

As everyone knows, there are different ways of asking the same question, and depending on the way the question is asked, one gets different answers. Every Gallup poll or opinion survey recognizes the importance of this problem, which is a particularly difficult one in medical questioning. For example, it has been shown that if a leading question has been asked such as "have you have headaches—or nausea or depression—this month" rather than a question such as "how have you been feeling this past month," one will record a frequency of headache—or nausea or depression—which is four to six times higher than if the second, nonleading question is asked. One may say, why not use the leading question and get a maximum estimate? Simply because the use of this question will suggest to many individuals that they ought to be having this symptom even if they do not.

If it is asked repeatedly, as we do in our studies where we follow every patient every month, more and more subjects will think they ought to be having this particular effect, and will report accordingly.

Another problem is the great differences in population groups, which I believe is at least one factor which markedly differentiates the American experience from the British experience where the population is known to be much more homogenous.

I ask you to consider the results of one large clinical study we monitored, where the same drug, the same protocol and the same method of questioning were used in 18 different clinics—17 in this country and one in Mexico—and this study involved some 5,400 patients, and some 75,000 cycles.

If you will look at the diagram: in the first cycle of treatment the response to the nonleading question "how have you been feeling" produced frequencies of nausea which ranged from 0 all the way to 33 percent. Now the question is, which of these values is correct? And the answer is, all of them—and none of them. There is no single answer which tells the whole truth.

Consider also that each of these numbers assumes that each case of nausea—headache, depression, et cetera—was associated with the pill. Obviously, women who do not take the pill also have nausea, depression, headache, et cetera from time to time. The real frequency is therefore some number less than the reported frequency. This spontaneous occurrence, the so-called placebo frequency, has been studied by very few groups aside from our own. There is a study in Switzerland, a study in Sweden, and there was one out at Stanford, and there is a double blind study in which we are involved at the present time.

One thing we did, before we got into the present double blind study, which is still simply an approximation to this problem, was to take our oral contraceptive questionnaire and simply apply those questions to a group of women who were coming into clinics for a routine checkup of their intrauterine device.

These women were not, and had never taken oral contraceptives; but the frequency of their complaints of headaches, depression, loss of sex drive and so forth were approximately the same as those of women who had been on the pill for 3 months or more.

A much better study—which appears in the book edited by Kipnis and others, and published earlier this year—is by Dr. Moos of Stanford. I have reproduced here some of his data where he asked women