

### THE CURRENT CONTEXT

In February the World Health Organization issued a “technical statement”<sup>1</sup> on hormonal contraceptives and HIV. The statement was issued after a two-day consultation to review existing data on hormonal contraceptives (HC) and HIV acquisition in HIV-negative women; HC and HIV transmission and disease progression in HIV-positive women. The technical statement stated the conclusion that “the World Health Organization should continue to recommend that there are no restrictions (MEC Category 1) on the use of any hormonal contraceptive method for women living with HIV or at high risk of HIV.”

However, the statement recommended that a new clarification (under Category 1) be added to the medical eligibility criteria for women using progestogen-only injectable contraception at high risk of HIV. It states:

*Some studies suggest that women using progestogen-only injectable contraception may be at increased risk of HIV acquisition, other studies do not show this association.*

*A WHO expert group reviewed all the available evidence and agreed that the data were not sufficiently conclusive to change current guidance. However, because of the inconclusive nature of the body of evidence on possible increased risk of HIV acquisition, women using progestogen-only injectable contraception should be strongly advised to also always use condoms, male or female, and other HIV preventive measures. Expansion of contraceptive method mix and further research on the relationship between hormonal contraception and HIV infection is essential. These recommendations will be continually reviewed in light of new evidence.*

There is a simple and essential message in this recommendation: **all women choosing hormonal contraceptives should be counseled about and offered male and female condoms, with an explanation that hormonal contraceptives do not protect against HIV.** The technical statement does not specify counseling messages such as explaining to women that there is a possibility that certain types of HC, particularly DMPA, might increase risk of HIV infection. **While the message to use condoms along with family planning may be simple to convey, it can be very difficult to put into practice.** Many women cannot negotiate condom use with their sexual partners. It is essential that women, HIV and family planning providers and programmers provide women with all of the relevant information, as complex and inconclusive as it is, so that women can make informed choices about their family planning options. **All women and men have the right to full information about the risks and benefits, “knowns” and “unknowns” of the strategies or commodities they choose to protect their health and lives.**

### Key Conclusions from the WHO Technical Note<sup>1</sup>

- Lack of research makes it impossible at this point to draw definitive conclusions about the HIV-related safety or risk of hormonal contraceptives;
- Current data do *not* definitively confirm or rule out the possibility of an association between injectable hormonal contraceptives and heightened HIV risk;
- The UN must *enhance* its messages about the need for couples to use condoms along with hormonal contraceptives in order to protect against HIV; and,
- Further research is urgently needed.

*The technical statement does not state that injectable contraceptives have been proven safe with respect to impact on HIV transmission or acquisition. An accompanying WHO “Note to the Media” suggested this conclusion. This document was subsequently corrected.*

### WHO COMMITMENTS TO DATE<sup>2</sup>

- Review three counseling and “decision-making” tools (for family planning clients and their providers; for community health workers; and, for provider use in HIV prevention settings) for potential revisions of information on condom use and delivery of DMPA and oral contraceptives for women at risk or living with HIV in the coming weeks.
- Task WHO regional focal points in sub-Saharan Africa, as well as program managers in some selected countries to help country offices and relevant ministries adopt these recommendations and strengthen services for HIV prevention and family planning.

### UNAIDS COMMITMENTS TO DATE<sup>2</sup>

- Start to do special education on the issue with UNAIDS staff.
- Reach out to local partners to figure out what the forums will be for making these issues understood to women.
- Continue global advocacy on women's reproductive health and rights, and for a better contraceptive method mix.

## WHAT'S NEXT

- Both WHO and UNAIDS have made commitments (see page 1) that can only be implemented in the context of an expanded set of messages for providers, policy makers and civil society. These groups have convened a stakeholder meeting on "Communicating and Operationalizing Recommendations for Family Planning and HIV Prevention" for May 2012. Civil society will both participate in, critique and monitor this and future engagement to ensure necessary actions are taken.
- Civil society coalitions are working at international and community levels to understand women's concerns and perspectives—and to document actions taken or not taken at the country level. These concerns will be disseminated via civil society networks as part of ongoing advocacy campaigns.
- Reproductive health service providers need to review their own programs both internally and in dialogue with HIV prevention advocates and practitioners to map next steps and needs for acting on the key content in the technical note.
- Countries need to review recommendations—and take particular action in increasing "method mix" (the range of family planning options available) as this is a consensus point which can be acted upon without delay.

## MAKING SENSE OF THE DATA

Some of the most recent data come from two prospective studies of HIV incidence among hormonal contraceptive users and their partners: the Partners in Prevention HSV/HIV Transmission Study, which reported flat results for HIV prevention in 2010, and a separate observational study of couples enrolled at Partners' sites. Approximately 3,800 HIV-1 serodiscordant couples (one partner is HIV-negative, one is HIV-positive) in seven countries in east and southern Africa were included in these trials. Analysis of these data showed that women participants using hormonal contraception, primarily injectable hormonal contraception, had a two-fold increase in risk of acquiring HIV. Women who were HIV-infected at the beginning of the study and using injectable contraception were also two times as likely to transmit the infection to their uninfected male partners and had higher genital HIV RNA concentrations.<sup>3</sup>

Other studies have found similar associations, or have found no association at all. Additional studies have been presented since the serodiscordant couples' data were published. Some suggest risk, and others do not.

The available information is primarily observational data. This means it was derived from trials or studies designed primarily to answer other questions. This type of information is hard to analyze since there are many variables that could have influenced or biased the outcome. There has not been a randomized, controlled trial (RCT) of HIV acquisition in women using hormonal contraceptives or using other methods.

An RCT could provide a definitive answer—but there is a range of technical and ethical concerns about whether such a trial could be conducted.

The commonality among studies was a consistent recommendation that further research be conducted to verify their findings. This is why the WHO review of the available studies concluded that the data are inconclusive. **There is the possibility that HC, particularly DEPO, increases risk of HIV infection, it can neither be verified nor completely dismissed.**

The message is complex, but it can be conveyed to women as they make their family planning choices.

Some stakeholders have raised concerns that raising awareness of the possible risk of HIV associated with injectable contraceptives could cause women to abandon the method—which may be one of just a few methods available to women living in many parts of the world, including sub-Saharan Africa. Given the risks to women associated with unwanted pregnancy, and the persistently and unacceptably high rates of maternal mortality in many parts of the world, these are important concerns.

The clearest message to emerge from conversations among civil society advocates is: give women the option to make sense of the data themselves. *Do not* withhold or simplify information because of the possibility that women will abandon their choices. *Do* use these data as an additional impetus for expanding method mix in family planning programs and for further integration of family planning and HIV prevention programs that provide comprehensive services and expanded, honest messages.

## CITATIONS

1. WHO, Department of Reproductive Health and Research. *Hormonal contraception and HIV: Technical Statement*, 16 February 2012. [http://whalibdoc.who.int/hq/2012/WHO\\_RHR\\_12.08\\_eng.pdf](http://whalibdoc.who.int/hq/2012/WHO_RHR_12.08_eng.pdf).

2. AVAC. *Global Teleconference on Hormonal Contraceptives and HIV*, 20 October 2011. <http://www.avac.org/ht/display/EventDetails/i/39350/TPL/MatDetails/pid/351>.

3. Heffron R, Donnel DI, Rees H, Celum C, Mugo N, Were E, de Bruyn G, Nakku-Joloba E, Ngure K, Kiarie J, Coombs RW, Baeten JM, for the Partners in Prevention HSV/HIV Transmission Study Team. "Use of hormonal contraceptives and risk of HIV-1 transmission: a prospective cohort study. *The Lancet Infectious Diseases*. 2012; 12: 19-26.

## ABOUT AVAC

Founded in 1995, AVAC is a non-profit organization that uses education, policy analysis, advocacy and a network of global collaborations to accelerate the ethical development and global delivery of AIDS vaccines, male circumcision, microbicides, PrEP and other emerging HIV prevention options as part of a comprehensive response to the pandemic. For more information and resources visit [www.avac.org](http://www.avac.org).