Stockholm Evaluation Unit

EVALUATION OF COMMUNITY HIV TESTING MODALITIES

MSF OCB in KwaZulu-Natal, South Africa

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This publication was produced at the request of MSF-OCB. It was prepared independently by *Richard Bedell*.

DISCLAIMER

The author's views expressed in this publication do not necessarily reflect the views of Médecins sans Frontières or the Stockholm Evaluation Unit.

Warning: Reading this report in its entirety will require stamina. The 'Findings' section alone comprises 32 (admittedly riveting) pages. There was a lot to evaluate. If you cannot read the entire report, it is imperative to read the Executive Summary (2.5 pages), the Conclusions and Recommendations (4.5 pages); those sections will allow you to decide which of the findings will be of greatest interest. (Richard Bedell)

Acknowledgements: I wish to thank the members of the MSF team particularly those in KZN who helped me understand how community HIV testing actually takes place, and those who helped me to obtain the data I needed to evaluate the project.

Cover Photo: MSF team in action at HIV education and testing event at a farm in KZN near Eshowe, 10 Dec 2015 (RB).

CONTENTS

ACRONYMS

ART	Antiretroviral Therapy
CHAP	Community Health Agents Programme
CS	Community Sites [type of M1SS site]
FS	Fixed Site [for HCT]
HCT	HIV Counseling & Testing [also HTC]
HS	High School [type of M1SS site]
HF	Health Facility [clinic or hospital]
ICER	Incremental Cost-Effectiveness Ratio
ITI	Inter-Test Interval
MSF	Médecins Sans Frontières
M1SS	Mobile 1-Stop Shop [mobile clinic]
MMC	Medical Male Circumcision [also Voluntary MMC = VMMC]
OpenMRS®	Open Medical Record System [type of database]
Q3	Third Quarter [July-August-September]
TIER.net	Electronic register for HIV & TB patients [from UCT/CIDER]
VL	Viral Load [HIV]

EXECUTIVE SUMMARY

Background: MSF has been providing 3 modalities of community HIV testing in KZN since late 2012, to complement the standard, health facility (HF)-based testing provided by the Department of Health. Fixed sites (FS), Mobile 1-Stop Shops (M1SS) and Door-to-Door Community Health Agents (CHAPs) provide testing throughout the project area of Eshowe, Mbongolowane and the adjacent rural areas. Given that community HIV testing is often more expensive than HF-based testing, it is important to fully understand the relative advantages of community testing modalities.

The UNAIDS 90-90-90 targets necessitate a dramatic increase in HIV testing and linkage to HIV care; implementers and health authorities need evidence on which to base their program plans in order to effectively approach those ambitious goals.

Approach: Each of the HIV testing modalities was examined with regard its client demographic structure (sex-age strata), its HIV+ case demographic structure, its efficiency in HIV diagnosis, and where possible the extent to which immunocompromised HIV+ persons were identified. Proportions of coverage of total testing volume were estimated to understand the contribution of each testing modality to total testing volume. Temporal trends in the performance of each community testing modality were examined over the lifespan of the project to guide future program choices.

Linkage to care was assessed indirectly by comparing client demographic structures of tested persons and those registered for HIV care and treatment, and by comparing CD4 count distributions of newly diagnosed HIV+ persons and those initiating ART; patient-level linkage data were not available.

Benefits of testing (other than linkage to care for HIV+ persons) were investigated in the light of what the published literature describes on this theme.

Methods: The evaluation was based on extensive review of program documentation and sex-age disaggregated data from each modality of testing for each year of program activity. A uniquely valuable source document for this evaluation was the 2013 population viral load survey performed in the project area by MSF/Epicentre (Paris). Data from this survey provided the basis for a comparator HTC client demographic structure, and for a comparator HIV+ client demographic structure, to which the actual program data could be compared.

Findings: are presented with extensive use of figures illustrating comparisons between actual and comparator client demographic (sex-age) distributions. Fixed Sites (FS) and Mobile 1-Stop Shops (M1SS) see both sexes and a wide range of ages; younger men are in particular well represented. M1SS client demographic vary between 2 predominant structures: a mixed gender, mixed age structure like that of FS found at community sites like taxi ranks and commercial areas, and a youth-focused, mixed gender structure made up predominantly of 10-24 year olds found at schools, college and youth-focused events.

Door-to-door testing by the Community Health Agents Program (CHAP) also reaches both sexes over a wide range of ages but with some underrepresentation of males 15-29. A large proportion of testing takes place among children <15 years and adults 60 years and older – together these groups made up 40% of the total volume of CHAP tests in 2015, whereas HIV prevalence among testers in these groups was only 0.2% and 0.5%, respectively.

HF-based testing data (although we have only Nov 2015 data with detailed sex-age stratification) shows the expected predominance of women 20-39 and a distinct lack of men 15-29 years of age.

The efficiency of each testing modality in identifying HIV infection varies. HF test more ill and symptomatic patients so their clients have the highest prevalence of HIV (17.4% for HF; 18.7% for ANC/HF, in late 2015). Of the community testing modalities, FS were the most efficient (6.8% HIV+), followed by M1SS-community sites (5.8% HIV+), whereas the FS-college and M1SS-high school sites saw fewer HIV+ (3.4% and 2.3 %, respectively). CHAP testing in late 2015 diagnosed HIV in only 0.9% of testers.

Taking all FS and M1SS testing together in 2015 the distribution of HIV+ cases is very close to what the population based survey predicts. There appears to be some demographic heterogeneity among youth (10-24 years) which is evidenced by differences in the HIV prevalence of testers who are school-associated versus non-school-associated, with much lower HIV prevalence among the school-associated testers, both male and female. This may reflect socio-economic differences and/or a protective association with school attendance.

CHAP testing has steadily increased in volume (3500-4000 tests per month in late 2015) but the prevalence of HIV has dropped steadily over the program lifespan. Sex-age disaggregation of CHAP testing data for 2013-2015 shows a significant drop over time in HIV prevalence for all age strata for women -- to levels much lower than age-matched women being tested in FS/M1SS sites, with a less clear pattern for men (although relatively few cases overall).

Data on previous testing for FS/M1SS clients indicates about a quarter reports no previous HIV test, and in late 2015 the median inter-test interval (ITI) for the remainder was 234 and 207 days for males and females, respectively. For CHAP clients only 20% report no previous HIV test and the ITI is similar to that for FS/M1SS clients.

The CD4 count distribution for FS/M1SS clients at the time of HIV diagnosis is similar to that found in the Epicentre survey for untreated HIV+ persons; in late 2015 20% of males and 13% of females had CD4 counts <200 cells/microliter.

Linkage was evaluated in terms of the client sex-age structure of patients registered for HIV care and treatment. The observed distribution is similar to the client sex-age structure predicted by the comparator derived from the Epicentre survey – with the exception of males and females 15-19 who appear underrepresented in the treated population. More specific data on persons diagnosed from M1SS also suggest that women 15-19 are missing treatment, as are some men 20-29. Similar data on CHAP-tested persons in care suggest missing men 15-24 and missing women 20-24 among those registered for HIV care and treatment.

Not surprisingly, HF data on the much lower CD4 count distribution of patients initiating ART indicate that many patients with advanced disease (low CD4 counts) still enter the system via HF testing. Between 35-40% of males, and 20-25% of females, in 2015 have CD4 <200 cells/microliter at registration. The lowest CD4 counts are seen in males 30-54, who may tend to have HTC late and/or present for HIV care later than others.

The literature describes numerous potential benefits from HIV testing apart from linkage to care for HIV+. TB screening by history is offered but in late 2015 only 1% of clients had sputum tests requested (with no data on results available); STI screening by history is offered but referral to HF is required for treatment (except for some farm clinic visits offering syndromic treatment); pregnancy testing is very popular at one FS suggesting there is likely unmet demand at other sites. There is no non-communicable disease screening. Identification of discordant couples is not a focus, partly because disclosure rates are low in KZN. HTC is thought to be protective against HIV acquisition in youth, and several studies suggest decreases in partner number after HTC, and increased condom use among HIV+ persons after HTC.

Conclusions: FS & M1SS testing together reaches men and women of all age strata 15-44 years; this is consistent with a large volume of literature indicating that mobile testing was superior in reaching men and youth, and more first-time testers. School testing has high levels of acceptance and provides good access to youth of both sexes.

CHAP testing is widely accepted, including among men, although most clients are female. The KZN program over-tests children <15 years and adults 60 years and older (where current HIV prevalence among those tested is only 0.2% and 0.5% respectively).

Cost-effectiveness was not evaluated in the current exercise but the literature indicates that home-based testing approaches could decrease HIV-associated morbidity, and HIV infections; that it is more cost-effective than HF-based HTC; and was cheaper than mobile HTC. Self-testing was advocated as cost-effective in any setting. The South Africa

Investment Case favours increased testing among adolescents, including with home-based and mobile approaches. Mobile HTC is also cost-effective in South Africa.

Linkage to care could only be inferred in this evaluation by comparing the demographic structure, and CD count distribution, of those tested versus those registered for HIV care, and suggests that mostly youth are missing from care. The literature identifies multiple determinants of linkage but also notes a large fraction of apparent lost-to-follow-up patients (up to half) may be in care elsewhere. Determinants include psychosocial issues (stigma the most important, but also co-morbid depression), structural barriers (transport & distance issues, wait times, lack of food), and misconceptions about ART, among others.

Recommendations:

(1) Consider another FS given good access to youth and men, and high efficiency in HIV diagnosis,

(2) Continue M1SS at a diverse range of site types including opportunities for non-school associated youth who have higher HIV risk,

(3) Increase the efficiency of the CHAP program by limiting testing of low risk children and older adults,

(4) Add CHAP testing at sites of natural congregation, especially of youth; share information with HF to support linkage to HIV care, and

(5) Advocate and educate for men to test even without symptoms and create low-threshold opportunities for testing them.

PROJECT BACKGROUND

MSF in partnership with the KwaZulu-Natal Department of Health supports a HIV/TB project in the Mbongolowane and Eshowe areas (uThunguluDistrict). The Bending the Curves (BTC) project was introduced in 2011 and aimed to implement multiple strategies to reduce the incidence of HIV and TB, in addition to reducing HIV and TB related morbidity and mortality (bend the epidemic curves downwards) in line with the South Africa National Strategic Plan (2012-2016).

A key part of this strategy has been to increase HIV testing in the community, which with good linkage to care will improve ART coverage. At the individual level, this contributes to reducing avoidable morbidity and mortality, at the community level it should also contribute to fewer new infections, given that once a person is adherent to ART their likelihood of transmitting HIV is reduced.

MSF has carried out a costing exercise which illustrates that community based testing approaches are more expensive than clinic based testing. Community based testing also yields fewer HIV positive individuals than does clinics based testing.

Community based models of testing should however be evaluated more broadly because they allow for different patient groups to be accessed, particularly the young and the "hard to reach" untested individuals who do not access services and play a significant role in ongoing transmission.

It is important also not to discount the potential benefits, in areas such as behaviour change and referral to other services, that negative test results may yield.

MSF recently (2013) carried out a large Population Based HIV Prevalence Survey study in the Eshowe and Mbongolwane area, which clearly illustrates that the greatest potential for transmission is seen in young people.

It is therefore important in the context of an incidence reduction project to establish the comparative costs and benefits of the different testing strategies not just in terms of the number of positive patients that those strategies yield, but also in term of their potential for contributing towards lowering HIV incidence by reaching populations who do not access clinic based HIV testing.

LOGICAL FRAMEWORK FOR KZN PROJECT (2015)

Objectives and Expected Results (Indicators & sources of verification are available in the Log Frame document)

General Objective	HIV& TB incidence and HIV/TB-related morbidity and mortality is reduced in the project area of Mbongolwane and Eshowe
Specific Objective	To demonstrate successful strategies for testing, treatment and prevention of HIV and TB
Expected Result 1	Communities mobilised for testing, prevention and treatment and to be accepting and supportive of those affected by and infected with HIV and TB
Expected Result 2	Uptake of HIV & TB testing and counselling and regular re-testing by well-trained lay counsellors is increased and Sexual & Reproductive Health (SRH) services are delivered
Expected Result 3	Primary Health Clinics and Hospital Mobile Clinics provide an enhanced and integrated package of HIV/TB Treatment – Prevention care services including SRH activities
Expected Result 4	Hospitals provide effective HIV services (HTC, ANC/PMTCT, HIV/TB, and SGBV/FP/TOP/STI) and secondary level referral service for complicated HIV and TB
Expected Result 5	Client-centred model of care -- spaced/fast-track appointments, clubs (in- and out-of-facilities) & CAGs -- continues to be developed & implemented to promote retention in care and adherence
Expected Result 6	Monitoring & evaluation, and operational research systems provide useful and regular feedback on the medical and public health impact of the project interventions
Expected Result 7	Advocacy to promote activities of the project to the local community and to national and international communities is successful in promoting change in both policy and practice
Expected Result 8	Improve services and coverage of Mbongolwane Hospital to serve the health needs of its catchment area and provide a proper training environment for health human resources

EVALUATION METHODS & LIMITATIONS

SCOPE OF THE EVALUATION

This evaluation concerns the relative performance of the following 4 strategies:

1. Door-to-door HIV testing using lay cadres (provided by MSF).
2. Testing through mobile outreach activities (provided by MSF).
3. Testing at standalone fixed sites (provided by MSF).
4. Conventional health facility-based testing (provided by MoH).

The questions posed in the Terms of Reference include some issues (costing) that have been previously investigated and will be further investigated outside of this evaluation per se. The remaining questions have been reformulated as follows:

HIV Testing

The HIV testing modalities in the project area need to be analysed and compared from several perspectives, in order to fully appreciate the unique features of each, and the summary effect of the combination of all HIV testing modalities. The aspects analysed here include:

- Client demographic structure:
    - To what extent are clients in various sex-age strata tested in the modality under consideration?
    - Are the new HIV+ cases identified found in the expected proportions for this population?
- Efficiency: how many new HIV+ diagnoses are made for the number of clients tested by each testing modality?
    - How many cases are diagnosed per day of service in each testing modality?
    - How well are the most immunocompromised patients identified?
    - How does the volume of testing performed compare among testing modalities?
- Coverage: how does a particular testing modality contribute to the total volume of HCT being provided in the project implementation area?
- What do temporal trends in HCT modalities indicate about any of the testing modalities or about the summary effect of all modalities of testing?

Linkage to HIV Care

This evaluation intends to assess linkage to HIV care (specifically antiretroviral therapy, ART) for each of the modalities of HCT. At the time of writing, data on linkage are not yet available although they are anticipated to be available in early January to allow for inclusion in the final analysis and report. The only data currently available (at the time of writing) that are relevant to linkage are data on CD4 counts of patients initiating ART at health facilities (HF). These data were compared to data on CD4 counts obtained at the time of HIV diagnosis through FS and M1SS testing.

Benefits of HIV testing (apart from linkage to care for HIV+)

Limited project data related to Medical Male Circumcision (MMC) and services offered during HCT activities were available and will be summarized. Published literature describing other benefits of HIV testing will be summarized.

METHODS

In order to address these aspects of HIV testing, linkage to care and secondary benefits of testing, the following methods were used:

- Review of project documentation, Epicentre HIV Prevalence Survey report, relevant published literature
- Discussion with Coordination (Cape Town) and Project (Eshowe) team members regarding all testing modalities
- Discussion with key informant staff members [list provided in Annex II]
- Observation and interviews with staff at FS, M1SS, CHAP, Farm and HF sites during service provision; observation and discussion at training & advocacy events and/or at staff meetings
- Extraction of program data from OpenMRS® and TIER.net databases [provided by project personnel], and from other periodic program reports and hard copy data sources, review and analysis of these data
- Based on data provided in the Epicentre survey, the structure of the adult population that needs to know their HIV status (sexually active 15-59 year old men and women) was derived; this provides a comparator for the client structure tested in any of the modalities where sex-age stratification is available for comparison [This is described in Annex IVa]
- Based on data provided in the Epicentre survey and estimated HIV incidence rates, the structure of the newly diagnosed HIV+ population was derived; this provides a comparator for the HIV+ population diagnosed in each of the HIV testing modalities. This comparator offers a measure of the extent to which expected cases are actually being diagnosed, and it can be viewed as complementary to the population structure suggested for the population testing perspective described above [This is described in Annex IVb]

LIMITATIONS

The initial concept for this evaluation was to include a detailed cost analysis to be melded with the analysis of the effectiveness of the various modalities of community HIV testing. Although the project has undertaken some comparative analysis of the costs of the community HIV testing modalities prior to this evaluation, this was not addressed further partly because it lies mostly outside my competencies and partly because the time available was already required for the remainder of a very extensive analysis of effectiveness.

It was initially anticipated that some patient-level data on linkage between HIV testing and enrolment in HIV care and treatment would be available for inclusion in this evaluation. In the end this was not the case, so the best I have been able to do is to compare the HIV+ client sex-age structure from the testing modalities to that observed among new registrants in the HIV care and treatment system (as indicated by registration in TIER.net); this has been complemented by a comparison of the CD4 distribution of persons testing HIV+ in FS/M1SS sites and the CD4 distribution of new ART initiators as found in TIER.net.

FINDINGS

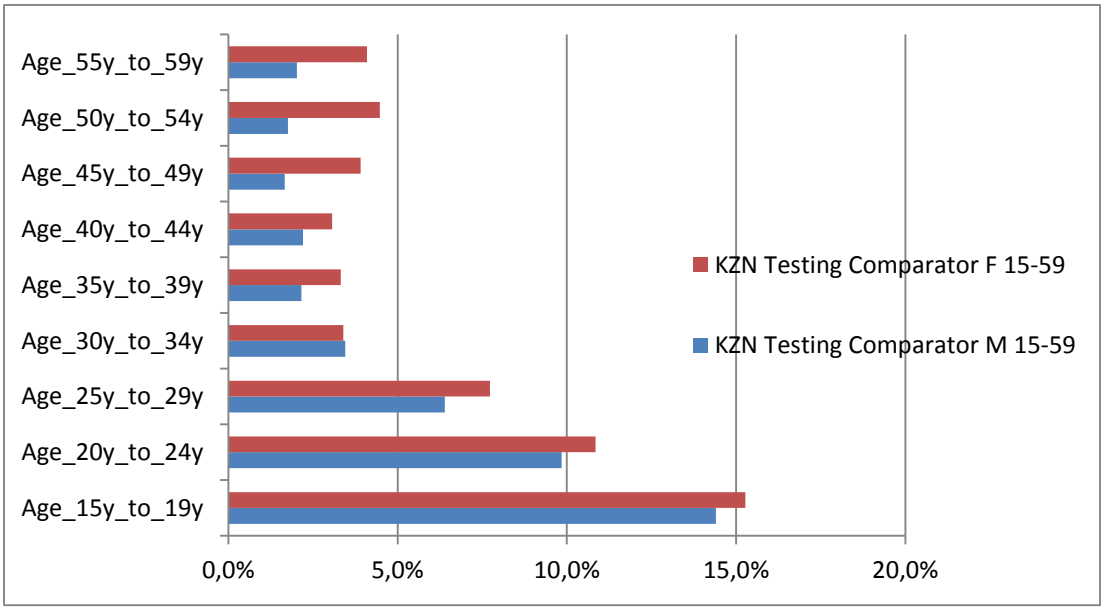
DEMOGRAPHIC REACH OF COMMUNITY HIV TESTING MODALITIES

In order to assess the extent to which a particular modality of HIV testing reaches the desired population we require some kind of reference or standard for comparison. This has to be a local standard as it should be based on the sex-age structure of the population, HIV prevalence, knowledge of HIV + status among those infected. We know that there are different risks of HIV acquisition in certain sex-age strata, and certain risk groups but since we do not want any sexually active HCT client presupposing his/her risk for HIV, it could be argued that we want to see the entire population at risk in proportion to the size of the sex-age stratum they occupy.

Knowledge of HIV status among sexually active persons 15-59 years of age:

The Epicentre VL survey conducted in 2013 (report issued 2014) provides the population structure for residents 15-59 years of age, the sex/age specific HIV prevalence figures, and the proportion of HIV+ persons aware & unaware of their status. We can use these data to estimate the size of each of the sex/age stratum that is HIV-, or is HIV+ but unaware of their status. (Only HIV+ persons that are already aware of their status do not require testing). These data allow us to estimate the proportions of persons 15-59 that need to know their HIV status. This offers a comparator for the client structures actually encountered in various testing modalities from the perspective of HIV status awareness. Since it does not specifically incorporate the variable risk of HIV acquisition for individuals in certain sex-age strata, is does not reflect the frequency of testing required, only the proportions of the population that need to have current knowledge of their HIV status at any point in time at which an enquiry is made. This perspective assumes that knowledge of HIV status is important whether it is negative or positive. Another way to check on the adequacy of an observed client demographic structure would be to evaluate how well it identifies HIV+ persons. This is the focus of a second proposed comparator distribution. [See Annex IV-a and IV-b for details]

Figure 1: Proposed Comparator for Population Needing HIV Testing in KZN



COMPARISON OF HCT MODALITIES: DEMOGRAPHIC REACH

Fixed Sites (FS):

The choice of location influences the client mix. Currently, 2 of the 3 FS (Osborne & Ikhwezi sites) have a client mix that is demographically distinct from that seen at the 3rd (TVET College). The Osborne & Ikhwezi FS see a mixture of adult men and women of various ages, whereas TVET is a college site and sees a predominantly younger population. In the OpenMRS database all FS are coded as one site type such that the demographic differences between different FS cannot be discerned. For the months Sept-Oct-Nov 2015 testing at the TVET fixed site constituted only 12% of the total volume of FS testing, so the sex-age structure of the client population at FS mainly reflects testing at the 2 busiest FS, which are Osborne & Ikhwezi.

The sex-age structure of the client mix tested at FS was calculated for Q3 for each of 2013-2015 and when compared it is essentially the same distribution every year.

Figure 2 a: Female Client Mix at Fixed Sites (2014-15) with Comparator Proportions; each red bar represents the observed proportion of female clients 15-59 years of age (out of the total tested population at FS); each yellow bar represents the proportion suggested by the comparator client mix

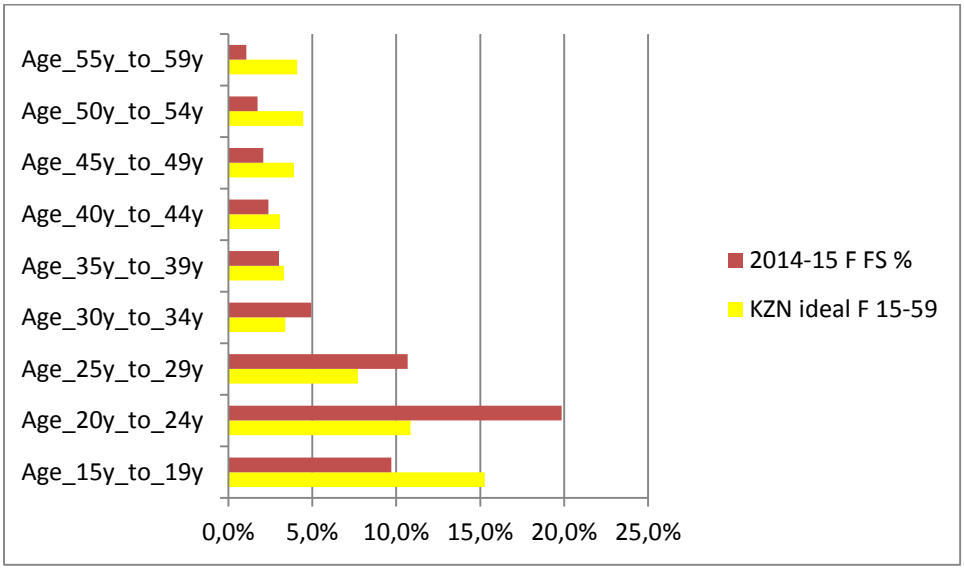
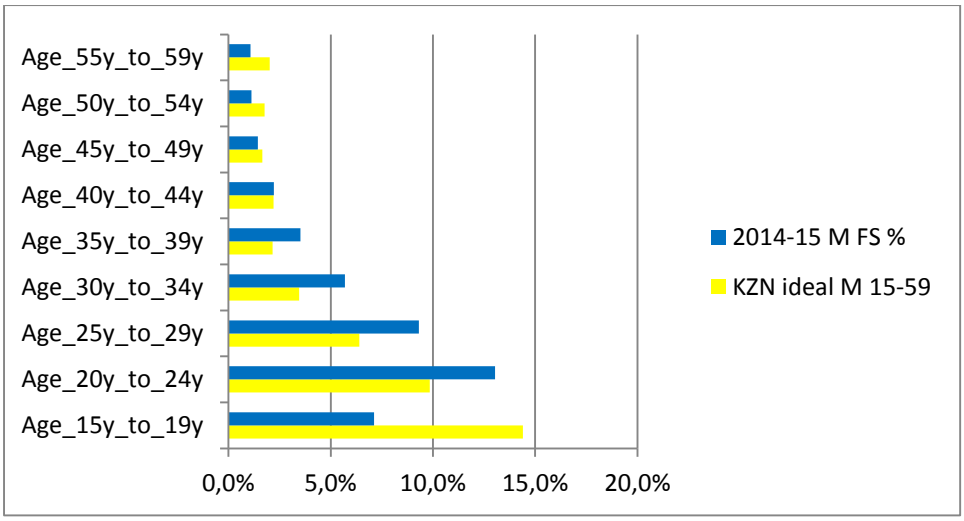


Figure 2 b: Male Client Mix at Fixed Sites (2014-2015) Against Comparator Proportions; each blue bar represents the observed proportion of male clients 15-59 years of age (out of the total tested population at FS); each yellow bar represents the proportions suggested by the comparator client mix



These comparisons indicate that the FS client mix is strongly weighted towards men and women 20-44 and that, overall, these segments are well served through FS services. The youngest strata 15-19 are not fully represented at FS.

Mobile 1-Stop Shops (M1SS):

Demographic variation between various M1SS sites is even more marked than that observed between the FS and this implies that M1SS activities cannot be considered homogeneous but need sub-analysis according to the demographic mix that is attracted to various M1SS sites. OpenMRS codes the 2 most important types of M1SS clearly as CS (Community Sites, such as busy taxi ranks and sites with similar populations of male and female adults of mixed ages) and HS (High Schools, which is self-explanatory). Although HS have a consistent population structure, CS includes some youth-focussed events with a different client structure than one sees at taxi ranks, etc. Only by looking at the client structure for a particular event would this be discerned. That proviso aside, CS and HS coded M1SS sites constitute the largest volume of M1SS activity and, within each category they offer good insight into the client populations tested in M1SS.

Community Sites (CS): The sex-age structure of the client mix tested at CS-coded M1SS was calculated for Q3 of each of 2012-2015. There is some year-to-year variability that because some CS are more youth-focussed than others.

Figure 3 a: Female Client Mix at CS-coded M1SS (2015); red bars are observed proportions, yellow bars are comparator proportions

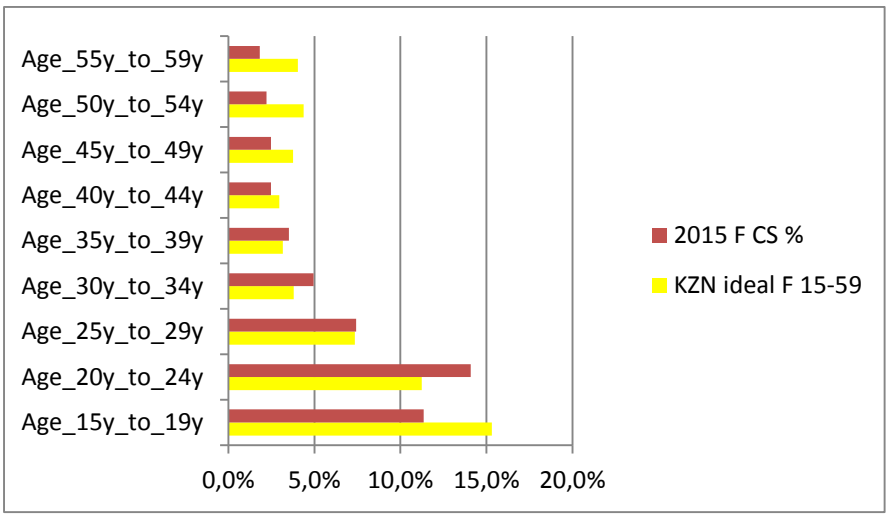
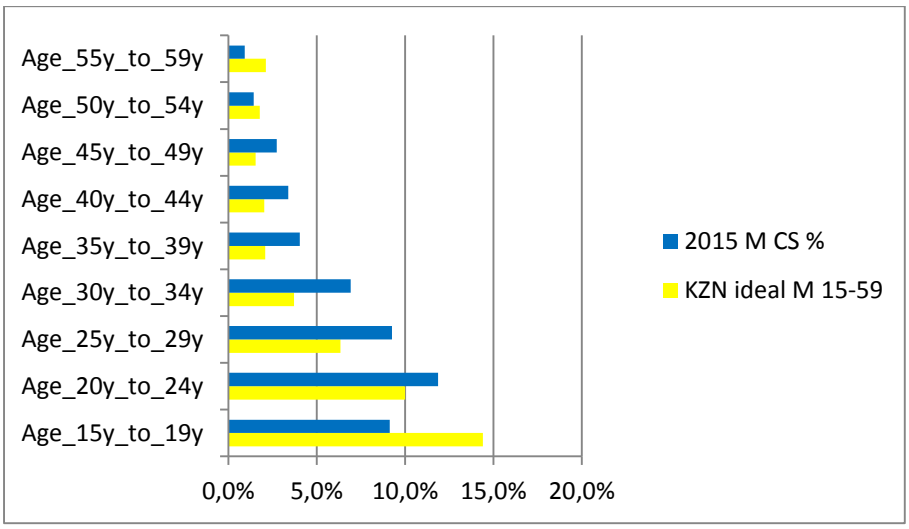


Figure 3 b: Male Client Mix at CS-coded M1SS (2015); blue bars are observed proportions, yellow bars are comparator proportions



In 2015 we can see that M1SS-CS testing reaches most strata of women and men in the 20-44 range but has incomplete representation of the 15-19 years stratum for both sexes.

High Schools (HS): Since M1SS-HS testing occurs in a demographically consistent population, the data for Q3 of 2013-2015 is presented together to illustrate the unique population structure of clients tested at HS locations

Figure 4 a: Female Client Mix at HS-coded M1SS (2013-2015): red bars are observed proportions, yellow bars are comparator proportions

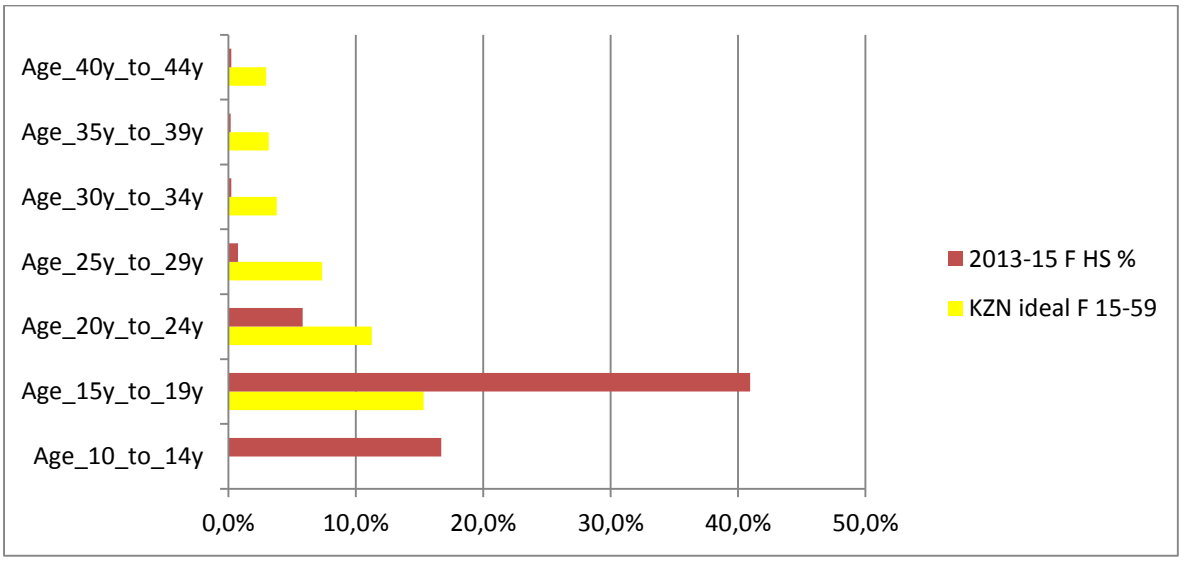
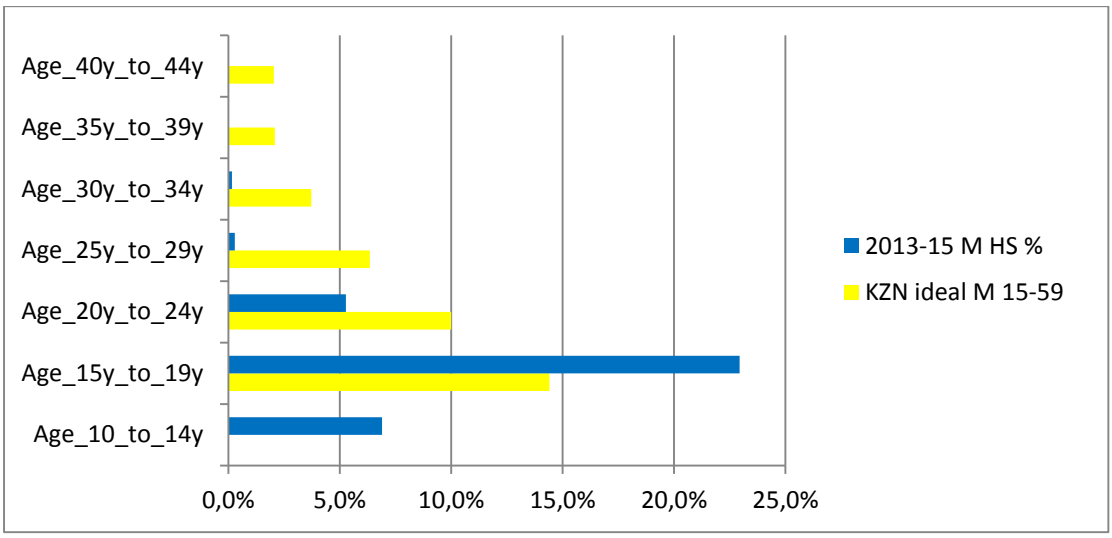


Figure 4 b: Male Client Mix at HS-code M1SS (2013-2015); blue bars are observed proportions, yellow bars are comparator proportions



The client mix for HS-coded M1SS is almost entirely 10-24 years of age, with only occasional testers above this age limit (likely staff or teachers). These are the only M1SS sites that see significant numbers of 10-14 year olds, but this is not a major target group for the identification of HIV+ persons as the prevalence is very low in this age stratum. Figures 4a and 4b illustrate the way in which M1SS-HS locations compensate for the underrepresentation of the youngest age strata in the client mix seen at M1SS-CS sites, or at FS.

In order to illustrate the composite effect of all M1SS activities combined with all FS activities, the overall client mix was calculated and is illustrated next to the comparator proportions in the figures below:

Figure 5 a: Female Client Proportions from all M1SS and FS Combined (2012-2015) with comparator

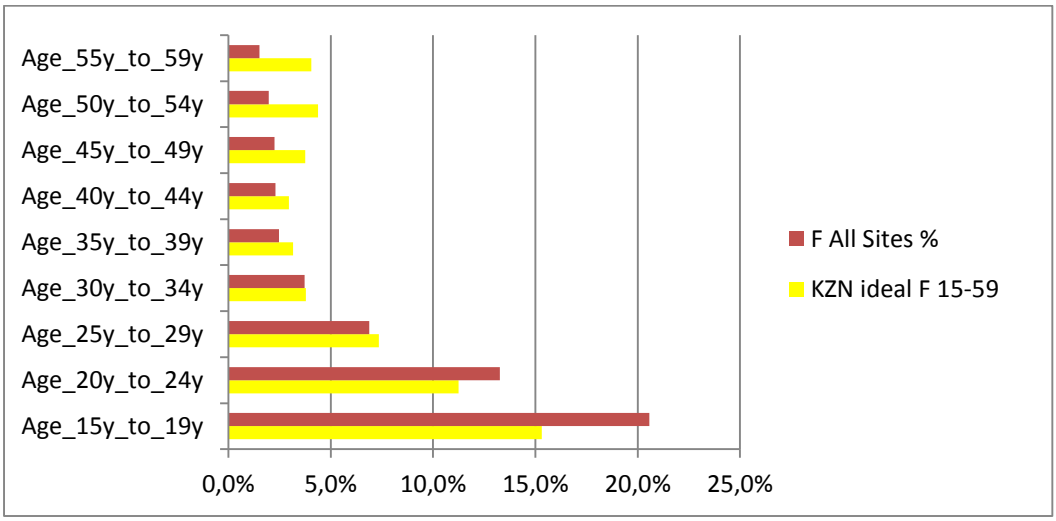
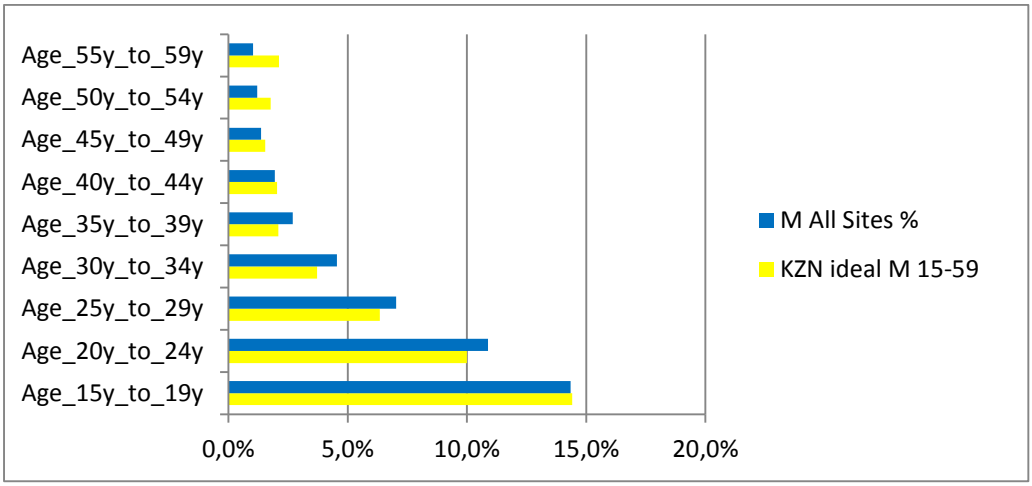


Figure 5 b: Male Client Proportions from all M1SS and FS Combined (2012-2015) with comparator



These composite figures illustrate that the sum of all FS and M1SS testing reaches almost all sex-age strata very effectively, with a particular intensity of testing among younger women.

Door-to-Door (CHAP) Testing:

This modality of HCT is mainly present in rural but also some peri-urban areas of Eshowe & Mbongolowane. The demographic structure of the client population is mainly accounted for by the large rural population encountered and its particular sex-age mix, which is partly related to migration among working-age adults.

Figure 6 a: Female CHAP client proportions (2015) with comparator, restricted to 15-59 year old target group

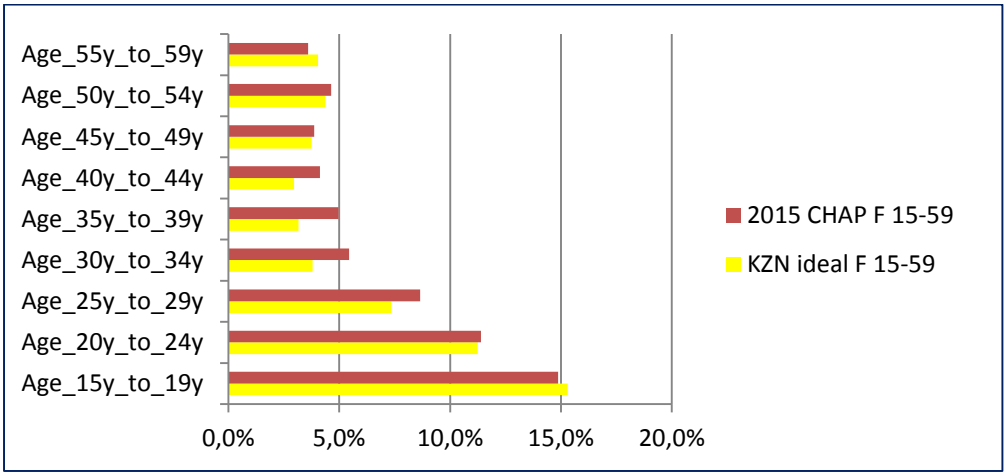
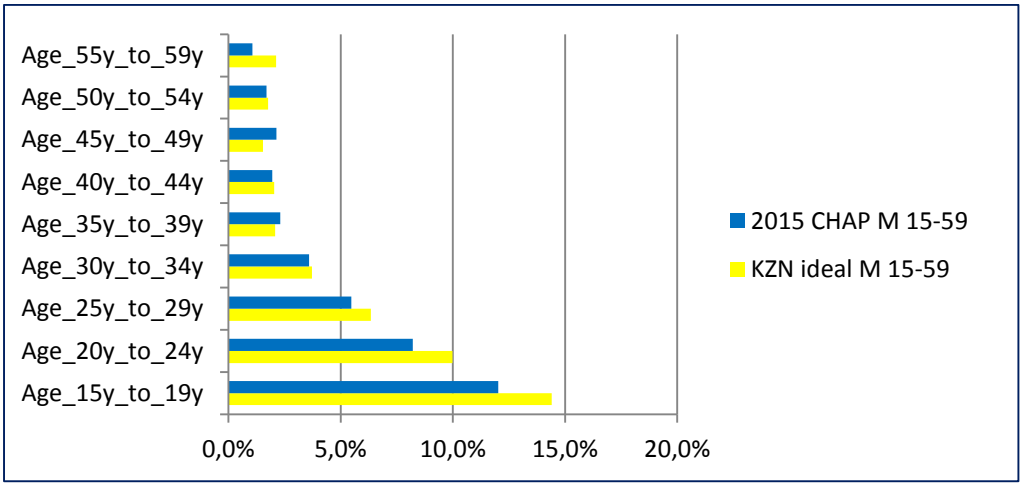


Figure 6 b: Male CHAP client proportions (2015) with comparator, restricted to 15-59 year old target group



These figures show that although women within the target group are well-represented in CHAP testing, younger strata of men are underrepresented.

One of the most striking aspects of the CHAP programme is the relatively large amount of HCT being offered to clients outside the target group of 15-59 years of age. The data indicate that the proportion of total testing outside of the target range now constitutes 40% of total CHAP testing, while children <15 years and adults ≥60 years of age have low HIV prevalence. (The increasing volume of CHAP testing is discussed later and is illustrated in Figure 13.)

Figure 7: Evolution of CHAP testing of children <14 and adults ≥60 years of age (2013-2015)

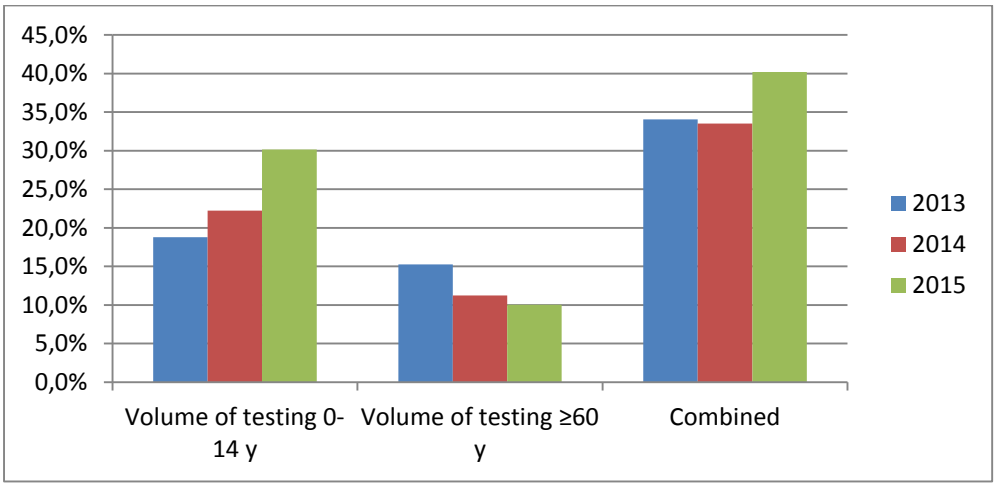
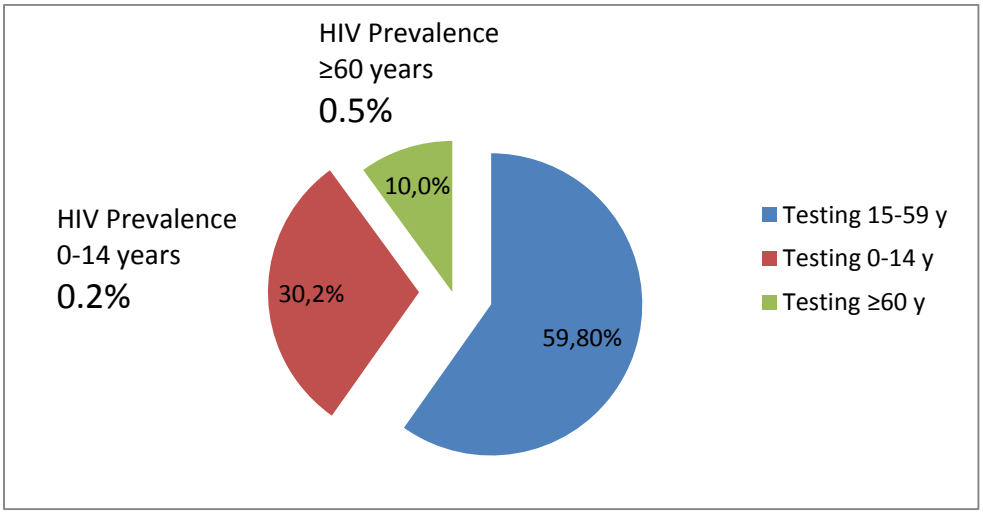


Figure 8: Proportions of CHAP testing (2015)



Health Facility-based HCT:

Data on HCT from the health facilities (HF) in the project area are typically divided into <15 years or ≥15 years of age, but we were able to obtain a more detailed sex-age stratification for the month of November 2015. It is unclear how much month-to-month variation exists in the proportions of clients seen in various sex-age strata, but the data from November 2015 illustrate the client mix seen in HF and they confirm the impression that women of childbearing age are well represented in the client mix whereas younger men are distinctly underrepresented. Note that these data do not include testing done in Antenatal Clinics.

Figure 9 a: Female Health Facility HCT client proportions (Nov 2015) with comparator in yellow

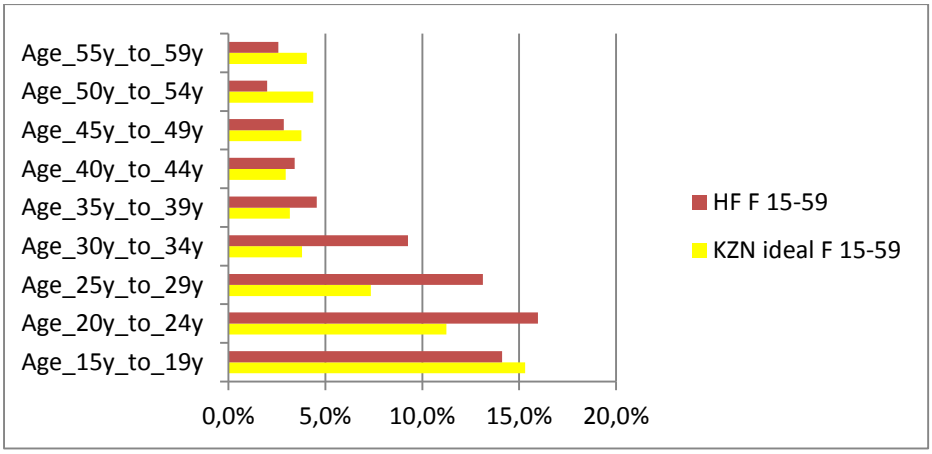
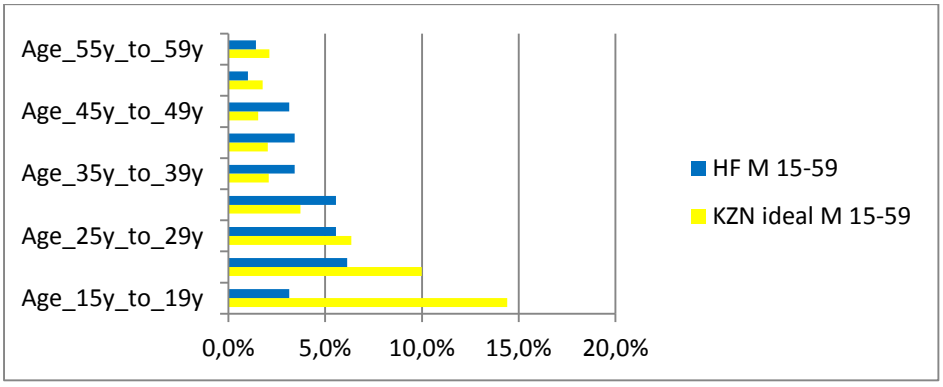


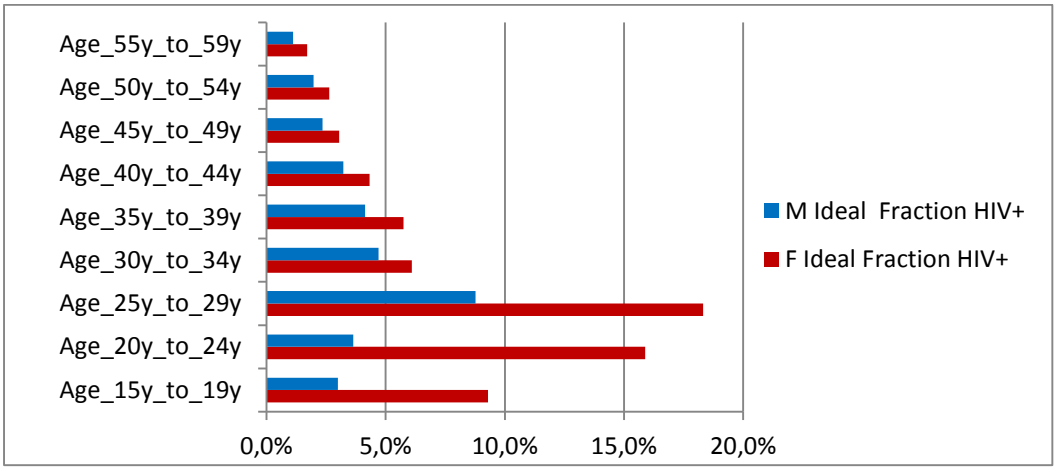
Figure 9 b: Male Health Facility HCT client proportions (Nov 2015) with comparator in yellow



IDENTIFICATION OF HIV+ PERSONS

Although knowledge of one's HIV status is valuable in and of itself (this will be expanded upon in a later section of this report on secondary benefits of testing), we are arguably more interested in the identification of new cases of HIV infection as an essential prerequisite for the individual health and survival benefits, and the HIV epidemiological benefits (treatment as prevention), of ART once patients are linked to care. In order to evaluate the capacity of a testing modality to identify cases, we need a comparator distribution for new HIV+ cases in the population residing in the project area. The expected population distribution of new cases can also be estimated using data from the Epicentre survey on the proportion of HIV+ persons who do not know their HIV status (the effective baseline population that needs to be diagnosed), and the calculated HIV incidence rates for various sex-age strata, also provided by the survey. This permits us to estimate the number of new HIV infections in each sex-stratum per year, which can be added to the baseline figures to yield the number of new cases needing diagnosis at a given interval after the survey. Although we know that the ability of any HCT system to diagnose HIV is imperfect, the comparator structure for the population of HIV+ cases can be used to indicate how close the observed case population structure is to this ideal. The discovery of new HIV+ persons in any HIV testing modality should be occurring in a way that is proportional to the generation of cases. [See Annex IVb for details/ justification].

Figure 10: Proposed Comparator for Distribution of HIV+ Cases Diagnosed in HCT



The Observed Efficiency of Testing Modalities in the Identification of HIV+ persons

The various testing modalities available in the project area offer differing volumes of service, often to different client populations and with different HIV+ prevalence rates among the client populations. Health facilities typically see a more symptomatic population of HIV-infected persons among whom the HIV prevalence can be expected to be much higher than among asymptomatic clients being tested through a community HCT modality.

Table 1: Identification of HIV+ Persons by various modalities of HCT (Sept-Oct-Nov 2015)

	# Tests	# HIV+	HIV Prevalence among tested clients
HF[1]	2121	368	17.4%
HF-*ANC*	551	103	18.7%
FS - Mixed Adults	2361	160	**6.8%**
FS- College	320	11	3.4%
M1SS -CS & similar[2]	1509	88	**5.8%**
M1SS - HS & similar[3]	641	15	2.3%
D2D (CHAP)	11984	103	0.9%
Totals	19487	848	

[1]Does not include ANC
[2]Includes CS (taxi ranks, shopping areas), work sites, farm clinics
[3]Includes HS (high schools), other youth-focused events, youth tested at some MMC events

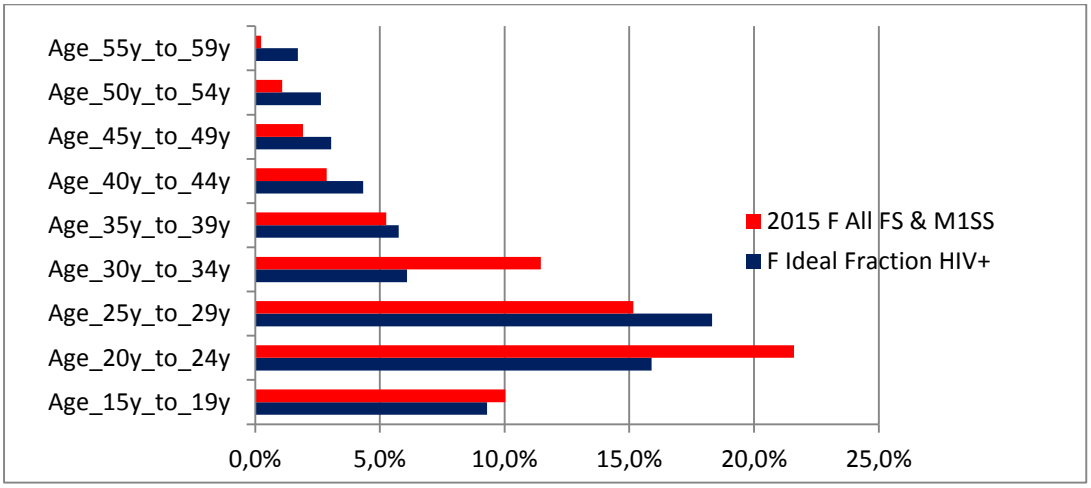
The table above illustrates that health facilities see most symptomatic HIV-infected persons and include many patients receiving provider-initiated HCT; antenatal clinics see a population with very high HIV prevalence in KZN.

FS & M1SS

Among the community testing modalities the highest client HIV prevalence rates are seen among clients at the FS seeing mixed male and female adults with a wide age range (Osborn & Ikhwezi FS), and the M1SS services with a similar client demographic and/or other relatively high risk adults. High school M1SS services and the TVET College fixed site see a much less HIV-exposed population, as reflected HIV prevalence levels that are much lower.

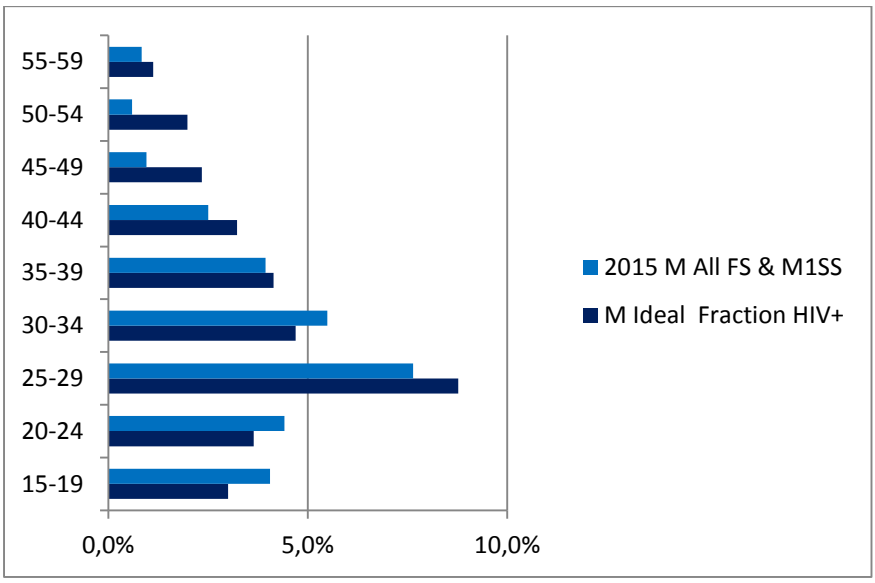
The age-sex distribution of HIV+ cases identified with FS and M1SS HCT was calculated for 2015 and is displayed separately for female and male HIV+ cases with the proposed comparator for the sex-age stratified target case distribution.

Figure 11 a: Distribution of Female HIV+ Cases Identified by the Combination of all FS and M1SS testing (2015)* [red] with comparator [dark blue]



**Data were available for Jan-Mar & July-Nov 2015*

Figure 11 b: Distribution of Male HIV+ Cases Identified by the Combination of all FS and M1SS testing (2015)* [light blue] with comparator [dark blue]



In Figures 11a and 11b the observed sex-age distribution of new HIV+ cases is compared to a very demanding standard (note that the comparator proportions are based on *complete* diagnosis of all unidentified and new HIV cases estimated to be present at the beginning of 2015). These are based on estimates of HIV prevalence, awareness of HIV+ status, and sex-age specific HIV incidence rates all of which have at least moderately large confidence intervals. In particular it should be noted that the estimate of the incidence rate for women was 2.9 cases/100 person-years from 15-29 years of age but only 0.3 cases/100 person-years from 30-59 years of age. This coarse stratification likely reflects a small number of incident cases per category but in reality it is unlikely that incidence drops so abruptly from the 25-29 stratum to the 30-34 stratum for women. This may explain why the actual proportion of female HIV cases in the 30-34 stratum is much larger than the comparator suggested. The comparator describes only the expected sex-age proportions of the case mix, not the absolute number of cases (although this could be estimated with population figures for adults 15-59 in the project implementation area). Nonetheless, these figures illustrate that most of the observed HIV+ cases occur in the sex-age strata where the comparator predicts them. The comparator calculation uses the same HIV incidence rate for all 3 strata between 15 and 29 years of age, whereas in reality there may be some variations in incidence rates from stratum to stratum. The apparent disproportion in the number of new HIV cases in young women (20-24, 30-34) appears to come at the expense of somewhat lower proportions of older women and older men who are proportionately underrepresented in the sex-age mix of new HIV+ cases.

Heterogeneity within the 10-24 year sex-age strata

HIV prevalence among M1SS clients was disaggregated for the adolescent and young adult sex-age strata – including the 10-14 year old stratum not usually included -- according to whether testing was school-associated, or not school-associated, in order to explore differences.

Figure 12 a: Comparison of HIV prevalence among Female Non-School Associated Testers [red] and Female School Associated Testers [orange] (2015)

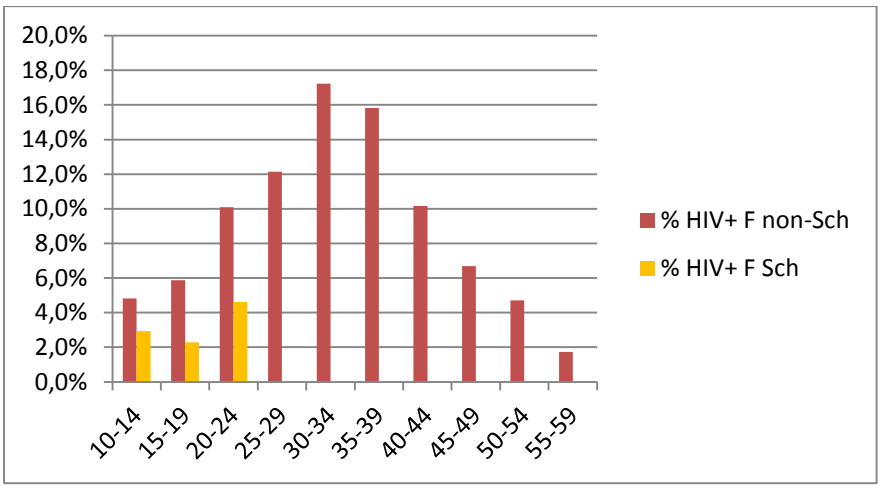
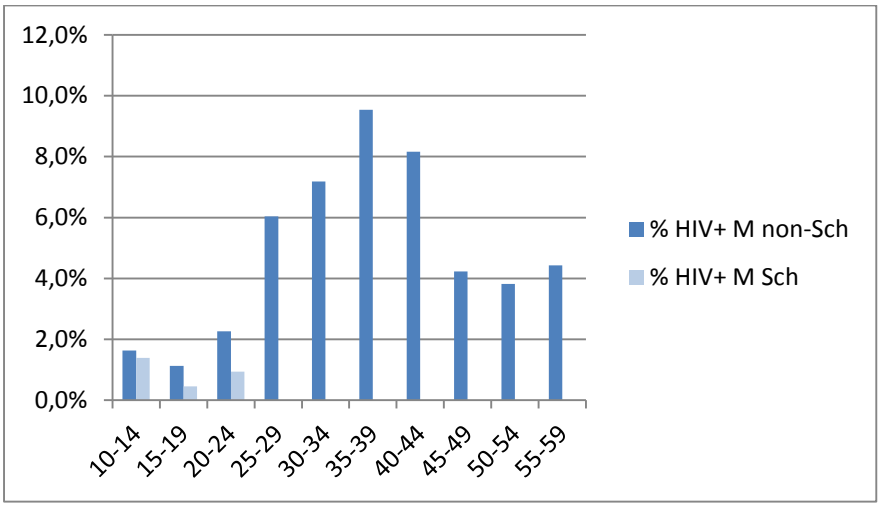


Figure 12 b: Comparison of HIV prevalence among Male Non-School Associated Testers [blue] and Male School Associated Testers [pale blue]



These figures illustrate that there is a divergence in HIV prevalence when school-associated testers are compared to sex-age matched testers who are not school-associated. While it is possible that some students attend other M1SS or FS for HCT this sort of misclassification error would tend to make the groups more alike and would diminish inter-group differences, so this is likely to be a real difference. It implies an association between school attendance and lower HIV prevalence (although it cannot tell us about confounders such as socio-economic status, or about causality).

Door-to-Door HCT (CHAP)

The CHAP program is unique among the community HIV testing modalities in that it has concentrated its efforts on repeated offers of HCT in a relatively stable population (although we do not have precise data on retesting of CHAP clients). Data on testing was reviewed from early 2013 when the programme was fully operational until Nov 2015. Although the total volume of testing performed by CHAP lay counselors has increased over time, the proportion of clients testing positive has overall trended downward over the 3 years of the programme. It is likely that in the first several months of operation of the programme many clients were offered testing for the first time or after a long inter-test interval, so the positivity rate was relatively high (4.6-8.3%) because there was, in effect, a kind of backlog of undiagnosed HIV+ persons in the rural areas. Over time, most of the accessible HIV+ population has been identified

leaving a relatively lower risk population who are being regularly retested and yielding relatively few new HIV diagnoses, considering the large volume of testing being performed.

Figure 13: Trend in CHAP Test volume over 3 years (2013-2015)

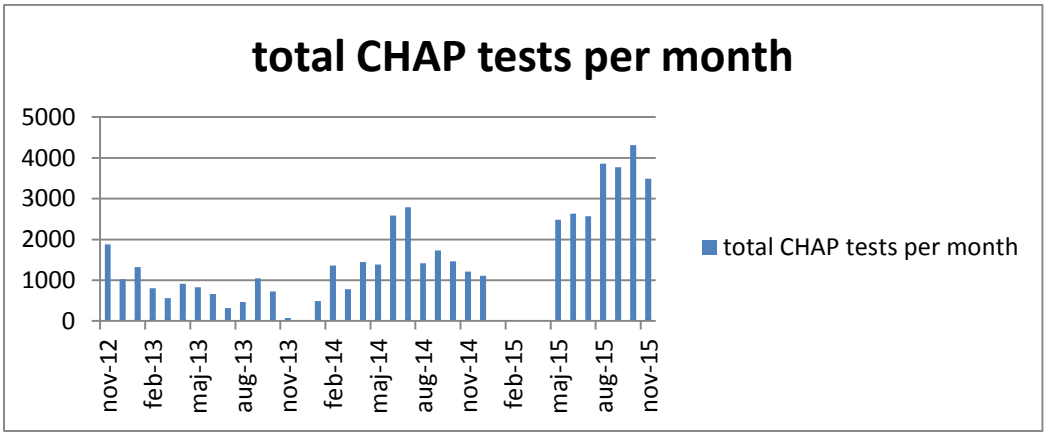
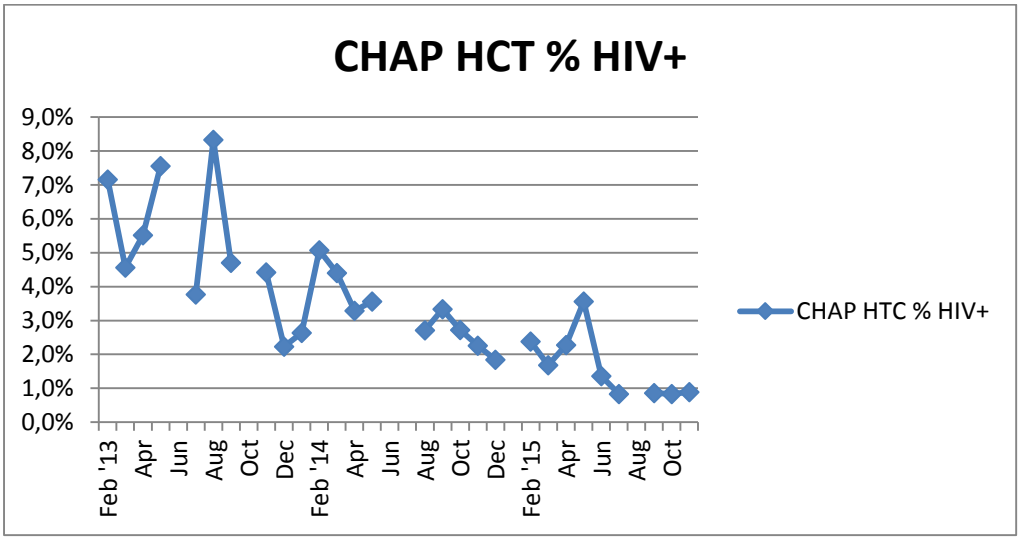
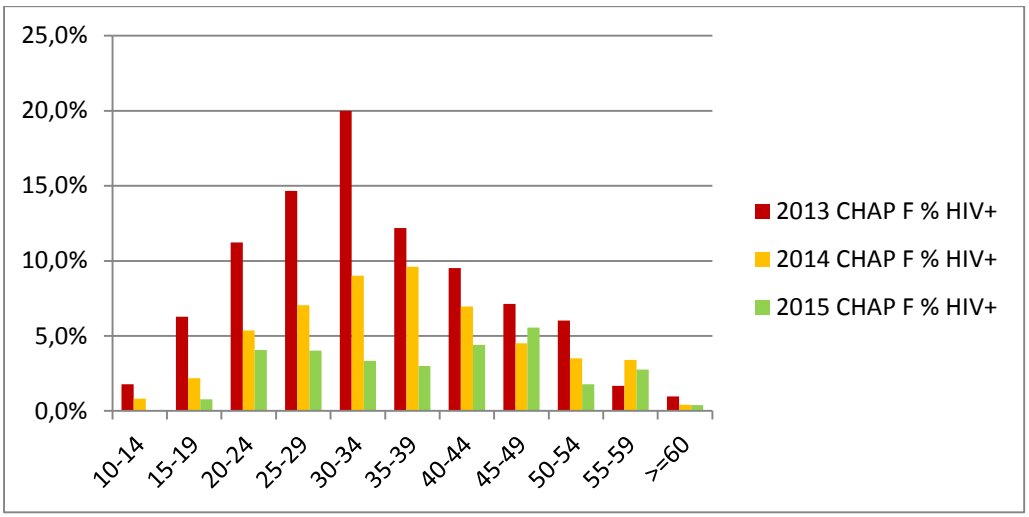


Figure 14: Trend in HIV prevalence among CHAP clients (2013-2015)



The falling HIV prevalence among CHAP HCT clients might be contributed to by the 40% of testing being performed on children < 15 years and adults ≥60 years, among whom HIV prevalence is particularly low. The sex-age specific prevalence was compared for each of the years 2013, 2014 and 2015 (using Q3 data for each year) to examine the trend in HIV prevalence, as illustrated in Figure 15 below.

Figure 15 a: Comparison of sex-age stratified HIV prevalence in 3 successive years of the CHAP program, shown for Female subjects



This clearly illustrates that HIV prevalence among CHAPs clients has fallen dramatically from year to year. This may be due to a combination of factors: removal of the most accessible HIV+ persons from the denominator of all future testing, retesting of persons with relatively low risk of HIV acquisition and saturation of testing over time. This likely also implies relatively limited population movement over time, or at least that most movement is within the project area covered by CHAPs activity. The data for male CHAP clients shows less of a trend but generally low prevalence levels. The absolute case numbers are much smaller so the variability in prevalence between strata may not be significant; the lack of trend may also reflect less overall stability in the male population, with continued introduction of undiagnosed HIV+ males.

Figure 15 b: Comparison of sex-age stratified HIV prevalence in 2 successive years of the CHAP program, shown for Male subjects [2013 omitted due to small n in many strata]

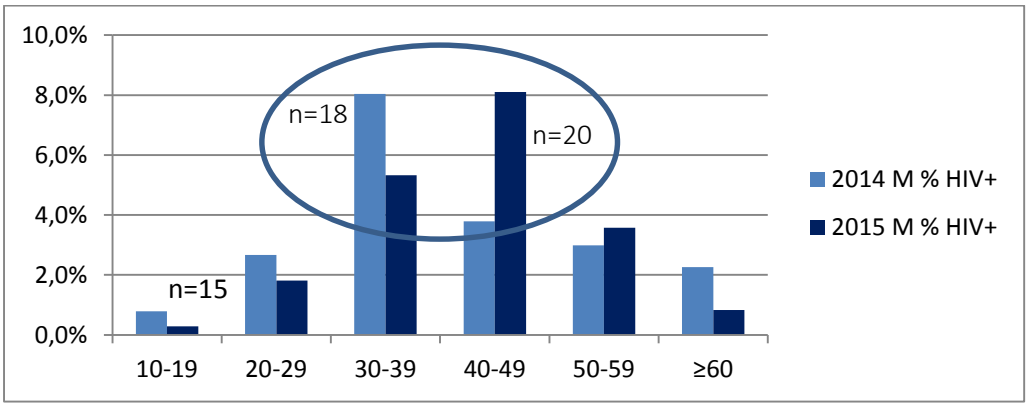


Figure 16 a: Comparison of HIV Prevalence among 2015 Female CHAPs and Non-School HCT clients (FS & M1SS)

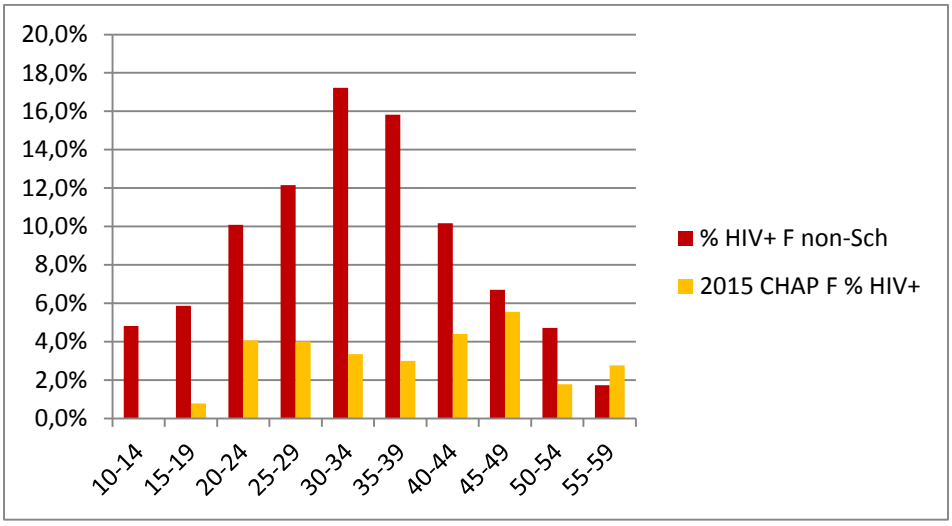
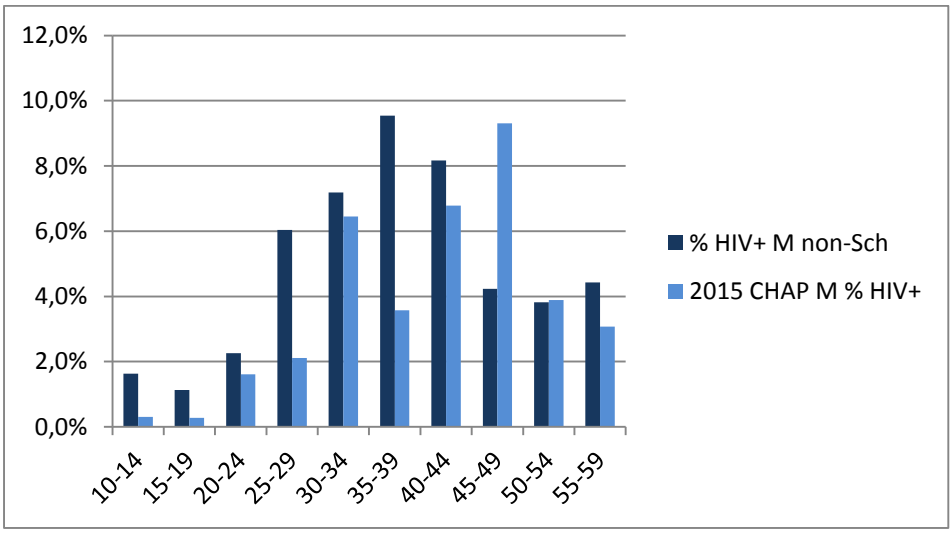


Figure 16 b: Comparison of HIV Prevalence among 2015 Male CHAPs and Non-School HCT clients (FS & M1SS)



Figures 16a and 16b suggest that, among the mainly rural women that CHAPs encounters subjected to intensive offers of testing over 3 years, HIV prevalence is much lower than among the more mobile, urban and peri-urban women being tested in FS & M1SS locations. The comparison is less striking for men with considerable stratum-to-stratum variation among male CHAPs clients and male Non-School associated testers. This may also reflect less demographic difference between these male populations, due to greater mobility and less saturation of testing due to lower degree of consistency of the male population seen by CHAPs.

TESTING INTENSITY: INTER-TEST INTERVALS

One of the expectations of enhanced availability of HIV testing opportunities is that the proportion of persons reporting no previous HIV test would decrease, and the interval between the current HIV test and the previous HIV test (inter-test interval, ITI) would decrease. Clients from FS/M1SS sites and CHAP clients self-report the interval since their last HIV test (or if there was no previous HIV test). Although these intervals cannot be independently verified they offer some indication of testing intensity over time.

FS/M1SS Clients

The proportion of FS/M1SS clients reporting no previous HIV test was 28%, 18% and 23% in Q3 of 2013, 2014 and 2015, respectively. These figures should be interpreted with caution though, since the proportion of clients for whom the response was 'unknown' was 0%, 12% and 18% for Q3 of 2013, 2014 and 2015, respectively. (Sex-Age stratification was not provided for the population reporting no previous test).

The median ITI for FS/M1SS clients 15-59 shows no clear variation with age stratum; the weighted (by number of observations) median ITI and the 3rd quartile ITI for the past 3 years are shown below.

Table 2: Median and 3rd Quartile inter-test intervals (in days) for FS/M1SS clients over 3 years

	Male median ITI	Female median ITI	Male 3rd quartile ITI	Female 3rd quartile ITI
Q3 2013	227	238	407	387
Q3 2014	330	339	576	574
Q3 2015	234	207	395	338

The ITI was longer for males and females in 2014 than either 2013 or 2015 but it is not clear what this means. It may be some artefact of recording previous test dates, or it could reflect new testing services in 2014 for persons with relatively limited prior access to HIV testing opportunities (although this is at odds with the low fraction reporting no previous test in 2014).

CHAP Clients

The proportion of CHAP clients reporting no previous test was 26%, 25% and 20% in Q3 of 2013, 2014 and 2015, respectively. Only a small fraction of clients had 'unknown' previous test information so these data appear more reliable than those for FS/M1SS clients. The reduction over time in the fraction of clients reporting no previous test is also consistent with data presented earlier, documenting the increased intensity of HIV testing (regular offers of repeat testing) among the relatively stable CHAP client population.

Table 3: Median and 3rd Quartile inter-test intervals (in days) for CHAP clients over 3 years

	Male median ITI	Female median ITI	Male 3rd quartile ITI	Female 3rd quartile ITI
Q3 2013	198	217	400	409
Q3 2014	276	261	512	499
Q3 2015	215	212	343	336

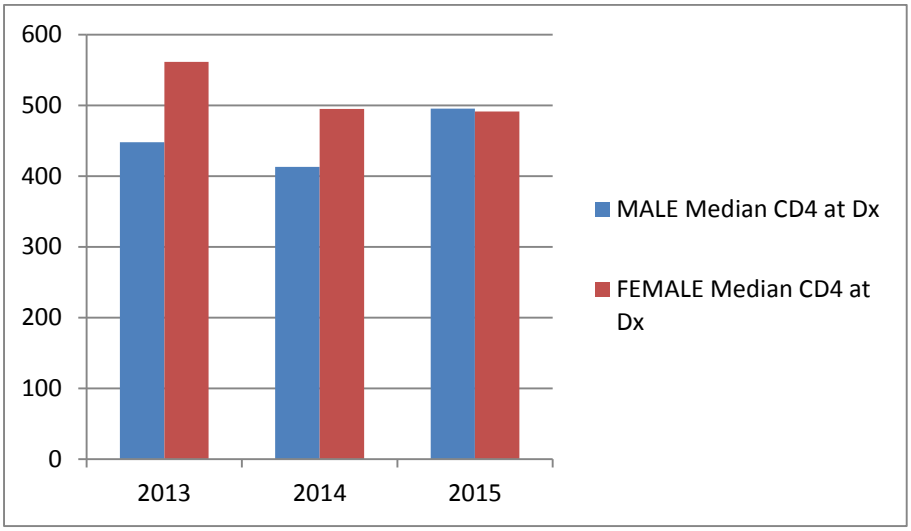
These data suggest that in 2015 median and 3rd quartile ITI is similar for male and female CHAP clients, and that those ITI are overall similar to the ITI seen for FS/M1SS clients. Year-to-year trends again show the (unexplained) increase in 2014 but for CHAP clients in 2015 the ITI are distinctly lower than in either of the previous years sampled. That reduction of ITI in 2015 is consistent with increasing testing intensity for CHAP clients over time.

Although ITI for male and female CHAP clients is generally similar over most age strata (not shown) the ITI in 2015 are particularly short for the age strata 5-9 and 10-14 years of age (even 3rd quartile ITI ranges from only 248-274 days for these strata) while almost all of these children will not yet have had sexual debut. This is consistent with over-testing of young children noted in earlier sections of this report.

TARGETING IMMUNOCOMPROMISED HIV-INFECTED PERSONS

We are interested in the extent to which any of the HIV testing modalities can diagnose HIV among patients with greater than average degrees of immunosuppression, since they should receive priority for rapid clinical assessment (to screen for TB and other opportunistic infections) and urgent ART initiation. For 2 of the community testing modalities, FS & M1SS, CD4 counts are usually provided on-site during the diagnostic visit.

Figure 17: Median male and female CD4 [PIMA] at FS & M1SS HCT diagnosis [Q3 data, 2013-2015]



These data do not show a clear trend in the median CD4 count at diagnosis but these median values are all high – clients at this level would likely be asymptomatic. Women typically have CD4 counts about 20% higher than males (in any population). The data were further disaggregated to characterize the lower CD4 end of the client spectrum.

Figure 18 a: CD4 Counts among Female FS/M1SS clients at HIV diagnosis

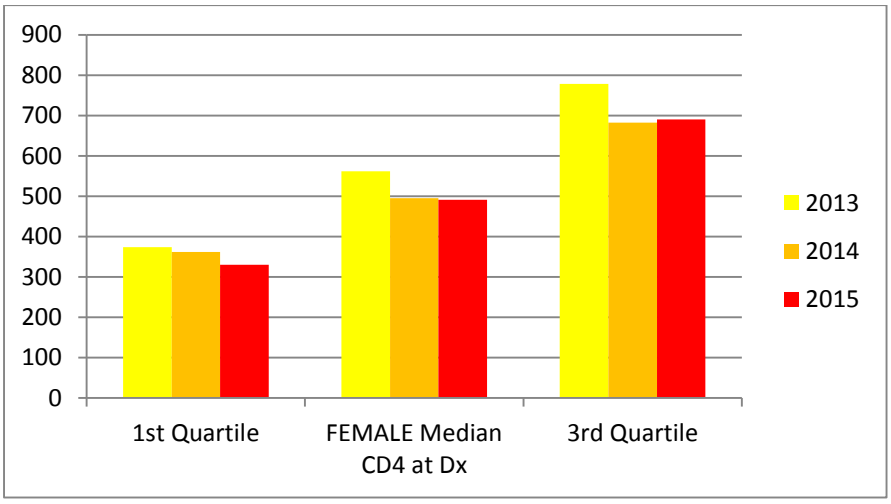
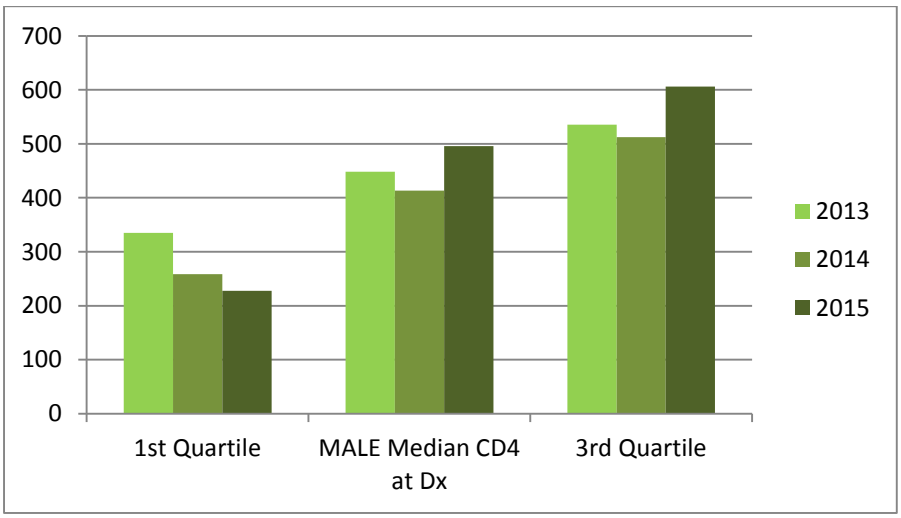


Figure 18 b: CD4 Counts among Male FS/M1SS clients at HIV diagnosis



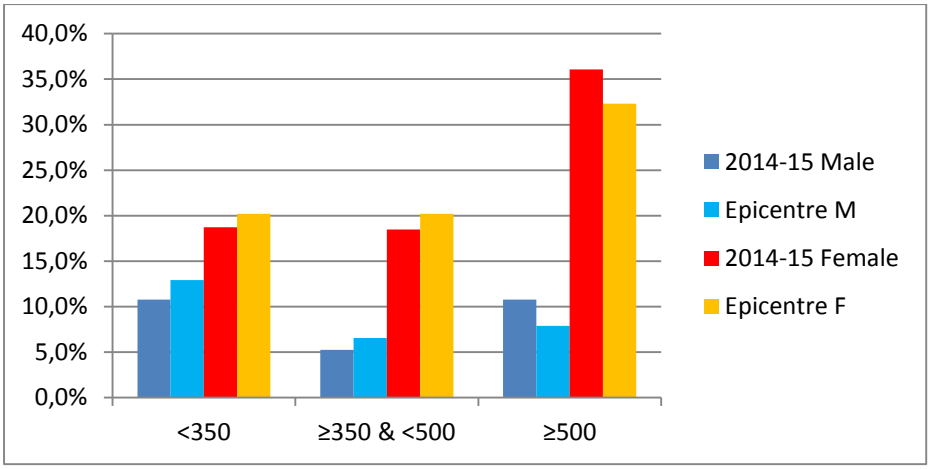
These figures illustrate that somewhat less than ¼ of newly diagnosed HIV+ women have CD4 counts <300 cells/microliter, whereas newly diagnosed HIV+ males subjects in the lowest quartile have CD4 counts that are often <200 cells/microliter. Men are thus more likely to have symptomatic HIV disease and/or opportunistic infections.

The proportion of newly diagnosed HIV+ FS/M1SS clients with CD4 <200 cells/microliter is shown below (Table 4); these data are from Q3 of 2013, 2014 and 2015 and although the n is small the same trend that is seen in Figures 18a and 18b is evident. This may reflect increasing availability of testing to persons with relatively advanced disease that have hitherto avoided testing; the increasing coverage of newly diagnosed clients with CD4 counts might be identifying a larger number of individuals at the extremes of the CD4 count distribution.

Table 4: Proportion of FS/M1SS diagnosed HIV+ Males & Females 15-59 years with CD4 <200, 2013-15

	MALES				FEMALES			
	Total HIV+	CD4 done	CD4 <200	% CD4 <200	Total HIV+	CD4 done	CD4 <200	% CD4 <200
Q3 2013	118	67	6	9%	226	94	7	7%
Q3 2014	84	47	6	13%	200	123	12	10%
Q3 2015	73	50	10	20%	183	143	18	13%

Figure 19: Comparison of observed CD4 counts at diagnosis and the population distribution of CD4 counts among HIV+ individuals not on ART (from the Epicentre survey)



This figure illustrates that very similar proportions of newly diagnosed male and female HIV-infected persons are found in the tested population compared to the overall CD4 distribution found in the overall population of untreated HIV-infected persons. This implies that FS and M1SS testing modalities attract an HIV+ client population which is neither more nor less immunocompromised than the overall population of untreated HIV+ persons.

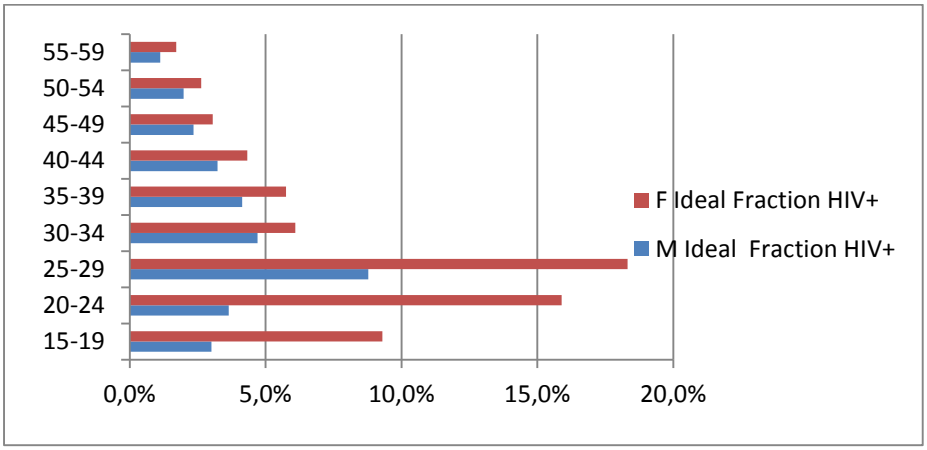
LINKAGE TO CARE

For this evaluation we have access to data that describe the population of patients registering for HIV care (pre-ART or ART care, depending on ART eligibility) but there are no available patient-level data on linkage between HIV testing and HIV care. Nonetheless we may infer something about linkage by comparing the characteristics of tested populations and the characteristics of populations registered for HIV care (as found in TIER.net, the Department of Health HIV care database). A comparison of the sex-age stratified client structure found among newly diagnosed HIV+ clients and TIER.net registrants is offered; this is followed by comparison of the spectrum of immunosuppression found in tested and treated patients.

Client population structures

The sex-age stratified proportions of the HIV+ case population needing diagnosis were proposed earlier, based on survey data on the estimated numbers of cases unaware of their HIV+ status, and estimates of HIV incidence in various sex-age strata (see also Annex IV b, for derivation). With the proviso that the incidence rate differences between some adjacent sex-age strata are likely to have wide confidence intervals, this case population structure offers a starting point. This comparison *cannot estimate the volume of linkage* (since that would require data on the timing of testing and the interval between testing and registration in TIER.net – which we do not have), only the relative sex-age proportions in the population successfully linked can be illustrated.

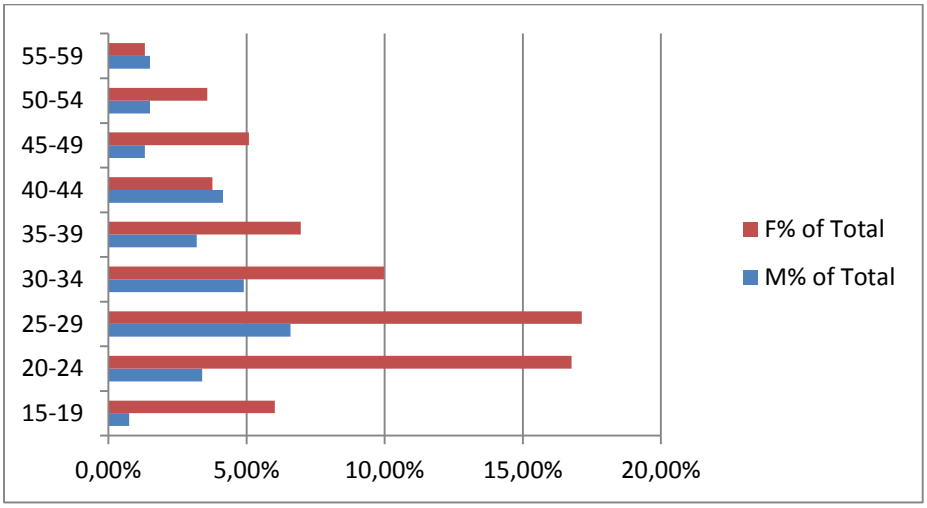
Figure 20: HIV+ Client population structure in 2014 suggested by Epicentre Survey (2013) for females (red) and males (blue); the sum of all proportions equals 100% of HIV+ persons 15-59 years of age.



Note that the apparently large step down between females 25-29 and 30-34 is likely an artefact of the way HIV incidence was estimated (calculated for 15-29 as one group and 30-59 as another group).

The actual HIV+ client population structure for new registrants in TIER.net for 2014 & 2015 (based on a data export on 18 Dec 2015) is illustrated below

Figure 21: New HIV+ registrants in TIER.net in 2014/15; client population structure



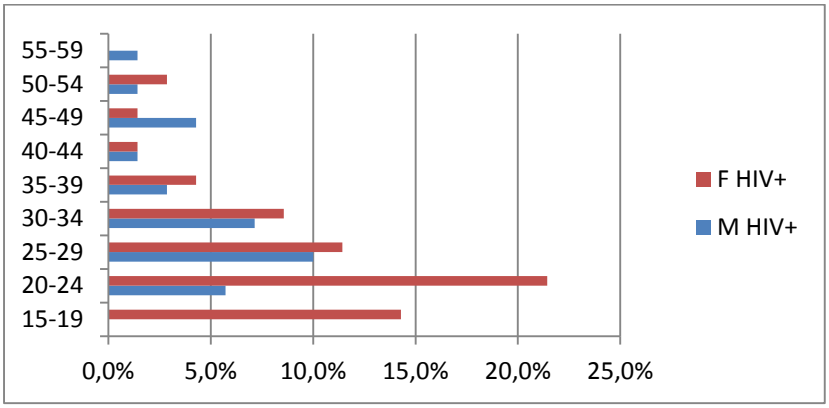
Comparison of the 2 client sex-age structures shows some overall similarities but a few differences are also apparent: the actual distribution of TIER.net registrants suggests that young men and women 15-19 are under-represented and that men 45-59 are relatively underrepresented, in comparison to the predicted proportions. The differences for women 30-34 and 35-39 are likely to be at least partly artefactual (related to the limits of the HIV incidence estimates, as noted above).

Ideally, we would like to assess the effectiveness of linkage between specific modalities of HIV testing to HIV care and treatment. The TIER.net database codes new registrants as having been referred from FS/M1SS or CHAP (door-to-door, D2D) testing. This allows for a comparison of the HIV+ client structure derived from testing records and that derived from TIER.net for the respective testing modality. Most new HIV+ diagnoses from M1SS come from 'commercial sites' (CS-coded) and their clients are demographically very similar to those seen at FS, so M1SS-CS data illustrate both.

M1SS clients

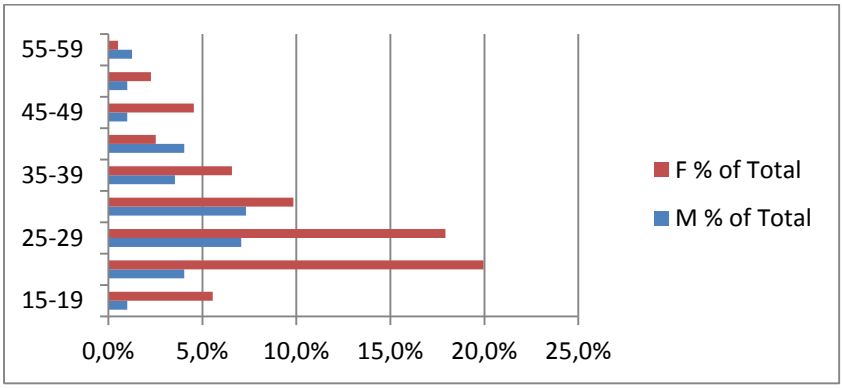
The distribution of new HIV+ cases diagnosed through M1SS testing provides a baseline from which to assess the appearance of M1SS-tested persons as TIER.net new registrants.

Figure 22: Persons testing HIV+ at M1SS-CS sites; Q3 2014 client population structure



Extracting data for new TIER.net registrants whose modality of testing is indicated as M1SS provides proportions of the linked population of M1SS-tested HIV+ persons.

Figure 23: Actual HIV+ TIER.net registrants referred from M1SS sites; 2014/15 client population structure

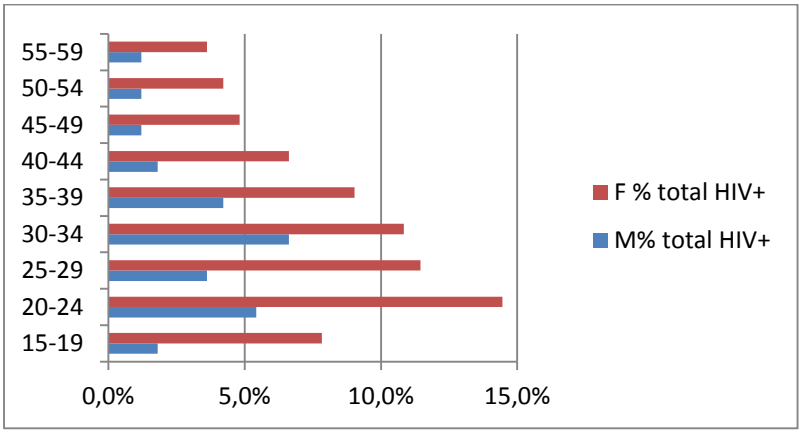


The most striking difference is the apparent low proportion of registration of HIV+ women 15-19 in the HIV care and treatment system, given what M1SS testing data describe; there may also be failures of linkage for men 20-24 and 25-29.

CHAP Clients

The distribution of new HIV+ cases diagnosed through CHAP testing provides a baseline from which to assess the appearance of CHAP-tested persons as TIER.net new registrants

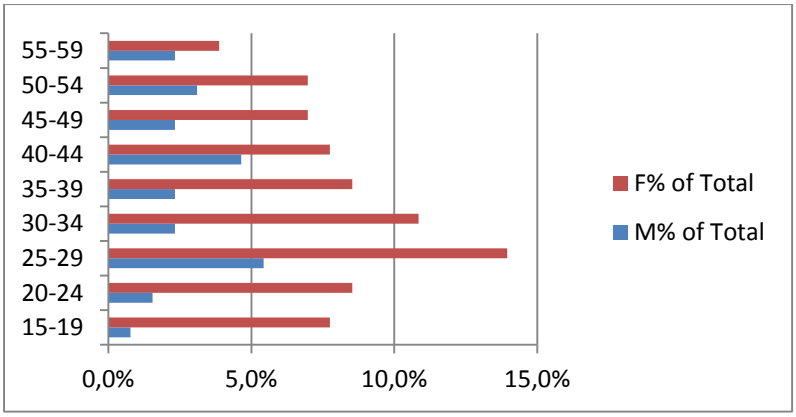
Figure 24: Persons testing HIV+ through CHAP testing; Q3 2014 client population structure



This illustrates the predominance of women among the newly diagnosed (72%) but the less striking predominance of younger women in the case distribution (compared to M1SS) may reflect that even by 2014 the prevalence of HIV among women tested by CHAPs had fallen markedly over earlier levels (illustrated earlier in Figure 15 a).

The client population structure in the figure above can be compared to the following one:

Figure 25: Actual HIV+ TIER.net registrants referred from CHAP testing; 2014/15 client population structure



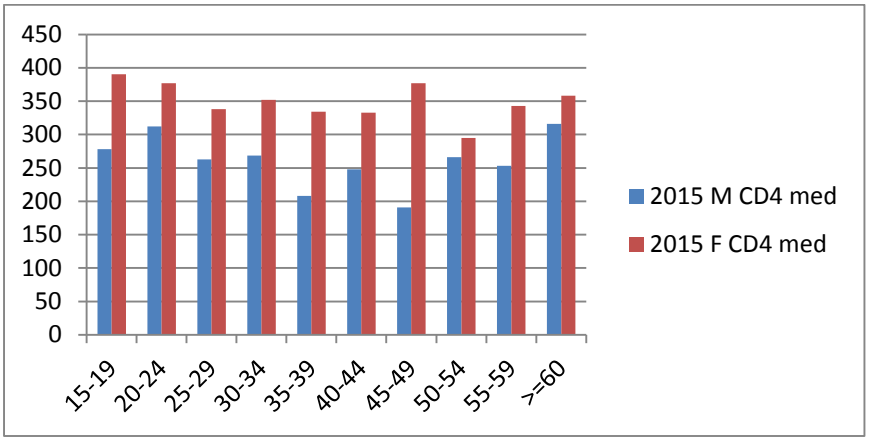
When comparing the same sex-age strata between the 2 distributions (tested versus registered for care) there appears to be a relative underrepresentation of young men 15-19 and 20-24, and of young women 20-24, among the population registered for HIV care and treatment (in TIER.net).

Immunosuppression among patients initiating ART at Health Facilities

The evolution of the median CD4 count among patients initiating ART over the past 4 years shows a predictable difference between median CD4 of men and women (typically 20% higher in women), and a gradual increase in the median CD4 which may reflect earlier diagnosis related to more frequent HIV testing opportunities, and the effect of ART initiation at progressively higher CD4 counts as the WHO guidelines have evolved and been adopted nationally.

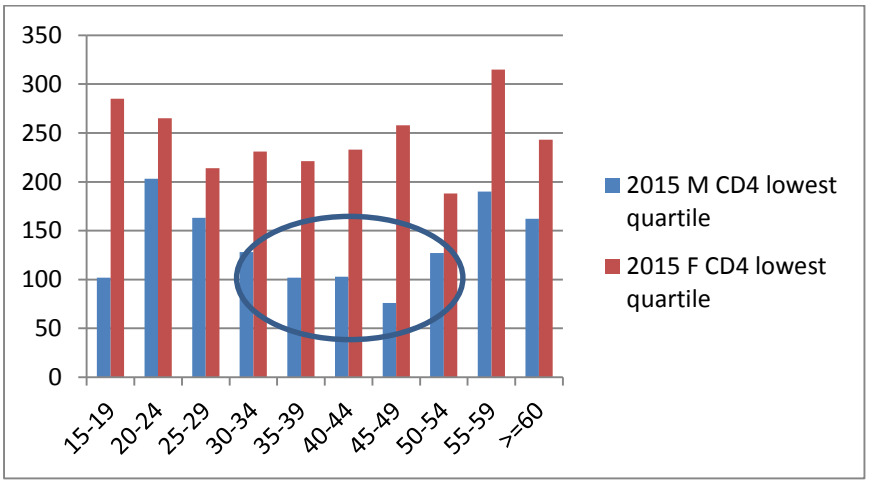
Figure 26: Median CD4 count among patients linking to care at HF [Q3 data for all HF combined, over 4 years]

Figure 27: Median CD4 counts by sex and age strata (2015 Q1 to Q3 combined)



The literature tells us that there is no relationship per se between CD4 and age; median CD4 is >300 cells/microliter for almost all women initiating ART whereas for men it is often 200-250. The following figure illustrates the lowest quartile of CD4 counts among male and female ART initiators. This shows greater divergence between values for females and males, with at least 4 age strata for men associated with CD4 counts of 100 or less – putting them at an elevated risk of poor outcomes related to TB, other opportunistic infections. The data may indicate that middle-aged men (35-54 years of age) link to care later, possibly related to delayed diagnosis.

Figure 28: Lowest Quartile CD4 counts by sex and age strata (2015 Q1 to Q3 combined)



Another complementary way to look at the distribution of CD4 counts among patients referred to HF for ART initiation is to note the proportion of men and women with a baseline CD4 count <200, <100 and <50 cells/microliter.

Figure 29: Proportion of baseline CD4 counts that are <200, <100, and <50, for **Males** registering at HF for ART, based on Q3 data for 2013-2015

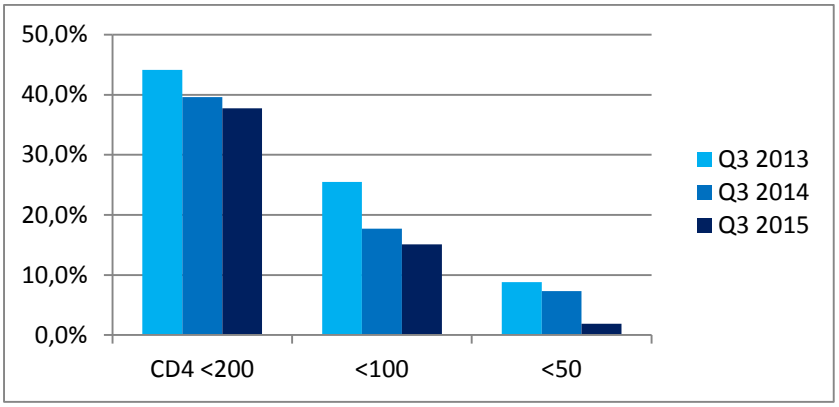
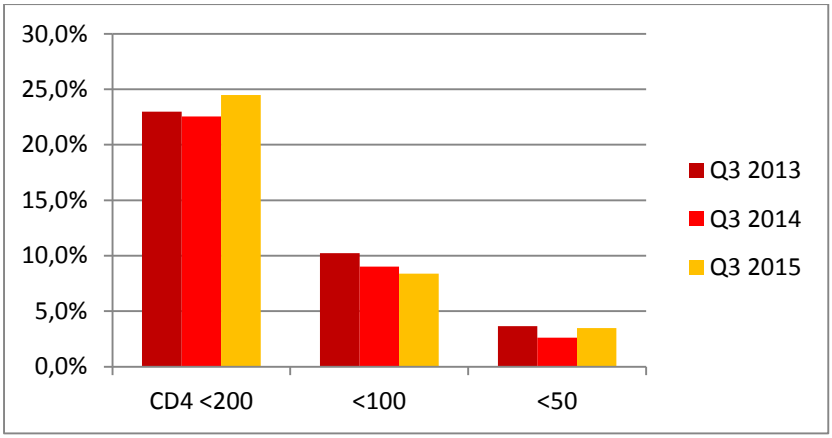


Figure 30: Proportion of baseline CD4 counts that are <200, <100, and <50, for **Females** registering at HF for ART, based on Q3 data for 2013-2015



The substantially lower CD4 counts seen among patients, particularly males, initiating ART compared to those diagnosed at FS & M1SS HCT locations may imply 2 things about HIV+ men:

- A sub-population of HIV+ men may be avoiding HCT until they experience serious illness or disabling symptoms; they may come to HIV diagnosis through HF-based HCT and are likely to have lower than average CD4 counts, pulling down the overall distribution of CD4 counts among ART initiators.
- Men may be diagnosed with HIV infection months or years before but less likely to link to care when they do not have symptoms of illness; they may wait for symptoms to arise before being motivated to seek treatment with ART. This would also lower the median CD4 of the pool of ART initiators.

Trends from 2013 to 2015 suggest that there may be some diminution in the proportion of males with very low CD4 counts at the time of presentation for ART. Although the proportion of women with low CD4 counts is consistently smaller than for men, there appears to be no real change from year to year. Increasing the accessibility of HIV testing may mitigate some of the effects of psychosocial factors related to delayed presentation for ART, but physiological factors relating to rapid disease progression amongst a minority of HIV infected persons may mean that severe

immunosuppression is inevitably found among some persons presenting for ART, regardless of improved access to HCT.

BENEFITS OF HIV TESTING – APART FROM LINKAGE TO CARE FOR HIV+ PERSONS

Inquiry was made regarding the following potential benefits of HIV testing; there are very limited project data available to quantify any of the potential benefits, but relevant literature is cited.

Screening and linkage for non-HIV diseases

Non-communicable diseases (hypertension HT, diabetes mellitus DM): no activity. In a multi-disease screening campaign (HIV, HT, DM) in Uganda associated with the SEARCH Collaboration, 4323 residents (63% of total) were screened in just 12 days (Chamie,G. 2014;). Later work by the same group showed 83% linkage to care within 6 months for hypertensives diagnosed at screening(Kotwani,P. 2014;) .

TB screening: all community testing modalities screen for TB with questions about the 4 cardinal symptoms (cough, fever, night sweats, weight loss). Anecdotally, this is practiced inconsistently and instead of using 'any cough' personnel inquire about 'cough >2 weeks' – which unfortunately decreases sensitivity for a small increase in specificity—staff should screen for 'any cough'. Sputum specimens must be submitted at a HF, which may prove to be a disincentive for some patients. During Sept-Oct-Nov 2015, FS/M1SS performed 4831 HIV tests and in the same time period sent 48 TB suspects (1%) for sputum examination. There are no available data on completion of sputum testing or results.

STI screening: FS and M1SS clients are questioned about STI symptoms but no specific diagnostics are available at testing locations. A referral to a HF is necessary to complete the evaluation or obtain treatment, except for farm clinics where syndromic treatment is offered. No data were available on completion of the referral process or on treatment.

Other: pregnancy testing is available at some FS and through M1SS testing. One of the FS (Osborn) appears to be known for pregnancy testing and that there is substantial demand for it: in Sept-Oct-Nov 2015 this site alone provided almost 14% (151/1109) of its total registered clients (not all of whom are women) with pregnancy testing, suggesting that if appropriate facilities were available elsewhere the uptake of pregnancy testing might be greater. All other FS/M1SS together performed only 42 pregnancy tests during the same calendar period. Referral to ANC/PMTCT is made for those with positive pregnancy tests.

HIV testing of sexual partners & children

Identification of discordant couples: Ideally discordant HIV+ persons should be offered immediate ART (as per WHO guidelines) but this is not yet practiced in South Africa; risk reduction for uninfected sexual partners would be important. HIV+ spouses or other HIV+ family members would ideally be linked to care as well as the index HIV+ person; there are no available data on any of these issues.

Literature suggests that disclosure of HIV status among adults in KZN is particularly low: 34.1% overall, 50% in stable relationships (Abdool Karim,Q. 2015;). A systematic review suggested that either supervised or unsupervised self-testing for HIV was associated with greater likelihood of partner self-testing (Pant Pai,N. 2013;) although much of the evidence came from well-resourced contexts., so its applicability in KZN is questionable.

Enhanced HIV prevention among HIV-

HTC appears to be protective against HIV acquisition in youth; 41% reduction in HIV incidence, sustained 4.5 years, despite greater risk; thought possibly due to less well-established sexual patterns among youth (Rosenberg,N.E. 2013;).

Uptake of VMMC: most MMC occurs *after* sensitization activities; HTC is a pre-condition for MMC. VMCC appears to be chosen after initial HTC decision only in a small minority of cases.

PrEP: This is not yet available in KZN, South Africa (in the public or NGO sector).

Condom use: Condom distribution has taken place throughout the life of the project but there are no data on who is using condoms or in which geographic areas they are being used. Couples counseling in Uganda was associated with increased condom use and reduction in sexual risk behaviors among men (King,R. 2015;}.

Partner number reduction: A Cochrane systematic review and meta-analysis of HIV-related risk behavior and HTC in developing countries found that the odds of reporting an increased number of sexual partners were reduced (OR 0.69) for persons who had HTC compared to those who had not (Fonner,V.A. 2012;). There was no evidence increased sexual risk taking associated with ART roll-out in KZN; and some increases in protective behaviours (McGrath,N. 2013;).

Enhanced HIV prevention among HIV+

Partner number reduction: The same meta-analysis cited above found partner reduction for HIV+ as well as HIV- persons (Fonner,V.A. 2012;).

Condom use increase: HTC was associated with increased condom use among HIV+ persons (but not HIV- persons) (Fonner,V.A. 2012;).

Increased disclosure to sexual partners: This was reported among HIV+ on ART in South Africa (Abdool Karim,Q. 2015;).

CONCLUSIONS

PERFORMANCE OF HIV TESTING MODALITIES

The analysis of HIV testing modalities demonstrates that each makes particular contributions to the entire system of community-based and health facility-based HCT. Although there is some overlap in the populations tested by different modalities, there are also unique features and particular demographic advantages to each. Furthermore, there are good arguments in favour of overlapping testing opportunities for some groups, particularly women 15-29 years of age who have a disproportionately higher HIV incidence rate compared to any other demographic sector.

A systematic review and meta-analysis of community-based HTC increased uptake and over HF-based HTC and increased HTC coverage (risk ratio 7.07), including a higher proportion of first-time testers and of HIV+ persons with CD4 >350 cells/microliter (Suthar,A.B. 2013;).

FS & M1SS Testing

HCT provided at FS or M1SS sites can be considered as variations of a single modality of testing, rather than 2 distinct modalities. Although some differences are evident, they have more to do with aspects of efficiency than with demographic reach. What becomes very clear on analysis is that FS and M1SS HCT need to be analyzed according to the demographic groups targeted by the choice of a particular site or time. It is misleading to group all FS together, or to group all M1SS together, since both modalities offer testing to very diverse client populations depending on site. Overall, FS and M1SS testing attracts 2 major demographics: a mixed male and female population of mainly urban and peri-urban adults with a wide range of ages and a moderately high risk of HIV acquisition on one hand (Fig 3a & 3b), and a more restricted, younger population of school-associated clients with a female predominance although with a gender-mixed clientele and a substantially lower risk of HIV acquisition (Fig 4a & 4b). A much smaller volume of testing is carried out on a third category made up of disparate groups with relatively high HIV prevalence (farm employees, prisoners, sex workers, MSM) but the total volume of testing from all of these subgroups is only a small fraction of the HCT performed for the 2 major demographic groups. There is no disaggregated project data on MSM; although one study found that 3.2% of rural South African men reported MSM behaviour, they identify as heterosexuals (Imrie,J. 2013;).

The combination of all FS and M1SS sites together reaches men and women all age strata from 15-44 years in proportions near the proposed reference client structure; there may be modest under-representation of men and women 45 years and above (Fig 5a & 5b). This is consistent with a review of 4 models of HCT in South Africa, which found that mobile testing reached men and youth best (Mabuto,T. 2014;).This review also found that mobile testing reached more first time testers. Mobile testing in Swaziland also reached men best (Parker,L.A. 2015;), and a systematic review of strategies to increase men's testing found large increases in male testing, particularly through mobile testing approaches (Hensen,B. 2014;).

The effectiveness of school testing and mobile testing for students is supported by studies showing high acceptability at schools (76.9%) Madiba,S. 2015;) and very successful access to youth (van Rooyen,H. 2013;) with >50% of testers under 24 years of age.

CHAP (Door-to-door) Testing

The CHAPs HCT program is entirely distinct from that provided by FS & M1SS testing. The demographic reach for CHAP testing is clearly determined by the rural location of most CHAP activities and the differences in the rural daytime population of the project area, with a noticeable relative absence of men, particularly young men, most of the time

(Fig 6a & 6b).Nonetheless there is high acceptability among men. These data are consistent with a study of home-based testing in a rural district of KZN (Naik,R. 2012;) where the majority of testers was female but acceptability was 70% among men (among HIV+ men, 46% had never tested before).

Door-to-door (CHAP) testing reaches men and women of all ages but is currently over-testing children <15 years and adults 60 and above. In 2015 tests for children <15 years constituted 30.2% of total testing volume (with only 0.2% HIV+) and tests for adults 60 and above constituted 10% of total testing volume (with only 0.5% HIV+) (Fig 7 & 8). This likely reflects the greater availability of persons in these age groups among the daytime, at-home resident population served by CHAPs. The Swaziland study cited above also noted more children and adolescents with door-to-door testing (Parker,L.A. 2015;).

The relatively intense testing coverage of the population, with regular offers of retesting, is saturating coverage such that increasingly fewer new HIV+ cases are identified. This reflects continual removal of successively identified HIV cases from the denominator of the population to be retested, leaving a population that has an increasingly low incidence of HIV infection. This phenomenon is not yet seen in the urban/peri-urban population being tested, among whom the prevalence of HIV infection is still similar to the initial levels seen in the CHAP program in 2013.

Health Facilities

Health Facility (HF) based testing (data from Nov 2015 only) illustrates the expected strong representation of women of childbearing age (15-39) with a marked underrepresentation of younger males <30 years (Fig 9a & 9b).

Efficiency of Testing for HIV diagnosis

The FS seeing men and women of all ages and M1SS-CS and other M1SS sites seeing a similar demographic are the most efficient of the community HIV testing services at diagnosing HIV infection. Data from late 2015 showed that FS and M1SS CS & similar sites diagnosed HIV infection in 6.8% and 5.8% of tested clients, respectively. In contrast the proportions HIV+ at the FS-college site and M1SS HS & similar sites were 3.4% and 2.3%, respectively. Among CHAP clients the proportion testing HIV+ was only 0.9% overall, although this is partly related to over-testing of persons <15 and 60 or older, where prevalence among testers is particularly low (Table 1).

The sex-age distribution of newly diagnosed HIV+ persons from the sum or all FS and M1SS activities in 2015 is close to that predicted by the proposed comparator (for derivation see Annex IV b); this suggests that not only are men and women tested in proportion to population-based need, but that cases are detected where they are predicted to occur (Fig 11a & 11b). (Discrepancies for women 20-34 are likely related to imprecision of the age-specific estimated HIV incidence rate used for the comparator case distribution).

School –associated versus non-school-associated testers

Disaggregation of HIV test results for M1SS clients 10-24 years shows that school-associated testers have much lower HIV prevalence than sex-age matched non-school-associated testers (Fig 12 & 12b); this may reflect underlying socioeconomic differences between these groups of youths, or possibly a protective association with school attendance.

Testing intensity

Data on previous HIV testing and inter-test intervals reported by clients (unverified) indicate that approximately a quarter of FS/M1SS clients report no prior HIV test, even in 2015; compared to 20% for CHAP clients in 2015. Among clients reporting a previous HIV test, median inter-test interval (ITI) is similar for males and females for FS/M1SS and

CHAP (207-234 days in late 2015). While median ITI shows no convincing trend from 2013-2015, the 3rd quartile ITI- which characterizes the less tested part of the distribution has fallen for CHAP clients (343 and 336 days for males and female respectively) (Tables 2 & 3). The ITI for CHAP-tested children 5-9 and 10-14 are even shorter, consistent with over-testing these low risk strata.

Reaching HIV+ persons with severe immunosuppression

Median CD4 count at HIV diagnosis through FS/M1SS services are approximately 500 for males and females in 2015, although further breakdown of the CD4 count distribution shows lower counts for males as expected (Fig 17, 18a & 18b). In Q3 2015 20% of males and 13% of females had CD4 counts <200 cells/microliter at the time of HIV diagnosis (Table 4).A systematic review of factors enabling and deterring uptake of HIV testing in Africa found that the most powerful enablers were deterioration of physical health and/or death of sexual partner or child; major barriers included perceived low risk of HIV infection and fear of stigma (Musheke,M. 2013;). Comparison of the client CD4 count distribution to that obtained from the Epicentre population survey shows that they are very similar, suggesting that the population of HIV+ persons being diagnosed by FS/M1SS is similar to the overall population of undiagnosed HIV+ persons.

COST-EFFECTIVENESS OF HIV TESTING

Although costing and cost-effectiveness analysis were not undertaken as a part of this evaluation exercise per se, these issues have been investigated by national and project MSF personnel and will continue to be. In order to plan and advocate to the Department of Health in KZN it is important to consider the effects of community-based HTC in relation to costs. Some relevant literature is cited below.

A health economic modelling analysis indicated that the addition of home HTC to current practice could decrease HIV-associated morbidity by 10-22% and HIV infections by 9-48% with increasing CD4 thresholds for initiation. The ICER (incremental cost-effectiveness ratios) were <20% of South Africa's GDP per person so are classed as very cost effective (Smith,J.A. 2015;).

In a cost-effectiveness analysis of home-based HCT versus HF-based HCT, home-based HCT was less costly and more effective. The ICER per client tested was USD 19 (Tabana,H. 2015;).

In Swaziland, home-based HTC was 50% cheaper than mobile HTC (both per person tested and per HIV+ person enrolled in HIV care) (Parker,L.A. 2015;).

An assessment of the potential impact and cost-effectiveness of self-testing for HIV in low-income countries concluded that self-testing should always be introduced no matter how poorly or well-resourced a health system is, because it leads to better health outcomes are reduced cost (Cambiano,V. 2015;).

The South Africa Investment Case favours increasing HCT among adolescents; overall there needs to be an increase to 35 million tests per year – including home and mobile testing (Meyer-Rath,Gesine 2015;).

Mobile VCT in Cape Town was considered highly cost-effective: the ICER for mobile unit testing was USD 2400 per year of life saved – far less than GDP per capita in South Africa (Bassett,I.V. 2014;).

LINKAGE TO HIV CARE

Linkage to care was assessed by comparing the actual sex-age structure of HIV+ persons linked to care to the expected distribution of HIV+ cases (the comparator described in Annex IV b). This comparison (Fig 20 & 21) suggests that young men and women 15-19 years are underrepresented in the linked population of HIV+ persons.

- Looking specifically at M1SS HIV+ client linkage a comparison of tested and linked clients again suggests underrepresentation of men and women 15-19 years, with more modest underrepresentation of men 20-29 as well (Fig 22 & 23).

- Looking specifically at CHAP HIV+ client linkage a comparison of tested and linked clients suggests and underrepresentation of males 15-24 and of women 20-24 (Fig 24 & 25).

Failure of linkage was more common among young men in KZN in a study (although self-reported stigma was not predictive) (Evangeli,M. 2014;). The meta-analysis of community HTC by Suthar et al found that overall 80.1% of newly diagnosed HIV+ persons obtained a CD4 count, and of those eligible for ART, 73.1% initiated (Suthar,A.B. 2013;). Another systematic review of retention in care between testing and treatment in sub-Saharan Africa found retention between testing and CD4 count or clinical staging was 59%, retention between staging and ART eligibility was 46%, and between ART eligibility and ART initiation was 68% (Rosen,S. 2011;). Of those not ART eligible less than a third was retained in care.

Home-based HTC was associated with 62.1% linkage (defined as obtaining a CD4 count) within 3 months of HTC in rural South Africa; lower likelihood of linkage was associated with younger age (15-24 years) and difficulty finding time for clinic visits (Naik,R. 2015;). A study conducted in KZN and in Mbarara, Uganda, found that linkage to ART after home HTC was 76% by 12 months overall, but 93% if CD4 was <200. The need for repeat CD4 counts at HF and for multiple visits were frequent structural barriers to ART initiation (Barnabas,R.V. 2014;).

In a review of retention in HIV care in resource-limited settings noted that in many instances patients who were lost to follow-up continue to receive care in other locations. From 14 studies where this was analysed a median of 48.5% of LTFU were in care elsewhere (Geng,E.H. 2010;). This review also found that LTFU correlated with the size of the program (quoting 2.2% for decentralized peripheral sites versus 19.3% at the central Lusikisiki site). Other studies cited in this review indicated that lack of transportation, high transport costs, or travel time > 2hours were all disincentives to retention in care. A study of barriers to ART initiation in KZN found ART initiation rates of 68.2% and 60.2% for men and women, respectively, within 3 months of eligibility. For men ART initiation was associated with living <2 km from the HF; for women it was associated with not being pregnant and with having at least 1 other household member on ART (Plazy,M. 2015;).

In a separate review of retention in care in East Africa among patients LTFU who were traced and found not to be in care, psychosocial issues (e.g., stigma) were the most prevalent barrier (76%)(Geng,E.H. 2015;) . A study from Zambia found that despite intensive pre-ART counseling more than half of patients held at least one false belief about ART effectiveness, side effects or the consequences of non-adherence (Nozaki,I. 2013;).

In a study of collective patient behaviours derailing ART roll-out in KZN, found that unmet subsistence needs interfered with adherence (lack of food, or of transport), that there were co-morbid rates of depression between 20-50% of PLWHA. They also observed that traditional and complementary medicine were so embedded in the culture that they recommended that traditional healers and faith institutions be integrated into the health system as partners in HIV care and treatment (Michel,J. 2013;).

The CD4 count distribution of linked HIV+ clients at HF indicates that males 30-54 present with the lowest CD4 counts (Fig 26, 27 & 28). Although there has been some improvement over the period 2013-2015, in Q3 2015 ~38% of males presented to HF with CD4 <200 cells/microliter, whereas fewer than 25% of females had CD4 counts this low (Fig 29 & 30). Overall, this suggests that a sub-population of men (in the middle age strata specified) may be avoiding HIV diagnosis and/or linkage to HIV care until they are more symptomatic than other HCT clients.

There is evidence that pre-ART patient retention in care is poorer than among those initiated on ART (Geng,E.H. 2010;), but the effect of CD4 count was bidirectional –poorer for high and low CD4 counts. The authors suggested "The bidirectional nature of this association may be because patients with high CD4 counts are more likely to move for work but those with low CD4 levels are at risk for unascertained deaths that appear to be failures of retention.

(OTHER) BENEFITS OF HIV TESTING

There are numerous potential benefits associated with HIV testing (in addition to linkage to care for HIV+) but only limited activities take place in the KZN project to enhance these benefits, and virtually no data exists to allow evaluation of them. TB screening is performed with all community HIV testing but in late 2015 only 1% of clients had referral for TB sputum evaluation (we have no data on results); pregnancy testing is very popular at one FS (requested by at least a quarter of female clients there) but uncommon everywhere else – there is likely unmet need for

pregnancy testing at other FS/M1SS locations. The choice of MMC rarely follows as a consequence of HCT so cannot be considered a benefit of testing. (Relevant literature is cited in *FINDINGS/BENEFITS OF HIV TESTING*)

RECOMMENDATIONS

⇒ Recommendations 1: FS testing is very effective at high volume testing and efficient identification of HIV+ persons including men 20-34; consideration could be given to another FS location at a suitable, well-exposed location.

⇒ Recommendations 2: M1SS activity needs to continue with a wide variety of site types targeting a range of sex-age strata as currently occurs; it is also important to include youth-friendly occasions for HCT for non-school associated youth as well as school-associated youth – as the former appear to have higher risk for HIV acquisition.

⇒ Recommendations 3: The CHAP program could increase its efficiency by limiting testing for children <15 to one test prior to sexual debut; testing should also be limited among men or women who are no longer sexually active and have no ongoing risk of HIV acquisition.

⇒ Recommendations 4: CHAP teams could enhance their effectiveness by offering testing at sites of natural congregation within their rural and semi-urban areas (stores, work sites, social gathering places) in addition to homes; information on HIV+ clients referred for HIV care and treatment should be shared with the relevant HF to enhance support for linkage.

⇒ Recommendations 5: Men undertake HCT and link to ART at lower CD4 counts than women, and for the lowest quartile that entails substantial risk of HIV-associated illness and poor health outcomes (including death). This implies that men need continued encouragement to test for HIV with conveniently located and time-efficient services, and with particular attention to linkage to care for those diagnosed HIV+.

ANNEXES

ANNEX I: TERMS OF REFERENCE

OVERALL OBJECTIVE and PURPOSE

This work should analyze programmatic data, in conjunction with existing research, in order to produce a well evidenced descriptive comparison of how different modalities of testing, community, as well as conventional clinic-based, differ. These differences will be in terms of cost, as well as benefits. Benefits should include a measure of new cases identified as well as ability to target particular risk groups, such as young people. Consideration should also be given to the additional benefits that may be gained by scaling up a given testing strategy. Note that community based testing and facility based testing would be scaled up by very different means.

As well as comparing the outputs of the competing testing strategies, it will be important to undertake some analysis of why those outputs vary as described. For example why is linkage high with strategy x but low with strategy y. This will inform options for the effective scale up and programmatic improvement of those strategies.

SPECIFIC OBJECTIVES / Evaluation questions

For each of the following 4 strategies:[1]

1. Door to door HIV testing using lay cadres (provided by MSF)
2. Testing through mobile outreach activities (provided by MSF)
3. Testing at standalone fixed sites (provided by MSF)
4. Conventional clinic based testing (provided by MoH)

Positive individuals identified

- How do the costs of identifying a positive individual vary by strategy (outputs)
- Why do costs vary as described and what options for cost saving exist (inputs)

Linkage to care *[this analysis is subject to the limitations of available linkage data]*

- How does linkage to care vary by strategy (output)
- Why does linkage to care vary in this way (process)
- How do the costs per person linked to care vary by strategy?

Ability to target those at high risk of morbidity and mortality *[this analysis will only be possible to the extent that we can identify risk groups of interest among the tested population]*

- How do strategies compare in their ability to identify those at high risk of morbidity (e.g. undiagnosed children, severely immunocompromised people, and people who avoid conventional clinic HCT?) (outputs)
- Why do the various strategies differ in this way? (process)

Ability to target those at high risk of transmitting to others (see MSF& Epicentre survey)

[This analysis will not yield a fully developed transmission model, which is beyond the scope of this evaluation; at best it may suggest relative risks for transmission between various sex/age strata for which data are available]

- How do the strategies differ in their ability to identify those at high risk of transmitting HIV? (outputs)

[1] Assuming that any additional information gained about home self-testing is additional and subject to discussion/exploration in the field.

- How do the strategies differ in their potential to prevent future incident cases (based on who they identify and how well those individuals link to care)

Benefits of testing (as an end in itself)

Irrespective of benefits gained in terms of positive individuals identified, what are the other benefits of these strategies, and how do they compare between the different strategies? Specific benefits may be analyzed to the extent that relevant data are available; data on testing of partners/children, & uptake of VMMC will be sought.

Overall comparison

Given the above, and with reference to the Project document and log frame, which strategy is likely to be most advantageous to MSF in achieving its stated objectives in the district? With reference to relevant provincial and national level planning documents (goal setting documents) where would resources be best allocated to help in achieving those plans?

**To understand the processes & reasons why strategies work as they do, some qualitative work may be needed, stakeholder interviews, etc..*

EXPECTED RESULTS

1. 'Visit Report' to be turned in within two weeks after her/his end of contract; providing recommendations detailing how resources allocated towards HIV testing may be best allocated within the project. This report should address what changes should MSF make to its HIV testing strategy, based on the understanding of what the 4 testing strategies have accomplished and what this suggests about optimisation of testing and linkage to care.

2. Broader recommendations for the HIV programme in the district. This should allow us to advise on recommendations for the province as well as potentially the country more broadly, as to whether community based testing strategies should play a larger role in the department of health's response to the HIV epidemic[2]

3. Outline for an academic paper presenting the findings of the cost-effectiveness analysis in collaboration with project and coordination OR team;

TOOLS AND METHODOLOGY PROPOSED

- Revision and analysis of documents and literature
- Meeting/discussion/interviews with key-team members at HQ and field levels.
- Work to obtain and clean existing programmatic data
- Analysis of existing programmatic data on testing
- Develop through the use of descriptive statistics relevant comparisons of the different testing modalities

RECOMMENDED DOCUMENTATION:

- Project document
- Project log frame
- MSF Epicentre prevalence & incidence survey conducted in the project area
- Scientific publications on the role of community HIV testing strategies
- Costing exercise (ingredients based approach) for community testing models

[2] It is not yet clear to what extent the findings in KZN will be generalizable to even other parts of SA, much less other countries. Until we see what kind of differences exist in the performance of the testing strategies we cannot say how clear the conclusions (and hence the advice) will be.

- National and provincial level documentation on objectives and plans.

ANNEX II: LIST OF INTERVIEWEES

Gilles van Cutsem	Medical Coordinator
Amir Shroufi	Deputy Medical Coordinator
Sarah Jane Taleski Steele	HQ Epidemiologist
David Maman	Epicentre Epidemiologist
Eric Goemaere	Advisor/ Éminence grise
Gemma Arellano	Project Medical Referent KZN
Tsion Solomon	Project Epidemiologist KZN
Gugu Ngidi	M1SS & FS Coordinator
Busi Ndlovu	CHAP Coordinator
Ntombi Gcwensa	Community Mobiliser Coordinator
Bongani Malevu	Head Lay Counselor
Mzwandile Khumalo	Lay Counselor
Zodwa Nxumalo	Lay Counselor
Jabu (Gloria) Mthimkhulu	Lay Counselor
Nonhlanhla Shezi	Lay Counselor
Cebo (Sibongiseni) Ngobese	Nurse / Male Wellness
Nobuhe Zondo	Nurse
Nozipho Zungu	Nurse CNP/HCT
Musa Ndlovu	Advocacy Manager
Sizakele Ngcobo	CHA
Thembani Sibiya	CHA
Fanele Luthuli	CHA
Zithulele Khanyile	CHA
Christopher Nkosi	Field Data Supervisor

ANNEX III: INFORMATION SOURCES

Documents (unpublished)

ARO 2015 – KZN – Community Models RIC (PowerPoint)

KZN scientific day presentation - revised (PowerPoint)

KZN Testing Data by testing modality (PowerPoint)

MSF role in incidence reduction ARO 2016 (PowerPoint)

Logical Framework 2015 ZA1-81 KZN draft 1910

Project Document 2015 ZA1-81 KZN draft 1710

NSP 2012-2016 FINAL

Lay Counselor Survey (7 documents)

Counseling Manager End-of-Mission Report (Jessie Shay; 5 documents)

KZN HIV survey Final Report (Epicentre) + 2 exports of additional data from 1st author

CROI costing analysis community testing – final

MMC data summary

M1SS Passport

CHAP Passport June 2015 Final

[This is not an exhaustive list of documents; in addition several data exports for testing modalities were specifically prepared for this evaluation but are not listed individually; 8 for CHAP, 15 for FS/M1SS, 8 for HF]

Site visits

Fixed Sites (Osborn, Ikhwezi); observation & interviews with counselors & mobilizers (1/12/15)

M1SS Sites; observation & interviews with counselors & mobilizers (1/12/15)

Farm Clinic; observation & discussion with nurses, lay counselor (26/11/15)

Farm education and testing event; observation & discussion with staff (10/12/15)

Health Centre –Ntumalo; observation, discussion with lay counselor, chart review (9/12/15)

CHAP - Mpumazi 02 team; observation, discussion on daily rounds (2/12/15)

CHAP – team leader meeting; observation & discussion (30/11/15)

Counselor training; observation, discussion with staff & participants (26/11/15)

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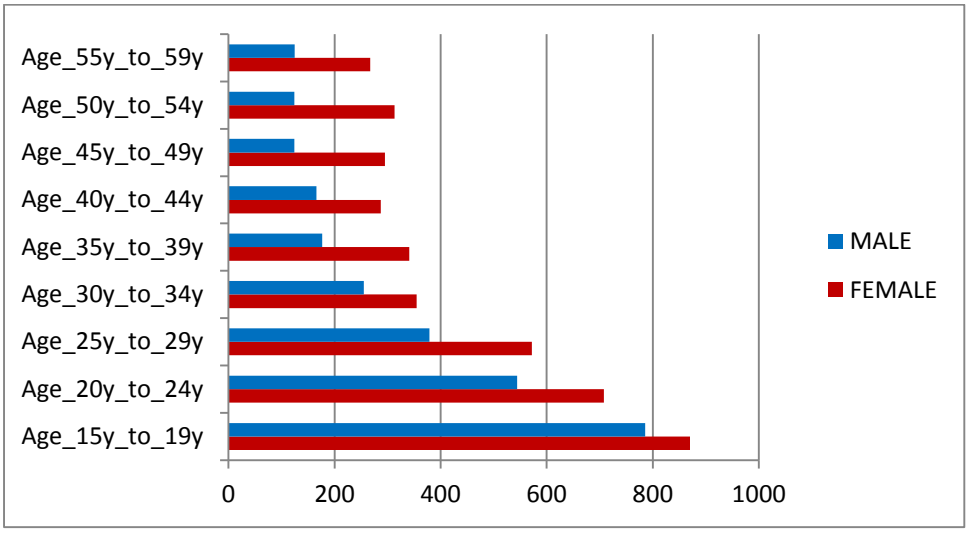
ANNEX IV A: DERIVATION OF COMPARATOR POPULATION STRUCTURE FOR TOTAL HCT CLIENTS

This is a justification for the proposed comparator. The Comparator Population is defined as the population needing to know their HIV status and is derived from:

- The sex-age stratification of the eligible survey population 15-59 (illustrated below) was used to generate proportions for each sex-age stratum



- The sex-age stratum-specific HIV-prevalence

	Women		Men		Total	
	%	(95%CI)	%	(95%CI)	%	(95%CI)
15/19	7.5	5.8-9.7	1.8	0.9-3.4	4.8	3.7-6.2
20/24	25.9	22.8-29.3	4.4	2.8-6.7	17.0	14.9-19.4
25/29	40.9	36.1-45.8	19.3	15.9-23.3	32.8	29.5-36.3
30/34	56.5	50.3-62.6	35.6	28.7-43.0	48.8	44.1-53.4
35/39	55.5	49.8-61.0	45.5	36.2-55.2	52.3	47.4-57.1
40/44	49.4	43.2-55.7	37.6	28.0-48.3	45.7	39.8-51.6
45/49	33.2	27.-39.3	36.6	27.5-46.7	34.1	29.1-39.5
50/54	26.6	21.4-32.6	30.7	22.5-40.4	27.7	23.0-32.9
55/59	19.8	14.9-25.7	16.7	11.0-24.5	18.9	14.9-23.6

- The estimate of awareness of HIV+ status: this is based on sex-age specific data but with relatively small numbers of observations in some sex-age strata (implying wide confidence intervals for the estimated proportions):

		Aware	Not aware	%
15-19	Women	39	19	67.2
20-24	Women	91	69	56.9
25-29	Women	146	56	72.3
30-34	Women	131	40	76.6
35-39	Women	136	21	86.6
40-44	Women	112	12	90.3
45-49	Women	79	6	92.9
50-54	Women	64	11	85.3
55-59	Women	41	7	85.4

		Aware	Not aware	%
15-19	Men	7	5	58.3
20-24	Men	3	15	16.7
25-29	Men	29	28	50.9
30-34	Men	39	25	60.9
35-39	Men	48	13	78.7
40-44	Men	39	4	90.7
45-49	Men	30	4	88.2
50-54	Men	23	8	74.2
55-59	Men	8	8	50.0

- Due to the relatively small number of observations in some strata, an weighted average for awareness of HIV+ status was calculated as follows:
    - Women 15-29: 65.7%
    - Women 30-59: 85.3%
    - Men 15-29: 44.8%
    - Men 30-59: 75.1%
- Lack of awareness of HIV+ status was defined as [1-fraction aware]
- The population needing to know their HIV status was defined as the sum of the HIV-negative and those who were HIV+ but unaware of their status
- Limitations: This comparator population structure assumes that all HIV uninfected persons 15-59 are sexually active and therefore at continued risk of HIV acquisition, whereas this is probably not the case as some young people may not yet have had sexual debut, and an unknown proportion of people in the upper age strata are no longer sexually active. This means the population structure may somewhat overestimate the proportions needing HIV testing in those age strata.

ANNEX IV B: DERIVATION OF COMPARATOR POPULATION STRUCTURE FOR HIV+ HCT CLIENTS

This is a justification for the proposed comparator. The Comparator population structure for newly diagnosed HIV+ persons would ideally be the sum of those persons already HIV+ who do not know their status, plus any persons subsequently infected with HIV over a chosen period of observation. If the diagnostic system was perfect all of these cases would learn their HIV status through HCT. The comparator population for HIV+ HCT clients is based on the following:

- The proportion of already HIV-infected persons who are unaware of their status and need diagnosis
- The estimated HIV incidence rate (among the HIV-uninfected) for various sex-age strata from the survey; the following incidence rates were used for this exercise:
    - Women 15-29: 2.9 cases/100 person-years
    - Women 30-59: 0.3 cases/100 person-years
    - Men 15-29: 0.9 cases/100 person-years
    - Men 30-59: 0.3 cases/100 person-years
- The survey data was collected in late 2013 so incident cases for one year (2014) were added to existing cases unware of their HIV+ status to yield an approximation of the number of HIV cases needing diagnosis at the beginning of 2015.
- As all forms of HCT have been ongoing during and after the survey, an unknown proportion of these cases have learned their HIV status at present; as time goes on HIV testing is more likely to occur but it is possible that newly infected persons are somewhat less likely to be aware of their infection than those infected for longer periods, as the latter have more opportunity to test; on the other hand, overall testing intensity in the community has increased over time so this may have increased the likelihood that an HIV+ person would learn his/her status. Regardless of these influences, it can be proposed that testing activity in 2015 would ideally identify HIV+ persons in proportions like the comparator distribution for cases, even if testing coverage is incomplete. Identification of HIV+ persons in actual testing modalities should ideally be proportional to the likelihood of HIV infection in each sex-age stratum, which is what the comparator population illustrates.

Stockholm Evaluation Unit

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