Human immunodeficiency virus (HIV) and infertility treatment: a committee opinion

Ethics Committee of the American Society for Reproductive Medicine

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Human immunodeficiency virus (HIV) is a serious but manageable chronic disease that affects persons of reproductive age, many of whom express a desire for biologic parenthood. This document is a revision of the original document of the same name, last published in 2010 (Fertil Steril 2010;94:11–5). (Fertil Steril® 2015;■:■–■. ©2015 by American Society for Reproductive Medicine.)

Key Words: Serodiscordant, reproduction, infection, transmission, fetus, ethics

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KEY POINTS

- Human immunodeficiency virus (HIV) is a serious but manageable chronic disease that affects persons of reproductive age, many of whom express a desire for biologic parenthood.
- Current treatments for HIV can limit the risk of viral transmission to partner and offspring. Recent studies show that in HIV-infected women, the use of antiretroviral therapy, and avoidance of breastfeeding reduce the chance of newborn infection to approximately 2%.
- In couples in which the man is infected with HIV, the use of sperm preparation techniques coupled with either inseminations or in vitro fertilization (IVF) with intracytoplasmic sperm injection (ICSI) has proven to be highly effective in avoiding seroconversion of uninfected women and offspring.
- Recent innovative approaches such as pre-exposure prophylaxis (PrEP) with antiretroviral drugs may reduce further the susceptibility of the uninfected female partner.
- There are no reports of HIV infection of laboratory personnel resulting from processing the gametes/embryos for serodiscordant couples using current laboratory protocols. Cross-contamination of the gametes or embryos of other couples in the same laboratory has also not been reported. The risk is theoretical only, particularly when standard universal precautions are used.
- For the above reasons, there is no ethical reason to withhold fertility services at clinics with the necessary resources to provide care to HIV-infected individuals and couples who are willing to use recommended risk-reducing therapies. Clinics without sufficient resources to offer care should assist in referral to providers equipped to manage such patients.
- In third-party reproduction, disclosure of an intended parent's HIV status to gamete donors or gestational carriers should be commensurate with principles of informed consent.

Human immunodeficiency virus (HIV) can infect people of all ages. The largest group affected (86%) are persons of reproductive age (15–44 years old), about one third of whom report the desire to have children. This fact underscores the concern of viral transmission to sexual partners and offspring. Because women make up approximately 20% of cases, and because HIV has become more prevalent among heterosexual couples than in the past, infected persons are increasingly asking their health-care providers for advice about and assistance with reproduction that minimizes the risk of viral transmission to an uninfected partner and offspring.

In 1994, the Ethics Committee of the American Society for Reproductive Medicine (ASRM) set forth ethical guidelines concerning patients with HIV who may request or need reproductive assistance (1). The Committee

Received April 2, 2015; accepted April 2, 2015.

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Fertility and Sterility® Vol. ■, No. ■, ■ 2015 0015-0282/$36.00

http://dx.doi.org/10.1016/j.fertnstert.2015.04.004

expressed concern about potential transmission of the virus to an uninfected partner or to the couple's offspring. It also addressed potential problems for the child related to the shortened life span of one or both infected parents. On the basis of these concerns, the Committee recommended that testing for the presence of the virus be offered to all couples requesting reproductive assistance. The Committee also recommended that institutions establish their own written policies on infertility treatment for people infected with HIV. It suggested that physicians counsel couples about the consequences of using potentially infected sperm and discuss the options of donor sperm, adoption, or not having children.

When these guidelines were published in 1994, HIV infection was considered to be a serious risk to establishment of a healthy pregnancy. Since then, understanding and treatment of HIV-infected persons and laboratory techniques for the preparation of virus-free sperm for reproductive assistance have improved substantially (2–5). With more effective treatment regimens, the death rate has decreased dramatically among persons who become infected, converting HIV from a deadly disease to a manageable chronic illness that much less commonly progresses to acquired immune deficiency syndrome (AIDS) and death.

Several methods of limiting the risk for HIV transmission to partner and offspring have also been developed. For example, zidovudine has reduced the vertical transmission of infection from 16%–24% to 5%–8% when given to HIV-infected pregnant women during the second and third trimesters and to their newborns for 6 weeks (5–8). More recent data demonstrate that combination antiretroviral treatment given to HIV-infected women antenatally further reduces transmission to offspring to less than 2% (9).

A meta-analysis of studies conducted in North America and Europe concluded that elective (planned) cesarean section added to antiretroviral treatment would decrease the vertical transmission rate to 2% compared with 7.6% in children of treated women who deliver vaginally. Subsequent studies have found that for those on potent antiretroviral therapy cesarean section is not needed to lower the risk of transmission if viral levels in the pregnant woman are undetectable (10–12).

Lack of apparent transmission of HIV to partner or child with sperm washing and intrauterine insemination (IUI), or with IVF with ICSI has been reported for discordant (male-positive) couples. Highly active antiretroviral therapy can reduce the viral burden in a person's serum and semen. Some centers have also adopted testing of sperm by using a polymerase chain reaction (PCR) assay to determine whether the virus is present in the washed sperm preparation, but the utility and effectiveness of this added step has been questioned by other centers that have eliminated PCR from their protocols (4, 5, 13–15). Recent innovative approaches such as pre-exposure prophylaxis (PrEP) with antiretroviral drugs may reduce further the susceptibility of the uninfected female partner (5, 16).

In light of these changes in the treatment and reproductive consequences for HIV-infected men and women who are HIV-infected, the Ethics Committee reexamined and periodically continues to review its earlier guidelines. This report addresses ethical issues concerning: 1) infertility treatment when one partner is infected with HIV; 2) infertility treatment when both partners are infected; 3) knowingly conceiving a child who may be born with HIV; 4) HIV testing for couples seeking fertility assistance; 5) potential risks to the health-care providers of HIV-infected patients; 6) improving access to infertility care for HIV-infected individuals; and 7) providing third party assisted reproductive services to individuals and couples in which one or both intended parents are infected with HIV.

INFERTILITY TREATMENT WHEN ONE PARTNER IS INFECTED WITH HIV

For some infected males, HIV and possibly antiretroviral therapy may be associated with borderline semen abnormalities including low sperm count, low motility, and low volume (5, 17–19). Thus, the presence of HIV may affect the reproductive potential of a seropositive person. For others, the virus will have no impact on reproductive functioning unless the person is ill due to an opportunistic infection. The HIV transmission rate to an uninfected partner is estimated to be approximately 1 in 500–1,000 episodes of unprotected intercourse (20). The risk of viral transmission increases dramatically if the HIV-infected partner's viral load is high or if the HIV-uninfected partner has a concomitant genital infection, inflammation, or abrasions. As outlined below there are a variety of ways in which conception can occur while either completely eliminating or minimizing the risk of HIV transmission between partners.

If a woman is infected with HIV and her male partner is uninfected, transmission of infection to the male partner can be avoided by using homologous insemination with the partner's sperm. If this option is not available to the couple, or for other reasons not desired, there are considerable data showing that the risk of transmission can be minimized by using timed intercourse, assuring that the woman's viral load is suppressed to undetectable levels on antiretroviral therapy and/or that the uninfected male is taking antiretroviral therapy as PrEP (5). While clinicians would need to emphasize that this option is not as safe as homologous insemination, it does represent an alternative option for select couples.

Regardless of the method used for insemination, the resulting pregnancy may still pose some risk to the HIV-infected woman and her child because opportunistic infections occurring during pregnancy can be devastating to the woman and fetus. An HIV-infected woman may require certain medications in the early stages of pregnancy that could have adverse effects on a developing fetus. Amniocentesis and chorionic villus sampling, invasive procedures in prenatal diagnosis, may also increase risk of transmission to the fetus. A recent report issued by the US Department of Health & Human Services found no cases of perinatal transmission following amniocentesis in women on effective antiretroviral therapy, although a small risk of transmission cannot be ruled out (5). In addition there is variable risk of transmission to the newborn in utero, during delivery and with breastfeeding. If an HIV-infected pregnant woman is not actively treated with antiretroviral drugs, the risk of

HIV transmission to the infant is >20% regardless of the viral load (6). As noted, administration of zidovudine to pregnant women and to newborns during the first 6 weeks of life can substantially reduce the risk of HIV transmission to 5%–8%. Administration of combination antiretroviral therapy and avoidance of breastfeeding may further reduce the chance of infection to approximately 2% (5–9).

Attempts at conception between HIV-infected men and their HIV-uninfected female partners that rely on using condoms except at the time of ovulation appear to reduce, but not eliminate, the risk of seroconversion compared with complete avoidance of condom use. In one study, the seroconversion rate was 4.3% of 92 HIV-uninfected women with HIV-infected partners trying to establish pregnancies through timed intercourse. Two of the women in that study seroconverted during pregnancy, and another 2 converted in the postpartum period. Those 4 women reported inconsistent condom use by their partners (20). Other studies show the risk of transmission through unprotected intercourse can be substantially reduced by the use of antiretroviral therapy in the infected partner (21). Even though some HIV-discordant couples have established pregnancies through timed unprotected intercourse without infecting the uninfected partner or child, this practice is not recommended.

More recent research is investigating the efficacy of PrEP in which the uninfected female partner is treated with antiretroviral therapy during the time conception is attempted. In one study of 46 serodiscordant couples in which the female was treated with oral tenofovir, none of the women became infected with HIV and pregnancy rates reached 75% after 12 attempts (22). This and other studies indicate that adherence to clinical protocols is essential for preventing transmission. The US Food and Drug Administration (FDA) has approved antiretroviral therapy for this use, although further research on the safety and efficacy of PrEP is ongoing (23). Clinicians who elect to offer this therapy are encouraged to educate their patients about its potential risks and benefits as well as all available alternatives for safer conception.

Several reports have described specific methods for sperm preparation and testing that can substantially reduce the chance of HIV transmission to the female partner and child. In 1998, a method was described using a density gradient and swim-up technique to obtain sperm, which were then tested by PCR assays for the presence of HIV (24). If the final sperm sample tested negative on these assays, it was used for insemination. With this technique, less than 1% of the samples (6 out of 623) tested positive for the virus and were not used, though it is unknown whether this small group contained any false positives. This study further reported almost 1,600 inseminations of 513 HIV-uninfected women, from which 228 pregnancies resulted. A follow-up of 97.5% of the women at 3 months and 92% at 1 year revealed that all children older than 3 months of age and all mothers tested were uninfected (24). World data reported in 2004 on the use of IUI for HIV-serodiscordant couples showed that of 1,097 patients in which 2,988 cycles were performed, there were no infections in either the HIV-uninfected female or any of the offspring (13). More recent multicenter retrospective studies show the same results: thousands of serodiscordant couples using sperm washing and IUI experience no viral transmission to the uninfected female partner (25).

Despite the reassuring data on the use of sperm washing and IUI, access to this technique in the US is extremely limited. One possible explanation is the persistence of a recommendation from the Centers for Disease Control and Prevention (CDC) "against insemination with semen from HIV-infected men" issued in 1990 based on a report of a single case of transmission to the uninfected female following suboptimal sperm-washing techniques (26). Given the advances in sperm washing as well as the routine use of the technique in other parts of the world, including Canada, Europe, and Australia, some US clinicians have called on the CDC to reverse its recommendation (27).

Recent data on the use of IVF with ICSI are promising in terms of avoiding transmission to uninfected women. In a 10-year retrospective review of a program offering assisted reproductive technology (ART) to HIV-discordant couples, 181 couples underwent treatment with IVF with ICSI in which sperm was prepared using a modified density-gradient centrifugation and swim-up method. As a result, there were 116 deliveries of 170 neonates (due to a multiple birth rate of 41%). There were no female seroconversions and no infections in any of the offspring (14).

These statistics are reassuring but more data are needed to demonstrate the complete efficacy of these techniques. Until then, couples must still be cautioned about the potential risk of HIV transmission to the uninfected partner and to their offspring. Couples seeking to avoid any risk of transmission of the virus when the male partner is HIV infected should be counseled about using donor sperm, considering adoption (which can be more difficult for HIV-infected prospective parents), or not having children.

When male-positive discordant couples want to have their own genetically related children, they should be informed of available risk-reduction techniques and encouraged to seek assistance at institutions that can provide the most effective methods of sperm preparation, as well as appropriate testing and treatment necessary to minimize the chance of HIV transmission to partner and offspring. To determine the true efficacy of the chosen method of treatment, these centers should use approved study protocols with informed consent and appropriate follow-up of patients, partners, and offspring.

INFERTILITY TREATMENT WHEN BOTH PARTNERS ARE INFECTED WITH HIV

As with any couple presenting for evaluation and treatment, both members of an HIV-infected couple may have normal fertility potential or one or both may have impaired fertility. If an HIV-infected couple asks for medical advice regarding pregnancy, they must be encouraged to adopt protocols that have been demonstrated to be safe and effective in Institutional Review Board (IRB)–approved research studies. Implementation of additional IRB-approved protocols for collection and publication of data on pregnancy and seroconversion outcomes is also encouraged. At least some couples in which both partners' viral loads were suppressed to

undetectable levels conceived children free of HIV (22). Aggressive drug therapy with protease inhibitors and other antiretroviral therapy can extend life and improve health in HIV-infected persons; however, it is unknown whether or not they will ultimately have a normal or near-normal life expectancy. The child may lose one or both parents to AIDS before he or she reaches adulthood, although recent success with combination antiretroviral therapy has significantly reduced death rates of infected persons.

While HIV-seroconcordant couples do not have the same concerns of transmission to an uninfected partner described for those serodiscordant, it is important to at least raise with the couple the possibility of HIV superinfection. While data are imperfect, there are increasing reports that one HIV-infected partner can transmit their unique strain of HIV to another infected partner (28). The risk of such events is expected to be very low in the setting where both partners have fully suppressed viral loads on effective antiretroviral therapy, which would be the best way to minimize this risk while optimizing outcomes for the couple and their offspring.

ETHICAL ISSUES RAISED BY KNOWINGLY RISKING THE BIRTH OF A CHILD WITH HIV

The risk of HIV transmission to offspring when one or both parents are seropositive can be greatly reduced but not completely eliminated. This risk raises ethical issues concerning the scope of freedom to reproduce, what is considered to be harm sufficient to justify restricting that freedom, and the responsibilities of health care professionals faced with a request to provide services to HIV-infected patients.

Does a couple's desire to have genetically related offspring justify the risk of transmitting a serious disease to their child? Although the risk can be significantly reduced, and recent data show no instances of vertical transmission using sperm-prepared IUI or IVF with ICSI, theoretically the risk cannot be completely eliminated. Assessing the ethics of assisting such patients to have children includes addressing the question of whether offspring born with HIV are harmed despite the preventive steps taken. In situations in which a child could be born with a serious disease, one can argue that individuals are not acting unethically in proceeding with reproduction if they have taken all reasonable precautions to prevent disease transmission and are prepared to love and support the child, regardless of the child's medical condition. Similarly, one can argue that health-care providers are not acting unethically if they have taken all reasonable precautions to limit the risk of transmitting HIV to offspring or to an uninfected partner. It would not, however, be ethically acceptable for a physician, clinic, or institution to proceed with reproductive assistance if they lacked the clinical and laboratory resources needed to effectively care for HIV-infected couples who wish to have a child. In such instances, the medical care provider should refer couples to a center that has these resources.

The ethical issues raised here are similar in some respects to those in which couples know that they are carriers of an autosomal recessive disease, such as Tay-Sachs disease, sickle cell anemia, or cystic fibrosis. Such couples may choose to take the risk of having an affected child rather than use IVF plus preimplantation genetic diagnosis, which enables prospective parents to deselect embryos found to express certain genetic anomalies, forgo biologic parenthood, adopt, use a gamete donor, or, if a prenatal test result is positive, terminate the pregnancy. The risk of transmitting an autosomal recessive genetic disease through natural conception cannot be reduced below 25%, whereas the risk of HIV transmission can be reduced to a substantially lower number—in some cases, to less than 2%—when appropriate therapeutic measures are taken. Health care workers who are willing to provide reproductive assistance to couples whose offspring are irreducibly at risk for a serious genetic disease should find it ethically acceptable to treat HIV-infected individuals or couples who are willing to take reasonable steps to minimize the risks of transmission.

TESTING INFERTILE COUPLES FOR HIV

The CDC estimates that approximately 200,000 persons in the United States have undiagnosed HIV (29). Because most of these persons are of reproductive age, the question arises of whether or not practitioners should require HIV testing for all couples seeking medical or surgical reproductive assistance. The American College of Obstetricians and Gynecologists recommends that obstetrician/gynecologists routinely screen their female patients aged 19–64 years for HIV regardless of individual risk factors (30). In order to address the concern of large numbers of Americans being infected with HIV and unaware of their status, in 2006 the CDC recommended that all individuals between the ages of 13 and 64 encountering the health care system, which would include those accessing fertility treatment, be told that HIV testing is the standard of care and will be performed unless the patients opts out (31). More recently, in 2013 the US Preventive Services Task Force recommended that clinicians screen for HIV infection in adolescents and adults aged 15–65 years (32).

In the case of gamete donors, testing for HIV and other sexually communicable diseases is ethically justified to protect the health of the gamete recipients. The FDA mandates that all anonymous and directed gamete donors be screened for high-risk factors and undergo testing for HIV and other viral infections (33). The CDC, the American Association of Tissue Banks, and the American Medical Association all strongly recommend HIV testing for every gamete donor. The ASRM Practice Committee recommends that all gamete donors and recipients be tested for HIV and other sexually transmitted diseases and that testing be offered also to the recipients' partners (34). Testing donors and recipients for potentially transmittable infectious conditions can be reassuring to all parties involved in ART and should be strongly encouraged.

While new guidelines recommend testing all individuals, repeated testing is recommended for those with ongoing risk for HIV infection, such as those who have a history of repeated sexually transmitted infections, a known HIV-infected sexually intimate partner, multiple sexual partners without barrier protection, bisexual or homosexual behavior, or intravenous drug use. Knowing the HIV status of the at-risk

individual or couple before establishment of a pregnancy could enable health-care providers to better assist their patients in making safer reproductive choices.

It is ethically appropriate for practitioners to encourage HIV testing for all couples who want to have children, not just those who request infertility treatment. However, it can be argued that to mandate people be tested solely because they request medical assistance in having a child would unreasonably infringe on their personal liberty and introduce an unjustifiable distinction between those who seek treatment for infertility and those who do not.

On the other hand, it may be appropriate to recommend HIV testing for all prospective parents as good medical practice because there are effective means to significantly lessen the chance for HIV transmission to an uninfected partner and to offspring. An analogy is the common practice of recommending that women seeking to become pregnant be tested for rubella immunity because infection during pregnancy could cause serious birth defects in the offspring. For couples in which the man has unexplained obstructive azoospermia or congenital absence of one or both vasa deferentia, it is becoming standard practice to recommend testing for mutations of the cystic fibrosis transmembrane conductor gene to evaluate the risk of having a child with cystic fibrosis. Similarly, routine HIV testing in prospective parents should be encouraged.

Couples should consider HIV testing as part of responsible parenting. National guidelines recommending testing for all adolescents and adults should allay prior concerns that testing is related to suspicions about past sexual or drug-related misbehavior. Clinicians have a responsibility to educate their patients about the possible means by which infections can be acquired and the advantages of knowing the test results before a pregnancy is established.

HIV AND THE HEALTH PROFESSIONAL

Health professionals care for patients with serious and potentially contagious diseases, knowing that they themselves could become infected. Knowledge of diseases, combined with careful hygienic practices, has allowed caregivers to reduce that risk. In the late 1990s, the CDC identified only 56 persons who had documented occupational transmission of HIV and another 138 people with possible occupational transmission (35). Most were nurses and laboratory technicians who accidentally inoculated themselves with a patient's blood by a needle stick or were splashed with bloody fluid and had significant mucocutaneous exposure. None of these cases of HIV transmission occurred in the context of current ART (13).

If standard universal precautions to prevent infectious disease transmission are taken, the risk of viral transmission to medical caregivers is very small and, in itself, is not a sufficient reason to deny reproductive services to HIV-infected individuals and couples. Clinicians have the same obligation to care for those infected with HIV as to care for patients with other chronic diseases. Concern about the public's perception of a clinic or provider that cares for HIV-infected patients is insufficient cause to deny services.

Clinicians faced with requests for reproductive assistance from persons who are infected with HIV should be aware of the 1998 United States Supreme Court decision in Bragdon v. Abbott (36). The Court ruled that a person with HIV is considered to be "disabled" and therefore protected under the federal Americans with Disabilities Act (36, 37). According to that decision, HIV-infected persons are entitled to medical services unless a physician can demonstrate "by objective scientific evidence" that treatment would pose "a significant risk" to the health or safety of others. In the context of ART care, "others" could include health care workers, patients receiving care at the same clinic, and embryos or gametes stored in proximity to those of HIV-infected patients.

To date, the lack of any occupational transmissions to ART health-care providers or bystander patients in a treating clinic suggests that the risk to these individuals from providing ART care to an HIV-infected patient is minimal and potentially nonexistent. Theoretically, the risk to gametes and embryos could arise through cross-contamination in the laboratory setting, although there is no documentation of contamination of stored human tissue. To avoid even the possibility of cross-contamination, the ASRM Practice Committee recommends that samples from a viral carrier be processed in a separate laboratory or designated space within the main laboratory, utilizing a dedicated storage tank (16). Unless health-care workers can show that they lack the skill and facilities to treat HIV-infected patients safely or that the patient refused reasonable testing and treatment, they may be legally, as well as ethically, obligated to provide requested reproductive assistance.

IMPROVING ACCESS TO CARE FOR HIV-INFECTED INDIVIDUALS

Despite improved outcomes in the use of sperm washing combined with IUI and IVF with ICSI, and the advent of prophylactic treatment of uninfected partners to virtually eliminate the risk of vertical and horizontal transmission of HIV, access to these reproductive technologies for seropositive individuals is extremely limited. Fewer than 3% of US ART practices registered with the Society for Assisted Reproductive Technology provides service to couples in whom one or both partners are infected with HIV (38). This lack of access is attributable to concerns about transmission to clinic personnel, fear of cross-contamination by gametes and embryos being cultured and stored on clinic premises, lack of expertise by clinicians in handling infectious patients and their gametes, and the high cost to clinics for providing separate laboratory space and equipment to minimize the risk of cross-contamination, as recommended by ASRM (16). Providers are strongly encouraged to reduce these barriers to care in order to make infertility treatment available to HIV-infected individuals.

As noted above, to date there have been no reported cases of occupational transmission to ART personnel or contamination of gametes or embryos in the clinic setting that would support denial of service to HIV-infected individuals or couples. The few centers that do provide care report

seeing happy and grateful families, many of whom travel a great distance for access to the safest method of reproduction currently available. To the extent it is economically and technically feasible, ART providers should widen access to HIV-infected patients who desire to procreate in a manner that minimizes the risk of viral transmission to their partners and offspring (39).

THIRD-PARTY ASSISTED REPRODUCTION FOR HIV-INFECTED INTENDED PARENTS

The presence of HIV infection can be a factor for individuals or couples who engage in third-party reproduction by enlisting assistance from a gamete donor or gestational carrier. In the case of an HIV-infected gamete donor or gestational carrier, state laws, federal regulations, and professional guidelines counsel against, and under certain circumstances prohibit, engagement of such individuals (34, 40). In the case where one or both intended parents are infected with HIV, questions arise as to the scope of disclosure that should be provided to third parties who are enlisted to assist in a reproductive plan. The principle of informed consent can be instructive in this circumstance.

Informed consent in the medical setting requires that physicians disclose any information that would be material to a person's decision to undergo or refuse treatment. Gamete donors and gestational surrogates do undergo medical treatment and thus are entitled to be fully informed of the risks and benefits of treatments prior to giving consent. In the case of an HIV-infected intended parent who plans to use his or her own gametes in third-party reproduction, for example an HIV-infected male who wishes to retain the services of an egg donor and gestational carrier, what duties of disclosure arise? In terms of medical risk, the egg donor and gestational carrier are not similarly situated because only the woman receiving the gametes is in a position of potential exposure to the virus. Therefore, disclosure of the intended parent's HIV status would be material to the gestational carrier's treatment decision as part of the risks/benefits calculus required by informed consent. Full disclosure of the sperm provider's HIV status must be provided in that case. A gestational carrier who is willing to provide service to an HIV-infected gamete provider/intended parent is entitled to be fully informed of the potential risks to her health, just as an HIV-infected male's female partner should be informed about potential risks associated with reproductive activity using the male partner's sperm. In some jurisdictions, recipients of gametes from HIV-infected donors must sign a specialized written waiver acknowledging the medical risks associated with such a transfer (41).

In the case of an HIV-infected intended parent who does not plan to use his or her gametes, the disclosure analysis is more complex. For example, in the case of a same-sex male couple in which one or both of the partners is infected with HIV but the couple does not plan to use either partner's sperm, does the physician (or any other professional actor such as an agency) have a duty to disclose the HIV status of the infected partner(s) to the egg donor or gestational carrier? Neither the egg donor nor the gestational carrier faces any medical risk by participating in this couple's assisted reproduction. The doctrine of informed consent has been interpreted to include nonmedical information that is considered material to a patient's decision making, but typically only when that information has a potential impact on the patient's treatment choices and medical outcome (42). An intended parent's serostatus would not be included in this category.

Arguments exist that a gamete donor or gestational carrier should be informed of an intended parent's HIV infection as part of the specialized informed consent process that accompanies third-party reproduction. Since the donor/carrier is providing a service that results in the birth of a child, factors in addition to the medical risks associated with treatment may be relevant to any prospective third-party participant. These factors might include the presence of a chronic medical condition, of which HIV is one of many, in an intended parent. Nonmedical factors might also be of interest to third-party participants. The ASRM Ethics Committee has addressed disclosure of nonmedical information to gamete donors in the context of informing egg donors about whether their donation resulted in a pregnancy or birth of a child (43). The Committee notes that revelation of such information may interfere with a recipient's privacy rights and thus encourages clinics to develop written policies regarding revelation of intended parent(s)' course of treatment to donors. We conclude that programs should clearly inform intended parents, gamete donors, and gestational carriers, before their participation, about what, if any, non risk-posing health information about the intended parents will be shared. To the extent a clinic policy requires or forbids disclosure of an intended parent's health status to a gamete donor or gestational carrier, HIV infection should be regarded the same as any chronic health condition.

CONCLUSION

Human immunodeficiency virus infection is classified as a chronic disease. It is treatable, but not yet curable. Significant advances in HIV treatment appear to have delayed the onset of AIDS and its consequences in many, though not all, infected persons. The potential for HIV-infected persons to live long and healthy lives, have uninfected children, and not transmit the virus to their partners has resulted in increasing numbers of individuals to seek out optimal means for creating biologic families. Health-care providers and HIV-infected persons together share responsibility for the safety of the uninfected partner and potential offspring. When an affected couple requests assistance to have their own genetically related child, they are best advised to seek care at institutions with the personnel and facilities that can provide the most effective evaluation, treatment, and follow-up. ART clinics with the necessary resources to provide care should offer services to HIV-infected individuals and couples who are willing to use recommended risk-reducing therapies. Clinics without sufficient resources to offer care should assist in referral to providers equipped to manage such patients. In third-party reproduction, disclosure of an intended parent's HIV status should be commensurate with principles of informed consent. When an intended parent's HIV status

poses no medical risk to gamete donors or gestational carriers, clinics should follow written policies that clearly define what information, if any, will be provided to each party prior to the commencement of any treatment. To the extent a clinic policy requires or forbids disclosure of an intended parent's health status to a gamete donor or gestational carrier, HIV infection should be regarded the same as any chronic health condition.

Acknowledgments: This report was developed by the Ethics Committee of the American Society for Reproductive Medicine as a service to its members and other practicing clinicians. While this document reflects the views of members of that Committee, it is not intended to be the only approved standard of practice or to dictate an exclusive course of treatment in all cases. This report was approved by the Ethics Committee of the American Society for Reproductive Medicine and the Board of Directors of the American Society for Reproductive Medicine.

This document was reviewed by ASRM members and their input was considered in the preparation of the final document. The following members of the ASRM Ethics Committee participated in the development of this document. All Committee members disclosed commercial and financial relationships with manufacturers or distributors of goods or services used to treat patients. Members of the Committee who were found to have conflicts of interest based on the relationships disclosed did not participate in the discussion or development of this document.

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REFERENCES

1. Ethics Committee of the American Fertility Society. Ethical considerations of assisted reproductive technologies. Fertil Steril 1994;62(Suppl 1):85s.
2. Anderson DJ. Assisted reproduction for couples infected with the human immunodeficiency virus type. Fertil Steril 1999;72:592–4.
3. Politch JA, Anderson DJ. Use of assisted reproductive technology to prevent the transmission of HIV-1 in HIV-1 discordant couples desiring children. In: Arici A, editor. Immunology and allergy clinics of North America. Philadelphia: W.B. Saunders; 2002:663–79.
4. Sauer M. Sperm washing techniques address the fertility needs of HIV-seropositive men: a clinical review. Reprod Biomed Online 2005;10:135–40.
5. HHS Panel on Treatment of HIV-Infected Pregnant Women and Prevention of Perinatal Transmission. Recommendations for use of antiretroviral drugs in pregnant HIV-1-infected women for maternal health and interventions to reduce perinatal HIV transmission in the United States. Available at: http://aidsinfo.nih.gov/contentfiles/lvguidelines/PerinatalGL.pdf. Accessed April 9, 2015.
6. Connor EM, Sperling RS, Gelber R, Kiselev P, Scott G, O'Sullivan MJ, et al. Reduction of maternal-infant transmission of human immunodeficiency virus type 1 with zidovudine treatment. N Engl J Med 1994;331:1173–80.
7. Graham WJ, Newell ML. Seizing the opportunity: collaborative initiatives to reduce HIV and maternal mortality. Lancet 1999;353:836–9.
8. Lindegren ML, Byers RH Jr, Thomas P, Davis SF, Caldwell B, Rogers M, et al. Trends in perinatal transmission of HIV/AIDS in the United States. JAMA 1999;282:531–8.
9. Centers for Disease Control and Prevention. Achievements in public health. Reduction in perinatal transmission of HIV infection—United States, 1985–2005. MMWR Morb Mortal Wkly Rep 2006;55:592–7.
10. International Perinatal HIV Group. The mode of delivery and the risk of vertical transmission of human immunodeficiency virus type 1—a meta-analysis of 15 prospective cohort studies. N Engl J Med 1999;340:977–87.
11. van Vliet A, van Roosmalen J. Worldwide prevention of vertical human immunodeficiency virus (HIV) transmission. Obstet Gynecol Surv 1997;52:301–9.
12. Stringer JS, Rouse DJ, Goldenberg RL. Prophylactic cesarean delivery for the prevention of perinatal human immunodeficiency virus transmission: the case for restraint. JAMA 1999;281:1946–9.
13. Kambin S, Batzer F. Assisted reproductive technology in HIV serodiscordant couples. Sex Reprod Menopause 2004;2:92–100.
14. Sauer MV, Wang JG, Douglas NC, Nakhuda GS, Vardhana P, Jovanovic V, et al. Providing fertility care to men seropositive for human immunodeficiency virus: reviewing 10 years of experience and 420 consecutive cycles of in vitro fertilization and intracytoplasmic sperm injection. Fertil Steril 2009;91:2455–60.
15. Peckham C, Newell ML. Preventing vertical transmission of HIV infection. N Engl J Med 2000;343:1036–7.
16. Practice Committee of American Society for Reproductive Medicine. Recommendations for reducing the risk of viral transmission during fertility treatment with the use of autologous gametes: a committee opinion. Fertil Steril 2013;99:340–6.
17. Garrido N, Meseguer M, Remohí J, Simón C, Pellicer A. Semen characteristics in human immunodeficiency virus (HIV)- and hepatitis C (HCV)-seropositive males: predictors of the success of viral removal after sperm washing. Hum Reprod 2005;20:1028–34.
18. Dulioust E, Du AL, Costagliola D, Guibert J, Kunstmann JM, Heard I, et al. Semen alterations in HIV-1 infected men. Hum Reprod 2002;17:2112–8.
19. Cardona-Maya W, Velilla P, Montoya CJ, Cadavid A, Rugeles MT. Presence of HIV-1 DNA in spermatozoa from HIV-positive patients: changes in the semen parameters. Curr HIV Res 2009;7:418–24.
20. Mandelbrot L, Heard I, Henrion-Geeant E, Henrion R. Natural conception in HIV-negative women with HIV-infected partners. Lancet 1997;349:850–1.
21. Cohen MS, Chen YQ, McCauley M, Gamble T, Hosseinipour MC, Kumarasamy N, et al. Prevention of HIV-1 infection with early antiretroviral therapy. N Engl J Med 2011;365:493–505.
22. Vernazza PL, Graf I, Sonnenberg-Schwan U, Geit M, Meurer A. Preexposure prophylaxis and timed intercourse for HIV-discordant couples willing to conceive a child. AIDS 2011;25:2005–8.
23. Public Health Service; Preexposure Prophylaxis for the Prevention of HIV Infection in the United States–2014. Available at: http://www.cdc.gov/hiv/pdf/PrEPguidelines2014.pdf. Accessed April 9, 2015.
24. Semprini AE, Levi-Setti P, Ravizza M, Pardi G. Assisted conception to reduce the risk of male-to-female sexual transfer of HIV in serodiscordant couples: an update [abstract]. Presented at the 1998 Symposium on AIDS in Women, Sao Paulo, Brazil, September 14–15, 1998.
25. Bujan L, Hollander L, Coudert M, Gilling-Smith C, Vucetich A, Guibert J, et al. Safety and efficacy of sperm washing in HIV-1 serodiscordant couples where the male is infected: results from the European CREAThE network. AIDS 2007;21:1909–14.
26. Centers for Disease Control and Prevention. HIV-1 infection and artificial insemination with processed semen. MMWR Morb Mortal Wkly Rep 1990;39:249. 255–6.
27. Cohan D, Weber S, Aaron E. CDC should reverse its recommendation against semen washing-intrauterine insemination for HIV-serodifferent couples. Am J Obstet Gynecol 2013;209:84.
28. Redd AD, Quinn TC, Tobian AR. Frequency and implications of HIV superinfection. Lancet Infect Dis 2013;13:622–28.
29. Neff S, Goldschmidt R. Centers for Disease Control and Prevention 2006 human immunodeficiency virus testing recommendations and state testing laws. JAMA 2011;305:1767–8.
30. American College of Obstetricians and Gynecologists. ACOG committee opinion. Routine human immunodeficiency virus screening. Obstet Gynecol 2008;112(2 Pt 1):401–3.

31. Branson BM, Handsfield HH, Lampe MA, Janssen RS, Taylor AW, Lyss SB, et al. Revised recommendations for HIV testing of adults, adolescents, and pregnant women in health-care setting. MMWR Morb Mortal Wkly Rep 2006;55:1–17.
32. U.S. Preventive Services Taskforce Recommendation Statement. Screening for HIV. Ann Intern Med 2013;159:1–36.
33. Food and Drug Administration; Part 1271–human cells, tissues and cellular and tissue based products; donor screening and testing, and related labeling; interim final rule 5/24/05. Federal Register, vol. 70, no. 100, May 25, 2005, Rules and Regulations. Available at: http://www.fda.gov/ohrms/dockets/98fr/05-10583.htm. Accessed April 9, 2015.
34. Practice Committee of the American Society for Reproductive Medicine, Practice Committee of the Society for Assisted Reproductive Technology. Recommendations for gamete and embryo donation: a committee opinion. Fertil Steril 2013;99:47–62.
35. Centers for Disease Control and Prevention. HIV/AIDS surveillance report, National Center for HIV, STD, and TB Prevention, Divisions of HIV/AIDS Prevention: surveillance of healthcare workers with HIV/AIDS, June 30, 2000. Available at: http://www.cdc.gov/hiv/pdf/statistics_hiv_surveillance_special_report_no_7.pdf. Accessed April 9, 2015.
36. Bragdon v. Abbott (1998); 524 U.S. 624, 118 S. Ct. 2196.
37. Americans with Disabilities Act of 1990. Available at: http://www.ada.gov/. Accessed April 9, 2015.
38. Sauer MV. American physicians remain slow to embrace the reproductive needs of human immunodeficiency virus–infected patients. Fertil Steril 2006;85:295–7.
39. Daar ES, Daar JF. Human immunodeficiency virus and fertility care: embarking on a path of knowledge and access. Fertil Steril 2006;85:298–300.
40. Practice Committee of American Society for Reproductive Medicine, Practice Committee of Society for Assisted Reproductive Technology. Recommendations for practices utilizing gestational carriers: an ASRM Practice Committee Guideline. Fertil Steril 2015;103:e1–8.
41. Cal. Health & Safety Code, Sec. 1644.5. Available at: http://www.leginfo.ca.gov/cgi-bin/displaycode?section=hsc&group=01001-02000&file=1644-1644.6. Last accessed April 27, 2015.
42. Moore v. Regents of the University of California (1990); 51 Cal. 3d 120.
43. Ethics Committee of the American Society for Reproductive Medicine. Interests, obligations, and rights in gamete donation: a Committee opinion. Fertil Steril 2014;102:675–81.