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prepared by the Bordeaux Working Group

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Bussmann H, Wester CW, Wester CN, Lekoko B, Okezie O, Thomas AM, DeGruttola SMV, Makhema J, Essex M, Marlink RG. **Pregnancy rates and birth outcomes among women on efavirenz-containing highly active Antiretroviral therapy in Botswana.** Journal of Acquired Immune Deficiency Syndromes 2007;45(3):269-273.

Abstr. Background: Millions of HIV-infected women in developing countries are in need of safe and highly effective antiretroviral therapy. Pregnancy rates are usually high in developing countries, and efavirenz (EFV) use in women of childbearing age is of concern because of its potential teratogenicity. Methods: As part of a prospective study comparing 6 initial highly active antiretroviral therapy (HAART) regimens, 3 of which contained EFV, pregnancy and birth outcomes were evaluated among female participants enrolled in a randomized clinical trial in Botswana. Before enrollment, all female participants indicated a willingness to avoid pregnancy for the 3-year duration of the study. Monthly urine pregnancy testing and regular contraceptive education and counseling were given to all women on Study. Results: Four hundred fifty-one (69.41%) of 650 enrolled Study participants were female and experienced 71 pregnancies, for a rate of 7.9 per 100 person-years during the study. The mean time from HAART initiation to time of first pregnancy was 385 days. The median birth weight of babies was 2950 g (interquartile range: 2700-3250 g); the gender of babies (24 female and 15 male) and occurrence of early pregnancy loss (42%) and stillbirths (3%) did not differ between EFV- and non-EFV-exposed pregnancies (P = 0.7). First-trimester EFV exposure occurred in 38 (53.5%) of the 71 pregnancies; 22 (57.9%) of these 38 pregnancies resulted in live births. One infant (4.5%) of the 22 EFV-exposed live births had a congenital abnormality with right limb shortening that was assessed to be unrelated to EFV exposure. Conclusions: The restoration of health and longevity in many HAART-treated women is often accompanied by childbearing, as evidenced by the large fraction of women in Our cohort who became pregnant despite their initial statements of intent to avoid pregnancy. Of 22 first-trimester EFV-exposed live births, 1 neonate was found to have a major congenital abnormality; however, this defect was unrelated to EFV exposure. The small sample size is insufficient to estimate accurately the underlying risk of congenital malformation after exposure to EFV in early pregnancy, underscoring the importance of reporting to the existing international Antiretroviral Pregnancy Registry. In addition to accessing safe and effective HAART regimens, HIV-infected women require access to comprehensive family planning services, including contraception and procreation counseling.

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Colvin M, Chopra M, Doherty T, Jackson D, Levin J, Willumsen J, Goga A, Moodley P. **Operational effectiveness of single-dose nevirapine in preventing mother-to-child transmission of HIV.** Bulletin of the World Health Organization 2007;85(6):466-473.

Abstr. Objective To determine the operational effectiveness of the South African programme for preventing mother-to-child transmission (PMTCT) of HIV in reducing rates of early transmission of infection. Methods Participants were mother-infant pairs who participated in the South African PMTCT programme between October 2002 and November 2004. This was a prospective cohort study. Three sites in different provinces were selected to represent differences in socioeconomic status and HIV prevalence. Data on antenatal care and labour ward care were obtained from maternal interviews and from reviews of medical records. A total of 665 mother-infant pairs in which the mother was HIV-positive were recruited and 588 (88.4%) were followed up at 3 or 4 weeks postpartum to determine the HIV status and vital status of the infant. Findings Rural participants were significantly poorer and their health care was significantly worse. Women of higher socioeconomic status and those who received better counselling were

more likely to be treated with nevirapine. Rates of early HIV transmission ranged from 8.6% to 13.7%. Maternal viral load was the only statistically significant risk factor for transmission. After adjusting for maternal viral load and prevalence of low birth weight, the odds of transmission were 1.8 times higher at the rural site. Controlling for having had ≥ 4 antenatal visits and any delivery complication reduced the odds of transmission to 1.5 higher at the rural site. Conclusion Rates of early transmission of HIV in an operational setting using single-dose nevirapine administered both to mother and child are similar to those obtained in clinical trials. Scaling up access to antiretroviral regimens for women will further reduce transmission to infants.

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Eholie SP, A TA, Polneau S, Ouiminga M, Djadji A, Kangah Koffi C, Diakite N, Anglaret X, Kakou A, Bissagnene E. **Field adherence to highly active antiretroviral therapy in HIV-infected adults in Abidjan, Cote d'Ivoire.** Journal of Acquired Immune Deficiency Syndromes 2007;45(3): 355-358.

Abstr. Objectives: To estimate adherence to highly active antiretroviral therapy (HAART) and its determinants in HIV-infected adults followed in field conditions in Abidjan. Methods: A standardized questionnaire was administered to all consecutive adults on HAART who attended 3 urban HIV outpatient clinics. Patients were asked to self-report their pill intake during the previous 7 days, and, when necessary, to explain the reason(s) why they missed at least 1 intake. The adherence rate was estimated as the number of pills actually taken divided by the number of pills that should have been taken. The association of incomplete adherence (adherence rate $< 90\%$) with patients' characteristics was studied using multivariate logistic regression. Results: Three hundred eight patients (male/female ratio: 1: 1, mean time on HAART: 22 months) were interviewed. The median self-reported adherence rate was 78% (interquartile range: 65%-90%), with 76% of patients considered as incompletely adherent (adherence rate $< 90\%$). The most frequent self-reported reasons for missing at least 1 intake were an antiretroviral drug being out of stock in the clinic pharmacy (28%), the fear of drug side effects (27%), the impossibility of paying the drug's price (20%), and the intervention of traditional practitioners (18%). The only variables significantly independently associated with incomplete adherence were a school level \geq secondary (odds ratio [OR] = 1.88; P = 0.03) and the absence of a patient's long-term formal commitment to adhere to HAART (OR = 3.08; P = 0.01). Conclusions: These data illustrate the difficulty in obtaining high levels of adherence in field conditions in Abidjan. Sustainable access to treatment should be promoted by combating access barriers such as running out of drugs and costs that are too high.

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Franceschi S, Jaffe H. **Cervical cancer screening of women living with HIV infection: A must in the era of antiretroviral therapy [editorial].** Clinical Infectious Diseases 2007;45(4):510-513.

Abstr. Women living with human immunodeficiency virus (HIV) infection have a much higher risk of human papillomavirus infection and cervical cancer than do HIV-uninfected women. Before the introduction of antiretroviral therapy, the lack of cervical cancer screening among HIV-infected women probably had little influence on their life expectancies because of the high competing mortality associated with other causes, but the situation is changing rapidly everywhere. In sub-Saharan Africa, for instance, similar to 400,000 HIV-infected women were receiving antiretroviral therapy in 2005. Funds

given to antiretroviral therapy programs in low-resource countries not only support the purchase of drugs, but they also support the development of clinical infrastructures and laboratories. Because women who receive antiretroviral therapy are observed regularly, they can also receive the continuity of care needed for cervical screening. Therefore, the real opportunity to prevent cervical cancer in HIV-infected women in low-resource countries should not be missed especially as new, inexpensive screening methods (e.g., rapid human papillomavirus tests) are under evaluation.

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Golub JE, Saraceni V, Cavalcante SC, Pacheco AG, Moulton LH, King BS, Efron A, Moore RD, Chaisson RE, Durovni B. **The impact of antiretroviral therapy and isoniazid preventive therapy on tuberculosis incidence in HIV-infected patients in Rio de Janeiro, Brazil.** AIDS 2007; 21(11):1441-1448.

Abstr. Background: Tuberculosis is a common complication and leading cause of death in HIV infection. Antiretroviral therapy (ART) lowers the risk of tuberculosis, but may not be sufficient to control HIV-related tuberculosis. Isoniazid preventive therapy (IPT) reduces tuberculosis incidence significantly, but is not widely used. Methods: We analysed tuberculosis incidence in 11026 HIV-infected patients receiving medical care at 29 public clinics in Rio de Janeiro, Brazil, between 1 September 2003 and 1 September 2005. Data were collected through a retrospective medical record review. We determined rates of tuberculosis in patients who received neither ART nor IPT, only ART, only IPT, or both ART and IPT. Results: The overall tuberculosis incidence was 2.28 cases/100 person-years (PY) [95% confidence interval (CI) 2.06-2.521]. Among patients who received neither ART nor IPT, incidence was 4.01/100PY. Patients who received ART had an incidence of 1.90/100 PY (95% CI 1.66-2.17) and those treated with IPT had a rate of 1.27/100 PY (95% CI 0.41-2.95). The incidence among patients who received ART and IPT was 0.80/100 PY (95% CI 0.38-1.47). Multivariate Cox proportional hazards modeling revealed a 76% reduction in tuberculosis risk among patients receiving both ART and IPT (adjusted relative hazard 0.24; $P < 0.001$) after adjusting for age, previous tuberculosis diagnosis, and CD4 cell counts at baseline. Conclusion: The use of both IPT and ART in HIV-infected patients is associated with significantly reduced tuberculosis incidence. In conjunction with expanded access to ART, the wider use of IPT in patients with HIV will improve tuberculosis control in high burden areas.

Notes: This article recently published in AIDS addresses the question of the added value of isoniazid preventive therapy (IPT) on tuberculosis (TB) incidence in an HIV-infected population with high levels of antiretroviral treatment (ART) use. As TB is among the most common causes of morbidity and mortality in people living with HIV, causing at least 12% of HIV deaths worldwide, this is an important public health issue affecting high TB and HIV-burdened resource-limited settings.

The premise for this observational study was that, even though isoniazid (INH) IPT in HIV-infected patients is known to lower TB incidence by 70–90%¹, the use of such prophylaxis has been tempered by long term concerns regarding the durability of protection, drug resistance, toxicity as well as adherence issues limiting the uptake of INH prophylaxis. In settings where the main issue is the detection of active TB cases, implementation of IPT has thus been delayed and remains limited even though several studies have shown that active TB can be excluded using relatively simple screening measures². Moreover, many studies have already shown that ART is associated with reduced TB incidence. Lawn³ in 2005 reported that the TB incidence density rate, which was 3.5/100 person-years (PY) in the first year of ART significantly decreased during follow-up, reaching 1.01/100 PY in the fifth year in South Africa ($p=0.002$). However,

the incidence of TB remained unacceptably high after ART was initiated and patients with advanced pre-treatment immunodeficiency still had a persistently increased risk of TB on ART.

The authors of this study carried out in 29 HIV clinics in Rio de Janeiro, Brazil and using retrospectively collected data, assessed the association between a history of ART or IPT, or both, and the risk of active TB during a 2-year period. ART and IPT were treated as time-dependent exposures and data from 11 026 HIV-infected subjects were analysed. Cumulatively, 74% of them were on ART and IPT was received by 10%, with 834 (76.1%) individuals having completed six months of prophylactic treatment and 17% having had a previous diagnosis of TB.

The authors found a high TB incidence in this Brazilian urban population with high levels of ART use, with an overall incidence of 2.28 cases per 100 PY, 4.01/100 PY with neither ART nor IPT, 1.90/100 PY (95% CI 1.66–2.17) on ART alone, 1.27/100 PY (95%CI 0.41–2.95) on IPT alone and 0.80/100 PY (95% CI 0.38–1.47) on both ART and IPT. ART in a multivariate analysis was independently associated with a 59% reduction in TB incidence, whereas the use of both IPT and ART reduced the risk further by 24%.

This observational survey concluded that the combined effect of IPT and ART could have a greater impact on TB incidence than the use of ART alone and therefore implementation of a public health policy promoting the uptake of INH prophylaxis would help lower significantly the number of cases of TB in resource-limited settings such as this one. Even though a recent WHO policy endorsing the use of IPT in HIV-infected patients has been promoted⁴, uptake has been very limited so far. The low uptake of IPT does not seem rationale in so far as INH is known to be well tolerated, inexpensive and easy to administer in addition to lowering TB incidence and that studies have not shown an increased risk of drug resistance⁵. Another interesting finding of this particular study was that previous TB was a significant risk factor for incident TB in patients with higher CD4 cell counts, which also pushes towards the need for clear recommendations regarding secondary INH prophylaxis in such populations.

Altogether, this study tends to show the benefits of IPT in combination with ART but the duration of the protective effect of preventive therapy remains unclear and must be clarified in future research.

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Hawkins C, Achenbach C, Fryda W, Ngare D, Murphy R. **Antiretroviral durability and tolerability in HIV-infected adults living in urban Kenya.** Journal of Acquired Immune Deficiency Syndromes 2007;45(3):304-310.

Abstr. Background: Insufficient data exist on the durability and tolerability of first-line antiretroviral therapy (ART) regimens provided by HIV treatment programs implemented in developing countries. Methods: Longitudinal observation of clinical, immunologic, and treatment parameters of all HIV-infected adult patients initiated on ART was performed at Saint Mary's Mission Hospital in Nairobi, Kenya from September 2004 until August 2006. Results: A total of 1286 patients were analyzed (59.1% female). Initial ART regimens were primarily stavudine, lamivudine, and nevirapine (62.1%). Median ART duration was 350 days (11.6 months). Significant improvements in clinical and immunologic status were noted after 12 months of therapy. ART switches occurred in 701 (54.5%) patients. The cumulative incidence of ART switch at 12 months was 78.4%. Concurrent ART-related toxicities (40.6%) and tuberculosis treatment interactions (28.1%) were the most frequent reasons for ART switch. Baseline AIDS symptoms

(hazard rate [HR] = 1.59, 95% confidence interval [CI]: 1.28 to 1.98; P < 0.01) and a CD4 count \leq 100 cells/mm³ (HR= 1.20, CI: 1.01 to 1.43; P = 0.04) were independent predictors of ART switch. ART-related clinical toxicity occurred in 341 (26.5%) patients. Peripheral neuropathy was reported most frequently (20.7%). A CD4 count \leq 100 cells/mm³ was an independent predictor of clinical toxicity. Conclusions: Excellent clinical and immunologic responses to ART were observed in this urban Kenyan population; however, frequent switches in ART among medication classes because of toxicity or drug interactions may limit the durability of these responses.

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Hoffmann CJ, Charalambous S, Thio CL, Martin DJ, Pemba L, Fielding KL, Churchyard GJ, Chaisson RE, Grant AD. **Hepatotoxicity in an African antiretroviral therapy cohort: the effect of tuberculosis and hepatitis B.** AIDS 2007; 21(10): 1301-1308.

Abstr. Objective: Hepatotoxicity is a significant complication of antiretroviral therapy (ART). We assessed the incidence of and risk factors for hepatotoxicity among HIV-infected individuals on ART in South Africa. Design: We conducted a retrospective cohort study in a workplace HIV care program in South Africa which uses a first-line regimen of efavirenz, zidovudine, and lamivudine and provides routine clinical and laboratory monitoring. Methods: We included subjects with baseline and follow-up alanine transaminase and aspartate aminotransferase tests. Severe hepatotoxicity cases were identified during the first 12 months of ART. Potential risk factors, including concomitant medication use, tuberculosis, and hepatitis B and C, were determined from clinical records, database queries, and serological testing. Associations with hepatotoxicity were investigated using Cox proportional hazards modeling. Results: Of the 868 subjects (94% male, median age 41 years), the median nadir CD4 cell count was 136/ μ l, 25% received concomitant tuberculosis treatment during ART, and 17% of a randomly selected subset were positive for hepatitis B surface antigen (HBsAg). We identified 7.7 episodes of severe hepatotoxicity per 100 person-years. Tuberculosis treatment increased risk 8.5 fold, positive HBsAg 3.0 fold, and nadir CD4 cells count < 100/ μ l 1.9 fold. Importantly, the fraction of patients with severe hepatotoxicity on ART (4.6%) was similar to the fraction with liver enzyme elevations > 5 times the upper limit of normal before starting ART (4%). Conclusions: In this African ART cohort, we found a low incidence of and minimal morbidity due to hepatotoxicity. HBsAg and concomitant tuberculosis therapy significantly increased the risk of hepatotoxicity.

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Miles K, Clutterbuck DJ, Seitio O, Sebege M, Riley A. **Antiretroviral treatment roll-out in a resource-constrained setting: capitalizing on nursing resources in Botswana.** Bulletin of the World Health Organization 2007; 85(7): 555-560.

Abstr. Problem: As programmes to deliver antiretroviral therapy (ART) are implemented in resource-constrained settings, the problem becomes not how these programmes are going to be financed but who will be responsible for delivering and sustaining them. Approach: Physician-led models of HIV treatment and care that have evolved in industrialized countries are not replicable in settings with a high prevalence of HIV infection and limited access to medical staff. Therefore, models of care need to make better use of available human resources. Local setting Using Botswana as an example, we discuss how nurses are underutilized in long-term clinical management of patients requiring ART. Relevant changes We argue that for ART-delivery programmes to be sustainable, nurses will need to provide a level of clinical care for patients receiving this therapy, including prescribing ART and managing common adverse effects. Lessons learned: Practicalities involved in scaling up nurse-led models of ART delivery include

overcoming political and professional barriers, identifying educational requirements, agreeing on the limitations of nursing practice, developing clear referral pathways between medical and nursing personnel, and developing mechanisms to monitor and supervise practice. Operational research is required to demonstrate that such models are safe, effective and sustainable.

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Mphatswe W, Blanckenberg N, Tudor Williams G, Prendergast A, Thobakgale C, Mkhwanazia N, McCarthy N, Walker BD, Kiepiela P, Goulder P. **High frequency of rapid immunological progression in African infants infected in the era of perinatal HIV prophylaxis.** AIDS 2007;21(10):1253-1261.

Abstr. Objectives: To determine the natural history of HIV infection following peripartum single-dose nevirapine (sd-NVP) prophylaxis in a resource-limited country, and to assess implications for antiretroviral therapy (ART) roll-out programmes. Methods: Infants of HIV-infected mothers in KwaZulu-Natal, South Africa, were tested on days 1 and 28 to detect intrauterine (IU) and intrapartum (IP) infection. Infant follow-up included monthly viral load and CD4 cell measurement. ART was initiated at infant CD4 cell% \leq 20%. Results: In 740 infants born to 719 HIV-infected women, mother-to-child transmission (MTCT) was 10.3% (69% IU, 31% IP). Median viral load was higher in mothers of infants infected IP than IU (279 000 versus 86 600 copies/ml; $P=0.039$) and lower in mothers of uninfected infants (median 26 750 copies/ml; $P<0.001$). Peak viraemia was higher in infants infected IP than IU (5 160 000 versus 984 000 copies/ml; $P<0.001$). Median viral load at birth in IU-infected infants (1 55 000 copies/ml) fell 1.4 log to 6510 copies/ml by day 5 and was beneath the detection limit using dried blood spot analysis in 38% of infants. CD4 cell% declined rapidly, to \leq 20% in 70% and \leq 25% in 85% [current World Health Organization (WHO) criteria for initiating ART] of infants by 6 months. Conclusions: MTCT was reduced by sd-NVP through an effect on IP transmission. Where MTCT occurred despite NVP, two-thirds of transmissions arose IU; IP-infected babies were born to mothers with very high viral load. Disease progression was particularly rapid, 85% infants meeting WHO criteria for ART within 6 months. These findings argue for more effective MTCT-prevention programmes in resource-limited countries.

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Rollins N, Little K, Mzolo S, Horwood C, Newell ML. **Surveillance of mother-to-child transmission prevention programmes at immunization clinics: the case for universal screening.** AIDS 2007;21(10):1341-1347.

Abstr. Background: Surveillance programmes for prevention of mother-to-child transmission of HIV (PMTCT) fail to quantify numbers of infant HIV infections averted, often because of poor postnatal follow-up. Additionally, infected infants are often not identified early and only gain access to comprehensive HIV care and treatment late in their disease. Methods: Anonymous, unlinked, HIV prevalence testing was conducted on dried blood spot (DBS) samples from all infants attending 6 week immunization clinics at seven primary health care clinics offering PMTCT. Samples were tested for HIV antibodies (indicating maternal HIV infection) and those determined to be from HIV-exposed infants were tested for HIV RNA by polymerase chain reaction. Infant and child mortality rates were determined using birth histories. Results: Samples were collected from 2489 infants aged 4-8 weeks. HIV antibodies were identified in 931 infants [37.4%; 95% confidence interval (CI), 35.4-39.4], of whom 188 were HIV RNA positive. The estimated vertical transmission rate (VTR) was 20.2% (95% CI, 17.8-23.1%); 7.5% of all infants at this

age were infected. Amongst mothers who reported that they had taken single-dose nevirapine for PMTCT, VTR was 15.0%. Amongst women who reported being HIV uninfected but whose infants had HIV antibodies, VTR was 30.5%. Infant mortality rates in KwaZulu Natal increased from 28/1000 live births in 1990-1994 to 92/1000 in 2000-2004. Conclusions: Anonymous HIV prevalence screening of all infants at immunization clinics is feasible to monitor the impact of PMTCT programmes on peripartum infection; linked screening could identify infected children early for referral into care and treatment programmes

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Yu JKL, Chen SCC, Wang KY, Chang CS, Makombe SD, Schouten EJ, Harries AD. **True outcomes for patients on antiretroviral therapy who are "lost to follow-up" in Malawi.** Bulletin of the World Health Organization 2007;85(7):550-554.

Abstr. Problem In many resource-poor countries that are scaling up antiretroviral therapy (ART), 5-25% of patients are reported as "lost to follow-up". This figure is 9% in Malawi. There is no published information about the true outcome status of these patients. Approach In four facilities in northern Malawi, ART registers and master cards were used to identify patients who had not attended the facility for 3 months or more and were thus registered as "lost to follow-up". Clinic staff attempted to trace these patients and ascertain their true outcome status. Local setting Of 253 patients identified as "lost to follow-up", 127 (50%) were dead, 58% of these having died within 3 months of their last clinic visit. Of the 58 patients (23%) found to be alive, 21 were still receiving ART and 37 had stopped treatment (high transport costs being the main reason for 13 patients). Sixty-eight patients (27%) could not be traced, most commonly because of an incorrect address in the register. Fewer patients were alive and more patients could not be traced from the central hospital compared with the peripheral hospitals. Relevant changes Better documentation of patients' addresses and prompt follow-up of patients who are late for their appointments are required. Lessons learned ART clinics in resource-poor countries should ensure that patients' addresses are correct and comprehensive. Clinics should also undertake contact tracing as soon as possible in the event of non-attendance, consider facilitating access to ART clinics and take loss to follow-up into consideration when assessing death rates.

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Zhou J, Paton NI, Ditangco R. **AIDS-defining illness diagnosed within 90 days after starting highly active antiretroviral therapy among patients from the TREAT Asia HIV Observational Database.** International Journal of Std and AIDS 2007;18(7):446-452.

Abstr. Using data from TREAT Asia HIV Observational Database (TAHOD), this paper aims to assess the rate of, and factors associated with the diagnosis of new AIDS-defining illness (ADI) within 90 days after antiretroviral treatment. Patients starting three or more antiretroviral combinations and having subsequent follow-up were included. New ADI cases were checked for evidence of immune reconstitution syndrome (IRS). Among the 1185 patients included, 75 (6.3%) were diagnosed with a new ADI within 90 days, giving a rate of 26.8/100 person-years, compared with a further 3.6% cumulative incidence of new ADI between 90 days to one year (4.2/100 person-years). Of the 75 patients, 21 were judged as definitive or presumptive IRS, giving a rate of 7.3/100 person-years. Patients with new ADI generally had lower CD4 counts before treatment started (median, 43 cells/ μ L). Lower CD4 count, lower body mass index and starting

treatment in the same year as the first HIV-positive test done were associated with developing a new ADI. The higher rate of new ADI within 90 days may be partly explained by IRS occurring shortly after treatment. Although it is difficult to identify IRS from observational data, it appears that in TAHOD setting IRS was relatively uncommon.

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