

Methods for obtaining valid data on time to pregnancy among men and women

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Growing evidence on reproductive effects associated with occupational and environmental agents has created the need for research using sensitive and well-validated methods.

There is a complex relationship between manifest effects and underlying pathogenic processes. Conceptions will, on the average, tend to be delayed in a population exposed to an agent that causes embryonic damage, an increase in germ cell mutations, or decreased fertility (1).

Time to pregnancy can be used to measure the degree of delay in conceiving, across the whole continuum of biological fertility, for either men or women. The distribution of time to pregnancy largely reflects a sorting process, as the more fertile couples become progressively less well represented with the passage of time (2).

The basic research strategy is a comparison of the time-to-pregnancy distributions of exposure-defined groups that allows for potential confounding factors relating not only to the study subject, but also to his or her partner. This approach is more sensitive statistically than dichotomizing the distribution at a cut-point, such as "clinical infertility" (12 months of unprotected intercourse without conception).

Prospective and retrospective methods are available, each having its strengths and weaknesses. Prospective studies have some theoretical advantages, but suffer from unrepresentative populations and problems of feasibility and cost.

A retrospective assessment of time to pregnancy is logistically much simpler, can cover an earlier period when exposures may have been higher, and can also examine time trends. It is feasible using a short questionnaire, without intruding into sensitive areas of respondents' lives, and has been found to be acceptable in a wide variety of cultural settings.

However, a crucial question relates to the validity of such retrospectively obtained data. To investigate the validity, three validation studies have been carried out.

In an American study of 523 predominantly white dental assistants, information from a short self-administered questionnaire was compared with data from a detailed telephone interview, concerning pregnancies that had occurred within the previous 4 years. Errors were mainly nondifferential, tending to reduce statistical power but not to lead to bias, and accuracy was unrelated to duration of recall. Although questioning was based on menstrual cycles, there was some evidence that women found it easier to think in months (3).

A Dutch study followed 132 participants in a prospective study of pregnancy failures and asked the participants about time to pregnancy. The duration of recall was up to 20 months. The reliability (test-retest) of the study showed great stability after 3 to 5 weeks, with both self-administered questionnaires and telephone or personal interviews, but random errors were fewer with personal interviews. No systematic errors were found (4).

In a British study, questionnaires were mailed to 1647 women who continue to be followed in the Oxford Family Planning Association Contraceptive Study, and a further 424 were approached for a personal interview. The response rates were 91% and 79%, respectively. The median recall time was 14 years (interquartile range, 11 to 16 years). At the group level, remarkably good agreement was found between the 2 sources of information; no difference was seen between the 2 formats. The findings were equally good when the analysis was confined to the half of the population for whom pregnancies had occurred more than 14 years previously (figure 1). Digit preference was present to a limited degree. At the individual level, some misclassification was evident, which

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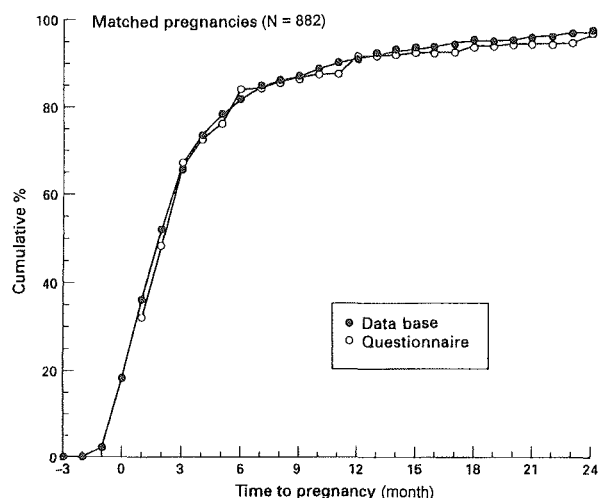


Figure 1. Comparison between data collected concurrently in the early or mid 1970s ("data base") as change of contraceptive method, occurrence of births, and the like with the results of a short time-to-pregnancy questionnaire self-administered in 1991 (5). All the pregnancies occurred 14 to 20 years prior to the questionnaire survey.

has implications for statistical power. Variations with the duration of recall, age at delivery, year of birth, parity, social class, smoking habit, last contraceptive method, and outcome (live birth or not) were generally small, and they were not statistically significant (5).

No validation studies have tested the ability of men to recall time to pregnancy. However, data quality can be assessed from an analysis carried out using the National Child Development Study, which has followed several thousand men and women since their birth in 1958. The male and female study members can thus be regarded as independent cohorts. In 1991, the interview included questions on time to pregnancy up to the age of 33 years. The time-to-pregnancy distributions of the men and women were identical, and separate analyses of the determinants of reduced fertility gave closely similar findings (tables 1 and 2) (6).

Thus time to pregnancy is a sensitive way of assessing reproductive function for either gender. Valid data at a group level can be derived retrospectively, with a long duration of recall, using a short questionnaire — and without the necessity of very large populations. Potential biases have been identified that can be minimized by careful design and analysis. The principal problem is the difficulty in obtaining high-quality data on exposures and covariates retrospectively.

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Table 1. Cox model of the effect of age and smoking on time to pregnancy in a representative sample of people born in Great Britain in 1958 (6). (95% CI = 95% confidence interval)

Model	Risk ratio	95% CI	P-value
Female cohort member (N=2942)			
Mother's age over 30 years	0.80	0.72-0.89	0.0001
Mother's smoking	0.89	0.83-0.97	0.005
Father's smoking	0.92	0.84-1.00	0.048
Male cohort member (N=2418)			
Father's age over 30 years ^a			0.195
Mother's smoking	0.89	0.81-0.98	0.022
Father's smoking	0.90	0.83-0.98	0.018

^a Variable did not meet the criteria for entry, as is indicated by the P-value.

Table 2. Cox model of the effect of age, smoking, and educational level on time to pregnancy in a representative sample of people born in Great Britain in 1958 (6). (95% CI = 95% confidence interval)

Model	Risk ratio	95% CI	P-value
Female cohort member (N=2612)			
Mother's age over 30 years	0.77	0.68-0.86	0.0001
Mother's smoking	0.90	0.83-0.98	0.015
Father's smoking ^a			0.383
Mother's advanced level qualification	0.85	0.77-0.93	0.0003
Father's education up to 16	0.90	0.83-0.99	0.031
Male cohort member (N=2294)			
Father's age over 30 years ^a			0.083
Mother's smoking	0.88	0.81-0.97	0.013
Father's smoking ^a			0.089
Mother's education up to 16 ^a			0.062
Father's advanced level qualification	0.90	0.83-0.98	0.011

^a Variable did not meet the criteria for entry, as is indicated by the P-value.

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