Figure 10.1. EXPERIMENTAL PLANS: An Example from Breast Cancer Research

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Link between high-fat diet, breast cancer sought

TORONTO (CP) – At least two Canadian cancer research centres are considering taking part in an expensive and ambitious study to determine whether a high-fat diet increases the incidence of breast cancer.

British Columbia's Cancer Control Agency will apply to enroll about 2,000 women in the study by U.S. researchers, and Toronto's Princess Margaret Hospital is in the process of deciding whether to take part.

Dr. Ross Prentice, associate director of the Fred Hutchinson Cancer Research Center in Seattle and the study's principal investigator, was in Ottawa Thursday to talk to federal Health and Welfare officials about the project.

The 30,000 women who will participate will be followed for between seven and 10 years to see whether cutting down on fats reduces the incidence of breast cancer.

It is estimated that one in 14 North American women will contract breast cancer and evidence suggests that diet plays a role in promoting the disease.

Prentice is recruiting women between 45 and 69 – when breast cancer most commonly strikes – who are at increased risk because of family history, who gave birth for the first time after 30, or who have had two or more benign breast tumours.

To enter the study, women must show a diet high in fats. About 40 per cent of their food intake must be fats from sources including red meat, dairy products and desserts.

The women will be divided into two groups: 60 per cent of them will maintain their normal fat consumption and the rest will be required to reduce their fat intake by half. A particular target will be saturated fats such as butter and some margarines.

The two groups will receive nutrition counselling and regular mammograms during the course of the study.

"The average North American diet is 40 per cent fat and international studies suggest that if that amount can be reduced to 20 per cent, we may be able to cut the incidence of breast cancer by half," Prentice said.

Studies of Polish and Japanese women, who have low rates of breast cancer in their native countries, show that when they immigrate to North America and adapt to its high-fat diet, their incidence of breast cancer increases quickly.

"Diet seems like a logical place to look," Prentice said.

He said the goal of the study "is not to reduce calories. It won't be necessary to go around hungry all day or prepare meals differently for the rest of a family."

So far, clinics in Seattle, Houston and Cincinnati have agreed to take part in the $100-million study, which is sponsored by the National Cancer Institute.

There have been several U.S. breast-cancer studies in which the diets of women were monitored but not changed and these have yielded mixed results.

The most recent study, done by researchers at Harvard University and described this month in *The New England Journal of Medicine*, found no link between dietary fat and incidence of the disease.

Dr. Kenneth Carroll, professor of biochemistry at the University of Western Ontario in London, has been studying diet and breast cancer in rats since the late 1960s.

REFERENCE: Willett, W.C., Stampfer, M.J., Colditz, G.A., Rosner, B.A., Hennekens, C.H. and F.E. Speizer: Dietary Fat and the Risk of Breast Cancer. *New Engl. J. Med.* **316**(#1): 22-28 (1987). [DC Library call number: PER R11.B7]

1. Identify the matter(s) mentioned in the article which are components of an adequate Plan for such an investigation.

2. Identify matter(s) *not* explicitly mentioned in the article which are components of an adequate Plan for such an investigation.
   - For each missing component you identify, indicate whether it would be practicable to incorporate it into this investigation; give reason(s) in each case.

3. Explain why it was necessary to carry out this investigation using an *experimental* Plan rather than an *observational* Plan.
   - Would there be any *advantages* of an observational Plan in this context? Explain briefly.

4. Do you know, or can you suggest, the type(s) of evidence that has led to the hypothesis of a link between level of dietary fat and the incidence of breast cancer?
   - What is the weakness(es) of the existing evidence for such a link?
   - Why is breast cancer a matter of appreciable concern to medical research?

5. Some time after this article appeared, the U.S. National Cancer Institute decided *not* to go ahead with this investigation; suggest possible reasons for this decision.

6. The last paragraph of the article mentions the use of laboratory rats to investigaste diet and breast cancer. For investigating diseases like human cancers:
   - what are the *advantage(s)* of using laboratory rats or other animals?
   - what are the *dis*advantage(s) of using laboratory rats or other animals?

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