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Elevated Risk: Injectable Contraceptives and HIV — a Reproductive Justice Perspective from South Africa

Marion Stevens

Editor's note: *DifferenTakes* has featured the hormonal contraceptive, Depo-Provera (DMPA) multiple times as new issues and controversies surrounding its use have arisen. Lately these include the release of more observational studies pointing to the possibility of an increased biological risk of acquiring HIV while using DMPA, new guidance from the World Health Organization (WHO) acknowledging that risk, the launch of an ethically questionable, large-scale clinical trial (known as the ECHO study) to test the association between DMPA and HIV, and the promotion of DMPA in a new self-administered form called the Sayana Press. Marion Stevens interprets these changes through her experience as a health and reproductive justice advocate in Cape Town. She argues that governments and international agencies provide inconsistent and contradictory policy and guidance on the provision of DMPA that might espouse reproductive rights but fail to uphold them in practice.

— Rajani Bhatia, guest editor

The World Health Organization (WHO) regularly assesses the risk/benefit profile of contraceptives to provide guidance to policymakers and providers of family planning for their safest use. The guidance categorizes contraceptives into 4 categories of "Medical Eligibility Criteria" (MEC). An MEC category 1 represents a condition for which there are no restrictions on the use of a particular contraceptive, because benefits far outweigh risks, while a category 4 indicates unacceptable risks. In early 2017 the WHO issued a new guidance concerning women who are at high risk of contracting HIV, which raised the MEC category for injectable contraceptives such as Depo-Provera from 1 to 2.

The new guidance is that women at high risk of acquiring HIV can use progestogen-only injectables but should be advised about concerns that these methods may increase risk of HIV acquisition, about the uncertainty over whether there is a causal relationship, and about how to minimize their risk of acquiring HIV (MEC category 2).[1]

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The guidance, which admits knowing since 1991 of a possible increased risk of contracting HIV while using DMPA, complicates the context for health programming in South Africa, where government and international agencies continue to provide complex and contradictory directives. South Africa adopted injectable contraceptives in the 1970s during the height of an internationally led movement for population control and national apartheid. Informed by business, technology and environmental stakeholders, population control policies emerged and became an enormous force with far-reaching resources deployed to curtail conceptions. Of concern has been the racial bias, with the orientation being to limit the numbers of black babies being born.

WHAT IS DEPO-PROVERA?

Depo-Provera (DMPA) is the trade name for depot medroxyprogesterone acetate, a progestin-only injectable contraceptive method that suppresses ovulation for three-month intervals. It is produced exclusively by the US pharmaceutical Pfizer, Inc. There are two formulations of the drug: one is an intramuscular shot (the most common form) and the other a subcutaneous injection with a lower dosage. The DMPA dosage of the intramuscular shot is associated with a number of adverse health effects including: menstrual irregularities (including bleeding or spotting), abdominal pain, weight gain, dizziness, headache, nervousness and decreased sex drive.[2] In addition, Depo-Provera is associated with bone mineral density loss, an elevated risk of breast cancer,[3] and an increased biological risk of HIV acquisition.[4]

South Africa was unique in adopting Depo-Provera, as it was viewed as controversial in the US. In 2004 the US Food and Drug Administration (FDA) required that its strongest form of warning, known as the "black box," be added to Depo-Provera to caution users of its impact on loss of bone density with prolonged use.[5] In 2015 health scholars and activists submitted a citizen petition requesting that the FDA provide a new warning that the shot can also increase a user's chance of acquiring HIV. In India, women's groups resisted for 30 years the adoption of injectable contraceptives into the government-supported family planning program. They raised concerns about marketing, adverse effects and poor consent practices in research clinical trials.[6] In comparison, there has been limited opposition to injectable contraceptives in South Africa.

At a workshop on Reproductive Health Politics in May 2017, Nomtika Mjwana, the advocacy and communications manager for the Sexual and Reproductive Justice Coalition, spoke about her experiences as a young black woman invited to participate in research community advisory bodies for the "Pre-exposure Prophylaxis" (PrEP) trials. These are large scale clinical trials conducted in various sites across the world that are designed to test the possible prevention benefit of a drug combination normally used to control HIV after exposure. Mjwana related the difficulty of this decision given issues of consent, whose bodies are being experimented on and which women will actually receive the benefit of PrEP should one be found. This sentiment echoes how reproductive justice advocates feel about the situation today in South Africa regarding progestogen-only injectables, where both other contraceptive options and the enabling conditions necessary for choosing among them are lacking.

The South Africa Department of Health reviewed their Contraception and Fertility Policy in 2013 expressly to address concern regarding DMPA and HIV risk.[7] Steps were taken to provide alternatives and improve messaging for women. Yet during the 2015 mid-term review of the Maternal Child and Women's Health (MCWH) Strategy, the government set targets for contraception use (while also noting the need to improve communication materials).[8] Target setting to increase contraceptive use contradicts the Contraception

and Fertility Planning Policy which is based on a human rights approach that acknowledges a need for improved method mix, informed consent and for addressing the needs of marginalized groups of sex workers and migrants. In practice the government seems to be shifting from its focus on Depo-Provera provision to the hormonal contraceptive implant, Implanon.[9] The matchstick-size plastic rod that releases contraceptive hormones is injected underneath the skin and lasts for three years. It is contraindicated for those who are diabetic, epileptic or taking particular anti-retrovirals and tuberculosis drugs.

The question remains as to whether these reassurances of additional counseling and information really protect women who in the first place are being asked to willingly submit to randomly selected long-acting contraception not of their own choosing.

With both high HIV-infection rates for young girls and concern for adolescent pregnancy, replacing one potentially risky long-term contraceptive with another is puzzling. Indeed, while announcing these policies in the health department's budget vote in 2014, the minister of health emphasized only the long-lasting implant method.[10] In so doing, he disregarded women's right to freely choose from a range of contraceptive options. In June 2017 at a Sexual and Reproductive Health and Rights (SRHR) technical meeting that I attended, the National Department of Health (NDOH) noted a steep downward trend in the numbers of Implanon implants inserted, which dropped from 800,000 to 100,000 in the last year, and that IUD insertions were on the rise.[11] There have been numerous media reports of women asking for removal of implants due to side effects. Injectable contraceptives, however, remain the most commonly distributed contraceptive (44%), besides condoms.

Despite some recent action taken by the WHO and South Africa that recognizes an elevated risk profile of DMPA, the question continues to be posed as to whether an association between DMPA use and HIV acquisition definitively exists. Citing conflicting data, a consortium of groups formed to launch the ECHO Study (Evidence for Contraceptive Options and HIV Outcomes) in December 2015. The study is a large-scale, multi-sited, randomized clinical trial designed to assess and compare the risk of HIV acquisition by women using three contraceptive methods: Depo-Provera, the levonorgestrel implant Jadelle and the nonhormonal copper IUD. The study will also evaluate the performance of these methods in relation to pregnancy rates, side effects and women's patterns of use. The study has already enrolled over half of the intended 7,800 voluntary participants at 12 research sites in Kenya, South Africa, Swaziland and Zambia, and is expected to yield results in early 2019.[12]

There has been considerable discussion regarding the ethics of conducting such trials.[13] Some of the concern regards the ethics of randomizing a woman to possible risk even though they are counseled. Anticipating high dropout rates, some epidemiologists argue that the study's methodology is flawed, suggesting it would be better to accept the levels of uncertainty of injectable contraceptives and work towards better health systems and increase contraception method mix for women.[14]

In May 2017, the ECHO researchers responded to the new guidance from the WHO on Depo-Provera by deciding not to halt their trial. They state, "As the study goes forward, the ECHO research team will ensure that current participants receive an information sheet explaining the updated WHO guidance. All recruitment and informational material, as well as counseling messages for current participants, will be similarly updated."[15] The question remains as to whether these reassurances of additional counseling and information really protect women who in the first place are being asked to willingly submit to randomly selected long-acting contraception not of their own choosing.

Promotion of DMPA continues in other forms as well, despite warnings. Repackaged under the name Sayana Press, which can be administered by users themselves or community health workers, the contraceptive is being introduced in research trials into a range of African countries.[16] Although touted for its accessibility, health advocates worry that the experimental self-injecting device currently tested on African women is really part of an ongoing population control industrial complex. They raise concerns that trial subjects may not be counseled on the revised risk/benefit profile of DMPA and that the design may limit interaction with health workers who can provide them with needed comprehensive SRHR counseling that can help prevent the spread of HIV.

With a lingering legacy of population control and a dominant contraceptive option that is embedded in closed sexual negotiation cultures in South Africa, what will good information and counseling practice enable women to choose?

There has been critique of the complexity of sexual and reproductive rights, where women are often not in a position to make decisions alone. The lack of choice comes from living in a patriarchal society with endemic violence where preconditions and systems do not enable real choice, despite the information that is given to women. Similarly there are different views of the reality that for some women being able to use a long-term contraceptive enables them to hide it and be discreet. This is sometimes viewed as providing women with agency. But in a state of 'unfreedom' is this really empowering? Three decades down the line with DMPA being the most common contraceptive used in South Africa, we have a context of sexual non-negotiation where women are expected to be on contraception. This is despite messaging for dual contraception given our HIV epidemic. Research that relies on self-reported condom use following last sexual encounter is being critiqued because people say a range of truths. In the highly published court proceedings concerning the sexual encounter between Fezeka Khuzwayo and President Jacob Zuma, for example, the president testified that after entering her he asked if she was on protection. She did not answer and he assumed she was taking protection.[17] Since the responsibility for protection is not shared by men, the assertion of women's agency and empowerment by not having to negotiate contraception or safer sex is not accurate.

What is also curious is how the question of burden is already decided for women. Many researchers, policy analysts and writers take for granted that pregnancy is a greater burden than the risk of HIV. This situation is analogous to the access to prevention of mother to child transmission (PMTCT) legal case in South Africa. As I have noted elsewhere, the legal arguments of Treatment Action Campaign (TAC) and the AIDS Law Project (ALP) presented women only as mothers wanting to protect their babies. Any other notion – of choice or reproductive rights or reproductive justice – was viewed as not viable for winning the case. The case was based on a limited notion that only looked to women's choice for motherhood. The primary claims advanced by the legal team (and the parties to the case) merged the interests of women with those of safeguarding children's rights to health and of health professionals' rights to treat their patients. These claims constructed women foremostly as bearers of children, and as patients, rather than as active agents in their own right. It could be argued that a significant part of the HIV and AIDS response in South Africa has been crafted within a maternal health framework.[18]

A reproductive justice lens requires us to ask deeper and interlinking questions. With a lingering legacy of population control and a dominant contraceptive option that is embedded in closed sexual negotiation cultures in South Africa, what will good information and counseling practice enable women to choose?

What is the emphasis of the counseling in relation to contraception? Is the burden preventing HIV acquisition or pregnancy? When the ECHO results arrive, will they provide answers? What does it mean to be a poor black woman in South Africa when health policy is not followed and what is implemented is up to the whim of service providers? That the South African minister of health can launch the Contraception and Fertility Planning Policy without referring to the actual policy but only to the long-acting, hormonal contraceptive implant is most illustrative. Contradictions abound.

In some ways it feels as if there is a fog and there is some waking up to do. It is astounding, given the information at hand, that there is not more questioning or concern regarding the use of DMPA in South Africa. But we are not alone it may seem; the situation is similar to the utterances in *The Handmaid's Tale* TV series, "we did not look up from our phones until it was too late." Information regarding DMPA is not in women's hands nor in their minds in order for informed choices to really be made, and this is a reproductive justice concern. The question remains as to what are the systemic conditions beyond counseling and the provision of information that will enable women to really be able to make decisions regarding contraception options.

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Notes

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