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Is "Option B+" Also Being Adopted in Pregnant Women in High-Income Countries? Temporal Trends From a National Study in Italy

To the Editor—The World Health Organization currently recommends lifelong continuation of antiretroviral therapy (ART) after delivery ("Option B+") as an option for human immunodeficiency virus (HIV)-infected women starting combination ART in pregnancy [1]. This approach is therefore increasingly being implemented in African countries with high HIV disease burden [2–4] and evaluated in economic studies [5, 6].

The advantages of this strategy include ease of implementation, no need for CD4 and HIV RNA testing, possibility to initiate immediately treatment, potential better retention in care, and reduced risk of sexual HIV transmission to uninfected male partners [7].

It is not known to which extent a similar approach is being adopted in high-income countries, where, despite a lower HIV disease burden and fewer economic constraints, some of the benefits may be the same. To explore this issue, we used data from the Italian National Program on Surveillance on Antiretroviral Treatment in Pregnancy [8], a national observational study of pregnant women with HIV established in 2001, where therapeutic decisions are taken by the individual physicians. We considered all pregnancies ending in live births among antiretroviral-naive women with no indication to ART for their own health (defined by symptomatic HIV disease or CD4 count <350 cells/μL), who started treatment in pregnancy by 32 weeks of gestation and had available information on treatment status after delivery.

Quantitative data were compared by Mann–Whitney *U* test and the temporal trends were analyzed using the χ^2 test for trend. *P* values <.05 were considered significant. All analyses were performed using SPSS software, version 22.0 (IBM, Somers, New York). Ethics approval was obtained on 28 September 2001 from the Ethics Committee of the I.N.M.I. Lazzaro Spallanzani in Rome (reference deliberation number 578).

Overall, between 2002 and 2012, 263 pregnancies met the above eligibility criteria. In most of them (159/263 [60.5%]), ART was continued after delivery, either unchanged (150/159 [94.3%]) or with changes (9/159 [5.7%]). The proportion of women continuing treatment after delivery increased significantly over the

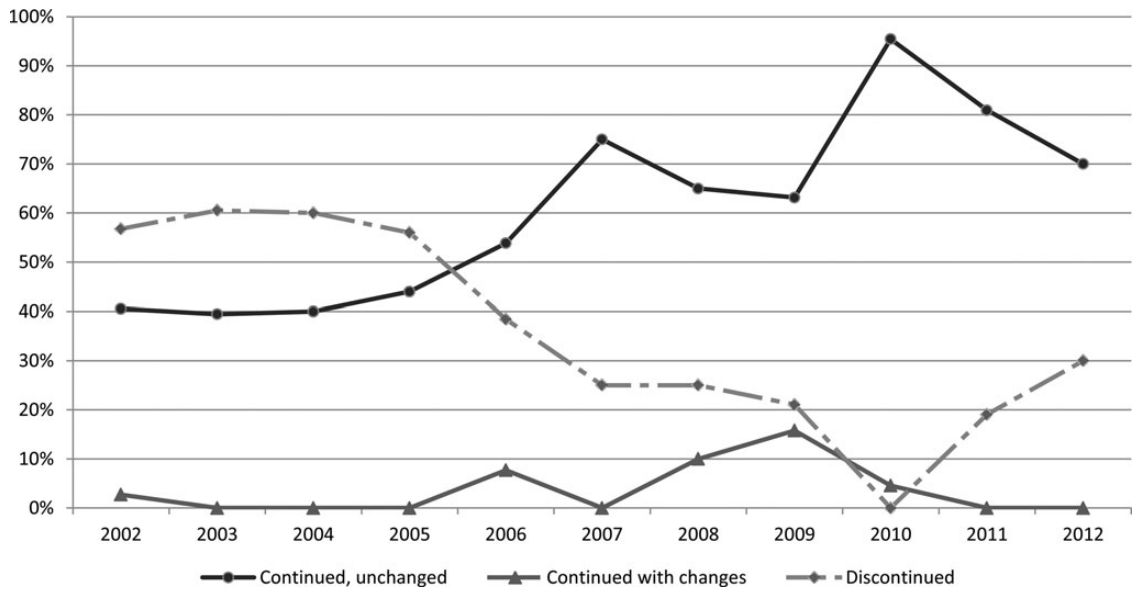

Figure 1. Temporal trends in continuation of treatment after delivery, 2002–2012. Continued with changes (1 or more changes): switch from zidovudine + lamivudine (3TC) to tenofovir (TDF) + emtricitabine (FTC), 5; switch between different protease inhibitors, 3; intensification (3TC or TDF added), 3; switch from nevirapine- or lopinavir/ritonavir-based regimens to TDF + FTC + efavirenz, 2.

period considered, from 43.2% in 2002 to 70.0% in 2012 ($P < .001$; Figure 1). Such changes were not accompanied by significant temporal changes in other conditions that could have affected the decision to maintain treatment, such as presence of an HIV-uninfected partner (overall proportion 2002–2012: 57.6%; P for temporal trend = .808), hepatitis virus B or C (overall proportion: 8.4% and 13.5%, respectively; $P = .721$ and .483, respectively), or CD4 between 350 cells/μL and 500 cells/μL (overall proportion: 50.3; $P = .823$).

Follow-up data on CD4 count and HIV RNA copy number were available for 118 and 114 women, respectively, at 1 year after delivery and for 77 and 74 women, respectively, at 2 years after delivery. One year after delivery, median CD4 counts were similar in the 2 groups (continuers: 672/μL [interquartile range {IQR}, 504–840]; discontinuers: 646/μL [IQR, 508–825], $P = .895$), but median HIV RNA copy number was higher in discontinuers (3100/mL [IQR, 170–17 370]) than in continuers (49/mL [IQR, 40–1207], $P < .001$). At 2 years, the discontinuers had significantly fewer CD4 cells (578/μL [IQR, 454–674] vs 686/μL [IQR, 530–1005], $P = .010$) and significantly higher HIV RNA levels (3191 copies/mL [IQR, 157–32 434] vs 49 copies/mL [IQR, 40–599], $P < .001$). No clinical progression of HIV disease was observed in the 2 groups.

Our study, based on a national sample from a high-income country, shows that an increasing proportion of HIV-infected pregnant women with no personal indication to treatment are maintained on ART after delivery, suggesting that this approach is being considered favorably also in high-income countries. Future studies based on a long-term follow-up evaluation will have to assess the clinical benefits of this approach, taking into account levels of retention in care, which are likely to represent a critical factor for the effectiveness of this approach [9].

Notes

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Disclaimer. The corresponding author had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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APPENDIX

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[a]The members of the Italian Group on Surveillance on Antiretroviral Treatment in Pregnancy group of members are listed in the Appendix.

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