Reports on nevirapine threaten public health

To the editor:

The *Nature Medicine* news story 'US AIDS chief altered report on nevirapine safety risks'[1] deals with a series of controversial *Associated Press* articles on a trial of single-dose nevirapine to prevent the transmission of HIV from mother to infant. Unfortunately, these articles have been widely misconstrued to the potential detriment of public health[2–5].

We and others in the public health and AIDS activist communities are concerned that an incomplete understanding of issues related to the single-dose nevirapine regimen may lead to the decreased use in developing countries of a proven intervention that blocks mother-to-infant transmission of HIV in situations where frequently no other options are available[2–5].

The single-dose nevirapine regimen has been endorsed by the World Health Organization for use in settings where more complex regimens are not available[6], and by the US Public Health Service for use under certain emergency circumstances in the United States[7].

HIVNET 012, the research trial that first detailed the safety and efficacy of the single-dose nevirapine regimen, has undergone multiple reviews[5]. In every instance, the most important study conclusions have been confirmed: nevirapine administered as one dose to the mother at the onset of labor and one dose to the child within 72 hours of birth is safe and effective. In addition, findings of other studies conducted in the US and internationally have consistently supported the results of the study[5–7].

Your readers should know that that National Institute of Allergy and Infectious Diseases (NIAID) has provided a detailed question-and-answer document regarding the HIVNET 012 trial on our website (http://www2.niaid.nih.gov/newsroom/Releases/HIVNET012QA.htm).

Of particular note, we would point out that the medical community knows no more about the single-dose nevirapine regimen after the recent flurry of media stories than it did before[5]. The safety and efficacy of the single-dose nevirapine regimen is well established[5–7]. In addition, the fact that HIV resistance mutations to nevirapine develop with this abbreviated treatment regimen also is well recognized, and was first reported in 2000 (refs. 6,7). As with any antiretroviral drug, long-term use of nevirapine (as opposed to the abbreviated single-dose regimen) has toxicities. These also are well established, including the rare, but potentially life-threatening liver toxicity highlighted in a 'black box' in the product labeling[8].

The final NIAID HIVNET 012 re-monitoring report to which the story alludes was scientifically accurate and reflected the technical difficulties encountered in the resource-poor context in which the study was conducted[5]. It was edited by the Director of the NIAID Division of AIDS (DAIDS), Edmund Tramont, M.D., an internationally respected physician, clinical investigator and administrator with decades of experience in conducting clinical trials, including those in developing countries[5]. Input for this final report came to him from DAIDS staff members responsible for several draft sub-reports related to various aspects of HIVNET 012 (ref. 5). Ultimately, Dr. Tramont, in accordance with his responsibility as DAIDS Director, incorporated extensive and comprehensive information from several sources into his final report, including data from staff members who conducted three re-monitoring site visits in Uganda, as well as re-monitoring reports generated by three independent consultants[5]. This is not 'altering' a report[1], a term that carries a negative connotation of inappropriate behavior.

We reiterate that all existing scientific evidence continues to show that single-dose nevirapine is a safe and effective intervention to prevent mother-to-child transmission of HIV. In settings where other options are not available, it remains a recommended and valuable public health tool.

COMPETING INTERESTS STATEMENT
The authors declare that they have no competing financial interests.

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