

# MSF@AIDS2016

## Abstracts

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## DEMOGRAPHIC REACH AND COSTS ASSOCIATED WITH 3 MODELS OF COMMUNITY HIV TESTING IN RURAL KWAZULU-NATAL

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**Background:** The UNAIDS 90-90-90 targets demand HIV testing and counselling (HTC) for all sectors of the population at risk of HIV acquisition. Community testing modalities may offer better access than HTC at health facilities to some hard-to-reach groups, but at additional cost which requires some justification.

**Description:** MSF implemented 3 modalities of HIV testing in uThungulu District, beginning 2012: fixed sites (FS), mobile sites (MS), and door-to-door (D2D). An ingredients approach was used to analyze costs associated with these testing modalities for 2014. Client structures were analyzed for men and women 15 to 59 years of age, for each testing modality, and compared to those of health facilities (HF).

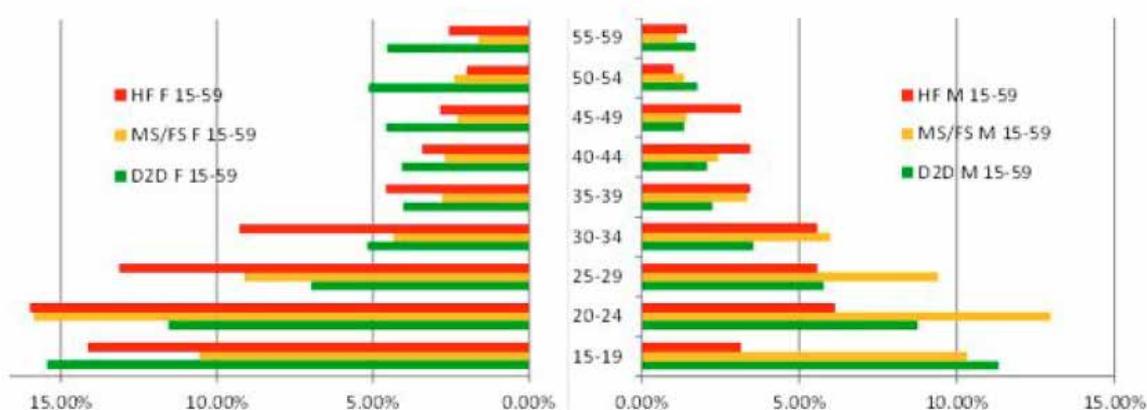
**Lessons learned:** Costs per clients varied from ZAR 192.55 to ZAR 249.70. D2D had the lowest cost per client (Table 1).

Ingredients		Fixed sites	Mobile sites	Door-to-door
	<b>Total tests (% positive) in 2014</b>	<b>7,065 (6.6%)</b>	<b>11,554 (3.3%)</b>	<b>15,112 (3.3%)</b>
Category	Items	Cost/test (ZAR)	Cost/test (ZAR)	Cost/test (ZAR)
1.HIV test supplies	Test kits HIV- / HIV+*	7.9 / 24.9	7.9 / 24.9	7.9 / 24.9
	Testing supplies HIV- / HIV+	9.8 / 11.2	9.8 / 11.2	9.8 / 11.2
2.Salaries	Lay counsellor/ community health agent (D2D)	52.42	48.56	112.68
	Support staff	130.83	79.99	61.39
3.Logistics	Sensitization, phones, equipment, transport	12.09	74.33	7.93
<b>Total cost</b>	HIV- and HIV+ tests	1,513,646	2,678,751	2,919,025
<b>Unit cost</b>	Cost per test: HIV- / HIV+	212.95/ 231.44	231.21/ 249.70	192.55/ 211.04

*[Cost analysis for 3 modalities of community HIV testing. All costs in South Africa Rand (ZAR) (2014).*

*\* All have test 1. Only HIV+ have test 2.]*

HF testing costs ZAR 81 to 346 per client. The demographic reach of each modality differs. Both FS and MS see men and women of all ages, but age differs markedly depending on MS site: MS at commercial sites see clients similar to FS, but MS at high schools see predominantly younger clients up to 24 years of age. Both FS and MS are most effective at reaching men, especially aged 15 to 29, when compared with HF testing. D2D testing reaches both sexes, but with fewer men aged 20 to 34 than FS or MS at commercial sites (Figure 1).



*[Client structure of community testing modalities compared to HF. Proportion of all clients 15 – 50 for each modality: Female (left); male (right)]*

**Conclusions / Next steps:** Approaching the UNAIDS targets will require community testing modalities, in addition to HTC at HF. Community testing increases testing of hard-to-reach and priority groups, at an affordable cost.

## REACHING THE FIRST 90: INDEX CASE HIV TESTING AND THE ROLE OF A COMMUNITY MODEL OF CARE IN TETE, MOZAMBIQUE

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**Background:** Community-based HIV testing and counseling (HTC) is an essential WHO-recommended complement to facility-based testing. Médecins Sans Frontières and the Mozambican Ministry of Health in Tete introduced Community ART groups (CAGs), a community-based strategy to simplify ART access, in 2008. Since 2012, the CAGs potential to promote community testing through an index case strategy and linkage to care has been explored at the community-level. This analysis describes the outcomes of this approach.

**Methods:** Retrospective analysis of routinely-collected data included persons tested in the community between July 2012 and December 2014. Positivity rate was stratified by age, sex and testing referral method: immediate CAG family member (spouse, sibling, child or parent), other CAG contact (non-immediate family member or neighbor), other referral (community leader, community health worker or activist referral) or self-referral.

**Results:** The analysis included 16,750 persons tested in the community; 61% were female and the median age of individuals was 20 [13-34]. HIV positivity of 5% was observed. Positivity dropped from 19% (69/355) in 2012 to 4% (418/11116) in 2014. The proportion of tests carried out on CAG family members decreased from 13% in 2013 to 6% in 2014. Immediate CAGs family members had higher HIV-positivity rates (9%) compared to other CAG contacts (4%); among non-CAGs contacts, self-referrals had a higher positivity rate (8%) compared to other linkage to testing methods (4%). Among youth (15-24), positivity was higher in females (4%) than males (2%). Among adults >25 years, positivity was higher among males (8%) than females (6%). 2% of children <15 years tested positive overall; 4% among immediate CAG family contacts, 1% among other CAG contacts, 1% among other referrals and 3% among self-referrals.

**Conclusion:** Community-based HTC activities increased testing among populations who typically do not utilize health services. The strategy identifying relatives of CAG contacts and self-referrals is a simple way to identify a high-risk population, though saturation was reached relatively quickly. Further investigation of strategies promoting testing via CAGs and other groups of PLHA at community level is essential to increase the yield of community testing, HCT coverage, and linkage to care.

## LAY COUNSELLOR REDEPLOYMENT IN KWAZULU-NATAL, SOUTH AFRICA LEADS TO CONSIDERABLE DROP IN HIV TESTING

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**Background:** In settings such as KwaZulu-Natal, South Africa, an area with both a high HIV burden and severe health worker constraints, lay counsellors have played a critical role in the provision of HIV testing and counselling services as well as adherence counselling. At the end of 2014, the KwaZulu-Natal Department of Health announced the phasing out of the cadre of lay counsellors, with the stated aim of retraining and identifying new careers for these individuals.

In the uMlalazi municipality, where Médecins Sans Frontières (MSF) works in collaboration with the local Department of Health in delivering HIV treatment, lay counsellors have been withdrawn from 9 clinics in two waves: Jan 5th, 2015 (CW1) and June 15th, 2015 (CW2). This stepwise counsellor withdrawal provides an analytical opportunity to examine the impact of this change in health worker capacity on the total number of clinic-based HIV tests.

**Methods:** We used clinic-level fixed effects analysis with data on monthly HIV testing rates from the national South African electronic HIV treatment records system (TIER.net) from August 2014 - December 2015. Clinic-level fixed effects and control for months allowed us to account for all unobserved and observed confounding variables at the clinic-level, and trends in HIV testing by calendar time, respectively.

**Results:** We observed over 16,000 tests (7,020 tests administered 5 months pre-CW1, 5,125 tests administered 5 months post-CW1 / pre-CW2, and 4,264 tests administered post-CW2). Following CW1, the monthly average of HIV tests decreased 25% and following CW2 the monthly average decreased a further 13%. After controlling for clinic-level fixed effects and months, we found that having one less counsellor is associated with 28 fewer tests per month (95% CI: 22.19 to 34.37).

**Conclusions:** These findings suggest that the counsellor withdrawal substantially decreased clinic-based HIV testing. If these findings are representative of the experience province-wide, they illustrate how lay counsellor withdrawal may jeopardize efforts to deliver the UNAIDS 90-90-90 strategy.

## UNDIAGNOSED HIV-INFECTED PARTNERS ARE THE MAJOR GAP IN THE CASCADE FOR SERODISCORDANT COUPLES IN 2 HIGH-PREVALENCE SETTINGS

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**Background:** Discordant couples are a major source of HIV transmission. We quantified the prevalence of HIV discordant couples and, among HIV infected individuals, evaluated each step of the cascade of care in two high prevalence settings in sub-Saharan Africa.

**Methods:** Two population-based surveys of persons age 15 to 59 were conducted in Ndhiwa (Nyanza, Kenya) and Chiradzulu (Malawi) between September 2012 and May 2013, to assess HIV incidence and cascade of care. Each individual who agreed to participate was interviewed and tested for HIV at home. All HIV-positive were tested for VL and CD4, regardless of their ART status. A couple consisted of two persons who were legally married or who were living together in a consensual union.

**Results:** In total 7,425 houses were visited and among 15,104 individuals eligible, 13,345 (88.4%) were included and tested for HIV. Among 2,970 identified as couples, HIV discordancy was found in 15.8% (95% CI: 13.9-17.9%) in Kenya and 10.0% (95% CI: 7.9-12.7%) in Malawi. Among couples with at least one HIV-infected partner, the proportion of HIV-discordancy was 45.8% in Kenya, and 40.9% in Malawi. Men were the HIV-positive partner in 63.6% (95% CI: 56.7-70.0%) of the discordant couples in Kenya, higher than in Malawi (47.9%; 95% CI: 40.4-55.5%). HIV status awareness among HIV-positive partner of discordant couples was 42.2% in Kenya, and 64.4% in Malawi. VL suppression was 34.6% in Kenya and 54.5% in Malawi, lower than in the general population (40.0% in Kenya, 61.9% in Malawi). VL suppression was higher in women compared to men, in Kenya (39.5% vs 26.8%,  $p=0.1$ ) and in Malawi (61.2% vs 46.5,  $p<0.01$ ).

**Conclusions:** Discordant couples were frequent and VL suppression ranged between 35 and 55% among HIV-positive partners. The high rate of unawareness of status among HIV-positive partners must be addressed in order to promote timely initiation of ART and/or PREP to reduce transmission within this high-risk group.

## MOVING TOWARDS THE SECOND 90: LINKAGE TO CARE AND THE ROLE OF A COMMUNITY MODEL OF CARE IN TETE

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**Background:** Community-based HIV testing and counselling (HTC) is an essential WHO-recommended complement to facility-based testing. Médecins Sans Frontières and the Mozambican Ministry of Health in Tete introduced Community ART groups (CAGs), a community-based strategy to simplify ART access, in 2008. Since 2012, the potential of CAGs to promote community testing and linkage to care has been explored at the community-level, including immediate connect of positive clients to CAG members and health facilities. The purpose of the analysis is to describe the linkage to care among individuals who tested positive in the community.

**Methods:** Retrospective analysis of routinely collected data included persons who tested positive in the community between July 2012 and December 2014. Individuals recorded in community testing registers were matched to electronic medical registers of facilities in Changara district. Linkage to care was defined as opening of a matched HIV file at a district facility within 6 months of test date. The linkage outcome was stratified by age, sex and testing referral method: immediate CAG family member (spouse, sibling, child or parent), other CAG contact (non-immediate family member or neighbour), other referral (community leader, community health worker or activist referral) or self-referral.

**Results:** Analysis included 772 positive persons, excluding forty individuals who had evidence of linking prior to community testing. 77 % (597/772) linked within 6 months, including 82% in 2012, 70% in 2013 and 82% in 2014. 84% of children (<15), 75% of youth (15-24), and 78% of adults (≥25) linked to care within 6 months. Self-referrals had higher linkage (85%) compared to patients referred by immediate family members in CAGs (79%), other CAG contacts (77%) or other referral (73%). Among 435 patients linked within 6 months and initiated on treatment before April 2015, the retention in care at 6 months was 88%.

**Conclusion:** Community testing with support from CAGs showed high levels of linkage to care regardless of approach to referral and has great potential to help achieve '90-90-90' targets. Further studies are needed to compare this approach with testing strategy at the health facility and community testing in areas without CAGs.

## POWER, AGENCY AND CHOICE: PEOPLE LIVING WITH HIV'S INITIATION OF EARLY ANTIRETROVIRAL THERAPY IN THE CONTEXT OF PRACTITIONER-PATIENT RELATIONSHIPS IN SHISELWENI, SWAZILAND

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**Background:** The World Health Organisation now recommends immediate antiretroviral therapy (ART) initiation after a HIV diagnosis for all adults, following evidence of associated health benefits and transmission reduction. Swaziland is one of the first countries to pilot early access to ART (EAA) for all adults diagnosed with HIV under routine programme conditions. A qualitative study was conducted to explore people living with HIV's (PLHIV) experiences with EAA in Shiselweni, Swaziland.

**Methods:** Médecins sans Frontières and the Swaziland Ministry of Health started EAA in Shiselweni in October 2014. Participants were recruited purposively from the pilot cohort, to include those otherwise ineligible for ART (e.g. with CD4 counts above 350), and those who had, and had not, initiated ART. 15 in-depth interviews were conducted with individuals newly diagnosed with HIV. Interview transcripts were analysed thematically using coding, with constant comparison of patterns and concepts within and between cases, and discrepancies from majority themes were actively sought. NVivo 11 aided analysis.

**Results:** Participants described the need to 'surrender to' and 'obey' the 'law' of health services, demonstrating subservience in their relationships with providers. There was an expectation that patients should follow health advice as prescribed, with the 'experts' being deemed as responsible for patients' lives. As a result, patients generally exhibited limited autonomy regarding the decision to initiate early ART, with some wanting to do as they were advised, as well as some feeling unable to refuse ART. However, patients' agency could break the bounds of these typically hierarchical practitioner-patient relationships, and some participants would exert their resistance of this power, for example by reportedly agreeing to initiate ART to providers and then not taking the drugs.

**Conclusions:** The power dynamics within practitioner-patient relationships can undermine patients' autonomy in deciding whether to initiate early ART. Some patients bow to the EAA rules and expectations, with many initiating early ART accordingly; and others demonstrate ways to resist them. Further research among those who initiate early ART is needed, to explore how these issues will influence their on-going engagement with treatment and care over time.

## IMPLEMENTATION OF ROUTINE VIRAL LOAD MONITORING IN LESOTHO, MALAWI, MOZAMBIQUE AND ZIMBABWE: A CASCADE ANALYSIS

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**Background:** Routine viral load (VL) to monitor the response to ART has been recommended by WHO since 2013. From 2012 routine VL testing to monitor ART was introduced in MSF projects in Lesotho, Malawi, Mozambique and Zimbabwe. All districts except Changara were rural settings where ART had been extensively decentralised. VL is performed annually in all sites except Malawi (2 yearly). To assess programmatic implementation of routine VL an analysis was carried to assess performance at each step of the VL algorithm.

**Methods:** Analyses were performed between January and November 2015 across six districts in four countries. Reviews of clinical and laboratory records of representative samples of patients were used to determine how each step of the routine VL algorithm (coverage of VL, uptake of enhanced adherence counselling, repeat VL testing (within 2-9 months), re-suppression, and appropriate switch to second-line ART) was implemented within a defined period according to local guidelines (18 months preceding date of analysis in Lesotho, Mozambique and Zimbabwe and 30 months in Malawi). Results were presented to programme staff and barriers for implementation identified. Results:

Site	Buhera, Zimbabwe	Gutu, Zimbabwe	Thyolo, Malawi	Nsanje, Malawi	Roma, Lesotho	Changara, Mozambique*
<b>Year routine VL testing started</b>	<b>2012</b>	<b>2013</b>	<b>2012</b>	<b>2013</b>	<b>2014</b>	<b>2013</b>
No of patients in the analysis	4760	2978	7576	2785	3069	3095
Coverage of routine VL testing (VL1)	91%	74%	56%	32%	70%	62%
VL ≥1000 copies/ml*	14%	15%	9%	20%	10%	40%
EAC documented for VL ≥1000 copies/ml*	57%	76%	62%	56%	70%	70%
Repeat VL test performed (VL2)	68%	67%	55%	40%	42%	23%
Resuppressed to <1000 copies/ml*	43%	39%	46%	32%		22%
VL threshold for switch to second-line ART	1000	1000	5000	5000	1000	3000
Eligible patients switched to second-line ART	37%	35%	15%	38%	37%	10%

\*In Changara, 3000 copies/ml was used as the threshold for action throughout the algorithm.

In those sites with low coverage of VL1 and VL2 challenges included lack of human resources to draw blood, dedicated staff to perform enhanced adherence counselling and lack of effective appointment and tracing mechanisms. Across all sites reluctance to task shift and decentralise second line ART care was cited as a barrier to switching.

**Conclusions:** This analysis demonstrated limited compliance with a routine VL algorithm based on WHO recommendations. Scale up plans for VL monitoring must address human resource issues and make implementation plans for provision of second-line in sites where ART care has been decentralised.

## VIRAL LOAD CASCADE AND PROGRAMMATIC CHALLENGES AFTER 2 YEARS OF ROUTINE HIV VIRAL LOAD TESTING IN MAPUTO, MOZAMBIQUE

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**Background:** Médecins Sans Frontières (MSF) together with the Ministry of Health (MoH) introduced routine viral load (VL) monitoring in December 2013 for ART-enrolled patients in Maputo city, Mozambique. This analysis aims to describe the VL cascade outcomes and the programmatic challenges of routine VL monitoring and counselling intervention after 2 years of implementation.

**Methods:** A retrospective cohort study design with routine program data was used. The study was conducted between July 2013 and March 2015 in six MSF-supported health centres in Maputo City where routine VL monitoring with enhance adherence counselling (EAC) for patients with detectable VL ( $\geq 3,000$  copies/ml) was implemented. All HIV patients more than 6 months on ART were included in the study. Data was analysed using Stata software version 14. Percentages (%) were calculated to report coverage detectability at first VL, coverage of EAC, VL re-suppression and switch to second-line treatment.

**Results:** Among 45,591 ART eligible patients, 14,026 (30.8%) had at least one VL. Median age was 37.5 years (24 to 51), 91.4% were above 15 years and 76.3% were female. Detectability rate was 19.8% ( $n = 2,617$ ) at VL  $\geq 3,000$  and 27.0% at VL  $\geq 1,000$  copies/ml. 34.5% of patients  $< 15$  years had a VL  $\geq 3,000$ , compared to 17.5% of adults  $\geq 15$  years. 702 (26.8%) high VL patients did at least one EAC session. 669 (36%) patients with high VL had a follow-up VL at least 3 months after. 249 (37.3%) re-suppressed. Out of 420 patients with the second high VL, 197 (47%) were referred and approved by the ART Committee to change regimen, and 59 (30%) had switched to second-line treatment.

**Conclusion:** VL coverage remains low after 2 years. The implementation of routine VL requires a multi-sectorial approach and a well-established VL flow. Outcomes reveal high failure rate and the importance of implementing early adherence interventions to prevent developing of treatment failure, specifically for children and adolescents. Access to second-line ART for patients in failure is still limited. Ensuring access to second-line should be a priority alongside ensuring patients with low VL are fast-tracked into a differentiated model of care.

## INCREASING ACCESS TO ROUTINE VIRAL LOAD WITH NEARLY POINT-OF-CARE SAMBA-1: OUTCOMES FROM A DECENTRALIZED HIV PROGRAM IN MALAWI

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**Background:** Viral load (VL) testing is key for timely provision of intensive adherence counselling or switching treatment regimen of suspect failures. From August 2013, Médecins Sans Frontières implemented gradually in 4 decentralised sites and 1 hospital of Chiradzulu district (Malawi) the semi-quantitative (1000 copies threshold) VL test with SAMBA-1, a nearly point-of-care (POC) system. The protocol recommends 2 follow-up tests after a high VL before a change in ART regimen for those remaining high. The objective is to review the VL cascade and identify challenges with VL monitoring.

**Objective:** We describe sequence of VL tests performed between August 2013 and December 2015 in five ART-treatment sites on first line ART-patients with at least 1 VL test, up-to 1 year after the first high VL.

**Results:** Over the study period, 13,675 patients had a VL test, among which 1,611 (11.8%) had a high VL. VL coverage ranged from 60 to 81% depending on POC implementation. Among patients with high VL, 1,146 (71.1%) had follow-up tests. Median time between tests was 3.2 months [IQR 2.8-4.6] and clinical review was same day for over 80% of tests in decentralised sites. Among the 1,146, 354 (30.9%) suppressed at 2nd test and 94 suppressed at 3rd test giving an overall suppression of 39.1% and a marginal gain of 11.3%. A total of 381 patients remained with high VL at 3rd test and 259 (68.0%) were switched to 2nd line regimen in a median time of 1.0 month [IQR 0-3]. Second VL test was missing for 465 patients and third one for 317. Among these, over 80% were still followed on 31/12/2015.

**Conclusion:** Good treatment adherence and VL coverage were observed. Use of POC VL demonstrated short turn-around time for clinical review. However VL follow-up of suspect failures remains a major challenge. Further the VL algorithm of 3 tests showed minimal gain in virological suppression whilst a large number of patients remained on a potentially failing regimen. One follow-up test at 3 months after high VL seems sufficient to confirm treatment failure. This will simplify the process and may lead to improvement in VL test monitoring and HIV treatment outcomes.

## CROSS-SECTIONAL ASSESSMENT OF VIROLOGICAL FAILURE, DRUG RESISTANCE AND THIRD-LINE REGIMEN REQUIREMENTS AMONG PATIENTS RECEIVING SECOND-LINE ART IN 3 LARGE HIV-PROGRAMMES IN KENYA, MALAWI AND MOZAMBIQUE

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**Background:** With access to viral load (VL) monitoring, the number of patients receiving second-line antiretroviral treatment (ART) is increasing in resource-limited countries. We assessed virological response and second-line drug resistance in three large HIV-programmes to inform regimen-requirements, evaluate patient outcomes and support forecasting of effective third-line drugs.

**Methods:** Between November 2014 and December 2015, patients aged  $\geq 5$  years receiving a standard second-line regimen for  $\geq 6$  months were recruited in three HIV outpatient-clinics supported by Médecins Sans Frontières in Kenya, Malawi and Mozambique. Viral load (VL) was quantified and resistance-genotyping performed if VL was  $\geq 500$  HIV RNA copies/ml (virological failure). Sequences were interpreted with Stanford and ANRS algorithms. Virological failures are assessed 6 and 12 months after counselling or regimen change.

**Results:** 824 patients were included (median age 41 years, 45.4% males). In Kenya: among 355 participants (26.9 month median duration of second-line; 71.6% 3TC-TDF-LPV/r), 18.3% (65/355) had VL  $\geq 500$  copies/ml, 16.9%  $\geq 1000$  copies/ml. Among those aged  $\leq 19$  years, 31.2% (20/64) had  $\geq 500$  copies/ml. Overall 24% (16/65) had major PI-resistance, 72.3% major NRTI-resistance, 80% major NNRTI-resistance, and 9.2% major etravirine-resistance (Stanford). Nineteen patients (29.2%) required replacement of ineffective NRTIs, 21 (32.3%) needed to start a third line regimen (change in PI-component), with 3 children requiring paediatric formulations. Six months after regimen change 77.8% (14/18) had VL  $< 20$  copies/ml. In Malawi: among 242 patients (36.3 month median duration of second-line; 81.4% 3TC-TDF-ATV), 16.5% had VL  $\geq 500$  copies/ml, 13.2%  $\geq 1000$ . Among those aged  $\leq 19$  years, 29.4% (10/34) had VL  $\geq 500$ . Sequencing (37/40) detected 2.9% major PI-resistance, 78.4% major NRTI-resistance, 83.8% major NNRTI-resistance, 18.9% major etravirine resistance. Seven patients required switch to a third-line regimen, 12 required NRTI-replacement. Complete resistance and regimen data will be available from all sites, including Mozambique (227 patients, 91.2% TDF-3TC-LPV).

**Conclusions:** These findings indicate good virological suppression in patients receiving second-line ART. Failure rates were notably higher among children and adolescents, highlighting the need for enhanced monitoring. Resistance data were essential to inform optimal regimen choice. Preliminary results indicate good short-term outcomes of patients who needed ART change. Increased access to resistance genotyping and affordable salvage ARVs, including paediatric formulations, are needed.

## ROLE OF COMMUNITY ART GROUP (CAGS) IN INTRODUCING ROUTINE HIV VIRAL LOAD MONITORING IN A RURAL DISTRICT OF MOZAMBIQUE

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**Background:** In December 2013, in line with WHO guidelines, Médecins Sans Frontières together with the Ministry of Health introduced routine monitoring of viral load (VL) for ART-enrolled patients in Changara District, Mozambique. Dried blood spots (DBS) were tested using the bioMérieux NucliSENS assay. More than 50% of ART patients in Changara are CAG members. The aim of the evaluation is to assess the VL cascade in Changara District, Mozambique and to compare outcomes between community ART group (CAG) and non-CAG patients.

**Methods:** Routinely-collected data from the VL monitoring program was analysed retrospectively. The study population consisted of all patients more than 6 months on ART and attending Changara district ART facilities between December 2013 and September 2015. Coverage of VL and VL cascade outcomes were analysed by age, sex, time on treatment, and CAG membership. The high VL cascade included patients with first VL before October 2014.

**Results:** Among 3378 eligible patients, 62% (2108) completed a first VL. Coverage was higher among CAG than non-CAG patients (72% vs. 47%). 40% had a VL  $\geq 1,000$  copies/ml; 60% and 38% among patients  $< 15$  years and  $\geq 15$  years, respectively. There was no significant difference in proportion with elevated VL by sex, CAG status, or time on treatment. Among 352 patients with VL  $\geq 3,000$  copies/ml, 70% had  $\geq 1$  adherence counselling session. Of 82 (23%) who had a repeat VL 3 – 9 months later, 22% had a VL  $< 3,000$  copies/ml. Of an additional 27% (97) with a repeat VL 9 – 15 months later, 30% had a VL  $< 3,000$  copies/ml. 10% (13/131) of patients switched to 2<sup>nd</sup>-line drugs.

**Conclusion:** Routine VL testing is feasible in this remote setting, with DBS sent to a centralised laboratory. Coverage remained low after 2 years but was higher among CAG members; CAGs were integral in disseminating information within CAG and mobilizing other members for VL sample collection. Rates of virological failure were worryingly high in all groups, suggesting that resistance and poor adherence are significant problems in this population. Further work is needed to clarify the reasons for failure and to ensure rapid access to second-line.

## HOW ACCURATE IS THE WHO VIRAL LOAD-BASED FIRST-LINE ART FAILURE DETERMINATION ALGORITHM?: EVIDENCE FROM SOUTHERN SWAZILAND

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**Background:** HIV drug-resistance (HIVDR) testing is used to determine the need for anti-retroviral treatment (ART) switching and make informed decisions on drug selections in resource-rich countries. However, the high costs and very limited testing capacities limit its routine use in resource-limited settings. Therefore, WHO recommends treatment switching when virological failure (VF) is detected, defined as two consecutive viral loads (VL)  $\geq 1000$  copies/ml despite intensive adherence counselling. We aimed to assess the performance of the WHO VL algorithm in rural Swaziland to predict HIVDR and the need for treatment switching.

**Methods:** From 08/2013 to 10/2014, dried blood spot (DBS) samples from patients (aged  $\geq 18$  years) on ART and with VF were genotyped using ATCC kits at the resistance testing laboratory at CDC, (Atlanta) and , DR mutations were interpreted with the Stanford HIVdb algorithm. We combined all levels of DR against first-line ART (lamivudine (3TC) with zidovudine (AZT)/ tenofovir (TDF) and nevirapine (NVP)/ efavirenz (EFV)) and the second-line drug lopinavir/ritonavir (LPV/r), and evaluated the positive predictive value (PPV) of the WHO VL algorithm to accurately identify patients with DR requiring treatment switching.

**Results:** Overall, 135 DBS samples were successfully genotyped and 123 (56.2%) were females. Fifty nine (43.7%) were on AZT/3TC/NVP, 23 (17.0%) on AZT/3TC/EFV, 13 (9.6%) on TDF/3TC/NVP and 40 (29.6%) on TDF/3TC/EFV. AZT resistance in the four regimens ranged from 17.5 - 74.6% ( $p < 0.001$ ), 3TC from 85.0 - 93.2% ( $p = 0.569$ ), TDF from 47.8 - 77.5% ( $p = 0.027$ ) and for NVP and EFV combined from 87.5 - 94.9% ( $p = 0.623$ ). Of the 53 patients receiving TDF, 12 (22.6%) showed resistance against AZT and none against LPV/r. Of the 82 patients receiving AZT, 40 (48.8%) had resistance against TDF and one (1.2%) against LPV/r. The overall PPV was 91.9% and ranged from 87.5% ( $p = 0.5986$ ) for TDF/3TC/EFV to 94.9% ( $p = 0.6477$ ) for AZT/3TC/NVP.

**Conclusions:** This study demonstrated high accuracy of the WHO VL switching algorithm in predicting HIVDR to the current first-line ART regimens. In our setting following a public health approach, most patients failing their first-line regimens may not require DR testing for diagnosis and confirmation of virological treatment failure.

## VIRAL LOAD AWARENESS AMONG PEOPLE ON ANTIRETROVIRAL TREATMENT IN NSANJE DISTRICT, MALAWI

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**Introduction:** In 2014 routine viral load (VL) monitoring was rolled out in Nsanje district, Malawi. To increase patient's awareness on VL, health talks were held in ART waiting areas. Patients' awareness on VL is vital to motivate their adherence and create demand for VL. We assessed patients' understanding of VL in order to further adapt the patient education strategies.

**Methods:** A questionnaire was developed and pretested in Chichewa, examining patients' understanding of the goal of a VL test, test proposal at the clinics and result interpretation. These were administered in August 2015 at 3 health facilities to people on ART above 18 years presenting in the ART waiting area of the facility, after informed verbal consent was requested.

**Results:** A total of 384 patients were interviewed, with 76% being female. Seventy percent had ever heard about VL testing. Of these 267 participants, 77% knew that a VL test measures the amount of HIV in the blood and 88% understood that an undetectable VL means there is still HIV to be found in the blood. Seventy-nine percent did not know what VL result they should worry about. The most common reason for high viral load was according to 65% poor adherence, while 24% thought this was due to having unprotected sex with an HIV+ person. As much as 58% never had a VL test done, with 63% out of the 101 stating that the test was not offered to them by the health care worker. Of the 111 who did get a VL test, only 50% received the result.

**Conclusions:** Patient education on VL has led to a majority of patients on ART being aware of new HIV treatment monitoring standards. Interpretation of VL results by patients remains unsatisfactory and further patient education on result interpretation is needed for viral load to promote patients' self-management. Empowerment of patients to request their VL and its result are important steps in the scale-up of viral load monitoring, which need to be implemented in conjunction with strategies targeting health care workers.

## EXTENDED ART INITIATION CRITERIA CAN BE IMPLEMENTED SUCCESSFULLY IN RURAL SOUTH AFRICA

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**Background:** There is concern that earlier initiation of antiretroviral treatment (ART) in lower resource settings may compromise access to care for patients with lower CD4 counts, and that patients with higher CD4 counts may have lower retention in care (RIC). In July 2014, we extended ART initiation criteria from CD4 cell counts of  $\leq 350$  to  $\leq 500$  copies/ $\mu\text{l}$  in 9 primary health clinics in KwaZulu-Natal, South Africa. Here we assess whether any compensatory reduction in initiation of sicker patients was seen and whether retention among those newly eligible was satisfactory in this public sector setting.

**Methods:** In this retrospective cohort analysis we compare proportions initiated on ART and RIC at 6 months among patients with baseline CD4 taken between July 1 and December 31, 2014 (CD4  $\leq 500$  copies/ $\mu\text{l}$  eligibility cohort) and between July 1 and December 31, 2013 (CD4  $\leq 350$  copies/ $\mu\text{l}$  eligibility cohort). Pregnancy, TB, age  $< 15$  years and WHO stage 3 or 4 were exclusion criteria. Outcomes were determined from baseline CD4 and analysed using survival analysis.

**Results:** There were 768 patients in the CD4  $\leq 350$  copies/ $\mu\text{l}$  eligibility cohort, with 31% having baseline CD4  $\leq 200$  copies/ $\mu\text{l}$ ; 51% 201 – 350 copies/ $\mu\text{l}$ , and; 12% 351 – 500 copies/ $\mu\text{l}$ . Of the 856 in the CD4  $\leq 500$  copies/ $\mu\text{l}$  eligibility cohort 23% had a baseline CD4  $\leq 200$  copies/ $\mu\text{l}$ , 37% 201 – 350 copies/ $\mu\text{l}$ , and 33% 350 – 500 copies/ $\mu\text{l}$ . In both cohorts, median age was 31 years and 67% were female.

Among participants with CD4 351 – 500 copies/ $\mu\text{l}$ , percentage initiated on ART within 3 months increased 10-fold between the periods from 7% (95% CI: 3.4 – 13.0%) to 70% (95% CI: 61 – 78%); among those with CD4  $\leq 200$  copies/ $\mu\text{l}$  this increased from 70% (95% CI: 55 – 80%) to 86% (95% CI: 79 – 93%). The proportion initiated within 3 months among those with baseline CD4 201 – 350 copies/ $\mu\text{l}$  remained unchanged at approximately 75%. RIC at 6 months was 82% (95% CI: 79 – 85%) in the CD4  $\leq 500$  copies/ $\mu\text{l}$  cohort and 80% (95% CI: 76 – 84%) in the CD4  $\leq 350$  copies/ $\mu\text{l}$  cohort.

**Conclusions:** Expanding eligibility for ART to CD4  $\leq 500$  copies/ $\mu\text{l}$  resulted in rapid change in time to ART initiation among those with baseline CD4 351 – 500 copies/ $\mu\text{l}$  without compromising initiation or RIC among those with a CD4  $\leq 350$  copies/ $\mu\text{l}$ . Extended initiation criteria can be successfully implemented in high HIV prevalence, low resources-settings without compromising access to care for more vulnerable patients.

## 6-MONTH TREATMENT OUTCOMES OF PATIENTS INITIATING ART UNDER THE WHO TEST & TREAT APPROACH

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**Background:** WHO recommends antiretroviral therapy (ART) for all people living with HIV regardless of CD4 count, known as Test and Treat (T&T). However, T&T is feared to lead to inferior treatment outcomes in patients initiating ART at high CD4 counts, specifically in men. We report on early outcomes of one of the first T&T demonstration projects in the public health sector in Sub-Saharan Africa.

**Methods:** This is a prospective cohort of non-pregnant patients (aged  $\geq 16$  years) who initiated ART in 9 public health facilities in the rural Nhlanguano health zone in Swaziland, from October 2014 to April 2015. Follow-up time was until the occurrence of an unfavourable treatment outcome (death/lost-to-follow), or censored at date of transfer-out and database closure (September 2015). Kaplan-Meier estimates described 6-month retention on ART rates, and Cox proportional hazard models assessed predictors of the unfavourable outcome while adjusting for baseline characteristics (sex, CD4 count, WHO stage, same-day treatment initiation, newly-diagnosed/ previously-diagnosed HIV infection, body-mass index, and baseline TB status).

**Results:** Of 625 patients initiated on ART, 427 (68.3%) were females, the median age was 33 years (IQR: 27 – 42 years) and 302 (48.3%) had newly-diagnosed HIV infection. At ART initiation, 280 (44.8%) patients had a CD4 count  $\leq 349$  copies/ $\mu\text{l}$ , 159 (25.4%) 350 – 499 copies/ $\mu\text{l}$ ; 182 (29.1%)  $\geq 500$  copies/ $\mu\text{l}$ , and 4 (0.6%) had missing value. The overall crude six-month retention on ART was 86.8%, and was similar among women (87.0%) and men (86.2%) ( $p = 0.74$ ). Retention was higher among those with a CD4 of 350 – 499 copies/ $\mu\text{l}$  (89.2%) or CD4  $\geq 500$  copies/ $\mu\text{l}$  (90.0%), compared to those with a CD4  $< 350$  copies/ $\mu\text{l}$  (83.5%) ( $p = 0.05$ ). In multivariate analysis, there was no difference in outcome by sex (women: adjusted hazard ratio [aHR]: 1.08, 95% CI: 0.68 – 1.72). However, an unfavourable treatment outcome was inversely associated with CD4 level (CD4  $\geq 500$  copies/ $\mu\text{l}$ : aHR: 0.71, 95% CI: 0.40 – 1.24; CD4 350 – 499 copies/ $\mu\text{l}$ : aHR: 0.75, 95% CI: 0.42 – 1.31) compared to those with a CD4  $< 350$  copies/ $\mu\text{l}$ ). The probability of an unfavourable treatment outcome was greater among those with WHO stage III/IV disease (aHR: 2.35, 95% CI: 1.41 – 3.89), or same-day ART initiation (aHR: 1.68, 95% CI: 1.02 – 2.79).

**Conclusions:** Patients with high baseline CD4 counts had good early treatment outcomes when ART was started under the T&T approach. Programme managers in similar settings should not be afraid of adopting T&T.

## USE OF DETERMINE TB-LAM IN HIV-POSITIVE ADULTS WITH LOW CD4 COUNTS IN PROGRAMMATIC CONDITIONS

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**Background:** Determine TB LAM is a new point-of-care test, performed on urine, for diagnosis of tuberculosis (TB) in HIV-positive patients. We assessed the diagnostic value of using TB LAM in programmatic conditions.

**Description:** HIV-positive inpatients, 15 years and older were recruited prospectively in Chiradzulu District Hospital, regardless of their reason for admission and CD4 count. TB diagnosis was done through clinical assessment, sputum microscopy, Xpert MTB/RIF, or chest X-ray. In addition, urine was tested using TB LAM, but the results were not used for treatment decisions. Prior to using TB LAM, the laboratory technicians were given a one-hour training. TB LAM was done in the laboratory with no extra equipment or additional staff, and with minimal supervision required.

**Lessons learnt:** From August to December 2015, 190 patients were included in the study. Their median CD4 count was 344 cells/ $\mu$ l (IQR: 166 – 469 cells/ $\mu$ l). In total, 189 (99.5%) patients provided a urine sample, 141 (74.2%) a sputum sample, and 133 (70.0%) had a chest X-ray. TB LAM results were available within 2 hours, microscopy and Xpert MTB/RIF within 2 days, and X-ray in average in 4 days. Agreement between two readers was 97.2% (kappa = 0.96) for the interpretation of a TB LAM result, and 98.3% (kappa=0.96) for the test grade. In total, 56 (29.5%) had a positive TB LAM result, 53 (27.9%) an X-ray suggestive of TB, 13 (6.8%) positive microscopy, and 15 (7.9%) a positive Xpert MTB/RIF result. Forty-eight patients were started on TB treatment within 2 months. Of the 56 patients with a positive TB LAM result, 34 (60.0%) were not started on treatment. Mortality at 2 months was 26.7%: 31.0% among those not on treatment and 16.7% among those on treatment. Mortality in TB LAM-positive patients was 28.6%: 35.7% among patients not on treatment, and 21.4% among those on treatment.

**Conclusion/Next steps:** The Determine TB LAM test is easy to implement in programmatic conditions, using a readily obtainable sample, and providing quick results. In a context where there are difficulties with doing other diagnostic tests, TB LAM may detect TB that would otherwise be missed among very sick HIV-positive patients.

## THE EFFECT OF COMMUNITY ART GROUPS ON RETENTION-IN-CARE AMONG PATIENTS ON ART IN TETE PROVINCE, MOZAMBIQUE

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**Background:** ART programs in many African countries have high attrition rates (death or loss-to-follow-up (LTFU) combined). In 2008 patients on ART in Tete Province, Mozambique, began forming community ART groups (CAGs) to overcome barriers to retention-in-care (RIC). CAGs are peer groups in which members take turns to collect ART at the health facility. Patients on ART can either join a CAG or remain in clinic-based care. We conducted a retrospective cohort study among adult patients on ART to quantify the effect of CAG versus individual care on RIC.

**Methods:** Information to May 2012 was collected from patient records at 8 health facilities. Patients who started ART  $\geq 6$  months before CAGs started at the health facility, or aged  $< 15$  years at ART initiation, were excluded from the analysis. Furthermore, patients had to remain in care for at least six months after starting ART to be included in the analysis. Survival analysis was used to compare RIC among patients in CAGs and patients in individual care by time on ART, with time to joining a CAG treated as an irreversible time-dependent covariate. Cox regression was used to determine hazard ratios (aHR) for attrition, adjusted for age, sex, and health facility.

**Results:** Of the 2,683 patients in the analysis, 62.6% were female. Their median age was 32 years. 12-month and 24-month RIC from point of eligibility were 99.3% (95% CI: 97.8% – 99.8%) and 96.3% (95% CI: 94.4% – 97.6%) among patients in CAGs, and 89.0% (95% CI: 87.3% – 90.2%) and 81.3% (95% CI: 78.8% – 83.4%) among those in individual care ( $p < 0.001$ ). Patients in CAGs were more than four times less likely to die or be LTFU (aHR: 0.22; 95% CI: 0.15 – 0.32;  $p < 0.001$ ).

**Conclusions:** Among patients on ART, RIC was substantially better among those in CAGs than those in individual care. While exclusion of the first 6 months on ART reduced the potential impact of survivor bias, residual or unmeasured confounders may contribute to the differences observed. Nevertheless this study confirms that patient-led ART distribution through CAGs results in high RIC, and supports the Mozambique Ministry of Health decision to implement CAGs nationally.

## IMPLEMENTATION OF COMBINATION ART REFILLS MODELS IN RURAL SWAZILAND

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**Background:** The WHO advocates for differentiated HIV care and considers a broad range of community-based care models for patients stable on anti-retroviral therapy (ART). These care models aim to better respond to patient needs and to alleviate pressure on health systems caused by rapidly growing patient numbers. Most settings, however, utilized a single community-based care model only. We operationalize a combination of community ART care models in public health sector and assessed early outcomes.

**Methods:** Three community ART delivery care models were deployed in the rural Shiselweni region (Swaziland), from February to December 2015. First, Treatment Clubs (TC) are groups of 30 patients stable on ART who meet every 3 months at a secondary health facility for patient education and drug-refills. Second, Community ART Groups (CAG) comprise a maximum of 6 patients who alternate to attend the primary health clinic for consultation and pick up drugs for the other group members. Third, Comprehensive Outreach Care (COC) integrates drug refills into existing mobile clinic outreach activities for geographically isolated communities. We described baseline factors at enrolment, and 6-month retention in community care models and proportion of patients transferred back to routine clinical care.

**Results:** On average, 47 patients enrolled into community-ART care each month: 51.1% into TC (242 patients in 8 groups), 34.0% in CAG (164 patients in 38 groups) and 14.9% in COC (65 patients in 2 remote communities). All patients had a VL<1,000 copies/ml, the median CD4 was 512 (TC), 528 (CAG) and 657 (COC) cells/ $\mu$ l ( $p=0.27$ ), the median age was 40, 40 and 45 years ( $p = 0.11$ ), and 74.8%, 66.5% and 64.6% were females ( $p = 0.03$ ). Retention in care after 6 months was highest in TC (97.5%) when compared to CAG (79.2%) and COC (78.4%) ( $p<0.01$ ). 53/471 patients (11.3%) returned back to and were retained in routine clinic care and one (0.21%) was recorded as death in COC.

**Conclusions:** Concurrent implementation of three community ART care models was feasible. Although a proportion of patients returned back to clinic care, overall ART retention was high and should encourage program managers to apply differentiated care models adapted to their specific setting.

## INTEGRATING HIV AND NCD PATIENTS IN ADHERENCE CLUBS IN KIBERA, KENYA: A QUALITATIVE STUDY

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**Background:** The number of people on antiretroviral therapy (ART) for the long-term management of HIV in low- and middle-income countries (LMICs) is continuing to increase, along with those suffering from non-communicable diseases (NCDs). The need to provide large volumes of HIV patients with ART has led to significant adaptations in medication delivery (including facility clubs and community adherence groups), but access to NCD care remains limited, particularly in resource-poor settings. In 2013, Medication Adherence Clubs (MACs) were introduced as an alternative to standard care for stable NCD and HIV patients in the urban slum of Kibera, Nairobi, Kenya. MACs enable combined groups of up to 30 HIV/NCD patients to collect medication refills every three months, rather than through individual appointments.

**Methods:** In 2015, we conducted qualitative research to assess patient and health-care worker perceptions and experiences of MACs. A total of 106 MAC and non-MAC patients and health-care workers participated, and 19 in-depth interviews and 10 focus group discussions were conducted. Data were translated and transcribed and a coding framework developed before analysis using NVivo (version 10, 2012). Routine data were also analysed to determine the characteristics of MAC patients and the number of MAC meetings held.

**Results:** During the first year of implementation, 109 MAC meetings took place, representing 2208 individual refills. Most (64%) MAC members were female; 71% were HIV-positive. MACs were perceived as acceptable, time-saving, and a valuable source of information about chronic diseases and peer-support by HIV-positive and NCD patients. Implementation challenges included recruitment, patients' understanding of MACs, and the timing of clubs. A small number of HIV-positive patients felt integrated groups affected disclosure.

**Conclusions:** Applying lessons learned from large-scale HIV drug rollout can aid the provision of medication and peer-support to large numbers of stable patients with chronic illness. Through MACs, we have demonstrated that an innovative, integrated approach to repeat prescribing for chronic diseases including HIV can be implemented in resource-poor settings. Extending models of care previously only offered to HIV-positive cohorts to NCD patients allows for the efficient management of co-morbidities and enables patients to benefit from faster refills, health education and peer support.

## NEW HEIGHTS FOR DIFFERENTIATED CARE: 3 YEARS OF COMMUNITY ART GROUPS IN THE MOUNTAINS OF RURAL LESOTHO

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**Introduction:** Lesotho, a mountainous country with approximately 2,171,000 inhabitants, has the third highest HIV prevalence in the world. The Lesotho ART programme suffers from high loss to follow up and treatment scale up has been plagued by chronic understaffing, medicines shortages and patient access challenges. Community ART groups (CAGs) allow stable patients take turns to collect antiretroviral therapy (ART) for fellow group members who only attend clinics once per year, allowing for VL measurement. We present outcomes from 3 years of CAG implementation in rural Lesotho.

**Method:** In this retrospective cohort study, we compare outcomes among CAG members with stable adult patients on ART at 9 clinics in rural Lesotho. Patients eligible to join CAGs were those retained in care after >6 months on ART with a CD4 above 350 cells/ $\mu$ l. Outcomes in CAG were analysed using survival analysis. Loss to follow-up (LTFU) was defined as missing a scheduled appointment by three or more months. A semi structured interview was used to explore perceptions of CAGs among a purposeful sample of patients and nurses.

**Results:** Between September 2012 and September 2015, 888 stable ART patients enrolled in a CAG at the sites of interest. There were 2,326 comparable stable ART patients in conventional care during this period. Retention at 12 months for CAG participants was 85% compared to 62% among non CAG patients. Virological suppression among those retained in CAGs at 1 year was 79%. Qualitative data show how CAG membership reduced the time and money spent by patients, and enhanced adherence, allowing patients to remain on ART. Clinicians working in the study area also reported a workload reduction following CAG introduction.

**Conclusion:** Patients in CAGs had a higher retention in care than patients in conventional care and good virological suppression. In Lesotho where almost 60% of people live below the poverty line and access to clinics is particularly challenging, CAGs have the potential to remove barriers to access ART and thus facilitate ART scale-up in this very constrained healthcare system.

## UPTAKE OF DIFFERENTIATED MODELS OF ART DELIVERY IN UTHUNGULU, KWAZULU-NATAL

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**Background:** In 2012, KwaZulu-Natal Department of Health supported by Médecins Sans Frontières implemented differentiated models of ART delivery aiming to decongest health facilities and support adherence and retention in care for stable patients on ART in uThungulu district. A mix of ART delivery strategies were offered: standard care (2-monthly clinical consultation and ART collection), facility (FC) and community clubs (CC, lay counsellor-led groups of up to 30 patients meeting 2-monthly for ART collection and yearly for clinical consultation) and/or Community ART groups (CAG, patient-lead groups of 3 to 8 patients rotating 2-monthly for ART collection for all members and yearly clinical consultation). By 2015, FC were implemented in 8 clinics, CC in 2 clinics and CAGs in 4 clinics. In order to further adapt the roll-out of these models, we assessed the uptake of patients per model.

**Methods:** Routine data was abstracted from national electronic database (Tier.net) and models' specific registers, marking the choice per patient per model.

**Results:** Out of 7,267 stable patients on ART, 1,512 (21%) opted for a grouped model of ART delivery. In the 3 urban clinics, out of 4743 stable patients, 897 patients (19%) enrolled in grouped model of ART delivery. Amongst them, 864 (96.3%) opted for FC, 20 (2.2%) for CC and 13 (1.4%) for CAG. In the 5 rural clinics, out of 2524 stable patients, 616 patients (24.4%) opted for a grouped model of ART delivery. Amongst them, 417 (67.7%) opted for FC, 91 patients (14.8%) for CC and 108 (17.5%) for CAG.

**Conclusion:** The high uptake of differentiated models of ART delivery shows they can decrease the burden on the health system and patients. Preferences for certain models depend on the setting; more patients in rural settings opted for community based models. Not all patients want to join a group, hence the need to develop improved individual ART delivery strategies such as fast lane spaced appointment systems. Qualitative research looking at patient and health care workers preferences is needed to ensure models best fit patients' need in a given context.

## "WE ARE PART OF A FAMILY". BENEFITS AND LIMITS OF COMMUNITY ART GROUPS IN THYOLO DISTRICT, MALAWI: A QUALITATIVE STUDY

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**Introduction:** In 2012 Community ART Groups (CAGs) were piloted in Thyolo District, Malawi as a community-based model of ART delivery to overcome patients' barriers in accessing treatment and decrease health care workers' workload. CAGs are self-formed groups of patients on ART who rotate at the health facility for drug pick up for all group members. We conducted a qualitative study to assess the benefits and challenges of CAGs from the patients' and health care workers' (HCWs) perspective.

**Methods:** Fifteen focus group discussions, 15 individual in-depth interviews and 2 days of participant observation were performed in 2 health centres. The 94 study participants included CAG members, ART patients eligible for CAGs but in conventional care, former CAG members who returned to conventional care and HCWs. They were purposefully selected from ART registers considering their socio-demographic characteristics. Narratives were audio-recorded, transcribed, and translated from Chichewa to English. Data was analysed through a thematic analysis. The study was approved by the National Health Sciences Research Committee of Malawi.

**Results:** Patients as well as HCWs highly appreciated the practical benefits of CAGs in reducing frequent clinic visits, resulting in fewer transportation and occupational costs for patients and a reduced workload for HCWs. Additionally peer support was perceived as an added value of the groups allowing not only sharing of the logistical constraints of drugs refills, but also enhanced emotional support, with the group acting as a forum for understanding and support to adhere to ART. Barriers to join a CAG were a lack of information on CAGs, unwillingness to disclose ones HIV status, mobility and group conflicts. HIV related stigma persists and CAGs were perceived as an effective strategy to minimize exposure to discriminatory labelling by community members.

**Conclusions:** CAGs are an acceptable model for ART delivery for PLHIV and HCWs. The CAGs addressed patient's practical barriers to accessing ART and improved peer support, a factor patients considered fundamental to their wellbeing. CAGs had a limited impact on reducing HIV-related stigma. Further expansion of this model of ART delivery should be considered in similar settings.

## YOUTH ART ADHERENCE CLUBS: OUTCOMES FROM AN INNOVATIVE MODEL FOR HIV POSITIVE YOUTH IN KHAYELITSHA, SOUTH AFRICA

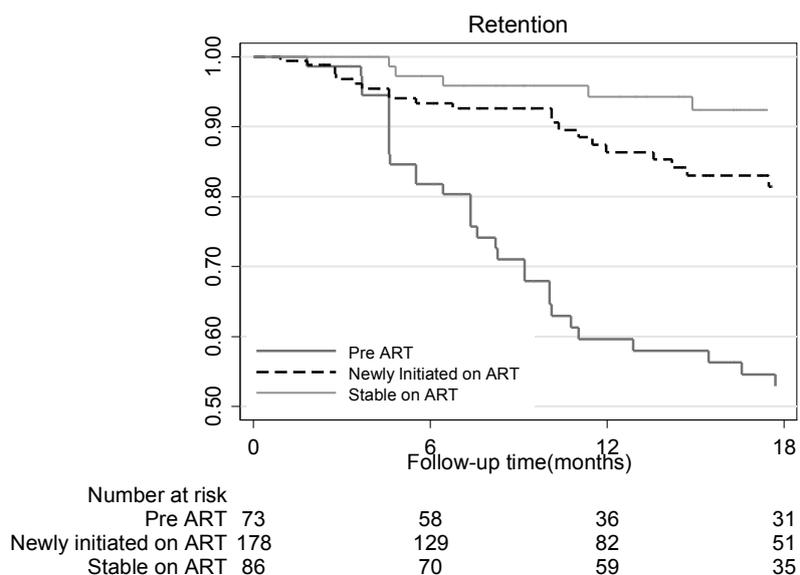
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**Background:** Retaining youth, both anti-retroviral treatment (ART) ineligible and those on ART, remains challenging with higher rates of loss to follow-up (LTFU) than their adult counterparts. Adjusting the ART adherence club model for youth, enrolling ART ineligible youth to expose them to peers on ART and integrating family planning (FP), may address this challenge.

**Methods:** From March 2012 to May 2015, HIV-positive youth aged 12 to 25 years old, attending a youth clinic, were enrolled in Youth Clubs (YCs). Those ineligible for ART, newly initiated on ART, or stable on ART, were combined in groups of about 20. Separate groups were formed for younger school-attending youth, and older youth. YCs were facilitated by a lay counsellor with structured session guides. ART supply, FP and HIV clinical management were integrated within the model. We conducted a retrospective cohort analysis with LTFU defined as no YC or clinic contact from June to August 2015. We describe characteristics and retention outcomes using Kaplan-Meier methods, stratified by enrolment category.

**Results:** 337 youth (21.7% ineligible for ART, 52.8% newly initiated on ART, and 25.5% stable on ART) enrolled in YCs. They contributed 414.8 person-years to the analysis (median: 1.2 person-years; interquartile range [IQR]: 0.5 – 1.9 person-years). The majority were female (85.8%) with median age at YC enrolment of 22.3 years (IQR: 20.3 – 23.7 years). 58 (17.2%) attended school clubs. Overall retention at 12-months was 81.7% (95% confidence interval [CI] 76.4 – 86.0%), and varied by enrolment category (p-value<0.001): 52.9% (95% CI: 40.0 – 64.2%) among those ineligible for ART; 86.4% (95% CI: 78.7 – 91.4%) among those newly-initiated on ART, and 94.3% (95% CI: 85.4 – 96.8%) among those stable on ART (Figure 1). Over the study period, 1 (3%) died, 101 (30.0%) transferred out (of whom 60 graduated to adult care), and 71 (21.1%) were LTFU. 18 initiated ART, and 84 became stable on ART.



**Conclusion:** The YC model supported high rates of retention among young adults on ART. Youth ineligible for ART remained difficult to retain, despite integration into groups with youth on ART.

## PILOT ASSESSMENT OF THE DIAGNOSTIC ACCURACY OF CEPHEID GENEXPERT HIV-1 QUAL FOR EARLY INFANT DIAGNOSIS

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**Background:** Implementation of early infant diagnosis (EID) of HIV infection requires availability of diagnostic tests that are affordable, simple to use, and which improve diagnostic and treatment outcomes by enabling earlier initiation of infected infants on antiretroviral therapy (ART). The Xpert HIV-1 Qual assay (Cepheid, CA, USA) is a novel platform licensed for diagnosis of HIV among children. There is limited information on its accuracy in field settings. MSF and the Malawi Ministry of Health collaborate on implementation of EID in Nsanje District, Southern Malawi. In preparation for a larger feasibility study on Xpert HIV1 Qual implementation, we carried out a pilot diagnostic accuracy study of Xpert HIV-1 Qual for diagnosis of HIV infection among infants and children.

**Methods:** The pilot study used heel-prick dried blood spot samples from HIV-exposed infants and children aged 6 weeks to 18 months, having HIV-PCR testing for diagnosis or confirmation of HIV infection. The samples were diagnostic samples from Nsanje District, using the Abbott RealTime HIV-1 Qualitative test at Queen Elizabeth Hospital Laboratory in Blantyre. The samples were from consecutive tests carried-out between 4 December 2015 and 6 January 2016 using the Abbott RealTime Assay. The sample size was limited by the availability of test cartridges (n = 400). Laboratory tests were performed according to the manufacturer's instructions. Samples taken more than 2 months before the start of the study, and those not meeting quality criteria, were excluded. Stata was used to estimate sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) of Xpert HIV-1 Qual.

**Results:** 378 samples were tested. 17/378 (4.5%) were HIV positive. Xpert HIV-1 Qual detected 16 out 17 HIV-positive, and 358 out 361 HIV-negative cases. The sensitivity of Xpert HIV-1 Qual was 94.1% (95% CI: 71.3 – 99.9%); the specificity was 99.2% (92% CI: 97.6 – 99.8%); the positive predictive value (PPV) was 84.2% (95% CI: 63.2 – 94.3%); and the negative predictive value (NPV) was 99.7% (95% CI: 98.2 – 100%).

**Conclusions:** The pilot study found a high accuracy of Xpert HIV-1 Qual in diagnosing HIV among infants and children <18 months of age. Further research is warranted to evaluate feasibility and effectiveness of decentralized Xpert HIV-1 Qual implementation at a district level.

## ACCESS TO ARVS AND SOUTH AFRICAN PATENT LAW REFORM: REFLECTION AND WAYS FORWARD FOR THE FIX THE PATENT LAW CAMPAIGN

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**Background:** Over the past 15 years, South Africa has been a pioneer of expanding generic medicine access, with constant battles led by civil society advocates to challenge patent monopolies of pharmaceutical companies that block sustainable access to affordable ARVs. Yet, in South Africa, many access challenges for newer ARVs and other medicines needed by people living with HIV remain, while ongoing patent law reform has triggered intensive debates and advocacy.

**Description:** This research will examine strategies pursued by civil society organisations in South Africa over the past 15 years, their impact on medicines access and lessons learned. It will further review the ongoing reform of South Africa's intellectual property (IP) system, and the opportunities and challenges to adopting pro-public health patent laws.

**Lessons learnt:** Over the past 15 years, significant victories have been won through strategies employed by civil society organisations to secure access to generic ARVs in South Africa, including filing competition commission cases and calling for the granting of compulsory licenses. Today, a first line ARV regimen is 96% cheaper than in 2000, supporting the scale-up of treatment. However, fighting access battles drug-by-drug on an ad hoc basis has not changed systemic problems, such as current patent law lacking accommodation of public health needs. Seeking to adopt a more systemic approach to improve accessibility of medicine for all, the Fix the Patent Laws Coalition was founded in 2011, with 18 patient groups joining to date. During 2013, the South African government released a draft policy committing to pro-public health reform of the country's intellectual property laws. Pharmaceutical companies have responded with various attempts to derail such reform.

**Conclusion/opportunities:** South Africa is at a critical stage in the ongoing battle for access to medicine versus expanding intellectual property protection. While there is opportunity for broad legislative reform to facilitate access to newer ARVs and all medicines there is significant push back from pharmaceutical companies. Fix the Patent Laws Coalition's experience demonstrates the need for greater international solidarity and coordination with adequate technical and political support in reforming the national patent laws for public health and pushing back on pharmaceutical companies' effort to thwart reform.

## PATENT OPPOSITIONS: BREAKING PATENT MONOPOLIES

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**Background:** The availability of affordable generic ARVs from India has been crucial in providing and expanding treatment for millions of people living with HIV globally. The key contributing factor for this uninterrupted supply have been safeguards in the patent law enabling the generic companies to develop, register and supply generic versions of drugs patented elsewhere. After introduction of product patent regime in 2005 in India restricting entry of generics in the market, use of public health safeguards such as patent oppositions facilitated in protecting generic competition.

**Description:** Our research will showcase all the key patent oppositions filed by patient groups in India on patent claims covering ARV drugs and the impact of these in stopping unwarranted patents from blocking people's access to more affordable medicines. Some of the key patent applications opposed that has been covered in this research include: Lamivudine/zidovudine, tenofovir, nevirapine syrup, abacavir, lopinavir/ritonavir, and atazanavir.

**Lessons learned:** Patent oppositions for ARVs have been very useful in deterring patent "evergreening" of HIV medicines. In most cases, patent oppositions have been followed by rejections, with the final result of ARVs being brought into the public domain. This has played a huge role in expanding HIV treatment to 16 million people globally today.

**Conclusions/Next steps:** Opposing patents is increasingly becoming a useful tool for civil society to challenge questionable monopolies, increase competition and access domestically. As PLHIVs today are dying of co-infections such as TB and hepatitis C, filing oppositions could pave the way for early market entry of generic versions of new ARVs, direct acting antivirals (DAAs) and TB medicines.

To encourage more people to file oppositions, a civil society platform in form of Patent Opposition Database has been set and is continuously updated with help from experts engaged in opposition work across the world. This is an online resource for individuals seeking to explore how to challenge the weak patents on essential medicines and actively seek contributions from the public to make the Database as complete and useful a resource as possible.

## PRIORITY FAST TRACKING HIV RESPONSE IN WEST AND CENTRAL AFRICA TO HALT HUMAN AND MEDICAL CONSEQUENCES OF LOW ARV COVERAGE

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**Background:** While access to HIV treatment expanded worldwide, Médecins Sans Frontières (MSF) witnesses first-hand serious delays in scale-up in West and Central Africa (WCA), where only one in four people living with HIV (PLHIV) have access to treatment and only 15% of children, much below average coverage in Southern Africa. The region accounts for 18% of all PLHIV, 45% of children born with HIV, 21% of new infections and one third of AIDS related deaths. Without urgent acceleration for the region, worldwide plans to reach the 90-90-90 targets by 2020 are in jeopardy.

**Descriptions:** We investigated key obstacles for expanded antiretroviral treatment (ART) initiation and retention in care in WCA, focusing on contexts where MSF provides HIV services, including three in-depth case studies (DRC, CAR, Guinea). Systematic review of key indicators for ART-coverage, enabling factors and strategies including alternative models of care was done.

**Lessons learned:** Recurrent crises compound problems, but backlog relates mainly to pre-existing health system problems. Integrating HIV care within weak health systems without ensuring equitable access undermines effective, timely and quality HIV-services. Early initiation and retention in care is hampered by frequent stock-outs, financial barriers and lack of staff motivation. Relatively lower HIV prevalence decreases priority for government and international actors. Global Fund is main or only funding source. Reluctance to task shifting, lay counsellors, longer periods of drug refills, community approaches etc. prevail. Pressure from patient associations is weak, with insufficient support to groups advocating for PLHIV's needs and rights, combating stigma and monitoring access barriers.

**Next steps:** Countries with biggest treatment gaps and most urgent unmet needs have proportionally less benefited from effective scale-up strategies. Governments and international actors need to step up fast track responses to close treatment gaps by adapting existing approaches. Urgent mobilization of all health actors is needed to mitigate barriers to ART initiation and adherence, including ensure HIV testing and treatment free of charge for all PLHIV, decentralised and simplified ART provision, task-shifting, guaranteeing uninterrupted supply of HIV commodities. Prone to crises or instability, relevant and regularly updated contingency plans need to be developed and implemented to ensure continued treatment and enrolment.

## SPATIAL ASSOCIATION BETWEEN POPULATION VIRAL LOAD AND HIV INCIDENCE

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**Background:** Treatment as Prevention programs aim at reducing HIV incidence by increasing the proportion of HIV-positive individuals with undetectable viral load (VL) through ART roll-out. However, critical data on the relation between population VL and incidence are needed. We explored the spatial association between HIV incidence and population VL in a high HIV prevalence setting in western Kenya.

**Methods:** We conducted a population-based survey of persons aged 15 to 59 years in Ndhiwa sub-county, Nyanza, Kenya, collecting spatial (cluster and health centre location) and individual (including, HIV status, incidence and VL) information. Population VL is defined as the proportion of individuals HIV positive with a VL >1,000 copies/ml among the entire population. Population VL, HIV incidence and distance to the nearest health centre (HC) delivering ART, were derived. A mixed Poisson regression model of incidence was used, adjusted for age (9 age groups), sex, distance to HC (3 groups) and population VL in each cluster (6 groups).

**Results:** A total of 6,076 individuals from 165 clusters participated to the survey. HIV prevalence was 24.1% (95% CI: 23.0 – 25.2%). VL suppression among HIV-positive participants was 39.0% (95% CI: 35.9 – 42.2%). Among all participants, 13.7% (95% CI: 12.9 – 14.6%) were HIV positive with a VL <1,000 copies/ml. Incidence increased with population VL and was 1.7, 3.3, 4.8 and 5.4 new cases per 100 person-years for a population VL of 5 – 10%, 10 – 15%, 15 – 20%, and 20 – 25%, respectively. In the model, incidence was strongly associated with population VL. Relative risks were 1.26 (95% CI: 0.6 – 2.6), 2.45 (95% CI: 1.3 – 5.0), 3.40 (95% CI: 1.8 – 7.0), 4.02 (95% CI: 2.0 – 8.4) and 4.46 (95% CI: 2.0 – 10.6) for a population VL of 5 – 10%, 10 – 15%, 15 – 20%, and 20 – 25% compared to reference 0 – 5%.

**Conclusions:** We found a strong association and gradient between HIV incidence and population HIV viral load. This association suggests that population-level reduction of HIV incidence could be achieved by reducing population viral load through ART roll-out in the general population.

## LINEZOLID FOR THE TREATMENT OF RIFAMPICIN-RESISTANT TB IN KHAYELITSHA, SOUTH AFRICA: STRATEGIES FOR IMPROVING ACCESS

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**Introduction:** Rifampicin-resistant TB (RR-TB) is a major source of morbidity and mortality for persons with HIV in South Africa, and treatment is only successful in approximately half of those diagnosed and initiated on treatment. The use of new drugs — bedaquiline and delamanid — and re-purposed drugs — linezolid (LZD) and clofazimine — have potential to improve outcomes. The cost of these medications, particularly LZD, has led to restricted use even in patients who might clearly benefit. We have previously described improved outcomes for patients treated with LZD in Khayelitsha. Here we focus on strategies for reducing drug costs to improve access.

**Methods:** A retrospective record review of persons receiving LZD through a programme supported by Médecins Sans Frontières (MSF) combined with a descriptive analysis of drug costs over time was conducted.

**Results:** A total of 128 patients in Khayelitsha were treated between 2011 and 2015. Between 2011 and early 2014, the average cost of LZD for MSF in South Africa was nearly 65 USD (700 ZAR) per tablet, which translated into about 49,000 USD (520,000 ZAR) per two-year treatment course. In June 2014, MSF obtained permission from South Africa's Medicines Control Council to import a quality-assured generic at an 88% price reduction (8 USD, or ~85 ZAR) for use in Khayelitsha, under Section 21 conditions. Section 21 allows for the import of non-registered medications for persons with serious diseases or diseases with public health implications. As a result of price reductions MSF procured LZD for 85 (66%) patients after June 2014 compared to 43 (34%) before June 2014. Nationally, however, LZD is not purchased on tender for TB in the public sector and costs remain high. Ongoing work is underway to support registration of generic forms of LZD in South Africa.

**Conclusions:** Linezolid is an important medication for improving outcomes among persons with RR-TB, however cost has hindered wider use in South Africa. MSF employed a variety of strategies to eventually secure access to a more affordable, generic version of LZD in Khayelitsha. Wider use of Section 21 import waivers to obtain more affordable LZD, as well as the fast-track registration of more quality assured suppliers in South Africa, could result in wider access nationwide and ensure that all patients with a clinical indication for RR-TB have access to this lifesaving medication.

## SELF-ADMINISTERED TREATMENT FOR THE CONTINUATION PHASE OF RIFAMPICIN-RESISTANT TUBERCULOSIS TREATMENT: FEASIBILITY AND IMPACT ON PATIENT OUTCOMES IN KHAYELITSHA, SOUTH AFRICA

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**Background:** Daily directly-observed therapy (DOT) is recommended for rifampicin-resistant tuberculosis (RR-TB) patients throughout the course of treatment. This can negatively impact adherence during the continuation phase when patients have clinically improved, particularly for HIV co-infected patients who are accustomed to self-managing care. Daily DOT also places a large burden on health care services. We assessed the impact of a self-administered treatment (SAT) intervention in a South African township with high rates of RR-TB/HIV co-infection.

**Methods:** Community-supported SAT for patients in the continuation phase was initiated progressively in four of nine MSF-supported clinics from January 2012 to December 2013. Patients were assessed for SAT eligibility by clinicians, based on their previous adherence record and clinical condition. SAT patients were assigned a weekly community treatment supporter, and attended the clinic monthly to monitor treatment progress and to collect medication. All RR-TB patients still receiving treatment at the end of the intensive phase within the SAT clinics were compared to those in the five clinics using DOT. Descriptive statistics and chi-squared tests were conducted to assess differences in final treatment outcomes.

**Results:** There were 158 patients (65% HIV co-infected) entering the continuation phase in SAT clinics, and 165 patients (66% HIV co-infected) in DOT clinics, during the study period. Due to phased implementation 99/158 (63%) patients were considered for SAT. Eighty-two (83%) were enrolled; reasons for exclusion included adherence concerns ( $n = 9$ ), patient choice ( $n = 2$ ), HIV-related issues ( $n = 2$ ), or other ( $n = 4$ ). Four of the 82 (5%) patients later returned to clinic DOT due to adherence concerns. Rates of loss from treatment (LFT) at the completion of treatment, excluding those LFT during the intensive phase or transferred during treatment, were 19% (27/143) among patients in SAT clinics versus 30% (45/150) for patients in non-SAT clinics ( $p = 0.027$ ). There was a trend toward increasing treatment success among SAT clinics (64% (91/143) compared to 57% (86/150)), although this was not significant ( $p = 0.27$ ).

**Conclusion:** Data from this non-randomized comparison suggests that structured SAT aids in reducing LFT. This intervention should be considered for wider implementation in order to improve retention in care and decrease the burden on patients and health facilities.

## INTERVENTION FOR PATIENTS INTERRUPTING RIFAMPICIN-RESISTANT TUBERCULOSIS TREATMENT FOR MORE THAN 2 WEEKS: AN INTERIM COMPARATIVE OUTCOME ANALYSIS FROM KHAYELITSHA, SOUTH AFRICA

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**Background:** Treatment for rifampicin-resistant tuberculosis (RR-TB) requires two years of treatment, often resulting in debilitating side effects. In South Africa, 30% of RR-TB treatment patients experience loss from treatment (LFT). We aimed to determine if a treatment interruption (TI) intervention could reduce LFT in the RR-TB cohort.

**Methods:** From September 2013, patients interrupting treatment for >2 weeks but <2 months, where recall methods had failed, were identified by a lay counselor at clinic-level, who undertook the TI intervention. Structured support was provided at home to identify and overcome barriers to adherence and facilitate return to care. In this before-after study, we characterize outcomes of patients initiated on RR-TB treatment from September 2011 to March 2012 (comparison cohort) and September 2013 through March 2014 (intervention cohort) at seven Khayelitsha clinics. Interruption was identified from routinely recorded compliance records. Logistic regression analysis was used to calculate odds ratios, 95% confidence intervals and p-values for differences in 18-month treatment outcomes.

**Results:** Eighty-two and 116 patients initiated RR-TB treatment in the comparison and intervention cohorts, respectively. HIV co-infection rates were similar (52 [63%] versus 82 [71%];  $p = 0.28$ ). There were 34 (41%) patients in the comparison cohort with interruptions identified compared with 30 (26%) in the intervention cohort ( $p = 0.02$ ); 26 (22%) were enrolled in the intervention. Among all patients, LFT at 18 months was higher in the comparison cohort than in the intervention cohort ( $p < 0.01$ ). Before the intervention, the majority of interrupters experienced LFT 24 (73%), whereas only 9 (30%) experienced LFT after the intervention ( $p = 0.0007$ ) (Table 1).

*Table 1: Comparison of 18 month RR-TB treatment outcomes amongst interrupters in the comparison and intervention cohorts*

18-month outcomes among interrupters	Comparison Cohort N = 33	Intervention Cohort N = 30	OR (95% CI)	P value
Still on treatment	7 (21.2%)	19 (63.3%)	0.2 (0.07 – 0.6)	0.0025
Success	1 (3.0%)	0 (0.0%)	—	
LFT	24 (72.7%)	9 (30.0%)	6.2 (2.1 – 18.3)	0.0007
Death	1 (3.0%)	2 (6.7%)	0.4 (0.0 – 3.6)	0.46

**Conclusion:** While the risk of interruption appeared to be declining, the TI intervention is likely to have contributed to a significant reduction in the risk of LFT among patients experiencing treatment interruption. Allocating resources to intensify support for these high-risk patients is likely to reduce LFT amongst RR-TB patients.

## SEXUAL VIOLENCE AND RAPE IN RUSTENBURG IMPLICATIONS FOR SERVICE PROVISION AND PREVENTION

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**Introduction:** Rustenburg Municipality (population 550,000) is one of Africa's fastest growing cities, and as the country's platinum mining capital, attracts many migrant workers. Bojanala district, in which Rustenburg is situated, has an HIV prevalence of 35% among antenatal women; its rape prevalence has not previously been reported. HIV transmission is higher during forced sex (particularly child sexual abuse) than consensual sex, which can exacerbate transmission in areas with concurrent epidemics of HIV and rape. Here we quantify prevalence of sexual violence and rape in Rustenburg.

**Methods:** In this cluster randomized household survey fieldworkers collected information from women aged 18 to 49 on their experience of rape, as well as associated behaviours and attitudes. The study population and prevalence of rape (forced sex or sexual acts) are described.

**Results:** The average age of participants (n = 1,123) was 32 years and 44% had completed secondary school or higher. The majority of women grew-up in South Africa; however, 62% grew-up in a rural area/village outside of the Rustenburg Municipality. Life-time prevalence of rape of 33%, with 10% experiencing at least one rape by a sexual partner, and 8% experiencing at least one rape by a non-sexual partner before the age of 15 years. The reported incidence of rape was 53 per 1,000 person years. Among those who had been raped, 17% reported seeking legal services after a previous experience of rape.

**Conclusions:** We report an extremely high prevalence of sexual violence, including rape by partners, non-partners, and among children in the platinum belt of Rustenburg, making women vulnerable to negative health outcomes, including HIV acquisition. Reported access to legal and comprehensive medical services is particularly poor in this highly vulnerable population, highlighting the need for improved service delivery. The HIV/AIDS and rape epidemics share similar risk factors and challenges to access, exacerbating harm. A coordinated local and national approach to the prevention, management, and planning of both is necessary.

## REMOVAL OF USER FEES IMPROVED ACCESS TO QUALITY MATERNITY CARE AND DECREASED MATERNAL AND NEONATAL MORTALITY IN A DISTRICT HOSPITAL, LESOTHO

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**Background:** Lesotho has one of the highest maternal mortality rates in the world due to HIV and poor access to skilled maternal health services. Hospital fees for delivery cost represent a major barrier to maternal health service utilization. This study aims to examine the uptakes of obstetric services following introduction of Free Maternal Care (FMC) in a district hospital in Lesotho, a setting where up to 60% of maternal deaths are associated with HIV.

**Methods:** A before and after study of the utilization of delivery services from July 2012 to December 2013, compared to January 2014 to June 2015, after commencement of FMC. Information on baseline characteristics, deliveries, obstetric outcomes and referrals was collected from maternity registers. Proportions and stillbirth, maternal and neonatal mortality rates are compared before and after introduction of FMC.

**Results:** A total of 3,782 women delivered during the study period, of which 684 (18%) were less than 19 years old. HIV prevalence was 23.7%. After the introduction of FMC, the number of hospital deliveries increased by 55% (from 1,484 to 2,298). Referrals from primary care clinics doubled (from 38 to 79) and referrals from secondary to tertiary hospital increased 5-fold (from 5 to 27). Maternal mortality ratios, neonatal death rates and stillbirth rates dropped respectively from 146/100,000 to 89/100,000, 5.1/100,000 to 1.3/100,000 and 26/100,000 to 19/100,000 live births.

**Conclusion:** Introduction of FMC resulted in a 55% increase in hospital based deliveries, as well as increases in referral rates and a drop in maternal, neonatal and stillbirth rates. Hospital fees for maternal care in Lesotho are a barrier to access to skilled birth attendants and should be urgently removed.

## FIELD PERFORMANCE OF POINT-OF-CARE HIV TESTING FOR EARLY INFANT DIAGNOSIS: POOLED ANALYSIS FROM SIX COUNTRIES FROM THE EID CONSORTIUM

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**Background:** The expansion of prevention of mother-to-child transmission programmes has resulted in a reduction in paediatric HIV infections. However, HIV transmissions still occur requiring accurate early infant diagnosis (EID) and early treatment initiation. Evaluations of new technologies for EID are essential to inform national regulatory approval and implementation, but the low HIV incidence in infants limits timely, adequately-sized evaluation studies. The EID Consortium is helping to accelerate the evaluation and subsequent implementation of EID point-of-care (POC) diagnostics across Africa. Here we report on field performance of HIV qualitative assays from Alere and Cepheid in exposed infants <18 months of age.

**Methods:** Data from 9 independent field evaluations of Alere q HIV-1/2 Detect and Cepheid Xpert HIV-1 Qual assays were pooled from ongoing studies in Kenya, Malawi, Mozambique, Tanzania, South Africa, and Zimbabwe. A range of health professionals from nurses, laboratory technicians to medical doctors operated the devices.

**Results:** Specimens from HIV-exposed infants <18 months old, were analysed on Alere q HIV-1/2 Detect (n = 1,884) or Cepheid Xpert HIV-1 Qual (n = 2,598) and compared to Roche COBAS AmpliPrep/COBAS TaqMan HIV-1 Test at all sites with the exception of Malawi, which compared to Abbott HIV m2000. Alere q had a sensitivity of 99.1% (95% CI: 95.5 – 99.95%), and specificity of 99.9% (95% CI: 99.7 – 100%), with an overall error rate of 6.4%. Cepheid Xpert HIV-1 Qual had a sensitivity of 96.9% (95% CI: 91.7 – 99.2%), and specificity of 99.9% (95% CI: 99.7 – 99.99%), with an overall error rate of 4.3%.

**Conclusions:** The EID Consortium has been able to aggregate data from multiple centres quickly and thus accelerating notable progress in the field evaluations of POC testing for EID. The analysis shows good performance of both the Alere q HIV-1/2 Detect and Cepheid Xpert HIV-1 Qual assays, suggesting that POC devices have the potential to complement the expansion of EID in the region.

Table 1: Performance of Alere q HIV-1/2 Detect and Cepheid Xpert HIV-1

Alere q HIV-1/2 Detect				Cepheid Xper HIV-1 qual		
Alere q	Reference Assay			Xpert	Reference Assay	
	Positive	Negative	Sum (n=)		Positive	Negat
Positive	106	1	107	Positive	93	2
Negative	1	1776	1777	Negative	3	250
Sum (n=)	107	1777	1884	Sum (n=)	96	250
Alere q HIV-1/2 Detect				Cepheid Xper HIV-1 qual		
	Point Estimate	Lower CI	Upper CI		Point Estimate	Lower
Sensitivity	99,07%	95,48%	99,95%	Sensitivity	96,88%	91,73%
Specificity	99,94%	99,72%	100,00%	Specificity	99,92%	99,74%

## SIX-MONTHLY APPOINTMENTS AS A STRATEGY FOR STABLE ANTIRETROVIRAL THERAPY PATIENTS: EVIDENCE OF ITS EFFECTIVENESS FROM SEVEN YEARS OF EXPERIENCE IN A MÉDECINS SANS FRONTIÈRES-SUPPORTED PROGRAMME IN CHIRADZULU DISTRICT, MALAWI

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**Background:** HIV clinics are struggling to absorb new patients in Malawi, and overburdened health workers and long waiting times can be detrimental to adherence. We evaluated a strategy of six-monthly appointments (SMA) for stable ART patients in Chiradzulu District, Malawi, where Médecins Sans Frontières is supporting the Ministry of Health's HIV programme.

**Methods:** Stable patients (aged  $\geq 15$ , on first-line ART  $\geq 12$  months, CD4 count  $\geq 300$  cells/ $\mu$ l and without opportunistic infections or ART intolerance, not pregnant or breastfeeding) were eligible for clinical assessments every 6 months instead of every 1 to 2 months at 11 HIV clinics. Early SMA enrollees were defined as patients who started SMA within 6 months of eligibility; late SMA enrollees were those starting  $>6$  months after eligibility. Kaplan-Meier methods were used to calculate cumulative probabilities of death and loss to follow-up (LTFU) among those eligible for SMA, stratifying by SMA enrolment status and baseline characteristics. Cox regression, using SMA enrolment as a time-dependent variable, was used to estimate crude and adjusted hazard ratios for the association between SMA and death or LTFU.

**Results:** Between 2008 and 2015, 18,957 individuals were eligible for SMA (contributing 43,888 person-years of observation), of whom 15,308 (80.8%) ever enrolled. Median time from SMA eligibility to enrolment was 6 months (interquartile range 0–17 months). The cumulative probability of death or LTFU five years after first SMA eligibility was 56.3% (95% CI: 52.4 – 60.2%) among those never SMA enrolled; 13.9% (95% CI: 12.5 – 15.6%) among early SMA enrollees and 8.1% (95% CI: 7.2 – 9.0%) among late SMA enrollees. After adjusting for age, gender, year of first SMA eligibility, and other baseline variables (CD4 count, months on ART and in cohort), a significantly higher rate of death or LTFU was observed among patients during non-SMA periods compared to those during SMA periods (adjusted rate ratio: 1.87, 95% CI: 1.68 – 2.08,  $p < 0.001$ ).

**Conclusions:** SMA represents a promising strategy for managing stable ART patients and should be rolled out, particularly with “test and treat” on the horizon, which will further stretch HIV clinics. However, further implementation research is needed, and selection biases which may explain poor retention among those eligible but never enrolled in SMA should be investigated.



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