Reply

To the Editors:

In their letter, Drobeniuc and Spaulding question the selected analytic approach to our randomized controlled trial of a comprehensive intervention to maintain plasma HIV RNA suppression after prison release. Specifically, issue is taken with the use of an intent-to-treat analysis comparing the rates of virologic suppression at 24 weeks after prison release between the 2 study arms.

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Although investigators use a variety of approaches to address missing outcome data in intent-to-treat analyses, including complete case analyses and simple imputation methods, we recognized that in this trial of men and women reentering their communities after incarceration, missing data due to lost to follow-up and re-incarceration would not be trivial. To address this, the primary analysis used multiple imputation to estimate missing outcomes based on 10 major characteristics measured at baseline.[1,2] Therefore, all participants contributed data to the primary endpoint of this study, regardless of whether or not the participant was reincarcerated.

The multiple imputation modeling, in our view, is preferable to the actual measurement of viral load of those reincarcerated for a number of reasons. Foremost, the overarching aim of our trial was to test an intervention to maintain viral suppression in the community after incarceration to reduce the risk of secondary transmission of the virus. Those who are reincarcerated are no longer in these communities, and therefore, the determination of the efficacy of the intervention to reduce secondary transmission is no longer possible. Our model estimates the rates of viral suppression had these men and women remained in their communities. In addition, the study intervention was designed to encourage and support community HIV care and treatment adherence, and not viral suppression while in a correctional facility. The systems in place to administer and support HIV therapy in prisons and jails are starkly different from those found in the community.

Importantly, there is no reason to believe that the inclusion of viral load data from the participants who were reincarcerated would have altered the main findings of our trial. That the study intervention would have led to better or worse odds of viral suppression during reincarceration is highly unlikely, and other interventions should be developed and tested to improve HIV outcomes during incarceration.

We do agree with Drobeniuc and Spaulding that there are consequences of mass incarceration, especially among HIV-infected persons, that impede success after prison release. The absence of a significant difference between the study arms in the primary and almost all secondary outcomes suggests to us that there are strong societal forces that our intervention did not address. That a substantial proportion of HIV-infected people in the United States, particularly those living in deep poverty, can only achieve and maintain desirable health outcomes while incarcerated implicates these forces as the main target for change, rather than the behaviors of those they affect.

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