Designing a quality assurance system for dietary data in a multicenter clinical trial: Women's Intervention Nutrition Study

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ABSTRACT

Reliable dietary intake data are essential for determining outcomes in nutrition-related clinical trials. Nevertheless, systems for quality assurance of dietary intake data are often slighted in the design of such trials and not incorporated or monitored as the trials continue. The Women's Intervention Nutrition Study (WINS), a multicenter clinical trial investigating the effect of reduction of dietary fat intake together with adjuvant systemic therapy on recurrence rates in and survival of postmenopausal women with early stage, surgically treated, breast cancer, has developed a quality assurance system to minimize errors and to produce data that are complete and reliable. The system involves development of standardized procedures for data collection, a quality control program to evaluate the data collected, and continual monitoring and reevaluation. The WINS system is offered as a model for studies collecting dietary intake data, no matter how simple or complex the trial design. *J Am Diet Assoc. 2000;100:1186-1190.*

A quality assurance system is essential to minimize errors and increase reliability of dietary intake data collected in a multicenter clinical trial. Such a system must provide standardized procedures for the collection of data and a quality control program to quantitatively evaluate procedures and data (1-5). The system must (a) standardize data collection procedures, preparation of participants, and training of study personnel, (b) review and evaluate quality control variables such as the timing and completeness of data collected, adherence to data collection procedures, and comparability of data with reference data, and (c) provide ongoing monitoring and evaluation of data collection policies and procedures (6,7).

Unfortunately, quality assurance for dietary data collection is often slighted at the time of study design and not incorporated into projects as they evolve (2). The Women's Intervention Nutrition Study (WINS) has developed and implemented a quality assurance system designed to ensure greater reliability and timely completion of collection of dietary intake data. This report highlights the system used in the WINS trial.

WINS is a multicenter clinical trial sponsored by the National Cancer Institute (CA45504) to investigate the effect of reduction of dietary fat intake together with adjuvant systemic therapy on recurrence rates in and survival of postmenopausal patients with early stage, surgically treated, breast cancer (8,9). WINS assigns participants randomly into an intensive intervention group that obtains 15% of energy from fat or a nonintensive intervention group that essentially maintains the usual diet. This long-term trial began recruiting participants in 1994. Recruitment ceases at the end of the year 2000; all participants will be followed for 4 years subsequent to randomization of the last participant. To date, 2,027 participants have been enrolled from 37 clinical sites nationwide, and the final projected sample is 2,500 women. Organizational design of WINS includes administrative, statistical, and nutrition units together with regional units that directly oversee the clinical sites.

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FIG 1. Women's Intervention Nutrition Study (WINS) clinical sites. WINS participants are selected randomly from the 37 clinical sites listed. Dietary intake data are collected from participants by 2 regional nutrition coordinating units, 1 on the East Coast and 1 on the West Coast.

METHODS AND RESULTS

Dietary Intake Data Collection

Dietary intake data are collected at baseline and annually by means of the 24-hour telephone recall method (10,11). Each data collection period includes three 24-hour telephone recalls conducted by an interviewer not known to the participant. All recalls (2 weekdays and 1 weekend day) are unannounced and take place on nonconsecutive days to obtain a representative sample of the participant's intake (12). Nutrient calculations were performed using the Nutrition Data System (NDS) software, versions 2.6 through 2.93, developed by the Nutrition Coordinating Center (NCC), University of Minnesota, Minneapolis, Minn, Food Database versions 8A through 4A and Nutrient Database versions 23 through 28, released between November 1993 and December 1998 (13).

The 24-hour telephone recall method was selected because collecting data by telephone has been shown to increase response rates, provide more comprehensive information than other methods, and reduce respondent burden (11,12,14-18). In addition, scientific research has shown that computer-assisted telephone recalls have less measurement error than self-reported food records (10).

Dietary data collection from the participants at WINS clinical sites (Figure 1) is coordinated by 2 regional nutrition coordinating units, 1 located on the East Coast (Boston, Mass) and 1 on the West Coast (Los Angeles, Calif). Dietary assessment tasks at each region are handled by a regional nutrition coordinator, quality control staff, and telephone interviewers. A national dietary assessment coordinator is responsible for maintaining consistency between regions. External reviews of data are conducted by the University of Minnesota Nutrition Coordinating Center. The WINS statistical coordinating unit is responsible for receiving, storing, and analyzing all dietary data (Figure 2).

Quality Assurance Methods

The WINS system for maintaining the quality of the data includes the following processes: development of standardized data collection procedures including participant and interviewer training, review and evaluation of data, and monitoring of policies and procedures (Table 1).

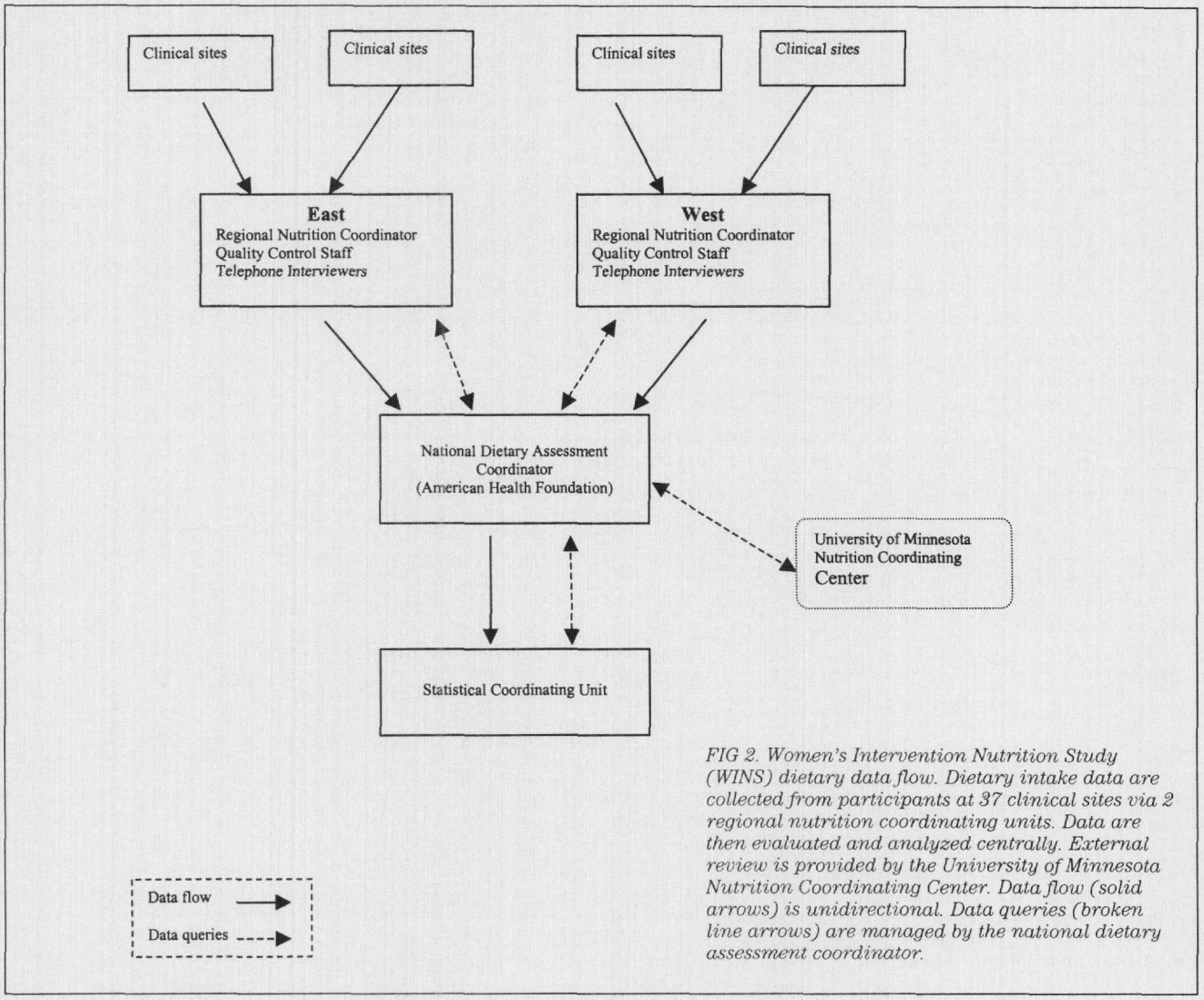

FIG 2. Women's Intervention Nutrition Study (WINS) dietary data flow. Dietary intake data are collected from participants at 37 clinical sites via 2 regional nutrition coordinating units. Data are then evaluated and analyzed centrally. External review is provided by the University of Minnesota Nutrition Coordinating Center. Data flow (solid arrows) is unidirectional. Data queries (broken line arrows) are managed by the national dietary assessment coordinator.

Standardized data collection WINS dietary data collection procedures are documented in procedure manuals distributed to all study personnel. Key to these procedures are the training of participants and the training of telephone interviewers.

All WINS participants are thoroughly prepared for the telephone recall process to maximize the efficiency of the interview and the reliability of the dietary data collected. Participants are prepared in person by the clinic site nutritionists who follow procedures outlined in the WINS nutrition procedures manual. Nutritionists describe the telephone recall process in detail and provide each participant with a set of standardized measuring tools for estimating portion sizes (measuring cups and spoons, a ruler, and a 2-dimensional food portion poster [19]) along with a written description of how to estimate portion sizes. Because studies indicate that the accuracy of reporting using standardized measuring tools improves with training, nutritionists conduct practice recalls with participants using these tools (20).

Additionally, participant training includes a discussion between participants and study personnel on "partnering in research." Participants are told that complete, accurate, and timely intake reports are critical to the trial's success. To reduce the potential for reporting bias, participants are assured that their clinic nutritionist will not be told what they report eating. WINS participants are retrained in the dietary recall process and on their role as partners in research annually by their clinic nutritionist, because the effects of training and education have been shown to deteriorate over time (20,21).

Evaluation of the data collection process has shown that more than 95% of WINS participants are prepared for the recalls; that is, they have their measurement tools available and are expecting the telephone recalls. Eighty-eight percent of the participants complete 3 recalls within 1 month of initiation of the recall process.

WINS dietary interviewers are trained to use Nutrient Data System software according to a standard 24-hour recall protocol as detailed in the WINS dietary assessment procedures manual. Training emphasizes proficiency in the use of the program, training and practice in interviewing techniques to enhance retrieval, and memorization of a script for recalls to eliminate subjective comments on topics (eg, "good" or "bad" food choices). After training, each interviewer is certified by completing a series of standardized certification telephone

Table
Women's Intervention Nutrition Study (WINS) quality assurance processes, personnel, procedures, and evaluations

Processes	Personnel	Procedures	Evaluations
Standardized data collection			
Participant training	WINS site nutritionists	Training of participants in recall procedures Establishment of recall time lines Discussion of trial and research partnership	% participants prepared for recalls (eg, portion-size aids available) % participants with recalls completed within designated time
Interviewer training	WINS regional nutrition coordinators and national dietary assessment coordinator	Initial training of interviewers Certification Monthly and quarterly updates and retaining Recertify annually	Adherence to protocol and script Qualitative evaluation of interview process Quantitative evaluation of standardized dietary recall
Review and evaluation of data			
Internal review	WINS interviewers	Postinterview review to avoid data entry errors	Frequency of errors
	WINS regional quality control staff	Review of 3 recalls per participant for consistency and accuracy	Frequency or % of questionable entries Completeness of interviewers' notes
	WINS national dietary assessment coordinator	Computerized check for nutrient values that are outliers Check for completeness and timeliness	Frequency of unexplained nutrient outliers Frequency of late or missing data
	WINS statistical coordinating unit	Monitoring of timeliness of data Data management	% of late or incomplete recalls
External review	University of Minnesota Nutrition Coordinating Center	Review of 10% of recalls	Frequency or % of errors Impact of errors on outcome variables
Monitoring of policies and procedures			
	External consultants	Review of policies and procedures and recommend modifications Site visits to regional nutrition coordinating units Reports to WINS nutrition committee	Documentation of change and consistency in recommended changes
	WINS nutrition committee	Assistance to external consultants on site visits Review of recommendations for changes policies/procedures Report to WINS external data monitoring advisory committee Review of monitoring report of statistical coordinating unit	Approval by WINS external advisory committee Comparability with other trials Collection of complete and timely data

calls with regional and national coordinators. After each certification telephone call, the interviewer's proficiency at interviewing, adherence to the recall script and recall procedures, and accuracy of data entry are evaluated and additional training is provided, if needed. Additional training to ensure continuity and uniformity within and across regions is provided at monthly regional meetings for interviewers and through quarterly conference telephone calls with the national dietary assessment coordinator. Regular telephone and e-mail contacts occur with each interviewer and the national coordinator. All interviewers are recertified annually.

This interviewer training process results in a mean interview time of 20 to 30 minutes per recall. Results of the annual recertification of interviewers (n=10 to 16) show that the percentage difference between scripted recalls and interviewer-entered recall data is 1% to 7.5% of energy intake (representing 6 to 50 kcal) and from 0.6% to 3% of fat intake (representing 0.2 to 1.6 g of fat). During the recertification process, interviewers adhered to the recall script and procedures 92% of the time.

Review and evaluation of data Reviews of dietary data take place at 5 levels and include internal and external components. Internal data review is conducted throughout the data management process as follows:

- First, interviewers review the dietary data immediately after completing each recall to check for any data entry errors. This postinterview review enables interviewers to telephone the participant to clarify any issues and ensures that unusual foods, unusual amounts, or foods that are missing in the database are noted in the record.
- Once all 3 recalls are completed, dietary data are submitted to the quality control staff at the regional nutrition coordinating units who review data from all 3 recalls together for consistency, accuracy, and reasonableness of entries (second level of review).
- After data are reviewed regionally, they are sent electronically to the national dietary assessment coordinator who completes the third level of review of all data to assess completeness and timeliness of data collection and out of range nutrient values, which are defined as values less than the 10th or above

the 90th percentile of the third National Health and Nutrition Examination Survey (22).

- Final dietary data are sent to the WINS statistical coordinating unit for the fourth level of review. The statistical unit monitors all WINS dietary data to ensure that recalls coincide with other WINS data collection periods. Data queries are returned to the national dietary assessment coordinator for clarification.

An external data review, the fifth level of review, is conducted concurrently with internal reviews. A 10% sample of the dietary recalls collected by each interviewer from each region is submitted to the University of Minnesota Nutrition Coordinating Center where a quality control nutritionist reviews each recall for appropriateness of data entries. Less than 1% of the dietary recalls reviewed at this stage have produced queries that could have a significant impact on the recorded nutrient intake of a trial participant.

Monitoring of policies and procedures WINS dietary assessment procedures, as defined in the procedure manuals, are reviewed and updated continually. Internally, procedures are monitored by WINS nutrition committee, which consists of the regional nutrition coordinators, the national dietary assessment coordinator, and the national study coordinator and chairperson of the nutrition committee. External oversight of dietary assessment procedures that relate to study function and protocol issues is provided by the director and the coordinator of the Pennsylvania State University Diet Assessment Center. All policies and procedures are reviewed during annual site visits to the regional nutrition coordinating units. The WINS nutrition committee and the external consultants present findings and recommend changes to the WINS external data monitoring advisory committee. Procedures related to data flow (Figure 2) presented in this article were recommended by the external consultants and approved by the WINS nutrition and external advisory data monitoring committees.

APPLICATIONS

- Organizing and maintaining a quality assurance system to collect reliable dietary data in a multicenter, long-term clinical trial involves a multitude of considerations as detailed in the Table.
- Quality assurance procedures are essential not only in multicenter studies but also in single-center trials, which need to incorporate many of the same quality assurance processes into their study design.
- Procedures to minimize errors and to produce data that are complete and reliable should be tailored to each study's needs.
- Clinical trial protocols should be written to include frequent retraining of all participants and personnel.
- Enhancements to quality assurance procedures need to be ongoing, no matter how simple or complex a trial's design.

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This article was funded by NCI grant CA45504, the American Health Foundation.

The authors most gratefully acknowledge the contribution of each WINS participant, whose continued dedication has made this research possible. Further, we give special recognition to each WINS clinical site and all WINS interviewers for their ongoing contributions. This paper is submitted by the authors with the support of the WINS Executive Committee: Daniel Nixon, MD, Principal Investigator, American Health Foundation, New York, NY; Rowan T. Chlebowski, Co-principal Investigator, Harbor-UCLA, Los Angeles, Calif; George Blackburn, MD, PhD, Beth Israel Deaconess Medical Center, Boston, Mass; Robert Elashoff, PhD, Biomathematics, UCLA, Los Angeles, Calif; Barbara L. Winters, PhD, RD, American Health Foundation, New York, NY.