



XVII INTERNATIONAL AIDS CONFERENCE

3-8 August 2008 | Mexico City

Oral Abstract Session

MOAE02 - Global Monies: International Assistance and Funding Mechanisms

MOAE0206 - Fiscal space for health expenditure in Mozambique: blocking effectiveness of international funds through budget support

G. Ooms¹, M. Philips²

¹Médecins Sans Frontières, General Direction, OC-B, Brussels, Belgium, ²Médecins Sans Frontières, Analysis & Advocacy Unit, OC-Bxl, Brussels, Belgium

Issues: HIV/AIDS compounds the health workforce gap in Mozambique. Mozambique receives much donor aid, including for health. General or sector-specific budget support is currently the only possibility to improve salaries or recruit additional MoH-staff with international funding. However, fiscal ceilings limit funding of these recurrent costs.

Description: Case study on health spending and wage bill caps as obstacle to use international funding for health and health workforce boosting in particular. Interviews were conducted with all major stakeholders in Mozambique. New findings: Mozambique applies the 'ceiling on primary deficit', which reflects the estimated 'capacity of Mozambique to accommodate expenditures financed with aid within the domestic budget constraint in a reasonable period of time'. For IMF and others foreign assistance is at best temporary, thus limiting recurrent expenditure to the domestic budget, excluding donor grants. This de facto acts as an international aid cap for recurrent expenditure. International funding in excess of this ceiling is rather diverted towards international reserves or public savings. During 2004-2006, reserves grew with 315 million US\$, equivalent to 91% of the increase in international funds. In 2006 for each additional aid dollar, 50 cents were programmed to increase international reserves. Most donors are unaware of this.

Lessons learned: All international funding through budget support will be affected by this 'IMF tax'. Specific 'common pool funds' are somewhat ring-fenced and project aid is not covered by the cap, thus could increase. These limitations basically have the same effect on any budget support as explicit ceilings. International aid will be accepted, but diverted to international reserves.

Next steps: These mechanisms de facto cap budget support, while project aid is not affected. Donors should adapt funding channels, in order to spend international aid for health more effectively than through comprehensive budget support grants with the current caps. Greater transparency on these matters is urgently needed.

Presenting author email: gorik.ooms@msf.be



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Oral Abstract Session

TUAB03 - Access and coverage in Resource Limited Settings

TUAB0303 - Achieving universal access to antiretroviral therapy in a rural district in Malawi: how was it done?

M. Massaquoi¹, R. Naligunkwi², U. Von Pilar², B. Mwangomba³, M. Bemelmans², R. Zachariah⁴, A.D. Harries⁵

¹Médecins Sans Frontières, Medical Coordination, Blantyre, Malawi, ²Médecins Sans Frontières, Thyolo, Malawi, ³District Health Office, Thyolo, Malawi, ⁴Médecins Sans Frontières, Medical Department, Brussels, Malawi, ⁵Ministry of Health and Population, HIV/AIDS Unit, Lilongwe, Malawi

Background: Malawi's antiretroviral treatment (ART) scale-up plan aims at placing 250,000 people on ART by 2010. The country has currently achieved approximately half of this target (125,610).

Thyolo, a rural district in Malawi, has approximately 600,000 inhabitants and an adult HIV prevalence rate of 21%. There are about 60,000 people living with HIV/AIDS of whom about 11,250 are in urgent need of ART. The district managed to achieve its universal coverage target of placing 80% of these individuals on ART.

Methods: To describe the process, outcomes, and lessons learnt in achieving universal access in Thyolo. Scale-up was achieved by using a standardized public-health approach viz:

- Single first-line ART regimen & standardized treatment protocols
- Clinical eligibility criteria for ART initiation
- Decentralized ART access
- Task-shifting
- Active community involvement

Results: From April 2003 to January 2008, a total of 11,932 were initiated on ART, of whom 9046 (76%) are alive. Overall death and defaulter rates are 11.4% and 7.9% respectively. Task-shifting increased monthly ART initiation capacity from an average of 100 patients/month in 2004 using a doctor-based approach to 400/month in 2007 using a team that included medical assistants, nurses and lay counselors. This also allowed decentralization to health centres. A community network comprising 675 volunteers, 9 community nurses and family care givers is actively involved in the symptomatic treatment of opportunistic infections, early referrals, defaulter tracing, adherence counseling and social support.

Conclusions: It is feasible to achieve a universal ART coverage target of 80% or more with acceptable outcomes in a district setting in sub-Saharan Africa by adhering to a public-health approach with active community involvement. Sustaining universal access is now faced with the challenges of lack of human resources, ensuring quality services and providing adequate coverage for those requiring second line therapy.

Presenting author email: msfb-blantyre-med@brussels.msf.org



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WEAB02 - Task Shifting and Decentralising Care

WEAB0202 - Task-shifting and decentralisation of HIV/AIDS care in a rural district of Malawi: some successes and lessons learnt from Thyolo district

M. Massaquoi¹, P. Gomani², R. Nalikungwi², M. Bemelmans², R. Zachariah³, M. Philips⁴

¹Médecins Sans Frontières, Medical Coordinator, OC-B, Blantyre, Malawi, ²Médecins Sans Frontières, Thyolo, Malawi, ³Médecins Sans Frontières, Medical Department - Operational Research, OC-B, Luxemburg, Luxembourg, ⁴Médecins Sans Frontières, Analysis & Advocacy Unit, OC-B, Brussels, Belgium

Issues: Lack of qualified health staff seriously challenges health systems in Malawi to scale up HIV/AIDS care. First-line care depends on few trained staff; services in district hospitals and HC are provided by clinical officers, nurses and other health workers. Malawi has nurse vacancy rates of 55% and only 1.7 doctors per 100,000 population. In an innovative approach in Malawi, lower cadre staff was used for defined tasks. Task shifting is a gap filling strategy for staff shortages.

Description: In line with the national ART scale up plan, MSF adapted the doctor driven approach towards a strategy with multiple patient tracks (according to patient profile) and with specific tasks in care provided by less qualified cadres. This was first applied in the hospital based ART-clinic of Thyolo and from June 2006 to December 2007, initiation of ART was done also in 3 HC. By end 2007, a total of 11,555 persons have ever started ART in Thyolo district.

Lessons learned: 1837 patients were initiated in the HC on standard first line regimen (Stavudine/Lamivudine/ Nevirapine), among which 1587 were in WHO stage 3 and 253 in WHO stage 4. Also 1127 patients on ARVs previously receiving care in the hospitals were referred to the HC. Overall, by 31/12/2007, 2706 (91%) of them were alive and on ARVs. ART initiation increased up to an average of 450 patients enrolled per month. Thyolo experience shows that in spite of serious lack of qualified staff, expansion of ART-capacity to HC and good programme outcomes are possible.

Next steps: Task shifting can contribute significantly to overcome the HR-hurdle to ART scale up. However, task shifting cannot replace and should not be an excuse for failing to address health worker shortages; retaining and attracting sufficient numbers of trained staff remains crucial.

Presenting author email: msfb-blantyre-med@brussels.msf.org



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Poster Discussion Session

THPDB2 - Highlighting issues for women in clinical research, treatment and care

THPDB205 - Cervical cancer screening among HIV-positive women in rural Cambodia: a pilot programme

M.-E. Raguenaud¹, P. Isaakidis¹, S.A. Khim¹, C. Ping², C. Kim³, L. Martello⁴, T. Reid⁵

¹Médecins Sans Frontières OCB, Phnom Penh, Cambodia, ²RHAC, Phnom Penh, Cambodia, ³Médecins Sans Frontières OCB, Takeo, Cambodia, ⁴Médecins Sans Frontières OCB, Siem Reap, Cambodia, ⁵Médecins Sans Frontières OCB, Brussels, Belgium

Issues: Cervical cancer is the most common malignancy among women in Cambodia. Since HIV+ women tend to have persistent Human Papillomavirus infection they are at higher risk for cervical cancer than the general population. To help plan a nationwide screening programme in Cambodia that is at its early development, a pilot screening programme targeting HIV+ women was conducted in one HIV clinic, aiming at early detection and treatment of cervical abnormalities.

Description: A referral system was set-up between the HIV clinic and a near-by reproductive health clinic. HIV clinic doctors systematically referred all female patients for PAP-test screening until a total of 100 women was reached. Transportation to the reproductive health clinic was provided on the same day as the HIV consultation. After screening, follow up and referral for biopsy and treatment, as necessary, were organized by the HIV clinic staff.

Lessons learned: In a period of 2½ months, 100 women were screened, representing 14% of all HIV-positive women enrolled in the programme. Pre-cancer lesions / cervical cancer were common among women screened. 25 women had confirmed LSIL or HSIL on PAP-test and 22 of them underwent biopsy. 2 had endocervicitis, 19 had pre-cancerous lesions (CIN1-3), and one had carcinoma in-situ. All patients with pre-cancerous lesions or cancer were referred for either cryotherapy or hysterectomy. One woman died and 2 women were lost to follow-up. This good record is most likely due to the well established recall system of the HIV clinic, the involvement of the HIV clinic doctors, and the support for transportation.

Next steps: Our pilot programme indicated that there is a high yield in offering cervical cancer screening to HIV+ women, that it is feasible and can be integrated into HIV care where there is access to diagnosis and treatment. This is encouraging information for the planned nationwide screening programme.

Presenting author email: msfb-phnom-penh-med@brussels.msf.org



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Poster Exhibition

Track B - Health Systems and Delivery of ART I

MOPE0039 - Quality-of-care indicators for international HIV/AIDS care: scaling up beyond the numbers

D. Olson, B. Lokuge, G. Elder

Doctors Without Borders/Médecins Sans Frontières (MSF), New York, United States

Issues: Many obstacles have been overcome to improve access to lifesaving antiretroviral therapy (ART) in resource-limited settings, where nearly 2 million people have started on ART to date. However, benefits of ART are realized only by remaining under long-term, uninterrupted treatment. Current success in ART implementation has been largely confined to total numbers of patients started on therapy.

Description: Médecins Sans Frontières (MSF) has provided ART for >100,000 patients in 32 countries, often in partnership with national Ministries of Health (MOH). Ensuring long-term, uninterrupted treatment of patients in resource-limited settings is a challenge. To this end, MSF has employed a variety of strategies, including adherence counseling; patient and outcome tracking; stockout prevention; and task-shifting and treatment simplification to enhance the likelihood of patients remaining under long-term ART. In referral areas for our programs, MSF has worked with nascent international donor-supported MOH ART clinics to facilitate coherence and cooperation. In doing so, MSF teams have observed significant challenges that impact on the quality of ART programs and thus the potential health benefits for patients. As one example, in 2006 MSF reviewed 10 national ART clinics, 4 of which were directly supported by MSF, and observed antiretroviral supply interruptions, absent or overworked healthcare providers, and early patient dropout from therapy.

Lessons learned: Based on these field-level observations, more needs to be done to identify and act on ART quality-of-care issues in developing countries to ensure patients maximize benefits from ART scale-up efforts.

Next steps: Systematic and standardized means of assessing ART programs using core quality indicators beyond total number of patients started on therapy should be established, including survival, retention, frequency and extent of treatment interruption, and measures of adherence. These indicators must drive methodical efforts to improve the quality of care in donor-funded scale-up of ART programs.

Presenting author email: david.olson@newyork.msf.org



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Track B - Health Systems and Delivery of ART I

MOPE0043 - Immuno-virological and toxicity outcomes of HIV-infected patients after 48 months of ART in Phnom Penh, Cambodia

B. Schramm¹, S. Balkan², L. Som³, E. Nerreniet⁴, C.C. Nget⁵, S. Moeung⁵, P. Narom⁵, L. Pinoges¹, L. Ferradini³, M. Pujades-Rodríguez¹

¹Epicentre, Paris, France, ²Médecins Sans Frontières, Paris, France, ³Médecins Sans Frontières, Phnom Penh, Cambodia, ⁴Pasteur Institute, HIV/Hepatitis laboratory, Phnom Penh, Cambodia, ⁵Khmer-Soviet Friendship Hospital, Phnom Penh, Cambodia

Background: Data on long-term immuno-virological outcomes and drug toxicity in patients treated with antiretroviral therapy (ART) in resource-limited settings are scarce.

Methods: Cross-sectional evaluation of adults treated with ART for 48 months (M48) in the Médecins Sans Frontières/Ministry of Health programme of Phnom Penh. Antiretroviral (ARV) toxicity was assessed by clinicians and through laboratory testing and adherence through pill counting and visual analogue scale. ARV mutations and resistance patterns were determined for patients with detectable HIV RNA viral load (VL) >250 copies/ml.

Results: At M48 the probability of remaining in care was 0.82. The 349 survey participants (98% of eligible) had a median age of 38 years. At ART initiation 94% were ARV naïve, 83% had been prescribed 3TC-D4T-EFV and the median CD4-count was 16 cells/ml (IQR: 4-71). At M48, 29% remained on a D4T-regimen and 58% received an AZT-regimen (compared to 94% and 3% at ART initiation, respectively); 10% were on second-line therapy. The median CD4-count was 410 cells/ml (IQR: 290-511), with only 10% of patients having <200 cells/ml. 15 patients (4%) had detectable VL and the most frequently observed mutations were M184V and K103N (9 and 5, respectively). 11 patients had reverse transcriptase inhibitor resistance(s) and 1 second-line patient protease inhibitor mutations without resistance. 83% of patients were classified as fully adherent to ART. 97% were diagnosed with ARV-related toxicity but this was severe only in 19% of patients. Most frequent diagnoses were: lipodystrophy (63%), hypertriglyceridemia (41%), asthenia (32%) and increased liver enzymes (27%). Only 1% of patients had anemia.

Conclusions: Despite of a severe immuno-compromised status at ART initiation, 90% of the patients remained on a first-line regimen after 48 months of treatment, and only 4% had virological failure. A severe ARV-toxicity was seen in one fifth of patients and mild and moderate lipodystrophy was common.

Presenting author email: mar.pujades@epicentre.msf.org



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Track B - Health Systems and Delivery of ART I

MOPE0048 - Discordant responses to antiretroviral treatment: prevalence, risk factors and associated mortality in Rwanda

J. van Griensven¹, F. Rasschaert², A. Asiimwe³, R. Zachariah²

¹Medecins Sans Frontieres, Kigali, Rwanda, ²Medecins Sans Frontieres, Brussels, Belgium, ³TRAC, Kigali, Rwanda

Background: Discordant (opposite virological and immunological) responses to antiretroviral treatment (ART) remain poorly understood in low-income countries. We aimed to identify the prevalence of and risk factors for discordant responses and the associated mortality.

Methods: Analysis of the outcomes of 962 adults within the ART program in two urban government health centers in Rwanda, where approximately 90% started a regimen containing stavudine/lamuvudine/nevirapine. Viral load measurement was performed routinely after 1 year of treatment. Virological failure (VL-) was defined as a viral load >1000 copies/ml. Immunological success (CD4+) was defined as an increase in CD4 count >50 cells/ul from baseline. Multivariate analysis was done to identify risk factors for discordant responses and to assess the association of discordant responses with mortality, with complete responders as reference group.

Results: In total, 691 (71.8%) subjects were complete responders, and 30 (3.1%) complete non-responders. Discordant responses were seen in 243 (25.1%) patients, with 188 (19.6%) virological-only responses (VL+/CD4-) and 53 (5.5%) immunological-only responses (VL-/CD4+). Patients with a virological-only response were significantly more likely to be > 40 years old, less likely to be of female sex and to be on ART for > 1.5 years. A baseline CD4 count >50 cells/μL and the development of tuberculosis while on ART were identified as additional risk factors. An immunological-only response was associated with a baseline body weight of >65 kg and with baseline CD4 counts <50 cells/μL. Virological-only responders had a higher short-term mortality (hazard ratio (HR) 7.16; P=0.006), no significant difference was observed for immunological-only responders (HR: 3.65; P=0.266).

Conclusions: This study confirms discordant responses to occur frequently in patients on ART in Rwanda, with different risk factors according to the type of discordance. Patients with virological-only responses are a population at risk and might require closer medical follow-up.

Presenting author email: jvgrie@yahoo.com



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Track B - Health Systems and Delivery of ART I

MOPE0049 - Increased baseline body weight is a risk factor associated with virological failure while on antiretroviral treatment

J. van Griensven¹, F. Rasschaert², E.F. Atté¹, R. Zachariah²

¹Medecins Sans Frontieres, Kigali, Rwanda, ²Medecins Sans Frontieres, Brussels, Belgium

Background: Few studies have specifically addressed the association of body weight and the risk of virological failure. The metabolism of non-nucleoside reverse-transcriptase inhibitors is known to be positively correlated with body weight and sub-therapeutic drug levels are associated with virological failure. We assessed the association between body weight and virological failure.

Methods: The study was conducted in two urban public health centers in Kigali, Rwanda where > 3000 patients have been started on antiretroviral treatment (ART) since 2003 (~90% with a regimen containing stavudine, lamuvudine and nevirapine). Viral load measurement was routinely performed after 1 year of treatment, and virological failure defined as a viral load >1000 copies/ml. Risk factor analysis was performed using a multivariate logistic regression model.

Results: We analyzed the data of 1166 adult patients who had been on ART for at least one year. In bivariate analysis, low baseline CD4 count, poor adherence, the use of zidovudine and a baseline body weight over 65 kg were associated with virological failure (OR 2.25; P=0.003). Increased body weight remained an independent risk factor for treatment failure in multivariate analysis, after controlling for differences in clinico-immunological parameters, ART regimen/toxicity, adherence and other baseline characteristics (OR 2.90; P=0.001, Table 1). The same was true if mean on-treatment body weight or body mass index (BMI) (significantly increased risk of failure for BMI > 25 kg/m²) was entered as the main risk factor (instead of baseline body weight), although the association tended to be less strong.

Conclusions: These data show "high baseline body weight" to be a risk factor for ART failure and this finding might suggest the consequences of sub-therapeutic drug levels for patients with higher body weight. The relevance of weight-adjusted dosing needs to be explored.

Presenting author email: rony.zachariah@brussels.msf.org



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Track B - Health Systems and Delivery of ART I

MOPE0059 - HIV/AIDS survival in adults and children under HAART in rural Malawi

P. Nkhoma¹, M. McGuire¹, L. Ahoua², S. Goossens¹, A. Kabwinja¹, M. Le Paih¹, A. Munger¹, J. Mpunga³, A. Jeannin⁴, E. Szumilin⁴, K. Kamoto⁵, A.D. Harries⁵

¹Médecins Sans Frontières, Chiradzulu, Malawi, ²Epicentre, Paris, France, ³Ministry of Health, Chiradzulu, Malawi, ⁴Médecins Sans Frontières, Paris, France, ⁵Ministry of Health, HIV Unit, Lilongwe, Malawi

Background: The range of estimated median survival rates of patients diagnosed with acquired immunodeficiency syndrome (AIDS), without antiretroviral therapy is 2.2 to 23 months in Africa. This cohort represent a long-term (60+ months) and large scale (n=9479) project for delivering HAART in a decentralized, rural setting in sub-Saharan Africa. Comparable data demonstrating effectiveness is limited.

Methods: We assessed survival rates of patients on HAART from August 2001 to January 2007 in Chiradzulu, Malawi. Patient data was extracted from FUCHIA monitoring system (Epicentre-MSF) and analyzed using STATA (Version 9).

Results: Over 66-months, HAART was initiated in 9,479 patients (64.8% female, 358 under 5 and 441 between 5-15); 91.7% were HAART naïve. At initiation, 70.3% of adults/adolescents were WHO Stage III/IV, 21.4% had a BMI < 17.5. When available, median CD4 count was 136 cells/mm³ (IQR, 73-199); in children, median CD4 cell percentage was 10% (IQR, 6-14%). Most adults/adolescents received [D4T-3TC-NVP] fixed dose combination. Median duration of follow-up on HAART was 20.2 months (range 0 - 64.9 months); 1361 (14.3%) died and 1,406 (14.8%) defaulted. At last visit, 1131 adults (12%) were on a first-line alternative regimen, including EFV- related to Tuberculosis treatment, 80 patients were on second-line regimen.

Kaplan Meier Probability of Remaining in Care					
	12-Months	24-Months	36-Months	48-Months	60-Months
Adult	79.30%	73%	68.60%	65.20%	62%
Adolescent	82.80%	78.2	73.5	68.40%	N/A
Child	82%	76.60%	69.6	68%	N/A

[Kaplan Meier Probability of Remaining in Care]

Conclusions: Treating a large cohort of patients in rural sub-Saharan is possible and access to HAART greatly improves survival rates. Challenges still persist including complicated co-infections, attrition, and limited human resources. As cohorts grow and survival rates improve, strategies for treating and monitoring patients living with HIV long-term are needed.

Presenting author email: msff-blantyre-epi@paris.msf.org



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Poster Exhibition

Track B - Children and Adolescent Specific Issues I

MOPE0213 - Good immune restitution but unsatisfactory viral suppression in children on ART in a remote Western Kenyan area

D. Sauvageot¹, L. Knight², M. Otieno², H. Huerga³, P. Muiruri³, F. Onyango², J. Dibogo², A. Afuata², M. Okonji³, O. barrack⁴, O. Lusi⁴, L. Nyabiage⁵, M. Pujades-Rodriguez¹, E. Szumilin⁶

¹Epicentre, Paris, France, ²Epicentre, Homa-Bay, Kenya, ³Médecins Sans Frontières, Homa-Bay, Kenya, ⁴Ministry of Health, Homa-Bay, Kenya, ⁵National AIDS Control Program, Kisumu, Kenya, ⁶Médecins Sans Frontières, Paris, France

Background: In the context of scaling-up of antiretroviral treatment (ART), WHO recommends simplifying the follow-up of children living in areas with restricted access to laboratory facilities. However, little information is available on the long-term outcomes of such strategy.

Methods: Kaplan Meier methods were applied to data collected through the Fuchia monitoring software (Epicentre, Paris, France), using deaths and losses-to-follow-up as combined endpoint. Between November 2006 and March 2007, a cross-sectional survey was conducted in children followed on ART for 24(M24) and 36(M36) months in the MSF HIV-AIDS programme of Homa-Bay, Kenya. Drug tolerance and pill-count information were collected by clinicians using standardised questionnaires and immuno-virological measurements were performed.

Results: Since December 2001, 432 children had commenced ART: 204(47%) aged <5 years and 228(53%) 5-14 years. At baseline 173(40%) were in WHO stage 3 and 89(21%) in stage 4; 97% received WHO recommended first line regimens, 49% d4T-3TC-NVP. In March 2007, the median duration on ART was 13.5 months [IQR 5.5-27.4]. Probabilities of remaining on care were 0.79 at M24 and 0.74 at M36. 51 and 34 children were assessed at M24 and M36. Children <5 had median CD4 percentages of 31% at M24 (n=19) and 32% at M36 (n=14); Children >5 had 717 (n=32) and 894 CD4/ μ l (n=20), respectively. Similarly, 57% and 50% had undetectable viral load (<300 copies/ml); and 88% and 79% reported good ARV-adherence (>80%). A total of 36(42%) children had WHO grade 1 hypersensitivity and 3(4%) grade 1 abdominal distension.

Conclusions: Survival of children after 3 years of ART was similar to that reported in adults living in remote areas. Immune restitution was good but, despite an apparently well tolerated treatment, the absence of viral suppression in 50% of children is worrying. Efforts to provide adapted ARV paediatric formulations and develop new long-term adherence strategies for children should be re-enforced.

Presenting author email: delphine.sauvageot@epicentre.msf.org



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Poster Exhibition

Track C - Monitoring and evaluation

TUPE0353 - Low level of virological failure and drug resistance among patients receiving antiretroviral treatment under programme conditions in Maputo, Mozambique

F. Maldonado¹, M. Biot¹, F. Roman², C. Masquelier², M. Anapenge³, R. Bastos⁴, H.C. Chuquela⁵, V. Arendt², J.C. Schmit², R. Zachariah⁶

¹Medecins sans Frontieres, Maputo, Mozambique, ²Retrovirology Laboratory, Centre de Recherche Public de la Santé, Luxembourg, Luxembourg, ³Central Hospital Maputo- MoH Mozambique, Maputo, Mozambique, ⁴Central Hospital Maputo- MoH Mozambique, Dermatology, Maputo, Mozambique, ⁵Primeiro de Maio Health Centre - City Health Authority-Mozambique, Maputo, Mozambique, ⁶Medecins sans Frontieres, Operational Research, Brussels Operational Centre, Brussels, Belgium

Setting: Primeiro-de-Maio day clinic, Maputo, Mozambique.

Objectives: Within a sample of individuals placed on first-line ART, we report on

- the feasibility of viral load monitoring using dried plasma spots (DPS) as a surveillance tool for programme performance in a setting where routine viral load is unavailable,
- the proportion of patients with virological failure and
- drug resistance patterns.

Design: Cross-sectional survey.

Methods: HIV-1 RNA viral load levels were determined using qualitative RNA-polymerase chain reaction and resistance mutations were sequenced using drug genotyping. The study was conducted between June and December 2006 in a sample of ART-naïve patients who had been on treatment for over one year.

Results: 149 consecutive patients (69% females, median age: 36.4 years) were included after a mean follow-up time of 23 months. 117(78.5%, 95% confidence interval CI: 71-85) patients had undetectable (<400copies/ml) viral loads, while in 32 (21%, 95% CI: 14-28) this was detectable (range 437-58,884 copies/ml). Among those with virological failure only 4(12.5%) patients were failing clinically and 3(9%) immunologically.

Of 15 patients with viral loads above 1,000 copies/ml, twelve viruses could be sequenced and included 8 C subtypes and 4 circulating recombinant forms CRF08. Eight (5% 95% CI: 2-9) of 32 patients with detectable viral loads had one or more major resistance mutations. Nucleoside reverse transcriptase inhibitor (NRTI) and Non-NRTI mutations were observed. There were no major mutations for resistance to protease inhibitors.

Conclusions: Among individuals placed on a first-line ART under programme conditions, the level of virological failure and drug resistance is reassuringly low. In resource-limited settings embarking on ART scale-up without access to routine viral load assays, punctual viral load surveys and targeted genotyping are useful to monitor programme quality and the circulation of HIV-drug-resistance strains.

Presenting author email: bastos_rui@yahoo.com



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Track A - Resistance in Treatment-experienced Patients

WEPE0034 - Drug resistance degree is associated with duration of ARV exposure and predicted by baseline CD4 and gender in HIV-infected patients failing first-line WHO-recommended ARV regimen: a cross-sectional viral load survey of a cohort in Cameroon (Médecins sans Frontières-Ministry of Health)

A. Soria¹, K. Porten², J.-C. Fampou Toundji³, R. Mougoutou³, J. Kfutwah Anfumbom⁴, D. Rousset⁴, R. Teck³, L. Ciaffi⁵, L. Galli¹, A. Calmy⁵, A. Lazzarin¹, N. Gianotti¹

¹San Raffaele Scientific Institute, Infectious Diseases, Milan, Italy, ²Epicentre, Geneva, Switzerland, ³Médecins sans Frontières, Yaoundé, Cameroon, ⁴Centre Pasteur du Cameroun, Yaoundé, Cameroon, ⁵Médecins sans Frontières, Geneva, Switzerland

Background: The absence of routine virologic monitoring in resource-limited settings may favor accumulation of resistance mutations, thus hampering second-line treatment efficacy. Knowing predicting factors for resistance extent could help to preserve options for future salvage regimens.

Methods: Cross-sectional viral load (VL) sampling with genotyping for VL >400 copies/mL on cameroonian HIV-infected subjects receiving ARV (nevirapine/efavirenz, stavudine/zidovudine, lamivudine) since 2001.

Results: Among 573 subjects with sampled VL, 97 (16.9%) had detectable viremia, 84 were genotyped (70% women). The mean number of reverse-transcriptase (RT) and, specifically, NRTI mutations increased per year of ARV exposure (0.33, 1.74, 2.81, 2.77 and 0.17, 0.85, 1.27, 1.77 at 1, 2, 3, >3 years; p for trend 0.03 and 0.02, respectively). Baseline CD4 counts were correlated with number of RT, NRTI and NNRTI mutations ($r=-0.35$, -0.38 , -0.23 ; $p=0.0009$, 0.0003 , 0.04 , respectively). Multivariable analysis: by GLM (covariates: age, baseline BMI, baseline CD4 \leq or $>50/\text{mm}^3$, gender, WHO stage), the adjusted mean number of RT, NRTI and NNRTI mutations was higher for subjects with baseline CD4 $\leq 50/\text{mm}^3$ vs $>50/\text{mm}^3$ (3.75 vs 1.32, 2.10 vs 0.56, 1.65 vs 0.76; $p<0.0001$, <0.0001 , 0.005 , respectively); the adjusted mean number of RT and NNRTI mutations in women vs men was 3.16 vs 1.91, $p=0.03$ and 1.60 vs 0.81, $p=0.015$, respectively. At logistic regression, being a woman was predictive of ≥ 1 NRTI mutation (OR 4.05, 95%CI 1.19-16.67); baseline CD4 $\leq 50/\text{mm}^3$ was predictive of ≥ 1 RT mutation (OR 5.36, 95%CI 1.68-20.58), ≥ 1 NRTI mutation (OR 7.49, 95%CI 2.20-32.14), ≥ 1 NNRTI mutation (OR 4.25, 95%CI 1.36-15.48), ≥ 1 TAM (OR 8.45, 95%CI 2.16-40.16), and etravirine resistance (OR 4.72, 95%CI 1.53-15.70).

Conclusions: Failing patients with baseline CD4 $\leq 50/\text{mm}^3$ are at higher risk of extensive drug-resistance, that increases over time of ARV exposure when virologic monitoring is not available. Earlier ARV initiation, and targeted VL testing, should be considered to preserve options for second-line regimens in resource-limited settings.

Presenting author email: soria.alessandro@hsr.it



XVII INTERNATIONAL AIDS CONFERENCE

3-8 August 2008 | Mexico City

Poster Exhibition

Track B - Health Systems and Delivery of ART II

WEPE0106 - Nurses and medical assistants taking charge: task-shifting HIV care and HAART initiation in resource-constrained and rural Malawi

M. McGuire¹, S. Goossens¹, W. Kukasha¹, L. Ahoua², M. Le Paih¹, A. Munger¹, A. Kabwinja¹, J. Mpunga³, E. Chazel⁴, A. Jeannin⁴, E. Szumilin⁴, K. Kamoto⁵, A.D. Harries⁵

¹Médecins Sans Frontières, Chiradzulu, Malawi, ²Epicentre, Paris, France, ³Ministry of Health, Chiradzulu, Malawi, ⁴Médecins Sans Frontières, Paris, France, ⁵Ministry of Health, HIV Unit, Lilongwe, Malawi

Background: Persistent healthcare worker shortages pose the greatest impediment to access to HAART and the scale-up of HIV services in resource poor settings. Malawi has one of the largest HIV-related health burdens in the world, with only 2 doctors per 100,000 people and an estimated 280,000 people in urgent need of treatment. In response, Médecins Sans Frontières, in collaboration with the Malawian Ministry of Health developed a task-shifting model, transferring HAART-naïve patient HAART initiation from Clinical Officers (COs) to Nurses/Medical Assistants (N/MAs) in rural health centers.

Methods: Data were analyzed on a sub-cohort of adult patients with symptomatic AIDS or CD4 count <250 cells/mm³. Patient ARV initiation indicators were compared, N/MAs-model versus COs; complicated patients, under-15, pregnant, diagnosed with Tuberculosis or Kaposi Sarcoma, were excluded for comparability. Data were extracted from the FUCHIA monitoring system (Epicentre-Paris).

Results: Between May and December 2007, 1676 HAART-naïve uncomplicated patients were initiated; 422 (25.2%) were by N/MAs. The mean age was 37.5; median time from enrollment to initiation was 21.5 days (IQR: 14-28) with N/MAs and 35 days (IQR: 27-147) with COs. At initiation, 40% of patients by N/MAs and COs were WHO Stage III/IV; the median CD4 count was 146 cells/mm³ (IQR: 88-201) for N/MAs and 175 cells/mm³ (IQR: 104-219) for COs. Of the 275 patients followed by N/MAs and 857 by COs for more than three months, 88% and 87% are still active. There was not significant difference between the outcomes of patients initiated by either group.

Conclusions: This preliminary review of Nurse/MA initiation of HAART in AIDS adult patients suggested that trained Nurses/MA's are capable of assessing and determining treatment appropriateness and sustaining follow-up compared to those achieved by COs. Additional operational research is needed to demonstrate that nurses/MA's can perform as safe, responsible, and suitable HIV/AIDS treatment and care than practitioners in resource-constrained settings.

Presenting author email: msff-blantyre-epi@paris.msf.org



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Poster Exhibition Track E - Issue Based Policy

WEPE1019 - "Fear of stigma is stronger than fear of death": a workplace initiative to reduce sickness and death due to HIV/AIDS among health staff in Malawi

M. Bemelmans¹, M. Massaquoi¹, B. Mwagomba², O. Pasulani¹, W. Jalasi¹, M. Philips³

¹Médecins Sans Frontières, Thyolo, Malawi, ²Ministry of Health, District Health Office, Thyolo, Malawi, ³Médecins Sans Frontières, Analysis & Advocacy Unit, OC-B, Brussels, Belgium

Issues: Sickness and death due to HIV/AIDS affect the health workforce and weaken health systems in SSA. Malawi is facing "crisis-level" shortages of healthworkers. The most important cause of attrition is death, often linked to HIV/AIDS. Also absenteeism of health staff is frequent, because of illness. Healthworkers find it particularly difficult to disclose their status and access HIV/AIDS services through existing channels. Improved access to ART-care and support should reduce sickness, death among and improve retention and availability of health staff.

Description: To provide increased access to quality HIV/AIDS treatment and support services for healthworkers and their families in Thyolo district, 2 initiatives were taken: · staff clinic within the hospital accessible for health staff and their primary dependants; · support group for HIV+ health workers; Standardized ART outcomes were reviewed during the period July 2006 - December 2007. Feedback was requested from health workers on the staff clinic and the support group.

Lessons learned: A total of 2268 consultations and 59 HIV counseling and tests were recorded over 18 months among health staff and dependents. During the same period 47 health staff received ARV treatment. Staff appreciated the possibility to attend services in a separate room, the one-stop concept (consultation & drug dispensing), care provided for all kinds of illness and the early morning opening hours, allowing for swift work resumption. Privacy and confidentiality are seen as key. Confidentiality and convenient service organisation, resulted in a short period of time into providing ART to almost 50 health workers. In the Hospital Support Group 27 HIV-positive health staff meet bi-weekly providing encouragement and support to each other. They also promote and encourage other colleagues to go for testing and to seek treatment in case tested positive.

Next steps: Confidentiality and convenient services resulted in 18 months to nearly 50 healthworkers on ART.

Presenting author email: msfb-thyolo-coord@brussels.msf.org



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Poster Exhibition Track B - Natural History

THPE0101 - Early mortality (pre and post antiretroviral treatment) amongst children with HIV/AIDS enrolled in two programs in Cambodia

M.-E. Raguenaud¹, P. Isaakidis¹, V. Te², S. Seitaboth³, K. Akao³, R. Zachariah⁴

¹Médecins Sans Frontières OCB, Phnom Penh, Cambodia, ²Donkeo Referral Hospital, MoH, Takeo, Cambodia, ³Angkor Hospital for Children, Siem Reap, Cambodia, ⁴Médecins Sans Frontières OCB, Brussels, Belgium

Background: There is very limited documented information on the significance of early mortality (death within the first 6 months) among children enrolled within HIV/AIDS programs in resource-limited settings.

Among children in two routine programme settings in Cambodia, we determined a) the incidence of early mortality prior-to and after initiating ART and b) assessed risk factors associated with early mortality.

Methods: Retrospective cohort and Cox-regression analysis of routine data from Donkeo Referral Hospital, Takeo and Angkor Hospital for Children, Siem Reap, Cambodia, since 2003 and 2004.

Results: A total of 1495 children were included in the analysis of whom 413 (27%) were aged <18 months, 445 (30%) 18-59 months and 637 (43%) 5-14 years. The median interval between being considered "eligible for ART" and actually "initiating ART" was 4.5 months (138 days): 25% of ART eligible children were still not initiated on ART at 9 months after enrolment.

There were a total of 70 (61%) deaths that occurred within the first 6 months after enrolment, of which 83% occurred in children not yet started on ART. Overall mortality rate was 4.8/100 person-years (95% CI, 4.0-5.8). 295 children were lost to follow up. Early mortality rate was 8 fold higher among children who had not yet started ART compared to those placed on treatment. Among children < 5 years, active tuberculosis was a significant risk factor for early death after adjusting for CD4%, WHO stage, sex, and year of admission.

Conclusions: There is a high early mortality among children enrolled within two program settings in Cambodia and these rates were eight-fold higher among children not yet initiated on ART compared to those placed on treatment. Reasons for treatment initiation delays and causes of death need to be further investigated and urgent measures to promptly initiate ART in eligible children should be taken.

Presenting author email: msfb-phnom-penh-med@brussels.msf.org



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Poster Exhibition

Track B - Complications of Therapy

THPE0149 - Weight evolution in patients after stavudine substitution for lipoatrophy in Rwanda: comparison of zidovudine with tenofovir/abacavir

J. van Griensven¹, F. Rasschaert², E.F. Atté¹, T. Reid², R. Zachariah²

¹Medecins Sans Frontieres, Kigali, Rwanda, ²Medecins Sans Frontieres, Brussels, Belgium

Background: In patients manifesting lipoatrophy on stavudine-containing first-line antiretroviral treatment (ART) regimens in Rwanda, to a) assess weight evolution after stavudine substitution and b) verify if there was a significant difference in weight evolution if zidovudine or tenofovir (TDF)/abacavir (ABV) was used for substitution.

Methods: Médecins Sans Frontières has been supporting the antiretroviral treatment (ART) program in two urban government health centers in Rwanda. All patients on stavudine-containing first-line regimens for an uninterrupted duration of minimal 6 months and substituting stavudine for lipoatrophy (diagnosed using a Lipodystrophy-Case-Definition-Study-based questionnaire) were included (N=116). The most severe cases replaced stavudine with TDF or ABV (N=40), the remainder with zidovudine (N=76). The weight evolution at 3, 6, 9 and 12 months after stavudine-substitution was recorded. Multivariate linear regression was performed to identify factors associated with the change in weight after substitution.

Results: For those patients changed to zidovudine, a progressive weight loss was seen (mean loss by 12 months: 1.62 kg; P=0.001). In contrast, those on TDF/ABV displayed stable body weight, with a tendency towards recovery after an initial period of 3 months although this difference did not reach statistical significance. The between-group difference was significant from 6 months on (difference at 12 months: 2.7 kg, P=0.008). In multivariate analysis, substitution with TDF/ABV and pronounced weight loss prior to stavudine-change was significantly associated with weight gain.

Conclusions: This is the first study in Africa assessing "weight gain" as a proxy of recovery after substitution of stavudine for lipoatrophy. In this regard and although we do not know the metabolic implications of this finding, it might suggest that TDF/ABV is superior to zidovudine. The slow recovery of weight particularly with zidovudine highlights the need of alternatives for stavudine in first-line regimens, and the need of pro-active switching.

Presenting author email: rony.zachariah@brussels.msf.org



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Track B - Complications of Therapy

THPE0179 - Risk factors for hepatotoxicity of nevirapine-containing antiretroviral drug regimens in a large antiretroviral treatment program in Rwanda

J. van Griensven¹, F. Rasschaert², E.F. Atté¹, A. Asimwe³, R. Zachariah², T. Reid²

¹Medecins Sans Frontieres, Kigali, Rwanda, ²Medecins Sans Frontieres, Brussels, Belgium, ³TRAC, Kigali, Rwanda

Background: Whereas studies from high-income countries have shown that female sex and a baseline CD4 cell count >250 cells/ μ L increase the risk of nevirapine-induced hepatotoxicity, data from low-income countries show conflicting results. However, given the tendency to start antiretroviral treatment (ART) at higher baseline CD4 cell counts, in particular within prevention-of-mother-to-child (PMTCT) programs, the safety of using nevirapine at CD4 counts > 250 cells/ μ L needs to be further assessed.

Methods: Analysis of toxicity-related drug substitutions of 2367 adults starting nevirapine-containing ART regimens in two urban government health centers in Kigali, Rwanda. Risk factors for severe nevirapine-related hepatotoxicity (grade III/IV) were assessed using multivariate Cox regression analysis.

Results: Of a total of 2367 patients, 73% were female (n=1724). The median baseline CD4 count was 162 cells/ μ L and 22% started ART with a baseline CD4 count > 250 cells/ μ L. Thirty patients (1.27%) developed severe hepatotoxicity (incidence rate 9/1000 patient-years). In multivariate analysis, abnormal baseline liver function tests (hazard ratio (HR): 5.37 (95% CI 2.04-14.14) P=0.001) and a body mass index (BMI) < 20 kg/m² (HR: 2.27 (95% CI 1.03-5.27.); P=0.037) were significantly associated with hepatotoxicity. There was no significant associated risk with baseline CD4 counts > 250 cells/ μ L (HR: 1.19 (95% CI 0.34-4.17.); P=0.778) or female sex (HR: 1.22 (95% CI 0.42-3.58.); P=0.711).

Conclusions: These data suggest that nevirapine administered to women with baseline CD4 counts > 250 cells/ μ L, as can occur in PMTCT programs, is not significantly associated with a higher risk of hepatotoxicity. Further evidence from other similar settings would be useful to compliment this finding.

Presenting author email: tony.reid@brussels.msf.org



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Track B - Complications of Therapy

THPE0188 - Toxicity of stavudine- and nevirapine-containing antiretroviral treatment regimens: incidence and risk factors after three years in a large cohort in Rwanda

J. van Griensven¹, F. Rassaert², E.F. Atté¹, A. Asimwe³, R. Zachariah², T. Reid²

¹Médecins Sans Frontières, Kigali, Rwanda, ²Médecins Sans Frontières, Brussels, Belgium, ³TRAC, Kigali, Rwanda

Background: Although stavudine- and nevirapine-containing regimens are currently the pillar of many antiretroviral treatment (ART) programs in low-income countries, long-term toxicity of these regimens in such settings remains poorly described.

Methods: Médecins Sans Frontières has been supporting the ART program in two health centers in Rwanda since 2003, where approximately 90% of the > 3000 patients started a regimen containing stavudine/nevirapine. Probabilities of "time to first-toxicity" related to nevirapine and stavudine were calculated, and a risk factor analysis was performed using multivariate logistic regression analysis.

Results: A total of 2694 patients started a stavudine-containing regimen, of whom 448 patients (16.6%) changed stavudine for reasons of toxicity. The main early side effect was peripheral neuropathy. After six months on ART, cases of symptomatic hyperlactatemia became more apparent and after 1 year of ART, a growing incidence of lipoatrophy was reported. It was the most frequent complication by 3 years of treatment (19.8%), without signs of stabilization. Whereas older age, advanced clinical disease and low baseline CD4 counts were associated with the occurrence of neuropathy, female sex, and a high baseline body mass index (BMI) > 25 kg/m² increased the risk of symptomatic hyperlactatemia/lipoatrophy. Of the 2667 patients starting nevirapine-containing ART, 170 experienced nevirapine-related toxicity requiring drug substitution, with 4.9% manifesting skin toxicity and 1.5% hepatotoxicity respectively. Elevated baseline liver function tests and a baseline BMI < 20 kg/m² were identified as risk factors for hepatotoxicity. No association with baseline CD4 count or sex was seen.

Conclusions: The currently used treatment regimens in low-income countries are associated with significant short and long-term toxicities. Lipoatrophy, in particular, is a major long-term side-effect. Alternative regimens are needed to prevent these toxicities. Meanwhile the identification of underlying risk factors could help target closer monitoring and earlier identification of patients at higher risk of drug toxicity.

Presenting author email: jvgrie@yahoo.com



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Track B - Complications of Therapy

THPE0196 - Evaluation of a systematic substitution of zidovudine for stavudine-based HAART in a program setting in rural Cambodia

P. Isaakidis¹, M.-E. Raguenaud¹, T. Phe¹, S.A. Khim¹, S. Kuoch², S.H. Khem¹, T. Reid³, L. Arnould³

¹Médecins Sans Frontières OCB, Cambodia, Phnom Penh, Cambodia, ²MoH Cambodia, Donkeo Referral Hospital, Takeo, Cambodia, ³Médecins Sans Frontières OCB, Brussels, Belgium

Background: Highly active antiretroviral treatment (HAART) drug toxicity is an increasingly important concern in resource-constrained settings. Strategies to reduce toxicity and enhance long-term use of existing drugs are needed. We report the outcomes of a treatment strategy of substituting zidovudine (ZDV) for stavudine-based (d4T) HAART among adult patients treated in a Ministry of Health and Médecins Sans Frontières program in rural Cambodia.

Methods: Survival probability, CD4-gain and anemia incidence rates were recorded for adults switched from d4T to ZDV-containing regimens from March 2006 to March 2007. Patients included were switched to ZDV-containing regimens after having received d4T-based HAART for at least 6 months. Factors associated with severe anemia were analysed using logistic regression. Programmatic implications of this strategy were analyzed based on qualitative methods (interviews with patients, clinicians and program coordinators).

Results: From August 2003 to March 2006, 1693 patients above 15 years of age had started HAART in this program. Among 527 patients switched to ZDV after d4T-based HAART for a median of 18 months, 4 (0.8%) patients died, 2 (0.4%) were lost to follow-up, 18 (3.4%) were transferred-out and 503 (95.4%) remained on HAART. Median CD4-gain was +263.5 cells/ml (IQR: 189.25-369.5) at 24 months. Within 1 year after the switch, 21.9% patients developed grade 1-4 anemia and 7.1% developed severe anemia (grade 3-4). Low BMI (≤ 18) and low CD4-count (< 200 cells/ml) were factors associated with severe anemia. Additional follow-up visits for lab monitoring and counselling resulted in increased absenteeism from work and transportation costs for the patients.

Conclusions: The switch strategy from d4T to ZDV led to satisfactory overall outcomes; however, it resulted in a relatively high incidence of mild to severe anemia and increased burden for the program and patients. Further research on the appropriateness of treatment switch strategies and their efficacy and safety is needed in resource-limited settings.

Presenting author email: msfb-phnom-penh-med@brussels.msf.org



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Poster Exhibition

Late Breaker Track B - Provision of care, diagnosis and treatment for HIV exposed

LBPE1155 - Analysis of clinical and immunological outcomes of an HIV positive paediatric cohort treated at Mpilo Hospital in Bulawayo, Zimbabwe

F. Parreño¹, M.N. Nyathi², W. Ndebele², E. Alonso¹, P.P. Palma¹, P. Roddy¹

¹Medecins Sans Frontieres-Spain, Barcelona, Spain, ²Mpilo Hospital, Paediatrics, Bulawayo, Zimbabwe

Background: In 2006, UNAIDS reported that 2.1 million children under 15 years of age were living with HIV/AIDS in sub-Saharan Africa. In Zimbabwe, the Ministry of Health estimated 160,000 children under 15 years of age were infected. In April 2004, Médecins Sans Frontières, with the Ministry of Health, started the provision of HAART to children in Mpilo Hospital in Bulawayo.

Methods: Data were extracted from the standard Médecins Sans Frontières HIV/AIDS monitoring system (FUCHIA, Epicentre-Paris).

Results: A total of 3,013 HIV positive patients under 18 years of age have been registered. 1,885 patients (62.6%) (254 < 18 months, 487 18 months to 6 years and 1,144 > 6 years) had started HAART. Of the patients initiated with HAART, 27.3% were classified as WHO stage I and II, 50.6% stage III and 22.1% stage IV. TB treatment was mentioned in the clinical history or was started before ARV therapy in 18.3% of the individuals. 38% of the children were classified with Global Acute Malnutrition on admission (20.9% were severe). Stunted growth was present in 61.2% of the children and 68.6% of them subsequently started ARV therapy. Baseline average CD4 count was 796.3 under 18 months of age, 476.2 for 18 months to 6 years and 198.8 for children greater than 6 years of age. Average CD4 Count was 1,160, 869 and 451 respectively after 6 months of therapy and 1,314, 1,194 and 557 after 12 months. The clinical outcome after 4 years, was a 6.3% mortality rate, 7.9% lost of follow-up, 1.7% treatment failure and 0.7% experienced side effects that required ARV treatment regime change.

Conclusions: The Mpilo Opportunistic Treatment Clinic experience suggests that we can successfully treat paediatric HIV on a large scale in a low income country with resources and specialized services limitations and where PMTCT programs are non-functional.

Presenting author email: fernandoparre@yahoo.com



XVII INTERNATIONAL AIDS CONFERENCE

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CD-ROM Publication

Track B - When to switch therapy

CDB0197 - A viral load of 10.000 copies/ml as threshold for antiretroviral treatment switch: risk of immunological deterioration in Rwanda

J. van Griensven¹, F. Rassaert², E.F. Atté¹, R. Zachariah²

¹Medecins Sans Frontieres, Kigali, Rwanda, ²Medecins Sans Frontieres, Brussels, Belgium

Background: Current WHO guidelines propose a viral load (VL) threshold of 10.000 copies/ml to switch to second-line antiretroviral (ART) therapy, given adequate adherence. However, there is limited data on the rationale of using such a high threshold within low-income countries.

Methods: Within a large ART program in Rwanda, where approximately 90% started nevirapine-containing ART regimens, VL was routinely performed after 1 year of therapy. Clinically stable patients with a VL 40-10000 copies/ml (n=47) received intensive adherence counseling, with subsequent VL measurements being performed every 3-6 months thereafter. Patients were switched to second line therapy if VL persisted >10.000 copies/ml. Immunological failure was defined according to the WHO immunological failure criteria.

Results: For 26 patients with an initial VL of 1000-10000 copies/ml, a median of 2.6 samples was available over a median period of 301 days (IQR 202-390). Five (19%) had a reduction in VL <1000 copies/ml, none had immunological deterioration. Fifteen (58%) maintained the VL between 1000-10000 copies/ml, of which 3 had immunological failure. Six (23%) progressed to a VL >10.000 copies/ml, one with immunological deterioration. For 21 patients starting with an initial VL of 40-1000 copies/ml, a mean of 2.2 samples were available over a median period of 294 days (IQR 214-390). Two (10%) had a VL rising to >10.000 copies/ml, one with associated immunological failure. A VL increase to 10-10.000 copies/ml was seen with two patients (10%), another five (23%) maintained a VL of 40-1000 copies/ml, all without immunological deterioration. Twelve (57%) had an undetectable VL on repeat assessment. None of all the patients had clinical progression.

Conclusions: Combined with adherence counseling and regular follow-up, patients with a VL between 1000-10000 copies/ml seem to be at intermediate short-term risk of immunological deterioration. However, the risk of drug-resistance and the long-term risk remain to be assessed.

Presenting author email: jvgrie@yahoo.com



XVII INTERNATIONAL AIDS CONFERENCE

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CD-ROM Publication

Track B - Diagnosis, and disclosure of HIV disease

CDB0365 - Appropriate counseling approach to disclose HIV status to HIV-infected children: Chiradzulu, Malawi

N. Bouithy¹, F. Chimbudzi¹, T. Makata¹, M. Le Paih¹, A. Jeannin², E. Szumilin², A. Munger¹, P. Blasco², M. McGuire¹

¹Médecins Sans Frontières, Chiradzulu, Malawi, ²Médecins Sans Frontières, Paris, France

Issues: Inadequate educational and counseling tools exist in limited resources setting to effectively disclose HIV status to children living with HIV/AIDS. Cultural beliefs, parental/guardian uncertainty to communicate virus transmission to children and difficulty understanding medical information has left children unclear of understanding what is HIV, the need for doctor visits and adherence to HAART. Disclosure of status routinely occurs when a child is seven years old. An integrated parent/child education and support system is needed to ensure proper follow-up.

Description: Parallel family and group-counseling education programs were developed for children and parents. "Working Together" provides information and tools to help parents incorporate HIV-related issues into discussions with children and other family members. Child-centered "Growing up Together" addresses the importance of CD4-count, how HIV attacks CD4, why blood is taken and need for clinical visits. Sessions include visual aid of need for medical check-up, CD4-count meaning, how the virus survives in the body, how ARVs fights the virus, and nutrition significance. Additionally, playing sessions with culturally representative dolls, arts and crafts facilitate the expression of feelings.

Lessons learned: Children, once given the opportunity, posed inquisitive questions: "Why am I the only one sick in the family? Where did I get virus?" Additionally, they expressed fear of parents becoming sick. Unresponsive children, after time, were able to express fears and uncertainty through drawing and roll playing. Difficulties included children understanding how the virus survives in the body and reiteration explaining CD4-counts. Parents found the most challenging issue was communicating to children how transmission occurred; culturally the process of childbirth is not explained to children.

Next steps: As children enter teen years, methods are needed to help them negotiate sexual relationships, long-term complications related to ARVs, and continued adherence. Measuring the effectiveness of the currently used tools by quantifying adherence and attrition in the program is needed.

Presenting author email: msff-blantyre-epi@paris.msf.org

Oral Abstract Session

THAD01 - Late Breaker Track D

THAD0106 - The price of change - replacing stavudine with tenofovir in first-line ART in scaling-up settings

J. Kivela¹, D. O'Brien², C. Mills², K. Sabapathy²

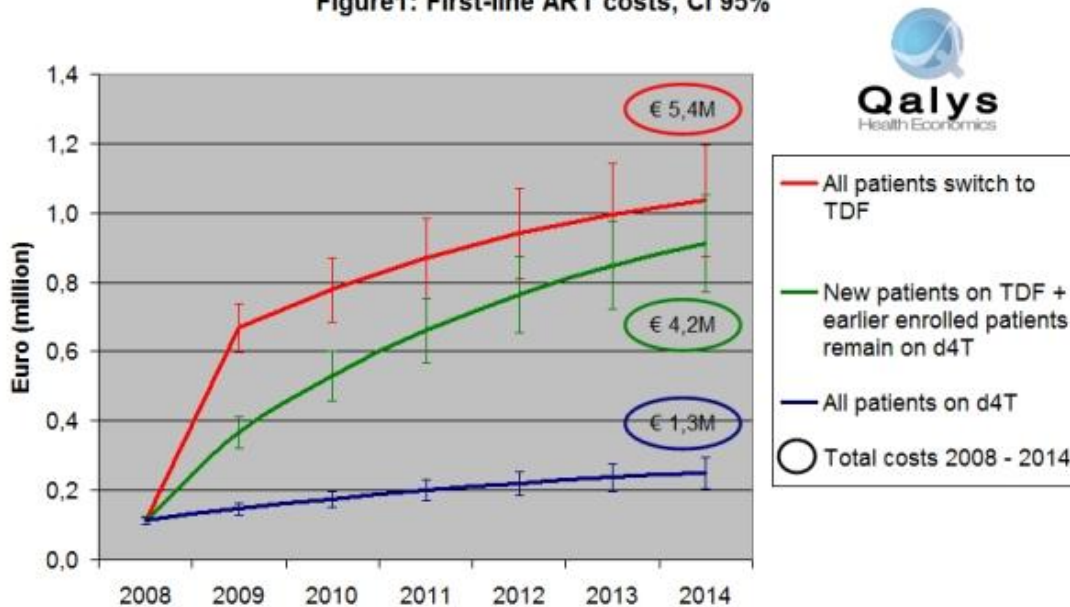
¹Qalys Health Economics, Amsterdam, Netherlands, ²Médecins Sans Frontières, Amsterdam, Netherlands

Background: Tenofovir (TDF) is one of the WHO recommended drugs to replace stavudine (d4T) in first-line ART regimens to minimise toxicity. Although this will increase treatment costs, the actual budgetary impact is usually unknown, especially as programs are scaled-up. A forecasting model was developed to provide guidance on the cost implications of introducing TDF-based first-line regimens.

Methods: The model predicts the budget impacts for the period 2008-2014 based on the current situation in a Médecins Sans Frontières HIV/AIDS program in Epworth, Zimbabwe. The main variables used in the model are: ART regimen forecast prices, ART survival, second-line switching rate, loss-to-follow-up, number of patients and scaling-up rate. Impacts of different implementation strategies and timing were modelled. Multi-variable sensitivity analyses were carried out with Crystal Ball[®] software.

Results: The replacement of stavudine/lamivudine/nevirapine (d4T/3TC/NVP) with tenofovir/lamivudine/efavirenz (TDF/3TC/EFV) would increase ART costs from €64 to €248 PPY (February 2008 prices). The most expensive option is to switch all patients to TDF immediately: first-line ART costs would increase from €1.3M to €5.4M (Figure 1). Treating only newly enrolled patients with TDF would reduce the cost to €4.2M. The timing of TDF implementation also has significant cost implications.

Figure1: First-line ART costs, CI 95%



[Figure1: First-line ART costs 2008-2014]

Recommendations: Medical decisions on ART regimen changes cannot be made in a vacuum. The model provides decision makers with costing information that enables comparison of different options and more informed resource allocation decisions. The current cost of TDF is a major barrier to implementation of a less toxic regimen and cheaper generic products are urgently needed.

Presenting author email: jari.kivela@qalys.eu