



**Thol'impilo: An evaluation of strategies to accelerate entry into care following HIV diagnosis among adults in Gauteng and Limpopo Provinces, South Africa**  
End of Project Report 2016



## EXECUTIVE SUMMARY

The global HIV epidemic continues to expand from 36.9 million people living with HIV (PLWH) currently and 2 million individuals becoming infected annually. In South Africa, while an estimated 86.4% of PLWH are aware of their status, **only one third of those eligible for life-saving antiretroviral medications are receiving them. The shift in earlier initiation of antiretroviral therapy (ART) to a test and treat model depends on improved engagement in care – whether to initiate ART or retain PLWH in care following dispensing ART.** To identify practical approaches to early engagement in care, Thol’impilo tested evidence-based, individual-level interventions designed to alleviate the main barriers to accessing HIV medical care in South Africa. The primary outcome was participant self-reported entry-into-care. Secondary and exploratory outcomes were clinic verified entry-into-care, ART initiation, and mortality.

Thol’impilo, meaning “to receive health”, was a four-year, randomized pragmatic trial. It compared the current standard of care to three interventions: 1) point of care CD4 (POC-CD4) testing alone 2) POC-CD4 combined with reimbursement for transportation costs and 3) POC-CD4 combined with care facilitation – an approach that adopted the ARTAS longitudinal strengths-based counselling approach. These three interventions were meant to focus at the individual level, rather than structural, because this approach responded to the best available evidence at the time Thol’impilo was being designed. In addition, all of these interventions can be applied without significantly restructuring the existing clinic infrastructure.

Potential participants were recruited into the study from mobile HIV counselling and testing (HCT) units deployed in communities, transport hubs, workplaces, and community events in rural, peri-urban, and urban areas in two Provinces. **Participants were randomized into one of the four study arms with 2,398 total roughly evenly split between the four study arms.** The majority of the participants (61%) were female, and the median age was 33. Participants entered care at over 200 public, NGO, and private clinics in South Africa.

**For the pre-defined primary outcome of self-reported entry-into-care by 90 days there was no statistically significant difference between arms (SOC: 50%, POC-CD4: 52%, POC-CD4 plus transport reimbursement: 49%, POC-CD4 plus care facilitation: 55%). According to clinic verified entry-into-care by 90 days, 29% of participants in the standard of care arm had entered into care compared to 31% in the POC-CD4, 31% in the POC-CD4 plus transport reimbursement, and 38% in the POC CD4 plus care facilitation. This increased entry-into-care in the POC-CD4 plus care facilitation was statistically greater [HR: 1.4 (1.1, 1.7) p=0.001].**

Verified ART initiation by 180 days (regardless of meeting the contemporary initiation threshold of a CD4 count  $<350$  cells/mm<sup>3</sup>) was 13% in the standard of care arm, 16% in the POC-CD4 only arm, 15% in the POC-CD4 plus transportation arm, and 18% in the POC-CD4 count with care facilitation arm. **The POC-CD4 with care facilitation arm was significantly different than the standard of care arm [HR: 1.4 (1.1, 1.9) p=0.02].** There were few deaths during the study (40 over 1 year of enrollment) and no differences between study arms in terms of mortality.

**The cost per additional, verified participant in care at 90 days was lowest for POC-CD4 plus care facilitation [1,603USD (range: 639, 4476)].** Participant characteristics associated with successful,



verified entry into care were female sex, older age (31+), rural site of HCT, born in South Africa, and residing closer to a clinic ( $\leq 5$ km).

These results are echoed in both of the qualitative strands of the Thol'impilo study. Many participants valued the psychosocial support received through care facilitation. The barriers described through interviews included stigma and scheduling conflicts between employment and medical care. The interpersonal health communication component was most effective when counsellors and participants worked together to identify participant's goals and create plans to work towards them. Other barriers to care identified through participant interviews include fear of job loss, unmet basic life needs (food, employment), opportunity costs associated with accessing clinics, non-empathic care received at health facilities, long waiting times, need for repeated visits, fear of lack of confidentiality, and being assigned to a particular clinic. Facilitating factors included understanding the severity of their illness, receiving tangible support, receiving emotional support, and seeing examples of PLWH living healthy lives.

Overall, Thol'impilo found that current rates of entry into care are extremely low. Only 30% of participants in the standard of care arm had verified entry into care within 90 days. This is consistent with prior reports from mobile HCT, but lower than from clinic-based HIV testing.

This study has implications for program implementers and policy makers. **Longitudinal counselling may be a potential strategy to increase entry-into-care and ART initiation in a low or middle income setting although the cost, as delivered in Thol'impilo, may be a barrier to use.** We believe that with adjusting the cadre delivering care facilitation, reducing the number of sessions to three (few participants utilized 4 or 5 sessions), and reaching capacity for each care facilitator, costs could be lower. While there are likely ancillary benefits of POC CD4 count testing and transport reimbursement, our results suggest that neither was an effective strategy to improve entry-into-care in this setting. Finally, achieving the ambitious target of 90% of diagnosed patients entering into care and initiating ART will likely require multiple approaches. Our qualitative components suggest that these approaches need to address a spectrum of barriers, including lack of patient self-efficacy, community level stigma, and clinic and health service delivery challenges. Future research needs to assess strategies for entry-into-care that address multiple levels, including clinical service delivery.

**In summary, this trial suggests that strengths-based longitudinal care facilitation may modestly improve entry-into-care at a relatively high cost, but also illustrates the challenges of linking newly-diagnosed patients into care and highlights the need for further systematic studies to identify effective pragmatic approaches to improve the care continuum.** This study provides insight into possible approaches to take or consider with caution.



# 1 TABLE OF CONTENTS

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2	Thol’impilo funding history .....	6
3	Introduction: HIV care continuum .....	6
4	Strategies to accelerate entry into care.....	7
4.1	Theoretical framework .....	7
4.2	Strategy descriptions .....	8
4.2.1	Standard of care.....	8
4.2.2	Point of care-CD4 testing (POC-CD4) .....	8
4.2.3	Care facilitation .....	8
4.2.4	Transport reimbursement.....	9
5	The Thol’impilo – Study Design.....	10
5.1	Study design .....	11
5.1.1	Participants .....	11
5.1.2	Randomization and masking.....	11
5.1.3	Follow-up procedures .....	11
5.1.4	Outcome definitions .....	12
5.1.5	Statistical analysis .....	13
6	Comparison of strategies to accelerate entry into care .....	13
6.1	Enrollment and baseline data .....	13
6.2	Entry into care.....	15
6.3	ART initiation.....	17
6.4	Mortality .....	18
7	Cost and cost-effectiveness of strategies for entry into care .....	18
7.1	Unit cost of interventions .....	19
7.2	Comparative costs and consequences of interventions .....	19
8	Participant responses to strategies (Qualitative) .....	20
8.1	Care facilitation arm participant responses.....	20
8.2	Point of Care CD4 testing participant responses .....	22
8.3	Transport arm participant responses .....	23
9	Providing precision health communication .....	24
9.1	Methods.....	25
9.2	Findings .....	25



9.3	Discussion.....	28
10	Factors associated with outcomes.....	28
10.1	Associations with entry into care.....	28
10.2	Associations with ART initiation.....	29
10.3	Associations with mortality.....	29
11	Barriers to seeking HIV care.....	30
11.1	Barriers to care.....	30
11.2	Results framework .....	31
11.3	Individual level .....	32
11.4	Interpersonal factors.....	33
11.5	Institutional/Health facility factors.....	34
11.6	Community factors.....	35
11.7	Policy factors.....	36
11.8	Denial of service at clinic (quantitative) .....	36
12	Understanding strategy utilization - Process measures .....	36
12.1	Point of care CD4 testing (POC-CD4) .....	36
12.2	Care facilitation .....	36
12.3	Transport reimbursement.....	38
13	Clinic switching and retention in clinical care.....	39
14	Dissemination activities .....	40
15	Recommendations / Interpretation of results / Policy implications.....	40
15.1	Major gap between goal and reality.....	40
15.2	Immediate and longer term implementation needs .....	41
15.3	Barriers to care.....	41
15.4	Tested entry-into-care strategies .....	41
15.4.1	Care facilitation – longitudinal counselling.....	41
15.4.2	Point of care CD4 count testing .....	42
15.4.3	Transport reimbursement.....	42
15.5	Approaches to improving entry into care and the care continuum .....	43
15.6	Documenting the care continuum .....	44
16	Summary .....	45
17	References .....	47



## 2 THOL'IMPILO FUNDING HISTORY

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On 12 July 2012, the US Agency for International Development (USAID) awarded the Aurum Institute Cooperative Agreement Number AID-OAA-A-12-00028 for the implementation science project “Thol’impilo: bringing people into care”. The initial grant was for a three-year project. In June 2015, a one year, no-cost extension was granted to allow the project to complete data cleaning and extend follow-up to 11 July 2016. The planned activities are complete, and this report describes the results.

## 3 INTRODUCTION: HIV CARE CONTINUUM

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Globally, there are approximately 36.9 million people living with HIV, an estimated 2 million new infections and 1.2 million HIV associated deaths annually.<sup>1</sup> Early diagnosis of HIV, coupled with timely initiation of antiretroviral therapy (ART), prevents both new HIV infections and HIV associated mortality through a marked reduction in transmission risk and by preventing immunological decline.<sup>2-5</sup> In addition, simple and well-tolerated ART regimens are now available that make early, lifelong ART practical and safe.<sup>6</sup> Considering these factors, the World Health Organization (WHO), UNAIDS, and other global and national bodies have endorsed policies to provide ART to all people living with HIV (PLWH).<sup>7,8</sup> Specifically, to achieve population level reductions in mortality and infections, UNAIDS has called for the ambitious targets of having 90% of people living with HIV diagnosed, 90% of those diagnosed on ART, and 90% of those on ART having an undetectable HIV RNA after one year on ART.<sup>9</sup>

In many regions of the world, HIV care is not reaching many or most of those living with HIV. In South Africa, only 86.4% of people living with HIV are estimated to be aware of their HIV status.<sup>10</sup> Approximately one-third of those diagnosed are receiving ART.<sup>11,12</sup> Substantial attrition across the HIV continuum of care occurs between testing positive for HIV and engaging in care.<sup>13</sup> Despite extensive evidence cataloguing factors associated with failure of entry into care, there are few demonstrated, effective approaches to improve the transition from testing to entry into care or ART initiation.<sup>14,15</sup> Absent the first step of engagement in the care system, subsequent steps including ART initiation (even same day in a test and immediate treatment approach) cannot occur. Potentially modifiable, individual factors include transport cost, ability to navigate the health care system, perceived stigma, fear of disclosure, lack of health self-efficacy, health perceptions, and denial of living with HIV.<sup>15,16</sup> Thol’impilo sought to address these individual-level factors through influencing health perceptions using point-of-care CD4 count testing, assisting with disclosure, addressing stigma, and increasing self-efficacy through care facilitation sessions, and provide transport reimbursement to overcome travel barriers.

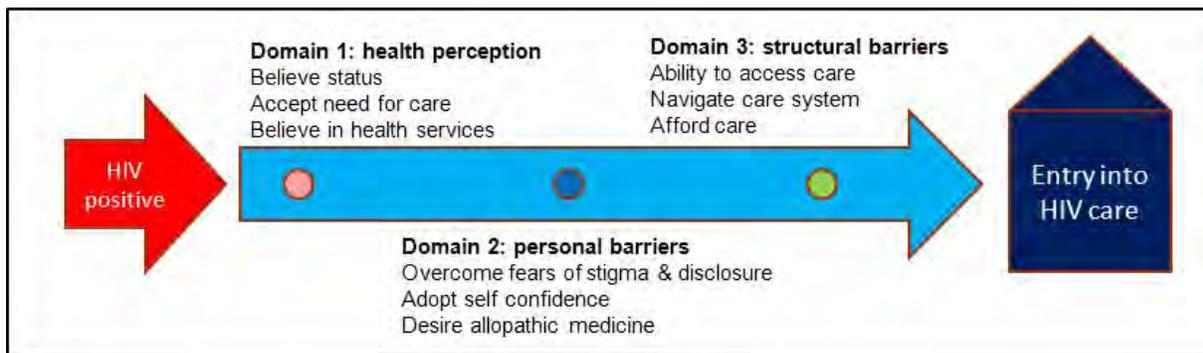


## 4 STRATEGIES TO ACCELERATE ENTRY INTO CARE

### 4.1 THEORETICAL FRAMEWORK

We focused this study on strategies to overcome individual-level barriers to entering care. The decision to focus on the individual level and not interpersonal, community, or clinic-level barriers or facilitators, was to identify generally applicable strategies that could be implemented without restructuring service delivery. Furthermore, at the time the study was designed, the majority of available research findings were on individual level barriers.

**Figure 1: Modifiable domains impacting entry into HIV care**



We grouped known individual-level barriers to entry into care into three domains: (1) health perception, (2) acceptance and self-efficacy, and (3) structural barriers (Figure 1). We hypothesized that strategies to facilitate these domains would accelerate the journey from testing HIV-positive to entry into care.

Domain 1: health perception. Several studies have found an association between disease-specific knowledge and entry into care for HIV. For example, individuals with a family member or friend living with HIV had a 30% increase in ART initiation.<sup>17</sup> Studies suggest that symptomatic people living with HIV are 60-80% more likely to access HIV care and treatment than those who are asymptomatic.<sup>18-21</sup> Knowledge of CD4 count, independent of symptoms, is also associated with increased entry into care.<sup>18</sup> In addition, this association between health care seeking and disease specific knowledge is thoroughly described for other diseases such as myocardial infarction and heart failure.<sup>22-24</sup>

Domain 2: personal barriers. A simple and applicable model for navigating personal barriers is the Stages of Acceptance Model which describes phases in an individual's acceptance of their medical condition and willingness to seek care.<sup>1</sup> In the South African context, stigma and disclosure of HIV status are especially significant personal aspects of health care seeking. For example, patients who disclosed their HIV status were 1.57 times more likely to register at an HIV facility than patients who did not disclose (95% CI: 1.00-2.48).<sup>25,26</sup>

Domain 3: structural barriers. Despite efforts of the South African government to decentralize ART delivery and increase its accessibility, many patients need to travel considerable distances from places of residence to facilities providing HIV care and treatment. The direct costs of traveling to health care facilities, opportunity costs from lost wages, and costs of child care are barriers to accessing care and

can represent a substantial proportion of a household budget. Distance and cost of transport have each been associated with a decreased probability of entering care and lower retention in care.<sup>20,30</sup>

## 4.2 STRATEGY DESCRIPTIONS

### 4.2.1 Standard of care

*Standard of care:* In the standard of care arm, study staff counseled participants on the importance of HIV care. They also provided a referral letter to the clinic closest to participant's residence.

### 4.2.2 Point of care-CD4 testing (POC-CD4)

A portable rapid POC-CD4 test platform (PIMA, Alere Inc. Waltham, Massachusetts, USA) which worked on battery power and used capillary blood provided CD4 count enumeration within 20 minutes. The same researcher who collected the blood sample then printed results and provided them to the participant along with counselling on the health implications of the result.

**Theoretical framework for point of care CD4 count testing:** The goal of this intervention strategy was to provide the participant with a POC-CD4 result coupled with visually aided result interpretation, patient education, and motivational counselling. CD4 testing occurred on the same day of diagnosis before the client left the mobile HIV testing unit. The theoretical framework for this intervention was borrowed from a construct common to most cognitive health seeking models: increasing the participant's perceived value of seeking health care. This theory suggests that by increasing the perceived value of seeking medical care, the value of medical care would outweigh the other tangible and non-tangible costs involved in pursuing HIV medical care, which would then lead to entry into care. This approach is supported by a small, single site trial in South Africa, which compared immediate CD4 testing and provision of results to the standard of care. It found a 40% increase in patients entering care after HCT in the POC-CD4 compared to the standard of care group (relative risk=1.4; 95% CI: 1.08-1.84) based on solely receiving CD4 results and education on the meaning of those results at the time of HCT.<sup>18</sup>

### 4.2.3 Care facilitation

Counsellors provided modified, strengths-based counselling provided over five sessions within 90 days of enrollment. The counselling sessions were discontinued when either of the following were achieved: five sessions had occurred, 90 days had passed since enrollment, the participant requested stopping, or the participant had entered into care. The structure of the strengths-based counselling was based on United States Centers for Disease Control and Prevention (CDC) antiretroviral treatment and access to services (ARTAS) counselling approach.<sup>31</sup> Counsellors had formal training as either a social worker or auxiliary social worker and received two days of didactic and practical training in strengths-based case management. After a participant was randomized to this arm, the research assistant who enrolled the participant contacted a counsellor via mobile phone to make introductions with the participant. Subsequently, the counsellor and participant arranged for times and places for counselling sessions that could be provided telephonically or in-person at a convenient, safe location. During care facilitation sessions, the counsellors worked with participants to identify goals for engagement in care and then to develop plans to reach those goals. In addition to the structured counselling sessions, staff sent



standardized text messages periodically, and provided *ad hoc* guidance and support when requested by participants.

**Theoretical framework of care facilitation:** As described above, this approach is supported by the ARTAS study conducted in the United States. ARTAS is a longitudinal strengths-based case management increased entry into care within 6 months of testing HIV positive from 60 to 87%.<sup>31</sup> The goal of ARTAS was to provide ongoing counselling to address an array of personal barriers interwoven in an individual's context requiring one-on-one, specific counselling and health communication. Furthermore, the strategy of strengths-based counselling requires introspection from the client. Addressing specific client needs and generating introspection are challenging, as best, during the relatively short post-test counselling HCT as these sessions occur at a period of potentially substantial psychologic distress.

The theoretical framework of this intervention was largely based on the strengths-based and motivational counselling approaches. Using both approaches, the care facilitator (CF) aimed to assist the client in identifying resources (innate, interpersonal, and material resources). These resources, in turn, would help clients achieve desired behaviors and outcomes in line with their health values and motivate them to address issues preventing their entry into HIV care.

#### **4.2.4 Transport reimbursement**

Following allocation into this arm, study staff described the process for making transport claims and receiving reimbursement at a standard rate of 6USD for urban or peri-urban and residents 10USD for rural residents. Participants also received reminder cell phone messages on how to make claims and the number of claims they were still eligible to make. Reimbursements were made for a maximum of three clinic visits within 90 days of enrollments through cell phone transfer or a code for receiving the reimbursement at an automated teller machine or designated grocery store chain after a reported clinic visit.

**Theoretical framework for transport reimbursement:** This approach is supported by a pilot program in Tanzania that provided transport allowances and volunteer patient escorts to assist with travel to HIV care facilities achieved a 70% increase in entry into care for HIV.<sup>32</sup> The goal of this intervention was to address one of the most frequently noted structural barriers to entry into care in resource constrained settings: prohibitive distance or transport cost to reach a health facility. Using the value-cost model, we assumed that a reduction in financial costs would favor the decisional balance towards entry into care. The hypothesis was that transport costs were a major barrier to entry into care and that the intervention would receive high uptake among study participants.

Achieving engagement in care may require several strategies to be effective, thus care facilitation and transport assistance were both paired with POC-CD4 count testing. In addition, there was a POC-CD4 only arm and a standard of care arm.

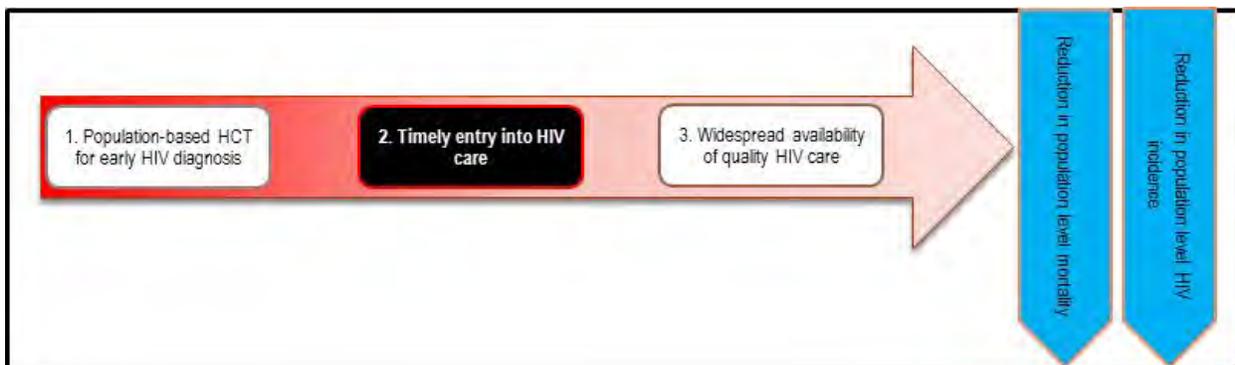


## 5 THE THOL'IMPILO – STUDY DESIGN

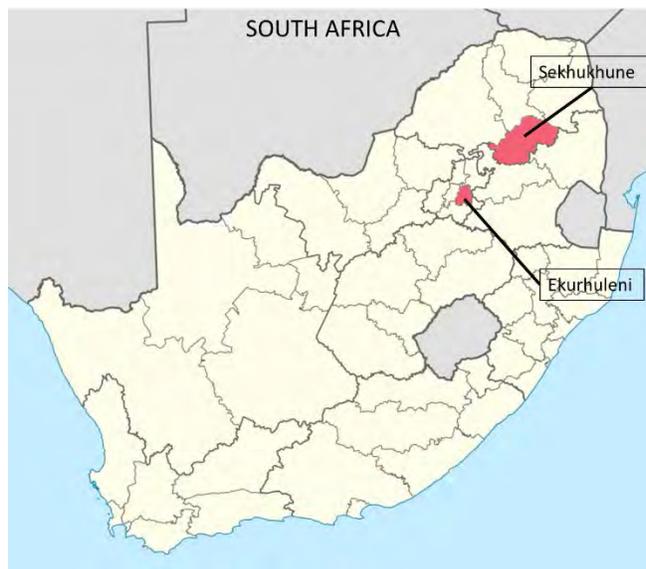
Thol'impilo means to “to receive health” in isiZulu and other southern African languages. The goal of the Thol'impilo study was to evaluate pragmatic strategies to improve health by accelerating entry into care following testing HIV positive (**Figure 2**).

Seven mobile HIV counselling and testing units (HCT) were deployed as part of routine service delivery in two large districts in South Africa representing urban, peri-urban, and industrial areas (Ekurhuleni District) and small towns and rural South Africa (Sekhukhune District; **Figure 3**). The mobile units provided HCT in communities, transport hubs, workplaces, special events hosted by local government, tertiary schools, and informal settlements. Following testing HIV-positive, clients were invited to participate and randomized to one of four strategy arms. HCT procedures were standardized across units, provided free-of-charge, performed by trained counsellors, and followed South African National HCT Policy Guidelines. Small incentives were provided for participating in HIV testing (value 0.25-1.00USD) as part of the service delivery program.

**Figure 2: Process of entering into HIV care**



**Figure 3. Districts where Thol’impilo HCT units operated**



## **5.1 STUDY DESIGN**

Thol’impilo was an individually randomized pragmatic trial. Further details are provided in **Appendix 1**.

### **5.1.1 Participants**

Clients were recruited to participate if they tested HIV-positive (regardless of prior HIV testing) at one of the mobile HCT units. Additional inclusion criteria were:  $\geq 18$  years old, capable of providing informed consent, reporting not currently receiving HIV-related care, and reporting remaining in South Africa for the next 6 months. Those who met eligibility criteria and were interested in participating were provided written and verbal information in the language of their choice.

### **5.1.2 Randomization and masking**

Participants were randomized in the ratio of 1:1:1:1 into four study arms using block randomization stratified by the seven mobile HCT units. Due to the nature of the strategies, the assignment arm was not masked from the participant or the recruiting research assistant. Research staff completing follow-up entry into care assessments and investigators were masked to allocation.

### **5.1.3 Follow-up procedures**

For study follow-up, participants were contacted telephonically at 30 and 60 days following enrollment to verify contact information. After 90 days and 180 days to ascertain care status at these time points. If a participant could not be reached easily, study staff called participants three times. Each call was at a different time of day and a different day of the week (including weekends). When telephonic contact was unsuccessful for ascertaining either the 90 day or 180 day care status, home visits were attempted. Research assistants made at least three attempts to visit the reported place of residence.

All participants who reported entry into care had verification of self-report through review of clinic paper records, electronic records, and national laboratory system electronic records starting 180 days



after enrollment. In addition, clinical and laboratory records were queried for participants who were unable to be contacted via telephone or home visits. Participant records (HIV registers, CD4 count registers, and clinic files) were abstracted after identifying the record through a name and date of birth. For participants who reported entry into care but had no record of entry, participants were asked if they entered care, their clinic, and the name they used at the clinic. Finally, national identification numbers were periodically matched with the South African national vital statistics registry to identify participants who had died and whose death was not otherwise reported.



Figure 4: Mobile HCT units in the field

#### 5.1.4 Outcome definitions

Entry into care was defined as completing registration for or receiving HIV-specific care at any allopathic medical facility in South Africa. Participants without care status data were considered not to be in care. The primary outcome was self-reported time to entry into care within 90 days of enrollment. Secondary outcomes were time to verified entry into care within 90 days, self-reported and verified time to entry into care within 180 days, and time to death 90 days from enrollment. We also assessed self-reported and verified ART initiation within 180 days, time to death within 180 and 365 days of enrollment, and care and ART initiation between the three arms with POC-CD4 count results, all as *a priori* exploratory outcomes. Given a hypothesis that the tested strategies may benefit some demographic groups more than others, we planned to assess for interactions between the following subgroups and study arm for the primary outcome: sex, age group ( $\leq 30$ / $> 30$  years), urban or rural residence, employment status, distance from the place of residence to the nearest or preferred clinic ( $< 5$ km/ $\geq 5$ km), self-reported cost of travel to the clinic ( $>$ / $\leq 2$ USD), presence of symptoms at enrollment, and CD4 count strata of  $< 350$  cells/mm<sup>3</sup> or  $\geq 350$  cells/mm<sup>3</sup> (in the three POC-CD4 count arms).

Self-reported time to entry into care was the date a participant reported first going to a clinic for HIV care. Verified time to entry into care was the first date of care documented in written or electronic clinic or laboratory records. ART initiation was similarly by self-report or verified by medical record review. Death and date of death was based on report by family members or linkage to the national population register data.

Distance from a participant's residence and the nearest clinic was calculated using the Haversine Formula by inputting GPS coordinates of the place of residence (based on an estimate using Google Earth) and the GPS coordinates of the nearest clinic or favored clinic as stated by the participant.<sup>33</sup>

### 5.1.5 Statistical analysis

Analysis was based on intention-to-treat including all randomized participants, except for those excluded post-randomization upon confirmation that they were already in HIV care prior to study enrollment. For the primary outcome, we used Cox proportional hazards regression with three pairwise comparisons of each of the three intervention arms versus standard of care and adjusted for randomization strata. A secondary analysis was planned to adjust for any major imbalances by study arm; there were no imbalances found between study arms, so this secondary analysis did not occur. Time at risk was measured from date of randomization to earliest of (i) date of entry into care; (ii) date of death; or (iii) 90 days after HIV testing. The following secondary outcomes were similarly assessed using time-to-event analyses. A conservative p value of <0.017 can be considered for statistical significance when using the Bonferroni correction based on three pairwise comparisons.<sup>34</sup>

## 6 COMPARISON OF STRATEGIES TO ACCELERATE ENTRY INTO CARE

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### 6.1 ENROLLMENT AND BASELINE DATA

From 13 March 2013 to 30 October 2014, 3,739 adults tested HIV-positive at the mobile HCT units, 2,930 were screened for eligibility, and 2,711 (92%) met eligibility criteria. Study recruitment ended when the pre-defined sample size was reached. Reasons for ineligibility were already receiving HIV care (129; 4.4%), not expecting to be available for follow-up (75; 2.5%), and other reasons (15; 0.5%). Of the 2,711 eligible, 2,558 gave consent (94%) and were randomized to a study arm (638 in standard of care, 641 in POC-CD4 testing, 637 in care facilitation, and 642 in transport reimbursement; **Figure 5**). The major reasons for not consenting were not feeling ready to participate in the study (67; 2.4%), not having time to continue with the enrollment process (47, 1.7%), and not willing to participate in a study (14, 0.5%). Post-randomization, 152 participants were identified as being in care at the time of enrollment and 8 had a second enrollment in the study; these participants were excluded from analysis.



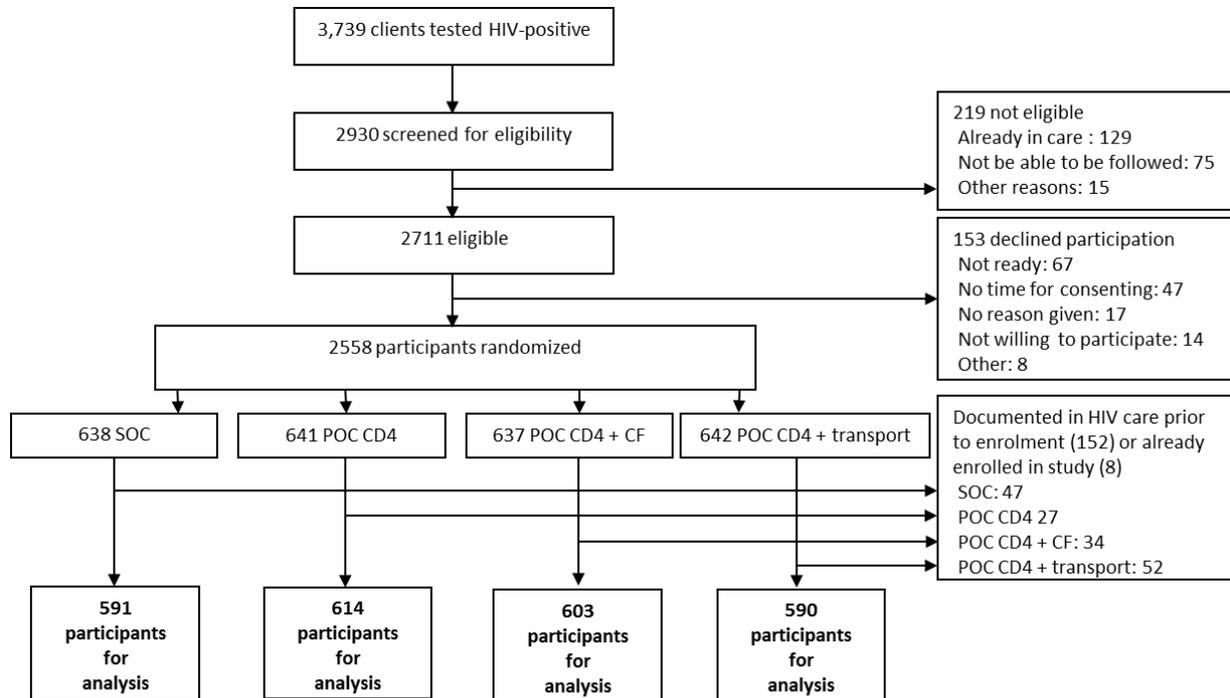
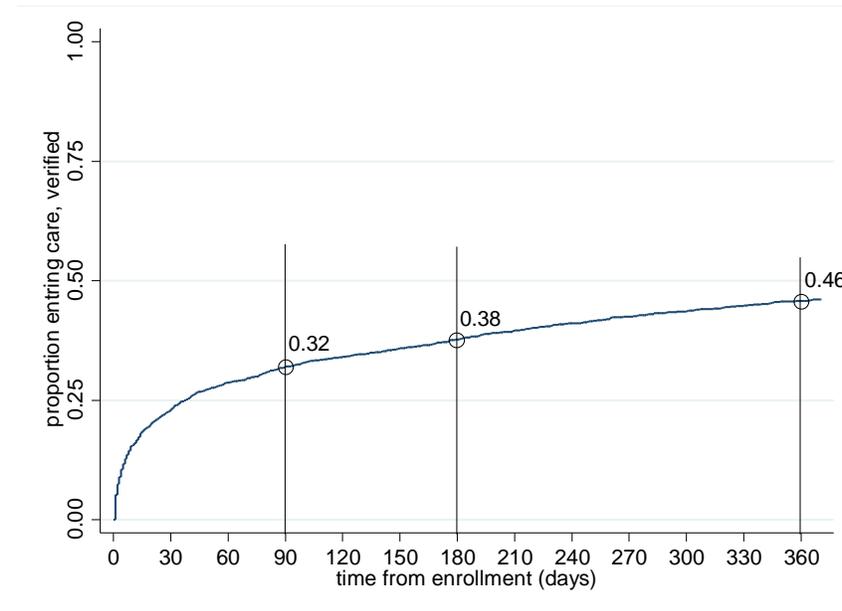


Figure 5: Consort diagram of study flow

The remaining 2,398 participants contributed to the study outcomes: 591 in SOC, 614 in POC-CD4 testing, 603 in care facilitation, and 590 in transport reimbursement arms. Following 90 and 180 days post-enrollment, we contacted or found clinical records for 2,133 participants (89%) and 2,047 participants (85%) to determine entry into care status, respectively.

Overall, 1,472 (61%) participants were female, the median age was 33 years (IQR: 27, 41), the median distance from place of residence to a clinic was 4.0 km (IQR: 1.5, 12), and 959 (40%) participants reported reaching the clinic from their residence by walking. Most of the participants [1,932 (80%)] attended HCT for asymptomatic HIV testing or to receive the incentive for participating in testing. Among participants in the three study arms that received POC-CD4 count testing, the median CD4 count was 427 cells/mm<sup>3</sup> (IQR: 287, 595); 629 (35%) had a CD4 count <350 cells/mm<sup>3</sup>, which means that they met ART initiation criteria in place in South Africa during the duration of study enrollment. The baseline characteristics were balanced by study arm with the exception of mode of transport to the clinic. A smaller proportion of participants in the transport reimbursement arm (32%) reported being able to walk to the clinic than the other three arms (42%). These data are shown in **Appendix 4**. We chose not to adjust for mode of transport because of concerns for reporting bias as the question was asked after participants were informed of their randomization arm.

**Figure 6. Proportion of participants entering into care by time**

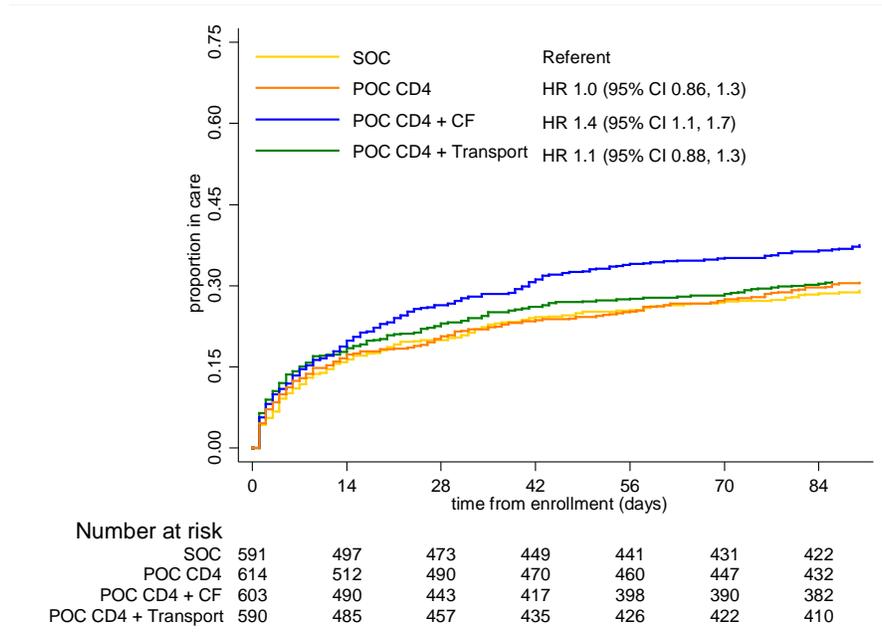


## 6.2 ENTRY INTO CARE

Overall, by self-report 1,239 (52%) participants entered care by 90 days; 1,443 (60%) by 180 days; and 1655 (69%) by 365 days. In terms of verified entry into care, which is likely to be more accurate. Thirty two percent, 38%, and 46% had clinical documentation of entry into care at 90, 180, and 360 days respectively (**Figure 6**).

By study arm, self-reported entry into care by 90 days was 298 (50%) for SOC, 319 (52%) for POC-CD4 count, 331 (55%) for care facilitation, and 291 (49%) for transport reimbursement. Compared to standard of care, the hazard ratios for time to self-reported entering care were: POC-CD4 count, 1.0 (95% CI: 0.89, 1.2;  $p=0.6$ ); care facilitation, 1.1 (95% CI: 0.94, 1.3;  $p=0.2$ ), and transport reimbursement 0.97 (95% CI: 0.83, 1.1;  $p=0.7$ ) (**Table 1**). We found no subgroup differences in response to entry into care strategies ( $p$  for interaction all  $> 0.1$ ).

**Figure 7. Proportion of participants verified in care by study arm and time**



In the outcome of verified entry into care by 90 days, 172 (29%) entered care in the standard of care arm, 187 (31%) in the POC-CD4 arm, 225 (38%) in the care facilitation arm, and 180 (31%) in the transport reimbursement arm (**Figure 7**). Hazard ratios were as follows: POC-CD4 count, 1.0 (95% CI: 0.86, 1.3; p=0.6); care facilitation, 1.4 (95% CI: 1.1, 1.7; p=0.001), and transport reimbursement 1.1 (95% CI: 0.88, 1.3; p=0.5) (**Table 1**).



**Table 1. Self-reported and verified proportion of participants in care by arm at 90 and 180 days**

	Standard of care	POC-CD4 count	POC-CD4 count + care facilitation	POC-CD4 count + transport reimbursement
<b>Entry into care</b>				
<b>90 days</b>				
Self-reported*				
In care at 90 days, Kaplan-Meier proportion (n)	0.50 (298)	0.52 (319)	0.55 (331)	0.49 (291)
HR (95% CI)	1	1.0 (0.89, 1.2)	1.1 (0.94, 1.3)	0.97 (0.83, 1.1)
p-value		0.6	0.2	0.7
Verified				
In care at 90 days, Kaplan-Meier proportion (n)	0.29 (172)	0.31 (187)	0.38 (225)	0.31 (180)
HR (95% CI)	1	1.0 (0.86, 1.3)	1.4 (1.1, 1.7)	1.1 (0.88, 1.3)
p-value		0.6	0.001***	0.5
<b>180 days</b>				
Self-reported				
In care at 180 days, Kaplan-Meier proportion (n)	0.59 (351)	0.59 (363)	0.64 (383)	0.59 (346)
HR (95% CI)	1	1.0 (0.87, 1.2)	1.1 (0.95, 1.3)	0.98 (0.84, 1.1)
p-value		0.9	0.2	0.8
Verified				
In care at 180 days, Kaplan-Meier proportion (n)	0.36 (210)	0.26 (218)	0.44 (265)	0.38 (218)
HR (95% CI)	1	1.0 (0.83, 1.2)	1.3 (1.1, 1.6)	1.1 (0.91, 1.3)
p-value		0.9	0.002**	0.3

\*denotes significance at the 0.05 level; \*\*denotes significance at the 0.01 level; \*\*\* denotes significance at the 0.001 level

### 6.3 ART INITIATION

By 180 days after enrollment, 667 participants (28%) self-reported initiating ART and 373 participants (15%) had verified report of ART initiation (**Table 2**). Hazard ratios for self-report of ART initiation when compared to the SOC were 1.2 (95% CI: 0.98, 1.5; p=0.08) for POC-CD4 count, 1.2 (95% CI: 1.0, 1.5; p=0.05) for care facilitation, and 0.99 (95% CI: 0.79, 1.2; p=0.9) for transport reimbursement. Assessing ART initiation verified by clinical records, the hazard ratios when compared to the SOC were 1.2 (95% CI: 0.91, 1.6; p=0.2) for POC-CD4 count, 1.4 (95% CI: 1.1, 1.9; p=0.02) for care facilitation; and 1.2 (95% CI: 0.89, 1.6; p=0.2) for transport reimbursement. Among those in the POC-CD4 count arms who met the ART initiation threshold (CD4<350), 326 of 631 (52%) had self-reported ART initiation and 207 (33%) had verified ART initiation by 180 days from enrollment. Univariable and multivariable characteristics correlated with ART initiation by 180 days are shown in **Appendix 6**.



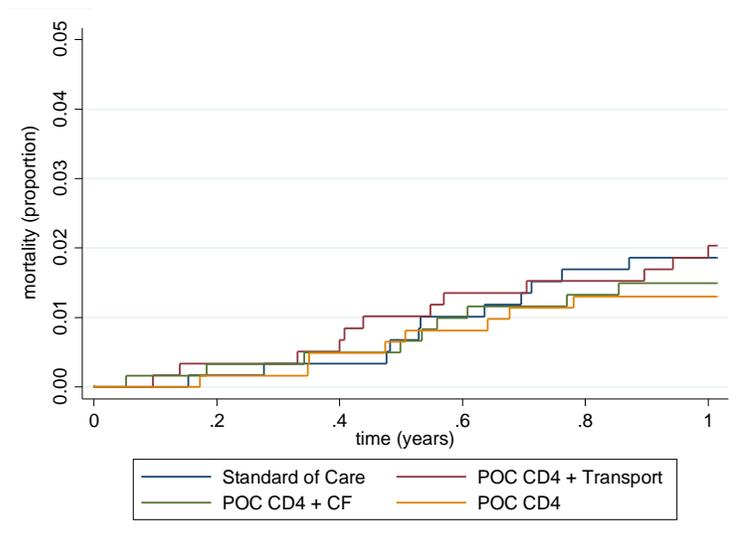
**Table 2. Self-reported and verified ART Initiation at 180 days by study arm**

	Standard of care	POC-CD4 count	POC-CD4 count + care facilitation	POC-CD4 count + transport reimbursement
<b>ART initiation</b>				
<b>180 days</b>				
Self-reported				
ART by 180 days, Kaplan-Meier proportion (n)	0.26 (151)	0.30 (184)	0.30 (184)	0.25 (148)
HR (95% CI)	1	1.2 (0.98, 1.5)	1.2 (1.0, 1.5)	0.99 (0.79, 1.2)
p-value		0.08	0.05	0.9
Verified				
ART by 180 days, Kaplan-Meier proportion (n)	0.13 (77)	0.16 (97)	0.18 (108)	0.15 (91)
HR (95% CI)	1	1.2 (0.91, 1.6)	1.4 (1.1, 1.9)	1.2 (0.89, 1.6)
p-value		0.2	0.02	0.2

## 6.4 MORTALITY

By 90 days following enrollment, 6 participants died; by 180 days, 19 had died, and by 365 days, 40 had died (**Figure 8**). Due to the small number of outcomes, we performed proportional hazards analysis only for 365 day mortality. We found no difference between study arm and mortality. Characteristics associated with mortality within one year of Thol’impilo enrollment are shown in **Appendix 7**.

**Figure 8. Mortality by study arm over time**



## 7 COST AND COST-EFFECTIVENESS OF STRATEGIES FOR ENTRY INTO CARE

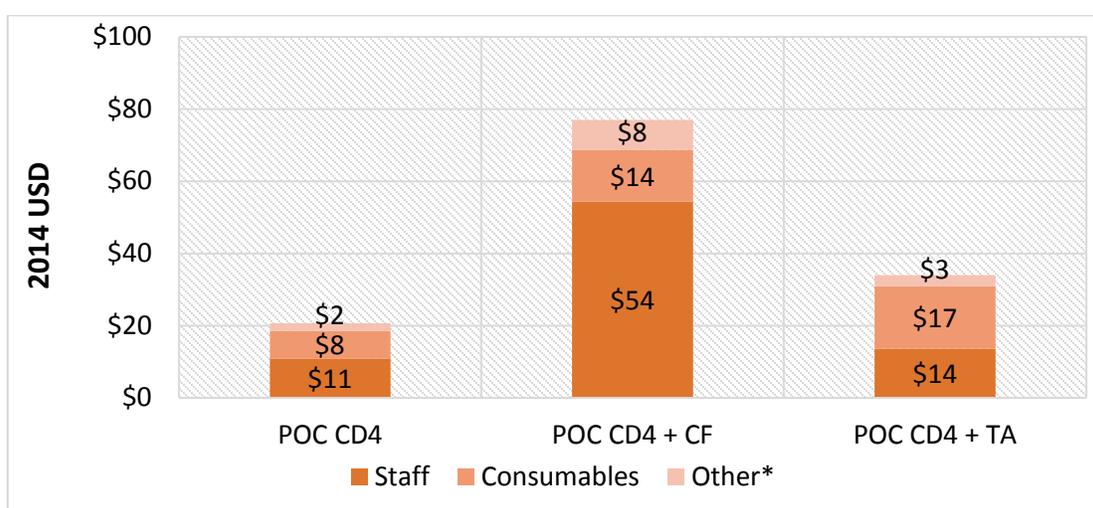
Costing and cost-effectiveness analysis assessed the delivery cost of the three strategies and the cost-effectiveness in terms of additional individuals in care. The costs reflect the actual costs to the program for these strategies. Several factors could modulate the costs in scaled-up implementation, especially for care facilitation, including providing the services to a higher volume of clients per facilitator and using a different cadre of worker to provide the care facilitation. For a detailed description of the costing methods, please see **section 5 of the Appendix**.



## 7.1 UNIT COST OF INTERVENTIONS

Across the three study sites, the mean cost of POC-CD4 was 20.68USD. The majority of POC-CD4 count arm costs were associated with staff, which contributed an average of 53% of the overall costs for this study arm across the three sites. The costs of consumables contributed an average of 37% across the three sites (**Figure 9**). The costs for the POC-CD4 + CF arm were substantially higher than for POC-CD4 alone across all sites, averaging 76.99USD (assuming an onsite supervisor). Costs for POC-CD4 + transport reimbursement were lower compared to those in the care facilitation arm and averaged 33.73USD across all three sites. Unlike the other arms, costs in the POC-CD4 + transport reimbursement arm were driven by the cost of consumables and participant reimbursements, which contributed to an average of 50.5% of total costs across the sites.

**Figure 9. Unit cost of intervention arms**



Costs in 2014 US dollars

\*\* Other: equipment, training, and overhead including rent, security, computers, finances, human resources, etc.

## 7.2 COMPARATIVE COSTS AND CONSEQUENCES OF INTERVENTIONS

Mean intervention costs per 1,000 clients in each arm ranged from 20,677USD (POC-CD4 alone) to 76,990USD (POC-CD4 + CF) (**Table 3**). Compared to the standard of care for 90 day verified entry-into-care, the cost per additional documented case in care was lowest in the POC-CD4 + CF arm (1,723USD).

The cost per case initiated on ART were highest among the outcomes considered. Costs ranged from 132.24USD in the POC-CD4 arm to 429.86USD in the care facilitation arm. Compared to the standard of care, the cost per additional participant initiating ART was lowest in the POC-CD4 arm (793.30USD) and highest in the care facilitation arm (1,577USD).



**Table 3: Cost per additional case linked to care or treatment across study arms**

Study Arm	Cost per 1,000 clients (USD)	Cost per Additional Self-Reported Linkage to Care (USD)	Cost per Additional Documented Linkage to Care (USD)	Cost per Additional Documented ART Initiation (USD)
SoC	--	Ref	Ref	Ref
POC-CD4	20,677	1,149*	1,983*	793*
POC-CD4 + CF	76,990	2,333*	<b>1,723**</b>	<b>1,577**</b>
POC-CD4 + TA	33,950	***	***	1,526*

\* Non-significant association  
 \*\* Significant association  
 \*\*\* Hazard ratio <1; not possible to calculate the cost of additional outcome.

## 8 PARTICIPANT RESPONSES TO STRATEGIES (QUALITATIVE)

Understanding participant responses to each arm of the study was important to understanding barriers and facilitators to care within each strategy. Participants were divided into groups based on study arm and strategy utilization, and Thol'impilo staff conducted 102 short, semi-structured interviews. Detailed methods and questions are in **Appendix 3**.

### 8.1 CARE FACILITATION ARM PARTICIPANT RESPONSES

#### No sessions

Participants who were randomized to the care facilitation arm, but did not attend any sessions, described several barriers to accessing counselling: counselling sessions interfered with participant's employment hours, not wanting to participate in counselling, did not know that counselling was available, transportation to counsellor's location was a barrier, lack of phone, difficulty navigating to location where counsellor was based, fear of what counselling might bring up, and worries that sessions would not be fully confidential.

Many participants were simply busy with their work or employment. As one participant explained, “The reason we couldn’t meet was because during the week I’m at work and there was no chance for us to meet.” Several participants initially described scheduling conflicts with employment said that they were not interested in meeting when questioned further. They did not have questions for the social worker or Aurum representative with whom they were speaking: “I don’t see the importance of continuing with this whole thing by meeting you and talking over nothing. I said I must not be contacted again, and they are busy calling and buzzing me.”

Many of the participants in this group did not understand that they were enrolled in the care facilitation or counselling arm. If they did understand this allocation, they did not know the number and timing of sessions for them. In addition, participants feared what might occur in the sessions. As one participant described, “I tore the envelope [with my arm assignment] and threw it away, I did not want to know



what was written inside.” One participant ascribed their hesitation to low mood: “I just felt depressed and unable to go.”

Several participants mentioned that money for transportation to meet social workers posed a barrier. In this study, social workers could meet participants on the phone or reimburse participants for travel. However, many participants in this arm did not understand how their study arm worked. Also, the transportation funds were delivered through reimbursement, and participants mentioned not having access to the initial funds needed:

*“I didn’t have any problem meeting with her and in most cases I am the one who was constantly phoning her ... [Social worker]. She suggested that we meet in Tembisa (Thol’impilo site office), but I told her that it was unfair for me because it is far from where I am staying. She said she will give me the money as soon as I got to Tembisa and I said as I’m speaking to right now I don’t have the cash to go to Tembisa from where I’m staying.”*

Others mentioned that the distance to where the social workers were was the problem. Several participants did not want to travel to an unfamiliar location. As one participant explains, “Not knowing where you were situated [stopped me]. I thought [meeting location] was not far and I might find time to go. I was scared of being lost because I didn’t know where I was going.” Confidentiality caused another participant to hesitate to meet with counsellors: “I was afraid of going to explain myself to the social worker because I was not sure if she might tell other people or not.”

#### Participated in counselling sessions

The participants that sought counselling through Thol’impilo found that it benefitted them by enhancing their understanding of the benefits provided by medical care, appreciating the counsellor's follow-up at the clinic and after, addressing unmet participant needs, training participants in how to disclose their status, and most of all, the provision of much-needed psychosocial support. One participant describes the benefits she received from her randomization to this arm:

*“Then [the social worker] told me that I have to be initiated on treatment... and I can live just like other people. After that, I went and went (to the clinic), and it took time for me to get started on treatment, but after that she called me to find out what was going on and then I explained to her...She then wrote me a paper (letter) to take (to the clinic) so that they could be able to assist me fast.”*

The main benefits participants described were training to disclose their HIV status to their partners, which included specific plans of how to approach the topic, what kind of reactions to anticipate, and how the participant might handle themselves and address their partner's response. One participant describes the help she received from a Thol’impilo social worker:

*“She did ask from the beginning if I had a partner, and that it was important to inform him but also to choose a good time to do it and to take my time, to think about it carefully, and not to speak to him about it when I am not in a good emotional state. She also said that I had to keep calm and take my time before talking to him about it.”*



By far, the benefit most lauded by participants was receiving psychosocial support from the social workers. In particular, participants felt affirmed by social workers, who helped to dispel some of the internalized stigma around HIV. One participant describes her experience: “I have learned that being HIV positive is not a shame, you don’t have to hide it and you have to accept it. You don’t have to worry about what other people are saying and I need to continue living your life as long as I take my treatment.”

## 8.2 POINT OF CARE CD4 TESTING PARTICIPANT RESPONSES

Overall, participants in the point-of-care CD4 testing arm understood the function of CD4 cells and the meaning of CD4 counts. They used this understanding to interpret the severity of their illness and overcome denial. This knowledge also led some participants to reduce risky sexual behaviors and substance use. Participants also appreciated the counselling they received with their CD4 counts and indicated that the results improved understanding of the severity of illness. As one participant describes, **“My understanding [of my CD4 count of 238] was that I had to take the ARVs as soon as possible.”** Another participant explicitly describes the influence of new knowledge of their CD4 count: **“[Knowing my CD4 count] influenced me in a positive way because I would not have known, I was blind...when you do not know your status so you do wrong things.”**

For one participant, the counselling clarified a previously held misconception about the meaning of CD4. The participant describes their prior misconception: **“When they say that my CD4 [count] was 525, actually I did not understand as it was my first time, just thought to myself that it had meant that there are 525 things that were wrong in my body.”** Another participant found that counselling helped her to understand that meaning of her test results, accept her status, and seek medical care sooner:

*“I don’t want to lie, at first I did not understand what was going on [during the HIV test], but the person that conducted the test explained to me that the results were going to be either negative or positive...that if I should test positive then they will do a CD4 count test. And that CD4 test is a test whereby they check to find out as to how many CD4 cells I have remaining... And to check whether I needed to start treatment or not. I was frightened because, firstly, I did not know that I had this disease, so shortly after that I was told that my CD4 was low, so I got a shock of my life. So the lady that was assisting me during that time was able to counsel me and made me to understand, so I was able to accept my status and accepted the situation. And this is how I have to live. So that helped me a lot because upon finding out I was able to find help faster.”*

Other participants described that learning their CD4 count allowed them to quickly overcome denial about not only their HIV status, but the urgency of their need for antiretroviral medications. As one participant describes, “I told myself that if things are like this [low CD4 count], I have to accept what they are telling me. Then I accepted and told myself that I am going to return. On the 1<sup>st</sup>, I went back although they took blood for CD4 count they didn’t give me the results. They just gave me the ARV’s and said I must return on the 16th.”

Several participants described health risk behavior change resulting from their new understanding of the significance of CD4 counts, as well as gaining insight into their own health status through CD4 counts. One participant started practicing safer sex. She recounted the change, saying “I explained to him [my boyfriend] that from today we must use condoms” Another participant began abstaining from sexual



activity: "From the time you told me [my CD4 count], I started to contain myself since my husband is working far. As for sex I have stopped myself from doing it." One participant described a reduction in alcohol consumption after understanding their CD4 counts: "after that - even beer - I used to be a heavy drinker. I stopped."

As with the counselling arm, participants described benefits received through counselling and social support. One participant appreciated the need for greater attention and engagement with Thol'impilo staff: "You don't attend us, you visit but it feels like you are not too interested in us. Because you are not supposed to forget us, you need to come more often." Another participant describes a need for counselling and support groups to boost motivation: "Arrange for us to have groups so that we can participate, like in Soweto... when one person comes with a specific suggestion to another one then we get motivated and are able to discuss it together and get more knowledgeable."

However, while most participants found point-of-care CD4 counts to be tremendously helpful in understanding and managing their illness, the specter of stigma remained. One participant described how their fear of their status being discovered by others made them nervous:

*"I think it helps getting it on the same day because it guides whether you need to go to the clinic and start with treatment. So it is better doing it the same day than waiting. Yet again it is not easy to do a CD4 count at the clinics since there's no privacy. Everything is done in an open space in the presence of other people. When you go in a certain room and they close the door automatically everyone knows what you there for."*

### **8.3 TRANSPORT ARM PARTICIPANT RESPONSES**

#### Group 1: no claim for reimbursement, but did visit clinic in past 3 months

Participants that did not submit any reimbursement claims for transportation but did attend their medical visits found funds or other means to access the clinic. However, some reported unsuccessfully attempts to claim transportation reimbursements or not understanding the process.

Rather than use Thol'impilo funds to reach the clinic, participants used alternatives. Some participants had access to their own funds to pay for transportation to the clinic. Several participants mentioned walking to the clinic instead and described it as a common practice: "Majority of [us] walk [to the clinic], unless maybe you are very sick and you are unable to walk. Even old ladies, they walk to the clinic." Others randomized to the transportation arm resided close to the clinic, so were not in need of transportation assistance.

Several participants described challenges with claiming reimbursement. One participant described confusion between himself and the Thol'impilo staff and eventually gave up trying to seek the funds:

*"They registered me and then they said to me I must get R50/3.5USD for transport. They called me and said they will send me money, they sent me numbers saying they are that of Shoprite. When I got to Shoprite they say the money has been declined, I can't withdraw the money, OK. After some time people from Aurum called me, what did they ask me about? I told them that they have sent me numbers but when I arrived at Shoprite there was no money. They asked me where I live, I told them. They asked me about the clinic that I was going to, I said yah. They*



*asked me how much I spend, I am being asked by the person over the phone. I said I am walking, and then she asked me why I demand money even though I am walking. Then I said to the lady that first of all they did not explain to me that the money is for people who stay far."*

Most of the participants who did not claim reimbursements did not understand that they could. When the interviewer asked these participants about whether or not they were aware that they could claim reimbursements and how, they did not know.

#### Group 2: no claim, delayed clinic visit or no clinic visit

Similar to the previous group, participants in this group either did not know how to claim reimbursements or did not recall details on how to do so. Others reported lacking contact details for Aurum staff. One participant worked through the process of claiming their reimbursement but was not able to receive the funds. Interestingly, throughout the interviews in this group, had available, consistent, reliable transportation. Transportation via taxi was available to all but one participant. As in other study arms, the fear of a lack of confidentiality prevented one of the participants from seeking medical care: "My challenge was that at [the] clinic, I am well known. I did not want to go there."

#### Group 3a: made 1 claim

As with the previous groups, those with one claim did not know how to claim their remaining reimbursements or did not realize that they could make more than one claim. One participant felt helped by the funds for transportation and felt more secure in their ability to reach the clinic: "I have a realization that I was no longer going to miss my clinic visits whenever the money is there."

#### Group 3b: made >1 claim

Among those making more than one claim, the barriers to reaching the clinic were similar: financial hardship that prevented availability of funds for travel and food. These participants all reported that money for transportation allowed them to gain access to the clinic and that they appreciated it. In the absence of funds from Aurum, participants reported borrowing money or delaying care. All participants used taxis and felt that these were available, reliable, and reasonably priced. Similar to others receiving funds for transportation, there was confusion about Aurum's procedures for claiming the funds. One participant said that they had not claimed any funds, but Aurum's records indicated that they had claimed funds more than once.

## **9 HEALTH COMMUNICATION TO IMPROVE ENGAGEMENT IN CARE**

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Health communication may be an important component of increasing care seeking during the period between testing HIV positive and entry into care.<sup>35–38</sup> Communication may take several forms including interpersonal health communication (IPC). IPC can bring constructs of client autonomy and shared decision making to health communication. Through this approach, communication can be provided that addresses a client's immediate concerns and most salient needs. We analyzed the content of longitudinal counselling sessions to describe how structured IPC can provide precision health communication to encourage care-seeking.



For this sub-study, twenty participants were randomly selected from the 603 participants in the care facilitation strategy study arm for analysis of counselling sessions.

## 9.1 METHODS

Inductive thematic analysis was used to identify, analyze, and report on themes from the interaction between the counsellor and client. Potential themes were collaboratively developed by two of the researchers, examining and reviewing the codes to identify patterned communication content and relational processes. NVivo 10™ (QSR International Pty Ltd. Version 10, 2012) software was used for data management and coding.

## 9.2 FINDINGS

The counselling sessions started with open-ended questions to build a foundation for further discussion by identifying immediate concerns or primary goals. While not always successful, this led to further reflective discussion during initial sessions and allowed the counsellor to understand the client's goals and to enable the client to verbalize his or her goals. The transcript below illustrates confusion and distress often described by clients.

Care Facilitator (CF): Alright then please tell me how you felt after being told you were HIV positive?

Participant (P): Mm... I have accepted but it is stressing me. I am beginning to think that my life might end anytime from now because I might die any day. I will die and leave my children behind. I want to know what I need to do when things are like this. I want to know if I will get any treatment. This thing is stressing me out. You see this disease is not like any other disease. Some diseases are easy to understand but it is a different story with HIV because when we first heard about it we were made to believe that one gets infected when they are sleeping around. I am stressed now because I was not sleeping around. I don't understand how I got this virus.

CF: It is encouraging to hear you saying that you have accepted your status. However I hear that you have a lot of fears and unanswered questions because of what you have heard about HIV.

P: Yes

CF: You also seem concerned about how you got the virus.

P: Yes, I know that it is not curable but I want to know what I need to do to get help.

Although simple in concept, it was challenging to bring a client to identify primary goals. At the start of sessions, clients often struggled to express goals. Counsellors used a variety of techniques to engage the client and elicit concerns (with varying success and some potential missed opportunities). One of the ways was by turning the discourse to common concerns among recently diagnosed people living with HIV (PLWH).

In the example below, the counsellor noted that the client had no children. To further understand her concerns, the counsellor raised the issue of pregnancy and procreation by opening a discussion of safe pregnancy for PLWH. Subsequent to the discussion, the participant disclosed that she was two months pregnant and had been harboring anxiety on the next steps to take. Once this information emerged, the



counsellor focused their communication on addressing this concern. This focus was particularly salient regarding communication around ART. At the time of the counselling, the South African ART initiation threshold was a CD4 count <350 cells/mm<sup>3</sup>; however, all pregnant women were eligible for fast-track ART. Thus, the communication changed from a discussion around pre-ART care to the urgency and availability of ART.

CF: So I will ask you not to lose hope. Make use of available healthcare services and also take care of yourself. The day you and your partner become ready, and he promises to marry you, you can go the doctor and explain your situation to the doctor and he will advise on better and safe ways than you use to have an HIV negative child.

P: Then can I ask you question, *sisi* [sister]?

CF: Mm. Yes I'm listening...

P: I am currently two months pregnant, what is it that I need to do, *sisi* [sister]?

Tailoring communication to client concerns allowed the client to reflect on the congruency of HIV treatment with their goals. Here is another example followed this theme:

CF: So after receiving your positive results, what are the things that you were worried about?

P: Isn't it that it is no longer going to be easy for me have children? Things like that?

CF: What do you mean when you say it is no longer going to be easy for you to have children?

P: Because it means I will have stay without a boyfriend.

CF: Have you heard that HIV positive people can still have children?

P: I heard about that but I don't know how possible it is for them to have kids.

CF: Oh ok, if you go to the clinic; nurses at the clinic will be able to give you more information because they help a lot with such situations. They can be able to explain in more detail.

Normally, once you find out that you are pregnant and you go to the clinic, they will give you additional treatment to protect the child. Even if you are positive, the child will be delivered HIV negative.

P: Ok

CF: Yes, and it requires you and your partner to talk and understand each other if you want kids. In the event that you are both positive, it is important to know what needs to be done to protect a child. It is important that you go to the clinic more especially if you want to have a child.

P: Ok [female, 18]

In some of the sessions, the counsellor failed to successfully engage in reflective counselling and identify a primary concern of the client. This interfered with delivery of precision communication as the communication was not guided by the client's underlying goals. In the example below, there was failure to achieve interactive discussion.

P: I came here today thinking I was going to get help.

CF: How does talking about taking your diagnosis make you feel?

P: It doesn't do anything for me.

CF: Would you like to come for the third session?



P: For what because I am not getting any help. I want treatment.

CF: Oh alright, no problem but is it possible for us to at least have a final session?

P: Again, no!

To maintain the focus on client's goals rather than persuading clients to do what the counsellors wanted, counsellors sought to assist participants in articulating their concerns or goals. In the example below, the client communicated resistance to involving her husband in the treatment journey. Through further discussion, specific issues around her partner and disclosure to her partner were identified. Identification led to further discussion.

CF: You are saying you will not disclose to him and he can go do the test on his own whenever is wants to?

P: Yes

CF: How are you going to take treatment when he is around?

P: I don't know. It will not be easy because I want to take the treatment, but the problem is that I'm still going to have unprotected sex with him because I haven't disclosed.

CF: Knowing your status and the issues around practicing safe sex. How are you going to handle the situation?

P: Eh (sigh)

*Silence*

P: I don't know where I'm coming from or going.

*Silence*

P: I am confused

**---Break---**

CF: Thank you too for talking to me. Do you have any questions?

P: My partner and I have not been faithful to each other. I have someone else that I am seeing other than my partner, and he also has someone else. The problem is that my other partner gives me money and my main partner doesn't give me enough money.

CF: It seems like there's a lot that you want to talk about, can we discuss some of this issue in our follow-up session.

IPC also allowed for discussion of how a client's planned action may be successfully completed. In other transcripts, the clients may not have fully thought through their plans and potential barriers. Through highlighting potential barriers and working to identify approaches around those barriers, messaging was focused toward the client and may have encouraged increased entry into care. In the example below, the elderly client had lived in a rural village that was serviced weekly by a mobile clinic. However, the client had not accessed care from the mobile clinic.

CF: Ok, so mother I can see that you are really stuck on the issue of money and how you are going to reach the clinic. So what do you think you can do to be able to go to [name] Hospital? What is the way forward?

P: I'm waiting to find money so that I can go to [town], there is nothing more to wait for.

CF: So you are waiting to find money so that you go to [town], but money is still issue?



P: Yes. Don't know when or how I will find it.

CF: I understand that your challenge is money so is it possible that you go mobile clinic when it comes next week?

### 9.3 DISCUSSION

Through exploring themes from counselling sessions, we have demonstrated specific ways that interpersonal health communication enabled a dialogue that fit clients' immediate needs, concerns and provided precision health communication. By applying basic principles of effective listening and inquiry, counsellors sought to maintain interactive discourse to assist clients in identifying goals and pathways to achieve their goals. A failure to lay this foundation may result in irrelevant messages or messages that are highly relevant but may have missed the client's salient concerns. Such off-target messaging, either via mass media or through interpersonal communication, which is not guided by the client's needs and situation may lead clients to tune-out and fail to achieve behavior change.<sup>39-41</sup>

## 10 FACTORS ASSOCIATED WITH OUTCOMES

### 10.1 ASSOCIATIONS WITH ENTRY INTO CARE

We explored both verified and self-reported entry into care by 90 days and by 180 days. Because entry into care data are more valid with verification, and because there was overall concordance in associations between entry into care by 90 and 180 days, only associations with verified 90 day entry into care are presented here. Factors associated with entry into care in an adjusted model (**Table 4**) included female sex, older age (31+), rural site of HCT, born in South Africa, and living ≤5 km from a clinic. Interestingly, in univariable analysis, sex was not associated with entry into care. Only with the addition of CD4 count was sex significant due to women having a considerably higher median CD4 count than men: 464 cells/mm<sup>3</sup> (IQR 320, 643) and 374 cells/mm<sup>3</sup> (IQR: 240, 526), respectively.

**Table 4. Characteristics associated with verified entry into care at 90 days**

	Univariable Hazard Ratio (95% Confidence interval)	Multivariable Hazard Ratio (95% Confidence interval)
Sex		
Male	Referent, 0.6	Referent, 0.01**
Female	1.0 (0.89, 1.2)	1.2 (1.0, 1.4)
Age		
<31	Referent, <0.001***	Referent, 0.001***
31-40	1.4 (1.2, 1.6)	1.3 (1.1, 1.6)
>40	1.7 (1.4, 2.0)	1.6 (1.3, 1.9)
Site		
Urban/Peri-urban	Referent, <0.001***	Referent, <0.001***
Rural	1.4 (1.2, 1.6)	1.4 (1.2, 1.6)
CD4		
≤100	3.4 (2.4, 4.9)	3.2 (2.2, 4.6)
101-350	2.2 (1.8, 2.7)	2.2 (1.8, 2.7)
351-500	1.2 (0.98, 1.6)	1.3 (1.0, 1.6)
>500	Referent, <0.001***	Referent, <0.001***
Unknown	1.2 (0.97, 1.5)	1.2 (0.97, 1.5)
Origin		



South Africa	Referent, 0.005*	Referent, 0.03*
Other	0.72 (0.58, 0.91)	0.79 (0.62, 0.99)
Income source		
Employed	Referent, 0.02*	-
Self-employed/unemployed	1.1 (0.90, 1.2)	-
Grants/Pension	1.3 (1.1, 1.6)	-
Student/Other	0.86 (0.53, 1.4)	-
Housing		
Formal house	Referent, 0.3	-
Traditional structure	0.99 (0.56, 1.8)	-
Structure in yard of house	0.95 (0.81, 1.1)	-
Informal settlement	0.82 (0.66, 1.0)	-
Other	1.2 (0.79, 1.8)	-
Travel mode		
Walk	Referent, 0.9	-
Bus/other	1.0 (0.86, 1.2)	-
Distance from residence to clinic		
≤5km	Referent, <0.001***	Referent, 0.07
>5km	0.85 (0.73, 0.99)	0.87 (0.74, 1.0)
Missing	0.79 (0.50, 1.2)	0.74 (0.47, 1.2)
Reason for HIV test		
Symptomatic	Referent, 0.04	-
Routine	0.78 (0.63, 0.96)	-
Partner positive / pregnant / other	0.98 (0.72, 1.4)	-

\*denotes significance at the 0.05 level; \*\*denotes significance at the 0.01 level; \*\*\* denotes significance at the 0.001 level

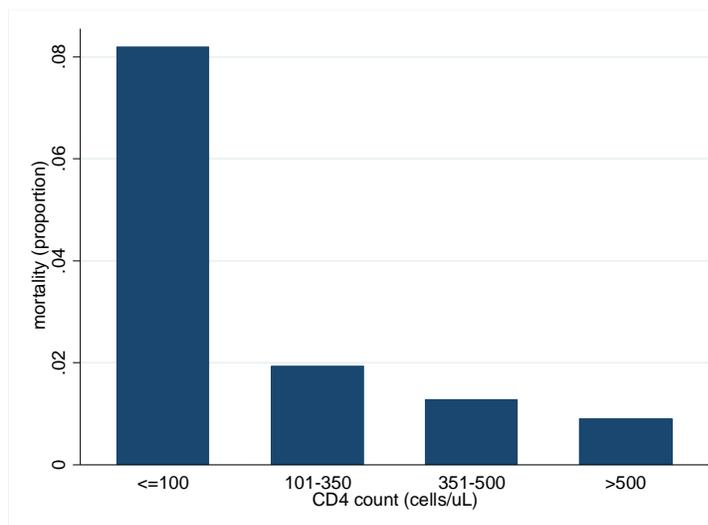
## 10.2 ASSOCIATIONS WITH ART INITIATION

We examined ART initiation at 180 days after enrollment for participants with verified entry into care by 90 days. ART initiation after entry-into-care requires (1) ART eligibility (criteria at time of study was a CD4 count <350 cells/mm<sup>3</sup>), (2) retention in care long enough to complete ART assessments and adherence counselling, and (3) a functioning clinic to deliver ART. The following were associated with ART initiation after clinic entry in the multivariable analysis: female sex (HR: 1.3 (1.0, 1.6)), rural residence (HR: 1.2 (0.99, 1.6)), and distance from residence to clinic <5km (HR: 1.2 (1.0, 1.5)). See **Appendix 6** for further details.

## 10.3 ASSOCIATIONS WITH MORTALITY



**Figure 10. Mortality among participants by CD4 count**



The population receiving HCT at the mobile units was receiving routine HIV testing (to get an incentive, interest in knowing their HIV status, or as something to do), and many were employed. Only mortality within 365 days of enrollment was evaluated due to the overall low mortality in this study (Figure 10). Time to event analysis was used to assess for associations between participant characteristics and mortality. The only characteristic associated with mortality was CD4 count with a hazard ratio of a CD4 count of  $\leq 100$  cells/mm<sup>3</sup>

of 9.4 (95% CI: 2.8, 31) when compared to a CD4 count of  $>500$  cells/mm<sup>3</sup> (see Appendix 7).

## 11 BARRIERS TO SEEKING HIV CARE

### 11.1 BARRIERS TO CARE

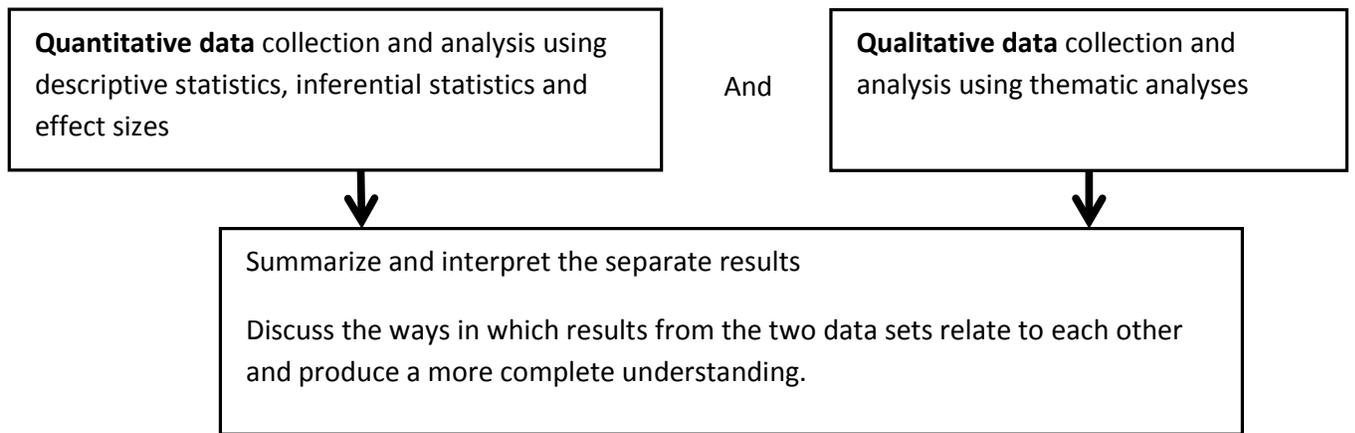
This substudy used a mixed methods design that included both qualitative and quantitative data. Two qualitative data strands were collected as part of this study, and are described below (Figure 11). A second qualitative strand was needed to extend the breadth of inquiry by investigating the timing and the process of engagement in HIV care.

#### 1. Longitudinal in-depth qualitative interviews – convergent parallel mixed methods design

Qualitative data was collected concurrently with quantitative data collection. We aimed to explore the processes of HIV care engagement through participant narratives in the context of interventions provided by the Thol'impilo study.

**Figure 11. Mixed-methods study design strands**

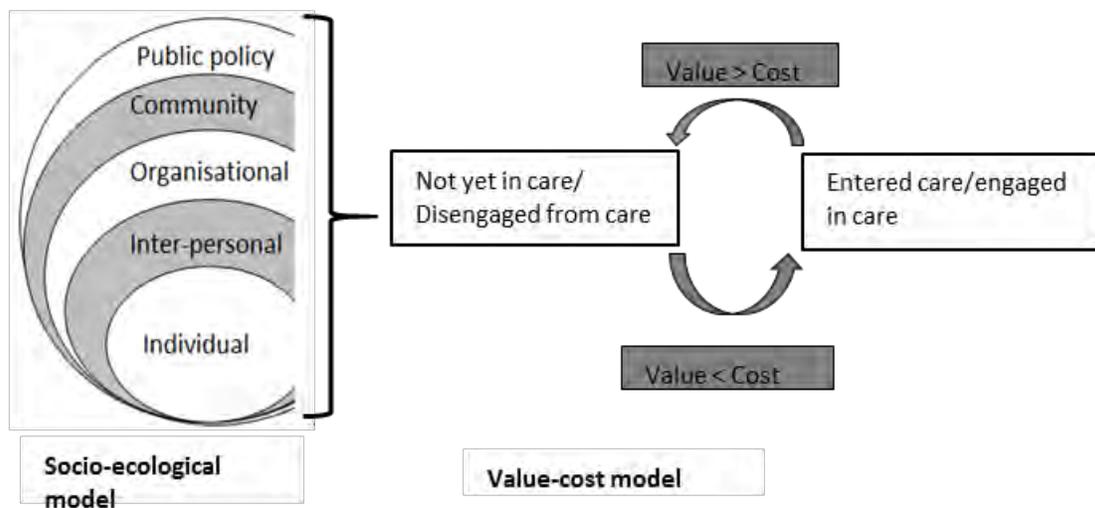
## Convergent parallel mixed methods design



A cohort of 40 participants was randomly selected from the Thol’impilo study. Participants were included if they had at least three months follow-up time at the time of sampling.

## 11.2 RESULTS FRAMEWORK

Figure 12. HIV care engagement theoretical framework



We organized barriers to HIV care engagement at the different levels of the socio-ecological model, and additional constructs of value and cost were incorporated at each of the levels to provide context to cognitive/volitional decision making.<sup>42</sup>

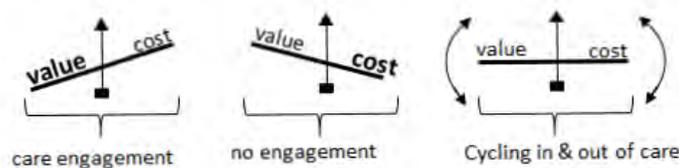
*Socio-ecological model*

The socio-ecological model illustrates how is that behaviour is affected by multiple levels of influence, and individual behaviour both influences and is influenced by the social environment. This bidirectional influence is called reciprocal causation.<sup>43</sup>

*Value-cost model*

Engagement in the care continuum can be viewed as the outcome of patients’ conscious subjective evaluations and psychologically unconscious drives regarding the balance between *value* and *costs* of engaging in care (**Figure 14**). When value exceeds costs, engagement in care is likely. When costs exceed value, entry into care may not occur or disengagement from care is increasingly likely. When value and costs are nearly equal, an individual may be ambivalent and the patient may cycle in and out of care<sup>42</sup>

**Figure 14. Value, cost, and care engagement**



**11.3 INDIVIDUAL LEVEL**

Theme 1: Subjective meaning of illness

This theme incorporated narratives on how much an individual perceived the HIV diagnosis as disruptive to their life, conception of self, and of health. When the subjective impact of the diagnosis was perceived to be low, the value or need for care was absent or nearly absent. This perception resulted in a lack of health care seeking behaviour. In some cases, this behavior was influenced by the absence of symptoms or the issue of a high (>350) point-of-care CD4 count.

*They told me that I have this thing, but I didn't believe that. I just told myself that I want to see first what will happen. What will happen are there any changes happening to me, and there hasn't been any changes happening to me.*

*They told me that my immune system is alright. For now I haven't been there (to the clinic). I told myself that I will go when I don't feel alright, so I have been feeling alright that is why I didn't go.*

Theme 2: Alternative explanations to source of illness and management

Some participants adopted non-biological explanations to the cause and management of HIV infection or other states of health. In moving away from biological explanations to health, the goal of accessing medical care became incongruent to the action required for them to manage their health situation. This shift reduced the perceived value of entry-into-care:



*All over here there was pus [clear] coming out, you see. Eish! I asked myself, why is this happening and someone told me that I was bewitched because of my business.*

*Since I have tested positive I haven't done anything, I am just saying time will come maybe God is still busy working on me. He is healing me. I am not in a hurry, I will go and test (to confirm healing). Now I can see that under God people are being cured.*

### Theme 3: Perceived stigma

This theme incorporated the internalized fear of being discriminated against due to living with HIV. One of the ways in which participants anticipated discrimination was through job loss. As such, participants delayed entering care to avoid local clinics.

*We have a clinic at the farms where I work but I thought that my status might affect my work. I might end up losing my job or being discriminated against. Hence I decided to use the clinic outside my working area. I didn't want my boss to know about my status.*

### Theme 4: Fear of job loss

For some participants who made a clinic visit, the fear of job loss due to long clinic wait times resulted in them not accessing the required medical care.

*"The clinic is not far from where I am living, but it depends on the service from the clinic, you don't always get the same people. You will wake up very early, but still leave late like someone who did not wake up early. When I arrive at work, I could see that my boss was starting to get irritated."*

For one participant, the cost of losing their job was seen as a temporary state and was outweighed by the individual's value of being alive.

*"It is not easy to find a job but one day I will get it. If I had continued listening to my employer it meant that I had to skip going to the clinic, and if I don't go to the clinic, [it was] obvious I was going to die. If I don't get those pills, and then what is going to happen. So I saw that instead of losing my life, I would rather lose the job."*

### Theme 5: Opportunity costs

For individuals who were self-employed, it was the opportunity cost of foregone income that reduced the net benefit of completing entry-into-care procedures

*"I took some time to go [to the clinic]. They told me that I am supposed to go to Thafeni Clinic or any [clinic] that is near Temong, as I reside in Temong Section. Whenever I went there at the end of the month it was always full. It was busy and on the other hand I also have to focus on my business so that I can make some money because I have to pay rent."*

## **11.4 INTERPERSONAL FACTORS**

Participants who involved their social network in managing and coping with their diagnosis mentioned how this was a facilitator to entering care.



### Theme 1: Social comparison

Participants were able to obtain motivation from immediate examples of PLWH who had become healthier by accessing medical care, and this relationship increased the value of seeking care.

*“I have a friend who is also taking ARVs; he motivated me to go to the clinic. He gave me the courage to go ahead with idea of going to the clinic.”*

### Theme 2: Emotional support

Participants progressed towards normalization within the context of the HIV diagnosis when they received emotional support from their social networks.

*“My elder sister was there all the way, she supported me. She encouraged me to never give up in life. She motivated me to go for an HIV test. After I tested positive my sister encouraged me to go for my treatment.”*

### Theme 3: Moral persuasion

Participant value structures were influenced by those close to them. Through reinforcement of existing or adoption of new value structures, participant health seeking behaviours were influenced.

*“It’s because my woman told me to go and check because if I had not, she was afraid that they (family) will die of hunger in the event of my death. She said that, “If I refuse to take my treatment, God will take me whilst it is still young and our children will die of hunger, but if I do take it my treatment I might live longer.” It gave me the pressure to go to the clinic.*

### Theme 4: Instrumental support

Participants also mentioned receiving tangible support which reduced the tangible and non-tangible costs of accessing care.

*“Most of the time if I am not around, I ask my sibling. I will tell her I am supposed to be at the clinic on this particular day to collect treatment. I will ask her to wake up very early and collect treatment on my behalf. Something like this once happened. It was my aunt’s funeral; I was forced to go at that time. She remained, so I asked her to go and collect treatment for then when she comes, she will bring it along.”*

## **11.5 INSTITUTIONAL/HEALTH FACILITY FACTORS**

### Theme 1: Non-empathic care

Some participants described clinic enacted stigmatization, lack of empathy from health care workers, and a lack of concern for issues raised during clinic consultation, as shown below. In contrast, so participants reported being encouraged to continue with follow-up due to supportive relationships with health care workers.

*“When I got to the clinic, I don’t want to lie to you my child, this clinic does not have... how can I put it so that you can get it? They don’t have patience, they are not patient. They are not patient towards the next person, even when you want to say something, like maybe I want to tell that I*



*can't sleep, I have pains, my body, head, and legs. I don't get a chance to sit down with them. They just check your papers. From there give you the pills then you leave."*

### Theme 2: Long waiting times

Participants described extremely long wait times at clinics that required patients to allocate the majority of a day to their clinic visit. However, even allocating this amount of time did not guarantee that patients would receive care that day. This theme is interrelated to themes of economic loss identified at the individual level.

*We had been there from 5 AM and they started working at 9-10 AM they were in a meeting so that did not make me feel good. To join the queue, you have to wake up as early as 5 AM because if you don't wake up at 5 AM and maybe leave at 7 AM, then you will delay and come back home at about 3 PM, sometimes they cut the queue and you are told to come back the next day only to find that you are sick. The time we spend is too long.*

### Theme 3: Repeated visits

The requirement for participants to conduct multiple visits to complete the entry process and the associated direct and opportunity costs resulted in a reduced net benefit of accessing medical care for some participants.

*I have been going to the clinic, but they have been turning me back. However the week before you called me, I went, and they told me that I need to start with treatment. I was just disappointed by the fact that it took time before I got helped. I was starting to lose hope because I was not getting my results. However, now I am relieved, because I have a file, and I have been given some pills.*

### Theme 4: Lack of confidentiality

Newly diagnosed individuals who may not have disclosed their status to anyone may be especially concerned about inadvertent disclosure. Going to a clinic can be suggestive of having HIV. This can be amplified by a different file color for people with HIV, loud conversations, open doors during consultations, or other ways that patient confidentiality was compromised at clinic. This is reflected in the following quote.

*There is no privacy in the clinic at the location, and I am known. (Nurses) would shout like saying, "those that are HIV positive this side" but so far I have never encountered any problem there, up to so far their service is good.*

## **11.6 COMMUNITY FACTORS**

### Theme 1: Enacted stigma

Stigma, and the fear of being ostracized, related to HIV remains pervasive in South Africa. The following quote reflects how one participant was stigmatized by a community member.

*Yes, there is a certain lady that they (community members) are belittling her saying that they cannot sit close to her because she is HIV positive and I was worried. They were saying that they cannot socialize with her because she will transmit the virus to them and to hear them talking like that it was painful. They are lot of people who are talking. I was thinking that they are going*



*to say the same things about me. I was thinking that if I test HIV positive they will be afraid to sit next to me because I will be HIV positive. So I thought that it is better I just sit and not test.*

## 11.7 POLICY FACTORS

### Demarcation of catchment areas

Public clinics in South Africa are officially available to all people living in South Africa, independent of place of residence or country of origin. At the actual clinic level, other policies may be instituted as illustrated in the following quote.

*“The next morning I went to the hospital at Ivory Park. When I got there, I told them where I was coming from. I gave them the letter and they opened it. That is when I was told that people from Winnie (area of residence) are not supposed to go there. So I went back home and cried. I took those letters and tore them apart. I tore them, threw them away in a bin, I did not do anything*

## 11.8 DENIAL OF SERVICE AT CLINIC (QUANTITATIVE)

In addition to in-depth interview data regarding clinic-level challenges or costs faced by some participants, we assessed the effect of being turned away from care at the first visit. Among the 2,398 participants, 71 (3% of all participants; 5% of self-reported entry-into-care) reported having been denied service on first attempt. Among those 71 participants, only 28 (39%) entered care within 90 days. Reasons provided for being denied care included residing outside of the clinic catchment area, the facility being full, having arrived too late to queue, and requiring a treatment buddy.

## 12 UNDERSTANDING STRATEGY UTILIZATION - PROCESS MEASURES

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Strategy effectiveness depended on utilization by participants. While the fidelity was high – delivery of strategy content – by the Thol’impilo team, participant utilization was less than desired for care facilitation and transport reimbursement. We explored uptake, perceived value, and reasons related to participant needs and concerns. We also explore delivery of these strategies by the Thol’impilo team. The majority of the findings are in the **Appendix 2**.

### 12.1 POINT OF CARE CD4 TESTING (POC-CD4)

**Implementation process:** This intervention was rolled out from mobile community-based HCT vans. The Thol’impilo Research Assistant (RA) was assigned to work with three other routine HCT counsellors in a single mobile unit.

### 12.2 CARE FACILITATION

#### **Delivery of core intervention elements**

The core elements of this intervention were adapted from the ARTAS trial. A review of 20 randomly selected participant sessions was conducted to evaluate the content of sessions and the relational nature between the CF and participant during the sessions.



### Core element 1: Build effective working relationships

The effectiveness of CF sessions relied on the open disclosure of information from the client in order for them to be effective; therefore, this component was considered a core element of the intervention. Effective interpersonal communication (IPC) facilitated building trusting relationships. CFs were able to create positive working relationships by consistently applying basic principles of effective listening, empathy, non-judgmental enquiry, and non-paternalistic approaches to the sessions. The commonly observed barrier to building the trusting relationship was unmet expectations by the participant. Unmet expectations included the extent of support they expected to get from the CF or treatment they expected to get from the facility.

### Core element 2: Focus on client strengths

For this element, counsellors primarily asked the client to narrate experiences from historical events, and identify specific situation(s) in his/her life where the client achieved success based on his/her actions and abilities. Although it was not always easy to communicate the relevance of identified strengths from other life domains to HIV diagnosis, the commonly identified strengths were adherence with medication (among clients with other chronic illnesses), problem-solving abilities, resilience, strong life purpose, and social support. Coupled with motivational counselling, participants were encouraged to use their skills to enter into care and accomplish their goals.

*“You tell them that these are your strengths, but they don’t see them. It took something special for them to see and acknowledge it.”*

*“It was not easy for them to identify (strengths) because they mostly focus on the negative things. They hardly see anything good, more especially most of my participants were not employed so for them it was not easy to see their strengths. The moment you talk about strengths, it seemed you were talking a different language. So, I don’t know. I guess for me it was sort of a challenge to help participants identify their strengths”*

### Core element 3: Identify goals and build self-efficacy to pursue goals

As a starting point, counsellors were instructed to apply inquiry and reflective feedback techniques to identify client immediate concerns and goals. The tailoring of communication to client narratives provided an opportunity to engage the client in reflection on the congruency of HIV treatment with stated goals. Following this, the counsellor and client collaboratively broke down identified goals into manageable and ordered tasks.

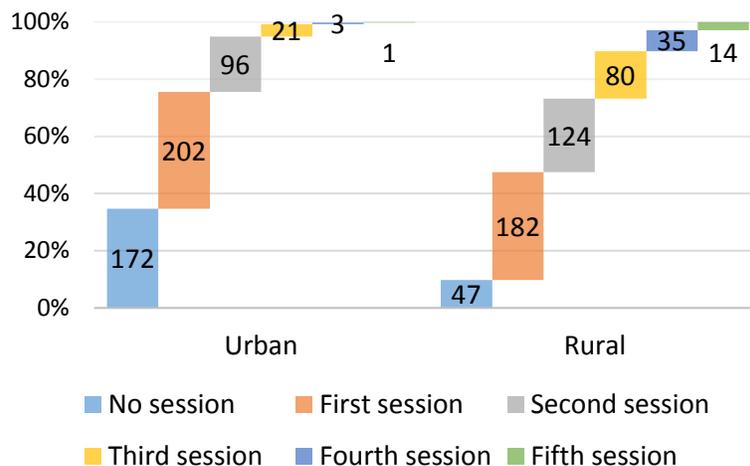
*“I also think that setting goals was not a challenge because you will hear from them as to what they want to do and what they think will help them. When they tell you, you write down - you said you want to go to the clinic, or you want to disclose to your family or your boyfriend. When you ask them, they also tell you when they are planning to do it.”*

### Core element 4: Maintain a client driven approach



Where possible, sessions were conducted at a venue convenient to the client in order to address the barriers of travel distance and opportunity costs for time lost by attending sessions. The CFs were instructed to pursue a non-paternalistic approach to the sessions, and encourage active participation from study participants. Although in concept simple, in practice, bringing a client to participate in the session was often a challenge. At the start of sessions clients often struggled to express goals. Counsellors used a variety of techniques to engage the client and elicit or bring to the surface concerns. One of the ways was by turning the discourse to concerns common among recently tested PLWH. In addition, the identification of tasks and development of a care plan were collaboratively performed by both the CF and the participant. **Process measures:** A total of 603 participants participated in care facilitation activities; 374 and 229 were allocated to the urban and rural CFs, respectively. A higher proportion of urban participants failed to attend their first session compared to rural participants (46% vs. 20%). Apart from the geographical location, we failed to identify any individual level factors or interaction terms associated with failure to attend a single CF session. Although urban CFs were assigned 145 more participants; rural CFs had a higher attendance resulting in the total number of sessions being similar across the two settings (urban = 495 sessions, rural = 482 sessions). Of the total number of sessions conducted 105 (21%) and 108 (22%) sessions were conducted telephonically in the urban and rural sites, respectively (**Figure 13**).

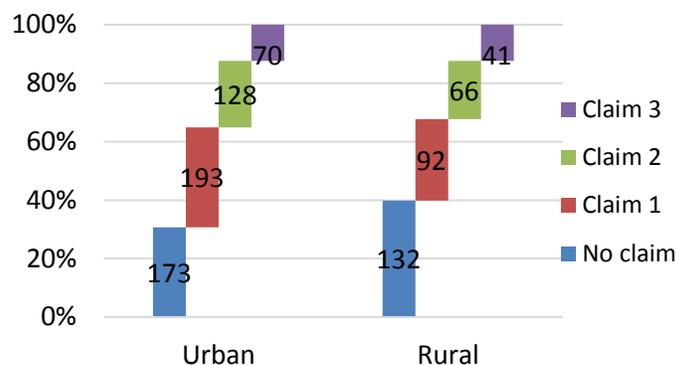
**Figure 13: Participant attendance at care facilitation sessions (urban vs. rural)**



### 12.3 TRANSPORT REIMBURSEMENT

**Figure 14. Participant transport claims (rural vs. urban)**





**Implementation process:** This was a time limited intervention with a maximum of three transport assists for healthcare visits over a 90-day period from the time of diagnosis. A standardized amount was issued for rural and urban participants; R80/USD10.7 or R50/USD6.7, respectively. Money was disbursed via cell phone and collected from automated teller machines (ATM) or a specified chain of supermarkets, without any additional transactional costs to the participant. Participants had the additional option of collecting the money directly from Aurum site offices in the areas of study operation. Participants received text messages reminding them of redeemable funds and expiry dates of the offer. Upon receiving a claim, the office-based transport support center aimed to complete electronic transfer of funds within a median of 72 hours (IQR: 48 – 96 hours). Disbursement of funds was based on participant self-report of clinic visit, without additional real-time verification of the event.

## 13 CLINIC SWITCHING AND RETENTION IN CLINICAL CARE

Retention in care is a critical component of the HIV care continuum. Two concerns related to this study were whether there was differential retention in care by entry-into-care strategy and how frequently participants transferred between clinics (**Table 5**). We followed participants for a median of 683 days (IQR: 571, 832) from enrollment and described retention and observations on describing the care continuum based on self-reported and clinic recorded results.

**Table 5. Switching among clinics by participants**

Self-reported	N (%)
Entry clinic differed from study enrollment referral clinic (entry up to 365 days from enrollment)	507/1101 (46.1)
Clinic switch after first clinic visits	
No switch	889 (80.6)
One or more switches	214 (19.4)
From clinic records	



Transfer documented in clinic records	19 (4)
Loss to follow –up documented	62 (14)

Key findings to highlight are:

- 1) The high proportion of participants who entered a clinic different from the closest or stated intended clinic (**Table 5**). This demonstrates the challenge of following individuals who test positive to care, especially from mobile HCT units. Following-up with a participant (in addition to clinics) would appear to be essential to achieve accurate findings, based on this study.
- 2) A majority of patients considered lost to follow-up may have actually been in care at another clinic (19% with switches based-on data from participants but only 4% with switches recorded in clinic files). This lack of information poses a substantial challenge to documenting a continuous journey through the care continuum for a single individual.

## 14 DISSEMINATION ACTIVITIES

Dissemination activities have included local, national, and international efforts. We have shared results and insights with our community advisory groups, clinic and district managers in Sekhukhune and Ekurhuleni, international audiences at International AIDS Society 2015, Conference on Retroviruses and Opportunistic Infections 2016, and International Conference on HIV Treatment and Prevention Adherence 2016, and through peer-reviewed publications in leading HIV journals (please see **Appendix 8** for greater detail). Additional local and national dissemination is planned in South Africa and multiple journal article submissions are in process or planned to further disseminate findings and how these may relate to on-the-ground activities.

## 15 RECOMMENDATIONS / INTERPRETATION OF RESULTS / POLICY IMPLICATIONS

### 15.1 MAJOR GAP BETWEEN GOAL AND REALITY

Thol'impilo provides valuable data on the current performance of the health system in achieving entry into care. The size of the study, geographic range, inclusion of numerous clinics, and pragmatic nature enables an accurate assessment of entry into care following testing from mobile HCT in South Africa. What we have demonstrated is that current rates of entry into care are abysmal: 30% of participants in the standard of care arm were in care within 90 days of testing HIV-positive. This finding is especially important because mobile, household, and other alternatives to clinic-based HCT are essential to expand a test and treat model beyond those sick enough to seek care at clinics or hospitals (and generally having low CD4 counts). Given similarities within the region among clinical services and barriers to care, these results likely represent the situation through southern Africa and elsewhere on the continent.



## 15.2 IMMEDIATE AND LONGER TERM IMPLEMENTATION NEEDS

Two tiers of strategies to improve entry into care and the rest of the care continuum are needed:

- (1) Rapidly implementable strategies that fit within the current care delivery structure and do not necessarily require a shift in policy (feedback from District and Provincial managers)
  - District and clinic-level managers have asked for guidance on what to do and what not to do immediately to improve care continuum indicators as they are being given targets but lack the guidance on strategies to achieve those targets. This request for guidance is built on the flexibility in how clinics can approach optimizing the care continuum. Such a bottom-up approach can lead to useful local adaptation or, alternatively, it can lead to considerable effort on approaches that lack effectiveness.
  - Although a “best” practice remains unclear at this point, synthesis of data from Thol’impilo and other USAID Annual Program Statement Implementation Science studies and other related studies may lead a list of approaches that could be adapted for immediate adoption at the clinic and District level without re-allocation of resources or new policy directives. Given the massive gap between current HIV care outcomes (30% entry-into-care by 90 days in Thol’impilo) and goals (>90% entry-into-care) in the care continuum, a basic guidance would be valuable to direct managers toward strategies more likely to be successful and away from strategies considered unlikely to be effective.
  
- (2) A pragmatic package of strategies that may take longer to implement and may require policy decisions.

This is described further in section 15.5.

## 15.3 BARRIERS TO CARE

Across all of the strategies, participants articulated a need for increased social and psychosocial support to address issues such as denial, disclosure training, stigma and distress from the diagnosis. The interviewers did not ask about stigma, but it was named as a barrier to care in multiple arms. In addition, participants expressed fears about a lack of confidentiality when seeking care at a clinic or from social workers. Timing also posed a challenge for employed individuals: clinics and social workers were available only during working hours, which prevented access by many participants. Clinics and linkage support programs should closely attend to concerns about confidentiality, even when indications of a patient’s serostatus may be subtle (e.g., patients spend different amounts of time in the clinic). Most participants also reported unmet, basic life needs (food, income through employment or grants). While providing support with these needs is likely beyond the scope of HIV care providers, referrals or linkages to organizations or individuals that could address these needs would be very worthwhile.

## 15.4 TESTED ENTRY-INTO-CARE STRATEGIES

### 15.4.1 Care facilitation – longitudinal counselling

The approach of longitudinal counselling is of potential, direct benefit. Notably, this approach can be rapidly implemented without health service or health system restructuring such as is needed to implement alternative care models. This makes the cost potentially lower per entry-into-care than other



health system approaches. Furthermore, the study points to approaches to reduce the cost of this strategy. The cost was 77USD per client and 1,723USD per additional participant entering care. Potential approaches to reduce cost are include reducing the total number of expected sessions as only 4% of participants who had the first sessions had all five sessions and only 14% had 4 or more sessions. An additional potential change is in the cadre of counsellors delivering the care facilitation. The Thol'impilo study utilized social workers and auxiliary social workers. The cost of such staff are higher than experienced counsellors who may be able to deliver the strategy with similar fidelity. It should also be noted that wage costs are considerably higher in South Africa than much of the rest of sub-Saharan Africa. As a result a similar effect in entry-into-care may be achievable at a substantially lower cost in other settings. Furthermore, the cost of care facilitation in Thol'impilo was based on the actual volume of care facilitation. The care facilitators could have provided services to a larger number of clients. A challenge of care facilitation in this study was the distance between the site offices on many participants place of residence. Greater coverage of counsellors based at clinics or municipal offices may reduce this challenge and increase utilization of the service.

Further implementation science research may better define a minimum package for care facilitation. Before such results are available, utilizing outreach teams or augmenting currently available counsellors to deliver longitudinal strengths-based counselling may be a practical and rapidly scalable approach to increasing uptake of HIV care services.

#### **15.4.2 Point of care CD4 count testing**

Point-of-care CD4 count testing made no difference, overall, in entry-into-care using self-report (hazard ratio 1.0) or verified outcomes (hazard ratio 1.0). Furthermore, while there was a trend toward increased ART initiation (hazard ratio 1.2 with 95% CI: 0.91, 1.6), there was not a clear, statistically significant benefit. Using in-depth interviews, we noted appreciation for receiving CD4 count results and reported behavior change based on hearing a low result. It is plausible that had a substantially greater proportion of the participants had a low CD4 count, this strategy would have resulted in accelerated entry into care.

#### **15.4.3 Transport reimbursement**

We based the concept of providing transport reimbursement on the considerable literature suggesting that distance from clinic and transport barriers are substantial structural barriers to entry into care and retention in care. In Thol'impilo, residing >5 kilometers (walking distance for many) from the clinic was associated with less entry into care and ART initiation. Despite distance being identified as a barrier, providing transport reimbursement did not increase overall verified entry into care (hazard ratio 1.1; 95% CI: 0.88, 1.3). Interestingly, the rural sites had a larger proportion of participants entering care despite generally greater distances to care. From this study it is unclear whether transport was not a substantial barrier or whether or this approach to overcoming the barrier was inadequate. Obtaining transport reimbursement may have been most challenging for those residing the farthest from commercial centers. Alternatives to transport assistance may include direct provision of transport services, vouchers to use of available transport, and mobile or community-based / home-based clinic services. Prior to selecting transport reimbursement we assessed provision of transport and transport vouchers. Both were less feasible and appeared to be more costly to implement than transport



reimbursement. Further expansion of mobile clinics and or community-based approaches to bring care closer to rural residents may be worth future evaluation.

## **15.5 APPROACHES TO IMPROVING THE CARE CONTINUUM**

A combination strategy that includes individual, interpersonal, clinic, and community levels may be the optimal approach to optimizing perceived value and reducing perceived cost to achieve care engagement.

Individual level: Based on the relative success of care facilitation, a modified (cheaper) care facilitation approach may be a component of a combination strategy. Other individual-level strategies currently lack evidence of effectiveness in low and middle income settings - such as cell phone reminders, POC-CD4 count testing, transport reimbursement (as we provided), and visit navigators.

Interpersonal level: The importance of social networks and emotional or financial support from family and friends was communicated through in-depth interviews. However, we did not investigate interpersonal strategies and are not aware of other studies to do so.

Our findings are consistent with other reports regarding both substantial value seen in clinical care from the perspective of many participants. This value includes health, reassurance of health, and social interaction. However, these values are not always apparent to a patient when the provision of services raises questions of the skills of the clinical staff as a result of unprofessional behavior, concerns about status disclosure, and/or rudeness. Eroding of value can shift the balance further away from care engagement.

Clinic level: Clinics / service delivery were a barrier to Thol'impilo participants and have been well documented in other studies to be a barrier to accessing care – despite the value in improved health and longevity. **Service delivery strategies to improving entry into care and the care continuum likely hold the key to improvements in the continuum. Re-orienting care to patient-centered (person-centered) care may address some of the costs currently leading to a lower than optimal proportion of entry into care at present.** Key aspects of such care could include:

- Orienting activities to service the needs or convenience of the client rather than the clinic
- Have clinics and clinic workers demonstrate efforts to maintain confidentiality including a single patient in a consultation room, a closed door, and a single clinician or clinician team in the room (no other activity)
- Improved empathy / caring of all clinic staff
- Train clinicians to follow a clear algorithmic approach through an encounter
- Reduce number of required clinic visits (managing laboratory results to avoid repeat visits purely to find out if results were returned)<sup>44</sup>
- Reduce wait time at clinic (at crowded clinics)
- Consider of community-based care and alternative models of care such as community adherence clubs for decreased time at clinic, reducing clinic burden, and increasing social connectedness related to clinic care



Community level: At a community-level, decreasing stigma and increasing ART and HIV treatment literacy may be part of a combination HIV continuum strategy. Further research into both stigma reduction and treatment literacy is needed.

Policy level: District leadership could provide a consistent message regarding policies and providing care for all inhabitants in South Africa, not based on specific catchment areas. This change could allow people living with HIV to access the most suitable clinic – one closer to the place of work, open on weekends, or one that affords greater anonymity by way of being further from a place of residence.

By addressing key aspects of value and cost at each of the social ecological levels, potentially a substantial improvement can be achieved in time entry into care and ART initiation (**Figure 14**).

## 15.6 DOCUMENTING THE CARE CONTINUUM

An important lesson learned from Tho’impilo is the challenge of documenting the care continuum, especially the step from testing positive to entering care (**Table 6**). We found that self-report was unlikely to be reliable based on the substantial proportion of self-reported entry that we could not verify along with acknowledgements from participants that they inaccurately reported entry into care. Superior ascertainment by clinic verification has been previously reported.<sup>2,3</sup>

**Table 6. Challenges associated with documenting the care continuum**

Care determination following testing positive	Limitations
Contacting the client	<ol style="list-style-type: none"> <li>1. Requires considerable resources to contact / trace individuals due to lack of cell phone, no phone service, or variable availability to answer phone</li> <li>2. Over-reporting of entry</li> </ol>
Reviewing clinic registers	<ol style="list-style-type: none"> <li>1. Entry clinic often different from referral clinic (40%) in Tho’impilo</li> <li>2. Registers may be incomplete, paper files misplaced</li> </ol>
Searching a national electronic laboratory database	<ol style="list-style-type: none"> <li>1. Only will have an entry verifiable for HIV care if HIV specific labs obtained, thus will miss some initial HIV care visits</li> <li>2. Matching by name and date of birth limited by a variety of names used and inaccuracies in date of birth recording</li> </ol>
Searching electronic district health information systems	<ol style="list-style-type: none"> <li>1. Name of clinic may be needed</li> <li>2. Matching by name and date of birth limited by a variety of names used and inaccuracies in date of birth recording</li> </ol>

Accessing records at a clinic is not ideal due to (1) challenges in clinic record review and (2) determining the correct clinic to abstract a visit from. Given that 40% of participants who entered care utilized a clinic other than the stated intended clinic at study enrollment, a regional or country wide system is needed to follow individuals, especially those diagnosed in mobile testing, into care. South African National Health Laboratory Service access helped us identify lab contacts for many participants when we were able to match names and dates of birth. Given the laboratory information infrastructure in place



in South Africa, this system may be a reasonable platform on which to build in ongoing care continuum surveillance. In settings without developed information technology infrastructure and widely used unique patient identifiers, a robust system is needed to estimate the proportion of people who test positive and enter care within a time frame or who test positive and initiate ART within a specific time frame. Implementation research is needed to better define an approach to reporting for routine continuum indicators.

## 16 SUMMARY

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Identifying ways to engage people living with HIV in care has never been more important. Current efforts to expand the test and treat concept require immediate (or at least rapid) engagement in care – either for ART initiation or for follow-up following initial ART dispensing. Thol’impilo is the largest study comparing strategies to increase entry into care. Key aspects include the size (2,398 participants), the geographical diversity (high density urban to low density rural areas), a focus on entry following testing at mobile HCT units, participant follow-up and clinic record review, the inclusion of any clinic a participant chose to attend, and full inclusion of all adults living with HIV not already receiving HIV care. For these reasons we believe that Thol’impilo should shape the direction of future investigation and program design regarding entry into care. This study contributes to our understand of what may work, what does not appear to work, challenges in strategy delivery, key ongoing barriers, and challenges to documenting the care continuum.

### **Successful Thol’impilo strategies:**

- Longitudinal contact with clients prior to entry into care
- Using a combination of clinic file abstraction, electronic district health information abstraction, and national laboratory data base searches to verify entry into care

### **Unsuccessful Thol’impilo strategies:**

- Point-of-care CD4 count testing
- Providing transport / transport assistance to reach clinics
- Providing a cash transfer (conditional cash transfer to visiting a clinic) for transport is a challenge and unlikely to be successfully implemented in rural areas.

### **Future research directions:**

- How to document the HIV care continuum
- Effect of bringing care to client (rather than trying to help a client get to care)
- Value of added community resources and local / community-based care or home-based care services
- Pragmatic sustainable approaches to delivering patient/person centered care
- Studies to characterize patients who would do best with fewer visits and those who would do better with more frequent visits



## Where to go next

- Assess multi-level combination strategies that include, at a minimum, individual-level and clinic-level components and potentially higher structural levels.
- Developing simple and pragmatic indicators for entry into care
- Consider proactive strategies to both accelerate entry into care and improve retention in care (such as improving the clinic experience)

Thol'impilo met study implementation and strategy comparison goals providing many valuable findings. At the time of this report, analysis was underway for further dissemination of manuscripts including findings contained in this report. Further secondary analyses on additional aspects of entry into care and delivery of mobile HCT and linkage strategies were also underway. We anticipate additional insights to help shape programming and the implementation science agenda around improving the HIV care continuum in low and middle income countries.



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