CHAPTER 21

PERFORMANCE IMPROVEMENT FOR THE RESEARCH KITCHEN

ELAINE J. AYRES, MS, RD; MARJORIE BUSBY, MPH, RD; PATTI RIGGS, RD; MICHELLE SANDOW-PAJEWSKI, MS, RD; AND CYNTHIA SEIDMAN, MS, RD

Performance improvement (PI) is a straightforward approach to ensuring the quality of dietetics and nutrition services for controlled feeding studies. PI programs start with externally imposed standards, such as those of the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO, 1 Renaissance Boulevard, Oakbrook Terrace, IL 60181; [630]792-5000) (1). They are supplemented with the research dietitian's professional knowledge of nutrition, foodservice process control, and research methodology. The goal is to provide the best possible participant-centered service in support of the research protocol.

Performance improvement has two distinct components. The first is quality control. (See Figure 21–1.) The second is customer service and relations. (See Figure 21–2.) Whereas traditional quality control focuses on inspection, the cycle of continuous PI is not complete without the interaction of the customer (in this case, the research participant).

Quality goals for controlled feeding studies are based on state-of-the-art service or product standards. Determinants of quality goals are derived from three sources. First, the dietitian and metabolic kitchen staff have professional standards or specifications for clinical service and foodservice aspects of controlled feeding studies. Second, the principal investigator has standards or expectations for the nutritional aspects of the protocol and how these parameters will affect the outcomes of the study. Lastly, the subject has standards or expectations for both the food and the service received during participation in the study. This interdependence of professionals and participants provides the opportunity for better participant compliance, clearer expectations regarding diets and protocols, and the ability to continuously improve the methodology and the execution of the nutrition component of research studies.

QUALITY CONTROL

Quality control (QC) is the process of measuring the outcome of a procedure, comparing the outcome to a quality goal, and acting on the difference (2). (See Figure 21–1.) Quality control is not a one-time process of inspection; rather, it is a continuous loop where the product or service is measured against a quality standard or specification. Differences between expectations and actual outcome are evaluated, and the product is improved based on the data gathered. Data are then gathered again and evaluated in an ongoing cycle. This cycle leads to better performance through improved outcomes.

From the research dietitian's and research kitchen's perspective, every function that produces a tangible output can be defined in terms of a process. For example, tray assembly is a process made up of defined tasks with a clear beginning and end. The outcome of this process is a completed tray ready for service. The assessment of a participant prior to the start of a study is another process with defined professional tasks, a defined beginning, and a defined end.

The dietitian's role is to understand and control each of the processes of service. The customers of that process, the

FIGURE 21-1. The continuous quality improvement cycle for controlled feeding studies—elements of the process.

participant and investigator, see only the outcomes of the process. Therefore, the dietitian guarantees the consistent output of each process so that the customers of that process are satisfied. To achieve true improvement, constant attention to quality control of processes is necessary as well as continuous customer input. (See Figure 21–2.)

From the participant's perspective, the research team operates as a whole, and all of the research processes are integrated. Therefore, quality control is not an isolated procedure for just the nutritional aspects of the study. The research team needs to synchronize all of the critical processes of a particular protocol or work unit with the goal of positive participant outcomes.

In patient care, the patient receives services from the medical team. In the research setting, the relationships among the investigator, the participant, and staff are of a very different nature. The research study participant takes on the role of ensuring positive outcomes for the investigator and therefore becomes a ''coproducer'' with the research team (3). A triangular relationship is thus established between the investigator, the staff, and the participant, rather than the linear relationship seen in classic patient care situations. The dietitian and kitchen staff play an integral role in helping the participant understand this relationship. Educational activities for participants should focus on the importance of adherence to meal consumption procedures and how the diet fits into the overall research protocol.

Constructing a Quality Control Program: The Seven-Step Approach

The concepts underlying process quality control are applicable to any aspect of controlled feeding studies. The Seven-Step Approach can be used to continuously monitor and improve the processes involved in diet development, food production, tray accuracy, tray delivery, and laboratory verification of diet composition. This approach can also be used to monitor and improve coordinated activities of the research team.

The number of critical points to monitor (ie, the number of indicators) should be determined by the operation. Professional judgment, the nature of the protocol, and the reactions of the customer will provide the best guide to which critical outcomes should be monitored. The JCAHO does not stipulate the number of indicators but advocates performance improvement programs that ultimately promote positive outcomes (1).

Quality control can and should be practiced by everyone who participates in research. Employees should be able to record and tabulate data if the data collection sheets are clear and easy to use. Data on factors such as food temperature, recipe yields, and refusals can be recorded by the staff. The dietitian, however, is responsible for reviewing the data, determining when a process is out of control or needs adjustment, setting the specifications for each critical element, and educating the staff as to these standards. The dietitian is also the liaison to other members of the research team. Indicators that measure protocol outcomes or ongoing processes of the

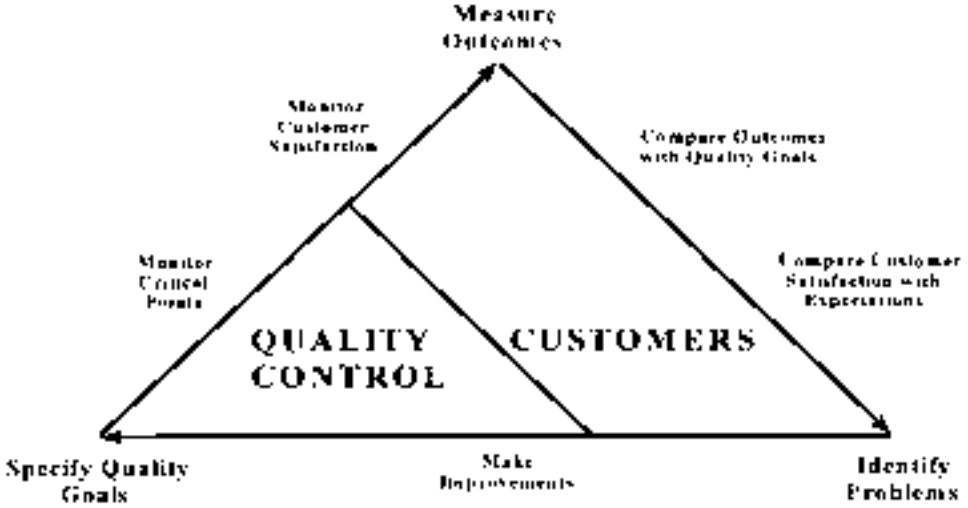


FIGURE 21-2. The continuous quality improvement cycle for controlled feeding studies—incorporating customer feedback.

whole research team are useful in improving the entire research process.

Step 1: Define the Process

Choose processes that are high-volume, high-risk, or problem-prone. Typical examples may be production of formula diets, the cook/chill process, or preparation of diet composites.

Step 2: Determine Which Critical Point(s) to Monitor

Any process may have one or more critical points. Choose the critical point or activity that most influences the outcome by constructing a flowchart. All critical points in a process need to be examined if improvements are to be achieved. Exhibit 21–1 describes how to flowchart a process and determine these points (4).

Step 3: Establish a Quality Goal or Specification for Each Critical Point

The critical point serves as the basis for what the JCAHO calls an ''indicator'' (1). An indicator is a measurement tool for gauging the success of a process. For foodservice procedures, the specification for critical points might be based on an industry standard, such as rethermalizing an entree to 165°F. The study protocol also can serve as a means of identifying goals or specifications. For example, a diet controlled for sodium might be specified to deliver 50 ± 1 mEq.

In the rethermalization example (Exhibit 21–1), a decision must be made when a prepared frozen item is removed from the freezer. Is the item used within the specified time frame? Does the item show signs of thawing or freezer burn? If so, the result would be an unsatisfactory product, with an ''off'' taste and poor texture. To ensure the desired outcome, the specifications for the critical point must be determined. In this case, specifications can be set for rotations of food in and out of the freezer; items can be dated and rotated accordingly.

Once specifications are determined, a quality control indicator can be identified, and compliance can be monitored. Such a quality control indicator might be stated as follows: Frozen prepared items are to be used within 2 months of production. If the data that have been collected on usage of frozen items indicate that wastage is occurring, then food production and storage practices should be examined and modified. The temperature critical point does not require extensive written documentation, but again, specifications for internal temperature of rethermalized foods need to be established and followed. See Exhibit 21–2 for guidelines (5–7).

Step 4: Collect Data About the Critical Point or Indicator

This step requires that measurable, observable facts be gathered about a particular point in a process. Examples would be the number of accurately assembled trays or the number of samples that meet the specifications for a liquid formula diet as determined by chemical analysis. Each critical point indicator should have a specially designed data collection sheet that reflects the conditions and sequence of activities for the particular operation or study.

Step 5: Determine the Difference Between the Data Collected and the Quality Goal

Some specifications are absolute, allowing no margin for error and no deviance from the standard. This concept of zero defects is necessary in certain situations; for example, a formula diet may not be served if the temperature exceeds 45°F. In other instances, variation is acceptable. For example, temperatures may fall within a certain range of acceptability. As specifications for foodservice and clinical activities are set, acceptable variation needs to be addressed and noted in the protocol. The concept of *threshold* is often used when defining acceptable variation. When variation of a process or outcome exceeds an acceptable level, an opportunity for improvement presents itself. It is at this time that a process is examined in detail for problems, and solutions are developed.

Customers may also signal that there is a problem by indicating dissatisfaction with the outcome; for example, there may be complaints that the food is always cold. Their expectations or standards may be different from the specifications established for the process. If this is the case, the process needs to be improved, and the specifications or quality goals must be set to meet or exceed the expectations of the customer.

Step 6: Improve the Process (Take Action on the Difference)

Improvement activities may include fine-tuning a process or eliminating unnecessary steps. If the process is complicated or the outcomes are poor, it may be necessary to establish a quality improvement team. In many cases, to guarantee the consistent output of a process, the monitoring phase continues even when thresholds are not crossed.

Step 7: Continue Data Collection for Continuous Improvement

Data collection about a critical point should continue until specifications are met or exceeded for at least 3 months. If

EXHIBIT 21-1

Using Process Flowcharts to Determine Critical Points

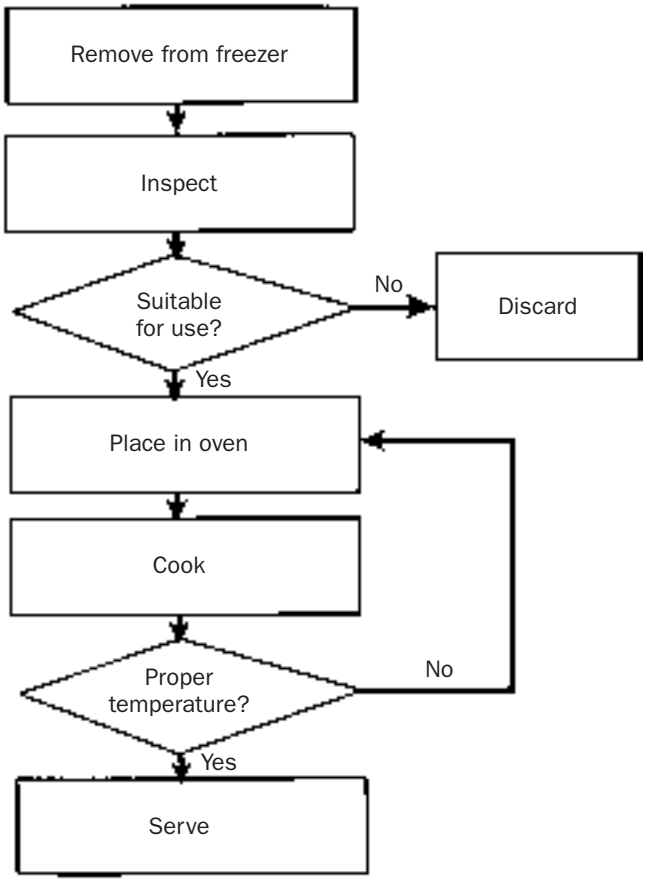
COMMENTARY

Flowcharts are used to help visualize a process. This enables the manager to specify how the system or process works (4). By definition, a process has a beginning and an end with a tangible output. The goal of the process is uniformity of product and consistent adherence to specifications. Once the critical points in the process have been identified, they can be used to develop performance specifications and can also serve as quality control indicators.

HOW TO CONSTRUCT A FLOWCHART

1. List each step in the process from beginning to end.
2. Identify the decision points (key junctions or critical points) in the process.
3. Enclose each step in a symbol:
   Decision points are enclosed by diamonds, ◇ .
   Other process steps are enclosed by rectangles, ▭.
4. At each decision point, show all possible options.

EXAMPLE OF A PROCESS FLOWCHART: RETHERMALIZATION OF A FROZEN ENTREE



the process is under control, the frequency of data collection can be decreased. For high-volume processes, the sample size can be decreased. Less frequent monitoring will spare the time and staffing required to collect and tabulate data.

If an indicator no longer provides useful information about a process, or if the specifications are met consistently and customers are satisfied, the indicator can be eliminated. It is advisable to archive old data as a reference point for similar protocols or procedures.

EXHIBIT 21-2

Principles of Time/Temperature Control of Potentially Hazardous Foods

Cook food for at least 15 seconds to a required internal temperature:
- 165°F for poultry, stuffed meats, stuffed pasta.
- 155°F for ground beef, pork, ham, sausage, bacon.
- 145°F for beef roasts, fish.

Reheat foods for at least 15 seconds to a minimum of 165°F.

Cool solid foods or liquid formulas rapidly within 4 hours to 45°F using:
- Shallow pans (2-in to 3-in depth).
- Ice bath.
- Agitation.
- Loose-fitting covers.
- No stacking.
- Placement of food in coldest part of cooling unit.

Maintain equipment at proper temperatures:
- Refrigeration units at 35°F to 45°F.
- Freezer units at 0°F or below.

Provide calibrated thermometers for checking foods for proper and safe temperatures.

The Application of Quality Control in Controlled Feeding Studies

There are many ways in which the principles of quality process control can be applied to feeding studies. The following examples do not constitute a complete quality control program but reflect approaches that can transcend a variety of research settings and protocols. Critical decision points (determined from flowcharts) and potential indicators are identified for each process.

Diet Development

The process of diet development begins with establishing specifications and ends with the successful calculation of diets that meet the requirements of the study. One critical point that must be monitored is the calculation of the diet and/or a specific food item. This is typically done with the help of iterative computer programs that compare the output with the specifications of the protocol. The quality goal of this process is to develop a diet with a nutrient composition that is within the range specified in the protocol. Therefore, diets exceeding this acceptable variation require modification and recalculation. To ensure optimum quality control, appropriate limits for nutrients should be established with the investigator during the development of the protocol.

Another critical point that may be used for diet development is a comparison of the computerized analysis and the laboratory analysis of prepared samples of the study diet. Again, the quality goal would be that the actual composition of the food falls within the levels specified by the research protocol.

The diet development phase of a study does not require an indicator per se. Because each diet will be reworked until it meets the specifications of the protocol, ongoing analysis of the calculation process itself is not necessary. In some cases, however, it may not be possible to meet original protocol specifications for specific foods or menus because of problems with availability, compositional variability, palatability, participant acceptance, difficulty of preparation, or storage. These obstacles should be addressed with the investigator during the protocol development stage.

Food Production

The purpose of food production for research diets is to provide a specialized diet or food product that meets protocol specifications. Because the actual production of the research diet involves multiple steps, a great deal of effort is required to ensure levels of accuracy and efficiency. Even the best planned diet, however, will not produce the desired outcome (ie, high compliance by participants) if it is not prepared safely, or on time, or if the food is so unpalatable that it is not consumed. The critical points to monitor in food production include:

- Procurement of food items that can be prepared to meet specifications.
- Preparation of individual food items according to recipes or research standards.
- Weighing of food items.
- Labeling of food items.

- Packaging of food items.
- Rethermalization of food items.
- Length of time the foods are stored (frozen, refrigerated, or on the shelf).

All of these areas are crucial internal controls for the food production process and applicable to any protocol.

Food Safety

Food safety is a serious concern in the production of research diets. Fortunately, the food industry has provided an excellent model for preventing foodborne illness. The Hazard Analysis Critical Control Point (HACCP) concept was devised by the Pillsbury Company, the US Army Natick Research and Development Laboratories, and the National Aeronautics and Space Administration in the 1960s for providing safe food in outer space (5). HACCP is a widely used systems approach to quality control that focuses particularly on microbial control.

HACCP is a preventive system in which safety checks are designed into the food formulation and production processes. The hazard analysis portion of HACCP as defined by Bauman (6) is ''the identification of sensitive ingredients, sensitive areas in the processing of the food or ingredients, people control, etc, from which we can identify the critical points that must be monitored to assure safety of the product. Critical control points are those areas in the chain of food production from raw materials to finished product where the loss of control can result in an unacceptable food safety risk.''

When analyzing hazards, Bobeng (7) considers the following factors: (1) potentially hazardous ingredients, (2) biologic and physical hazards in processing, and (3) potential for consumer abuse. Therefore, critical control points commonly fall into the following categories: microbiology, sanitation, time/temperature ranges, and employee cleanliness.

Potentially hazardous foods are usually of animal origin and have high moisture content and neutral pH. Cooked vegetables and legumes and raw bean sprouts also have these characteristics. Other foods fall into this category because they involve multiple preparation steps or major temperature changes (ie, cook/cool/reheat), or are prepared several hours or days before serving.

Compared to other hospital foodservice systems, the production of controlled research diets is distinguished by additional steps. These may include:

1. Precise, time-consuming weighing of food on electronic balances.
2. Freezer, refrigerator, or shelf storage of weighed foods for a period of time before the diet study begins.
3. Overnight thawing of precision-weighed foods.
4. Tray assembly of foods that are inspected for accuracy prior to service.
5. Overnight refrigeration of completed trays.
6. Microwave heating at the time of service.
7. Packing of research diets for consumption away from the research center.

To establish critical control points, determine the production stages at which bacteria can be destroyed, growth minimized, and contamination prevented. Specifications to minimize bacterial growth should be based on time/temperature ranges and sanitation guidelines for equipment and dietary staff.

Monitoring involves checking and verifying proper processing and handling procedures at the identified critical control points. One of the most important monitoring techniques is measuring food temperatures during preparation and storage. Time/temperature analysis should be performed by taking several readings at varied intervals to ensure that potentially hazardous foods reach a safe temperature within the required time period.

Foods used for weighed research diets are usually small portions that readily attain the safe temperature range when refrigerated. However, the time it takes to weigh and prepare these foods must be as short as possible to prevent excessive bacterial growth. The dietary staff needs to be well informed about the relationship of time and temperature ranges to risk of foodborne illness (Exhibit 21–2).

Tray Accuracy

The process of ensuring accuracy of tray contents includes not only accurate delivery of food items to the study participant but also accurate substitutions for foods not consumed at the previous meal. Critical points in this process include:

- **Using the correct utensils to portion foods.** For each food item or group, establish specifications for appropriate utensils that correspond to the desired portion. Consistency and accuracy are crucial in the production of research diets. Quality control for portioning is governed by clear specifications and training of kitchen staff; data collection is not usually necessary.
- **Correctly weighing each food item on the menu.** Again, consistency and accuracy are crucial for research diets.
- **Placing foods on the tray.** The specification or the indicator for this would be that all trays contain all of the items, and only the items, listed on the menu. This can be monitored as the tray leaves the kitchen or at the point of service. The expected standard is 100% accuracy. Monitoring returned trays is useful in delineating compliance to a protocol. For offsite meals, accuracy is extremely important because substitutions are not readily available.
- **Establishing substitutions for each research kitchen's and each protocol's procedures and specifications.** Making inappropriate substitutions may prompt further data collection, or the staff or participants must be educated as to suitable alternatives. When substitutions are needed routinely for a particular research diet, the appropriateness of the diet or the restrictions or the production process should be investigated. Requests for replacement foods

also may signal participant dissatisfaction. Procedures should be established for documenting substitutions.

Tray Delivery

Tray delivery is the process of serving the meal trays in the appropriate location and in a timely fashion. The critical points in tray delivery are:

- The trays must be served to participants either over a particular time period established by the feeding facility or at more precise times specified by a protocol. A common specification is that trays be served within 15 minutes of the established meal times. If a protocol specifies timed meal service, staff must establish a realistic variance on the specified time with the investigator. Once the allowed variance is established, service can be evaluated against this goal.
- The time elapsed between tray assembly and delivery must be in compliance with foodservice standards. Tray assembly and delivery time should not exceed 20 minutes to maintain appropriate food temperatures, appearance, and palatability. This can be easily measured by monitoring the time from the beginning of tray assembly to the time the tray is served to the participant. If this process takes longer than normal variance will allow, the process of assembly and delivery should be examined.

Intake

The goal of the intake process is the full consumption of the research meal. The critical points include: educating the participant about the importance of full consumption; recording intake, substitutions, or discrepancies; and communicating any issues related to intake or discrepancies to the research team. The process begins by determining preferences via questionnaire or interview so that the planned diet reflects participants' wants and needs.

It also is vital to educate participants regarding the importance of intake. The participants' understanding can be increased by providing printed materials about the research diet, written expectations about consumption, and one or more sample research meals. As a general rule, the more information provided to participants, the better the compliance with the research meal. The dietitian must inform the investigator about dietary noncompliers and document each instance of noncompliance.

During the feeding period, the research participant may also be provided with incentives to comply with the diet. By using the behavior modification techniques of reward and withdrawal of privileges, compliance can be increased. For example, adults who consume a research diet can be treated to a gourmet dinner after the protocol is finished. Incentive programs are especially important for the pediatric population; children can be given small trinkets.

Questionnaires about the acceptability of meals can provide documented feedback from the participants. This information then can be used to make adjustments to the research meals as described in the next section.

Refusals

Food refusals may indicate that the research diet is in some way unacceptable to the participant. Collecting data about refusals thus will help investigators decide whether they need to educate the participants, train the staff, or modify the food. Critical points in the process of monitoring food refusals include weighing or estimating food after it is returned to the research kitchen and documenting the episode. Sometimes the refused food is labeled and stored. Each one of these critical points requires standardized procedures with which staff are familiar. Data on the process can then be tracked by participant or by protocol. If specified by the protocol, substitutions may be needed.

Research kitchen personnel are responsible for recording the refusals of all foods. This should be done using the same balance on which the food was originally weighed during production. The dietitian is responsible for collecting the data on refusals and calculating the research participants' actual intake. Once this calculation has been done, a prompt report to the investigator and/or a note on the medical record is required. The dietitian must maintain an accessible record of all intake data to use for development of future research diets.

Diet Composition

Research diets must be prepared to meet the specifications of the protocol. This means that the diet must contain relevant nutrients at the levels required to test the hypothesis. Once the diets are designed and produced, their composition must be verified through an independent method of chemical assay. Food analysis protocols should reflect study design features such as the number of research diets, the length of the menu cycles, and the required degree of precision for nutrients of highest interest (such as the range of dietary sodium values for a study of blood pressure). A detailed discussion of food composition methodology is provided in Chapter 22, ''Validating Diet Composition by Chemical Analysis.''

Demonstrating that nutrient composition is constant over time is concrete evidence that good quality control has been used in producing the research diet. *Calorimetry,* the science of measuring quantities of heat, can be used as a tool to ensure consistent quality by determining the gross energy of the food (8). This is a particularly convenient way to monitor compositional consistency of formula diets, which are constructed from a small number of constituent components. The oxygen bomb calorimeter is considered the standard method for measuring the caloric value (heat of combustion) of liquid or solid foods. The bomb calorimeter

consists of a closed container surrounded by an enclosure with a constant volume of water. The weighed food sample is ignited by an electric spark and burned in an oxygen atmosphere inside the closed chamber. The rise in the temperature of the water after complete burning of the food is used to calculate the heat energy liberated. (Bomb calorimetry is rarely used for assessing the caloric content of whole-food diets.)

The heat energy measured in a bomb calorimeter may be expressed either as calories (cal), British thermal units (Btu), or Joules (J). One calorie is equivalent to the heat energy needed to raise the temperature of one gram of water 1°C (from 15°C to 16°C); 1,000 calories are equivalent to the familiar kilocalorie (kcal). The gross energy is determined by the heat of combustion and is calculated from the initial weight. Conversion factors are used to convert from gross energy to metabolizable energy per gram of test sample (Table 21–1) (9, 10).

There are several critical points in this process which can be monitored to ensure quality data. (See Figure 21–3 for the flow chart of the bomb calorimetry process.) The first critical point is the consistency of the sample. Samples must be homogenized to a uniform consistency. This is best determined by taking aliquots from successive layers of the homogenate and assaying them separately. (This topic is also addressed in Chapter 22, ''Validating Diet Composition by Chemical Analysis.'') If complete homogenization is not achieved, another sample is prepared.

A minimum of six replicates is run for each food (or diet) and the average taken. There are two other samples that must be used to ensure accuracy. The first is a known standard such as benzoic acid. At this point, if a variance is noted, corrections must be applied to adjust the test sample for any heat transfer occurring during the runs. In addition, a previously analyzed ''known'' sample is also assayed and compared to the test sample. Results must fall within the specifications or range set by the investigator and the dietitian; usually a 5% variance is allowed. If the analysis indicates that the composition falls outside the limits set by the investigator, it may be necessary to discard the batch and evaluate the process of formula preparation from start to finish.

THE ART OF SERVICE: GUARANTEEING PARTICIPANT SATISFACTION

The transition from traditional quality control to PI is contingent on feedback from individuals who receive a product or service. In PI terminology, those who receive a product or service are called ''customers'' (2). Therefore, PI for controlled feeding studies should include monitoring the processes of the research kitchen, but it should also reflect the needs and wants of participants and investigators.

Quality of service is measured through ''the eye of the beholder,'' and, in the case of a research study, a dissatisfied participant is a noncompliant participant. The first step in ensuring that participants remain satisfied is to understand that quality service is not the same as quality control. A service is created at the instant of delivery, and it is at that point that the participant decides whether it is good or bad. Albrecht (11) describes this critical point as a ''moment of truth.'' The job of the research kitchen staff is to engineer positive moments of truth for the participant.

The concepts of quality service vs quality products are compared in Table 21–2 (12). The key to quality service revolves around the personnel involved in the research setting. Each time any member of the research team interacts with a participant at any point in the research process, the concept of positive moments of truth should be used. Why? Without the participant, there is no clinical research.

A typical moment of truth for a controlled feeding study occurs when the tray is delivered and the cover removed. It is at this point that the participant experiences the reality of a research diet. A positive moment of truth in this situation would be an attractively arranged tray with foods served at their proper temperatures. Another moment of truth may be the interaction with the staff. Friendly encouragement and a sense of how the diet relates to the study as a whole are crucial elements in participant compliance, especially if the diet is difficult to consume.

The best way to find out whether service is measuring up to expectations of the participant is to ask. It is more difficult to design and complete service measurements than

TABLE 21-1

Energy Value of a Liquid Formula as Determined by Bomb Calorimetry[1]

Source	Nutrient	Gross Energy (Heat of Combustion) (kcal/g)[2]	Metabolizable Energy (Physiological Fuel Value) (kcal/g)[2]
Milk whey (Promix®)	Protein	5.65	4.0
Corn oil	Fat	9.30	9.0
Dextrin (Polycose®)	Carbohydrate	4.10	4.0
Prepared formula (calculated)[3]	—	1.37	1.25

[1]Courtesy of Cindy Seidman, MS, RD, and Jalanta D. Tremaroli, MS, RD, General Clinical Research Center, Rockefeller University, New York.
[2]Energy values are based on the Atwater system as reported in references 9 and 10.
[3]Observed gross energy value of prepared formula = 1.41 ≠ 0.02 kcal/g (n = 102 batches). Distribution of energy: 15% protein, 40% fat, 55% carbohydrate. Recipe: 25 g Promix, 21.2 g corn oil, 58.4 g Polycose, 295.4 g water.

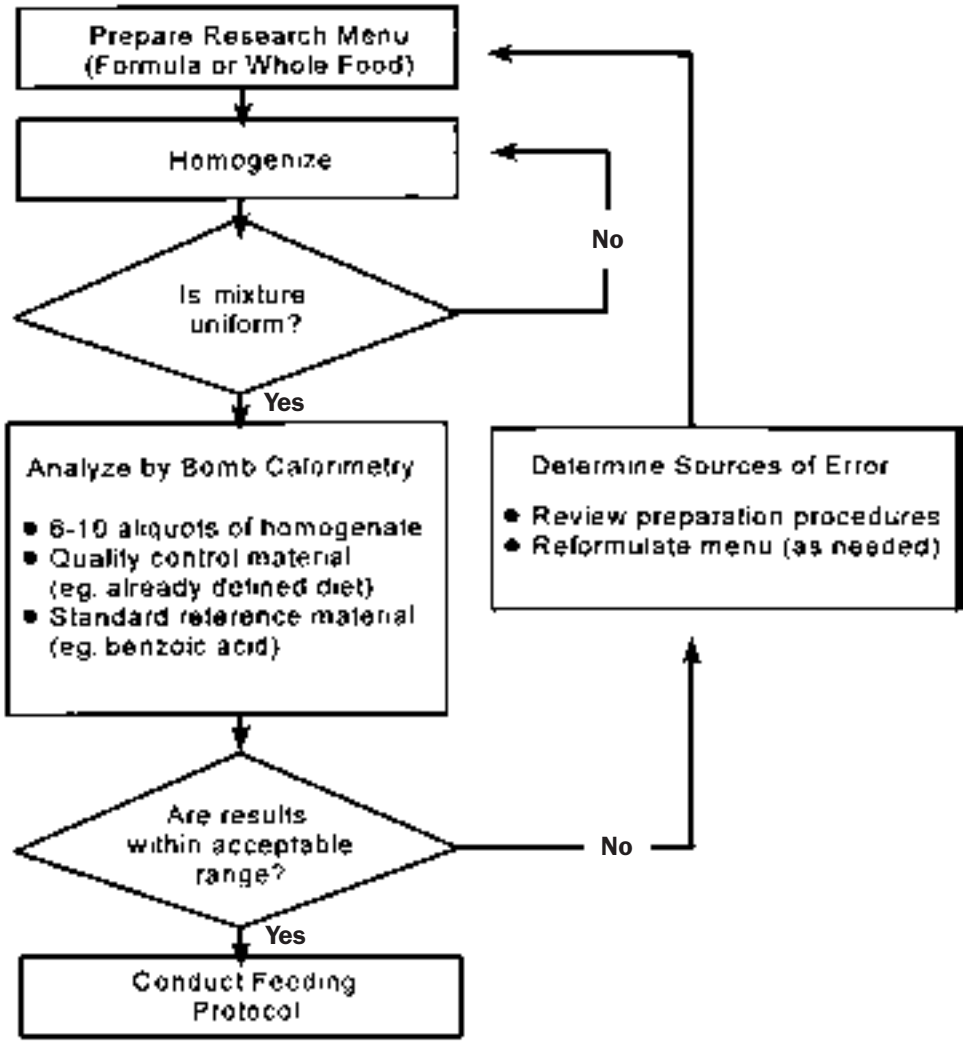


FIGURE 21-3. Flowchart of the bomb calorimetry process.

TABLE 21-2

Comparison of Quality Control Features for Processes or Products vs Services (12)

Process or Product	Service
The goal is uniformity.	The goal is uniqueness; each participant is ''special.''
A product can be put into inventory.	A service happens ''at the moment''; it cannot be stockpiled.
The participant is an end user who is not involved in the production process.	The participant is a coproducer who is a partner in creating the service.
Managers conduct quality control by comparing output to specifications.	Participants conduct quality control by comparing expectations to experience.
If improperly produced, the product can be discarded.	If improperly performed, apologies are the only means of recourse.
The morale of production employees is important.	The morale of service employees is critical.

to check whether a product meets a specification. The best assessments of quality service measure both customer perceptions and employee behaviors. Participant surveys (verbal or written) are the most direct way of obtaining this information. Participants need not be asked for information that can be measured directly by the staff (eg, the correct serving temperature). Survey tools are best used to ask questions that only the ''customer'' can answer. Exhibit 21–3 provides a sample participant satisfaction survey.

Conclusion: Recommendations of the JCAHO

The Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) periodically revises its standards on quality assessment (1). This process has traditionally focused on monitoring mistakes or errors. Performance improvement recognizes that mistakes or errors may occur. However, when management recognizes that the staff are motivated and competent to perform their duties, it becomes the norm to view problems as opportunities to improve processes and therefore improve participant outcomes.

Quality control activities typically have been conducted along departmental or discipline lines. With performance improvement, teams or groups that span different disciplines are encouraged to integrate assessment and improvement activities. The research team provides a natural organizational unit for these activities, and each protocol provides a mechanism for clearly defining desired participant and research outcomes. When these outcomes are well defined, the critical processes can be monitored and improved using the seven-step process described earlier. The protocol states the expected outcome. The indicator simply enables the team to assess whether the study methodology is producing the desired outcomes. If not, corrections in the study can be made.

The JCAHO recommends that processes that are high-risk, high-volume, or problem-prone in terms of participant outcome become the primary indicators for data collection. For a research kitchen or metabolic diet ward these indicators may be designed for a specific protocol or they may transcend multiple protocols. An indicator that might apply to all protocols, for example, addresses adequate prestudy blood work to ensure sound nutritional status. Another might be whether participants actually attained the desired blood level of a nutrient after consuming a depletion diet.

EXHIBIT 21-3

General Clinical Research Center Patient Satisfaction Questionnaire[1]

Date: _____ Type of Diet: _____

How many meals did you eat at the GCRC?

Did you receive enough food?

How would you rate the metabolic research staff?

How would you rate the appearance of your food?

How would you rate the taste of your food?

What did you like best about the meals?

What did you like least about the service?

Other comments:

[1]Provided courtesy of General Clinical Research Center, University of Virginia, Richmond, Va.

The research team should examine the frequency of the event or activity in question, the significance of the event in the context of the research question, and the extent to which an indicator has been demonstrated to be free of problems. Ongoing monitoring and data collection efforts should be focused on critical activities in processes that affect participant or research outcomes. The JCAHO does not specify numbers of indicators, and an indicator need not be continued if it does not reveal the potential for improvement. The goal is to generate meaningful information that can be used to improve the process. If a process is under control, it should be stopped and another critical area examined. If a process is out of control and exceeds a tolerable threshold, the team must plan and implement a solution and continue to monitor the indicator until the outcome reaches the expected level.

References

1. Joint Commission on the Accreditation of Healthcare Organizations. *1998 Hospital Accreditation Standards*. Oakbrook Terrace, Ill: JCAHO; 1998.
2. Juran JM, ed. *Juran's Quality Control Handbook*. 4th ed. New York, NY: McGraw Hill; 1988.
3. Barzelay M. *Breaking Through Bureaucracy—A New Vision for Managing in Government*. Berkeley, Calif: University of California Press; 1992.
4. Senge PM. *The Fifth Discipline*. New York, NY: Doubleday Currency; 1990.
5. Sperber W. The modern HACCP system. *Food Technol*. 1991;45:115–120.
6. Bauman H. HACCP: concept, development, and application. *Food Technol*. 1990;44:146.
7. Bobeng GJ, David BD. HACCP models for quality control of entree production in hospital food service systems. *J Am Diet Assoc*. 1978;73:524–529.
8. Greenfield H, Southgate DAT. Analytical methods for the production of food composition data. In: *Food Composition Data: Production, Management, and Use*. New York, NY: Elsevier Applied Science; 1992.
9. US Dept of Agriculture. *Energy Value of Foods: Basis and Derivation*. Agricultural Handbook No 74. Washington, DC: Agricultural Research Service; 1975. (Electronic version can be downloaded from the USDA Web site http:/www.nal.usda.gov/fnic/foodcomp.)
10. US Dept of Agriculture. *Composition of Foods: Raw, Processed, Prepared*. Agricultural Handbook No 8. Washington, DC: Agricultural Research Service; 1963: 159–165.
11. Albrecht K. *At America's Service*. Homewood, Ill: Dow JonesIrwin; 1988.
12. Zemke R. The emerging art of service management. *Training*. January 1992:37–42.

PART 5

Enhancing the Outcome of Dietary Studies