TITLE: ART denial: results of a home-based study to validate self-reported antiretroviral use in rural South Africa

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ABSTRACT

OBJECTIVE: There is increasing interest in home based testing and treatment of HIV to expand access to treatment in sub-Saharan Africa. Such programs rely on self-reported HIV history and use of antiretroviral therapy (ART). However, the accuracy of self-reported ART use in community settings is not well described. In this study, we compared self-reported ART (SR-ART) use in a home based survey against biological exposure to ART (BE-ART), in a population study of older adults in South Africa.

METHODS: Health and Aging in Africa: a Longitudinal Study of an INDEPTH community in South Africa (HAALSI) is a cohort of adults aged 40+. The baseline home-based interview included self-reported HIV status and ART use. All participants also underwent biological testing for HIV antibodies, viral load and exposure to emtricitabine (FTC) or lamivudine (3TC), which are included in all first-line and second-line ART regimens in the public-sector South African HIV program. We calculated the performance characteristics for SR-ART compared to BE-ART and fit multivariable logistic regression models to identify correlates of invalid SR-ART responses.

RESULTS: Of 4,560 HAALSI participants with a valid HIV test result available, 1,048 (23%) were HIV-positive and 734 [70% of people living with HIV (PLWH)] were biologically validated ART users (BE-ART). The sensitivity of SR-ART use was 64% (95% CI: 61–68%) and the specificity was 94% (95% CI: 91-96%); the positive predictive value (PPV) was 96% (95% CI: 94-98%) and negative predictive value (NPV) was 52% (95% CI: 48-56%). We found no sociodemographic predictors of accurate SR-ART use.

CONCLUSIONS: Over one in three individuals with detectable ART in their blood denied current ART use during a home-based interview. These results demonstrate ongoing stigma related to HIV and its treatment, and have important implications for community health worker programs, clinical programs, and research studies planning community-based ART initiation in the region.

INTRODUCTION

The roll-out of antiretroviral therapy (ART) in endemic regions of sub-Saharan Africa has been among the most consequential global health achievements of the past two decades. Widespread availability of ART in the communities most acutely affected by HIV has resulted in large gains in both life expectancy and economic productivity for people living with HIV (PLWH).[1,2] Given the overwhelming evidence for both the individual and population-level benefits of ART, the Joint United Nations Programme on HIV/AIDS (UNAIDS) has established an ambitious "90-90-90" target, whereby 90% of all people living with HIV will know their diagnosis, 90% of PLWH will receive sustained ART and 90% of all PLWH on ART will be virally suppressed by 2020.[3]

In the context of these efforts to achieve nearly universal access to ART, the concept of Community Health Worker (CHW)-delivered models of care has taken hold.[4,5] There is a growing interest in the role that Community Health Workers (CHWs) will play in the delivery of many kinds of health services, particularly in the resource-strapped health systems of low- and middle-income countries where HIV continues to be highly prevalent.[6] This anticipated model of care will include delivery of HIV prevention, testing, linkage to care and even distribution of antiretroviral therapy by CHWs.[5,7] As these tasks shift from clinics to home-based care delivery, simple, low-cost methods of identifying those most in need of HIV services will be needed. As such, self-reported use of antiretroviral therapy (SR-ART) in the home setting is a potentially important entry point for CHWs to provide services to improve ART retention, adherence, and outcomes. In this study, we compared SR-ART use in a home-based survey against biological exposure to ART (BE-ART), in a population study of older adults in South Africa. This study can help to determine whether the accuracy of self-reported ART use may be sufficiently good for future home-based interventions.

Two previous studies in Uganda and Kenya have shown a high sensitivity and moderate specificity of self-reported ART use among people living with HIV (PLWH).[8,9] However, neither of these studies addressed the utility of SR-ART data in areas with hyperendemic HIV prevalence or among older adults. These studies also involved retrospective analyses of data collected in 2011 and 2012, respectively. We conducted a validation study of SR-ART use in a large population-based cohort of aging adults in the Agincourt sub-district of South Africa. Our study is the first validation of SR-ART data among older adults in a community with hyperendemic HIV and reflecting recent home-based reporting behavior.

METHODS

Study population

The Health and Aging in Africa: a Longitudinal Study of an INDEPTH community in South Africa (HAALSI) is a cohort of adults age 40 years and older in rural Mpumalanga, South Africa.[10,11] The focus of this study on adults over the age of 40 is particularly relevant given the aging of the HIV-positive population on ART in endemic regions such as South Africa.[12] The HAALSI survey is nested within a health and demographic surveillance system (HDSS) that covers the Agincourt sub-district adjacent to southern Mozambique.[13,14] The HAALSI baseline survey enrolled 5,059 participants in 2014-2015, with a response rate of 86%. The survey was conducted by trained, local fieldworkers who recorded participant responses in a Computer Assisted Personal Interview system and collected data on sociodemographic characteristics, healthcare utilization and economic productivity. The fieldworkers read all questions and entered the participant responses in the tablet-based CAPI. In addition, anthropometry, blood pressure, point-of-care glucose and dried blood spots (DBS) were collected for all consenting participants.

Defining HIV infection and ART use

Information about HIV infection status and ART use were collected via self-report and confirmed by biomarker in the HAALSI baseline survey.[10] All participants were asked: (1) "Have you ever been tested for HIV?" (2) "When was the last time you had an HIV test?" (3) "Do you know your HIV status?" and (4) "Have you ever tested positive for HIV?". Those participants who responded "yes" to question (4) in this series were then asked, "Have you ever received ART prescribed by a doctor, nurse or other healthcare worker?". The answer to this final question was used to define SR-ART use, where those who responded "yes" were considered to be SR-ART users.

All DBS samples were tested for HIV antibody by enzyme-linked immunosorbent assays (ELISA) as well as for viral load. The HIV screening and confirmatory assays used were the Vironostika HIV 1/2 Ag/Ab MicroELISA System (BioMérieux, France) and the Roche Cobas E411 Combi Ag (USA). The Viral Load Platform was BioMérieux NucliSens and the lower limit of detection was <100 copies by Dried Blood Spot.

In those participants with a positive HIV antibody test, assays were then performed to detect metabolites of emtricitabine (FTC) or lamivudine (3TC) by DBS. Study samples were analysed at the Pharmacokinetic Laboratory at the University of Cape Town in South Africa. A semi-quantitative LC/MS/MS assay with a lower limit of detection of 0.02 µg/ml was validated for the determination of 3TC and FTC from DBS. The method consisted of a protein precipitation, followed by high performance liquid chromatography with MS/MS detection using gradient elution. An AB Sciex API 4000 mass spectrometer at unit resolution in the multiple reaction monitoring (MRM) mode was used to monitor the transition of the protonated precursor ions at m/z 248.0 and 230.2 to the product ions at m/z

129.9 and 112.0 for emtricitabine and lamivudine, respectively. Electro Spray Ionisation (ESI) was used for ion production.[9,15] Samples that fell above the lower limit of detection for either of the antiretroviral drugs tested were classified as positive for ART use. BE-ART was defined by the presence of at least one of these two drugs as either FTC or 3TC or both have been included in any of the first- and second-line ART regimens ever used in South Africa; thus at least one of these two drugs would be expected in the blood of any person who is actively taking an ART regimen. Participants with biologically confirmed HIV-infection and a viral load that was below the lower limit of detection of the study assay (<100 viral copies) were also considered BE-ART users, regardless of their ART metabolite status.

Data Analysis

We calculated descriptive statistics for all HIV-positive participants, for the sub-group of BE-ART users and for the subset of participants who accurately self-reported their ART use. We then used BE-ART as a gold standard based on which we calculated the sensitivity (proportion of participants truly taking ART who also reported taking ART), specificity (proportion of participants truly not taking ART who also denied taking ART), positive predictive value (proportion of participants reporting ART use who were truly taking ART [PPV]) and negative predictive value (proportion of participants denying ART use who were also truly not taking ART [NPV]) of SR-ART use. We calculated these test statistics for the total population and stratified by sex and 10-year age group. We also calculated and plotted the PPV and NPV of SR-ART over the range of all possible ART prevalence values.

We then used multivariable logistic regression to assess the association between accurate SR-ART use and several sociodemographic factors, including age, sex, educational attainment and wealth quintile. Finally, we also analyzed the proportion of PLWH who self-reported their diagnosis by interviewer and

compared differences in these proportions with a chi-squared test. All analyses were performed in Stata Statistical Software v. 14.

Ethics Statement

This study received ethics approval from the University of Witwatersrand (#M141159), the Harvard T.H. Chan School of Public Health (#13-1608), and the Mpumalanga Provincial Research and Ethics Committee.

RESULTS

In the baseline survey, 4,707 (93%) consented to DBS biomarker testing. Valid results were available for 4,560 individuals, among whom 1,048 (23%) were HIV-positive. As reported previously, consent to DBS did not differ significantly by age or sex.[16] Of those who were HIV-infected and tested for ART exposure (n=1,035), 734 (71%) were positive for at least one ART drug or were virally suppressed: 573 (87%) tested positive for FTC, 84 (13%) for 3TC and 5 (1%) for both FTC and 3TC; 72 additional participants were virally suppressed despite the lack of ART metabolites in their blood. Among these 734 participants, 473 had also self-reported ever accessing an ART program in the survey. (Figure 1) The sex, age and educational distribution of the total HIV-positive population were similar for the sub-population of BE-ART users and those who accurately self-reported their ART use status (Table 1).

We calculated the sensitivity of SR-ART use and found that it was 64% (95% CI: 61-68%) while the specificity of SR-ART use was 94% (95% CI: 91-96%). The sensitivity and specificity did not vary substantially by age and sex. The sensitivity was lowest in the 70+ age group (38.0 [95% CI: 27.0 – 50.3]) and highest in the 50-59 year old age group (66.9 [95% CI: 60.1 – 72.2]). Assuming the true

prevalence of ART use was 71%, PPV was 96% (95% CI: 94-98%) and NPV was 52% (95% CI: 48-56%). The PPV was also stable when stratified by age and sex, and was lowest in the 40-49 year old age group (91.7 [95% CI: 85.3 – 95.6]) and greatest in the 60-69 year old age group (98.6 [95% CI: 93.3 – 99.7]). The NPV did vary over a wider range, from 45.6 [95% CI: 36.9 – 54.7] in the 60-69 year old age group to 59.3 [95% CI: 51.5 – 66.6] in the 40-49 year old age group. (Table 2). We also provide a figure displaying the PPV and NPV over a range of possible ART use prevalence values. (Figure 2)

In multivariable logistic regression, accurate SR-ART use was not significantly associated with participants' age, sex or wealth (Table 3). Accurate SR-ART use was associated with education but only for those with primary school education (1-7 years of formal schooling) as compared to those with no formal education. Finally, we found that there were significant differences in the rate of disclosure of HIV status among PLWH, with the rate of disclosure stratified by interviewer ranging from 13.8% to 71.4%, $p<0.001$. In contrast, we did not observe significant differences in disclosure of ART status by interviewer (range 92.3 – 100%, $p=0.231$).

DISCUSSION

In this community-based study of HIV testing and ART testing, we found a high specificity for SR-ART use. The corresponding high PPV indicates that SR-ART can be used to identify patients that could benefit from interventions supporting ART use, such as retention- and adherence-enhancing interventions. However, in contrast to prior research, we found high levels of "ART denial" – in the form of a low sensitivity of ART use, suggesting that SR-ART may not be a sufficient way to identify individuals who are not yet in ART care and require ART linkage. While interventions to promote linkage to ART programs after home-based testing based on SR-ART offer large potential benefits to

PLWH who are not on ART,[5] our finding suggest that such interventions might also unnecessarily divert resources to those already in care due to "ART denial." This phenomenon could also result in underestimates of ART coverage during efforts to monitor and evaluate progress toward international treatment targets.

Two previous studies have sought to estimate the performance characteristics of SR-ART use with BE-ART data as a gold standard. The first was undertaken as part of the 2012 Kenya AIDS Indicator Survey (KAIS). KAIS is a nationally representative survey with more than 11,000 participants, among whom 689 (5.6%) were HIV-positive in 2012.[9] This study included tests of exposure to ART metabolites, and found the sensitivity of SR-ART was 71%, the specificity was 94%, the PPV was 90%, and the NPV was 82% in Kenya. More recently, a second study in Uganda suggested a similar specificity of self-reported ART use but a higher sensitivity at 77% (95% CI: 70-83%). The PPV in this Ugandan context was 97% and the NPV was 89%. We found that the specificity and PPV of SR-ART are nearly identical in this rural South African context but that the sensitivity and NPV are much lower. The reasons for this difference are unclear but may include the long history of HIV-denial in South Africa or relate to differences in stigma in these contexts.[17]

The results of the validation study presented here offer important information for HIV care delivery going forward. While our findings do not undermine the growing consensus that questions related to HIV status, diagnosis and treatment, including ART use, should be included in population-based surveys, clinical trials and epidemiological surveillance systems[18], they do raise questions about what other information, including data on biological exposure to ART, should be collected in surveys or surveillance systems in order to optimally guide linkage to care, including home-based linkage efforts

that may be implemented by CHWs. To date, efforts to link information about ART use from the clinic setting to the home have been challenging. In addition, assays to determine biological exposure to ART are not available for point-of-care use. As such, presently there is only self-reported ART use to guide home-based interventions to increase linkage to HIV prevention and care.

The high level of ART denial that we found in this community may suggest that further behavioral and social interventions should be trialed to increase the sensitivity and PPV of self-reported ART use. Several types of interventions have been previously explored to reduce the stigma associated with HIV in this context. For instance, interventions based on community-based peer support groups have demonstrated qualitative psychosocial benefits in terms of the ability to re-engage in communities.[19] In addition, individual peer adherence support and treatment buddying have also been explored as an approach to reduce stigma in other South African communities and at least one study demonstrated lower felt stigma, in particular with the use of treatment buddies.[20] Moreover, a study in Kenya showed that a multisectoral agricultural livelihood intervention, consisting of a human-powered water pump, a microfinance loan to purchase farm commodities, and education in sustainable farming practices and financial management also led to less stigma and positive changes in confidence and self-esteem for PLWH who received the intervention.[21] This study showed that participants in the intervention group felt that other community members perceived them as active, economically productive, and contributing while those in the control arm of this study described ongoing and continued stigma.[22] Such interventions are especially important in our study context of a hyperendemic community of aging adults, where ART denial was higher than in prior studies. Also of interest is that in our study men and women self-reported their ART-use to a similar degree, even though ART uptake is generally slightly greater among women.

There are several important limitations of this study. First, biological exposure to ART is defined by a single measure of exposure at one point in time. As such, it is possible that this measure underestimates true ART coverage as there may be participants who are enrolled in an ART program but were non-adherent at the time of the survey and thus the drug metabolites were not detected. This would be especially relevant if the data were being used to inform efforts to link patients to ART programs. Second, the skip pattern in the survey questionnaire only asks those participants who self-report their HIV-positive status about their use of ART.[16] Specifically, 537 (51.5%) of 1,043 PLWH (as defined by a HIV antibody test) self-reported that they had ever tested positive for HIV whereas 506 (48.5%) denied that they had ever tested positive for HIV. The implications of this approach to questioning about HIV status and ART use make it challenging to disentangle self-reported HIV status and participation in care. Given the stigma associated with HIV-infection in some contexts, it is possible that if all participants were asked about ART use, independent of self-reported HIV-status, the performance characteristics of SR-ART use would be more favorable. Third, it is possible that the specific fieldworker conducting the interview may have influenced reporting behavior through their interpersonal approach to questioning, and this may be especially influential when asking questions about sensitive or personal concerns such as HIV status. Our analysis found that there were significant differences in the proportion of people reporting their HIV-positive status by interviewer, but no differences in the reporting of ART use by interviewer; however, due to the structure of the survey, differences in the reporting of HIV status may have indirectly influenced our findings here. Finally, this survey did not collect data about use of formal or informal pre-exposure prophylaxis (PrEP) or informal use of ART for instance, through sharing of ART medications among household members or friends. However, it is important to note that PrEP was also not available in the public sector in this region at the time of this survey.

This study suggests that further research is needed before self-reported ART use can be used with confidence to promote linkage to care by CHWs or to measure population-based progress toward the 90-90-90 targets. In particular, the optimal approach to structuring questions about HIV status, HIV diagnosis and ART use remains unclear, including whether ART use should be asked of all participants irrespective of self-reported HIV status. Finally, further validation of these performance characteristics are needed, in particular in geographies outside sub-Saharan Africa and among high-risk groups such as men who have sex with men (MSM) and sex workers, as HIV-related stigma and disclosure may differ in these contexts.

Competing Interests

The authors declare no conflicts of interest.

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Table 1. Demographic characteristics of all HIV-positive, ART-users and accurate self-reported ART users in HAALSI

	HIV+ Population	BE-ART Users	Accurate SR-ART Users
N	1,048	734	473
Male (%)	475 (45.9)	342 (46.6)	222 (46.9)
Female (%)	560 (54.1)	392 (53.4)	251 (53.1)
Age 40-49	310 (29.6)	192 (26.2)	122 (25.8)
Age 50-59	392 (37.4)	287 (39.1)	192 (40.6)
Age 60-69	244 (23.3)	184 (25.0)	115 (24.3)
Age 70+	102 (9.7)	71 (9.7)	44 (9.3)
Education <1	429 (41.1)	296 (40.5)	185 (39.4)
Education 1-7	364 (34.9)	266 (36.4)	188 (40.0)
Education 8-11	162 (15.6)	108 (14.8)	63 (13.4)
Education 12+	89 (8.4)	61 (8.3)	34 (7.2)

Table 2. Performance criteria of self-reported ART use by age and sex in HAALSI

Population	PPV (95% CI)	NPV (95% CI)	Sensitivity (95% CI)	Specificity (95% CI)
Overall	96.1 (94.4 – 97.8)	51.9 (47.8 – 56.1)	64.4 (60.9 – 67.9)	93.7 (90.9 – 96.4)
Male	94.8 (90.9 – 97.2)	50.2 (43.7 – 56.7)	64.9 (59.6 – 69.9)	90.9 (84.4 – 95.0)
Female	97.2 (94.2 – 98.8)	53.3 (47.5 – 59.0)	64.0 (59.0 – 68.7)	95.8 (91.3 – 98.1)
Age 40-49	91.7 (85.3 – 95.6)	59.3 (51.5 – 66.6)	63.5 (56.2 – 70.2)	93.2 (82.9 – 94.8)
Age 50-59	96.9 (93.2 – 98.8)	49.2 (41.9 – 56.6)	66.9 (60.1 – 72.2)	93.9 (86.6 – 97.5)
Age 60-69	98.3 (93.3 – 99.7)	45.6 (36.9 – 54.7)	62.5 (55.0 – 69.4)	96.7 (87.5 – 99.4)
Age 70+	100.0 (84.5 – 100.0)	40.5 (29.5 – 52.6)	38.0 (27.0 – 50.3)	100.0 (85.8 – 100.0)

Table 3. Regression analysis of factors associated with accurate self-reported ART use

COVARIATE	ESTIMATE (OR + 95% CI)
AGE 40-49	REF
AGE 50-59	1.05 (0.69 – 1.58)
AGE 60-69	0.86 (0.53 – 1.38)
AGE 70+	0.87 (0.46 – 1.63)
MALE	REF
FEMALE	0.94 (0.69 – 1.29)
NO FORMAL EDUCATION	REF
EDUCATION 1-7 YEARS	1.53 (1.04 – 2.25)
EDUCATION 8-11 YEARS	0.90 (0.53 – 1.52)
EDUCATION 12+ YEARS	0.82 (0.43 – 1.57)
WEALTH QUINTILE 1	REF
WEALTH QUINTILE 2	0.98 (0.60 – 1.60)
WEALTH QUINTILE 3	0.78 (0.48 – 1.27)
WEALTH QUINTILE 4	0.74 (0.45 – 1.22)
WEALTH QUINTILE 5	0.68 (0.39 – 1.19)
OBSERVATIONS	731

Figure 1: HIV Infection & ART use in HAALSI, Agincourt sub-district, South Africa, 2015

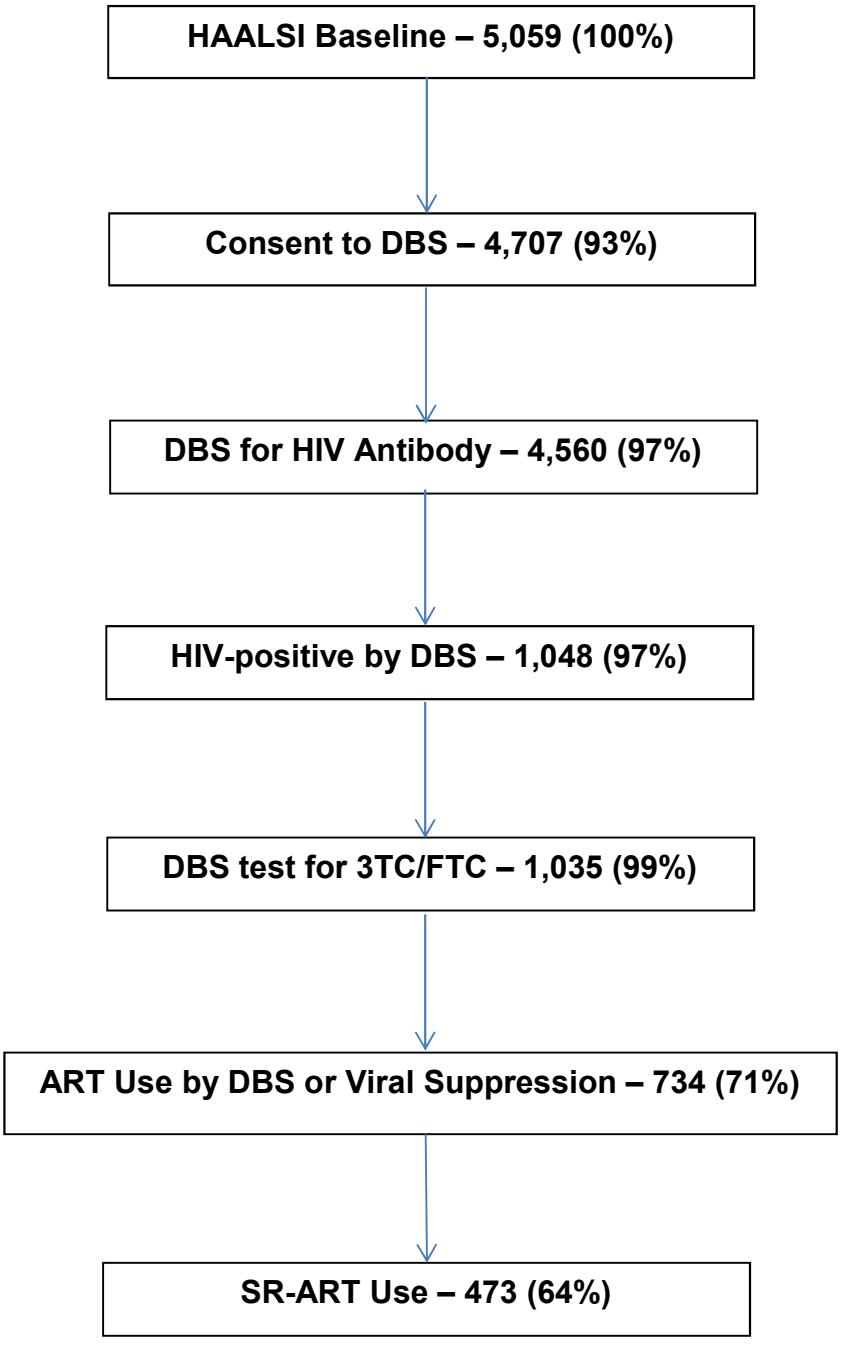
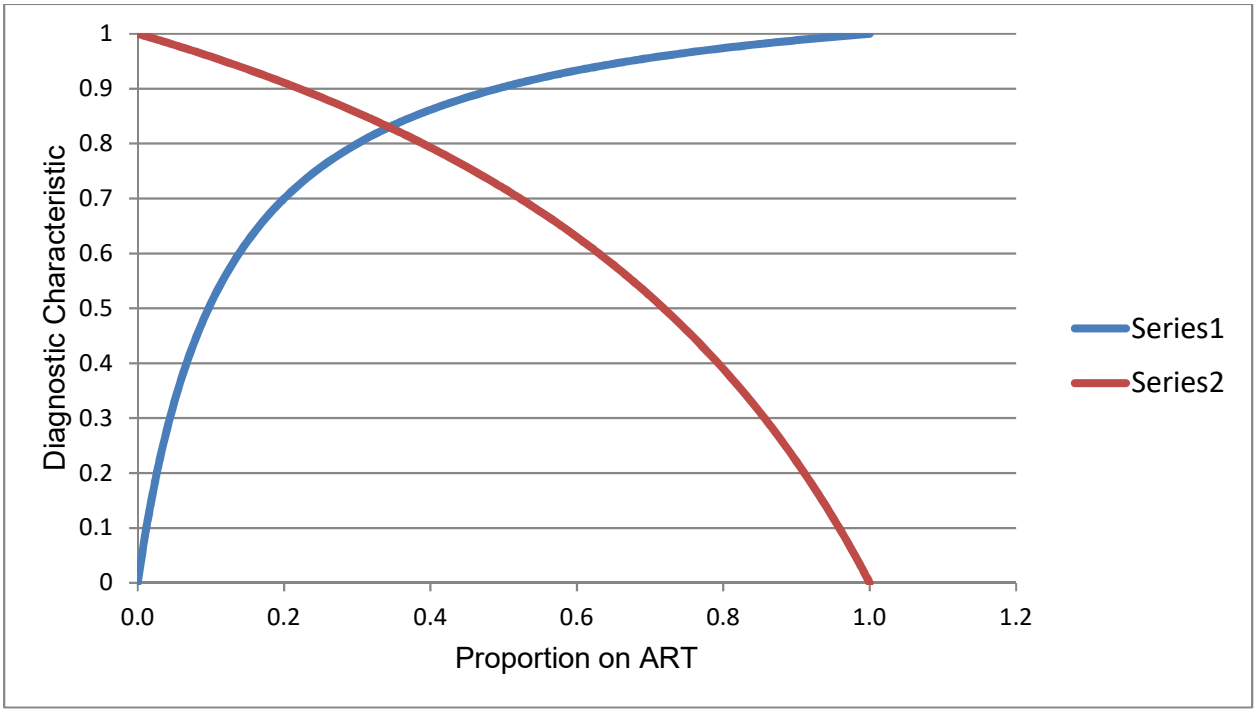


Figure 2. PPV and NPV over the range of ART coverage in Agincourt, South Africa*



***Series 1 = PPV, Series 2 = NPV**