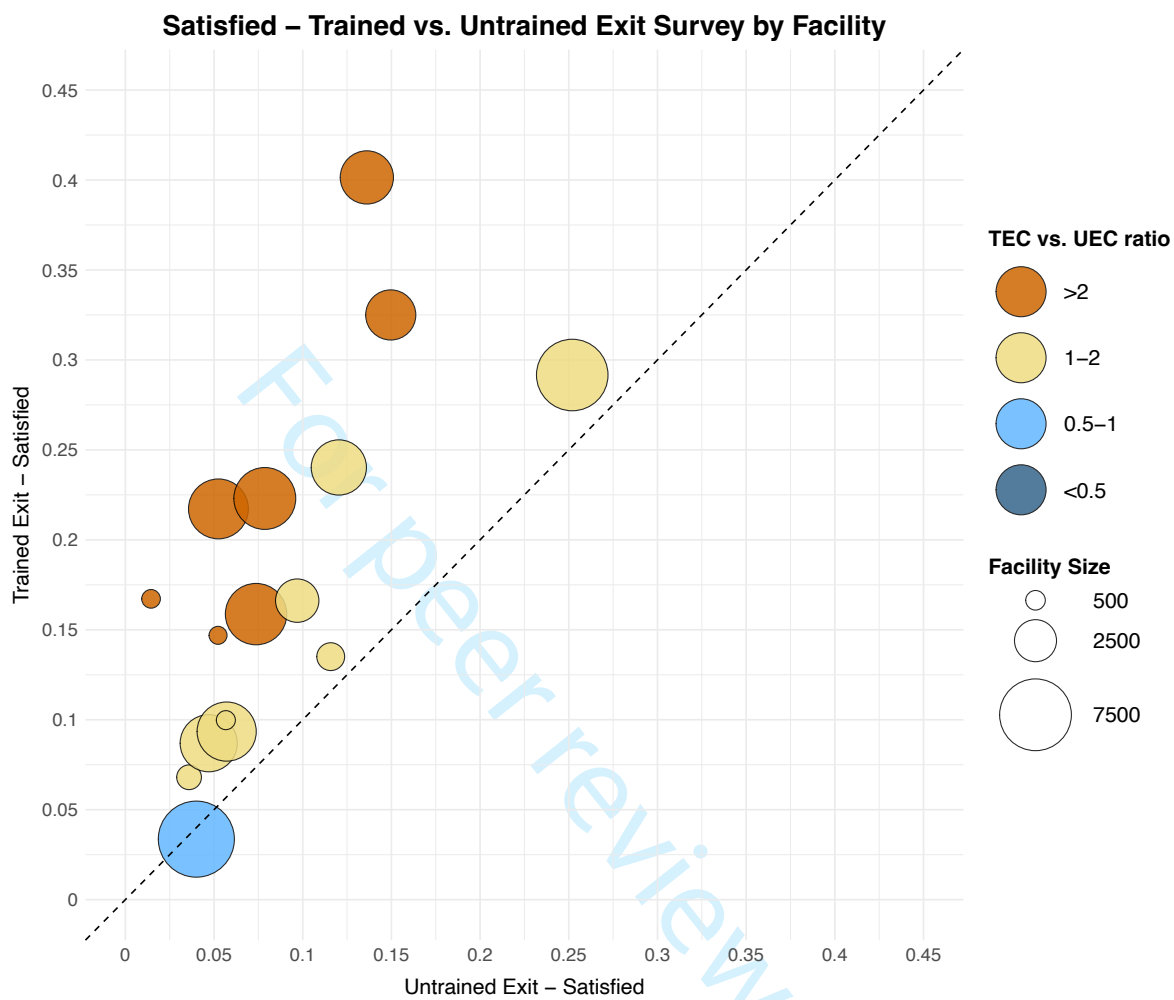




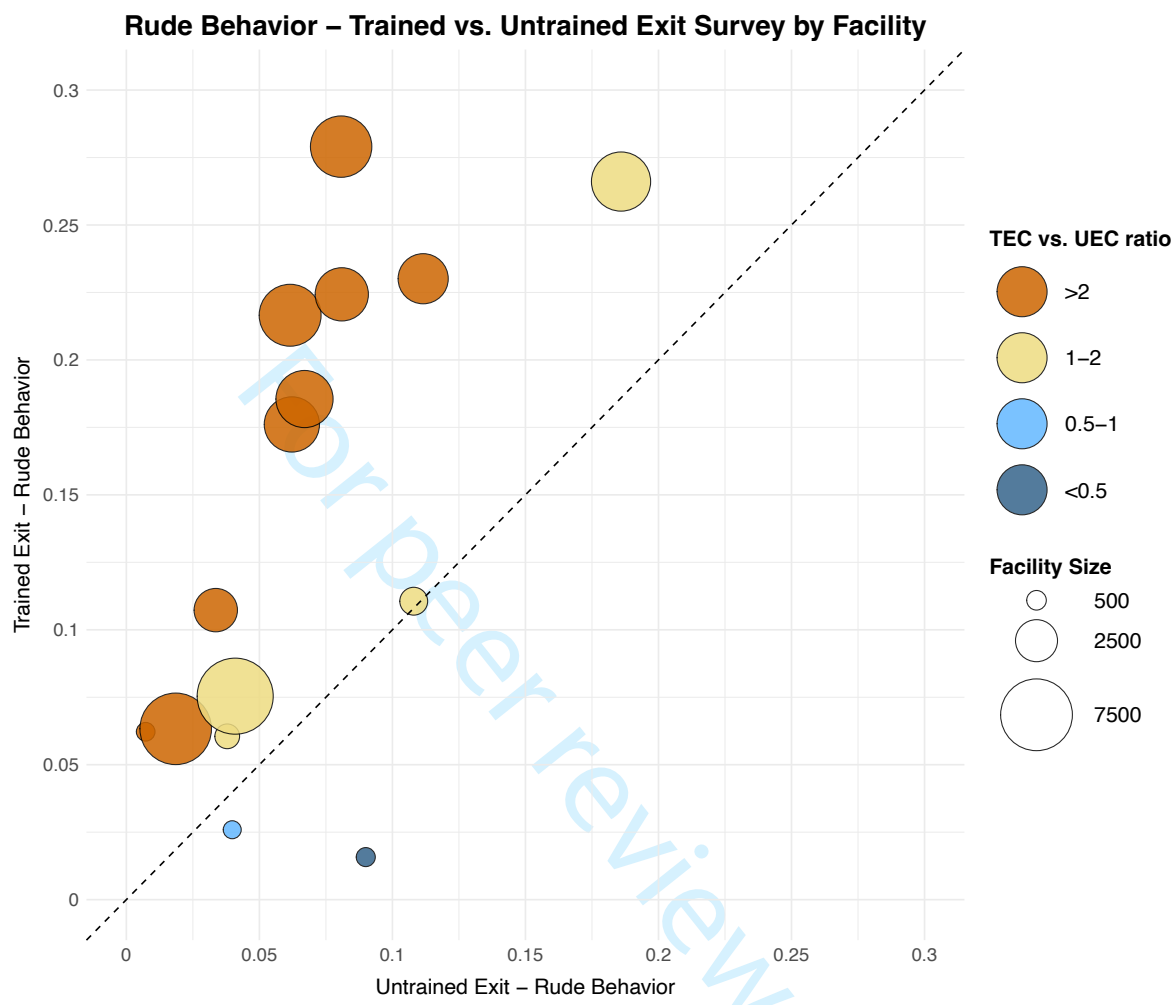


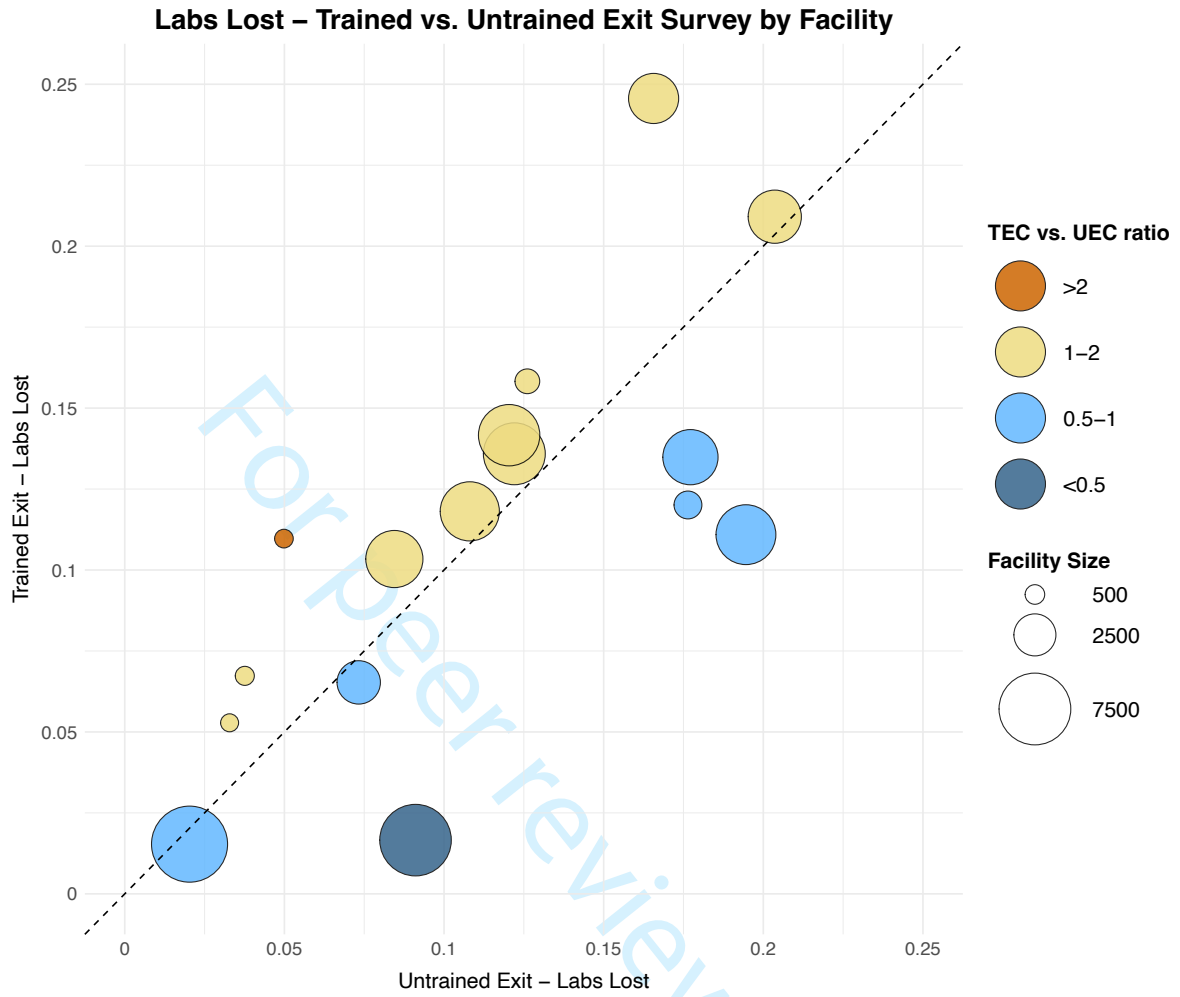
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## STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation	Page No
<b>Title and abstract</b>	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	1
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	1
<b>Introduction</b>			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	3,4
Objectives	3	State specific objectives, including any prespecified hypotheses	3
<b>Methods</b>			
Study design	4	Present key elements of study design early in the paper	4,5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	5
Participants	6	(a) <i>Cohort study</i> —Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up <i>Case-control study</i> —Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls <i>Cross-sectional study</i> —Give the eligibility criteria, and the sources and methods of selection of participants	5,6
		(b) <i>Cohort study</i> —For matched studies, give matching criteria and number of exposed and unexposed <i>Case-control study</i> —For matched studies, give matching criteria and the number of controls per case	N/A
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	5,7,8
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	5-7
Bias	9	Describe any efforts to address potential sources of bias	4
Study size	10	Explain how the study size was arrived at	8
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	7
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	7
		(b) Describe any methods used to examine subgroups and interactions	7
		(c) Explain how missing data were addressed	N/A
		(d) <i>Cohort study</i> —If applicable, explain how loss to follow-up was addressed <i>Case-control study</i> —If applicable, explain how matching of cases and controls was addressed <i>Cross-sectional study</i> —If applicable, describe analytical methods taking account of sampling strategy	N/A
		(e) Describe any sensitivity analyses	N/A

Continued on next page

<b>Results</b>			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	9
		(b) Give reasons for non-participation at each stage	9
		(c) Consider use of a flow diagram	N/A
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	9, 10
		(b) Indicate number of participants with missing data for each variable of interest	9,10
		(c) <i>Cohort study</i> —Summarise follow-up time (eg, average and total amount)	N/A
Outcome data	15*	<i>Cohort study</i> —Report numbers of outcome events or summary measures over time	N/A
		<i>Case-control study</i> —Report numbers in each exposure category, or summary measures of exposure	N/A
		<i>Cross-sectional study</i> —Report numbers of outcome events or summary measures	10
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	7,11
		(b) Report category boundaries when continuous variables were categorized	
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	12,14
<b>Discussion</b>			
Key results	18	Summarise key results with reference to study objectives	14,15
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	18
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	19,20
Generalisability	21	Discuss the generalisability (external validity) of the study results	18
<b>Other information</b>			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	20

\*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

**Note:** An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at [www.strobe-statement.org](http://www.strobe-statement.org).