When adjusting for the same variables, QOL was higher in pts with undetectable viremia (78.7±0.7% vs 74.0±1.58%; p=0.004), in males (78.3±0.89% vs 74.5±1.39%; p=0.009), in MSMs vs heterosexuals vs others [78.5±1.37% (p<0.0001) vs 77.2±1.33% (p=0.008) vs 73.3±1.07% (reference group)], and also associated with age (β=-0.25, p<0.0001), current CD4+ (β=0.011, p<0.0001), and the number of pills (β=-0.77, p=0.019), but not with dosing interval.
Conclusions: In this highly adherent population, adherence was not associated with the number of daily pills or dosing interval. QOL was associated with the pill burden, but the pill burden explained <1% of QOL. Both adherence and QOL were strongly associated with virological response.

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Changing HIV guidelines: how to communicate treatment start

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Purpose of study: Recent treatment guidelines support the start of antiretroviral treatment (ART) in HIV-infected persons already at a CD4-cell count threshold 350 cells/µl. This includes to a large proportion asymptomatic individuals who do not necessarily see a good reason to start ART. In such cases, counselling can become a challenge. There is a lack of structured tools to optimally assess patients' readiness and to support them in this process. The purpose of this project was twofold: First to develop an algorithm for health care providers (HCP) to guide patients in the situation of treatment start. Second to develop a workshop during which HCP are instructed how to implement the algorithm and how to improve communication skills.
Methods: Based on an action research approach, consecutively literature review, own quantitative and qualitative studies and expert panel discussions were performed. We developed an algorithm and piloted an educational program for HCP. For this program critical incident reporting by experienced HIV providers was used and usability was evaluated in two workshops with HCP (self-reporting and group feedback).
Results: The readiness counselling algorithm has been integrated into updated European guidelines (http://www.europeanaidsclinicalsociety.org/guidelines.asp). It takes into account that patients are at different stages of readiness to start ART and that there are barriers (e.g. depression) before starting ART which have to be identified. An assessment of patients' actual stage of readiness and stage-based decision making support is recommended. The pilot workshop uses techniques of patient-oriented communication (waiting, echoing, mirroring, summarising) and a video-based interaction module, in which HCP present individual patients in whom the initiation of ART proved to be difficult. Re-playing these short case vignettes gives all participants a chance to apply newly acquired communication techniques. Participants rated these workshops very positive, emphasizing the high degree of practicality, closeness to their daily work, and usefulness of communication tools.
Conclusion: We developed an algorithm to assess and improve patients' readiness to start ART and a corresponding workshop on the use of the algorithm. Pilot workshops show that the algorithm is easy to implement into daily practice, shows excellent acceptance and provides a basis for the successful initiation of ART and long-term adherence to treatment.

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Relating protease inhibitor resistance at time of virological failure with drug exposure

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Background: The absence of detectable HIV resistance after treatment failure may result from non-adherence, especially for drugs such as ritonavir-boosted PIs (PI/r) for which minimum adherence may be sufficient to achieve suppression. This analysis aimed to investigate the association between adherence, indicated by a detectable PI plasma concentration, and development of PI resistance in patients presenting with virological failure of a PI/r regimen.
Methods: Patients were included if they had virologically failed a PI/r, defined as a viral load (VL) >1000 copies/mL after ≥4 months continuous exposure to a PI/r and with a plasma sample available within 1 month of the estimated VL failure date. Samples were analysed for PI levels by a validated reversed-phase HPLC method; an undetectable PI level was defined as below the PI-specific lower limit of detection. Genotypic sequencing was also carried out retrospectively on the identified sample for those with no previous PI failure and PI resistance was defined as the presence of ≥1 major PI mutation (IAS-USA). Logistic regression was used to assess risk factors for an undetectable PI level and for detection of PI resistance at VL failure using exact methods for small datasets.
Results: 85 patients were included. PI/r regimens were started in Sept 2002 (median) with VL failure occurring a median time of 17 months later. At time of starting the PI/r (baseline), 57% were ARV-naïve, median CD4 count was 217 cells/mm^3 and median VL was 4.8 $\log_{10}$copies/mL. 43 patients (51%) had an undetectable PI level at time of VL failure and were similar to those with detectable levels in terms of demographics, ARV history and previous VL failure. However, injecting drug use was associated with a greater risk of undetectable PI level (univariate odds ratio (OR) IDU vs. not: 3.7; 95% CI: 1.1-12.5; p=0.038).
44 (52%) of the 85 patients were successfully tested for resistance and had no previous PI failure. Those with undetectable PI levels were significantly less likely to have PI resistance (0% of 24 patients, 95% CI: 0-14%) than those with detectable levels (25% of 20, 95% CI: 9-49%), exact median unbiased estimate of OR: 0.1; p=0.029. Baseline VL, CD4 count, demographic and ARV-related variables were not associated with PI resistance due to limited power in this dataset.
Conclusions: Non-adherence to a PI/r regimen, as measured by an undetectable PI level is linked to a lower rate of detection of PI resistance at time of VL failure.

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Treatment adherence, quality of life and clinical variables in HIV/AIDS infection

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Purpose of the study: The purpose of the study was to analyze the relationship between treatment adherence, quality of life and clinical variables in HIV/AIDS infection.
Methods: Data was collected by voluntary fulfilment of three questionnaires: one for socio-demographic variables, one to Assess Adherence to Antiretroviral Treatment-HIV and the WHOQOL-Bref to measure the quality of life (QoL). Clinical records were inspected in order to collect clinical information from the patients. The relationship between these variables was accessed by ANOVA using Tukey and LSD as the post-hoc test. A 5% significance level was used.
Summary of results: The analysis was performed on a cohort of 295 HIV-1 infected to ART individuals followed at the two Portuguese Hospitals (Hospital de Joaquim Urbano and Curry Cabral). Median age was 40 years-old, 64.4% were men. Median (range) TCD4+ cell count and viral load were 402 (238-620) cells/mm3 and 50 (20-50) cps/ml. Regarding disease stage, the post-hoc analysis showed that asymptomatic patients have a better level of adherence (p<0.001) and QoL (p=0.000) when compared to those in more advanced stages of the disease. Undetectable viral load <20 copies/mL and T CD4+ cell count >500 cells/mm3 were also associated with higher QoL (p=0.04 and p<0.001, respectively) and higher adherence (p<0.001 and p<0.001, respectively). Patients on NRTI+NNTRI regimens

have higher adherence when compared to those on NRTI+PI regimens [72.4 (10.4) vs 69.1 (10.8); p=0.012] and higher QoL indexes [55.9 (20.1)] vs 49.6 (22.2); p<0.001]. When compared to twice daily regimens, patients on single dose per day regimens have higher adherence [73.5 (9.6) vs 68.9 (11.2); p<0.001] and higher QoL [55.9 (20.1) vs 49.6 (22.2); p=0.001]. The study also shows evidence of a positive and statistical association between the adherence behavior and quality of life overall, with the highest correlation found in the psychological domain (r=0.58, p<0.001) and the lowest in the social relations (r=0.35, p<0.001) domain.
Patients experiencing adverse events have lower QoL [47.6 (22.2) vs 56.5 (20.0); p<0.001] and lower adherence levels [66.9 (11.3) vs 74.0 (9.3); p<0.001] when compared to those not experiencing such events.
Conclusions: Both clinical variables and regimen characteristics were found to be associated with adherence and QoL. These should thus be considered when defining interventions to improve the adherence to the antiretroviral therapy.

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Does feedback of medication execution using MEMS caps aid adherence to HAART?: the MEMRI study (MEMS as Realistic Intervention)

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Purpose of the study: Medication adherence is crucial for successful Highly Active Antiretroviral Treatment (HAART). Adherence may be divided into execution (how dosing history corresponds to the prescribed drug dosing regimen) and persistence (the time from the first to last taken dose). Medical Electronic Monitoring System (MEMS) monitors record bottle opening events providing a graphical printout of adherence. This can be used to provide positive feedback and correct any perceptual inaccuracies as to adherence. MEMRI assesses the use of such feedback as an intervention to support adherence. The primary endpoint is based on execution.
Methods: 265 patients were recruited. 180 were suitable for randomisation. All subjects were attending for HIV outpatients at Birmingham Heartlands Hospital. MEMS cap data was available for analysis for 145 of these. 78 (Group A) were given regular feedback using graphical readouts by clinical staff predominantly pharmacists. 67 (Group B) were blinded to feedback and no graphical output was available. MEMS 6 monitors (LCD display) were used on the most frequently dosed component of the HAART regimen. MEMS were downloaded at each clinic visit. At time of this interim analysis 12 months of follow-up had been completed for all subjects.
Summary of results: 123 patients took qid regimens, 14 took bid regimens, and 8 took multiple regimens during monitoring each divided evenly between Group A and Group B. Medication execution was high in both groups (>90%) for those patients who continued using the MEMS cap. Feedback (Group A vs. B) was not associated with a significant difference in execution but execution improved over time. There was a larger drop-out rate in Group B vs. Group A (22 vs. 13 patients) although this was not statistically significant. Execution was significantly worse at weekends (p=0.0001).
Conclusions: A preliminary analysis of the MEMRI study primary endpoint is presented. On limited follow-up at 12 months MEMS feedback showed no effect on medication adherence but this was only on patients with high initial adherence execution. This large adherence study includes a wide range of patients and may be able to extrapolate to other groups. Data based further follow-up will be presented and when complete the study will include analysis of other factors such as perceived needs and concern, self-efficacy and conscientiousness.

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Antiretroviral regimen complexity as a predictor of adherence

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Purpose of study: Even with the introduction of once daily antiretroviral (ARV) regimens of low pill burden, long-term adherence remains a challenge, particularly in subgroups, such as patients with drug addiction. We aimed to determine levels of adherence and identify factors associated with suboptimal adherence in treated, HIV-infected patients attending a busy European inner-city HIV outpatient clinic.
Methods: In a prospective cohort study, adherence was assessed in HIV-infected patients on antiretroviral therapy by self-report (ACTG adherence questionnaire). Relationships between suboptimal adherence (defined as <95%) and 49 covariates, including demographics, treatment factors, Centre for Epidemiological Studies Depression (CES-D) score and comorbidities were assessed using simple regression. Variables significant ($P < 0.05$) in univariate analyses were evaluated using multivariate logistic regression.
Results: 130 subjects (median [IQR] age 38 [11]; 27% female; 33% African origin; 27% IDU, 30% heterosexual and 20% MSM) were recruited. 83% were on once daily ARV and 16%, 34%, 48% and 2% were on regimens comprising one, two, three and four ARV medications respectively. Median CD4+ was 389 [285] cells/μL. 91% had HIV RNA < 50 copies/ml. Median adherence was 92% [range 0-100%] and 28% had suboptimal adherence. In univariate analyses, recent illicit drug use, on methadone, higher CES-D score, taking a higher number of ARV medications, greater pill burden, missed clinic appointments and lower CD4+ were associated with suboptimal adherence. In multivariate analysis, missed clinic appointments [OR 1.45; 95% CI (1.16, 1.81)] a higher CES-D score [OR 1.14; CI (1.01-1.28)] and being on a higher number of antiretroviral medications [OR 3.45; CI (1.46, 8.54)] were all independent predictors of suboptimal adherence.
Conclusions: In a cohort where many patients are on once daily ARV, although attending clinic visits and psychological status remain important, the number of antiretroviral medications is the strongest independent predictor of adherence. Medication complexity (number of ARV) rather than the pill burden is more predictive of poor adherence in this cohort of patients from varied demographic backgrounds. Single pill, fixed dose combinations (FDC) may improve adherence and these data support further development of FDC especially for those with drug addiction and psychological issues in which current FDC medications may not be suitable.

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Naïve patients receiving TDF/FTC-EFV as 2 pills are more likely to modify regimen components than patients receiving a TDF/FTC/EFV single pill

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Purpose of the study: To estimate the short-term probability of treatment change in antiretroviral naïve patients receiving tenofovir (TDF), emtricitabine (FTC) and efavirenz (EFV) as a one (1p) or two pills (2p) regimen.
Methods: We evaluated, by logistic regression and Cox proportional model analysis, factors associated to treatment modification during the first year of HAART in antiretroviral naïve patients from a single HIV unit in Madrid who started treatment with TDF, FTC and EFV as 1 p or 2p. For this analysis we censored patients who switched from 2p to 1p.
Results: From Jan/06 to Dec/09, 136 patients started HAART with TDF, FTC & EFV as 1p (59, 42.8%) or 2p (79, 57.2%). Mean age: 38.5 (1p) and 38.6 (2p), 83.1% male (1p) and 75.3% (2p). Median CD4: 250 (1p) and 244 (2p), mean viral load (log): 4.53 (1p) and 4.48 (2p), HCV coinfected: 15.3% (1p) and 19.5% (2p). One-year probability of HAART modification was