

Higher Levels of Risky Sexual Behavior Reported In Polling Booth Surveys Than in Face-to-Face Interviews

Survey respondents report higher levels of risky sexual behavior when they answer questions anonymously in private polling booths using marked tokens than when they take part in face-to-face interviews, according to a study conducted in Cotonou, Benin.¹ For example, the proportion of married men who reported ever having had sex with a female sex worker was 20% in face-to-face interviews, but 42% in polling booth surveys. Similarly, among married women, the proportion reporting ever having had extramarital sex was 5% in face-to-face interviews and 24% in polling booth surveys. Differences by interview type in the prevalence of sexual behaviors were greater than those of condom use and STI symptoms.

Although face-to-face interviews are widely used to collect data on sexual behavior, especially in populations with low literacy, the method is subject to social desirability bias—respondents may underreport socially proscribed behaviors or overreport those that are socially approved. Methods that improve confidentiality have been developed, but are more suitable for populations with high literacy rates. As part of an HIV-prevalence study conducted in Cotonou in 2008 among men aged 15–64 and women aged 15–49, researchers conducted face-to-face interviews with a random sample of 2,580 respondents and polling booth surveys with an independent random sample of 1,095 individuals from the same population. Dichotomous questions on HIV-related risk behaviors were read aloud to the polling booth survey participants, who then placed a token marked with a number corresponding to the question number into a box labeled “yes” or “no” (the tokens were placed to the side if the question was not applicable). To ensure the respondent’s anonymity, the box was shielded from the interviewer’s sight. The same questions were asked in the face-to-face interviews, along with questions on social and demographic characteristics. Pearson chi-square and Fisher’s exact test were used to compare the proportions of affirmative answers obtained by each survey method,

stratified by gender and marital status, yielding four demographic groups—married men, unmarried men, married women and unmarried women.

The vast majority (90–96%) of eligible men and women participated in the two surveys. The median age of respondents interviewed face-to-face was 36 for married men, 22 for unmarried men, 30 for married women and 19 for unmarried women. In all four groups, the proportion of respondents who acknowledged having engaged in various risky sexual behaviors was generally greater in the polling booth group than in the face-to-face interview group. For example, among married men, those who answered questions in the polling booth were far more likely than their counterparts in the interview group to say that they had had extramarital sex in the past year (54% vs. 18%) or ever (67% vs. 59%), had sex with a female sex worker in the past year (24% vs. 12%) or ever (42% vs. 20%), or had ever had anal sex with a woman (18% vs. 3%) or man (8% vs. 0%). Among married women, participants in the polling booth surveys were more likely than those in the face-to-face interviews to say that they had had extramarital sex in the past year (21% vs. 3%) or ever (24% vs. 5%), had been paid for sex in the past year (13% vs. 1%) or ever (17% vs. 2%), or had had anal sex (18% vs. 3%). Results for unmarried men and women were generally similar, with a few exceptions; for example, the proportion of unmarried men who reported having ever had sex with a woman, and the proportion of unmarried women who reported having ever had sex with a man, did not differ between the polling booth and face-to-face interview groups.

Findings for measures of condom use were less consistent. Among married men, those in the polling booth surveys were more likely than those in the face-to-face interviews to report having used a condom at last sex with their first spouse (25% vs. 7%) or with a female sex worker (73% vs. 56% of those who had had sex with a sex worker). On the other hand, among unmarried man, reported lev-

els of condom use in various contexts were higher in face-to-face interviews than in polling booth responses; a possible reason for this finding, according to the authors, is that unmarried men were more inclined than their older, married counterparts to report condom use behavior in line with recent local interventions. Women in the polling booth samples were more likely than those in the interview samples to report condom use, with one exception: Among unmarried women, the prevalence of condom use at last paid sex did not differ by interview format.

In addition, respondents surveyed at polling booths were more likely than those interviewed face-to-face to report having had STI symptoms (genital ulcers or urethral or vaginal discharge) in the past year or having ever injected illicit drugs. And although they were generally less likely than their peers in the face-to-face interview group to say that they had heard of HIV or AIDS, they were more likely to have been tested.

The researchers acknowledge several limitations of the study: The participants were not randomly assigned to a specific survey type, and unlike face-to-face interviews, the polling booth survey method does not permit interaction between the participant and the interviewer (to clarify questions) or allow researchers to check for inconsistent responses. Moreover, the polling booth survey method allows only for collection of aggregated data. Despite these limitations, the researchers note that polling booth surveys “seemed to have increased respondents’ willingness to report stigmatized behaviours.” The investigators conclude that polling booth surveys “are suitable to monitor reliable HIV/STI risk behaviours and ... could be used to adjust for answers to sensitive behavioural questions in [face-to-face interviews].”—L. Melhado

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Many Bangladeshi Pharmacies Do Not Provide Accurate Information on How to Use Misoprostol

Pharmacy workers in urban Bangladesh commonly provide medicines and dosing regimens for menstrual regulation that are not effective, according to a cross-sectional survey that used trained individuals posing as clients.¹ When these mystery clients inquired about obtaining a drug to end a pregnancy or induce menstruation, three-quarters of pharmacy workers offered misoprostol, another medication or both. But fewer than one in 10 of those who provided misoprostol recommended an effective dosing regimen for menstrual regulation, and more than seven in 10 did not provide any advice on what to do in the event of complications. In addition, the vast majority of pharmacy workers did not provide post-menstrual regulation family planning methods or refer clients for such services.

Investigators conducted the survey in 2011 in the Mirpur and Badda areas of Dhaka district, and the Sadar area of Gazipur district. They trained young (aged 18–24) and middle-aged (25 or older) male and female mystery clients to approach pharmacy workers and ask about the use of misoprostol specifically or the use of a drug generally for menstrual regulation, either for themselves, a friend or a spouse. (At the time of the study, misoprostol was approved in Bangladesh only for treatment of peptic ulcer and prevention of postpartum hemorrhage.) The mystery clients asked about the availability, cost, dosage, route of administration, effectiveness, adverse effects and complications of any drugs they received, as well as about family planning methods and counseling. Researchers interviewed the “clients” immediately afterward to capture details about the encounter. The investigators computed descriptive statistics and compared differences in study outcomes by characteristics using chi-square tests.

The mystery clients interacted with workers (all of whom were male) at 331 pharmacies. Overall, 76% of clients were offered one or more medications, 23% received information and referrals (usually to a private clinic or hospital) and 2% received neither. When pharmacy workers offered medicines, 39% offered only misoprostol, 16% offered another drug (e.g., emergency contraceptive pills, herbal medicines, hormonal preparations or

the combination of methylestrenolone and methylestradiol) and 46% offered both.

Among pharmacy workers who provided misoprostol, just 7% told the client the effective dosage (four pills daily for two days), while the rest gave ineffective ones. Only 32% correctly indicated that the drug should be taken orally, while 65% said that it should be used both vaginally and orally; the remaining 3% indicated that they did not know the route of administration. Only small proportions of pharmacy workers counseled misoprostol recipients about the potential adverse effects of nausea and vomiting (17%), fever and chills (5%) and diarrhea (1%). Nearly half (46%) advised clients that excessive bleeding was a danger sign, but few (4%) counseled clients that fever lasting more than a day might signal infection. Twenty-eight percent of pharmacy workers who offered misoprostol told the clients to go to trained providers in the event of complications, but the rest did not give any suggestion about where to go in that situation. The vast majority (94%) did not provide any post-menstrual regulation family planning methods or referrals.

Provision patterns varied by area and by the nature of the mystery client's request. The proportion of pharmacy workers offering other medicines in addition to misoprostol was higher in Badda (58%) than in Mirpur or Gazipur (42% in each). Workers in Gazipur were about twice as likely as their peers in Mirpur or Badda to recommend using oral and vaginal routes together for misoprostol administration (90% vs. 46–47%). Finally, compared with workers who were asked for a nonspecified drug, those who were asked about misoprostol were more likely to offer misoprostol alone (65% vs. 7%) and to counsel clients that nausea and vomiting are adverse effects of the drug (23% vs. 12%).

Study limitations include potential recall bias and misreporting, the possibility that the mystery client scenarios were unrealistic or aroused pharmacy workers' suspicion, and the findings' questionable generalizability to rural areas, the investigators acknowledge. Nonetheless, although the results show that misoprostol is widely available in pharmacies in the study areas and that pharmacy workers are willing to provide the drug to clients seek-

ing to use it for self-induction of menstrual regulation, they also reveal that workers have “considerable knowledge gaps,” the researchers maintain. “Pharmacy workers have the potential to expand access to safe menstrual regulation with medication in Bangladesh in the future, particularly with the recent approval of mifepristone-misoprostol [for menstrual regulation]. Training pharmacy workers and increasing their awareness of appropriate referral networks will help to ensure safe, effective, and quality menstrual regulation services,” they conclude.—S. London

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In Vietnam, Telephone Follow-up for Medication Abortion Is Feasible

Telephone follow-up using a semiquantitative pregnancy test is a feasible, safe and acceptable alternative to clinic follow-up after early medication abortion, suggests a randomized controlled trial conducted in Vietnam.¹ Eighty-five percent of women followed up by telephone were able to avoid returning to the clinic, and the complication rate did not differ between women monitored by telephone and those who returned to the clinic for an examination and ultrasound. In addition, telephone follow-up was highly sensitive and specific for detecting ongoing pregnancy, and was associated with a sharply reduced risk of women being lost to follow-up.

The trial, conducted at four Vietnamese hospitals, examined outcomes among women who underwent an early medication abortion (i.e., within nine weeks' gestation) using oral mifepristone followed by buccal misoprostol taken at home. The women were randomly assigned to clinic follow-up (standard care) or telephone follow-up. Those in the former group were asked to return two weeks after mifepristone administration for a clinic visit, during which their abortion status was assessed by interview, bimanual examination and transvaginal ultrasound. Women in the telephone follow-up group took a semiquantitative urine pregnancy test before swallowing the mifepristone to determine their approxi-

mate baseline level of human chorionic gonadotropin (hCG), and were given a second test kit and a symptom checklist to complete at home before a follow-up call two weeks later. Clinic staff reviewed the results during the call and asked women who screened positive for ongoing pregnancy (by answering “yes” to any of the three checklist questions or having a pregnancy test that was invalid or showed an increase or no change in hCG level) to return to the clinic. The investigators compared characteristics of the two study groups using various bivariate tests, calculated relative risks for abortion outcomes and assessed the sensitivity and specificity of telephone follow-up for detecting ongoing pregnancy.

The 1,433 study participants were 27 years old, on average. Most had at least a secondary school education, and two-fifths had attended university. About one in three had previously had a surgical abortion, and one in six had previously had a medication abortion.

The vast majority of women in each group (95%) were found to have had a complete medication abortion and did not require or have a surgical evacuation. Of the remaining women, about half had a surgical evacuation for an ongoing pregnancy and half had an evacuation for other reasons (retained products of conception, missed abortion, heavy bleeding or patient’s request). None of these outcomes differed between groups. However, only 1% of women in the telephone follow-up group could not be reached for their scheduled call, whereas 8% of their counterparts in the clinic follow-up group failed to return for their appointment; this difference translated to a 90% lower risk of loss to follow-up in the former group (relative risk, 0.1).

Among women who had not made an interim visit to the clinic, 85% of those in the telephone follow-up group screened negative for ongoing pregnancy during their call and were released from the study because no additional follow-up was necessary. The remaining 15% were asked to return to the clinic, and all did. Three-fourths of these women had not had a decline in hCG levels on the pregnancy test, had had at least one “yes” response on the symptom checklist or both; the others had screened negative on both tests but were asked to return because of persistent bleeding, anxiety, pregnancy symptoms not covered by the checklist or other reasons.

The combination of the pregnancy test and the symptom checklist during telephone follow-up had 93% sensitivity and 91% speci-

ficity for detecting ongoing pregnancy. Use of the pregnancy test alone had the same sensitivity, but higher specificity (96%). Of the 14 women in the telephone follow-up group who had an ongoing pregnancy, 10 had positive results on both the pregnancy test and checklist, three had only a positive pregnancy test and one had negative results on both.

Nearly all women in the telephone follow-up group completed the pregnancy test and the checklist (99% and 98%), and most of these women reported that these tasks were easy (98% and 97%). Eighty-eight percent of women who were followed up by telephone said they would prefer the same approach if they ever needed another medication abortion; however, only 40% of those in the clinic follow-up group indicated that they would prefer telephone follow-up to clinic follow-up in the future.

The researchers caution that the study’s results may not apply outside Vietnam or to women who are less well educated, and that

it is possible (although unlikely) that some women in the telephone follow-up group sought abortion care elsewhere. They note that telephone follow-up using the semiquantitative urine test alone was effective for identifying women with ongoing pregnancy, and that the addition of the symptom checklist provided no clear additional clinical benefit. Replacing routine clinic follow-up after early medication abortion with such a urine test would simplify care and might reduce costs for women and the health care system alike, the researchers maintain. “Such efforts may be especially beneficial in resource-poor countries, where clinics may be overcrowded and understaffed with limited access to serum hCG testing and transvaginal ultrasonography,” they conclude.—*S. London*

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Training Clinical Officers in Tubal Ligation May Help Meet Rural Ugandan Women’s Need for Sterilization

In a prospective study designed to examine whether mid-level providers can safely perform tubal ligation in rural Uganda, where physicians are in short supply, almost all women whose procedure was performed by a clinical officer had a successful outcome and reported that they were satisfied with the ligation.¹ Newly trained clinical officers were able to successfully complete more than nine-tenths of the tubal ligations they attempted, in most cases without the help of a supervisor, and three days after the operation only 2% of women reported having a major complication. During follow-up interviews 45 days after the surgery, 99% of women indicated that their experience at the clinic had been good or very good.

Uganda’s high unmet need for contraceptives is compounded by the lack of health care providers, especially in rural areas, as the number of public-sector physicians (approximately one for every 1,000 Ugandans) is too small to provide many types of preventive care, such as sterilization. Clinical officers, who receive three years of clinical training, are taught to perform minor surgical procedures, but generally not tubal ligation, even though they are legally permitted to provide this ser-

vice. However, data have been lacking on the safety of tubal ligations performed in Africa by medical personnel other than physicians.

To evaluate the outcomes of and patient satisfaction with such procedures, researchers conducted a study in which four clinical officers, chosen on the basis of their general surgical expertise, received six weeks of training in tubal ligation, which included their performing at least 50 supervised surgeries. Each officer then joined a mobile family planning clinic team that served a rural area in central, western or eastern Uganda.

Between March and June 2012, the researchers enrolled 518 women aged 18 or older who had given birth at least three weeks earlier and wished to undergo a tubal ligation. They were informed that although a clinical officer would be performing the procedure, a supervisor (physician or medical officer) would be on hand in case of need. (Participants were also given the option of having a doctor perform their ligation; women who chose this option were not included in the study sample.) A nurse took note of complications that occurred during surgery.

During follow-up visits to the clinic three days, one week and 45 days after the opera-

tion, women rated their tubal ligation and their experience as a clinic patient, and indicated whether they would recommend the clinic to a friend. Women also reported on any related health problems (e.g., pain, fever, poor healing, infection) they had had since the surgery. These were classified as minor if the woman could treat herself at home; moderate if she needed medical attention; and major if she had to be hospitalized or suffered lasting impairment, or if the tubal ligation was unsuccessful. At each time point, 93–94% of patients were interviewed.

Participants were split fairly equally among the four clinics, and two-thirds were aged 30–39. They had seven children, on average; four in 10 had at least eight. Half had used the injectable in the month prior, while one-fifth were not using any form of contraception. Other reported methods included condoms, the pill, IUD and lactational amenorrhea (1–10%).

In 93% of the surgeries, the clinical officer operated successfully; in 7%, the supervising physician had to complete the procedure. Of the procedures they performed successfully, clinical officers completed 70% without assistance and 29% with verbal guidance from the physician on how to resolve a complication. In the remaining 1%, the physician physically assisted in the surgery.

Three days after their procedure, most women (69%) reported having minor complications, though the proportion fell to 4% by day 45. Moderate and major adverse events were far less common; they were reported by 12% and 2% of women, respectively, at day 3, and by fewer than 1% of women at the final follow-up visit. At each time point, the most commonly reported complaint was minor or moderate pain.

Respondents' approval of the surgery and of the mobile clinic was consistently high at all three visits; 92–99% rated their procedure as good or very good, and 94–99% chose one of these ratings when asked about the clinic. Similarly high proportions of women (93–98%) said they would recommend the clinic to a friend.

The authors recognize that ideally, the study would have compared clinical officers' tubal ligations with those performed by physicians, and would have had a larger sample to yield a more precise estimate of the incidence of adverse events. Moreover, women could have given incorrect accounts of the nature and severity of their postoperative complica-

tions. Despite these limitations, the authors note that tubal ligations performed by clinical officers appear to be safe, and that training clinicians to provide such procedures "could help to address the high unmet need for permanent contraception in Uganda, particularly in remote settings." Indeed, on the basis of the study findings, the Ugandan government is planning a national rollout of the program to train clinical officers to perform tubal ligations. —S. Ramashwar

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Thailand Unprepared to Offer Newborn Circumcision For HIV Prevention

Male circumcision is a relatively safe procedure associated with a host of health benefits, including reductions in the risk of some STIs, genital ulcer disease, urinary tract infections and female-to-male HIV infection. Promotion of newborn circumcision is one long-term strategy for prevention of HIV transmission. However, a recent survey of Thailand's hospitals indicates that the country's health system, despite having the requisite medical infrastructure, may not be prepared to implement newborn circumcision as a public health intervention.¹ Among facilities thought to be able to provide newborn circumcision, just 31% of private and 2% of public hospitals had actually performed the procedure in the last year. Only a minority of responding health professionals considered newborn circumcision safe (39%) and agreed that their hospital should offer the procedure (29%), although half reported wanting to be trained to perform it.

Data come from a 2011 survey of all hospitals in Thailand that were capable of providing obstetric services and hence considered potentially able to perform circumcision. Each hospital was sent a questionnaire requesting information about the facility's characteristics and its provision of newborn circumcision in the previous year; specific topics included the type of staff who performed the procedure, the reasons for performing it and the surgical techniques used. A second questionnaire was to be completed by a doctor or nurse familiar

with delivery and postpartum care; it asked about the difficulty of providing newborn circumcision, the safety of the procedure, desire for training in newborn circumcision and opinions on whether the procedure should be performed in the respondent's hospital and how it should be paid for.

Staff at just over half (55%) of hospitals responded to the survey. Of the 747 participating facilities, 85% were government hospitals and 15% were private hospitals, representing 68% of public and 27% of private facilities in the country. Only 6% of the hospitals (31% of private and 2% of public facilities) had provided newborn circumcision in 2010.

At the 46 facilities where newborn circumcision was available, the procedure was typically provided in response to parents' request (38 hospitals); less commonly, respondents reported that circumcision was performed for medical indications (12 hospitals) or on a physician's advice (five hospitals). At three-quarters of institutions, pediatric or general surgeons usually performed the procedure. Five of the 11 public facilities, and all but one of the 35 private hospitals, reported that patients paid the full cost of the newborn circumcision. Health professionals at public hospitals typically used free-hand surgical techniques, whereas private hospital surgeons tended to use specialized tools.

A total of 562 health professionals responded to the second questionnaire; 65% were nurses and 35% physicians. Overall, just 39% agreed that newborn circumcision was safe; physicians and private facility employees were more likely to agree with this statement than were nurses and public employees. Fewer than a third (29%) of respondents agreed that their hospital should offer newborn circumcision, but about half of all doctors (53%) and nurses (50%) reported wanting to be trained to perform the procedure. Respondents generally felt that if newborn circumcision were to be promoted as a public health measure, the decision to circumcise should rest with parents (55%); however, 33% believed the procedure should be performed only when medically indicated. Forty-three percent believed that the service should be free of charge, while the same proportion felt that the parents should bear some or all of the cost. (The remainder said that other individuals should pay or that they did not know who should do so.)

The authors conclude that although the use of newborn circumcision for HIV preven-

tion is appropriate for Thailand for a variety of reasons—including the primarily heterosexual nature of the country's HIV epidemic, the availability of qualified medical staff and well-equipped hospitals, and a lack of cultural proscriptions against circumcision—further steps are needed before the procedure can be promoted. In addition to suggesting that currently practicing doctors and nurses be offered training on how to perform newborn circumcision and provide postsurgical care, they recommend that newborn circumcision be incorporated into medical and nursing school curricula and that government stakeholders be educated about the potential benefits of the procedure. Until these and other preparatory steps are taken, the authors state, “a promising approach to disease prevention will not be implemented in the country.”—*H. Ball*

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Cash Transfers Associated With Reduced HIV Risk Among South African Girls

Household enrollment in government child welfare programs may be associated with reductions in young women's engagement in sexual behaviors that could put them at risk for HIV, according to a longitudinal study conducted in two South African provinces.¹ Researchers compared the behaviors of adolescents whose families received benefits from either of two cash transfer programs—one available to low-income families with children and the other to foster families—with those of adolescents who were socially and demographically similar but whose families did not receive a cash transfer. Compared with those in the comparison group, female adolescents in the cash transfer programs had reduced odds of engaging in transactional sex (odds ratio, 0.4) and age-disparate sex (0.3) in the year between baseline and follow-up. Such reductions were not found among male participants.

The data come from a prospective, observational study conducted in two rural and two urban health districts in Mpumalanga and Western Cape, South Africa. The investigators recruited one male or female adolescent aged 10–17 at random from every household

in randomly selected census enumeration areas within the study districts until the desired sample size was reached. Participants completed private, face-to-face interviews in 2009–2010 and again one year later. The interviews collected demographic and family information, as well as data on whether participants had had transactional sex (sex in exchange for food, shelter, school fees, transport or money), age-disparate sex (sex with a partner more than five years older than the participant), sex without a condom, sex with multiple partners and sex after drinking alcohol or taking drugs.

Because differences in family characteristics and circumstances could account for variation in whether families had access to cash transfer programs, the researchers used propensity score matching to account for 23 possible covariates of inclusion in the program, including participant age, sex and location; caregiver characteristics and parenting practices; and household unemployment and assets. The researchers constructed a control group made up of youth whose households were not participating in a cash transfer program at both baseline and follow-up and who matched the program participants on as many of these variables as possible; participants who could not be matched or were younger than 12 at follow-up were included in descriptive analyses but excluded from regression analyses.

The full sample consisted of 1,926 females and 1,475 males, two-thirds of whom were in a cash transfer program at both baseline and follow-up. Among those whose households received cash transfers, the vast majority (99%) were in the child support program. At baseline, participants in the cash transfer and control groups had a mean age of 13 and 14, respectively. About one-third lived in informal housing, and at least two-thirds lived with one or both biological parents.

Transactional sex in the previous year was reported by 1% of both males and females in the cash transfer program and by 3% of males and 5% of females whose households did not receive a grant. About 1% of grant recipients of each sex and 3–4% of nonrecipients reported age-disparate sex, and 7% and 13–15%, respectively, reported unprotected sex. Drug or alcohol use before sex in the past year was reported by 1% of male and female grant recipients and by 3% of nonrecipient males and 1% of nonrecipient females. Finally, 8% of males and 4% of females in cash transfer

programs said they had had sex with multiple partners in the past year, compared with 19% of males and 10% of females not in the programs. All types of risky sexual behaviors were associated with each other, and reports of these behaviors increased with age.

A logistic regression analysis of the propensity score-matched sample revealed that among females, household receipt of cash transfer payments at both baseline and follow-up was associated with reduced odds of having had transactional sex or age-disparate sex in the past year (odds ratios, 0.5 and 0.3, respectively) and of having ever engaged in either behavior (0.5 and 0.4, respectively). Among males, cash transfers were associated only with reduced odds of having had multiple partners in the past year (0.7). Findings were similar in multivariate models that also controlled for baseline covariates.

The researchers emphasize that the positive relationship between the receipt of cash transfers and young women's sexual risk behaviors supports “the use of cash transfers as part of a combination prevention approach that targets structural, behavioural, and biomedical drivers of infection,” and they suggest that the household financial stability promoted by the transfers may help to reduce adolescent females' recourse to deprivation-driven sex. Because the study revealed little evidence of a relationship between household receipt of cash transfers and males' sexual risk behaviors, the investigators suggest that new strategies for reducing young men's HIV risk are needed.—*H. Ball*

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Prophylactic Treatment For HIV Does Not Lead To Risky Sexual Behavior

Receipt of HIV preexposure prophylaxis (PrEP) is not associated with an increase in sexual risk behaviors, suggests an international randomized trial among men who have sex with men or who identify as transgender or female.¹ Participants had reductions from baseline in levels of both acute HIV infection and syphilis infection. Those who believed that they were receiving PrEP instead of pla-

cebo had neither an increase in receptive anal intercourse without a condom while on study medication nor a decrease in this behavior after stopping it. Moreover, placebo recipients who believed that they were receiving PrEP did not have any rise in HIV infection relative to peers who believed that they were receiving placebo; the finding was the same if they also believed that PrEP was highly effective.

Researchers analyzed data from the Pre-exposure Prophylaxis Initiative (iPrEx) trial, which enrolled men who have sex with men or who identify as transgender or female at 11 sites in Peru, Ecuador, South Africa, Brazil, Thailand and the United States in 2007–2009. Participants were assigned to once-daily oral PrEP (emtricitabine plus tenofovir) or placebo on a double-blind basis. At various intervals, they were counseled about risk reduction, were screened for HIV and syphilis, completed questionnaires pertaining to sexual risk behaviors in the past three months, and indicated which treatment group they believed they had been assigned to and how effective they thought PrEP was at preventing HIV. Treatment lasted nearly three years; the final study visit took place eight weeks after participants had stopped taking their medication. The investigators used Poisson regression, t tests and chi-square tests to assess and compare temporal trends in sexual behaviors and infection rates, and developed mixed log-binomial regression models to identify correlates of changes in behavior from baseline.

Analyses were based on 2,408 participants who completed at least one quarterly study visit during which they reported on sexual behavior. All were male at birth, but 13% identified as women or transgender. They were 25 years old, on average, and three-fourths had been tested for HIV prior to the study.

At baseline, 0.4% of participants had acute HIV infection and 6% had syphilis. At the end of the treatment period, the incidence of acute HIV infection had fallen to 0.06% in the PrEP group and to 0.1% in the placebo group; the incidence of syphilis had dropped to zero in each group.

At the first quarterly study visit, 25% of participants believed they were in the PrEP group, 10% believed they were in the placebo group and the rest said that they did not know their group assignment. Overall, 24% believed that PrEP was highly effective. Eight weeks after participants discontinued their medication, no association was apparent between perceived treatment assignment

and changes in the number of partners with whom participants had recently had receptive anal intercourse: The number fell both among those who believed that they had been receiving PrEP (from 13 to four) and among those who believed that they had been receiving placebo (from eight to two).

At baseline, 39% of participants reported that they had not recently had receptive anal intercourse without a condom. Within this subset, the likelihood of reporting this risk behavior at any time during follow-up was elevated for participants who were younger than 25 (risk ratio, 1.3), identified as transgender or female (1.7), or had symptoms of depression (1.6). In contrast, these participants had a reduced risk of reporting unprotected receptive anal intercourse during follow-up if they had never been tested for HIV before starting the study (0.7). Notably, the risk of unprotected receptive anal intercourse was not associated with the belief that one was receiving PrEP or that PrEP was highly effective.

Among the 58% of participants who reported recent unprotected receptive anal intercourse at baseline, the likelihood of not reporting this behavior during follow-up was reduced for those who were younger than 25 (risk ratio, 0.8), identified as transgender or female (0.8), or had symptoms of depression (0.7); it was increased for those who had never been tested for HIV (1.4). Again, the behavior was not related to perceived treatment group or perceived effectiveness of PrEP.

Among participants who provided behavioral data both when they stopped using the study drug and eight weeks later, the proportion who reported receptive anal intercourse without a condom declined from 26% to 23% during that interval. Participants who believed they were receiving PrEP were no more likely than others to show a change in this behavior; moreover, findings were similar for the subset who believed PrEP is highly effective.

In the placebo arm, the incidence of HIV infection during follow-up was not elevated for participants who believed they were receiving PrEP, who believed that it was highly effective or who held both beliefs. In the entire trial population, the incidence of syphilis during follow-up did not differ by perceived treatment group.

Study limitations include potential lack of generalizability to clinical settings and reliance on self-reported sexual practices, according to the investigators; also, the results may have been influenced by treatment adherence,

and the trend toward safer behaviors may have reflected regression toward the mean or greater loss to follow-up of participants having risk behaviors. Nevertheless, the researchers note, the study's results show "no evidence of risk compensation that would offset the benefits of PrEP"; if anything, they suggest, the findings indicate trends toward safer sexual behavior and a reduction in HIV and syphilis infections. "Frequent clinic visits, HIV testing and counseling, and daily PrEP use itself may motivate and popularize safer sexual practices. Social interactions may be more important determinants of sexual decisions than individual weighing of risks and benefits," they conclude.

—S. London

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