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Short Communication

Quality control of nutrient data entry for a long-term, multi-centre dietary intervention trial

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ABSTRACT

The Diet and Breast Cancer Prevention Study is a multi-centre, randomized intervention trial to determine if a low-fat, high-carbohydrate diet would reduce the incidence of breast cancer in women at increased risk for the disease. The study began in 1988 and was completed in December 2005. We recruited 4690 women from 5 cities across Canada and asked them to provide 3-day food records at each clinic visit. We analyzed 82,000 food records using Nutrition Data System from the Nutrition Coordinating Centre, University of Minnesota. Our quality control program needed to maximize accuracy and consistency despite a large staff in various locations, changes to the NDS that excluded Canadian foods and an astounding number of new food products. We screened prospective staff to assess their food knowledge and provided extensive training and continuing education. We compiled a supplementary database of new product information and data entry rules. Records with energy and fat intakes beyond usual thresholds were checked. Inter-dietitian variation was assessed by re-entering a sample of food records and achieved a correlation of greater than 0.9 for all macronutrients. This is the only study of diet and breast cancer prevention to collect food records and blood samples over a prolonged period. High quality nutrient data allows us to examine diet and breast cancer risk and phenotype.

1. Introduction

The Diet and Breast Cancer Prevention Trial was a long-term, multi-centre, randomized controlled study to determine if a low-fat, high-carbohydrate diet would reduce the incidence of breast cancer in healthy women, at increased risk of the disease due to extensive breast density (Boyd et al., 1995). The study began in 1988 and we recruited 4690 women from 5 study centres in Ontario and British Columbia. Subjects were randomly assigned to either the intervention or control group and follow up of all study participants continued until December 2005. Dietary data were collected using 3-day food records at baseline and at intervals throughout the trial. We have analyzed 82,000 food record days to date.

Food records were used to assess the individual intake of the participants because they provided a more detailed account of eating habits than other dietary assessment methods. The specific information collected from food records was particularly useful when counselling participants in the intervention group. Food records allowed us to detect deviations from the prescribed diet and provided insight into food preferences that enabled dietitians to suggest practical and useful strategies to improve adherence. Although there are limitations and burdens associated with them, it has been shown that estimates of nutrient intakes from food records have a higher validity than food frequency questionnaires (Bingham et al., 2003; Freedman et al., 2006).

Quality control was considered essential to maximize the accuracy and consistency of nutrient data collection and analysis, especially in view of the large amount of nutrient data and the unique contribution our research could provide to the field of breast cancer prevention. In this paper we describe our quality control program for nutrient data entry that was based on hiring and training skilled dietitians and nutritionists, providing information tools to standardize the data entry process, and reviewing and evaluating our process.

2. Methods and results

2.1. Overview of trial

Women with greater than 50% breast density as seen on their mammogram were recruited from mammography units in

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Toronto, Hamilton, London, Windsor and Vancouver. Potential participants were contacted by mail and invited to attend two screening visits to learn more about the study and how to keep food records. The instruction about record keeping began at the first screening visit when the dietitian completed a 24-h recall with the potential participant to demonstrate the type of information required on a food record. At the end of the first interview the participant was given a food record booklet and asked to complete 3 days of food records before the second screening visit, which took place about 2 weeks later. The food record booklet included instructions and guidelines about documenting product information, preparation techniques, recipes and measurements according to the different types of foods or beverages consumed. Each food record sheet in the booklet also included a ruler printed along the side of the page to facilitate the documentation of serving sizes when measuring with a scale or measuring cups or spoons was not feasible. Eligible subjects who provided food records of adequate quality and gave consent were randomly assigned to one of the two study groups and then given a scale to be used for food records.

Women in the control group were given a copy of Canada's Food Guide and were not asked to make any changes to their fat intake. They were seen every 3 months in the first year, every 6 months in the second year and then annually. Women in the intervention group were given individualized instruction to achieve and maintain a low-fat, high-carbohydrate diet that was based on an isocaloric replacement of fat with carbohydrate with a target energy distribution of 15% fat, 65% carbohydrate and 20% protein. The intervention was designed to reduce fat and increase carbohydrate while emphasizing grains, vegetables and fruit, limiting animal protein foods and maintaining body weight. Subjects in the intervention group were seen monthly for the first year, every 3 months in the second year, and every 6 months thereafter. All subjects were followed for 7–17 years and for an average of 10 years for the development of breast cancer or other outcomes.

At baseline and every visit thereafter, subjects in both groups were asked to provide food records on three non-consecutive days, selected by the dietitian. All food records were reviewed at the clinic visit by a dietitian to ensure adequate detail and clarity; and portion sizes were verified with food models when necessary. Dietitians analyzed the records without knowledge of the identity and study group of the subjects. They used the Nutrition Data System (NDS Versions 2.1–2.91) developed by the Nutrition Coordinating Centre at the University of Minnesota.

2.2. Quality control methods

2.2.1. Screening and training of nutrient data entry staff

Over the 17-year duration of the trial, 46 dietitians and nutritionists performed nutrient data entry in five different study sites in Ontario and British Columbia. To preserve the integrity of the nutrient data it was very important to hire and train highly qualified staff. Dietitians and nutritionists were required to have extensive knowledge of cooking methods and domestic and imported foods to efficiently and accurately analyze food records from thousands of participants with diverse preferences and eating habits. Prospective candidates were screened using a short knowledge test that asked about measurements used in cooking, commercial and ethnic foods and nutrition composition (see Fig. 1 for the test questions).

The nutrient data manager (LG) was responsible for the rigorous training and certification program to ensure that staff developed proficiency in the use of NDS software, followed uniform procedures and demonstrated good judgment for data entry of foods that did not have a direct match in the database. Each dietitian and nutritionist was closely supervised for about 3 months or until 100 records were entered. During this time the nutrient data manager checked their work regularly and gave feedback for all data entry errors. After this comprehensive training program, most staff were performing at a high level of competency with very few food selection or typographical errors. In cases when the nutrient data manager felt additional supervision was required, their training continued until their work was considered acceptable. In addition, the nutrient data manager provided continuing education to all nutrient data entry staff at annual dietitian meetings to deal with challenges to data entry posed by changing trends in eating habits.

Food Knowledge Test

1. **Measurements**
   How many
   a) tsp in a cup =
   b) tbsp in a cup =
   c) oz in a lb =
   d) FO in a cup =
2. **Commercial and Ethnic Foods**
   What is
   a) orangina
   b) Jamaican patty
   c) Challah
   d) Marmite
   e) Boursin
   f) Mesculin mix
3. **Math Skills**
   Calculate the volume of a wedge using the formula:

$$\frac{\text{Width of rounded edge} \times \text{radius} \times \text{height}}{2}$$

   rounded edge = 3" radius = 4" height = 2.5"
4. **Nutrition Composition**
   Approximately how many calories in 4 oz of cooked, lean beef?

Fig. 1. Food knowledge test.

2.2.2. Standardizing nutrient data entry

Although NDS has a very extensive database including some Canadian products, it could not include every food consumed by our study participants. Therefore, from the outset a supplementary database was compiled of these additional food items called the "Missing Food Book" (MFB). The MFB standardized the entry of new items and maximized accuracy, efficiency and consistency. Over time, tremendous changes occurred in the marketplace and reliance on restaurant meals was increasing. The number and variety of convenience and ethnic foods and foods modified in fat and fibre were increasing and popular and needed to be accommodated in the data entry system. We also needed to deal with changes to NDS that occurred in 1998 when a new version removed Canadian foods. We decided to continue with Version 2.91 and incorporate information about new products into the MFB.

Dietitians and nutritionists recorded information about new products on a "Missing Food Form". This standardized form helped to ensure that the data necessary to understand and guide the entry for new products was collected. It included: product name, source of the nutrition information, i.e. whether it came from the label, website or telephone contact with company, package size and format, preparation instructions for mixes, main ingredients, nutritional composition and NDS entry required to closely match the nutritional content. A sample form is shown in Fig. 2.

The format of the MFB also progressed so that it could be updated relatively quickly and easily. The final version was developed using two Microsoft Office programs, Access and Excel. Access was used to assemble and organize the product database