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Journal:	*BMJ Open*
Manuscript ID	bmjopen-2016-013733
Article Type:	Research
Date Submitted by the Author:	20-Aug-2016
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Primary Subject Heading:	HIV/AIDS
Secondary Subject Heading:	Health services research
Keywords:	HIV, Linkage to care, Facility-based HIV testing, Mobile and outreach HIV testing, Mbeya-Tanzania

Comparison of linkage into care among newly diagnosed HIV positive individuals tested through outreach versus facility-based HIV testing models in Mbeya-Tanzania (Cohort study)

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ABSTRACT

Objective: Linkage to care is the bridge between HIV testing and HIV treatment, care and support. The study compares linkage to care of HIV positive individuals tested at mobile/outreach versus public health facility-based services within the first six months of HIV diagnosis.

Setting: Rural communities in four districts of Mbeya Region-Tanzania.

Participants: A total of 1,012 newly diagnosed HIV positive adults from 16 testing facilities were enrolled into a two-armed cohort and followed for six months between August 2014 and July 2015. 840 (83%) participants completed the study.

Main outcome measures: We compared the ratios and time variance in linkage to care using the Kaplan Meier estimator and Log rank tests.

Results: At the end of six months follow up, of the 607 HIV positive individuals tested at health facilities, 84% (CI= 81% -87%, n= 512) were linked to HIV care cliniccompared to 69% (CI= 65% -74%, n=281) of 405 individuals tested at mobile sites. Those tested at public health facility-based sites were significantly more likely to have linked to care sooner than those tested at the mobile sites ($p<0.0001$). The median time to linkage was 1 (IQR: 1-7.5) days for facilities and 6 (IQR: 3-11) days for mobile or outreach testing. The independent predictors of rate of linkage were: disclosing HIV status (AHR=0.35, 95%CI=0.28-0.44), the site of HIV testing (AHR=1.73, 95%CI=1.49-2.003) and intentionally testing for HIV with the hope of receiving treatment (AHR=1.25, 95%CI=1.07-1.45).

Conclusions: Newly diagnosed individuals tested at health care facilities linked sooner and in higher proportions than those tested through mobile/outreach services. Although mobile/outreach service delivery models bring HIV testing services closer to people, there is a

need to address associated gaps in linkage to HIV care in resource constrained settings and novel strategies to improve linkage from outreach models need to be explored.

Strengths and limitations of this study

- Prospective adequately-powered cohort study
- Participants from 16 sites
- Participants followed up for six months, with good retention.
- Possible that some participants moved elsewhere during the study and may have accessed care elsewhere; this warrants further investigation.
- Participant tracking was aimed at enabling follow-up during the study, but may have enhanced linkage to care.

Key words

HIV, Linkage to care, Facility-based HIV testing, Mobile and outreach HIV testing, Mbeya - Tanzania.

1. INTRODUCTION

HIV remains a major burden in Sub-Saharan Africa (SSA), with 790,000 deaths associated with HIV in 2014. [1] Despite the high prevalence and the increasing numbers of people living with HIV in need of highly active anti-retroviral therapy (HAART), timely linkage to care is generally poor across SSA. [2], [3] The Mbeya region is among three regions in Tanzania with the highest HIV prevalence, with an average of 9% compared to the national average of 5.1%, [6] and AIDS-related deaths are among the three leading causes in the area. [4], [5]

Linkage to care is the bridge between HIV testing and HIV treatment, care and support. Timely HIV diagnosis and effective linkage into care and treatment are key to improved outcomes. [6], [7] All individuals diagnosed HIV positive must be linked to HIV care and treatment, even if local treatment guidelines do not indicate that a person be started on anti-retroviral therapy immediately. [8] CD4 cell count, HIV staging, evaluation of the client's need for ART initiation need to be done immediately. [8] The importance of linkage to care during HIV counselling and testing has been well advocated in Tanzania, however available literature indicates that linkage to care after testing HIV positive is still low[9], [10], leading to failure of HIV positive individuals to benefit from HIV care. Hence, efforts are hampered to improve coverage for HIV care and treatment services as well as resulting in increased risk of HIV transmission to others. [11], [12]

Mobile and outreach testing sites have been introduced in Tanzania, reflecting an increasing interest in providing early detection of HIV and subsequent care and support in the hard to reach populations in remote areas. [13], [14] However, linkage to care remains at sub optimal levels in the country due to barriers such as lack of understanding of the importance of care regardless of disease stage, distance from the clinic and transport costs. [9], [14], [15]

Furthermore, fear of stigma related to HIV, failure to disclose, being asymptomatic at the time of diagnosis and negative attitude of health care providers were some of the factors reported to interfere with linkage to HIV care.[16]–[18] In the context of existing options to receive testing, including at health facilities, through mobile and outreach sites in Tanzania, there is little research on whether linkage to care differs between clients diagnosed at outreach or facility-based testing sites, as well as factors facilitating or inhibiting successful linkage to care between these two models of service delivery. [19], [20] These differences may occur at patient level, at service provider level or at the facility or the health system as a whole. For example, factors enhancing access to testing, such as dedicated outreach staff, may enhance linkage to care for those testing in mobile/outreach facilities, while other factors such as geographic distance between patients' homes, testing sites and treatment sites, weak referral systems and lack of structural links between testing and treatment sites may lead to disconnects between testing and care. [9], [14], [21]

One South African study found that individuals testing at mobile services were 33% less likely to undergo CD4 testing than individuals testing at static clinic services, and only10% of mobile testers were successfully linked into care versus 72% of clinic testers. [19] However, in South Africa nearly all health facilities now offer treatment, care and support, while this is not the case in Tanzania – hence South African findings about differences between mobile and facility-based testing and subsequent linkage to care may not be directly transferable to Tanzania and other settings where in the majority of health facilities testing and care are not available as a 'one stop shop'. Active referral or self-referrals are therefore more critical in these situations.

Mbeya region has a total of 312 health facilities where clients can receive testing and counselling (HTC) services through recommended approaches. However only 68 facilities offer HIV care and treatment service 21.7%. [22] At least two outreach partners or non-

governmental organizations offer HIV counselling and testing in each district of the Mbeya Region. The Mbeya Medical Research Centre (MMRC)-Mobile Diagnostic and Training Centre (MDTC) has been offering CD4 count tests at point of care [4] since 2009, covering between 8 to 12 sites every three months. Available statistics from the Mbeya regional AIDS control program (MRACP) [5] suggest that more people undergo HIV testing at mobile /outreach HIV testing services (56%) compared to facility based services (44%). However, only about 28% of all people tested were linked into HIV care. [22] An earlier study conducted in Mwanza reported that despite increased testing opportunities only 14% of newly diagnosed patients had linked into care 4 months after HIV diagnosis [9]. Another study on linkage to care conducted in Ifakara showed a linkage of about 23%, indicating that linkage to care is a challenge in Tanzania. [10]

This article compares the outcomes of linkage and time to linkage into care for individuals tested HIV positive at mobile/outreach sites, versus individuals tested HIV positive at facility-based services over the first six months after diagnosis in rural parts of the Mbeya region. The findings from this paper are expected to inform policy makers and other stakeholders in the Tanzanian health care system on the optimization of HIV testing and immediate linkage to care, an issue of critical importance for timely initiation of antiretroviral therapy.

2. STUDY METHOD AND DESIGN

Study Setting

The study population comprises rural communities in four of the then eight districts of the Mbeya Region in 2014. In 2012, the Mbeya region had a population of 2,707, 410 with 52% women and 48% men (National Bureau of Statistics, 2013). The four study districts were selected to include high HIV prevalence areas and hard-to-reach populations. Two districts (Kyela and Mbozi) are along the highways and have borders to Zambia and/or Malawi. The population in Kyela district was 221,495 in 2012, while Mbozi reported 446,339 residents. High population mobility linked to cross-border business and social interactions is likely to create challenges with linkage to and continuity of care. The other two districts (Mbeya Rural and Chunya) are remote districts where a larger than average proportion of residents live 10 km or more from a health facility. The population in these remote districts was 305,319 and 290,478 respectively (NBS, 2013).

The HIV prevalence among the people tested for HIV in 2014 in the selected district were Mbeya Rural -13.0%, Chunya- 9.2%, Kyela- 9.2%, and Mbozi - 8.7%. [22] The 16 study sites were randomly selected and included four sites in each district (2 facility based and 2 mobile/outreach sites).[23] The eight facility based sites had a care and treatment centre (CTC) or HIV care unit within the facility. Sites had different arrangements for linkage to care (i.e. registration); in some facilities, registration was possible on the same day as testing, while other facilities had chosen a single day or two per week for newly diagnosed clients to register into HIV care. Almost no mobile/outreach sites had direct access to CTCs; they had to refer their clients to the closest HIV care unit for further management (HIV staging, laboratory test, ART initiation etc.). The MDTC from MMRC was offering CD4 tests at the point of care, but

still had to refer newly diagnosed clients to nearby HIV care units, however already with the CD4 results for registration and continuation of care

Sampling

The sampling strategy for testing sites is described above. The sampling framework for the cohort comprised all adults above 18 years receiving HIV testing at facility based and mobile/outreach sites in the four study districts of Mbeya region. The sample size was calculated using Epi Info software with confidence interval of 95% and power of 90%, assuming that the two study groups would have the same number of subjects. Thirty per cent of individuals tested through mobile /outreach services and 41% of individuals tested at facility-based services were expected to link into HIV care. The estimated sample size was 828; we adjusted this sample size to account for possible dropouts and non-responders (10%) resulting in a total estimated sample size of 900 participants.

Study design, data collection and outcome measures

For this prospective mixed-method cohort study, 1,012 adults who tested HIV positive were recruited into a two-armed cohort (facility-based vs. mobile/outreach HIV testing sites) and followed up for 6 months to gather quantitative and qualitative information on linkage to care since diagnosis. Recruitment of participants was done at the HIV testing unit, the researcher team was introduced to all of the clients by the nurse counselor to give brief explanation of the study and all interested individuals were invited in a private room for detailed explanation, asked for permission to get their test results and follow up. Interested individuals were then

invited for the enrollment and informed consent discussion and initial questionnaire administration (which occurred either at that time or at another time and place convenient to the participant within 7 days of the testing visit).

Initial data were collected between August and December 2014. Follow up questionnaire administration continued until June 2015. Data collection was done by research assistants who underwent two days of training on informed consent and data collection procedures. This paper reports on preliminary outcomes, for which a structured questionnaire was administered to respondents at enrolment, at 3 months and at 6 months to ascertain time to linkage into HIV care and to explore factors related to linkage to care. The operational definition for linkage to care in this study is registration for the next step of care: [24] a newly diagnosed individual has completed registration procedures and has been provided with a Care and Treatment Centre (CTC) registration number and clinic card. The key outcome is the proportion of participants successfully linked to an HIV care unit across the sample as a whole, and between the two arms of the cohort. In this paper facility-based sites means fixed or static facilities such as hospitals, health centres and dispensaries while mobile sites means all outreach HIV testing services, including campaigns, mobile testing clinics, home visits or special event testing services.

Data Analysis

Quantitative data from sites were recorded, cleaned and analysed using Stata Version 13 (College Station Texas. USA). Descriptive analysis methods were used to present the characteristics of participants. Categorical data were presented using frequencies and percentage, while quantitative data were presented using the measure of central tendency and measure of dispersion. Cross-tabulation was used to show the distribution of study subject by

testing site. We compared the ratios and time variance in linkage to care using the Kaplan Meier estimator and Log rank tests. Cox proportional hazards regression models were used to evaluate the factors associated with time variance in linkage to care. Statistical significance was declared at p-values less than 0.05 for the entire analysis.

Ethical considerations

The study was approved by the University of Western Cape (UWC) Senate Research Committee, the Mbeya Medical Research Centre, the Mbeya Medical Research Ethics Committee (MMREC) and the Tanzanian National Institute of Medical Research ethics committee (NIMR). Participation was entirely voluntary and it was explained to participants that they were free to withdraw from the study at any time without negative consequences. Volunteers were provided with an information sheet containing all details about the study. They signed an informed consent and confidentiality procedures were observed.

3. RESULTS

3.1. Participant characteristics and comparison between facility based and mobile-based testing models

The cohort of 1,012 HIV positive individuals included 58.5% female participants (56% facility; 61% mobile), with a mean age of 35.8 (SD 10.5) years for facility based and 35.3 (SD 10.0) years for mobile/outreach participants. By the end of six months follow up overall 83% of participants were still active in the study, 87% from facility-based arm and 76% from mobile/outreach arm. In both testing models, about 60% of participants were married and more than 80% of participants were self-employed with small-scale farming or petty businesses. A detailed listing of the patient characteristics is presented in Table 1. Age, gender, level of education and occupation were not statistically different between the two testing models, while statistical differences in marital status, means of transport, time to reach clinic and time to linkage were observed.

3.2. Linkage to care at six months:

At six months, 78% of enrolled participants were linked into care across both arms. 0.84 (95%CI: 0.81-0.87) of participants tested at the facility based sites were linked into care within the first six months of HIV diagnosis, compared to 0.69 (95%CI: 0.65-0.74) from the mobile/outreach tested group “Fig 1”. The interval from the day of HIV testing to the day of registration at a CTC was compared between participants who tested at a health facility and those tested through a mobile/outreach model. The median time to linkage was 1 day-(IQR 1-

7.5 days) for those who tested at a health facility and 6 days – (IQR 3-11 days) for those who tested through any mobile/outreach model.

Table1: Background characteristics of study subjects by site

Variable	Facility based	Mobile	N
Gender			
Male	265(43.66)	157(38.77)	422(41.70)
Female	342(56.34)	248(61.23)	590(58.30)
Age ,mean (SD)	35.8(10.5)	35.3(10)	
Marital status			
Single	78(12.85)	48(11.85)	126(12.45)
Married	361(59.47)	252(62.22)	613(60.57)
Separated	82(13.51)	37(9.14)	119(11.76)
Divorced	13(2.14)	26(6.42)	39(3.85)
Widower	73(12.03)	42(10.37)	115(11.36)
Level of education			
None	104(17.13)	81(20.00)	185(18.28)
Primary	470(77.43)	299(73.83)	769(75.99)
Secondary	29(4.78)	24(5.93)	53(5.24)
Vocational	4(0.66)	1(0.25)	5(0.49)
Main occupation			
Unemployed	28(4.61)	15(3.70)	43(4.25)
Student	18(2.97)	3(0.74)	21(2.08)
Driver	9(1.48)	5(1.23)	14(1.38)
Employed	18(2.97)	11(2.72)	29(2.87)
Self employed	530(87.31)	369(91.11)	899(88.83)
Other	4(0.66)	2(0.49)	6(0.59)
Means of transport			
Walking	163(26.85)	200(49.38)	363(35.87)
Bicycle	93(15.32)	77(19.01)	170(16.80)
Motor cycle	143(23.56)	71(17.53)	214(21.15)
Public Transport	201(33.11)	55(13.58)	256(25.30)
Private car	7(1.15)	2(0.49)	9(0.89)
Time to reach clinic			
<1 hour	397(65.40)	295(72.84)	692(68.38)
1-2 hours	157(25.86)	76(18.77)	233(23.02)
2-5 hours	50(8.24)	26(6.42)	76(7.51)
>5 hours	3(0.49)	8(1.98)	11(1.09)
Time to linkage, Median(IQR)	1(1-7.5)	6(3-11)	

Figure 1: Linkage status

Separately attached

The time to linkage (registration) was significantly shorter in the facility tested group, compared to the mobile/outreach tested group (p <0.001), "Fig 2". Log rank test showed that there was a significant difference between the two groups (p- value <0.001).

Figure 2: Survival analysis (KPM)

Separately attached

3.3. Linkage from mobile sites with point of care CD4 test versus no CD4 test

Of 405 participants testing at mobile/outreach sites, 182 (44.94%) individuals had tested for HIV at the Mbeya Medical Research Centre mobile site, where CD4 test was offered at the point of testing, but no registration or ART was provided. 223(55.06%) individuals tested for HIV at mobile/outreach sites without the availability of CD4 tests, registration and ART. A total of 66.5% of study subjects testing for HIV with an immediate CD4 test and 72% of those testing at a site without CD4 test were linked into care within the first six months. However, this difference was not statistically significant.

3.4 Factors associated with time to linkage

Multivariate Proportion Hazard model showed that participants who tested in facilities had a 78% higher rate of earlier linkage compare to those tested in mobile/outreach sites (UHR=1.78, 95% CI=1.53 – 2.07), but after controlling for effects of other variables, this rate decreased to 73% (AHR=1.73, 95% CI=1.49 – 2.003), Similarly, disclosure of HIV status was found to be a significant factor associated with time to linkage; participants who disclosed their HIV status had a 35% earlier rate of linkage to care compared to participants who did not disclose their HIV status (AHR=0.35; 95% CI:0.28- 0.44) (Table 2). Finally, participants whose reported main reason for testing was wanting to receive treatment had 25% earlier linkage (AHR=1.25; 95% CI: 1.07- 1.45)

Table2: Factors associated with time to linkage at bivariate and Multivariate Cox regression

**Significant at p-value <0.05

Variable	Crude HR	95% CI	Adjusted HR	95% CI
Gender				
Male	Ref		Ref	
Female	0.98	0.84-1.14	0.97	0.84-1.12
Age				
18-30	Ref		Ref	
30-45	0.99	0.83-1.17	0.95	0.81-1.11
45-60	1.12	0.87-1.44	1.18	0.95-1.47
>60	1.11	0.66-1.88	1.06	0.65-1.73
Marital status				
Single	Ref		Ref	
Married	1.06	0.83-1.35	1.24	0.99-1.56
Separated	0.87	0.64-1.19	1.14	0.85-1.53
Divorced	1.19	0.78-1.83	1.27	0.84-1.91
Widower	1.15	0.82-1.61	1.37	1.02-1.83
Time to reach clinic				
<1 hour	Ref		Ref	
1-2 hours	1.03	0.86-1.23	1.06	0.89-1.25
2-5 hours	1.17	0.88-1.55	0.97	0.74-1.28
>5 hours	1.09	0.54-2.22	0.75	0.37-1.52
Testing site				
Mobile based	Ref		Ref	
Facility based	1.78	1.53-2.07**	1.73	1.49-2.003**
Health improved because of ARV				
Yes	Ref		Ref	
No	0.99	0.80-1.22	0.69	0.58-0.82**
Any friend/Family taking ARVs				
Yes	Ref		Ref	
No	0.98	0.83-1.18	0.74	0.63-0.86**
I want to receive treatment				
Yes				
No	Ref		Ref	
	1.28	1.07-1.46**	1.25	1.07-1.45**
Tell anyone about HIV Status				
Yes	Ref		Ref	
No	0.38	0.29-0.49**	0.35	0.28-0.44**

3. DISCUSSION

This study compared successful linkage and time to linkage to HIV care through two HIV testing service delivery models in rural settings of the Mbeya region in Tanzania. The findings in this study showed that 78% (n=793) of individuals of the overall cohort had registered at care and treatment centres within the first six months after diagnosis, representing a dramatic improvement in linkage to care after HIV diagnosis compared to the recent past in Tanzania.[9], [10], [22] A number of studies on HIV testing and linkage to care in other Sub Saharan African countries reported linkage rates of more than 60%, similarly encouraging findings. [15], [19], [25]–[28]

Linkage to care in the group of people tested through the facility-based model was significantly better compared to the group tested through the mobile/outreach services – more people were linked to care, and they linked sooner. This aligns with earlier studies in Kenya, South Africa and systematic review and meta-analysis of community and facility based HIV testing.[15], [19], [28] Likewise, a meta-analysis conducted in the United States on entry into medical care after HIV positive diagnosis reported high entry by people testing at clinics and hospitals compared to other community testing settings. [29] While the dramatic improvement in linkage across the overall cohort is an encouraging finding, the continued gap in linkage to care between mobile and facility-based testing is important to address.

The study indicates that the majority of participants who reported wanting to receive treatment as one of the reason for testing HIV, tested at facility based sites, suggesting that they already intended to seek care for their symptoms and that individuals testing at facilities were more willing to link immediately into care because they needed treatment.[16] This could also be associated with intention of clients to seek care where integrated HIV testing, care and

treatment services within the same facility/site. Furthermore the disclosure of HIV sero-status to partners and/or family members was associated with earlier linkage to care compared to those who did not disclose to anyone, again corresponding with similar studies in HIV testing and disclosure of status to significant others[30]–[32] and highlighting the continued importance of facilitating disclosure and social support.

More than 50% of individuals who tested at facilities were able to link on the same day as the day of HIV testing, while only12% of those testing through the mobile/outreach model were able to link on the same day. This could be associated with integration of HIV testing and HIV services within the same facility/site. Some studies have indicated that having HIV testing services and HIV care on the same spot improves rates of linkage to care and ART coverage. [16], [33] Further analysis of our qualitative and quantitative data will help elucidate these findings. Nevertheless, studies on HIV testing indicate that outreach testing services increase access in remote areas, but linkage to care remains a problem.[20], [34]

Some studies report that CD4 testing at the point of care reduces time for linkage , eligibility assessment and ART initiation.[35], [36] While the participants in our study who tested at the research -Mobile and Diagnostic Training Centre received a CD4 count at the point of testing, 33.5% of them never registered into HIV care, suggesting that on the spot CD4 testing is not sufficient to lead to a decision to link immediately into care and that other factors have to be taken into consideration.

The strength of this study is that we had a large sample size of newly HIV positive diagnosed individuals in the cohort, enrolled from 16 different sites who were followed up for six months

from the time of diagnosis . The study has some limitations: we are able to assess linkage of those who linked in the 16 selected study sites, however it is likely that some of the people we counted as "lost to follow up" may have accessed HIV care elsewhere, since some of the study sites were trade routes with extensive cross border migration. It is possible that some participants moved elsewhere during the study and this warrants further investigation. Participant tracking was aimed to assist the study team to remind participants for follow up interviews, however this process in itself may have been one of the factors that facilitated or enhanced linkage to care among the study participants.

4. CONCLUSION

Linkage to care is the bridge between HIV testing and treatment/care services for HIV positive individuals. This study shows that significantly more newly diagnosed HIV positive individuals linked to care from health facility-based HIV-testing sites compared to mobile/outreach sites, and they were linked into care significantly sooner, particularly at sites where same day registration for care and treatment was possible in rural areas of Mbeya region, Southern Tanzania. Furthermore, this study showed a dramatic improvement in linkage into care after testing HIV positive, compared to studies conducted in 2009, 2012, and 2014 in Tanzania. Individuals who reported wanting to receive treatment as a reason for testing HIV were more likely to be linked into care, compared to other reasons for HIV testing. Individuals who had disclosed their HIV status to their partner and/or family members were more likely to link into care earlier than those who did not disclose to anyone. Findings from this study suggest that although mobile/outreach service delivery models brings HIV testing services closer to people in remote and resource restrained areas, there is still a significant gap in immediate linkage to HIV care compared to sites within established health facilities. Thus, more effective strategies are needed to further improve linkage in this model of service delivery, including increased attention to effectively communicating the importance of linkage to care even for people who do not feel sick. Alternatively, the availability of care and treatment at facility-based testing sites should be significantly increased from the current low levels of less than 21.7% of public facility-based testing sites offering treatment and care.

5. ACKNOWLEDGEMENTS

We thank our dedicated research assistants: Jane Merete, Philmin John, Nestory Sidinda, Aloyce Kabuche, Elesia Kaduma, Obeth Emmanuel, Mariam Paul, Benson Msomba and the study participants.

We thank the project coordinators for the MMRC Mobile Diagnostic and Training Centre (MDTC) and all health care providers working at the study sites and the Home based cares (HBCs) for their hard work, and HJF- Global Health International for funding the MDTC.

We thank the Regional Medical Officer (RMO), the District Medical officers (DMOs), the District AIDS Control Coordinators (DACC) and the facility /site in-charges/managers for their continued cooperation and support.

We thank the MMRC management and data entry team and all other MMRC support staff.

We thank the University of Western Cape (UWC) team

We thank you the Mbeya Medical Research Centre (MMRC) and the African Doctoral Dissertation Research Fellowship (ADDRF) award 2014, offered by the African Population and Health Research Centre (APHRC) in partnership with the International Development Research Centre (IDRC) for financing and supporting the study.

Author contributions: E.S. collected and assembled the data, E.S., P.C., L.M., A.M. drafted the article. C.Z., L.W., study supervisors and critically revised the article. W.O analysed and interpreted the data,

Conflicts of interest: None.

Data sharing statement: Data collected from this study will be shared with BMJ open and other interested scientist.

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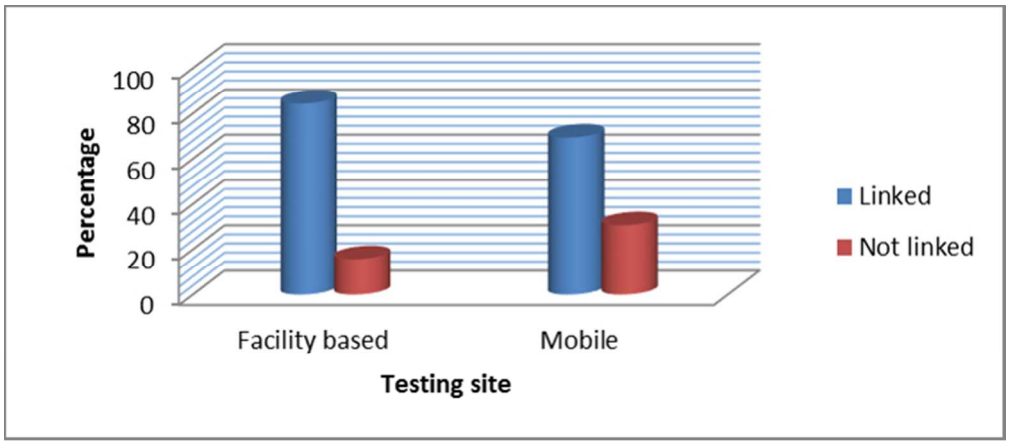

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Linkage status after six month
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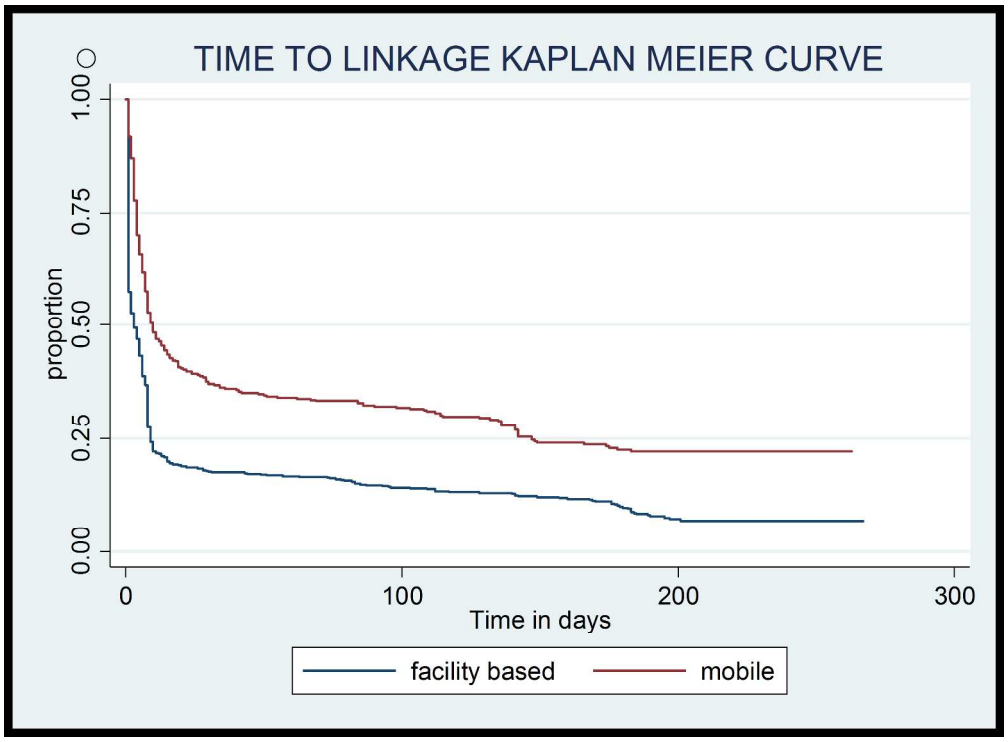

"Fig 2" Survival analysis-tif
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STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of *cohort studies*

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1,2
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	3-4
Objectives	3	State specific objectives, including any prespecified hypotheses	4-5
Methods			
Study design	4	Present key elements of study design early in the paper	6
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	6-7
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	7-
		(*b*) For matched studies, give matching criteria and number of exposed and unexposed	607/405
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	7
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	*8*
Bias	9	Describe any efforts to address potential sources of bias	9
Study size	10	Explain how the study size was arrived at	7
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	8
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	8
		(*b*) Describe any methods used to examine subgroups and interactions	8
		(*c*) Explain how missing data were addressed	8
		(*d*) If applicable, explain how loss to follow-up was addressed	
		(*e*) Describe any sensitivity analyses	
Results			

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

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

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

BMJ Open

Comparison of linkage into care among newly diagnosed HIV positive individuals tested through outreach versus facility-based HIV testing models in Mbeya, Tanzania: a prospective mixed-method cohort study.

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2016-013733.R1
Article Type:	Research
Date Submitted by the Author:	17-Nov-2016
Complete List of Authors:	Sanga, Erica; Mbeya Medical Research Centre; School of Public Health-University of Western Cape Wondwossen, Lerebo ; University of Western Cape, School of public health; School of Public Health, Mekelle University Mushi, Adiel; National Institute for Medical Research (NIMR) Clowes, Petra; 1. NIMR-Mbeya Medical Research Centre (MMRC); Division of Infectious Diseases and Tropical Medicine, Medical Centre of the University of Munich (LMU), Germany Olomi, Willyhelmina; Mbeya Medical Research Centre, Data Management Maboko, Leonard; Mbeya Medical Research Centre, HIV Research Zarowsky, Christina; University of Western Cape, School of public health; 5. University of Montreal Hospital Research Centre and School of Public Health, Université de Montréal
Primary Subject Heading:	HIV/AIDS
Secondary Subject Heading:	Health services research
Keywords:	HIV, Linkage to care, Facility-based HIV testing, Mobile and outreach HIV testing, Mbeya-Tanzania

Comparison of linkage into care among newly diagnosed HIV positive individuals tested through outreach versus facility-based HIV testing models in Mbeya, Tanzania: a prospective mixed-method cohort study.

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ABSTRACT

Objective: Linkage to care is the bridge between HIV testing and HIV treatment, care and support. In Tanzania, mobile testing aims to address historically low testing rates. Linkage to care was reported at 14% in 2009 and 28% in 2014. The study compares linkage to care of HIV positive individuals tested at mobile/outreach versus public health facility-based services within the first six months of HIV diagnosis.

Setting: Rural communities in four districts of Mbeya region, Tanzania.

Participants: A total of 1,012 newly diagnosed HIV positive adults from 16 testing facilities were enrolled into a two-armed cohort and followed for six months between August 2014 and July 2015. 840 (83%) participants completed the study.

Main outcome measures: We compared the ratios and time variance in linkage to care using the Kaplan Meier estimator and Log rank tests. Cox proportional hazards regression models to evaluate factors associated with time variance in linkage.

Results: At the end of six months, 84% (CI= 81% -87%, n= 512) of individuals tested at facility-based were linked to care compared to 69% (CI= 65% -74%, n=281) of individuals tested at mobile/outreach. The median time to linkage was 1 day (IQR: 1-7.5) for facility-based and 6 days (IQR: 3-11) for mobile/outreach sites. Participants tested at facility-based site were 78% more likely to link than those tested at mobile/outreach when other variables were controlled (AHR=1.78; 95%CI: 1.52-2.07). HIV status disclosure to family/relatives was significantly associated with linkage to care (AHR=2.64; 95%CI: 2.05-3.39).

Conclusions: Newly diagnosed individuals tested at facility-based linked sooner and in higher proportion than mobile/outreach tested group. Although mobile/outreach testing models bring HIV testing services closer to people, there is need to address associated gaps in linkage to

HIV care in resource-constrained settings and novel strategies to improve linkage from mobile/outreach models need to be explored.

Strengths and limitations of this study

Strengths

- Prospective adequately-powered cohort study
- Participants from 16 sites
- Participants followed up for six months, with good retention (83%).

Limitations

- Some participants may have moved elsewhere during the study and may have accessed care elsewhere; this warrants further investigation.
- Retention was higher in facility-testing arm (87%) than in mobile-testing arm (76%)
- Participant tracking might have enhanced linkage to care.
- Despite a random selection process, all of the facility-based testing sites in our sample had care and treatment centres on site.

Key words

HIV, Linkage to care, Facility-based HIV testing, Mobile and outreach HIV testing, Mbeya, Tanzania.

1. INTRODUCTION

HIV remains a major burden in Sub-Saharan Africa (SSA), with 790,000 deaths associated with HIV in 2014. [1] Despite the high prevalence and the increasing numbers of people living with HIV in need of highly active anti-retroviral therapy (HAART), timely linkage to care is generally poor across SSA. [2], [3] The Mbeya region is among three regions in Tanzania with the highest HIV prevalence, with an average of 9% compared to the national average of 5.1%, [6] and AIDS-related deaths are among the three leading causes of death in the area. [4], [5]

Linkage to care is the bridge between HIV testing and HIV treatment, care and support. Timely HIV diagnosis and effective linkage into care and treatment are keys to improved outcomes. [6], [7] All individuals diagnosed HIV positive must be linked to HIV care and treatment, even if local treatment guidelines do not indicate that a person should be started on anti-retroviral therapy immediately. [8] CD4 cell count, HIV staging, and evaluation of the client's need for ART initiation need to be done immediately. The Ministry of Health and Social Welfare in Tanzania guideline for initiation of ART is a CD4 count ≤ 500 cells [9]; however, during the period of this study, the actual cut-off point for ART initiation was a CD4 count of 350. The importance of linkage to care during HIV counselling and testing has been well-advocated in Tanzania; however, available literature indicates that linkage to care after testing HIV positive is still low, with only 14% linkage at 4 months reported in a 2009 study, and only 23% in Ifakara and 28% in Mbeya region in 2014. [10]–[12] Low or delayed linkage to care leads to failure of HIV positive individuals to benefit from HIV care. Hence, efforts are hampered to improve coverage for HIV care and treatment services as well as resulting in increased risk of HIV transmission to others. [13], [14] Linkage to care remains at sub-optimal levels in the country due to barriers such as lack of understanding of the importance of care regardless of

disease stage, distance from the clinic and transport costs. [10], [15], [16] Fear of stigma related to HIV, failure to disclose HIV status, being asymptomatic at the time of diagnosis and negative attitudes of health care providers are other factors reported to interfere with linkage to HIV care. [17]–[19]

Mobile and outreach testing sites have been introduced in Tanzania, reflecting an increasing interest in providing early detection of HIV and subsequent care and support in the hard to reach populations in remote areas. [16], [20] Most government health facilities in Mbeya region, the site of this study, offer provider-initiated testing and counselling (PITC) and voluntary counselling services, but only about 21% also offer HIV care and treatment services. On the other hand mobile and outreach services, operated mostly by non-governmental organizations (NGOs), usually offer only voluntary counselling and testing (VCT). These sites do not offer HIV care services, with the exception of the research mobile laboratory operating under the Mbeya Medical Research Centre (MMRC) that offers CD4 testing on site. Clients who test HIV-positive must then go to facility-based sites for registration and other procedures for HIV care and treatment.[5], [13]

There has been little research on overall linkage to care in Tanzania, and none to our knowledge on whether linkage to care differs between clients diagnosed at mobile/outreach sites compared to health facilities, nor on factors facilitating or inhibiting successful linkage to care between these two models of service delivery. [21], [22] These differences may occur at patient level, at service provider level, at the facility level or the health system as a whole. For example, factors enhancing access to testing, such as dedicated outreach staff, may enhance linkage to care for those testing in mobile/outreach facilities, while other factors such as geographic distance between patients' homes and testing sites and treatment sites, weak referral systems and lack of structural links between testing and treatment sites may lead to disconnects between testing and care. [10], [16], [23]

One South African study found that individuals testing at mobile services were 33% less likely to undergo CD4 testing than individuals testing at static clinic services, and only 10% of mobile testers were successfully linked into care versus 72% of clinic testers; [21] however, in South Africa nearly all health facilities now offer treatment, care and support. Hence, findings about differences between mobile and facility-based testing and subsequent linkage to care may not be directly transferable to Tanzania, where testing and care are not always available as a 'one stop shop'. Active referral or self-referrals are therefore more common in Tanzanian situations.

Mbeya region has a total of 312 health facilities where clients can receive testing and counselling (HTC) services through recommended approaches; however, only 68 facilities (21.7%) offer HIV care and treatment service. [12] At least two outreach partners or non-governmental organizations offer HIV counselling and testing in each district of the Mbeya Region. The Mbeya Medical Research Centre MMRC mobile laboratory, also known as the Mobile Diagnostic and Training Centre (MDTC) has been offering CD4 count tests at point of care [4] since 2009, covering between 8 to 12 sites every three months. Available statistics from the Mbeya regional AIDS control program (MRACP) [5] suggest that more people undergo HIV testing at mobile/outreach HIV testing services (56%) compared to facility based services (44%); however, only about 28% of all people tested were linked into HIV care. [22] An earlier study conducted in Mwanza reported that despite increased testing opportunities only 14% of newly diagnosed patients had linked into care 4 months after HIV diagnosis. [10] Another study on linkage to care conducted in Ifakara showed a linkage of about 23%, indicating that linkage to care is a challenge in Tanzania. [11]

This article reports new findings on linkage to care and compares the outcomes of linkage and time to linkage into care for individuals tested HIV positive at mobile/outreach sites, versus individuals tested HIV positive at facility-based services over the first six months after

diagnosis in rural parts of the Mbeya region. The findings from this paper are expected to inform policy makers and other stakeholders in the Tanzanian health care system on the optimization of HIV testing and immediate linkage to care, an issue of critical importance for timely initiation of antiretroviral therapy.

2. STUDY DESIGN AND METHODS

This was a prospective mixed-method cohort study of 1,012 adults who tested HIV positive recruited into a two-armed cohort (health facility-based vs. mobile/outreach HIV testing sites). The study participants were followed for six months to gather quantitative and qualitative information on linkage to care since diagnosis.

Study Setting

The study population comprises rural communities in four of the then eight districts of the Mbeya Region in 2014. In 2012, the Mbeya region had a population of 2,707,410 with 52% women and 48% men (National Bureau of Statistics, 2013). The four study districts were selected to include high HIV prevalence areas and hard-to-reach populations. Two districts (Kyela and Mbozi) are along the highways and have borders to Zambia and/or Malawi. The population in Kyela district was 221,495 in 2012, while Mbozi had 446,339 residents. High population mobility associated with cross-border business and social interactions is thought to pose challenges to linkage to and continuity of care in these districts. The other two districts (Mbeya Rural and Chunya) have a larger proportion of residents who live 10 km or more from a health facility. The population in these remote districts was 305,319 and 290,478

respectively. [24] The HIV prevalence among the people tested for HIV in 2014 in the selected district were Mbeya Rural -13.0%, Chunya- 9.2%, Kyela- 9.2%, and Mbozi - 8.7%.

All public, mission health facility-based and outreach/mobile sites in the selected districts were listed, -a total of 27 health facility and 4 mobile/outreach sites were listed in Mbeya rural, 20 health facility-based and 4 mobile/outreach sites in Chunya district, 14 facility-based and 5 mobile/outreach sites in Kyela district and 29 health facility-based and 5 mobile/outreach sites in Mbozi district. Four sites in each district (2 facility-based and 2 mobile/outreach) were randomly selected from the list in each district using table of random numbers. The eight facility-based sites selected had a care and treatment centre (CTC) within the facility. Sites had different arrangements for the first step of linkage to care, registration: in some facilities, registration was possible on the same day as testing, while other facilities had chosen a single day or two per week for newly diagnosed clients to register into HIV care. None of the mobile/outreach sites offered CTC services; they had to refer their clients to the closest CTC for further management (HIV staging, laboratory test, ART initiation etc.). The mobile site from MMRC was offering CD4 tests at the point of care, but still had to refer newly diagnosed clients to nearby HIV care clinic or CTC, already with the CD4 results for registration and continuation of care

Sampling

The sampling strategy for testing sites is described above. The sampling framework for the cohort comprised all adults above 18 years receiving HIV testing at facility based and mobile/outreach sites in the four study districts of Mbeya region. The sample size was calculated using Epi Info software with confidence interval of 95% and power of 90%, assuming that the two study groups would have the same number of subjects. Thirty per cent of individuals tested through mobile /outreach services and 41% of individuals tested at facility-

based services were expected to link into HIV care. The estimated sample size was 828; we adjusted this sample size to account for possible dropouts and non-responders (10%) resulting in a total estimated sample size of 900 participants.

Data collection procedures

Prior to data collection at clinic, the research team briefed the nurse counselors at study sites on the study objectives and procedures. In turn, these nurse counselors introduced the research team to clients. Interested individuals were invited in a private room for detailed explanation, informed consent process, and agreement on a convenient time and place for questionnaire administration. Initial data were collected between August and December 2014. Follow up questionnaire administration continued until June 2015. Eight out of 1,020 individuals who were approached for participating during data collection were not enrolled in the study because two of them were seriously sick and needed hospital admission, three were planning to move out of Mbeya to their home villages after receiving the results and the other three did not come back for enrollment and interviews within seven days of testing and we were unable to track them. Research assistants who underwent two days of training on informed consent and data collection procedures did data collection.

Outcome measures

The key outcome was the proportion of participants successfully linked to HIV Care and Treatment Centre across the sample and in each arm of the cohort. In this study, "facility-based sites" refers to fixed or static facilities such as hospitals, health centres and dispensaries while

"mobile/outreach sites" means all outreach HIV testing services, including campaigns, mobile testing clinics, home visits or special event testing services.

The operational definition for linkage to care in this study is that a newly diagnosed individual has reported to care and treatment centre, completed registration process as the first step of linkage to care and has been provided with a Care and Treatment Centre (CTC) registration number and clinic card. This definition of linkage to care is based on Rosen and Fox [25] and the National AIDS Control Program in Tanzania[20]; it was chosen to allow comparison with earlier studies of linkage to care.

This paper reports on preliminary outcomes for which a structured questionnaire was administered to respondents at enrolment, at 3 months and at 6 months to ascertain time to linkage into HIV care and to explore factors related to linkage to care. Information collected at enrolment included demographic data, date of HIV testing, reasons for testing, plans for linkage into care and plans for disclosure of HIV status to any family member, other relative or friend. All baseline information was self-reported by participants. In follow up interviews at three and six months, we asked about registration/linkage into care, CD4 count testing, ART status and results disclosure status. At these follow-up interviews we also we also reviewed the participants' clinic card to verify the reported dates of linkage, ART initiation and CD4 count results.

Data Analysis

Quantitative data from sites were recorded, cleaned and analysed using Stata Version 13 (College Station Texas. USA). Descriptive analysis methods were used to present the characteristics of participants. Categorical data were presented using frequencies and

percentage, while quantitative data were presented using the measure of central tendency and measure of dispersion. Cross-tabulation was used to show the distribution of study subject by testing site. We compared the ratios and time variance in linkage to care using the Kaplan Meier estimator and Log rank tests. Cox proportional hazards regression models were used to evaluate the factors associated with time variance in linkage to care. Statistical significance was declared at p-values less than 0.05 for the entire analysis.

Ethical considerations

The study was approved by the University of Western Cape (UWC) Senate Research Committee, the Mbeya Medical Research Centre, the Mbeya Medical Research Ethics Committee (MMREC) and the National Health Research Ethics Sub-Committee (NatHREC) under Tanzanian National Institute of Medical Research (NIMR). Participation was voluntary and it was explained to participants that they were free to withdraw from the study at any time without negative consequences. Volunteers were provided with an information sheet containing all details about the study. They signed an informed consent and confidentiality procedures were observed.

3. RESULTS

3.1. Participant characteristics and comparison between facility based and mobile-based testing models

The cohort of 1,012 HIV positive individuals included 58.5% female participants (56% facility; 61% mobile), with a mean age of 35.8 years (SD 10.5) for facility based and 35.3 years (SD 10.0) for mobile/outreach participants. By the end of six months follow up overall 83% of participants were still active in the study, 87% in the facility-based arm and 76% in the mobile/outreach arm ($p<0.0001$). In both testing models, about 60% of participants were married and more than 80% of participants were self-employed with small-scale farming or petty businesses. A detailed listing of the patient characteristics is presented in Table 1. Age, gender, level of education and occupation were not statistically different between the two testing models, while statistical differences in marital status, means of transport, time to reach clinic, income and time to linkage were observed.

3.2. Linkage to care at six months

At six months, 78% of enrolled participants were linked into care across both arms. Eighty-four percent (95%CI: 0.81-0.87) of participants tested at the facility-based sites were linked into care within the first six months of HIV diagnosis, compared to 69% (95%CI: 0.65-0.74) from the mobile/outreach tested group "Fig 1". The interval from the day of HIV testing to the day of registration at a CTC was compared between participants who tested at a health facility and those tested through a mobile/outreach model. The median time to linkage was 1 day (IQR 1-7.5 days) for those who tested at a health facility and 6 days (IQR 3-11 days) for those who tested through any mobile/outreach model.

3.3. CD4 cell counts facility-based sites and Mobile sites

Of the 793 clients linked into care, 512 (64.5%) tested in facility-based sites and 281 (35.4%) tested in mobile/outreach sites. Most of the clients (n=774, 97.6%) had a recorded CD4 count. The median CD4 count among participants who tested in facility-based sites was 220 (IQR: 114-382), whilst among those tested in mobile/outreach sites the median CD4 count of 255 (IQR: 174-394). Student t-test showed no statistical difference in CD4 count at the point of linkage to care between the two testing models (p=0.49).

Table1: Background characteristics of study subjects by site

Variable	Facility based	Mobile	N	p-value
Gender				
Male	265(43.66)	157(38.77)	422(41.70)	0.122
Female	342(56.34)	248(61.23)	590(58.30)	
Age ,mean (SD)	35.8(10.5)	35.3(10)		0.9
Marital status				
Single	78(12.85)	48(11.85)	126(12.45)	
Married	361(59.47)	252(62.22)	613(60.57)	
Separated	82(13.51)	37(9.14)	119(11.76)	0.002
Divorced	13(2.14)	26(6.42)	39(3.85)	
Widower	73(12.03)	42(10.37)	115(11.36)	
Level of education				
None	104(17.13)	81(20.00)	185(18.28)	
Primary	470(77.43)	299(73.83)	769(75.99)	0.4
Secondary	29(4.78)	24(5.93)	53(5.24)	
Vocational	4(0.66)	1(0.25)	5(0.49)	
Main occupation				
Unemployed	28(4.61)	15(3.70)	43(4.25)	
Student	18(2.97)	3(0.74)	21(2.08)	0.23
Driver	9(1.48)	5(1.23)	14(1.38)	
Employed	18(2.97)	11(2.72)	29(2.87)	
Self employed	530(87.31)	369(91.11)	899(88.83)	
Other	4(0.66)	2(0.49)	6(0.59)	
Means of transport				
Walking	163(26.85)	200(49.38)	363(35.87)	
Bicycle	93(15.32)	77(19.01)	170(16.80)	P<0.0001
Motor cycle	143(23.56)	71(17.53)	214(21.15)	
Public Transport	201(33.11)	55(13.58)	256(25.30)	
Private car	7(1.15)	2(0.49)	9(0.89)	
Time to reach clinic				
<1 hour	397(65.40)	295(72.84)	692(68.38)	
1-2 hours	157(25.86)	76(18.77)	233(23.02)	0.004
2-5 hours	50(8.24)	26(6.42)	76(7.51)	
>5 hours	3(0.49)	8(1.98)	11(1.09)	
Time to linkage, Median(IQR)	1(1-7.5)	6(3-11)		P<0.0001
Income(Tsh)				
<100,000	497(81.88)	320(79.01)	817(80.73)	
100,000-500,000	39(6.43)	56(13.83)	95(9.39)	
500,000-1,000,000	3(0.49)	2(0.49)	5(0.49)	0.0006
>,1000,000	0(0.00)	1(0.25)	1(0.1)	
NA	52(8.57)	21(5.19)	73(7.21)	
Refused to answer	16(2.64)	5(1.23)	21(2.08)	

Figure 1: Linkage status

Separately attached

3.4. Time to linkage facility-based and Mobile sites

The time to linkage (registration) was significantly shorter in the facility tested group, compared to the mobile/outreach tested group (p <0.001), "Fig 2". Log rank test showed that there was a significant difference between the two groups (p <0.001).

Figure 2: Survival analysis (KPM)

Separately attached

3.5. Linkage from mobile sites with point of care CD4 test versus no CD4 test

Of 405 participants testing at mobile/outreach sites, 182 (44.94%) individuals had tested for HIV at the MMRC mobile site, where CD4 testing was offered at the point of testing, but no registration or ART was provided. 223 (55.06%) individuals tested for HIV at mobile/outreach sites without the availability of CD4 tests, registration and ART. A total of 66.5% of study subjects testing for HIV with an immediate CD4 test and 72% of those testing at a site without CD4 test were linked into care within the first six months; however, this difference was not statistically significant.

3.6. Factors associated with time to linkage

Bivariate Cox regression showed that there were several factors associated with hazard of time to linkage, and multivariate Cox regression analysis revealed that a person tested at facility-based increase the risk of linkage by 78%(AHR=1.78; 95%CI: 1.52-2.07) compared to persons tested at mobile centre when other variables were controlled. Disclosure of HIV status to partners, family, relative or friend was found to be significant factor associated with two and a half times increased risk of linkage to care (AHR=2.64; 95%CI: 2.05-3.39), and participants whose main reason for testing was to receive treatment were 25% more likely to link to care (AHR=1.25; 95%CI: 1.06-1.46)

Table2: Factors associated with time to linkage at bivariate and Multivariate Cox regression

**Significant at p-value <0.05

Variable	Crude HR	95% CI	Adjusted HR	95% CI
Gender				
Male	Ref		Ref	
Female	0.97	0.84-1.12	0.98	0.84-1.14
Age				
18-30	Ref		Ref	
30-45	0.95	0.81-1.11	0.98	0.83-1.17
45-60	1.18	0.95-1.47	1.12	0.87-1.44
>60	1.06	0.65-1.73	1.11	0.66-1.88
Marital status				
Single	Ref		Ref	
Married	1.24	0.98-1.56	1.06	0.83-1.35
Separated	1.14	0.85-1.53	0.87	0.64-1.18
Divorced	1.27	0.84-1.91	1.19	0.78-1.83
Widower	1.37	1.02-1.83	1.15	0.82-1.61
Time to reach clinic				
<1 hour	Ref		Ref	
1-2 hours	1.06	0.89-1.25	1.03	0.86-1.22
2-5 hours	0.97	0.74-1.28	1.17	0.88-1.55
>5 hours	0.75	0.37-1.52	1.09	0.54-2.22
Testing site				
Mobile based	Ref		Ref	
Facility based	1.73	1.49-2.003**	1.78	1.53-2.07**
Health improved because of ARV				
No	Ref		Ref	
Yes	1.46	1.22-1.74**	1.01	0.82-1.24
Any friend/Family taking ARVs				
No	Ref		Ref	
Yes	1.35	1.16-1.58**	1.01	0.85-1.203
I want to receive treatment				
No	Ref	1.07-1.45**	Ref	1.06-1.45**
Yes	1.25		1.25	
Disclosure of HIV Status				
No				
Yes	Ref		Ref	
	2.82	0.25-3.54**	2.64	2.05-3.39**

4. DISCUSSION

This study prospectively measured linkage to care in remote and hard-to-reach areas and populations, and compared successful linkage and time to linkage into HIV care between two HIV testing service delivery models in rural settings of the Mbeya region in Tanzania.

The study was designed and implemented against the background of historically low rates of linkage to care, recent widespread implementation of mobile testing to address low population rates of HIV testing, and evidence from other settings of significantly poorer linkage to care after HIV diagnosis at the mobile/outreach-based testing sites compared to facility-based testing sites.

Our study found that 78% (n=793) of individuals of the overall cohort had registered at care and treatment centres within the first six months after diagnosis, representing a dramatic improvement in linkage to care after HIV diagnosis compared to the recent past in Tanzania. [10]–[12]

A number of studies on HIV testing and linkage to care in other SSA countries reported linkage rates of more than 60%, [15], [21], [26]–[29] these encouraging findings likely reflect a combination of health system and social changes, including reduction in stigma. Our study itself may also have increased linkage to care through regularly contacting and following up HIV positive individuals.

Linkage to care in the group of people tested through the facility-based model was significantly higher compared to the group tested through the mobile/outreach services. More people were linked to care, and they linked sooner in the health facility than mobile clinic arm. This aligns

with earlier studies in Kenya, South Africa and systematic review and meta-analysis of community and facility based HIV testing. [15], [21], [29]

Likewise, a meta-analysis conducted in the United States on entry into medical care after HIV positive diagnosis reported high entry by people testing at clinics and hospitals compared to other community testing settings. [30]

While the dramatic improvement in linkage across the overall cohort and the early linkage to the first step of care are encouraging findings, the continued gap in linkage to care between mobile and facility-based testing is important to address. It is possible that some of the respondents lost to follow up in the mobile/outreach arm sought and were linked to care in other sites; however, we believe that significant health system-level barriers must be addressed to ensure timely linkage and, ultimately, retention in care.

Some of the outreach testing activities are done very far from the clinics that offer CD4 testing and HIV care. For example, some clients in Chunya district must travel more than 100 kilometres on a rough road to reach a facility that offers CD4 test services and ART. We suggest expansion of mobile staging and ART services in remote areas. Furthermore, health care providers should ensure that education and emphasis on the importance of being in HIV care, even if the client does not yet require ART according to local guidelines, are emphasized during counselling.

Disclosure of HIV sero-status to partners and/or family members was strongly associated with earlier linkage to care compared to those who did not disclose to partners, and/or family members/relatives, again corresponding with findings elsewhere [31]–[33] and highlighting the continued importance of facilitating disclosure and social support.

We found that the majority of participants who reported, "Wanting to receive treatment in case they are infected with HIV" as one of the reason for testing for HIV, tested at facility based sites. This may suggest that they perceived themselves to be at higher risk, or that they already intended to seek care for their symptoms and that individuals testing at facilities were more willing to link immediately into care because they needed treatment.[17] This would align with studies elsewhere that have reported higher CD4 counts at mobile sites than at facility-based sites; [34] however, while we found slightly higher CD4 counts in the mobile testing arm, this difference was not statistically significant. We therefore think it is important to explore and address health system facilitators and barriers, such as the availability of integrated HIV testing, care and treatment services within the same facility/site.

This interpretation is supported by other findings, a total of 265 individuals, 51.7%, who tested at facility-based sites were able to link on the same day of HIV testing, while only 12% of those testing through the mobile/outreach model were able to link on the same day. This is likely associated with availability of HIV testing and HIV care and treatment services within the same compound at facility sites. Not surprisingly, some studies report that CD4 testing at the point of care reduces time for linkage, eligibility assessment and ART initiation, [35], [36], and having HIV testing services and HIV care (CTC) at the same location improves rates of linkage to care and ART coverage. [17], [37] While Tanzania has made significant progress in increasing testing and linkage to care, our study strongly supports arguments for increasing the proportion of health facilities with care and treatment services from the current low level of 21.7%

Further analysis of our qualitative and quantitative data will help elucidate these findings. Nevertheless, studies on HIV testing indicate that outreach testing services increase access in remote areas, but linkage to care remains a problem.[22], [38] Our study supports these

findings, whilst reporting significant improvements in overall linkage to care since 2009 and 2014.

The strength of this study is that we had a large sample of newly HIV positive diagnosed individuals in the cohort, enrolled from 16 different sites who were followed up for six months from the time of diagnosis. The project team used telephone calls to follow clients on their dates of next visit to clinic. Use of phone calls may have been one of the factors that facilitated or enhanced linkage to care among the study participants.

The study has some limitations: We were not able to see all clients during study period, despite efforts to track them through telephone calls by study team, CTC and community based health care providers in their respective areas. It may be assumed that the clients might have moved to other places due to prevailing trade routes with extensive cross border migration; however, there was a limitation in our study as it was not designed to ascertain such linkage beyond the study sites. This warrants further investigation, an additional limitation of our study is that the random selection of facility-based sites yielded a sample where all facilities had on-site care and treatment centres.

5. CONCLUSION

Linkage to care is the bridge between HIV testing and treatment/care services for HIV positive individuals. In comparison with previous studies conducted in 2009, 2012, and 2014 in Tanzania, this study shows that significantly more newly diagnosed HIV positive individuals had linked to care within a short time of testing. We also found that linkage to care within 6 months of HIV testing was significantly higher from health facility-based HIV-testing sites compared to mobile/outreach sites. These individuals were linked into care significantly sooner, particularly at sites where same-day registration for care and treatment was possible. Individuals who had disclosed their HIV status to their partner and/or family members were more likely to link into care earlier than those who did not disclose to anyone. Findings from this study suggest that although mobile/outreach service delivery models bring HIV testing services closer to people in remote and resource restrained areas, there is still a significant gap in timely linkage to HIV care compared to sites within established health facilities. Thus, more effective strategies are needed to further improve linkage through this model of service delivery, including increased attention to effectively communicating the importance of linkage to care even for people who do not feel sick. In addition, the availability of care and treatment at facility-based testing sites should be significantly increased from the current low levels of less than 21.7% of public facility-based testing sites offering treatment and care.

6. ACKNOWLEDGEMENTS

We are very thankful to all study participants and dedicated research assistants namely Jane Merere, Philmin John, Nestory Sidinda, Aloyce Kabuche, Elesia Kaduma, Obeth Emmanuel, Mariam Paul, Benson Msomba, and data entry team at MRCC for special cooperation that facilitated data collection and processing.

Special thanks to the MMRC Mobile Diagnostic and Training Centre (MDTC) project coordinators for and all health care providers at the study sites and the home-based cares (HBCs) for their hard work, and HJF- Global Health International for funding the MDTC.

We thank the Regional Medical Officer (RMO), the District Medical officers (DMOs), the District AIDS Control Coordinators (DACC) and the facility /site in-charges/managers for their continued cooperation and support.

We thank the management of University of Western Cape (UWC) for approving the study, supervision and financing through the Social Innovation in Public Health Implse (SIPHI) fellowship.

We thank the management of Mbeya Medical Research Centre (MMRC) and the African Doctoral Dissertation Research Fellowship (ADDRF) award 2014, offered by the African Population and Health Research Centre (APHRC) in partnership with the International Development Research Centre (IDRC) for financing and supporting the study.

Author contributions: E.S. collected and assembled the data, E.S., P.C., L.M., A.M. drafted the article. C.Z., L.W., study supervisors and critically revised the article. W.O analysed and interpreted the data.

Conflicts of interest: None.

Data sharing statement: Data from this study will be submitted to the Dryad digital repository to be released under the terms of the creative common zero (CC0) available at BMJ open http://dx.doi.org/10.5061/dryad.4g0vt.

Permission to publish: This manuscript is published with the permission from the National Institute for Medical Research in Tanzania.

Foot note: First line ART in Tanzania is Tenofovir , Lamivudine and Efevirenz [9]

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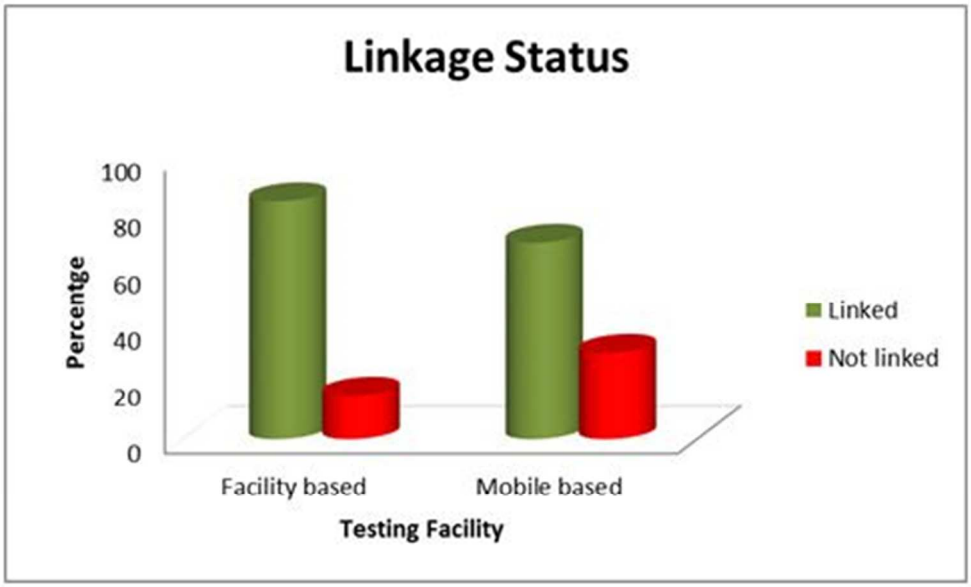
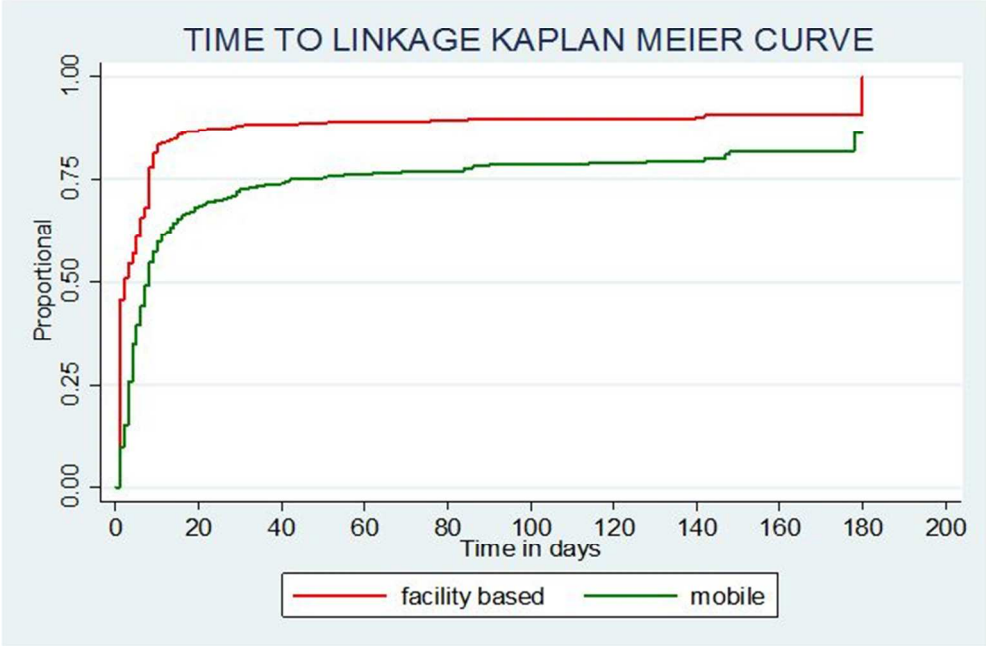
Figure 1: Linkage status



Linkage status at six months

129x88mm (96 x 96 DPI)

Figure 2: Survival analysis (KPM)



Survival Analysis (KPM)

183x132mm (96 x 96 DPI)

STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of *cohort studies*

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1,2
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	3-4
Objectives	3	State specific objectives, including any prespecified hypotheses	4-5
Methods			
Study design	4	Present key elements of study design early in the paper	6
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	6-7
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	7-
		(*b*) For matched studies, give matching criteria and number of exposed and unexposed	607/405
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	7
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	*8*
Bias	9	Describe any efforts to address potential sources of bias	9
Study size	10	Explain how the study size was arrived at	7
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	8
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	8
		(*b*) Describe any methods used to examine subgroups and interactions	8
		(*c*) Explain how missing data were addressed	8
		(*d*) If applicable, explain how loss to follow-up was addressed	
		(*e*) Describe any sensitivity analyses	
Results			

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

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

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

BMJ Open

Linkage into care among newly diagnosed HIV positive individuals tested through outreach and facility-based HIV testing models in Mbeya, Tanzania: a prospective mixed-method cohort study.

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2016-013733.R2
Article Type:	Research
Date Submitted by the Author:	18-Feb-2017
Complete List of Authors:	Sanga, Erica; Mbeya Medical Research Centre; School of Public Health-University of Western Cape Wondwossen, Lerebo ; University of Western Cape, School of public health; School of Public Health, Mekelle University Mushi, Adiel; National Institute for Medical Research (NIMR) Clowes, Petra; 1. NIMR-Mbeya Medical Research Centre (MMRC); Division of Infectious Diseases and Tropical Medicine, Medical Centre of the University of Munich (LMU), Germany Olomi, Willyhelmina; Mbeya Medical Research Centre, Data Management Maboko, Leonard; Mbeya Medical Research Centre, HIV Research Zarowsky, Christina; University of Western Cape, School of public health; 5. University of Montreal Hospital Research Centre and School of Public Health, Université de Montréal
Primary Subject Heading:	HIV/AIDS
Secondary Subject Heading:	Health services research
Keywords:	HIV, Linkage to care, Facility-based HIV testing, Mobile and outreach HIV testing, Mbeya-Tanzania

Linkage into care among newly diagnosed HIV positive individuals tested through outreach and facility-based HIV testing models in Mbeya, Tanzania: a prospective mixed-method cohort study.

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ABSTRACT

Objective: Linkage to care is the bridge between HIV testing and HIV treatment, care and support. In Tanzania, mobile testing aims to address historically low testing rates. Linkage to care was reported at 14% in 2009 and 28% in 2014. The study compares linkage to care of HIV positive individuals tested at mobile/outreach versus public health facility-based services within the first six months of HIV diagnosis.

Setting: Rural communities in four districts of Mbeya region, Tanzania.

Participants: A total of 1,012 newly diagnosed HIV positive adults from 16 testing facilities were enrolled into a two-armed cohort and followed for six months between August 2014 and July 2015. 840 (83%) participants completed the study.

Main outcome measures: We compared the ratios and time variance in linkage to care using the Kaplan Meier estimator and Log rank tests. Cox proportional hazards regression models to evaluate factors associated with time variance in linkage.

Results: At the end of six months, 78% of all respondents had linked into care, with differences across testing models. 84% (CI= 81% -87%, n= 512) of individuals tested at facility-based were linked to care compared to 69% (CI= 65% -74%, n=281) of individuals tested at mobile/outreach. The median time to linkage was 1 day (IQR: 1-7.5) for facility-based and 6 days (IQR: 3-11) for mobile/outreach sites. Participants tested at facility-based site were 78% more likely to link than those tested at mobile/outreach when other variables were controlled (AHR=1.78; 95%CI: 1.52-2.07). HIV status disclosure to family/relatives was significantly associated with linkage to care (AHR=2.64; 95%CI: 2.05-3.39).

Conclusions: Linkage to care after testing HIV positive in rural Tanzania has increased markedly since 2014, across testing models. Individuals tested at facility-based sites linked in

significantly higher proportion and modestly sooner than mobile/outreach tested individuals. Mobile/outreach testing models bring HIV testing services closer to people. Strategies to improve linkage from mobile/outreach models are needed.

Strengths and limitations of this study

Strengths

- Prospective adequately-powered cohort study
- Participants from 16 sites
- Participants followed up for six months, with good retention (83%).

Limitations

- Some participants may have moved elsewhere during the study and may have accessed care elsewhere; this warrants further investigation.
- Retention was higher in facility-testing arm (87%) than in mobile-testing arm (76%)
- Participant tracking might have enhanced linkage to care.
- Despite a random selection process, all of the facility-based testing sites in our sample had care and treatment centres on site.

Key words

HIV, Linkage to care, Facility-based HIV testing, Mobile and outreach HIV testing, Mbeya, Tanzania.

1. INTRODUCTION

HIV remains a major burden in Sub-Saharan Africa (SSA), with 790,000 deaths associated with HIV in 2014. [1] Despite the high prevalence and the increasing numbers of people living with HIV in need of highly active anti-retroviral therapy (HAART), timely linkage to care is generally poor across SSA. [2], [3] The Mbeya region is among the three regions in Tanzania with the highest HIV prevalence, with an average of 9% compared to the national average of 5.1%, [6] and AIDS-related deaths are among the three leading causes of death in the area. [4], [5]

Linkage to care is the bridge between HIV testing and HIV treatment, care and support.[6] Timely HIV diagnosis and effective linkage into care and treatment are keys to improved outcomes. [7], [8] All individuals diagnosed HIV positive must be linked to HIV care and treatment even if local treatment guidelines do not indicate that a person should be started on anti-retroviral therapy immediately. [9] CD4 cell count, HIV staging, and evaluation of the client's need for ART initiation need to be done immediately. The Ministry of Health and Social Welfare in Tanzania guideline for initiation of ART is a CD4 count ≤ 500 cells [10]; however, during the period of this study, the actual cut-off point for ART initiation was a CD4 count of 350. The importance of linkage to care during HIV counselling and testing has been well-advocated in Tanzania; however, available literature indicates that linkage to care after testing HIV positive is still low, with only 14% linkage at 4 months reported in a 2009 study, and only 23% in Ifakara and 28% in Mbeya region in 2014. [11]–[13] Low or delayed linkage to care leads to failure of HIV positive individuals to benefit from HIV care. Hence, efforts are hampered to improve coverage for HIV care and treatment services, thus resulting in increased risk of HIV transmission to others. [14], [15] Linkage to care remains at sub-optimal levels in the country due to barriers such as lack of understanding of the importance of care regardless

of disease stage, distance from the clinic and transport costs. [11], [16], [17] Fear of stigma related to HIV, failure to disclose HIV status, being asymptomatic at the time of diagnosis and negative attitudes of health care providers are other factors reported to interfere with linkage to HIV care. [18]–[20]

Mobile and outreach testing sites have been introduced in Tanzania, reflecting an increasing interest in providing early detection of HIV and subsequent care and support in the hard to reach populations and remote areas. [17], [21] Most government health facilities in Mbeya region (the site of this study) offer provider-initiated testing and counselling (PITC) and voluntary counselling services, but only about 21% also offer HIV care and treatment services.[13] On the other hand mobile and outreach services, operated mostly by non-governmental organizations (NGOs), usually offer only voluntary counselling and testing (VCT) services. [13] These sites do not offer HIV care services, with the exception of the research mobile laboratory operating under the Mbeya Medical Research Centre (MMRC) that offers CD4 testing on site. Clients who test HIV-positive must then go to facility-based sites for registration and other procedures for HIV care and treatment. [5], [13]

There has been little research on overall linkage to care in Tanzania, and none to our knowledge on whether linkage to care differs between clients diagnosed at mobile/outreach sites compared to health facilities, nor on factors facilitating or inhibiting successful linkage to care between these two models of service delivery. [22], [23] These differences may occur at the patient level, at service provider level, at the facility level or at the level of the health system as a whole. For example, factors enhancing access to testing, such as dedicated outreach staff, may enhance linkage to care for those testing in mobile/outreach facilities, while other factors such as geographic distance between patients' homes and testing sites and treatment sites, weak referral systems and lack of structural links between testing and treatment sites may lead to disconnects between testing and care. [11], [17], [24]

One South African study found that individuals testing at mobile services were 33% less likely to undergo CD4 testing than individuals testing at static clinic services, and only 10% of mobile testers were successfully linked into care versus 72% of clinic testers; [22] however, in South Africa nearly all health facilities now offer treatment, care and support. Hence, findings about differences between mobile and facility-based testing and subsequent linkage to care may not be directly transferable to Tanzania, where testing and care are not always available as a 'one stop shop'. Active referral or self-referrals are therefore more common in Tanzanian situations.

Mbeya region has a total of 312 health facilities where clients can receive testing and counselling (HTC) services through recommended approaches; however, only 68 facilities (21.7%) offer HIV care and treatment service. [13] At least two outreach partners or non-governmental organizations offer HIV counselling and testing in each district of the Mbeya Region. The Mbeya Medical Research Centre MMRC mobile laboratory, also known as the Mobile Diagnostic and Training Centre (MDTC) has been offering CD4 count tests at point of care [4] since 2009, covering between 8 to 12 sites every three months. Available statistics from the Mbeya regional AIDS control program (MRACP) [5] suggest that more people undergo HIV testing at mobile/outreach HIV testing services (56%) compared to facility based services (44%); however, only about 28% of all people tested were linked into HIV care. [22] An earlier study conducted in Mwanza reported that despite increased testing opportunities only 14% of newly diagnosed patients had linked into care 4 months after HIV diagnosis. [11] Another study on linkage to care conducted in Ifakara showed a linkage of about 23%, indicating that linkage to care is a challenge in Tanzania. [12]

This article reports new findings on linkage to care and compares the outcomes of linkage and time to linkage into care for individuals tested HIV positive at mobile/outreach sites, versus individuals tested HIV positive at facility-based services over the first six months after

diagnosis in rural parts of the Mbeya region. The findings of this study are expected to inform policy makers and other stakeholders in the Tanzanian health care system on the optimization of HIV testing and immediate linkage to care, an issue of critical importance for timely initiation of antiretroviral therapy.

2. STUDY DESIGN AND METHODS

This was a prospective mixed-method cohort study of 1,012 adults who tested HIV positive recruited into a two-armed cohort (health facility-based vs. mobile/outreach HIV testing sites). The study participants were followed for six months to gather quantitative and qualitative information on linkage to care since diagnosis.

Study Setting

The study population comprises rural communities in four of the then eight districts of the Mbeya Region in 2014. In 2012, the Mbeya region had a population of 2,707,410 with 52% women and 48% men.[25] The four study districts were selected to include high HIV prevalence areas and hard-to-reach populations. Two districts (Kyela and Mbozi) are along the highways and have borders with Zambia and/or Malawi. The population in Kyela district was 221,495 in 2012, while Mbozi had 446,339 residents. High population mobility associated with cross-border business and social interactions is thought to pose challenges to linkage to and continuity of care in these districts. The other two districts (Mbeya Rural and Chunya) have a larger proportion of residents who live 10 km or more from a health facility. The population in these remote districts was 305,319 and 290,478 respectively.[25] The HIV prevalence among

people tested for HIV in 2014 in the selected districts were Mbeya Rural -13.0%, Chunya- 9.2%, Kyela- 9.2%, and Mbozi - 8.7%.

All public and mission health facility-based and outreach/mobile sites in the selected districts were listed. A total of 27 health facility and 4 mobile/outreach sites were listed in Mbeya rural, 20 health facility-based and 4 mobile/outreach sites in Chunya district, 14 facility-based and 5 mobile/outreach sites in Kyela district and 29 health facility-based and 5 mobile/outreach sites in Mbozi district. Four sites in each district (2 facility-based and 2 mobile/outreach) were randomly selected from the list in each district using a table of random numbers. The eight facility-based sites selected had a care and treatment centre (CTC) within the facility. Sites had different arrangements for the first step of linkage to care, registration: in some facilities, registration was possible on the same day as testing, while other facilities had chosen a single day or two per week for newly diagnosed clients to register into HIV care. None of the mobile/outreach sites offered CTC services; they had to refer their clients to the closest CTC for further management (HIV staging, laboratory test, ART initiation etc.). The mobile site from MMRC was offering CD4 tests at the point of care, but still had to refer newly diagnosed clients, already with their CD4 results to nearby HIV care clinic or CTCs for registration and continuation of care.

Sampling

The sampling strategy for testing sites is described above. The sampling framework for the cohort comprised all adults above 18 years receiving HIV testing at facility based and mobile/outreach sites in the four study districts of Mbeya region. The sample size was calculated using Epi Info software with a confidence interval of 95% and power of 90%, assuming that the two study groups would have the same number of subjects. Thirty per cent of individuals tested through mobile /outreach services and 41% of individuals tested at facility-

based services were expected to link into HIV care. The estimated sample size was 828; we adjusted this sample size to account for possible dropouts and non-responders (10%) resulting in a total estimated sample size of 900 participants.

Data collection procedures

Prior to data collection at clinic, the research team briefed the nurse counselors at study sites on the study objectives and procedures. In turn, these nurse counselors introduced the research team to clients. Interested individuals were invited in a private room for detailed explanation, informed consent process, and agreement on a convenient time and place for questionnaire administration. Initial data were collected between August and December 2014. Follow up questionnaire administration continued until June 2015. Eight out of 1,020 individuals who were approached for participating during data collection were not enrolled in the study because two of them were seriously sick and needed hospital admission, three were planning to move out of Mbeya to their home villages after receiving the results and the other three did not come back for enrolment and interviews within seven days of testing and we were unable to track them. Research assistants who underwent two days of training on informed consent and data collection procedures did data collection.

Outcome measures

The key outcome was the proportion of participants successfully linked to HIV Care and Treatment Centre across the sample and in each arm of the cohort. In this study, "facility-based sites" refers to fixed or static facilities such as hospitals, health centres and dispensaries while "mobile/outreach sites" means all outreach HIV testing services, including campaigns, mobile testing clinics, home visits or special event testing services.

The operational definition for linkage to care in this study is that a newly diagnosed individual has reported to a care and treatment centre, completed the registration process and has been provided with a Care and Treatment Centre (CTC) registration number and clinic card. This definition of linkage to care is based on Rosen and Fox [26] and the National AIDS Control Program in Tanzania[21]; it was chosen to allow comparison with earlier studies of linkage to care.

This paper reports on preliminary outcomes for which a structured questionnaire was administered to respondents at enrolment, at 3 months and at 6 months to ascertain time to linkage into HIV care and to explore factors related to linkage to care. Information collected at enrolment included demographic data, date of HIV testing, reasons for testing, plans for linkage into care and plans for disclosure of HIV status to any family member, other relative or friend. All baseline information was self-reported by participants. In follow up interviews at three and six months, we asked about registration/linkage into care, CD4 count testing, ART status and results disclosure status. At these follow-up interviews we also we also reviewed the participants' clinic card to verify the reported dates of linkage, ART initiation and CD4 count results.

Data Analysis

Quantitative data from sites were recorded, cleaned and analysed using Stata Version 13 (College Station Texas. USA). Descriptive analysis methods were used to present the characteristics of participants. Categorical data were presented using frequencies and percentage, while quantitative data were presented using the measure of central tendency and measure of dispersion. Cross-tabulation was used to show the distribution of study subject by

testing site. We compared the ratios and time variance in linkage to care using the Kaplan Meier estimator and Log rank tests. Cox proportional hazards regression models were used to evaluate the factors associated with time variance in linkage to care. Statistical significance was declared at p-values less than 0.05 for the entire analysis.

Ethical considerations

The study was approved by the University of Western Cape (UWC) Senate Research Committee, the Mbeya Medical Research Centre, the Mbeya Medical Research Ethics Committee (MMREC) and the National Health Research Ethics Sub-Committee (NatHREC) under the Tanzanian National Institute of Medical Research (NIMR). Participation was voluntary and it was explained to participants that they were free to withdraw from the study at any time without negative consequences. Volunteers were provided with an information sheet containing all details about the study. They signed an informed consent and confidentiality procedures were observed.

3. RESULTS

3.1. Participant characteristics and comparison between facility based and mobile-based testing models

The cohort of 1,012 HIV positive individuals included 58.5% female participants (56% facility; 61% mobile), with a mean age of 35.8 years (SD 10.5) for facility based and 35.3 years (SD 10.0) for mobile/outreach participants. By the end of six months follow up overall 83% of participants were still active in the study, 87% in the facility-based arm and 76% in the mobile/outreach arm ($p<0.0001$). In both testing models, about 60% of participants were married and more than 80% of participants were self-employed with small-scale farming or petty businesses. A detailed listing of the patient characteristics is presented in Table 1. Age, gender, level of education and occupation were not statistically different between the two testing models, while statistical differences in marital status, means of transport, time to reach clinic, income and time to linkage were observed after Chi square analysis.

3.2. Linkage to care at six months

At six months, 78% of enrolled participants were linked into care across both arms. Eighty-four percent (95%CI: 0.81-0.87) of participants tested at the facility-based sites were linked into care within the first six months of HIV diagnosis, compared to 69% (95%CI: 0.65-0.74) from the mobile/outreach-tested group "Fig 1". The interval from the day of HIV testing to the day of registration at a CTC was compared between participants who tested at a health facility and those tested through a mobile/outreach model. The median time to linkage was 1 day (IQR 1-7.5 days) for those who tested at a health facility and 6 days (IQR 3-11 days) for those who tested through any mobile/outreach model.

3.3. CD4 cell counts facility-based sites and Mobile sites

Of the 793 clients linked into care, 512 (64.5%) tested in facility-based sites and 281 (35.4%) tested in mobile/outreach sites. Most of the clients (n=774, 97.6%) had a recorded CD4 count. The median CD4 count among participants who tested in facility-based sites was 220 (IQR: 114-382), whilst among those tested in mobile/outreach sites the median CD4 count of 255 (IQR: 174-394). Student t-test showed no statistical difference in CD4 count at the point of linkage to care between the two testing models (p=0.49).

Table1: Background characteristics of study subjects by site

Variable	Facility based	Mobile	N	p-value
Gender				
Male	265(43.66)	157(38.77)	422(41.70)	0.122
Female	342(56.34)	248(61.23)	590(58.30)	
Age ,mean (SD)	35.8(10.5)	35.3(10)		0.9
Marital status				
Single	78(12.85)	48(11.85)	126(12.45)	
Married	361(59.47)	252(62.22)	613(60.57)	
Separated	82(13.51)	37(9.14)	119(11.76)	0.002
Divorced	13(2.14)	26(6.42)	39(3.85)	
Widower	73(12.03)	42(10.37)	115(11.36)	
Level of education				
None	104(17.13)	81(20.00)	185(18.28)	
Primary	470(77.43)	299(73.83)	769(75.99)	0.4
Secondary	29(4.78)	24(5.93)	53(5.24)	
Vocational	4(0.66)	1(0.25)	5(0.49)	
Main occupation				
Unemployed	28(4.61)	15(3.70)	43(4.25)	
Student	18(2.97)	3(0.74)	21(2.08)	0.23
Driver	9(1.48)	5(1.23)	14(1.38)	
Employed	18(2.97)	11(2.72)	29(2.87)	
Self employed	530(87.31)	369(91.11)	899(88.83)	
Other	4(0.66)	2(0.49)	6(0.59)	
Means of transport				
Walking	163(26.85)	200(49.38)	363(35.87)	
Bicycle	93(15.32)	77(19.01)	170(16.80)	P<0.0001
Motor cycle	143(23.56)	71(17.53)	214(21.15)	
Public Transport	201(33.11)	55(13.58)	256(25.30)	
Private car	7(1.15)	2(0.49)	9(0.89)	
Time to reach clinic				
<1 hour	397(65.40)	295(72.84)	692(68.38)	
1-2 hours	157(25.86)	76(18.77)	233(23.02)	0.004
2-5 hours	50(8.24)	26(6.42)	76(7.51)	
>5 hours	3(0.49)	8(1.98)	11(1.09)	
Time to linkage, Median(IQR)	1(1-7.5)	6(3-11)		P<0.0001
Income(Tsh)				
<100,000	497(81.88)	320(79.01)	817(80.73)	
100,000-500,000	39(6.43)	56(13.83)	95(9.39)	
500,000-1,000,000	3(0.49)	2(0.49)	5(0.49)	0.0006
>,1000,000	0(0.00)	1(0.25)	1(0.1)	
NA	52(8.57)	21(5.19)	73(7.21)	
Refused to answer	16(2.64)	5(1.23)	21(2.08)	

Figure 1: Linkage status

Separately attached

3.4. Time to linkage facility-based and Mobile sites

The time to linkage (registration) was significantly shorter in the facility tested group, compared to the mobile/outreach tested group (p <0.001), "Fig 2". Log rank test showed that there was a significant difference between the two groups (p <0.001)**.** Sensitivity analysis was carried out on the 840 participants who were successfully followed for six months. Cox regression analysis revealed that a person tested at a facility-based site increased the "risk" of linkage by 61% (AHR=1.61; 95%CI: 1.39-1.85) compared to persons tested at mobile sites. Log rank test found a significant difference between the two groups (p <0.001).

Figure 2: Survival analysis (KPM)

Separately attached

3.5. Linkage from mobile sites with point of care CD4 test versus no CD4 test

Of 405 participants testing at mobile/outreach sites, 182 (44.94%) individuals had tested for HIV at the MMRC mobile site, where CD4 testing was offered at the point of testing, but no registration or ART was provided. 223 (55.06%) individuals tested for HIV at mobile/outreach sites without the availability of CD4 tests, registration and ART. A total of 66.5% of study subjects testing for HIV with an immediate CD4 test and 72% of those testing at a site without CD4 test were linked into care within the first six months; however, this difference was not statistically significant.

3.6. Factors associated with time to linkage

Bivariate Cox regression showed that there were several factors associated with hazard of time to linkage, and multivariate Cox regression analysis revealed that a person tested at facility-based increase the risk of linkage by 78% (AHR=1.78; 95%CI: 1.52-2.07) compared to persons tested at mobile centre when other variables were controlled. Disclosure of HIV status to partners, family, a relative or a friend was found to be a significant factor associated with two and a half times increased risk of linkage to care (AHR=2.64; 95%CI: 2.05-3.39). Participants whose main reported reason for testing was an intention to receive treatment were 25% more likely to link to care (AHR=1.25; 95%CI: 1.06-1.46), "Table 2".

Table2: Factors associated with time to linkage at bivariate and Multivariate Cox regression

**Significant at p-value <0.05

Variable	Crude HR	95% CI	Adjusted HR	95% CI
Gender				
Male	Ref		Ref	
Female	0.97	0.84-1.12	0.98	0.84-1.14
Age				
18-30	Ref		Ref	
30-45	0.95	0.81-1.11	0.98	0.83-1.17
45-60	1.18	0.95-1.47	1.12	0.87-1.44
>60	1.06	0.65-1.73	1.11	0.66-1.88
Marital status				
Single	Ref		Ref	
Married	1.24	0.98-1.56	1.06	0.83-1.35
Separated	1.14	0.85-1.53	0.87	0.64-1.18
Divorced	1.27	0.84-1.91	1.19	0.78-1.83
Widower	1.37	1.02-1.83	1.15	0.82-1.61
Time to reach clinic				
<1 hour	Ref		Ref	
1-2 hours	1.06	0.89-1.25	1.03	0.86-1.22
2-5 hours	0.97	0.74-1.28	1.17	0.88-1.55
>5 hours	0.75	0.37-1.52	1.09	0.54-2.22
Testing site				
Mobile based	Ref		Ref	
Facility based	1.73	1.49-2.003**	1.78	1.53-2.07**
Health improved because of ARV				
No	Ref		Ref	
Yes	1.46	1.22-1.74**	1.01	0.82-1.24
Any friend/Family taking ARVs				
No	Ref		Ref	
Yes	1.35	1.16-1.58**	1.01	0.85-1.203
I want to receive treatment				
No	Ref	1.07-1.45**	Ref	1.06-1.45**
Yes	1.25		1.25	
Disclosure of HIV Status				
No				
Yes	Ref		Ref	
	2.82	0.25-3.54**	2.64	2.05-3.39**

4. DISCUSSION

This study prospectively measured linkage to care in remote and hard-to-reach areas and populations, and compared successful linkage and time to linkage into HIV care between two HIV testing service delivery models in rural settings of the Mbeya region in Tanzania.

The study was designed and implemented against the background of historically low rates of linkage to care, recent widespread implementation of mobile testing to address low population rates of HIV testing, and evidence from other settings of significantly poorer linkage to care after HIV diagnosis at the mobile/outreach-based testing sites compared to facility-based testing sites.

Our study found that 78% (n=793) of individuals of the overall cohort had registered at care and treatment centres within the first six months after diagnosis, representing a dramatic improvement in linkage to care after HIV diagnosis compared to the recent past in Tanzania. [11]–[13]

A number of studies on HIV testing and linkage to care in other SSA countries have reported linkage rates of more than 60% [16], [22], [27]–[30]. Our encouraging findings likely reflect a combination of health system and social changes, including reduction in stigma. Our study itself may also have increased linkage to care through regularly contacting and following up HIV positive individuals.

Linkage to care in the group of people tested through the facility-based model was significantly higher compared to the group tested through the mobile/outreach services. More people were linked to care, and they linked modestly sooner in the health facility than mobile clinic arm. This aligns with earlier studies in Kenya, South Africa and systematic review and meta-analysis of community and facility based HIV testing. [16], [22], [30]

Likewise, a meta-analysis conducted in the United States on entry into medical care after HIV positive diagnosis reported high entry by people testing at clinics and hospitals compared to other community testing settings. [31]

While the dramatic improvement in linkage across the overall cohort and the early linkage to the first step of care are encouraging findings, the continued gap in linkage to care between mobile and facility-based testing is important to address. It is possible that some of the respondents lost to follow up in the mobile/outreach arm sought and were linked to care in other sites; however, we believe that significant health system-level barriers must be addressed to ensure timely linkage and, ultimately, retention in care.

Some of the outreach testing activities are done very far from the clinics that offer CD4 testing and HIV care. For example, some clients in Chunya district must travel more than 100 kilometres on a rough road to reach a facility that offers CD4 test services and ART. We suggest expansion of mobile staging and ART services in remote areas. Furthermore, health care providers should ensure that education and emphasis on the importance of being in HIV care, even if the client does not yet require ART according to local guidelines, are emphasized during counselling.

Disclosure of HIV sero-status to partners and/or family members was strongly associated with earlier linkage to care compared to those who did not disclose to partners, and/or family members/relatives, again corresponding with findings elsewhere [32]–[34] and highlighting the continued importance of facilitating disclosure and social support.

We found that the majority of participants who reported, “Wanting to receive treatment in case they are infected with HIV” as one of the reason for testing for HIV, tested at facility based sites. This may suggest that they perceived themselves to be at higher risk, or that they already intended to seek care for their symptoms and that individuals testing at facilities were more

willing to link immediately into care because they needed treatment.[18] This would align with studies elsewhere that have reported higher CD4 counts at mobile sites than at facility-based sites; [35] however, while we found slightly higher CD4 counts in the mobile testing arm, this difference was not statistically significant. We therefore think it is important to explore and address health system facilitators and barriers, such as the availability of integrated HIV testing, care and treatment services within the same facility/site.

This interpretation is supported by other findings from our study: a total of 265 individuals, 51.7%, who tested at facility-based sites were able to link on the same day of HIV testing, while only 12% of those testing through the mobile/outreach model were able to link on the same day. This is likely associated with availability of HIV testing and HIV care and treatment services within the same compound at facility sites. Not surprisingly, some studies report that CD4 testing at the point of care reduces time for linkage, eligibility assessment and ART initiation, [36], [37], and having HIV testing services and HIV care (CTC) at the same location improves rates of linkage to care and ART coverage. [18], [38] While Tanzania has made significant progress in increasing testing and linkage to care, our study strongly supports arguments for increasing the proportion of health facilities with care and treatment services from the current low level of 21.7%. [13]

Further analysis of our qualitative and quantitative data will help elucidate these findings. Nevertheless, studies on HIV testing indicate that outreach testing services increase access in remote areas, but linkage to care remains a problem.[23], [39] Our study supports these findings, whilst reporting significant improvements in overall linkage to care since 2009 and 2014.

The strength of this study is that we had a large sample of newly HIV positive diagnosed individuals in the cohort, enrolled from 16 different sites who were followed up for six months

from the time of diagnosis. The project team used telephone calls to follow clients on their dates of next visit to clinic. Use of phone calls may have been one of the factors that facilitated or enhanced linkage to care among the study participants.

The study has some limitations: We were not able to see all clients during study period, despite efforts to track them through telephone calls by study team, CTC and community based health care providers in their respective areas. It may be assumed that the clients might have moved to other places due to prevailing trade routes with extensive cross border migration**;** however, our study was not able to ascertain the exact name of linkage site and linkage beyond the study sites. This warrants further investigation. An additional limitation of our study is that the random selection of facility-based sites yielded a sample where all facilities had on-site care and treatment centres.

5. CONCLUSION

Linkage to care is the bridge between HIV testing and treatment/care services for HIV positive individuals. In comparison with previous studies conducted in 2009, 2012, and 2014 in Tanzania, this study shows that significantly more newly diagnosed HIV positive individuals had linked to care within a short time of testing. We also found that linkage to care within 6 months of HIV testing was significantly higher from health facility-based HIV-testing sites compared to mobile/outreach sites. Finally, though of more modest clinical and population health significance, these individuals were linked into care significantly sooner, particularly at sites where same-day registration for care and treatment was possible. Individuals who had disclosed their HIV status to their partner and/or family members were more likely to link into

care earlier than those who did not disclose to anyone. Findings from this study suggest that although mobile/outreach service delivery models bring HIV testing services closer to people in remote and resource restrained areas, there is still a significant gap in timely linkage to HIV care compared to sites within established health facilities. Thus, strategies that are more effective are needed to further improve linkage through this model of service delivery, including increased attention to effectively communicating the importance of linkage to care even for people who do not feel sick. In addition, the availability of care and treatment at facility-based testing sites should be significantly increased from the current low levels of less than 21.7% of public facility-based testing sites offering treatment and care.

6. ACKNOWLEDGEMENTS

We are very thankful to all study participants and dedicated research assistants namely Jane Merere, Philmin John, Nestory Sidinda, Aloyce Kabuche, Elesia Kaduma, Obeth Emmanuel, Mariam Paul, Benson Msomba, and data entry team at MRCC for special cooperation that facilitated data collection and processing.

Special thanks to the MMRC Mobile Diagnostic and Training Centre (MDTC) project coordinators for and all health care providers at the study sites and the home-based cares (HBCs) for their hard work, and HJF- Global Health International for funding the MDTC.

We thank the Regional Medical Officer (RMO), the District Medical officers (DMOs), the District AIDS Control Coordinators (DACC) and the facility /site in-charges/managers for their continued cooperation and support.

We thank the management of University of Western Cape (UWC) for approving the study, supervision and financing through the Social Innovation in Public Health Implse (SIPHI) fellowship.

We thank the management of Mbeya Medical Research Centre (MMRC) and the African Doctoral Dissertation Research Fellowship (ADDRF) award 2014, offered by the African Population and Health Research Centre (APHRC) in partnership with the International Development Research Centre (IDRC) for financing and supporting the study.

Author contributions: E.S. collected and assembled the data, E.S., P.C., L.M., A.M. drafted the article. C.Z., L.W., study supervisors and critically revised the article. W.O analysed and interpreted the data.

Conflicts of interest: None.

Data sharing statement: Data from this study will be submitted to the Dryad digital repository to be released under the terms of the creative common zero (CC0) available at BMJ open http://dx.doi.org/10.5061/dryad.4g0vt.

Permission to publish: This manuscript is published with the permission from the National Institute for Medical Research in Tanzania.

Foot note: First line ART in Tanzania is Tenofovir , Lamivudine and Efevirenz [10]

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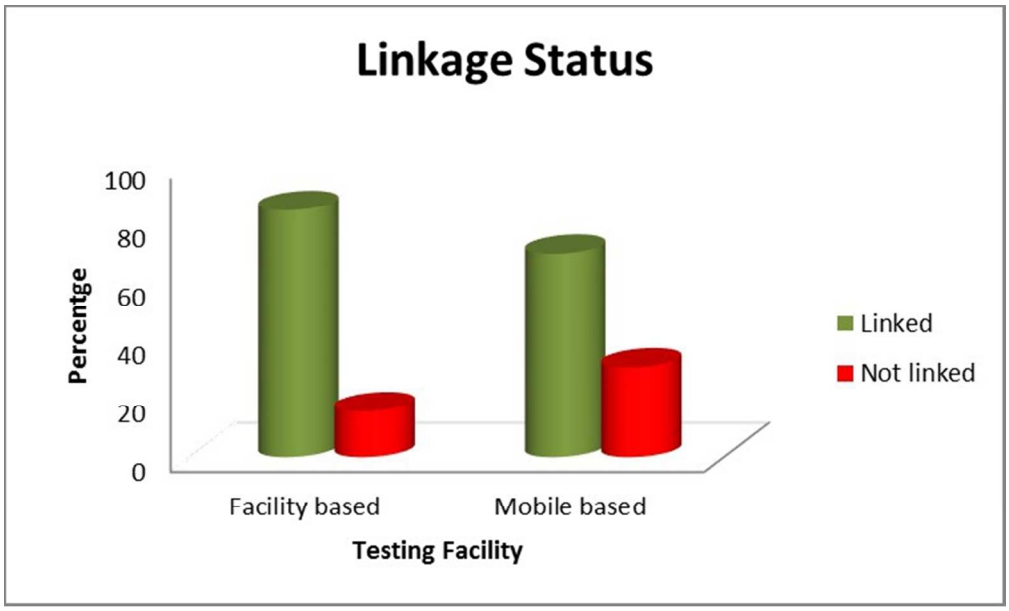

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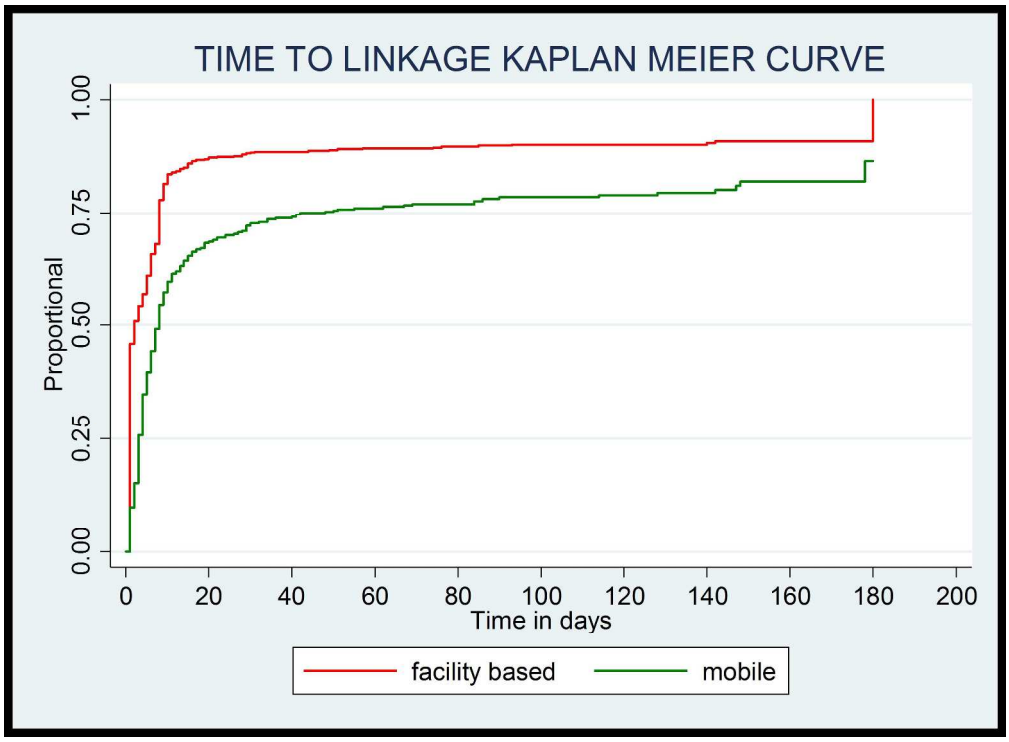

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STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of *cohort studies*

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1,2
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2-3
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4-6
Objectives	3	State specific objectives, including any prespecified hypotheses	5-6
Methods			
Study design	4	Present key elements of study design early in the paper	7
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	7-8
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	8
		(*b*) For matched studies, give matching criteria and number of exposed and unexposed	607/405
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	9
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	*10*
Bias	9	Describe any efforts to address potential sources of bias	10-11
Study size	10	Explain how the study size was arrived at	10
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	9-10
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	10-11
		(*b*) Describe any methods used to examine subgroups and interactions	9-11
		(*c*) Explain how missing data were addressed	9-11
		(*d*) If applicable, explain how loss to follow-up was addressed	
		(*e*) Describe any sensitivity analyses	15
Results			

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	9
		(b) Give reasons for non-participation at each stage	9
		(c) Consider use of a flow diagram	
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	8-9
		(b) Indicate number of participants with missing data for each variable of interest	
		(c) Summarise follow-up time (eg, average and total amount)	
Outcome data	15*	Report numbers of outcome events or summary measures over time	9-10
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	12-16
		(*b*) Report category boundaries when continuous variables were categorized	12-16
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	12-16
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	15-17
Discussion			
Key results	18	Summarise key results with reference to study objectives	18
Limitations			
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	18-21
Generalisability	21	Discuss the generalisability (external validity) of the study results	19-21
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	22

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

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