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RESEARCH ON INFERTILITY: DEFINITION MAKES A DIFFERENCE

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Although different definitions of infertility are used, research findings based on various definitions have not been systematically compared. To contrast the impact of five definitions of infertility on research findings, the authors analyzed data from the control group (randomly selected US women aged 20–54 years) of the Cancer and Steroid Hormone Study (1980–1983). For all definitions, an absence of recognized conception was the outcome of interest. Specifically, the authors examined the effect of various definitions of infertility on demographic characteristics of women classified as infertile, prevalence of a history of infertility, age at infertility classification, and cumulative incidence of conception after infertility classification. Results indicated that women classified as infertile by definitions based on *unprotected intercourse for 12 months* and *unprotected intercourse for 24 months* were more likely to be black, less educated, and classified as infertile at younger or older ages than women classified by alternative definitions. The prevalence of a history of infertility ranged from 6.1% (*physician diagnosis*) to 32.6% (*unprotected intercourse for 12 months*). For the definitions based on *unprotected intercourse for 12/24 months* and for *physician diagnosis*, the cumulative incidence of conception by >120 months after infertility classification was 86.3%, 76.7%, and 75.4%, respectively. The authors conclude that the definition of infertility has an impact on research findings related to which and how many women are classified as infertile, the age at infertility classification, and the probability of future conception.

Infertility; reproduction; women

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Infertility affects approximately 10–15 per cent of all couples in the United States (1, 2). For these couples, the monetary and emotional costs of infertility are profound (3–6). Despite the importance of infertility as an individual and public health problem, there is a paucity of research on the epidemiology of infertility. Efforts to better characterize the epidemiology of infertility are hampered by the lack of a standard definition (7–11). Although different definitions of infertility are used, research findings based on these various definitions have not been systematically compared.

To contrast the impact of various definitions of infertility on research findings, we analyzed data from the control group of the Cancer and Steroid Hormone Study conducted by the Centers for Disease Control (12). Specifically, we examined the effect of various definitions of infertility on: 1) demographic characteristics of women classified as infertile; 2) prevalence of a history of infertility; 3) age at infertility classification; and 4) cumulative incidence of conception after infertility classification.

Materials and methods

The Cancer and Steroid Hormone Study has been described in detail elsewhere (12). Briefly, it was a multicenter population-based case-control investigation of breast, endometrial, and ovarian cancers. Since infertility is a risk factor for all three of these cancers (13–15), persons with reproductive malignancy were not included in the present analysis. Instead, we used the control group of the Cancer and Steroid Hormone Study as our study population.

Study population

In the Cancer and Steroid Hormone Study, Waksberg's method of random digit dialing was used to select women aged 20–54 years from eight areas of the United States: the metropolitan regions of Atlanta, Georgia, Detroit, Michigan, San Francisco, California, and Seattle, Washington; the states of Connecticut, Iowa, and New Mexico; and the four urban counties of Utah. A proportion of women in each five-year age group was matched to the age distribution of breast cancer patients enrolled in the study. Of 5,698 women selected, 4,754 (83.4 per cent) agreed to participate, 11.9 per cent refused, and 4.7 per cent could not be located or interviewed within six months of selection.

Interviews

From December 1980 to April 1983, trained interviewers administered a detailed questionnaire to each study participant in her home. Lasting about an hour, the interviews focused on reproductive, contraceptive, and medical histories, use of medical services, and personal habits. A life calendar from menarche to menopause was constructed for each woman so that reproductive and contraceptive dates could be recalled in relation to such major events as marriages, divorces, births, and deaths.

Definitions of infertility

Although infertility is sometimes defined as difficulty in achieving a term or live birth (16–18), for this analysis we viewed infertility (difficulty in conceiving) as a subset of subfecundity (difficulty in achieving term birth) (1, 2). This view is consistent with that used in clinical medicine (19–23), and it highlights the fact that difficulty in conceiving may be related to factors that are distinct from difficulty in carrying a pregnancy to term (17).

We examined five possible definitions of infertility (table 1). In all five, an absence of a recognized conception was the outcome of interest. The first three definitions were based on self-reported answers to direct questionnaire items and were limited to couples specifically trying to conceive. The fourth and fifth definitions were based on computations from each respondent's calendar of reproductive and contraceptive events. The five definitions were not mutually exclusive. Because we did not have dates of infertility for the definitions *tried*

for two years and *physician consultation*, these definitions were excluded from time-dependent analyses. While infertility is a problem that is shared by the couple, we have reported characteristics of the female partner only, since the Cancer and Steroid Hormone Study did not collect information on characteristics of the male partner. In this paper, primary infertility refers to infertility that was not preceded by at least one conception. In contrast, secondary infertility had been preceded by at least one conception.

Analysis

For each definition of infertility, we computed the crude prevalence of a history of infertility as the proportion of women in the total study population who met the criteria for that particular definition. To facilitate comparisons with national data, prevalence proportions of a history of infertility were age-adjusted by the direct method (24). The age distribution of the 1980 US female population aged 20–54 years was used as the standard age distribution (25).

To determine the probability of at least one conception after infertility classification, we calculated cumulative incidence of conception using the product-limit (Kaplan-Meier) method (26). This technique of risk estimation allowed us to compute the proportion of women conceiving after infertility classification while decrementing the denominator to take various periods of follow-up into account. Conception distributions for primary versus secondary infertility were compared using the generalized Wilcoxon test proposed by Breslow (26).

RESULTS

Demographic characteristics

There was a preponderance of older women in the study population, because the ages of the women in this study were matched with those of breast cancer patients. Predominantly, the study population was white, had 16 or fewer years of education, and was raised as Protestant or Catholic (table 2). Within the study population, age and childhood religion distributions remained fairly constant with all five definitions of infertility. However, the characteristics of race and education varied according to which definition was used. Greater proportions of black women and less educated women were classified as in-

TABLE 1

Five possible definitions of infertility from the Cancer and Steroid Hormone Study, 1980–1983

Data source and infertility definition	Explanation
Specific item on questionnaire	
Tried for 2 yrs.	No conception after two years of trying to conceive
Physician consultation	No conception after two years of trying to conceive, and couple consulted physician for problem
Physician diagnosis	No conception after two years of trying to conceive, couple consulted physician for problem, and physician diagnosed problem in woman, partner, or both
Life event calendar	
Intercourse for 12 mos.	No conception after 12 months of unprotected intercourse
Intercourse for 24 mos.	No conception after 24 months of unprotected intercourse

TABLE 2

Demographic characteristics (%) of the study population, by five different definitions of infertility, Cancer and Steroid Hormone Study, 1980–1983

Characteristic	% of total study population (n = 4,754)	Definition of infertility				
		Tried for 2 yrs (n = 764)	Physician consultation (n = 582)	Physician diagnosis (n = 321)	Intercourse for 12 mos (n = 1,837)	Intercourse for 24 mos (n = 1,285)
Age at interview (years)						
20–29	5.8	2.5	2 2	3.7	3 5	2.7
30–39	21.6	21.6	22.3	25 2	20.3	17.9
40–44	16.4	16.5	16 0	14.6	15.2	14.4
45–49	26 1	24.7	24.2	24.3	28.1	28 2
50–54	30 1	34 7	35.2	32.1	32.9	36.9
Race						
White	86.9	89.9	91 0	90 3	84 5	82 3
Black	10.4	6.8	5.5	5.3	12.6	14.5
Other	2.8	3.3	3.6	4.4	2.8	3 3
Education (years)						
≤12	48 7	46.6	43.0	41.1	56 5	58 1
13–16	38.3	39.7	40 9	41 4	33.5	32 8
>16	13.0	13.6	16.0	17 5	9.9	8.9
Religion						
Protestant	55.3	52 8	52.6	53.6	56.0	56.7
Catholic	32 1	32.2	32.3	30.2	32.7	32.5
Jewish	2.6	2 0	2 2	2.8	1 7	1.3
Other	10.0	13.1	12 9	13 4	9.7	9.6

fertile by the definitions *unprotected intercourse for 12 months* and *unprotected intercourse for 24 months* than by other definitions.

Prevalence of a history of infertility

The prevalence of a history of infertility varied by definition (table 3). Since the study population was older than the standard population, age adjustment resulted in a somewhat lower prevalence of a history of infertility. The definition *unprotected intercourse for 12 months* reflected the highest prevalence; the definition *physician diagnosis* reflected the lowest. Thus, prevalence declined as criteria for infertility became more stringent.

Age at infertility classification

For all definitions, the highest proportion of women classified as infertile was in the age group 20–29 years (table 4). However, compared with the other definitions, a greater proportion of *physician-diagnosed* infertility was classified in this age group. When the definitions *unprotected intercourse for 12 months* and *unprotected intercourse for 24 months* were used, greater proportions of women were classified as infertile at younger and older ages. For example, 26.2 per cent of infertility defined as *unprotected intercourse for 12 months* was in the age stratum <20 years, compared with 7.6 per cent of *physician-diagnosed* infertility; 4.7 per cent of infertility defined as *unprotected intercourse for 24 months* was in the age stratum >39 years, compared with 0.4 per cent of *physician-diagnosed* infertility.

Cumulative incidence of conception

Women classified as infertile by the definition *unprotected intercourse for 12 months* had an 86.3 per cent probability of at least one conception by >120 months after infertility classification; women classified as infertile by the definitions *physician diagnosis* and *unprotected intercourse for 24 months* were also ultimately likely to conceive, but with a somewhat lower prob-

ability (75.4 per cent and 76.7 per cent, respectively) (table 5). Examination of the likelihood of conception by time interval after infertility classification showed that the greatest discrepancy among definitions occurred in the first six months. After the first six months, the proportions of women conceiving became more uniform for the three definitions. Approximately 20 per cent of women classified as infertile by any of the three definitions had their first conception after infertility classification in the interval between 24 and 72 months. Within each of the three definitions, the incidence of conception did not differ significantly for primary versus secondary infertility (table 6): For *physician diagnosis*, $p = 0.85$; for *unprotected intercourse for 12 months*, $p = 0.36$; and for *unprotected intercourse for 24 months*, $p = 0.13$. However, for all three definitions, the cumulative incidence of

TABLE 3

Prevalence (%) of a history of infertility, by five different definitions of infertility, Cancer and Steroid Hormone Study, 1980–1983*

Definition of infertility	Crude prevalence†	Age-adjusted prevalence‡
Tried for 2 yrs.	16.1	12.5
Physician consultation	12.2	9.6
Physician diagnosis	6.8	6.1
Intercourse for 12 mos.	38.6	32.6
Intercourse for 24 mos.	27.0	20 6

* A history of infertility included but was not restricted to current infertility.

† Computed as the proportion of women in the total study population who met the criteria for each definition of infertility; for example, among 4,754 women in the total study population, 764 (16.1%) met criteria for the definition *tried for 2 years*; the five definitions are not mutually exclusive.

‡ Standard population of US females aged 20–54 years, 1980

TABLE 4

Age at infertility classification (%), by three different definitions of infertility, Cancer and Steroid Hormone Study, 1980–1983

Age at infertility classification* (years)	Definition of infertility		
	Physician diagnosis (n = 236)†	Intercourse for 12 mos (n = 1,761)‡	Intercourse for 24 mos (n = 1,220)§
<20	7.6	26.2	15.7
20–29	73.8	59.9	61.7
30–39	18.2	11.0	17.9
>39	0 4	2.9	4 7

* Age of the female respondent

† Because of unavailable dates of infertility, excludes 85 women whose infertility was attributed exclusively to a male factor.

‡ Because of unavailable dates of infertility, excludes 76 women whose infertility was attributed exclusively to a male factor.

§ Because of unavailable dates of infertility, excludes 65 women whose infertility was attributed exclusively to a male factor.

TABLE 5

Cumulative incidence of conception (%) after infertility classification, by three different definitions of infertility, Cancer and Steroid Hormone Study, 1980–1983

Mos after infertility classification	Definition of infertility		
	Physician diagnosis (n = 236)*	Intercourse for 12 mos (n = 1,760)†	Intercourse for 24 mos (n = 1,219)‡
6	13.1 (13.1)§	30 4 (30 4)	20.0 (20.0)
12	28.0 (14.9)	42.8 (12.4)	32 6 (12.6)
24	47.4 (19.4)	59.7 (16 9)	46 7 (14 1)
72	67.5 (20.1)	78.6 (18 9)	68 2 (21.5)
120	72.2 (4.7)	83.8 (5 2)	74.7 (6.5)
>120	75.4 (3.2)	86.3 (2 5)	76 7 (2.0)

* Because of unavailable dates of infertility, excludes 85 women whose infertility was attributed exclusively to a male factor.

† Because of unavailable dates of infertility, excludes 76 women whose infertility was attributed exclusively to a male factor; excludes one woman because of uncertainty of conception status.

‡ Because of unavailable dates of infertility, excludes 65 women whose infertility was attributed exclusively to a male factor; excludes one woman because of uncertainty of conception status.

§ Stratum-specific incidence.

TABLE 6

Cumulative incidence of conception (%) after infertility classification for women with primary infertility versus women with secondary infertility, by three different definitions of infertility, Cancer and Steroid Hormone Study, 1980–1983

Mos. after infertility classification	Definition of infertility					
	Physician diagnosis*		Intercourse for 12 mos †		Intercourse for 24 mos ‡	
	Primary (n = 131)	Secondary (n = 105)	Primary (n = 955)	Secondary (n = 805)	Primary (n = 524)	Secondary (n = 695)
6	11.5	15 2	29.0	31.9	19 8	20.2
12	27.5	28.7	40.7	45.3	34.5	31.2
24	49.0	45.3	59 1	60 4	48 6	45.2
72	66.8	68.3	80.2	76 4	71.9	65.2
120	73.8	69.5	85 9	81 1	79.2	71 2
>120	77.8	71.3	88 4	83.3	81.0	73.2

* Because of unavailable dates of infertility, excludes 85 women whose infertility was attributed exclusively to a male factor.

† Because of unavailable dates of infertility, excludes 76 women whose infertility was attributed exclusively to a male factor; excludes one woman because of uncertainty of conception status.

‡ Because of unavailable dates of infertility, excludes 65 women whose infertility was attributed exclusively to a male factor; excludes one woman because of uncertainty of conception status

conception by >120 months was higher for primary infertility.

DISCUSSION

Infertility has been defined in a variety of ways. Most clinical definitions focus on an inability to conceive. Although failure to conceive after one year of attempting conception is the standard criterion, shorter or longer periods of time have been used (27, 28). In most clinical definitions is an implication that a person has attempted to conceive without success and has requested medical assistance. In contrast, research definitions of infertility may be less restrictive and may focus on the lack of conception after unprotected intercourse, regardless of whether a couple was actually trying to conceive (1, 2). In this analysis, we examined the relation between selected definitions of infertility and specific epidemiologic outcomes. Our results indicate that the definition of infertility has an impact on research findings related to who is classified as infertile, the age at infertility classification, and the probability of future conception.

Differences in demographic characteristics among women with various definitions of infertility cannot be completely explained by medical care utilization. The definition *tried for two years*, like the definitions *unprotected intercourse for 12 months* and *unprotected intercourse for 24 months*, is not predicated on access to health care. It is possible that the difference in demographic composition among the various definitions is, at least in part, a result of different data sources: The definitions *tried for two years*, *physician consultation*, and *physician diagnosis* were based on self-reported answers to direct questionnaire items, whereas the definitions *unprotected intercourse for 12 months* and *unprotected intercourse for 24 months* were based on data derived from each woman's life event calendar. However, to construct the life event calendar, each woman had to respond to direct questionnaire items related to contraception, sexual activity, and reproductive events. It is therefore unlikely that different data sources (i.e., direct report vs. computed report) fully account for observed differences.

We evaluated the prevalence of a history of infertility which included, but was not restricted to, current infertility. Although information on current infertility would have been of programmatic interest, evaluating a history of infertility allowed us to

assess the probability of conception after infertility classification. Since the Cancer and Steroid Hormone Study did not collect information on inability to conceive after a 12-month attempt, we could not evaluate a history of one of the most common clinical definitions of infertility. However, if the relation between the definitions *unprotected intercourse for 24 months* and *tried for two years* is similar to that between *unprotected intercourse for 12 months* and a hypothetical definition of *tried for one year*, then the prevalence of a history of infertility for *tried for one year* would be approximately 19.8 per cent ($32.6/x = 20.6/12.5$; $x = 19.8$).

Observed differences between the definitions *unprotected intercourse for 12/24 months* and *physician diagnosis* with respect to age at infertility classification are probably related to a woman's trying to conceive. All women classified as infertile by *physician diagnosis* had been trying to conceive, but this was not necessarily true of those classified by *unprotected intercourse for 12/24 months*. Although younger and older women may be more likely to have difficulty conceiving, they may be relatively less likely to be trying to conceive and to seek medical assistance for help in conceiving.

From a clinical perspective, our finding that most women had at least one conception by >120 months after infertility classification must be interpreted cautiously, since we were unable to determine how the probability of conception was influenced by medical evaluation and treatment. Both the high proportions conceiving and the similar predictive value of the definitions *physician diagnosis* and *unprotected intercourse for 24 months* may, to an important but unknown extent, reflect the efficacy of medical intervention. Without medical intervention, the likelihood of conception, especially after *physician-diagnosed* infertility, would probably be considerably lower. It is noteworthy that approximately 20 per cent of women classified as infertile by any of the three definitions had their first conception after infertility classification in the interval between 24 and 72 months. This challenges the frequently held assumption that couples who do not conceive within one to two years after infertility classification are likely to never conceive.

Since we could obtain information only from women who were alive at interview, selective survival could have influenced our findings. For example, since women with a history of infertility are at greater risk of reproductive malignancies, our prevalence proportions of a history of infertility are underestimates to the extent that such women died before they could be interviewed in our study. On the other hand, our estimates of cumulative incidence of conception are overestimates to the extent that women with a history of infertility but no subsequent conceptions died prior to interview.

Since the Cancer and Steroid Hormone Study was retrospective, some misclassification of information undoubtedly occurred. For the definitions *unprotected intercourse for 12 months* and *unprotected intercourse for 24 months*, women were required to remember the number of months of contraceptive use and of sexual activity. We have no reason to assume that women would be likely to preferentially overreport or underreport such events. Misclassification due to recall was minimized with the use of individual life calendars as memory aids.

Infertility encompasses a heterogeneous group of problems. Couples with different types of infertility are likely to have different risk factors, a different clinical course, and a different probability of future conception. As noted in Materials and Methods, the Cancer and Steroid Hormone Study was not specifically designed to investigate infertility. Thus, our ability to contrast definitions by cause of infertility and by treatment for infertility was limited. In fact, researchers often lack this ability, since definitions of infertility that are not predicated on medical care utilization (i.e., *tried for two years* and *unprotected inter-*

course for 12/24 months) can never be fully examined by type of infertility or by method of treatment, because not all women meeting these definitions have been evaluated by a physician. However, our study provided extensive information on contraception, reproductive events, and periods of sexual activity. This allowed us to look comprehensively at infertility in the aggregate.

We are aware of no other studies that compare research findings based on different definitions of infertility. Other studies have suggested, however, that research findings are likely to vary when different definitions of infertility are used. First, some studies have indicated that not all women who are infertile seek medical care for this problem (3, 29, 30). Second, the demographic profiles of women who seek medical services for infertility are different from the demographic profiles of women who do not (30). Therefore, while prior research suggests that different definitions of infertility could yield different research findings, our study has documented and quantified such differences.

Because the Cancer and Steroid Hormone Study was not designed to provide national estimates of infertility parameters, the major purpose of this paper was to make internal comparisons among the various definitions studied. However, since reliable information on the prevalence of infertility is readily available from the National Survey of Family Growth (1, 2), we adjusted our prevalence proportions of a history of infertility for age to facilitate comparisons with these national data. According to the 1982 National Survey of Family Growth, 8.5 per cent of all married couples in the United States in which the wife was aged 15–44 years were infertile based on the definition of no conception after one year or more of unprotected intercourse; among those who were not surgically sterile, 13.9 per cent were infertile (1, 2). We found, using the definition *unprotected intercourse for 12 months*, that the age-adjusted prevalence of a history of infertility was 32.6 per cent. Since our definition of a history of infertility included current infertility as well as past infertility, it is reasonable that our estimate was higher than estimates from the National Survey of Family Growth.

Our findings with respect to cumulative incidence of conception after infertility classification are consistent with the view that a diagnosis of infertility is not proof of sterility (1, 2). We found, as have other investigators (31–36), that a substantial proportion of women classified as infertile eventually conceive. This finding should not be misinterpreted as implying that infertile women who conceive have not been accurately classified as infertile. Infertility does not reflect inability to conceive. Rather, infertility reflects difficulty in conceiving during a specific period of time. While a conception occurring after this period of time would alter current infertility status, it would not negate past infertility status.

In summary, this analysis provides evidence that the definition of infertility has an impact on research findings related to which and how many women are classified as infertile, the age at infertility classification, and the probability of future conception. Since we did not have data on cause of infertility or treatment for infertility, our findings have more direct application in research than in clinical medicine. In addition, clinicians must consider a variety of factors as they decide who should undergo infertility evaluation and treatment. Our findings have important implications for researchers who must operationally and uniformly define infertility as an exposure variable, an outcome variable, or a control variable. It is important that researchers be aware that the definition of infertility makes a difference.

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