



**USAID communication to the field (October 7, 2011):  
USAID updated response to publication of findings on hormonal contraception and HIV  
acquisition in uninfected women and HIV transmission from infected women to men**

Sent to USAID Missions by:  
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On August 5, 2011, USAID shared a communication with the field regarding a presentation by Renee Heffron. This presentation suggested that hormonal contraception (HC) may double risk of HIV acquisition in women, and also double transmission from an HIV-infected woman to a male partner. On October 4<sup>th</sup>, this study was published in *Lancet Infectious Diseases*. While the information in the publication is similar to that presented earlier this year in Rome, we wish to provide a brief update on the response from USAID.

USAID takes these findings seriously, and is working closely with the World Health Organization to convene an expert technical consultation in January 2012. At this meeting, experts will carefully evaluate this study, along with the entire body of evidence on this subject, and will issue a statement based on the conclusions of the consultation.

**USAID, like the [World Health Organization](#), continues to believe that a change in contraceptive policy or programming is not warranted at this time, for the following reasons:**

- 1. Careful evaluation of strengths and weaknesses of this study is required.**  
This analysis has several strengths, including assessing HIV discordant couples (who have known exposure to HIV) and use of sophisticated statistical techniques. However, it also has several weaknesses. Since the study was not originally designed to examine whether HC impacts the risk of HIV, the findings may not accurately reflect biological effects of HC. As discussed in our previous statement, HC users and non-users differ in important ways, and statistical adjustment may not be able to adequately account for such differences, particularly when sensitive behaviors like condom use are self-reported and of unknown accuracy. In this study, couples using condoms for contraception (who therefore have lower risk of HIV) were included in the comparison population; studies addressing this issue using other methodological approaches have not found increased risk of HIV associated with HC.
- 2. Inconsistencies in this body of literature must be examined.**  
Previous studies have examined these issues, with inconsistent results. To date, systematic reviews have concluded that the weight of evidence does not indicate increased risk of HIV acquisition or transmission in the general population associated with use of HC. Variation in study findings must be considered in conjunction with variation in the design and methods used in other studies, in order to elucidate potential reasons underlying these differences.

As described in our previous communication, any potential risks of HC, if verified, must be considered in light of other competing health risks. Contraception directly benefits women and their families, and USAID continues to support a wide range of contraceptive methods in countries where it has family planning programs. In addition, we continue to stress the need for dual protection, which can be achieved by using condoms along with a highly effective method of contraception. For more information, please refer to our communication dated August 5, 2011, or contact Chelsea Polis ([cpolis@usaid.gov](mailto:cpolis@usaid.gov)) or David Stanton ([dstanton@usaid.gov](mailto:dstanton@usaid.gov)).

**USAID communication to the field (August 5, 2011): USAID response to new findings on hormonal contraception and HIV acquisition in uninfected women and HIV transmission from infected women to male partners**

Sent to USAID Missions by Scott Radloff, Director, Office of Population and Reproductive Health

Results from an unpublished new analysis<sup>1</sup> presented at the 2011 International AIDS Society conference in Rome suggested that using certain methods of hormonal contraception (HC) (particularly injectable contraception) may double the risk of HIV acquisition in a previously uninfected woman, and may also double the risk that an HIV-infected woman will transmit HIV to a previously uninfected male sexual partner. In addition, HC appeared to be associated with higher levels of genital HIV viral load, which the investigators suggest may explain why HC appears to have increased HIV transmission from women to men.

Previous studies have examined these issues. Some found similar associations (including one of the largest studies on this topic); most have not found HC to be associated with HIV acquisition or transmission in a general population. The new findings raise concerns, particularly since the analysis involved a large sample size of serodiscordant couples, used sophisticated statistical techniques, and may provide biological support by measuring viral shedding.

Still, a cautious interpretation of the findings is justified as the scientific community gathers additional information. Like previous analyses, these findings were derived from observational data, which may be biased by self-selection. HC users may differ in important ways from non-users (for example, HC users may have higher coital frequency and lower use of condoms). Even with statistical adjustment, observational data may not be able to account perfectly for such differences. A randomized controlled study could provide more definitive evidence on this important issue.

If HC increases risks of HIV acquisition or transmission, such risks must be evaluated in light of (1) risks of unintended pregnancy, maternal morbidity, and maternal mortality, which may increase in the absence of highly effective contraceptive methods; (2) risk of acquiring HIV, which varies substantially by geography (and which may be elevated during pregnancy); (3) risk of transmitting HIV to sexual partners (which may be elevated during pregnancy); (4) risk of mother-to-child HIV transmission; (5) social and economic benefits of contraception; and (6) available and acceptable contraceptive alternatives.

USAID does not believe that a change in contraceptive policy or programming is appropriate or necessary at this time. We do not yet have full information on this analysis or its implications. We have encouraged WHO to convene a high level meeting of experts to clarify research and programmatic needs moving forward. After more thorough review, as needed, we will update any guidance change to patients, providers, and programs to reflect evolving understandings. USAID will continue striving to ensure that women and couples have access to a wide variety of contraceptive methods, are counseled about the known risks and benefits of those methods (including that all methods other than male and female condoms provide no protection from sexually transmitted infections (STIs), including HIV), and are able to select the method that best fits their individual needs. Dual protection against unintended pregnancy and STIs, including HIV, can be achieved by using condoms along with a highly effective method of contraception. Program managers should continue to promote condoms to prevent transmission of STIs, including HIV.

For further information, please contact Chelsea Polis at [cpolis@usaid.gov](mailto:cpolis@usaid.gov) or David Stanton at [dstanton@usaid.gov](mailto:dstanton@usaid.gov).

<sup>1</sup> Heffron R et al. Hormonal contraceptive use and risk of HIV-1 transmission: a prospective cohort analysis. Sixth International AIDS Conference, Rome, abstract WEAX020620, 2011.