USE OF PERSONAL COMPUTERS IN NIH SPONSORED CLINICAL TRIALS

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The use of personal computers was essentially nonexistent for nutrient calculations in the 1970's. Calculations were done manually from information obtained in face-to-face interviews with patients. In many cases use of diet histories in clinical trials was discouraged because of the tedious work with manual calculations. Assessment of compliance to diet was written in a sentence or two in a very subjective format and was based on quick unquantified food frequency.

Diet histories, when they were conducted, were evaluated using food tables, like Bowes and Church, for specific nutrient values of foods. Dietitians would spend hours looking up reference values and then calculate exact quantities for the specific diet history or food diary in question. It might take 2 hours to complete this task for a single day's intake by one subject.

My first experience with a nutrition coding center was the center at Minneapolis during my work with the Lipid Research Center. The earliest codebook I received was basically a worksheet where brand names of margarines, for example, were written down and a label sent to the coordinating center. This label information would then be a part of the codebook. The most recent version is much different. Many more margarines are on the market and an elaborate classification system is included.

This is just the beginning of new technology for clinical trials. The 1980's have brought the use of personal computers in NIH Clinical Trials which provide immediate feedback to families with hypercholesterolemia in one study and to patients with renal insufficiency in another study. No longer are tedious calculations necessary. The nutrition coordinating center in Minneapolis has a program for the personal computer which is interactive and makes doing a diet history or food diary a simple task.

This kind of feedback to patients can be very quick and beneficial. The Minnesota program, called Minnesota Nutrient Data System, can be used with the patient present and provides for immediate feedback. In essence, it allows for the type of dietary counseling which will optimize compliance over time.

In a second study, dealing with diet in early stage renal disease, a personal computer is used in a different fashion. Because diets in renal disease are very complicated including modifications in protein, phosphorus, calories, sodium and at times other nutrients, the design of the diet in terms of exchanges or just the fitting of a menu to a prescription can take an entire day to accomplish. We are using a program with allows us to match exchanges to a prescription, set-up sample menus, print-out lists of food preferences with nutrient values, and calculate recipes. This program has essentially made a clinical trial using diet in early stage renal disease possible. Without it the cost of dietitian time would be prohibitive.

The changes just described from 1970 to 1980 have helped to place dietitians in a more prominent place in the world of medicine. We are now able to provide information in minutes as opposed to hours or days. We are a vital part of the medical team able to spend time in team sessions with nurses, doctors, psychologists, physician's assistants, and physical therapists voicing our understanding of medical treatment without being tied to a pencil, a calculator, and a food table. Our energies can be channelled into counseling patients and prescribing dietary therapy.

Although these changes have been great, there is still a need for improvement. In clinical trials there are two levels of compliance: patient and staff. Personal computers allow for more immediate feedback to patients but also can allow for patient involvement in making their diets more tailored versions of what will actually happen when they go home and try to follow a diet prescription on their own.

In a clinical trial where sitting down and discussing a diet and its effect on lifestyle is the crux of a counseling session, computers can give needed time to focus on this area. More research is needed in this area to

determine whether personal computers actually increase compliance to diet and develop better programs for facilitating change.

In clinical trials staff compliance to protocol among many centers is important. When a nutrition coordinating center is involved in collecting data and analyzing it, the data sent by each center must be of the highest quality. This means quick checks on questions which a coordinating center may have regarding data sent. The shorter the turn-around time for questions the more likely that data can be retrieved from memory or from notes taken during an interview. Use of the computer for mail messages for food recall queries which allow a two to three day turn-around time is excellent. Communication with a mainframe will allow the database to be much larger in regard to numbers of foods and food attributes. The mainframe operated by a central or core facility also provides uniformity of data among several clinical centers. In the future we may see use of mainframes as a way of getting more detailed data on all foods indicated on a food diary. Getting data directly from coordinating center to clinical center quickly will allow patients to see accurate detail in nutrient information quickly.

The need for change in use of computers depends on the type of data used in a clinical trial. If data is blinded to researchers so that nutritionists are not aware of results of physiological measurement of their subjects then use of computers to provide ongoing laboratory data is limited. If data is not blinded and blood and urine chemistries are available for each counseling session then flow sheets may be useful.

One of the most frustrating parts of my job as a diet counselor working in clinical trials involves the continuous upgrade of databanks. Without a continuous upgrading and auditing of nutrient values for new products, such as fast foods and convenience foods, the database is of little use. Making sure that a database has complete nutrient information, is crucial to a clinical trial for two reasons. The first is obvious: it is necessary for the information collected and analyzed to be the most recent and the most complete. The second is less obvious and very important to patient adherence: nothing makes a patient more confused and frustrated than seeing two values for a food in two different sources.

Over the past 15 years there has been a radical change in the amount of dietary information available and in the ease and convenience of assessing this information. We have a long way to go before any system of data collection can be called complete. In terms of information -- in 1963 USDA offered a table (Handbook No. 8) with 17 components offered for about 2500 foods. A few other tables offered other nutrients for some of their foods. Today's USDA tables offer 67 components (about 4 times as many) on about twice as many foods.

The magnitude of the effort to compile this data is evidenced in the approximately 20-year timeline required to properly tabulate it. In clinical trials we take this monumental task for granted. One-half or more of foods eaten by many people are engineered and are described by brand names which change continually.

The real challenge for clinical trials is to capture dietary information from the patient and immediately (and accurately) translate it to nutrient information so the patient knows today, to what degree today's eating pattern matches his or her goal -- so strategies for change can be designed by the subject which will help facilitate dietary compliance.