



# The Brazilian Journal of INFECTIOUS DISEASES

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## Letter to the Editor

# Real-world evidence in antiretroviral therapy: drug safety data



Dear Editor:

Adverse drug reactions (ADR), despite being underreported, are a serious public health problem, associating with high mortality and morbidity.<sup>1,2</sup> In the case of antiretroviral therapy (ART), some studies have demonstrated that ADR is the main factor for drug change, often preventing adherence by the patient to treatment and reducing the durability of the initial regimen.<sup>3,4</sup>

A recent case-control study nested in a cohort of people living with HIV/AIDS was published in your journal to investigate factors associated with the modification of first-line ART due to ADR.<sup>5</sup> This study is important because ART in Brazil is recommended for all people living with HIV, regardless of their CD4 count. In addition, the methodology of the study allowed researchers to circumvent limitations of other methods such as spontaneous notifications.

In Portugal, the recommendations for this type of therapy are similar to those in Brazil. We conducted a retrospective observational study in a consecutive sample of people living with HIV/AIDS who started ART between 2007 and 2011, and who were followed in a tertiary public hospital of Northern Portugal. In that study, we sought to identify the main reasons for changing ART through the information contained in hospital prescriptions and by examining whether detected adverse reactions had been reported to the Portuguese Pharmacovigilance System. From the 517 patients, 259 changed ART, of which 60 (24%) were due to ADR. However, only 6 (8.5%) of the changes of ART due to ADR had been reported to the Portuguese Pharmacovigilance System. The most commonly involved System Organ Class (SOC) was “Skin and subcutaneous tissue disorder”.

Therefore, we found a similar frequency of ADR-associated ART changes in Portugal compared to that described by Azevedo et al. Our results highlight that despite ADR being a common reason for therapeutic change in people living with HIV/AIDS, they tend to be underreported. We would like to emphasize the importance of reporting ADR to the Pharmacovigilance System, because it is the only way to get real world drug safety data and to increase knowledge about the marketed drugs.

## Conflicts of interest

The authors declare no conflicts of interest.

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