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Assessing access to assisted reproductive services for serodiscordant couples with human immunodeficiency virus infection

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Abstract

Objective: To understand the barriers that serodiscordant couples with human immunodeficiency virus (HIV) face in accessing services for risk reduction and infertility using assisted reproductive technology (ART).

Design: Two-arm cross-sectional telephone “secret shopper” study.

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Setting: Infertility clinics designated by the Society for Assisted Reproductive Technology (SART), 140 from 15 American states with the highest prevalence of heterosexual HIV-infected men.

Patient(s): Clinical and nonclinical staff at SART-registered clinics.

Intervention(s): Standardized telephone calls to SART-registered clinics by investigators in the roles of physician and patient callers.

Main Outcome Measure(s): Availability and difference in services offered to callers and the rate of referral if the clinic did not provide these services.

Result(s): Of the 140 sampled SART clinics across 15 states, callers in both patient and physician roles spoke to a staff member at greater than 90% of targeted clinics (127 clinics total). Of the physician callers 63% were told that the clinic could offer services, as compared to 40% of patient callers. Of the 55 clinics that were unable to provide services to the patient caller, 51% referred to other clinics with confidence that they could offer these services; 67% of clinics would provide services for both prevention and infertility purposes.

Conclusion(s): Risk reduction services for HIV were more available at the sampled fertility clinics than previously reported in the literature. However, the responses depended on the person calling. The clinics demonstrated low rates of concordance with the American Society for Reproductive Medicine's guidelines, which endorse referral of patients to other facilities from sites unable to offer services.

Keywords

Assisted reproduction; fertility; HIV prevention; risk reduction; serodiscordant couples

Individuals of reproductive age account for approximately 65% of new human immunodeficiency virus (HIV) infections in the United States (1). Persons living with HIV have been shown to have similar childbearing motivations or future pregnancy desires as their HIV-uninfected counterparts (2). As a result, and much like the general population, HIV-infected individuals have demonstrated an acceptance and demand for assisted reproductive technology (ART) (3–5). Sperm washing with intrauterine insemination (IUI), in vitro fertilization (IVF), and IVF with intracytoplasmic sperm injection (ICSI) are among several risk reduction strategies effective in preventing HIV transmission and in assisting pregnancy for HIV-serodiscordant couples (6–8).

In 2015, the American Society for Reproductive Medicine (ASRM) revised a committee opinion on HIV and infertility treatment where they found “no ethical reason[s] to withhold fertility services at clinics with the necessary resources to provide care to HIV-infected individuals” (7). Previous studies indicated, however, that only 3% of ART practices provide services to patients with HIV (7, 9). Poor access has been attributable to personnel transmission concerns, cross-contamination concerns, lack of expertise among clinicians in handling such specimens, and high cost of the separate laboratory facilities recommended by the ASRM (7). The ASRM strongly encourages providers to “reduce these barriers to care in order to make infertility treatment available to HIV-infected individuals” (7). Despite reports

of low access and clear guidelines, no studies to date have rigorously examined this issue (9).

This study investigated the availability of assisted reproductive services for women seeking to conceive with an HIV-infected partner. The study focused on couples composed of an HIV-infected man and HIV-uninfected woman. We hypothesized that the majority of clinics would not offer services to these couples, with lower rates of availability when a patient called compared with when a physician called on behalf of a patient.

MATERIALS AND METHODS

To determine the level of access and barriers that HIV-serodiscordant couples face when accessing ART, we conducted a two-arm cross-sectional telephone secret shopper study of fertility clinics in the United States. Our population of interest prompted us to select 15 states with the highest HIV prevalence among heterosexual individuals. We selected states with the highest prevalence due to a likely higher need and demand for ART services among their populations. The 15 states included Connecticut, Delaware, the District of Columbia, Florida, Georgia, Louisiana, Maryland, Massachusetts, Mississippi, New Jersey, New York, North Carolina, Pennsylvania, Rhode Island, and South Carolina. Using the Society for Assisted Reproductive Technology (SART) database, we called all 140 clinics within the 15 highest prevalence states (10). The primary study outcomes included the availability of services to the patient caller, the differences in the services offered to the patient and physician callers, and rates of referral if the clinic was unable to offer services. The secondary outcomes included the type of fertility services offered to the physician callers; whether the clinics agreed to accept referral for risk reduction, for fertility only, or for both; and whether clinics would also provide their patients with pre-exposure prophylaxis (PrEP) services.

The first arm of the study consisted of author A.L. (female) posing as an HIV-uninfected woman with an HIV-infected male partner. Specifically, she described herself as a 30-year-old nulliparous woman who had recently moved to the area near the clinic being contacted and was interested in attempting to conceive safely with her HIV-infected husband. In this scenario, neither the patient nor her husband had a diagnosis of infertility. The patient's goal was to gain information about access to ART. The second arm of the study consisted of author P.B. (male), C.R. (female), or M.C. (female) posing as a new obstetrician-gynecologist in the area near the clinic. The physicians were calling to refer a 30-year-old nulliparous HIV-uninfected woman with an HIV-infected husband for ART. In this scenario, the physician stated that neither the patient nor the husband had a diagnosis of infertility but were interested in using ART for risk reduction.

To ensure uniformity of data collection, the callers used an eight-item call script, consistent of domains covering access, experience, services offered, and referral patterns (Supplemental Appendix, available online). The development of both the physician and patient call scripts was a collaborative effort among health services researchers, obstetrician-gynecologists, and infectious disease specialists. We piloted scripts in 10 clinics within the

states of Virginia and Illinois, the highest HIV-prevalent states in the nation following the selected study sample.

The callers phoned clinics between January and March 2016. Physician and patient calls were separated by at least 3 weeks to minimize recall bias. The initial order in which they called each clinic was random with an attempt to vary physician and patient call order to each clinic. Calls were made during regular business hours. When unable to reach a clinic, both physician and patient callers were instructed to leave call-back numbers or voicemails. The callers aimed to mimic real situations in which physician callers sought to speak with a clinician in the clinics. The patient callers began by inquiring at the receptionist or patient coordinator level.

We recorded all call data in Google Forms for immediate data collection and analyzed the data using SAS 9.4 (SAS Institute). We powered our sample at 80% with a two-sided alpha of 0.05. The power estimation applies to our hypotheses that the majority of clinics would not offer services to HIV-positive individuals and that across all clinics and by state the patient callers would elicit dissimilar rates of availability from clinics compared with physician callers. Because we were interested in testing the discordance between the physician and patient responses among the same clinics, the data are correlated and thus cannot be analyzed as two independent samples. We used McNemar's test for marginal homogeneity to test the discordance between responses to the physician and patient callers. The Boston University institutional review board deemed this study to be non-human subjects research.

RESULTS

Of the 140 identified SART clinics across 15 states, both patient and physician callers reached greater than 90% of targeted clinics. Physician callers reached 127 (90.7%) of 140 clinics, and the patient caller reached 138 (98.6%) of 140. Inability to reach a clinic was defined as a failure to make contact after three call attempts. Patient and physician callers spoke with clinical staff including physicians, nurse practitioners, nurses, or physician assistants. Callers also spoke with nonclinical staff, defined as receptionists or patient coordinators. Patient callers interacted with 54% clinicians (85% of this indirectly through patient coordinators), 35% nonclinical staff, and 11% others. Physician callers interacted with 70% clinical staff, 29% with nonclinical staff, and 0.8% others.

Of the 138 clinics reached by the patient callers, 41% of clinics said they could offer services using sperm from an HIV-infected male, and 40% did not offer services. The remaining 19% were unsure about offering services. All 138 clinics reached agreed to schedule an appointment with the patient caller, even clinics that did *not* offer services for these couples. Of the 127 clinics reached by physician callers, 63% of clinics reported they could offer services to the physician's patient using her partner's HIV-infected sperm, and 33% could not. The remaining 4% were unsure about offering services.

Across the 127 clinics that both the physician and patient callers reached, physician and patient callers elicited different rates of availability of ART services for this population,

with rates of 63% and 40%, respectively ($P<.0001$) (Table 1). Six clinics offered treatment to the patient caller but not to the clinician. When we compared the responses received by physician and patient callers from matched facilities that spoke with the clinicians only, we found no statistically significant difference in the rates of availability between callers (64% and 55%, respectively; $P=.1025$). This finding suggests that the differing rates of availability of ART services for this population could stem from varying answers given by clinical versus nonclinical personnel.

Of the clinics that offered services to the physician caller, 74% offered sperm washing with banking, 81% offered IUI, 96% offered IVF, and 94% offered ICSI. Clinics that could not provide sperm washing with banking but could provide the spectrum of other services discussed washing and banking sperm at an outside facility. Based on physician inquiries, 67% of clinics that offered services to the physician caller would provide services to couples for both prevention and infertility purposes; 33% of clinics said they would treat for infertility purposes only. Of the clinics that would provide services for both indications, 19% offered or recommended PrEP to patients undergoing ART (Table 2).

Of the 55 clinics that could not offer services to the patient caller, 51% referred to other clinics with conviction of them offering services, 18% referred but were uncertain of whether the clinics offered services, and 31% could not identify another facility for referral. Of the 38 clinics that could refer to another clinic, 21 (55%) referred within the same state, and 17 (45%) referred to a facility or physician in another state. Of the 42 clinics that denied services to the physician callers, 48% referred to other clinics with confidence, 33% referred but were uncertain of whether the clinics offered services, and 19% could not refer to another facility.

DISCUSSION

This study provides evidence that HIV risk reduction services using ART are more available than previous literature has cited. However, the reported availability is statistically significantly associated with the role of the person inquiring: patient or physician. Further, a notable number of SART clinics sampled demonstrated low rates of concordance with the ASRM guidelines that endorse routine referral of patients to other facilities from sites unable to offer risk reduction services to HIV-serodiscordant couples. As per ASRM's 2015 committee opinion on HIV and infertility treatment, clinics without "sufficient resources" to offer appropriate care should refer such patients to providers/clinics equipped to manage their treatment (7). Of the clinics that did not offer services, about half referred to clinics that they were certain offered such services; however, these clinics frequently were not in the same state as the reporting clinic. The popular referral clinics included Columbia University in New York and the Bedford Institute in Massachusetts.

Although both the ASRM and the American College of Obstetrics and Gynecology (ACOG) support fertility services for HIV-infected individuals, the physician callers elicited statistically significant higher rates of service availability compared with the patient callers (63% compared 40%, respectively, $P<.0001$). Further studies are needed to elucidate the potential reasons leading to this finding, but the physician callers more often spoke with

clinical staff. When we compared the responses between the physician and patient callers from matched facilities when they spoke with clinicians only, we found similar rates of availability between the callers. Therefore, the disconnect in the rate of service availability between provider and patient callers could be due to differing responses between clinical and nonclinical staff. Nonclinical staff might be less aware of the less commonly provided services offered by their clinics, particularly in situations in which confidentiality could conceal such services from schedulers and other nonclinical personnel. A patient's first line (and often only line) of contact is with nonclinical staff, so tailored education of staff on these issues could be an important factor in closing the gap of uncertainty reflected in the differing responses received by the patient and provider callers.

The difference in access could also suggest the relative lack of experience of fertility clinics treating HIV-infected patients, whether clinics have in place the appropriate laboratory and training procedures according to the current clinical guidelines, and/or an underlying stigma toward persons living with HIV who wish to have children (7,11–13). There is thus a potential need for enhanced provider advocacy for persons living with HIV who wish to have children and prioritization of improving access among clinics working with these patients.

Our study selected clinics within a sample of high HIV-prevalent states, and our results indicate much better access than has been reported in the literature to date, with 40% of clinics offering services compared with only 3% as indicated in the prior literature (9). It is thus reassuring that the states with the highest HIV prevalence are offering greater access than previously reported. A misperception that only 3% of clinics in the United States offer fertility services for these couples may have impacted the physician referral rates for these services in the past and, in return, the patient demand for these services.

Furthermore, of the clinics that offered services to the physician callers in this study, most clinics had the capacity to offer a variety of services. Over 80% offered IVF, ICSI, and IUI. In addition, sperm washing with banking was common, with nearly three quarters of the clinics offering this service on site or using outside facilities to wash and quarantine the sperm. As reported in the literature, the reasons given for low access to services among this population include concerns regarding transmission and cross-contamination, lack of expertise, and high costs for maintaining separate laboratory space, the latter in which is recommended by ASRM (7, 11, 12). It is thus encouraging that clinics are finding ways to wash and bank sperm offsite to enable access to services for these couples.

Moreover, although 19% of clinics offered PrEP services in their armamentarium of risk reduction strategies, the addition of PrEP to strategies with nearly zero transmission risk is unlikely to provide an appreciable benefit (14–17). However, PrEP could be a way to scale up conception interventions that do not require specialized fertility clinics, which could possibly improve access to care. Antiretroviral therapy for the HIV-infected partner alone reduces HIV transmission by up to 96% among serodiscordant heterosexual couples, with PrEP adding further value when the male partner is not consistently suppressed (18; Leech A, et al. Cost-effectiveness of pre-exposure prophylaxis for HIV prevention for conception. Submitted.). Based on effectiveness, patient preference, and fertility indication,

however, ART services should be among the menu of included strategies for prevention of transmission as well as assisted fertility for individuals at high-risk for HIV infection (4, 6, 8, 17, 19; Leech A, et al. Cost-effectiveness of pre-exposure prophylaxis for HIV prevention for conception. Submitted.).

Our study is not without its limitations. First, race and sex concordance or discordance between the caller and the respondent on the phone could bias results. Accent and assumed demographic characteristics of the patient caller could bias the results away from the null (e.g., patient and physician callers would illicit similar rates of availability of services). While we aimed to control for gender differences by ensuring both female and male physician callers, we did not collect data on differences in responses based on physician gender because it was outside the scope of our study. The patient and physician calls were separated by at least 3 weeks to prevent recall bias. We chose a 3-week period based on clinical judgment, but we may have underestimated the time needed to minimize such bias. However, because we did detect a difference between the patient and physician callers, the impact was likely minimal. In addition, this study was based on telephone calls to clinics and thus does not reflect in-person interactions; however, a telephone call would likely be the mode of initial contact by any patient or provider and may most replicate reality.

Notwithstanding these limitations, this study addresses important issues surrounding access to ART services for HIV-serodiscordant couples where the man is HIV-infected. The major advantages of secret shopper/audit studies lie in their ability to detect subtle forms of discrimination such as “opportunity-diminishing” and “opportunity-denying behavior” (20). This study thus uniquely depicts a realistic picture of access and detects more subtle forms of inequity.

CONCLUSION

This study demonstrates that ART services for serodiscordant couples are likely much more available than shown by previous reports, but that there is still a large gap. Further, access depends on who calls, so patients might need advocacy or help in engaging with this system. Although there are other risk reduction options for these couples such as antiretroviral therapy for the HIV-infected partner and PrEP for the uninfected partner, serodiscordant couples should have access to ART for the purpose of risk reduction or supported fertility. Furthermore, evidence regarding fertility desires of persons living with HIV in the United States indicates an acceptance and demand for ART services among this population (3–5). Efforts to expand the availability of services and ensure a more uniform experience when seeking care could improve HIV and pregnancy outcomes for women and their children. Future research should examine the reasons leading to differences in access between physician and patient callers and seek to better understand the barriers in providing services and coverage for this population.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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TABLE 1

Characteristics of clinics reached by patient and physician telephone callers.

Characteristics	Patient caller n (%)	Physician caller n (%)	P value
Clinics			
Number reached	138 (98%)	127 (91%)	
Unreachable	2 (1.4%)	13 (9.3%)	
Person reached			
Clinician ^a	56 (41%)	89 (70%)	
Nonclinical staff ^b	67 (48%)	37 (29%)	
Other ^c	15 (11%)	1 (0.8%)	
Offered fertility services for serodiscordant couples			
Yes	57 (41%)	80 (63%)	<.0001
Matched calls: 51 (40%) ^d			
No or Not sure	81 (59%)	47 (37%)	
Matched calls: 76 (60%) ^d			
Referral			
Could not refer	17 (31%)	8 (19%)	
Referred and unsure	10 (18%)	14 (33%)	
Referred and sure	28 (51%)	20 (48%)	

^aIncluding cases in which the patient was placed on hold to inquire with a clinician (we only included these cases in which the patient knew with certainty that a clinician was consulted).

^bReceptionist, clinic coordinator, office manager.

^cLaboratory or unknown.

^d“Matched calls” indicates the clinics reached by both physician and patient callers. We were interested in testing the discordance between the responses to physicians and patients among the same clinics, so the data are correlated and thus cannot be analyzed as two independent samples. Because the physician callers reached 127 clinics and the patient callers reached 138 clinics total, we could not analyze this specific research question using clinics that the patients reached but the physicians did not. We had to thus match the clinics reached by the patient callers to the 127 clinics reached by the physician callers.

Leech. ART for couples with HIV. Fertil Steril 2017.

TABLE 2

Fertility services offered by clinics that provide ART care to serodiscordant couples.

Clinic responses	N (%)
Services (n = 80) ^a	
Sperm washing and banking	59 (74)
Intrauterine insemination	65 (81)
In vitro fertilization	77 (96)
Intracytoplasmic sperm injection	75 (94)
Purpose of services (n = 76) ^b	
Infertility only	25 (33)
Both risk reduction and infertility	51 (67)
Pre-exposure prophylaxis (PrEP) (n = 51) ^c	
Offered	10 (19)
Not offered	20 (39)
Not sure	21 (41)

Note: Couples can be assigned to more than one category; thus the proportions sum to more than 100%.

^aDefined by information from the physician callers; 80 is the number of clinics that offered services to the physician callers.

^bFour clinics did not respond to this question: "If yes to services, do you still see couples if the reason for seeking services is for prevention of an infection in the female partner, for infertility, or both."

^cIf respondents answered "both" to the question in regard to the purpose of services offered, we asked whether they also give their patients PrEP ("If yes to 'both prevention and infertility,' do you give them PrEP?").

Leech. ART for couples with HIV. *Fertil Steril* 2017.