

# **Trials involving switching HIV drugs may not be beneficial to participants**

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A increasingly used type of HIV study which involves switching patients on one type of antiretroviral therapy (ART) to another, to see whether the new drug is as good as the at preventing replication of the HIV virus, may be unethical, according to a new Essay published in this week's *PLoS Medicine*. The studies, termed non-inferiority trials, are only ethical if participants can meaningfully benefit from the treatment change and are more likely to benefit than suffer harm, according to Andrew Carr from the HIV unit in St Vincent's Hospital in Sydney, Australia, Jennifer Hoy from the infectious diseases unit in Alfred Hospital in Melbourne, Australia, and Anton Pozniak from the Chelsea and Westminster Hospital in London, UK. The authors argue in their essay that such trials are not in the best interests of patients, especially as often, these trials have inadequate numbers to assess the key expected benefit and reports all outcomes.

The authors say: "There are several potential advantages and disadvantages for patients of switching or simplifying ART. Potential advantages include reduced toxicity, pill burden, or cost. One key potential disadvantage is that effective, well-tolerated ART is abandoned."

The authors argue that such trials often enrol patients who cannot benefit with the switch, do not capture or report all potential risks, and are designed with a view to a pharmaceutical company's profits rather than participant benefit. They make a strong case for measuring, analysing and reporting relevant disadvantages of the switch and argue that patients

must be informed about all potential advantages and disadvantages.

The authors conclude: "Switching ART regimens when virologically suppressed may be appropriate for many reasons, but the full risk–benefit profile should be determined beforehand. The diminishing antiretroviral drug pipeline suggests greater care will need to be given in coming years to extending the benefits of existing drugs for what is likely to remain lifelong therapy."

**More information:** Carr A, Hoy J, Pozniak A (2012) The Ethics of Switch/Simplify in Antiretroviral Trials: Non-Inferior or Just Inferior? *PLoS Med* 9(7): e1001240. [doi:10.1371/journal.pmed.1001240](https://doi.org/10.1371/journal.pmed.1001240)

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