In Clinical Trial, Women Using Once-a-Month Injectable Contraceptive Avoid Pregnancy and Approve of Method

A new monthly injectable contraceptive is highly effective, safe and well accepted among women, according to two studies based on a U.S. clinical trial comparing the injectable with an oral contraceptive. A study of the efficacy and safety of the Lunelle Monthly Contraceptive Injection reports that during the first year after participants chose their method, no pregnancies occurred among women using the injectable, while oral contraceptive users had two pregnancies.[1] Side effects among women in the injectable group were generally minor and were similar to those documented in other studies of women taking combined hormonal contraceptives, including weight gain, irregular or prolonged bleeding, and acne. An assessment of women's satisfaction with their method reveals that more than 80% of those using the injectable considered their experience with it somewhat or very favorable, and more than 90% said that they were likely to recommend the injectable to a friend.[2]

Both studies are based on data collected from 1,103 women who sought contraceptives at 42 clinical sites in the United States between April and August 1998. Women were eligible to participate in the trial if they were aged 18–49, were not pregnant, had not had an abortion within the past five days and had not given birth within the past four weeks. All of the women had used contraceptives (hormonal or nonhormonal) prior to enrollment. Women were excluded if they had contraindications to hormonal contraceptive use; were older than 35 and smoked or had chronic hypertension or diabetes; had a history of alcoholism or drug abuse; or had received another injectable contraceptive within the past six months.

The investigators offered each participant the choice of receiving either the monthly injectable (which contains 25 mg of medroxyprogesterone acetate and 5 mg of estradiol cypionate) or a commonly prescribed triphasic oral contraceptive. Participants (of whom 782 chose the injectable and 321 the pill) agreed to use their method for at least 60 weeks and to return monthly to receive their next injection or packet of pills.

Efficacy and Safety

In both the injectable and the oral contraceptive groups, the women's average age was 27–28 years; the groups also were similar with respect to weight, body mass index and previous menstrual patterns. Injectable users were less likely than women who chose the pill to be white (68% vs. 74%) and to have used a hormonal contraceptive in the past (44% vs. 65%); they were more likely ever to have been pregnant (64% vs. 45%). Fifty-five percent of women in the injectable group completed the trial, as did 68% of those in the oral contraceptive group.

One-year contraceptive efficacy was assessed on the basis of 8,008 woman-cycles of use for the injectable and 3,434 woman-cycles for the triphasic oral contraceptive. During that year, no pregnancies occurred in the injectable group, and one occurred in the oral contraceptive group. (Another pregnancy occurred during the 15th cycle in the oral contraceptive group.)

The women used monthly diary cards to report the number of days on which they experienced bleeding or spotting. Users of both methods experienced regular menstrual cycles after the first month, and reported fewer days of bleeding or spotting as the duration of use increased. For the first six months, pill users reported more frequent bleeding than women in the injectable group; throughout the year, however, injectable users had more irregular bleeding than women taking the pill.

Over the course of the study, 89% of women in the injectable group experienced some adverse effect of method use, including infection, headache, breast tenderness, weight gain, irregular or prolonged bleeding, and acne. Eighty-four percent of pill users experienced similar effects. Only 20% of injectable users and 8% of pill users dropped out of the study because of these side effects. The only serious medical problems that investigators linked to the contraceptive method being used were two instances of gallbladder disease, which required laparoscopic surgery. Both were in the injectable group, and these women continued to participate in the study after surgery.

Acceptability

The acceptability study was based on the women's responses to three questionnaires: one assessing their contraceptive history and attitudes toward the method they chose for the study, one addressing specific aspects of using the method they selected and one exploring their feelings about their psychological well-being. The questionnaires were administered at the beginning of the trial and 20, 40 and 60 weeks later. Approximately 85% of the women completed the initial and final questionnaires. To assess the influence of recent pill use, the investigators divided the oral contraceptive group into those who had been using the pill for at least 60 days before they entered the study (209 women) and new users (112).

Women in the injectable group were less likely than those in the oral contraceptive group (prior and new users combined) to report that use of the method was not at all bothersome (80% vs. 92%). They also were less likely to find it very comfortable to take their method (55% vs. 75–79%); the investigators state that this discrepancy is to be expected when comparing use of an oral with an injectable method.

Of women using the injectable, 86% said that the method did not interfere with social activities (interactions with friends and family that were not work- or school-related); similar proportions of pill users (90–94%) gave this response. Somewhat greater differences emerged with respect to daily activities (such as attending work or school, or doing housework): Eighty percent of injectable users reported interference, compared with 92–95% of pill users.

About half of injectable users (47%) reported that their sexual relationship was always satisfactory; the proportion was similar among new pill users (44%), but

was higher among prior users of oral contraceptives (62%). Fewer than one-fifth (17%) of the injectable group reported a dampening or loss of libido, as opposed to nearly one-fourth (23%) of new users and one in 10 (11%) prior users of oral contraceptives.

When asked whether it was difficult to return for the monthly office visits, the women in all three groups gave similar responses: Eighty-seven percent of the injectable group said it was not difficult to return monthly; 80% of new and 86% of prior users of oral contraceptives agreed that it was not.

Roughly equal proportions in all three groups (83–86%) rated their overall experience with the method as somewhat to very favorable. Likewise, more than 90% in each group said they probably or definitely would recommend the method to a friend.

In all three groups, the women's assessment of their psychological well-being decreased over time. However, the changes did not differ substantially for injectable users and new pill users; furthermore, results of regression analyses indicated that the changes were similar for the injectable group and the pill group overall.

The investigators note that the results may be limited by selection bias: First, participants chose their contraceptive method and were not randomly assigned. Second, two-thirds of women in the oral contraceptive group had been using the method for some time and therefore are not strictly comparable to women using a new method. Nevertheless, the researchers conclude that the monthly injectable "may be well accepted by those women who desire the convenience of an effective but noncoital, nondaily-use method that maintains regular cycles and causes minimal lifestyle alterations."—*M. Reiss*

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Infants Fathered by Men Who Are Exposed to Radiation In the Workplace Have an Elevated Risk of Being Stillborn

A man's workplace exposure to ionizing radiation, a known mutagen, may increase the risk that an infant he fathers will be stillborn, according to a study based on workers at a British nuclear reprocessing plant.[1] The risk of stillbirth increased by 24% for each 100 millisieverts (mSv) of radiation that a man had been exposed to in his lifetime; it rose even further if the infant had a congenital anomaly, particularly a neural-tube defect.

The study is based on data linking records of all singleton births (live births and stillbirths) in 1950–1989 in the county of Cumbria to employee records from a nuclear plant there. Men's records included information that was routinely gathered for regulatory and radiological protection purposes on occupational exposure to radiation. The researchers conducted both a cohort analysis and a case-control study to examine the effects of a worker's radiation exposure on the risk of stillbirth. They focused on this outcome because the causes of stillbirth include congenital anomalies, which in turn may result from genetic factors.

Workers' lifetime exposure to ionizing radiation up to the time that their partners conceived varied widely (0.1–911 mSv), but generally was low. The median lifetime exposure was 30.1 mSv; only 1% of men had had a total dose of more than 350 mSv. The median exposure in the 90 days before conception was 1.7 mSv.

Over the study period, partners of radiation workers had 9,078 live births and 130 stillbirths. The resulting stillbirth rate (14.1 per 1,000 live births) was essentially the same as the rate among women in the county whose partners did not work at the nuclear plant (14.7 per 1,000). However, when the investigators standardized the data for year, social class and birth order, they found significantly more stillbirths among the offspring of radiation workers (130) than expected (115).[2]

For the cohort analysis, the investigators used logistic regression techniques to assess the risk of stillbirth, controlling for birth order and year of birth, and for father's social class and age. Results indicated that for every 100 mSv of a man's lifetime exposure to ionizing radiation, the odds that his infant would be stillborn increased by 24%; for every 10 mSv of exposure in the 90 days before conception, the odds of stillbirth rose by 86%. To assess whether the stillborn infant whose father had the highest lifetime exposure to radiation affected the results, the researchers recalculated the odds, excluding that birth; in this analysis, the increase in risk dropped to 17% and was no longer statistically significant. Additional calculations to examine the relationship between a man's total dose of radiation and the odds of stillbirth revealed that the risk increased gradually up to about 425 mSv of lifetime exposure and then rose steeply.

Beginning in 1961, information was available on the cause of death among stillborn infants. Analyses using these data revealed that each 100 mSv increased the risk of stillbirth resulting from congenital anomalies by 43%; the increased risk of stillbirth attributable to neural-tube defects was even higher—69%. The stillborn infant whose father had been exposed to the highest dose of radiation did not have a congenital anomaly and so did not influence these results.

In the case-control study, which used more accurate dose measures than the cohort study, the investigators used conditional logistic regression analysis to assess the odds of stillbirth versus live birth among partners of radiation workers. Results for lifetime exposure to radiation were similar to those from the cohort analysis: The risk of stillbirth increased by 30% for every 100 mSv of exposure, but when the stillbirth associated with the highest lifetime dose of radiation was excluded from the analysis, the risk was reduced and was no longer statistically significant. This analysis, however, showed no significant effect of exposure in the 90 days before conception; according to the researchers, the differences in results for short-term exposure may relate to differences in how exposure was measured in the cohort and case-control studies.

Finally, the researchers used a variety of approaches to estimate the number of stillbirths that could be attributed to the father's exposure to radiation. Results varied according to the estimation procedure, but suggested that of the 130 stillbirths occurring among workers' partners throughout the study period, 0–32 might (with 95% likelihood) have been caused by the effects of radiation.

The analysts observe that their study was "the largest and most comprehensive investigation of transgenerational effects in any workforce occupationally exposed to

ionising radiation and…one of the few to use prospective dose measurements for each individual." Furthermore, they note that "statistical analysis showed no evidence of unmeasured factors influencing stillbirth risk." Nevertheless, they acknowledge the possibility that some unmeasured risk factor confounded their results.

A commentary accompanying the study stresses the need to keep the possible risk of stillbirth associated with exposure to radiation "in perspective."[3] Particularly, the author points out that with "no obvious mechanism" to explain this association, it cannot be assumed to be causal. Furthermore, she notes that both stillbirth rates and workers' exposure to radiation declined sharply over the years studied, and if the association is causal, the increased risk is lower than that associated with above-average maternal age.—*D. Hollander*

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As Many Lesbians Have Had Sex with Men, Taking a Full Sexual History Is Important

Roughly three-quarters of lesbians who responded to a magazine survey have had sexual intercourse with men, and nearly two-thirds have had unprotected heterosexual intercourse. One-sixth of respondents have ever had anal intercourse with a male partner, and the same proportion have ever had a sexually transmitted disease (STD). Researchers analyzing the survey results point out that clinicians should be aware of the need to take a full sexual history of their lesbian patients, so opportunities to refer women for needed Pap smears or STD screening will not be missed.[1]

The data come from responses to a 186-item questionnaire that was included as an insert in the March 1995 issue of *The Advocate,* a national newsmagazine for gay, lesbian and bisexual men and women. The sample of 6,935 self-identified lesbians who returned the questionnaire responded to items asking about their sexual experience with men and about their history of STD testing and diagnosis. Respondents were also asked to provide information on their social and demographic characteristics, including race or ethnicity, age, annual income, educational attainment and population size of their community. Researchers performed multivariate logistic regression analyses (with the variables that proved significant in bivariate analyses) to determine which factors independently affected women's likelihood of ever having had vaginal intercourse, of having had sexual intercourse without a condom and of having had a male sexual partner in the previous year.

The majority of the women were white (88%), were aged 25–49 (85%) and had graduated from college (63%). Seventy percent reported an annual income of more than $20,000, and 35% lived in cities of more than a million people.

Six percent of the sample had had sex with a male partner in the past year. Some 77% had ever had a male sexual partner, and 71% had had penile-vaginal intercourse; while the first of these proportions varied significantly by the respondent's race, age, education and community size, the latter varied significantly by all five characteristics under study. The proportion ever having had intercourse without a condom—64%—also varied significantly by each characteristic, except for community size. One-sixth of the women (17%) had ever had anal intercourse, and a similar proportion (16%) had ever done so without a condom; the proportion ever having had anal intercourse differed significantly by the respondent's age, education and community size, and the proportion ever having had unprotected anal intercourse varied by these same three characteristics, plus income.

Overall, 17% of the sample had had an STD; this proportion was significantly higher among lesbians who had ever had heterosexual intercourse than among those who had not (21% vs. 7%). Similarly, the proportion testing positive for an STD was significantly greater among those who had had anal intercourse (31%) than among those without such experience (14%).

While the overall proportion who had ever had an abnormal Pap smear was 17%, it rose to 20% among lesbians who had ever had penile-vaginal intercourse and to 26% among those who had ever had anal intercourse. Again, the proportions were significantly lower among lesbians who had not participated in these activities (10% and 16%, respectively).

Rates of HIV testing were higher in the subgroups of lesbians who had experienced anal (63%) or vaginal (58%) intercourse than in the overall sample (53%). Nevertheless, among those who had engaged in unprotected anal or vaginal sex, two-fifths had never had an HIV test.

In the multivariate analyses, the variables that independently raised lesbians' likelihood of having had a male sexual partner within the past year were young age, low income, nonwhite race and not having graduated from college. For example, respondents younger than 25 were 6.7 times as likely as those older than 50 to have had a male partner in the past year; lesbians with an annual income of less than $20,000 were 1.5 times as likely as those who made more than $50,000 to have done so; nonwhites were 1.4 times as likely as whites to have had a recent male partner; and non–college graduates were also 1.4 times as likely as graduates of a professional school to have had a male sexual partner in the past year.

Advocate readers who had not graduated from college were significantly more likely than those with a postgraduate degree to have ever had heterosexual intercourse (odds ratio, 1.5). Lesbians younger than 50 were significantly less likely than older women to have done so (0.4–0.7); respondents who lived in either rural areas or in cities of fewer than one million inhabitants also had a reduced likelihood of having had heterosexual sex (0.8).

Among respondents with a history of vaginal intercourse, women younger than 25 were substantially less likely than those older than 50 to have ever had heterosexual intercourse without a condom (odds ratio, 0.2); those aged 25–50 also had reduced odds of having had unprotected vaginal intercourse (0.5). Respondents who had not graduated from college had slightly elevated odds of having had penile-vaginal intercourse without a condom (1.6). This analysis also took into account the number of male partners a woman had had, and the results are dramatic. Compared with respondents who had had sex with only one man, those who had had 2–5 male partners were 2.3 times as likely, and those who had had six or more male partners were 11.2 times as likely, to have had unprotected penile-vaginal sex.

The researchers affirm that because the study did not use probability sampling, its generalizability to all U.S. lesbians is limited. What is more, they acknowledge that respondents to sex surveys tend to hold more liberal sexual attitudes and be more sexually active than those who choose not to respond; this sample of magazine readers was also relatively affluent and well educated. According to the researchers, however, the magazine-insert

approach improved on previous efforts to ascertain levels of sexual activity among U.S. lesbians, since it was a broad-based media solicitation that reached a large number of lesbians in all 50 states.

The data reveal that substantial proportions of lesbians have engaged in sexual activity with men, which places them at risk for a range of STDs and for cervical cancer. Therefore, the researchers assert that if clinicians automatically assume that lesbians have had no sexual contact with men, these health professionals might miss opportunities to give appropriate advice or recommendations to patients in their care. They conclude that "it is important for the clinician to know a patient's complete medical and social history, including current and past sexual activity, to make appropriate decisions regarding the provision of appropriate health care."—*L. Remez*

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Repeated Screening for Sexually Transmitted Diseases In School Programs Lowers Males' Chlamydia Rate

Chlamydia infection was detected during the 1997–1998 school year among 3% of male students in three Louisiana high schools where a program offering repeated screening and treatment for sexually transmitted diseases (STDs) had been introduced in 1995. By contrast, the prevalence rate was 6% among young men at five schools where an STD program was initiated only that year. The presence of an STD screening and treatment program was not associated with a similar decline in the rate of infection among female students.[1]

The three schools that initially introduced the program were located in urban areas, had on-site health centers and had a total enrollment of about 2,200–2,500 students in grades 9–12 each year from 1995 through 1998; 52–65% of students participated in the program each year. The five schools that began the program in 1997 were demographically similar to the original three, but four of these did not have a school-based health center; the 2,652 students in these schools who obtained at least one STD test through the program served as a comparison group for studying the effect of repeated testing. All students in the original three schools were black, as were 98% of students in the comparison group. Approximately two-thirds of each group participated in a free or reduced-fee lunch program.

During the recruitment process, all students were educated about STDs and were encouraged to be tested, whether or not they were sexually active. Students could participate in the screening only if they had parental consent to receive services from the school-based health center or to obtain testing through the STD program. In the 1995–1996 school year, programs used urine tests to screen for chlamydia; in the 1996–1997 and the 1997–1998 academic years they also tested for gonorrhea. Students who tested positive for an infection were counseled and treated with antibiotics. Screening was offered twice annually during the first two years of the program and once during the third year. Researchers calculated prevalence and incidence rates of STDs according to the number of students who participated in testing. They also examined the prevalence of symptoms and students' likelihood of seeking STD services.

In all eight schools combined, the prevalence of chlamydia among students tested for the first time was 12% for young women and 6% for young men. A chlamydia diagnosis was more common among older students than among younger ones. For example, 9% of female ninth graders tested positive for chlamydia when first screened, compared with 14% of young women in grade 12. In grades 9–11, female students were approximately twice as likely to have chlamydia as their male counterparts.

Gonorrhea rates were also higher among young women than among young men. Overall, nearly 3% of young women tested positive for gonorrhea at their first STD test, compared with 1% of young men. Rates were similar among students in different grades (1–2% among male students and 2–3% among females).

Repeated STD screening was associated with a decrease in chlamydia prevalence among young men. During the third year of testing, the chlamydia rate was 3% among males in the schools where screening was offered repeatedly—half the rate in those schools at the start of the program and half the rate in the comparison schools. Gonorrhea prevalence among males was similar at all schools and at all points in the study (about 1%).

The chlamydia rate for women during the third year of testing was 10% at the original three schools, compared with 12% at the schools where STD screening had not initially been offered. The gonorrhea rate among women in the original group of schools declined from 3.3% during 1996–1997 to 1.8% during 1997–1998, differing only slightly from the rate of 2.1% among women at the comparison schools.

The combined incidence of chlamydia diagnoses in the three schools offering repeated testing varied over time from 6.6 to 11.4 new infections per 1,000 person-months for women and from 2.1 to 4.5 per 1,000 person-months for men. Ultimately, the incidence decreased for males between the first and fifth testings (from 4.5 to 2.8), while it increased for females (from 7.2 to 11.4). The incidence of gonorrhea, which was measured only three times, dropped from 1.1 to 0.4 infections per 1,000 person-months among males and from 5.1 to 2.5 per 1,000 person-months among females.

The majority of STD infections diagnosed by the screening programs were asymptomatic. Of those students with chlamydia or gonorrhea for whom researchers had information about symptoms, approximately 90% did not report a symptom. In the final year of testing at the original schools, 3% of students reported having had an STD symptom during the past year, and young women were more than twice as likely as young men to do so.

Among those with STD symptoms in the previous 12 months, 75% of male students and 85% of females had pursued treatment. Among students with no symptoms in the past year, 13% of males and 25% of females said they had been screened for an STD outside the school-based clinic. Young women who reported having been screened for an STD in the past year were about twice as likely to test positive for chlamydia or gonorrhea as were those who had not been tested (20% vs. 10%).

The researchers suggest that the successful implementation of the in-school STD screening and treatment programs was dependent on the support of individual principals and teachers, and that there can be financial barriers to replicating these programs on a wide scale. Further, the researchers note that some students may be having sexual intercourse with partners who are older than high school age and unreached by an in-school program, thus potentially compromising

STD treatment. However, they contend that the "continued overall decline in prevalence and incidence [of chlamydia] among boys was very promising," and that "if the United States develops a national strategy to control chlamydia and gonorrhea in adolescents, school-based testing and treatment will be a critical component."—*M. Moore*

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Women Aged 15–29 Are Increasingly Having First Children Before Marriage

The proportion of first births to 15–29-year-old women that occur outside of marriage has more than doubled in the United States since the early 1970s, rising from 18% in 1970–1974 to 41% in 1990–1994.[1] Additionally, women who become pregnant before marriage are less likely to marry today than they were in the early 1970s (23% vs. 49%). A Census Bureau analyst examining women's marriage and childbearing patterns considers the increasing tendency of women to delay marriage in favor of education and career, as well as the growing prevalence of cohabiting relationships, to be contributing to these changes.

The analysis is based on data from fertility and marital history supplements to the June 1980 and 1995 Current Population Surveys. Women were classified as having had a premarital birth if their first child was born before their first marriage. Those whose first birth occurred within seven months after their first marriage were said to have had a premarital conception. Women whose first child was born eight months or more after their first marriage were classified as having had a postmarital conception. The analyst looked at first births because their status is often predictive of women's future reproductive choices.

In the early 1970s, among women aged 15–29 who became first-time mothers, about one in three infants were born or conceived premaritally. This proportion rose to one in two in the early 1990s, but the pattern of change was very different for premarital births and conceptions. The proportion of first children who were born before their mother married increased from 18% to 41%, while the proportion conceived premaritially decreased from 17% to 12%.

The proportion of premaritally pregnant women who married before the birth of their first child also decreased from the early 1970s (49%) to the early 1990s (23%). According to the analyst, this decrease may be attributed, in part, to social changes that occurred from the early 1960s to the early 1980s. She notes that although fertility control was reaching new heights in these decades because of the pill and easing of abortion laws, women were postponing marriage longer to pursue education or a career and were becoming sexually active at younger ages. She also speculates that women became less likely to marry the father of their child simply because they were pregnant.

Patterns of marriage and childbearing differed considerably according to a woman's race. Among black women, 86% of first children were premaritally born or conceived in the early 1990s; the proportion had been 74% in the early 1970s. In both periods, premarital births far outnumbered premarital conceptions. One in 10 black women in the early 1990s married before their premaritally conceived child was born, half the proportion who had done so in the early 1970s.

By contrast, in the early 1990s, 45% of white women's first births were premarital or resulted from premarital conception; 20 years earlier, the proportion had been 29%. Interestingly, while premarital births were less common than premarital conceptions in the early 1970s (11% vs. 18% of first births), the reverse was true in 1990–1994 (32% vs. 13%).

Among women of Hispanic origin, who could be of any race, 46% of first children were born or conceived premaritally during the early 1970s and 54% during the early 1990s. Thirty-five percent of premaritally pregnant Hispanic women married before the birth of their first child in the early 1970s. This rate dropped to 27% in the late 1970s and remained in that area through the early 1990s. The rate at which Hispanic women marry after a premarital conception is not significantly different from the rate among their non-Hispanic counterparts (26% vs. 23% in the early 1990s).

Among teenagers, the proportion of first births that occurred premaritally or resulted from premarital conceptions rose from 65% in the early 1970s to 89% in the early 1990s. Teenagers became two-thirds less likely to marry before the birth of a premaritally conceived child between the early 1970s (47%) and the early 1990s (16%).

Premaritally born or conceived children represented 85% of all first births to white teenagers in 1990–1994; they had accounted for 59% of first births two decades earlier. Only one-fifth of white teenagers married before their premaritally conceived child was born in the early 1990s, compared with three-fifths in the early 1970s. Among black teenagers 98% of first children were born or conceived premaritally in the early 1990s; this proportion had increased from 88% in the early 1970s. The proportion of black teenagers who married before the birth of their premaritally conceived first child dropped from 15% in the early 1970s to 7% by the early 1990s.

In 1990–1994, 81% of first children born to Hispanic teenagers were premaritally born or conceived. This proportion represents an increase from 66% in the early 1970s. The proportion of premaritally pregnant Hispanic teenagers who married before giving birth fell by about half between 1970–1974 (38%) and 1990–1994 (18%), roughly paralleling the pattern among their non-Hispanic peers.

Which women who become pregnant before marriage are likely to marry before their child is born? One-quarter of premaritally pregnant women aged 15–44 in 1990–1994 married before the birth of their child. Using logistic regression techniques, the analyst found that teenagers were less likely than women 20–24 years old to marry (odds ratio, 0.5), and women in their early 30s were more likely than women in their early 20s to do so (3.0). The researcher speculates that women aged 30–34 may have been cohabiting with their partners at the time the pregnancy occurred, and thus may have been more likely to decide to marry than younger adults or teenagers. In addition, black women, women who did not graduate from high school and women in the Midwest had significantly reduced odds of marrying while premaritally pregnant (0.2–0.6).

As the analyst observes, out-of-wedlock births have long been a national concern, especially when they occur among teenagers, because of "the emotional and economic vulnerability of young women and the…consequences for their infant children." Nevertheless, she notes that a growing societal acceptance of premarital pregnancies and births has been accompanied by an increase in programs that seek to "look at the issue from the viewpoint of mothers' and their children's health and well-being."—*L. Gerstein*

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Fertility Drugs Do Not Raise Breast, Ovarian Or Uterine Cancer Risk

Women who take ovulation-inducing drugs in conjunction with in vitro fertilization are not at increased risk of developing breast, ovarian or uterine cancer, according to a large Australian cohort study.[1] However, women who seek treatment but do not take fertility drugs have more than twice the expected incidence of uterine cancer, and women with unexplained infertility have elevated rates of uterine and ovarian cancer.

The study was based on data on 29,700 women who registered for treatment at 10 in vitro fertilization clinics before January 1, 1994. Clinic records provided background information on the women (including the cause of their infertility) and details about their treatment (including dates and type of treatment, fertility drugs used and number of oocytes collected after each cycle of treatment). By linking clinic records to population-based cancer registries and the national death index, the analysts were able to assess the frequencies of breast, ovarian and uterine cancer in the cohort. They calculated standardized incidence ratios by comparing the frequency of each disease among women seeking infertility treatment with the expected frequency, given rates of cancer in the general population.

About two-thirds of the women underwent treatment involving drugs to induce ovulation; the remainder did not take fertility drugs, predominantly because they received no treatment (although a small proportion were treated without drugs). The median duration of follow-up was seven years for women who had taken drugs and 10 years for those who had not. In both groups, tubal factors were the most common cause of infertility (reported for about two-fifths of women); the cause of infertility could not be explained for about one in seven women in each group.

In all, 143 breast cancers, 13 ovarian cancers and 12 uterine cancers occurred among women in the study. Compared with the general population of Australian women, those who had taken fertility drugs were no more likely to develop these diseases. The frequency of uterine cancer, however, was nearly three times the expected frequency among women who were not treated with drugs (standardized incidence ratio, 2.5). Women with unexplained infertility had elevated frequencies of ovarian and uterine cancer (standardized incidence ratios, 2.6 and 4.6, respectively), and those with tubal infertility experienced a significantly reduced incidence of breast cancer (0.6).

While the frequency of disease was not related to the number of treatment cycles or the type of fertility drug used, the data suggest that it may be associated with a woman's responsiveness to ovarian stimulation. However, the results are based on small numbers and, the researchers comment, require further exploration.

Results of an analysis restricted to the 12 months following the last treatment showed an elevated incidence of breast cancer (2.0) and uterine cancer (5.0). The investigators suggest two possible explanations for these findings: The increases may have been partly attributable to early diagnosis of cancer during clinical management of infertility or related health problems. Alternatively, fertility drugs may promote the development of existing tumors.

As the analysts note, although their study has the advantage of being based on a large cohort, it has several important limitations. For example, 71% of the women had had no more than three treatments with fertility drugs; consequently, the effects of more extensive use of these drugs cannot be assessed from the data. Additionally, with a median follow-up period of only seven years, this study cannot predict the long-term incidence of cancer among women who have taken fertility drugs.

The authors of an editorial accompanying the study, while expanding on these concerns and others, remark that the results nonetheless provide "some reassurance for similarly treated women." They also point out that as symptomless cancers are increasingly detected in the context of treatment for infertility, "the study of cancer risk among women [receiving such treatment] will become increasingly complex."[2]—*D. Hollander*

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Range of Risky Behaviors Is Tied to Risk of Multiple Partners Among Teenagers

South Carolina high school students who have engaged in or who have been the victim of a range of risky behaviors are at risk of having had multiple sexual partners. For example, adolescent women who have experienced date violence or smoked marijuana are especially likely to have had two or more sexual partners, as opposed to no partners. Among adolescent men, those who have carried a weapon or have consumed alcohol are especially likely to have had multiple partners. Levels of involvement with risky behavior and its effect on sexual activity vary widely by race and gender. These findings, according to the researchers, point to the need for multifaceted prevention programs.[1]

The cross-sectional data come from responses to questionnaires distributed over the 1993–1994 academic year in 56 public high schools (grades 9–12) across South Carolina. A total of 3,805 anonymous questionnaires were used in the analysis—1,156 from white female adolescents, 1,143 from white males, 829 from black females and 677 from black males. Respondents were asked whether they had ever had sexual intercourse and with how many partners, and whether they had any involvement in 10 health risk behaviors—carrying a weapon, physical fighting, violently assaulting a date, being a victim of date violence, committing rape, being a rape victim, drinking alcohol, bingeing on alcohol, smoking marijuana and smoking cigarettes.

The researchers conducted polychotomous logistic regression analyses, controlling for grade level, for each racial-and-gender subgroup. These analyses explored how the 10 health risk behaviors were associated with three outcomes—having had one sexual partner, having had 2–3 partners and having had four or more. The resulting odds ratios compare the likelihood of each outcome with that of never having had sex.

Bivariate Results

Fifty-two percent of the white female adolescents had ever had sexual intercourse (19% with just one partner, 18% with two or three partners and 15% with four or more); the corresponding proportion among white male high school students was 61% (18% had had one partner, 18% had had two or three and 25% four or more). Among the young black women, 70% were sexually experienced (20% had had one partner, 24% had had 2–3 and 26% four or more); 88% of the black male adolescents had ever had sex (10% with one partner, 22% with 2–3 and 56% with four or more).

In all four racial-and-gender subgroups, the proportion of students reporting individual risk behaviors varied from less than 10% to about 50%. Young men in both racial subgroups were far more likely to have carried a weapon (35–50%) than were young women (9–14%). Important

gender differentials also emerged in the proportions reporting having physically fought (43–46% among males vs. 28–30% among females), having been raped (5–9% among males vs. 17–18% among females) and having been victimized by date violence (4–6% vs. 10%).

White high school students were more likely than black students to have ever smoked cigarettes (34–35% vs. 4–8%) or marijuana (25–35% vs. 9–23%), but differences by race in the proportions who had ever drunk alcohol were smaller (46–52% among whites vs. 32–42% among blacks). While there was virtually no difference among young women by race in the proportions who reported having been raped (17–18%), black men were more than twice as likely as white men to report having committed a rape (9% vs. 4%).

Multivariate Results

•*White females.* Once grade level and all risk behaviors were controlled for, four individual behaviors independently increased white female students' likelihood of ever having had sexual intercourse and of having had multiple partners: having been raped (odds ratios, 4.3–15.5), having been the victim of date violence (3.2–4.0), having drunk alcohol (1.5–2.5) and having smoked cigarettes (1.7–2.9). Smoking marijuana significantly increased the likelihood of having had 2–3 partners (3.5) and of having had four or more (8.1), but had no significant impact on the likelihood of ever having had intercourse.

•*Black females.* The same five risk behaviors were significantly associated with sexual activity among black females, although the pattern of the results was somewhat different than that observed for young white women. Having been a victim of date violence and having drunk alcohol again had independent effects on all three outcomes (odds ratios, 5.9–9.3 and 1.9–4.1, respectively). However, having been raped raised black females' likelihood only of having had four or more partners (4.5), and having smoked cigarettes was associated only with an increased likelihood of having had 2–3 partners (7.8) or four or more partners (5.4). Having smoked marijuana elevated the odds of four or more partners ninefold (odd ratio, 9.3). Physical fighting emerged as a sixth significant predictor of sexual activity in this subgroup: Black females who had been in a fight were roughly 2–3 times as likely as those who had not done so to have ever had sex, to have had 2–3 partners and to have had four or more partners (odds ratios, 1.9–2.6).

•*White males.* As expected, a somewhat different set of risk behaviors independently affected the number of sexual partners among adolescent men. For white young men, once grade level was controlled for, ever having consumed alcohol raised the likelihood of ever having had sex (odds ratio, 2.0) and of having had multiple partners (3.0–3.5). Other factors did not affect the odds of being sexually experienced, but elevated the likelihood of having had 2–3 or four or more partners: having carried a weapon (1.9–2.5), having been in a fight (1.7–5.2) and having smoked marijuana (2.8–4.1). A history of cigarette smoking increased the likelihood that young white men had had sex with four or more partners (2.6).

•*Black males.* While having carried a weapon independently elevated the likelihood of having had four or more partners among young black males (odds ratio, 4.7), having gotten into a fight doubled the likelihood of 2–3 and four or more partners (2.2–2.3). Having consumed alcohol had the strongest independent effect in this subgroup, increasing the likelihood of 2–3 partners by a factor of 13.3 and that of four or more partners by a factor of 15.2. However, having smoked cigarettes or marijuana failed to have any independent association with sexual activity among black males. In addition, none of the risk factors that were significant in this subgroup emerged as independent predictors across all three sexual-partner outcomes.

Conclusions

The researchers caution that their study is limited by its cross-sectional nature, so causality cannot be inferred, and by possible bias inherent in self-reported information. In addition, the in-school administration of the questionnaire might have introduced another potential source of bias, since students who were absent the day the survey was conducted are not represented. Nonetheless, the investigators assert that their robust findings of "associations between an increased number of sexual partners, violence, and aggression, and alcohol, tobacco and other drug use suggest the need for multicomponent prevention programs addressing all these risk behaviors." They recommend that clinicians elicit a thorough history of risk behaviors from their adolescent clients, along with a complete sexual history.—*L. Remez*

Reference

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