SEVENTH EDITION

THE PRACTICE OF NURSING RESEARCH

Appraisal, Synthesis, and Generation of Evidence

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20 CHAPTER

Collecting and Managing Data

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Data collection is one of the most exciting parts of research. After all the planning, writing, and negotiating, you should be eager and well prepared for this active part of research. The passion that comes from wanting to know the answer to your research question brings a sense of excitement and eagerness to start collecting your data. However, before you leap into data collection, you need to spend some time carefully planning this adventure and pilot test each step. Planning data collection begins with identifying all the data to be collected. The data to be collected are determined by the research questions, objectives, or hypotheses of the proposed study. As you develop the data collection plan, be sure that you gather all the data needed to answer the research questions, achieve the study objectives, or test the hypotheses. Chapter 16 includes detailed information about measurement, so the focus in this chapter is on the logistical and pragmatic aspects of quantitative data collection. Data collection strategies for qualitative studies are described in Chapter 12.

To start planning the data collection process, you need to determine the best mode by which the data can be collected. Factors that influence the plan to collect and enter data into a database for analysis include cost, time, the availability of assistance, and the need for consistency. The development of the data collection plan is followed by developing data collection forms and a codebook for data entry. Conducting a pilot test with a small group of subjects is the next recommended step. The pilot test may result in modifications of the plan, and then the actual data collection can begin. During data collection, various problems may arise. Potential situations are described in this chapter along with problem-solving strategies. The chapter concludes with the discussion of data entry and management.

Data Collection Modes

Data can be collected by interview (face-to-face or telephone); observations; focus groups; self-administered questionnaires (online or hard copy); or extraction from existing documents such as patient medical records, motor vehicle department accident records, or state birth records (Figure 20-1). Many factors need to be considered when a researcher is deciding on the mode for collecting data. Harwood and Hutchinson (2009) describe four factors that need to be part of your decision-making process: (1) purpose and complexity of the study, (2) availability of financial and physical resources, (3) characteristics of study participants and how best to gain access to them from the population, and (4) your skills and preferences as a researcher.

Researcher-Administered or Participant-Administered Instruments

If you need a subject's accurate blood pressure or height and weight, a self-report measure may be neither valid nor reliable for the purpose of your study. However, if the purpose of your study can be accomplished with a self-report survey method, you must decide whether the format will be researcher-administered or self-administered. It may be best for the researcher to administer self-report paper-and-pencil instruments if the potential subjects have minimal language or literacy ability, whereas it may be best to consider electronic data collection or medical record extraction if the subjects are likely to have hearing impairments, transportation problems, or physical difficulties.

If the researcher is administering the survey, will it be in person or by telephone? If self-administered, will

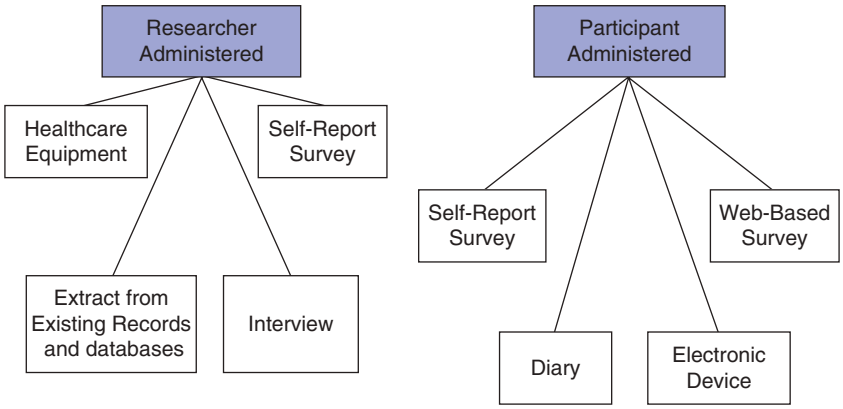

Figure 20-1 Data collection modes.

the participant complete a pencil-and-paper copy or an online electronic copy? Internet survey centers specialize in this mode of data collection and have expert help or tutorials for assessing the best mode for your study purpose. For example, in deciding on a telephone survey, how many times will you try to reach a potential subject before you give up, what days of the week or hours of the day will you call and how might that bias your sample or their responses, and how will you accurately determine the response rate (Harwood, 2009)? If you decide on a mailed paper-and-pencil survey, what will you do with undelivered or incomplete returns? Will you search for correct mailing addresses and try again? Will you send a reminder if the survey is not received within a particular time frame, and, if so, what time frame will you give a respondent, and how many reminders will you send (Harwood, 2009)?

Electronic Data Collection

When you are using an existing instrument, you may need permission to convert the questions into an online format, a special type of form that allows the data to be scanned into a database, or into an application for a phone or other electronic device. Each of these modes of data collection may require special hardware and software. Universities, schools of nursing, and funded researchers are purchasing these sometimes expensive products because the costs of acquiring the hardware and software are considerably less than the costs of entering data manually.

Scannable Forms

Other software allows the preparation of special data collection forms that rely on optical character recognition (OCR), which requires exact placement on the page for each potential response. To maintain the precise location of each response on print copies of these instruments, careful attention must be given to printing or copying these forms. The complete form is scanned, and the answers (data) are automatically recorded in a database. Additional features include data accuracy verification, selective data extraction and analysis, auditing and tracking, and flexible export interfaces. Figure 20-2 shows the scannable version of the Parents and Newborn Screening Survey developed by Patricia Newcomb, PhD, RN, CPNP, and Barbara True, MSN, CNS. Subjects completing the survey fill in the circle that corresponds to the appropriate option for each question.

Online Data Collection

Computer software packages developed by a variety of companies (e.g., Zoomerang and SurveyMonkey) enable researchers to provide an online copy of instruments and other data collection forms. These types of software programs have unique features that allow the researcher to develop point-and-click automated forms that can be distributed electronically. The following questions need to be considered with use of these programs. For an online survey, is it a secure site for the purposes of confidentiality and anonymity? How will you ensure that only eligible participants complete the survey? Will potential subjects receive a personalized email from you with a link to a website? How will you obtain the email addresses? Can you offer help if the subjects have any questions about your study?

Online services can be easy to use for both the researcher and study participants but may be costly and require specific assurances about confidentiality

Text continued on p. 513

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Parents and Newborn Screening Survey
The University of Texas at Arlington College of Nursing
Andrews Women's Hospital

Instructions: Please use a BLACK PEN for completing the survey. Do not use pencil.

Please shade circles like this: ●
Not like this: ✗ ✓

1. My age is:

○ Less than 18 ○ 18-24 ○ 25-30 ○ 31-35 ○ 36+

2. My race/ethnic group is:

○ African-American ○ Asian ○ Caucasian ○ Hispanic ○ Other

3. My highest level of education is:

○ Less than high school ○ High school diploma ○ Some college ○ Bachelor's degree ○ Master's degree or more

4. I work in the healthcare field:

○ Yes ○ No

5. I started pregnancy care:
○ In the first 3 months of my pregnancy
○ In the second 3 months of my pregnancy
○ In the last 3 months of my pregnancy
○ I did not get medical care during my pregnancy

6. My care for this pregnancy and birth was paid for by:
○ Medicaid
○ Private insurance
○ I paid for it by myself
○ I don't know how it will be paid for

7. I learned about newborn screening from (may circle more than one):
○ I never heard of newborn screening before this
○ My doctor or midwife
○ My child's doctor or nurse practitioner
○ A book, video, or brochure
○ My hospital nurse
○ My doctor's nurse
○ Internet
○ Friend or family member
○ Other

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Parents and Newborn Screening Survey
08/22/2011

Please Turn Over
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Figure 20-2 Scannable form: Parents and Newborn Screening Survey. (Developed by Patricia Newcomb, PhD, RN, CPNPN, and Barbara True, MSN, CNS; Teleform designed by Denise Cauble and Whitney Mildren, Graduate Research Assistants and PhD students, College of Nursing, The University of Texas at Arlington.)

Continued

ID ☐☐☐☐

Instructions: Please use a BLACK PEN for completing the survey. Do not use pencil.

Please shade circles like this: ●
Not like this: ✗ ✓

8. I have other children.

○ Yes ○ No

9. I learned about newborn screening before this baby was born.

○ Yes ○ No

10. The language I speak most of the time is:

○ English ○ Spanish ○ Other_____

Please put a check in the box that shows how much you agree or disagree with the statement.

	Strongly Agree	Agree	Not sure	Disagree	Strongly Disagree
11. I understand what I need to know about newborn screening.	○	○	○	○	○
12. I know when my baby should have another newborn screening.	○	○	○	○	○
13. If my baby has a disease that shows up on newborn screening, serious problems can be prevented if my baby gets treatment right away.	○	○	○	○	○
14. I will get the results of the newborn screening tests by mail.	○	○	○	○	○
15. My baby's doctor will get the results of the newborn screening tests by mail.	○	○	○	○	○
16. Doing the newborn screening is worth the discomfort the baby feels.	○	○	○	○	○
17. I know what genetic testing is.	○	○	○	○	○
18. I know where to take my baby for the second newborn screening test.	○	○	○	○	○
19. Newborn screening can identify babies with certain serious inherited diseases.	○	○	○	○	○
20. I understand what DNA does.	○	○	○	○	○
21. If my baby's newborn test is abnormal, my baby's father might have something wrong with his DNA.	○	○	○	○	○

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Figure 20-2, cont'd

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Instructions: Please use a BLACK PEN for completing the survey. Do not use pencil.

	Strongly Agree	Agree	Not sure	Disagree	Strongly Disagree
22. All babies should have genetic testing when they are born.	○	○	○	○	○
23. If my baby's newborn test is abnormal, I might have something wrong in my DNA.	○	○	○	○	○
24. Newborn screening will test for some, but not all, serious diseases that run in families.	○	○	○	○	○
25. Babies with serious disorders may look healthy when they are born.	○	○	○	○	○
26. I am scared that the newborn test might find something wrong with my baby.	○	○	○	○	○
27. I know what newborn screening bloodspots are.	○	○	○	○	○
28. The state of Texas will keep my baby's bloodspots unless I mail them a form telling them not to.	○	○	○	○	○
29. I wish I had more information about newborn screening.	○	○	○	○	○
30. Some of the tests in the newborn screening are genetic tests.	○	○	○	○	○
31. There is DNA in my baby's blood spots.	○	○	○	○	○
32. It would be OK to use my baby's bloodspots for research to find treatments for serious diseases.	○	○	○	○	○
33. It is OK for the state to keep my baby's bloodspots for research without getting special permission from me.	○	○	○	○	○
34. It would be OK to keep my baby's DNA for future study if my baby's name or other private information is not connected to the DNA sample.	○	○	○	○	○

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Parents and Newborn Screening Survey
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Figure 20-2, cont'd

Continued

ID

Instructions: Please use a BLACK PEN for completing the survey. Do not use pencil.

Please shade circles like this: ●
Not like this: ✗ ✓

35.It would be OK with me for the state to share my baby's bloodspots with researchers all over the nation.	○	○	○	○	○
36. It would be OK to let the state share my baby's bloodspots with researchers if an ethics committee reviews the research first.	○	○	○	○	○
37. If future research is done on my baby's bloodspots I want to know.	○	○	○	○	○
38. I do not want the state or any other group to keep the bloodspots from my baby's testing for any reason.	○	○	○	○	○
39. I want my baby to have newborn screening.	○	○	○	○	○
40. My baby will have another newborn screening, but I do not really want it.	○	○	○	○	○

This is the End. Thank you!

Please share any comments that would help us improve the newborn screening process:

If you would like to learn more about newborn screening, please pick up some of our information about newborn screening at the desk or from your nurse when you leave today.

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Figure 20-2, cont'd

of data and anonymity of subjects. The National Institutes of Health (NIH) supports a secure Internet environment for building online data surveys and data management packages (Harris et al., 2009). This service, developed by experts at Vanderbilt University, is called REDCap (Research Electronic Data Capture) and may be available at your university research site (http://project-redcap.org/).

Im et al. (2007) conducted a survey in the United States of gender and ethnic differences in the experience of cancer pain. These researchers administered their questionnaire over the Internet and through a paper-and-pencil format based on subject preference. The following excerpt describes the data collection procedure for their study:

> "To administer the Internet questionnaire, a Web site conforming to the Health Insurance Portability and Accountability Act standards, the System Administration, Networking, and Security Institute Federal Bureaus of Investigation recommendations, and the Institutional Review Board [IRB] policy of the institution where the researchers were affiliated was developed and published on an independent, dedicated Web site server. When potential participants visited the project Web site, informed consent was obtained by asking them to click a button labeled *I agree to participate*. After this, questions on specific diagnoses, cancer therapies, and medications were asked, and the appropriateness of answers was checked automatically through a server-side program; participants were connected automatically to the Internet survey web page if the answers were appropriate.
>
> "Upon request, pen-and-pencil questionnaires were provided by mail to the community consultants, who distributed the questionnaires in person only to those who were identified as cancer patients. These questionnaires accompanied hard copies of the same informed consent form included in the Internet format of the questionnaire, and the pen-and-pencil questionnaire included a sentence 'Filling out this questionnaire means that you are aged over 18 years old and giving your consent to participate in this survey.' After the self-administered questionnaires were completed, community consultants retrieved all except five (these were mailed directly to the research team by the participants) in person at the community settings and mailed them to the research team. Supplementing pen-and-pencil questionnaires was essential to recruit the target number of ethnic minority cancer patients across the nation who did not have access to the Internet but were interested in participating in the study. Among the 276 participants who were recruited through community settings, 246 … used the pen-and-pencil questionnaires. … There were no statistically significant differences in psychometric properties between the Internet format and the pen-and-pencil format of the questionnaire. … It took an average of 30-40 minutes for the participants to complete either the Internet format or the pen-and-pencil format of the questionnaire." (Im et al., 2007, pp. 299-300)

Im et al. (2007) maximized their sample size and obtained a more representative sample by giving participants an option to complete their questionnaire on the Internet or using paper-and-pencil format. The researchers took steps to ensure that the data collected by the two formats were comparable by testing for significant differences and finding none. The time to complete the Internet and paper-and-pencil questionnaires did not vary. Im et al. (2007) also ensured that an ethical study was conducted and subjects' rights were protected.

The additional advantage of Internet data collection is that responses can be time/date stamped. For example, if subjects are instructed to complete the questionnaire before bedtime, the time can be verified. If subjects are instructed to complete a daily diary, date of entry would be documented, and subjects would be discouraged from entering all diary days on the last day just before returning the diary to the researcher (Fukuoka, Kamitani, Dracup, & Jong, 2011).

Computer-Based Data Collection

With the advent of laptop and tablet computers, data collectors can code data directly into an electronic file at the data collection site. If a computer is used for data collection, a program must be written for entering, cleaning, and storing data. A computer enables users to collect large amounts of data with few errors that can be readily analyzed with a variety of statistical software packages. In addition to researchers using technology at the point of data collection to record data, technology has made it possible to interface physiological monitoring systems with computers for data collection. An advantage of using computers for the acquisition and storage of physiological data is the increased accuracy and precision that can be achieved by reducing errors associated with manually recording or transcribing physiological data from a monitor. Another advantage is that more data points can be recorded electronically than could

be recorded manually. Computers linked to physiological monitoring systems can store multiple data for multiple indicators, such as blood pressures, oxygen saturation levels, and sleep stages. Because data can be electronically recorded, data collection is less labor intensive, and the data are ready to analyze more quickly. The initial cost of equipment may be high, but it is reasonable when the cost of hiring and training human data collectors is considered.

There are some concerns with the use of computerized data acquisition systems, but physiological data are usually best gathered and stored directly into a computer database to ensure accurate, complete data collection. Physiological data typically require large computer storage space. The computer-equipment interface may require more space in an already crowded clinical setting; when possible, existing equipment should be used to collect data. Purchasing the equipment, setting it up, and installing the software can be time-consuming and expensive at the start of your project. Thus, initial studies usually require substantial funding. Another concern is that the nurse researcher may focus on the machine and technology and neglect observing and interacting with the subject.

The most serious disadvantage of computerized data collection is the possibility of measurement error that can occur with equipment malfunctions and software errors. Regular maintenance and calibrations, or reliability checks of the equipment and software, reduce this problem. The benefits of collecting repeated measures over time may outweigh the risk of missing data because of poor compliance. For example, collecting continuous rectal temperature data from a subject is easier and less burdensome than asking the subject to measure an oral temperature every 1 to 2 hours.

Savian, Paratz, and Davies (2006) conducted a single-blind randomized, crossover study with 14 mechanically ventilated intensive care unit patients.

> "[The purpose of the study was to determine the effectiveness of] manual hyperinflation (MHI) and ventilator hyperinflation (VHI) on respiratory mechanics (static compliance [C_{st}]), oxygenation (arterial oxygen tension [PaO_2]/fraction of inspired oxygen [FIO_2] ratio), and secretion removal (wet weight of sputum and peak expiratory flow rate [PEFR]) at different levels of PEEP [positive end-expiratory pressure] … a secondary aim was to investigate the hemodynamics heart rate [HR], mean arterial pressure [MAP] and metabolic response (carbon dioxide output [VCO_2]) during MHI and VHI." (Savian et al., 2006, p. 335)

The computerized systems used to collect and record data in the study by Savian et al. (2006) are detailed in the following excerpt:

> "PEFR and CO_2 [carbon dioxide] production were measured using a flow and CO_2 sensor connected to the patient's airways and to the CO_2SMO [carbon dioxide] respiratory mechanics monitor (CO_2SMO Plus Model 8000, Novametrix Medical Systems Inc., Wallingford, CT). All information from the CO_2SMO monitor was simultaneously recorded in the Analysis Plus computer program.
>
> "Static lung compliance was recorded by the static measures function device on the Bennett 7200 ventilator where a plateau pressure was obtained by including an inspiratory pause of 2 seconds into the mandatory breath. …
>
> "PaO_2/FIO_2 ratio was calculated from arterial blood samples taken immediately before and immediately after MHI and VHI. Four milliliters of arterial blood were drawn into a syringe containing heparin and analyzed by a blood gas machine (Bayer Australian Limited 865, Pymble, NSW, CAN 000128714). This procedure was standardized across subjects.
>
> "HR and MAP were read directly from the monitoring system (Merlin pressure module M1006A Hewlett Packard, Palo Alto, CA) and recorded every minute before, during, and for 5 minutes after MHI and VHI." (Savian et al., 2006, p. 336)

The use of computerized data collection by Savian et al. (2006) enabled them to collect repeated measures on several physiological variables in an accurate and precise way. The data were collected by sensors and stored in the computer to reduce error and facilitate data analysis.

Phones and Other Electronic Devices

Software applications for mobile phones have evolved from personal digital assistants (PDAs) that allow the researcher to collect and download data directly into the computer from observations as they occur. Healthcare providers load applications that facilitate accurate assessment, diagnosis, and pharmacological and nonpharmacological management of patients. PDAs are also used to store deidentified data from office computers in a form that is easily transportable. PDA software is currently available that may help nurse practitioners collect data for research. Multiple nurse practitioners involved in a research project could

forward data electronically from PDAs to a central research site for analysis. Encrypted electronic devices are needed to protect the confidentiality of data during transmission. These electronic devices can be misplaced or stolen, threatening confidentiality. Researchers need to protect the data with a security code to ensure that no one but themselves can access data in these formats.

Mobile phones and computers are becoming more similar with the increased sophistication of applications for mobile phones. Some of these applications can be used to collect various data. Other electronic devices include pill containers that record when pills are accessed and watches with timers to remind participants to take certain health-related actions. However, the use of these devices for research may require considerable preparation. You may need to hire programmers with the needed expertise, and you may need to purchase, rent, or borrow the needed number of devices or monitors.

Factors Influencing Data Collection

When planning data collection, cost, time, the availability of assistance, and the need for consistency are critical factors to consider. The researcher balances these factors with the need to maintain the reliability and validity of the study in the development of the data collection plan.

Cost Factors

Cost is a major consideration when planning a study. Measurement tools, such as continuous electrocardiogram monitors (Holter monitor), wrist activity monitors (accelerometers), spirometers, pulse oximeters, or glucometers, used in physiological studies may need to be rented, purchased, or loaned from the manufacturer or other company. You may need to pay a fee to use instruments or questionnaires. Some instruments and questionnaires are available only if a copy is purchased for each participant. Data collection forms may need to be formatted or developed for electronic use. In some cases, printing costs for materials such as teaching materials or questionnaires that will be used during the study must be considered. Providing the required copy of the signed consent form doubles the expense of consent forms. Small payments to participants in the form of cash or gift cards should be considered as compensation for a subject's time and effort in providing the data. Sometimes childcare may need to be provided for parents and other caregivers who would not otherwise be able to participate in your study. In some studies, postage is an additional expense. There may be costs involved in coding the data for entry into the computer and for conducting data analyses. Consultation with a statistician early in the development of a research project and during data analysis must also be budgeted. You may need to hire someone who can remain blinded for data entry or analysis or someone who can type the final report, develop graphics or presentations, or type and edit manuscripts for publication.

In addition to the above-described direct costs of a research project, there are costs associated with the researcher's time and travel to and from the study site. You also must estimate the expense of presenting the research findings at conferences and include those expenses in the budget. To prevent unexpected expenses from delaying the study, examine all costs in an organized manner. A budget is best developed early in the planning process and revised as plans are modified. Seeking funding for at least part of the study costs can facilitate the conduct of a study.

Time Factors

Researchers often underestimate the time required for participants to complete data collection forms and for the research team to recruit and enroll subjects for a study. The first aspect of time—the participant's time commitment—must be determined early in the process because the time needed for participant involvement must be included in the informed consent process and document. While conducting your pilot study, make note of the time required to collect data from a subject. You may need to revise your timeline and consent form to reflect the expected time commitment accurately.

The second aspect of time—the time needed to complete data collection—is especially challenging to predict because events during the data collection period sometimes are not under the researcher's control. For example, a sudden heavy staff workload may make data collection temporarily difficult or impossible, or the number of potential subjects might be reduced for a period. In some situations, researchers must obtain permission from each subject's physician before they are permitted to collect data on that subject. Activities required for this stipulation, such as contacting physicians, explaining the study, and obtaining permission, require extensive time. In some cases, potential subjects are lost before the researcher can obtain the mandatory permission, extending the time required to obtain the necessary number of subjects.

How long will it take to identify potential subjects, explain the study, and obtain consent? How much time will be needed for activities such as completing questionnaires or obtaining physiological measures? Novice researchers have difficulty making reasonable estimates of time and costs related to a study. Validating the time and cost estimates with an experienced researcher can be very informative. Experienced researchers know the challenges of data collection and have learned that data collection may take two to three times longer than predicted. If the cost and time factors are prohibitive, you may need to simplify your study so that fewer variables are measured, fewer instruments are used, or fewer subjects are needed. Make the design less complex, and use fewer data collectors. A blinded intervention study involves more research staff and is generally not feasible for a novice researcher. These are serious modifications, however, with implications for the validity of the findings, so you and your team should thoroughly examine the consequences before making such revisions. If preliminary time or cost estimates go beyond expectations, you can revise the time schedules and budget with new projections for completing the study.

Consistency

Consistency in data collection across subjects is critical. What time of year will data be collected? For example, if you collect data during holiday seasons, data about sleeping, eating, or exercising may vary. Pediatric patients with asthma may experience more symptoms during the winter months than during summer. Planning data collection for a study of symptom management with this population would need to take this possibility into consideration.

The specific days and hours of data collection may influence the consistency of the data collected and must be carefully considered. For example, the energy level and state of mind of subjects from whom data are gathered in the morning may differ from that of subjects from whom data are gathered in the evening. With hospitalized study participants, visitors are more likely to be present at certain times of day and may interfere with data collection or influence participant responses. Patient care routines vary with the time of day. In some studies, the care recently received or the care currently being provided may alter the data you gather. The subjects you approach on Saturday to participate in the study may differ from the subjects you approach on weekday mornings. Subjects seeking care on Saturday may have a full-time job, whereas subjects seeking care on weekday mornings may be either unemployed or too ill to work.

Who will collect the data? If you decide to use data collectors, they must be trained in responsible conduct of research and issues of informed consent, ethics, and confidentiality and anonymity (see Chapter 9). They must be informed about the research project, familiar with the instruments to be used, and have equivalent training in the data collection process. In addition to training, data collectors need written guidelines or protocols that indicate which instruments to use, the order in which to introduce the instruments, how to administer the instruments, and a time frame for the data collection process (Harwood, 2009; Kang, Davis, Habermann, Rice, & Broome, 2005).

If more than one person is collecting the data, consistency among data collectors (interrater reliability) must be ensured through testing (see Chapter 16). The training needs to continue until interrater reliability estimates are at least 85% to 90% agreement between the expert and the trainee or trainees. Waltz, Strickland, and Lenz (2010) suggest that a minimum of 10% of the data needs to be compared across raters before interrater reliability can be adequately reported. The trained data collector's interrater reliability with the expert trainer should be assessed intermittently throughout data collection to ensure consistency from the first to the last participant in the study. Data collectors also must be encouraged to identify and record any problems or variations in the environment that affect the data collection process. The description of the training of the data collectors is usually reported in the methods section of an article so that others can assess the data collection process (Harwood & Hutchinson, 2009).

Availability of Assistance

Who is going to help you with the study? If you are a student, will your mentor or supervising faculty member participate? Does your mentor or supervising faculty member have research assistants who could assist in your study? Will nurses, physicians, and other health professionals assist with recruitment? Do they have time to do this? Are they willing to help?

Will the researcher collect all the data, or will data collectors be employed for this purpose? Can data collectors be nurses working in the area? Data collection may be delayed when nurses providing patient care are also expected to be data collectors. Even when a nurse agrees to help you with subject recruitment or data collection, patient care takes priority over data collection and increases the risk for missing data or missing the opportunity to enroll eligible subjects.

If clinicians are going to recruit subjects or collect data, the clinicians need to complete training for

protection of human subjects during research. An IRB requires documentation of this training for each person involved in recruitment and data collection. If you are going to be doing all the data collection yourself, will you be available every day of the week? What hours will you be available? If others will be involved in collecting data, allow time for training on data collection procedures. You need to be available by telephone or other means for questions and emergencies when others are collecting data for your study. Keeping these factors in mind, you are now ready to plan the data collection process for your study.

Data Collection and Coding Plan

The factors of cost, time, availability of assistance, and need for consistency shape the data collection plan that you develop. A **data collection plan** details how you will implement your study. The plan for collecting data is specific to the study being conducted and requires that you consider some common elements of research. You need to map out procedures you will use to collect data, anticipate the time and cost of data collection, develop data collection forms that ease data entry, and prepare a codebook that will help you to code the variables to be entered in a database. This extensive planning increases the accuracy of the data collected and the validity of the study findings. The validity and strength of the findings from several carefully planned studies increase the quality of the research evidence that is then available for implementing into clinical practice (Melnyk & Fineout-Overholt, 2010).

Identifying data include variables such as patient record number, home address, and date of birth (see Chapter 9). Avoid collecting these data unless they are essential to answer the research question. For example, collect a patient's age instead of date of birth. Review regulations by the Health Insurance Portability and Accountability Act about the participant's private health information (www.hhs.gov/ocr/hipaa).

The methodology of a study may include contacting subjects later for additional data collection. In this case, you will need to obtain the subject's address and telephone number and protect the information appropriately. Names and phone numbers of family members or friends may also be useful if subjects are likely to move or may be difficult to contact. This information can be obtained only with subjects' permission as part of their informed consent. Consider the importance of each piece of data and the subject's time required to collect it. If the data can be obtained from patient records or any other written sources, you do not need to ask the subject to provide this information. To collect data from a patient's records, make sure to include permission to do this in the consent form, and ensure that the IRB has authorized your team to do this.

Data Collection Forms

Before data collection begins, you may need to develop or modify forms on which to record data. These forms can be used to record demographic data, information from the patient record, observations, or values from physiological measures. The demographic variables commonly collected in nursing studies include age, gender, race, education, income, employment status, diagnosis, and marital status. You may want to collect additional demographic data if researchers have identified participant characteristics that affect the study variables. You also might need to collect other data that may be extraneous or confounding variables, such as the subject's physician, stage of illness, length of illness or hospitalization, complications, date of data collection, time of day and day of week of data collection, and any untoward events that occur during the data collection period. If there are only women in your sample, the subject's age and reproductive status, parity, and number of children in the home may be confounding variables. In a study of patients with ventilator-associated pneumonia, the researcher needs to record the length of time between when the patient was intubated and when ventilator-associated pneumonia was diagnosed. The researcher for this study also needs to record whether the patient had a preexisting pulmonary disease.

Data collection forms must be designed so that the data are easily recorded, coded, and entered into the computer. You need to decide whether data will be collected in raw form or coded at the time of collection. **Coding** in quantitative studies is the process of transforming data into numerical symbols that can be entered easily into the computer. For example, variables such as race, gender, ethnicity, and diagnoses can be categorized and given numerical labels. For gender, the male category could be identified by a "1" and the female category by a "2." You may also want to include an "other" category (coded "3") for participants who are transgendered or transsexual. To be able to compare your sample with samples in federally funded studies, you may need to separate the questions about ethnicity and race. In 2003, the Office of Management and Budget of the U.S. government directed researchers and others collecting data for federal purposes or at federal expense to separate the questions of race and ethnicity (Office of Minority Health,

2010). At the same time, the Office of Management and Budget specified the categories for each. The following questions are correct according to these federal guidelines. How would a subject who is biracial or multiracial complete the form? You may want to word the question to ask the participant's primary race or allow multiple responses.

Ethnicity

(1) Hispanic or Latino
(2) Non-Hispanic or Latino

Race

(1) American Indian or Alaskan Native
(2) Asian
(3) Black or African American
(4) Native Hawaiian or Other Pacific Islander
(5) White

The coding categories developed for a study not only must be mutually exclusive but also exhaustive, which means that the value for a specific variable fits into only one category, and each observation must fit into a category. For example, a subject is highly unlikely to want to reveal his or her exact income but would be more willing to indicate that the income is in a particular range. The income ranges would not be mutually exclusive or exhaustive if they were categorized in the following way on a demographic questionnaire:

Income range (please check the range that most accurately reflects your income)

___ (1) $30,000 to $40,000
___ (2) $40,000 to $50,000
___ (3) $50,000 to $59,000
___ (4) $60,000 to $70,000
___ (5) $70,000 or more

These categories are not exclusive because they overlap, and a subject with a $40,000 income could mark category 1 or category 2 or both. The categories are not exhaustive because a subject may have an income of either $25,000 or $59,500, yet the questionnaire does not contain categories that include each of these incomes. How much detail do you need on income? Do you want to know if the participant's household income is below poverty level? To determine poverty level, you must know not only the household income but also how many people live in the household and compare this information with federal poverty guidelines (http://aspe.hhs.gov/poverty/09poverty.shtml).

The following income ranges are both exclusive and exhaustive and would be appropriate for collecting demographic data from subjects:

Income range (please check the range that most accurately reflects your family's income for a year, before taxes)

___ (1) Less than $30,000
___ (2) $30,000 to $49,999
___ (3) $50,000 to $69,999
___ (4) $70,000 or greater

Data collection forms offer many response styles. The person completing the form (subject or data collector) might be asked to check a blank space before or after the words "male," "female," or "other" or to circle one of the words. If code numbers or variable name codes are used, the meaning of the codes should be clearly indicated on the collection forms so that the individual completing the form understands them and is not confused or misled by the code. Developing a codebook for your data collection forms and data entry is discussed later.

Placement of the data on the forms is important because careful placement makes it easier for subjects to complete the form without missing an item and for data entry staff to locate responses for computer entry. Placement of blanks on the left side of the page seems to be most efficient for data entry, but this layout may prove problematic when subjects are completing the forms. The least effective arrangement is when the data are positioned irregularly on the form because the risk of data being missed during data entry is high. Subjects' names should not be on the data collection forms; only the subject's identification number should appear. The researcher may keep a master list of subjects and their code numbers, which is stored in a separate location and either encrypted in an electronic file or data repository or locked in a file drawer to ensure the subjects' privacy. Often this master list of subjects and codes is kept with the subjects' consent forms in a locked file drawer. This master list is required if collecting data later or recontacting the subject is a necessary component of your study.

You should always organize your data collection forms and instruments to begin with less personal types of questions about age and education before delving into more personal questions about contraceptives or feelings and attitudes. Also, you would not want to save your most important items for the last page of the questionnaire and risk missing data if a participant becomes too fatigued or bored to finish the questions. Different types of questions require more or less time to complete, a factor that needs to be considered. Also, questions may ask for a response related to different time frames. For example, if one questionnaire asks about the past week and two other questionnaires ask about the past month, these should be organized so that the subject is not confused by going back and forth between time frames. If you have several instruments or forms, you may want to put

them together in a booklet to minimize the likelihood that a questionnaire or form will be missed.

Figure 20-3 provides a sample data collection form. It includes four items that could be problematic for coding, data analysis, or both. The blank used to enter "Surgical Procedure Performed" would lead to problems when it is time to enter the data into a computerized data set. Because multiple surgical procedures could have been performed, developing codes for the various surgical procedures would be difficult and time-consuming. In addition, different words might be used to record the same surgical procedure. It may be necessary to tally the surgical procedures manually. Unless this degree of specification of procedures is important to the study, an alternative would be to develop larger categories of procedures before data collection and place the categories on the data collection form. A category of "Other" might be useful for less commonly performed surgical procedures. This method would require the data collector to make a judgment regarding which category was appropriate for a particular surgical procedure. Another option would be to write in the category code number for a particular surgical procedure after the data collection form is completed but before data entry. If the specific surgical procedure is important to your study, you may want to record the code the facility uses to bill for the procedure. Similar problems occur with the items "Narcotics Ordered after Surgery" and "Narcotic Administration." Unless these data are to be used in statistical analyses, it might be better to categorize this information manually for descriptive purposes. If these items are needed for planned statistical procedures, use care to develop appropriate coding. You may need detailed information if you want to know the appropriateness of the narcotic doses given. The researcher might be interested in determining differences in the amount of narcotics administered in a given period in relation to weight and height. For blinded studies, you do not want to record the treatment group assignments on the data collection form. Placing the treatment group code on the data collection form would be problematic because the information is no longer blinded and could influence the data recorded by the data collectors.

Data Collection Detailed Plan

To ensure consistency in the data collection process, you need to develop a detailed plan. Envision the overall activities that will be occurring during data collection. Write each step and develop the forms, training, and equipment needed for that step. Focus on who, what, when, where, why, and how. How will you

DATA COLLECTION FORM

Demographics
____Subject Identification Number
____Age
____Gender
1. Male
2. Female
____Weight (in pounds)
____Height (in inches)
_____Surgical Procedure Performed
__/__/__Surgery Date (Month/Day/Year)
__/__/__Surgery Time (Hour/Minute/AM or PM)
Narcotics Ordered After Surgery_____
_____

Narcotic Administration

Date	Time	Narcotic	Dose
1.			
2.			
3.			
4.			
5.			

Instruction on Use of Pain Scale
__/__/__Date (Month/Day/Year)
__/__/__Time (Hour/Minute/AM or PM)
Comments:

__Treatment Group
1. TENS
2. Placebo-TENS
3. No-Treatment Control

Treatment Implemented
__/__/__Date (Month/Day/Year)
__/__/__Time (Hour/Minute/AM or PM)
Comments:

Dressing Change
__/__/__Date (Month/Day/Year)
__/__/__Time (Hour/Minute/AM or PM)
_____Hours since surgery
Comments:

Measurement of Pain
_____Score on Visual Analogue Pain Scale
__/__/__Date Pain Measured (Month/Day/Year)
__/__/__Time Pain Measured (Hour/Minute/AM or PM)
_____Hours since surgery
Comments:

_____Data Collector Code
Comments:

Figure 20-3 Data collection form.

recruit subjects? At what point is a subject assigned to a group? It is optimal to assign subjects randomly to an intervention group or control group after baseline data are collected but before introducing the intervention. In this way, all subjects demonstrate the ability to complete the questions and measures and have the opportunity to decline further participation before group assignment. When and how will you implement the intervention? Will data be collected from more than one subject at a time, or is it necessary to focus attention on one subject at a time? How much time is needed to collect data from each subject? The length of time per subject is determined by study design, setting, and available space. In addition, if you plan for three subjects in the morning and three in the afternoon, what are the contingencies for subjects who arrive late or need additional time? Some subjects may be available only during their lunch break or in the evening.

You might develop a data collection flow diagram to illustrate the process for collecting data in your study. An example is shown in Figure 20-4. The Consolidated Standards of Reporting Trials (CONSORT) guidelines for reporting randomized trials in publications (Bennett, 2006) would also be very useful for depicting the design and flow of your data collection process and expected enrollment numbers, expected attrition rates, and final sample sizes for each group (see Chapter 19).

Decision Points

Decision points that occur during data collection must be identified, and all options must be considered. One decision may pertain to whether too few potential subjects are meeting the sampling inclusion criteria. Will you review study progress every week or every month? If too few subjects from your potential pool are eligible, at what point will you consider changing exclusion criteria? For example, if you are recruiting only first-time mothers older than 30 years of age, and you are turning away willing participants because they are too young, you and your research team need to reconsider the rationale for that criterion and perhaps decide either to lower the age range or to seek different recruitment sites.

Other decisions include whether the subject understands the information needed to give informed consent, whether the subject comprehends instructions related to providing data, and whether the subject has provided all the data needed. As you look through the completed data forms, are all responses completed? If the subject skips a page, you will need to return that page to the subject for completion. If the question about income is not completed, how will you handle that missing response? Your data collection flow chart should indicate how much missing data will be allowed per subject. At what point will you decide to exclude a participant from your study?

Developing a Codebook for Data Definitions

We advise that you develop your codebook before initiating data collection or during the pilot study. A codebook identifies and defines each variable in your study and includes an abbreviated variable name (*income*), a descriptive variable label (*gross household annual income*), and the range of possible numerical values for every variable entered in a computer file (*0 = none; 1 = <$30,000; 6 = >$100,000*). Some codebooks also identify the source of each datum, linking your codebook with your data collection forms and scales. The codebook keeps you in control and provides a safety net for when you access the data later. Some computer programs, such as SPSS for Windows, allow you to print out your data definitions after setting up a database. Figure 20-5 is an example of data definitions from SPSS for Windows. Another example of coding is presented in Figure 20-6.

Developing a logical method of abbreviating variable names can be challenging. For example, you might use a quality-of-life (QOL) questionnaire in your study. It will be necessary for you to develop an abbreviated variable name for each item in the questionnaire. For example, the fourth item on a QOL questionnaire might be given the abbreviated variable name *QOL4*. A question asking the last time a home health nurse visited might be abbreviated *HHN Lstvisit*. Although abbreviated variable names usually seem logical at the time the name is created, it is easy to confuse or forget these names unless they are clearly documented with a variable label.

During the piloting phase of your research with the first few pilot subjects, you can easily refine your variable names and labels and request your research team or a statistician to review the variables. This practice encourages you to identify places in your forms that might prove to be a problem during data entry because of lack of clarity. Also, you may find that a single question contains not one but five variables. For example, an item might ask whether the subject received support from her or his mother, father, sister, brother, or other relatives and ask the subject to circle the number that represents those who provided support. You might think that you could code mother as "1," father as "2," sister as "3," brother as "4," and other as "5." However, because the individual can circle more than one, each relative must be coded separately. Thus, mother is one variable and would be a

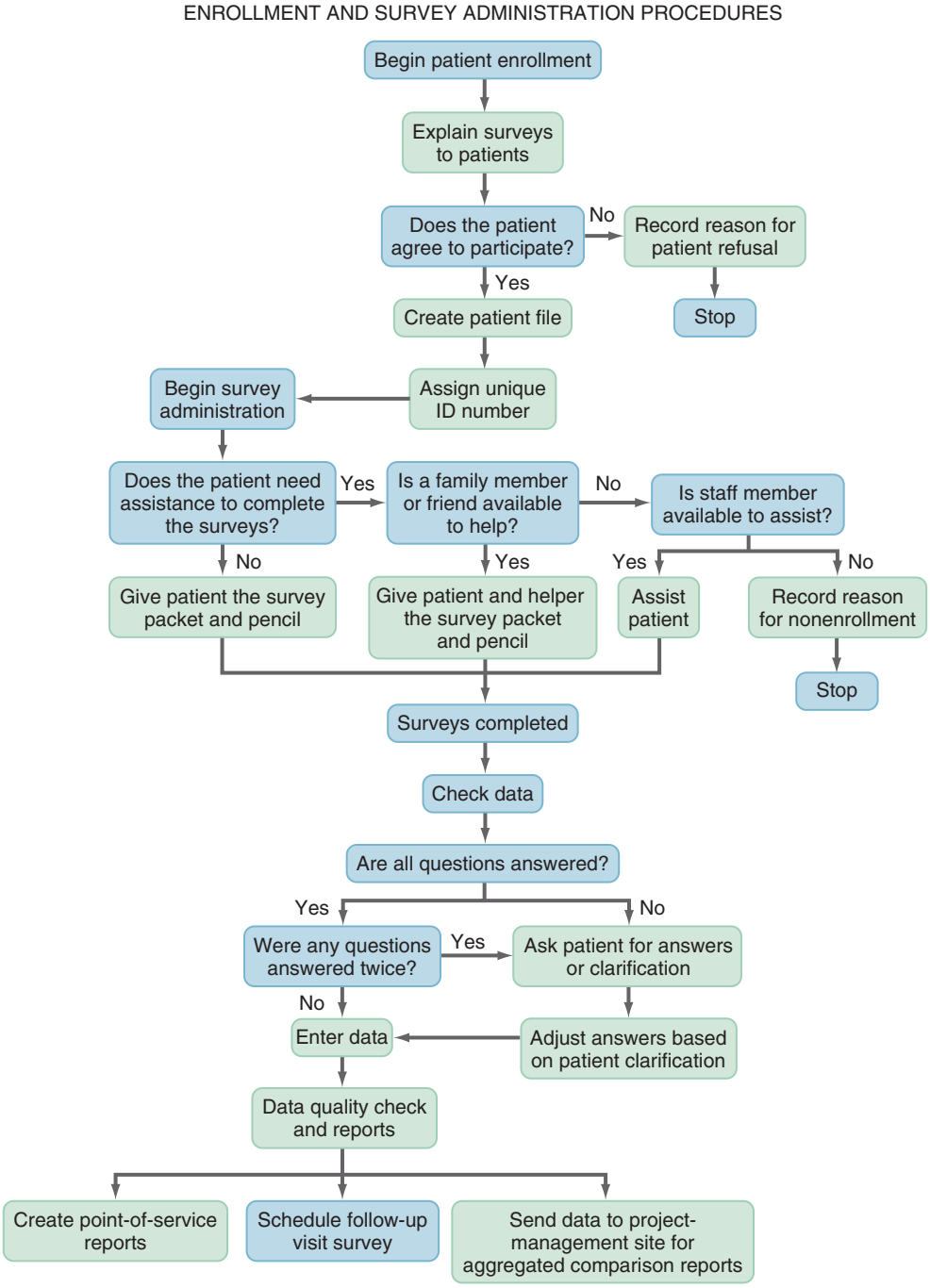

Figure 20-4 Data collection flow chart.

Q1		Value
Standard Attributes	Position	2
	Label	I was motivated to migrate from my country because my pay was too low.
	Type	Numeric
	Format	F8
	Measurement	Ordinal
	Role	Input
Valid Values	1	Strongly Disagree
	2	Disagree
	3	Neutral
	4	Agree
	5	Strongly Agree
Missing Values	System	

Q 39		Value
Standard Attributes	Position	40
	Label	What is your gender?
	Type	Numeric
	Format	F8
	Measurement	Nominal
	Role	Input
Valid Values	1	Male
	2	Female
Missing Values	System	

Figure 20-5 Example of data definitions from SPSS for Windows. (Source: Nurse International Relocation Questionnaire 2 [Gray & Johnson, 2009].)

Q50		Value
Standard Attributes	Position	54
	Label	Which of the following best describes your current employment situation?
	Type	Numeric
	Format	F8
	Measurement	Nominal
	Role	Input
Valid Values	1	Employed and working full time
	2	Employed and working part time
	3	Employed, currently on leave
	4	Self-Employed
	5	Unemployed
	6	Other
Missing Values	System	

Variable Name	*Variable Label*	*Source*	*Value Levels*	*Valid Range*	*Missing Data*	*Comments*
A1 to A5	Family Apgar	Q2Family Apgar	1=never 2=hardly ever 3=some of the time 4=almost always 5=always	1 – 5	9	Code as is (CAI)
MF3	Mother's feeling, Day 3	Tuesday diary, mother	1=poor 6=good	1 – 6	9	Code 1 to 6 left to right

Figure 20-6 Example of coding.

dichotomized value, coded "1" if circled and "0" if not circled. The father would be coded similarly as a second dichotomous variable, and so on. Identifying these items before data collection may allow you to restructure the item on the questionnaire or data collection form to simplify computer entry.

Give the codebook with its data definitions to the individual or individuals who will enter your data into the computer *before initiating data collection*. Decision rules for data entry should also be finalized. For example, if a subject selects two responses for a single item, will the variable be coded as missing, or does convention dictate that the lowest or highest value should be entered? Individuals who are entering data need to have clarity on the distinctions between coding a missing value or nonapplicable value as blank rather than entering a "0" value.

In addition, provide the following information to the person entering the data:

- Dates for data collection initiation and completion
- Estimated number of subjects to be included in the study and how often batches of subjects' data will be entered
- Plan for documenting refusal rate, sample size, and attrition during the study
- Copies of all scales, questionnaires, and data collection forms to be used in the study
- Location of every variable on scales, questionnaires, or data collection forms
- Statistical package to be used for analysis of the data
- Statistical analyses to be conducted to describe the sample and to address the research purpose and the objectives, questions, or hypotheses
- Contact information for the statistician or project director who is available to consult about data entry questions or data analysis
- Computer directory location of the database in which the data will be entered and copied for backup
- Timeline for receiving the data—for example, whether you will deliver the data in batches or wait until all the data have been gathered before delivering it

With this information, the assistant can develop the database in preparation for receiving the data. The time needed to prepare the database varies depending on the number of variables and the complexity of the response categories. Approximate dates for completion of the data entry, analyses, or both must be negotiated before beginning data collection. If you have a deadline for completing the study or presenting your results, you should share this information with the people performing data entry and analysis.

Pilot Study

Completing a pilot study may save you difficulty later when you implement the final steps of the research process. Pilot testing helps you to identify problems you might encounter while collecting data and helps you develop strategies for addressing potential problems. Chapter 3 provides reasons to conduct a pilot study. Following approval of the study by your IRB, use your research plan to recruit three to five subjects who meet your eligibility criteria. Use the data collection methods that you have selected and prepared. Pay attention to how long it takes to recruit a subject, obtain informed consent, and collect the data. Ask the participant to identify questions or aspects of the process that were unclear or confusing. Based on the pilot study and feedback of the first subjects, modify your data collection forms and methods of data collection to ensure the feasibility, validity, and reliability of the study.

Collecting Data

Data collection is the process of selecting subjects and gathering data from these subjects. The actual steps of collecting the data are specific to each study and depend on the research design and measurement methods. Data may be collected on subjects by observing, testing, measuring, questioning, recording, or any combination of these methods. The researcher is actively involved in this process either by collecting data or by supervising data collectors. You will apply ethical principles, people-management strategies, and problem-solving skills constantly as data collection tasks are implemented. Even after pilot testing, snags in the research plan can occur, and support systems are needed for data collectors who encounter situations in the home or clinic that require reporting to legal authorities. For example, during a home visit, a data collector may find that family members are neglecting a subject in the study who cannot get out of bed. Frequent interactions with data collectors on your team are also essential for assessing any minor or major risks and reporting adverse effects to your IRB.

Data Collection Tasks

In both quantitative and qualitative research, the investigator performs four tasks during the process of data collection. These tasks are interrelated and occur

concurrently rather than in sequence. The tasks are (1) selecting subjects, (2) collecting data in a consistent way, (3) maintaining research controls as indicated in the study design, and (4) solving problems that threaten to disrupt the study. Selecting subjects is discussed in Chapter 15. Collecting data may involve administering Internet or paper-and-pencil scales; asking subjects to complete data collection forms in person or online; or recording data from observations, patient medical records, or monitoring equipment (Chapters 16 and 17 provide information on measurement strategies). Data collection tasks for qualitative studies are discussed in more detail in Chapter 12.

Maintaining Control

Maintaining control and consistency of the design and methods during subject selection and data collection protects the integrity or validity of the study. Researchers build controls into the design to minimize the influence of intervening forces on the study findings. Maintenance of these controls is essential. For example, a study to describe the changes in sleep stages during puberty may require controlling the environment of the bedroom to such an extent that a sleep laboratory is the only setting in which integrity can be maintained. Control is not always realistic in a natural field setting, and, in some cases, these controls can fail without the researcher realizing it. Often the researcher must opt for a randomized controlled study to address potential control failures so that they are equally likely to occur in either group.

In addition to maintaining controls identified in the research plan, you must continually watch for previously unidentified extraneous variables that might have an impact on the data being collected. These variables are often specific to a study and tend to become apparent during the data collection period. The extraneous variables identified during data collection must be considered during data analysis and interpretation. These variables also must be noted in the research report to allow future researchers to control them. For example, Lee and Gay (2011) studied sleep quality in new mothers and asked about the infant's sleep location, but the location at the beginning of the night was often not the same by morning and could not be controlled in the home setting.

Problem Solving

Little has been written about the problems encountered by nurse researchers. Research reports often read as though everything went smoothly. The implication is that if you are a good researcher, you will have no problems, which is not true. Research journals generally do not provide enough space for the researcher to describe the problems encountered, and inexperienced researchers may get a false impression. Some of the problems are hinted at in a published paper in either the limitations section or in a discussion of areas for future research. A more realistic sense of the problems encountered by a researcher can be obtained through personal discussions with the primary author about his or her process of data collection for a particular sample or using a particular method or instrument. Some common problems experienced by researchers are discussed in the following section.

A problem can be perceived either as a frustration or as a challenge. The fact that the problem occurred is not as important as successfully resolving it. The final and perhaps most important task during the data collection period may be debriefing with your research team in weekly meetings for problem resolution.

Data Collection Problems

Murphy's law (if anything can go wrong, it will, and at the worst possible time) seems to prevail in research, just as in other dimensions of life. For example, data collection frequently requires more time than was anticipated, and collecting the data is often more difficult than expected. Even following a pilot study, you may encounter challenges during the data collection process. Sometimes changes must be made in the way the data are collected, in the specific data collected, or in the timing of data collection. People react to the study in unpredictable ways. Institutional changes may force modifications in the research plan, or unusual or unexpected events may occur. You must be as consistent as possible during the data collection process, but you must also be flexible in dealing with unforeseen problems. Sometimes, sticking with the original plan at all costs is a mistake. Skills in finding ways to resolve problems that protect the integrity of the study can be critical.

In preparation for data collection, possible problems must be anticipated, and solutions for these problems must be explored. The following discussion describes some common problems and concerns and presents possible solutions. Problems that tend to occur with some regularity in studies have been categorized as people problems, researcher problems, institutional problems, and event problems.

People Problems

Nurses cannot place a subject in a laboratory test tube, instill one drop of the independent variable, and then measure the effect. Nursing studies are

often conducted by examining subjects as they interact with their environments. Many aspects of the environment can be controlled by using a laboratory setting, but other studies require the natural setting to have external validity. When research involves people, nothing is completely predictable. People, in their complexity and wholeness, have an impact on all aspects of nursing studies. Researchers, potential subjects, family members of subjects, healthcare professionals, institutional staff members, and others ("innocent bystanders") interact within the study situation. You will need to observe closely and evaluate these interactions to determine their impact on your study.

Problems Selecting a Sample

The first step in initiating data collection—selecting a sample—may be the beginning of people problems. You may find that few people are available who fit your inclusion criteria or that many people you approach refuse to participate in the study even though the request seems reasonable. Appropriate subjects, who were numerous a month earlier, seem to have disappeared. Institutional procedures may change, which might make many potential subjects ineligible for participation in the study. You may have to evaluate the inclusion and exclusion criteria or seek additional sources for potential subjects. In research institutions that care for the indigent, patients tend to be reluctant to participate in research. This lack of participation might arise because these patients are frequently exposed to studies, feel manipulated, or misunderstand the research. Patients may feel that they are being used or fear that they will be harmed in some way. For example, recruiting Spanish-speaking women for a study of stress and acculturation may be met with high refusal rates if these women are worried about revealing their legal status in the United States. Recruiting women who are planning a pregnancy in the next 6 months may not yield participants because they are fearful that others (work colleagues or friends) will find out about their plan.

Subject Attrition

After you have selected a sample, certain problems might cause **subject attrition** (a loss of subjects from the study over time). For example, some subjects may agree to participate but then fail to follow through. Some may not complete needed forms and questionnaires or may fill them out incorrectly. To reduce these problems, a research team member can be available to subjects while they complete essential questions. Some subjects may not return for a second interview or may not be home for a scheduled visit. Although you have invested time to collect data from these subjects, their data may have to be excluded from analysis because of incompleteness. Generally, the more data collection time points you require as part of your design, the higher the risk for attrition. Attrition can occur because of subject burden accumulating over time, because healthy adults relocate for employment or family reasons, or because of death in a more critically ill population.

Sometimes subjects must be dropped from the study by the research team because of changes in health status. For example, a patient may be transferred out of the intensive care unit where the study is being conducted. Another possibility might be that the patient's condition may worsen and the patient no longer meets the inclusion criteria. The limits of third-party reimbursement may force the healthcare provider to discontinue the services you are studying.

Subject attrition occurs to some extent in all longitudinal studies. One way for you to deal with this problem is to anticipate the attrition rate and increase the planned number of subjects to ensure that a minimally desired number will complete the full study. Review similar studies to anticipate the attrition rate. For example, Lim, Chiu, Dohrmann, and Tan (2010) reported a 31% attrition rate in their quasi-experimental study of the knowledge of registered nurses employed in long-term care. The investigators collected pretest data from 58 subjects and 4 weeks later collected post-test data from 40 subjects. If subject attrition is higher than expected, consider additional small incentives along the way or a bonus for completing the final assessment to achieve an adequate final sample size. Attrition is usually higher in the placebo or control group, but a well-designed, attention-control group should have an attrition rate that is similar to the attrition seen in your intervention group. Sometimes a study might end with a smaller than expected sample size. If so, the effect of a smaller sample on the power of planned statistical analyses must be considered because this smaller sample may be inadequate to test the hypotheses.

Researchers should report information about subjects' acceptance to participate in a study and attrition during the study to determine if the sample is representative of the study target population. Journal editors often require that manuscripts include a flow chart indicating the number of subjects meeting sample criteria, the numbers refusing to participate, and the reasons for refusal. If data are collected over time (repeated measures) or the study intervention is implemented over time, subjects often drop out of a

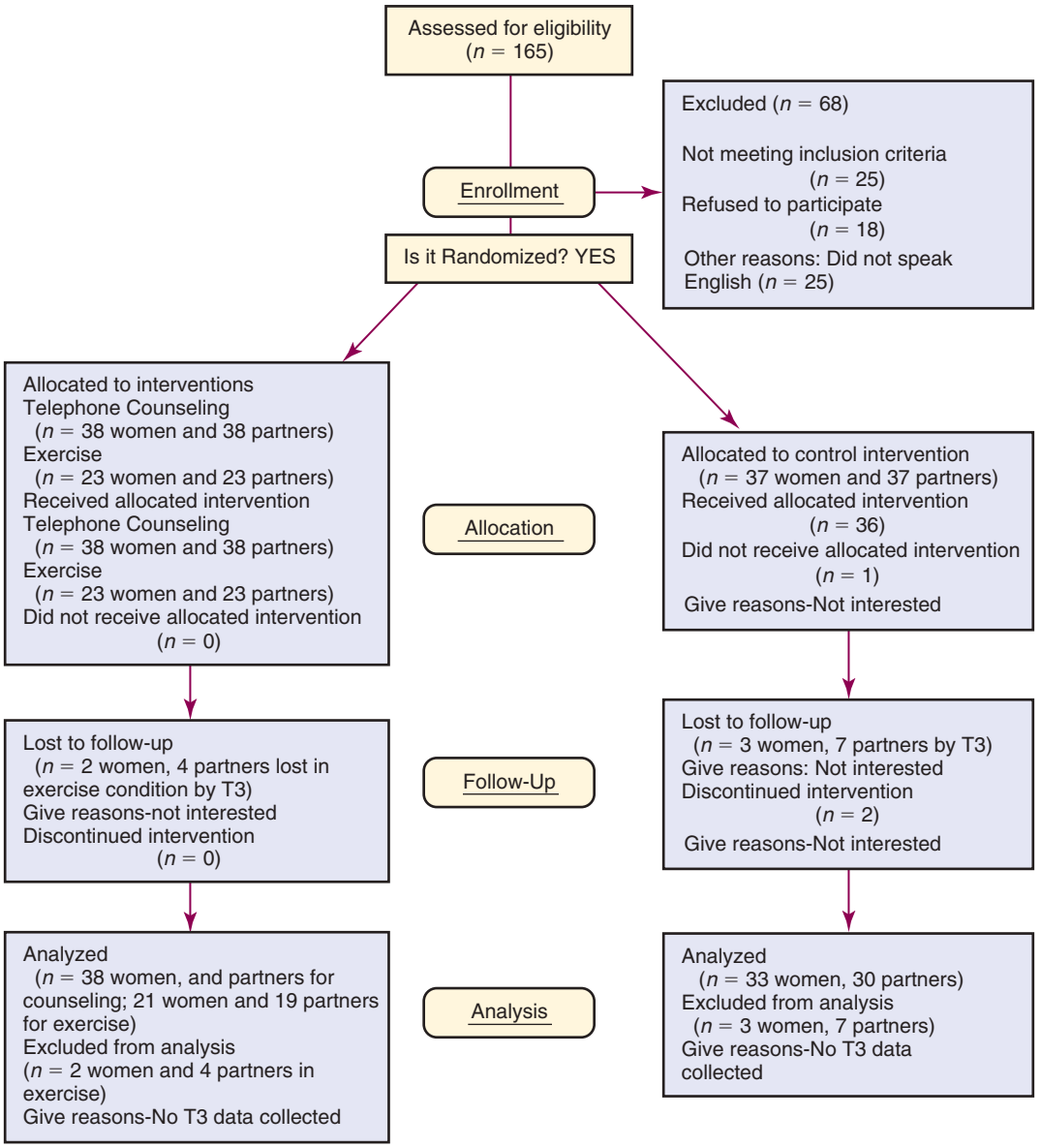

Figure 20-7 Sample selection and allocation.
T3 = Tumor more than 5cm across. (From Badger, T., Segrin, C., Dorros, S., Meek, P., & Lopez, A. M. [2007]. Depression and anxiety in women with breast cancer and their partners. *Nursing Research, 56*[1], 44–53.)

study, and it is important to document when and how much attrition occurred. Using the CONSORT guidelines published by Bennett (2006), Badger, Segrin, Dorros, Meek, and Lopez (2007) provided a flow chart to document participants' selection, refusal rate, assignment to group, and attrition over the weeks of data collection (see Figure 20-7). The flow chart clearly identifies important aspects of the sampling process and reasons for attrition. This information enables researchers and clinicians to evaluate the representativeness of their sample for external validity and for any potential bias in interpreting the results.

Subject as an Object

The quality of interactions between the researcher and subjects during the study is a critical dimension for

maintaining subject participation. When researchers are under pressure to complete a study, people can be treated as objects rather than as subjects, particularly if electronic data collection is used. In addition to being unethical, such impersonal treatment alters interactions, diminishes subject satisfaction, and increases likelihood for missing data and subject attrition. Subjects are scarce resources and must be treated with care. Treating the subject as an object can affect another researcher's ability to recruit from this population in the future. Treating the subject as an object can be minimized by building strategies into the consent process, such as offering them a personal copy of their results, recognizing their valuable participation with small gifts as tokens of appreciation, or providing monetary reimbursement for their time and effort.

External Influences on Subject Responses

People interacting with the subject, the researcher, or both can have an important impact on the data collection process. Family members may not agree to the subject's participation in the study or may not understand the study process. These individuals often influence the subject's decision to participate. Researchers benefit from taking the time to explain the study and seeking cooperation of family members. Family cooperation is essential when the potential subject is critically ill and unable to give informed consent.

Family members or other patients may also influence the subject's responses to scales or interview questions. In some cases, subjects may ask family members, friends, or other patients to complete study forms for them. The subject may discuss questions on the forms with other people who happen to be in the room, and therefore the data recorded do not reflect the subject's real feelings. If interviews are conducted while others are in the room, the subject's responses may depend on his or her need to meet the expectations of the other persons. Sometimes a family member may answer questions addressed verbally to the patient. The setting in which a questionnaire is completed or an interview is conducted may determine the extent to which the answers are a true reflection of a subject's feelings. If the privacy afforded by the setting varies from one subject to another, the subjects' responses may also vary and threaten both the internal and the external validity of the findings.

Usually, the most desirable setting for an interview is a private area away from distractions. If it is not possible to arrange for such a setting, the researcher can be present at the time the questionnaire is completed to decrease the influence of others. If the questionnaire is to be completed later or taken home and returned at a later time, the probability of influence by others increases, and return of the questionnaire packet becomes less likely, even if the subject is provided with a stamped return envelope. The impact of this problem on the integrity of the data depends on the nature of the questionnaire items. For example, a marital relationship questionnaire may have different responses if the subject is allowed to complete it alone and return it immediately to the researcher or have to complete it aloud with the spouse in attendance.

Passive Resistance

Healthcare professionals and institutional staff members working with the study participants in clinical settings may affect the data collection process. Some professionals verbalize strong support for the study and yet passively interfere with data collection. For example, nurses providing care may fail to follow the guidelines agreed on for providing the specific care activities being studied, or information needed for the study may be left off patient records. The researcher may not be informed when a potential subject has been admitted, and a physician who has agreed that his or her patients can be participants may decide as each patient is admitted that this one is not quite right for the study. In addition, when the permission of the physician or nurse practitioner is required, the provider might be unavailable to the researcher.

Nonprofessional staff members may not realize the impact of the data collection process on their work patterns until the process begins. The data collection process may violate their beliefs about how care should be provided (or has been provided). If ignored, their resistance can completely undo a carefully designed study. For example, research on skin care may disrupt a nursing aide's bathing routine, so he or she may continue the normal routine regardless of the study protocol and invalidate the study findings. When there is funding to support subject recruitment and data collection, funds can be used to reimburse the clinic or hospital staff members for their time, to create a raffle for one substantial gift, to offer a gift certificate to buy something needed for the clinic, or to send a nurse to a continuing education course. When funding is limited, staff members' enthusiasm for your study may be enhanced if they are able to participate in the research as authors or presenters in dissemination of the research findings.

Because of the potential impact of these problems, the researcher must maintain open communication and nurture positive relationships with other professionals and staff members during data collection. Problems that you and your team recognize early and deal with

promptly have fewer serious consequences than problems you try to ignore. However, not all problems can be resolved. Sometimes you may need to seek creative ways to work around an individual or to counteract the harmful consequences of passive resistance.

Researcher Problems

Some problems are a consequence of the researcher's interaction with the study situation or lack of skill in data collection techniques. These problems are often difficult to identify because of the researcher's personal involvement. However, their effect on the study can be serious.

Researcher Interactions

Researcher interactions can interfere with data collection in interview situations. To gain the cooperation of the subject, the researcher needs to develop rapport with the subject. One way to do this is to select data collectors who resemble the types of subjects being recruited as much as possible. Rapport may suffer if a young man collects data from female caregivers of elderly adults about their experience with end-of-life care. Similarly, a white middle-aged woman collecting data from young African American men or Hispanic teens is likely to be more disadvantaged than a data collector who is more similar to the population of interest.

A balance is needed between rapport and overinvolvement. The researcher can become so involved in interactions with a study participant that data collection on that particular subject is not completed. If you are collecting data from patient records while you are surrounded by professionals with whom you interact socially and professionally, it is sometimes difficult to focus completely on the study situation. This lack of attention usually leads to loss of data.

Lack of Skill in Data Collection Techniques

The researcher's skill in using a particular data collection technique can affect the quality of the data collected. A researcher who is unskilled at the beginning of data collection might practice the data collection techniques with the assistance of an experienced researcher. A pilot study to test data collection techniques is always helpful. If data collectors are being used, they also need opportunities to practice data collection techniques before the study is initiated. Sometimes a skill is developed during the course of a study; if this is the case, as one's skill increases, the data being collected may change and confound the study findings and threaten the validity of the study. If more than one data collector is used, the degree to which skills improve may vary across time and data collectors. The consistency of data collectors must be evaluated during the study to detect any changes in their data collection techniques.

Researcher Role Conflict

As a researcher, one is observing and recording events. Nurses who conduct clinical research often experience a conflict between their researcher role and their clinician role during data collection. In some cases, the researcher's involvement in the event, such as providing physical or emotional care to a patient during data collection, could alter the event and bias the results. It would be difficult to generalize the findings to other situations in which the researcher was not present to intervene. However, the needs of patients must take precedence over the needs of the study.

The dilemma is to determine when the needs of patients are great enough to warrant researcher intervention. Some patient questions or situations are life-threatening, such as respiratory distress and changes in cardiac function, and require immediate action by anyone present. Other patient needs are simple, can be addressed by any nurse available, and can be answered if the response is not likely to alter the results of your study. Examples of these interventions include giving the patient a bedpan, informing the nurse of the patient's need for pain medication, or helping the patient to open food containers. These situations seldom cause a dilemma.

Solutions to other situations are not as easy. For example, suppose that your study involves examining the emotional responses of patients' family members during and immediately after the patient's surgery. Your study includes an experimental group that receives one 30-minute family support session before and during the patient's surgery and a control group that receives no support session. Both sets of families are being monitored for 1 week after surgery to measure level of anxiety and coping strategies. You are currently collecting data on the control group. The data consist of demographic information and scales measuring anxiety and coping. One of the family members is in great distress. After completing the demographic information, she verbally expresses her fears and the lack of support she has received from the nursing staff. Two other subjects from different families hear the expressed distress and concur; they move closer to the conversation and look to you for information and support.

In this situation, a supportive response from you is likely to modify the results of the study because these responses are part of the treatment to be provided to

the experimental group only. This interaction is likely to narrow the difference between the two groups and decrease the possibility that your results will show a significant difference between the two groups. How should you respond? Are you obligated to provide support? To some extent, almost any response would be supportive. One alternative is to provide the needed support and not include these family members in the control group. Another alternative is to recruit the help of a nonprofessional to collect the data from the control group. However, most people would provide some degree of support in the described situation, even though their skills in supportive techniques may vary.

Other dilemmas include witnessing unethical behavior that interferes with patient care or witnessing subjects' unethical or illegal behavior (Humphreys et al., 2011). Consent forms are often required to stipulate that any member of the research team is legally required to report illegal behaviors, such as neglect or abuse of children and elderly adults. Try to anticipate these dilemmas before data collection whenever possible and include this information in the consent form (Wong, Tiwari, Fong, Humphreys, & Bullock, 2011). Pilot studies can help you to identify dilemmas likely to occur in a study, and you can build strategies into the design to minimize or avoid them. However, some dilemmas cannot be anticipated, and you must respond to these problems spontaneously. There is no prescribed way to handle difficult dilemmas; each case must be dealt with individually. You should discuss any unethical and illegal behavior with members of your IRB or ethics committee or with legal advisors. These situations must be reported to the IRB, and experts there can advise you on the next step or course of action. After you have resolved the dilemma, it is wise to reexamine the situation for its effect on study results and consider options in case the situation arises again.

Another type of conflict arises when a subject makes inaccurate statements or asks a question about health practices or treatment. Rather than offering professional advice or responding to the question, the research nurse should acknowledge that it is a good question, but that the research protocol does not allow for a response during data collection. When data collection is complete, the research nurse can help formulate the question for the subject's healthcare provider or provide a readily available pamphlet or website for more information.

Maintaining Perspective

Data collection includes both joys and frustrations. Researchers must be able to maintain some degree of objectivity during the process and yet not take themselves too seriously. A sense of humor is invaluable. You must be able to experience the emotions and then become the rational problem solver. Management skills and mental health are as invaluable to a research career as being obsessive about data collection and data management.

Institutional Problems

Institutions are in a constant state of change. They will not stop changing for the period of a study, and these changes often affect data collection. A nurse who has been most helpful in your study may be promoted or transferred. The unit on which your study is conducted may be reorganized, moved, or closed during data collection. An area used for subject interviews may be transformed into an office or a storeroom. Patient record forms may be revised, omitting data that you and your team are collecting. The medical record personnel may be reorganizing files and temporarily unable to provide needed records.

These problems for the most part are completely outside of the researcher's control. Pay attention to the internal communication network of the institution for advanced warning of impending changes. Contacts within the institution's administrative decision makers could warn you about the impact of proposed changes on an ongoing study. In many cases, the IRB in the local hospital will have a nurse representative who can provide the needed consultation. However, in many cases, data collection strategies might have to be modified to meet the newly emerging situation. Balancing flexibility with maintaining the integrity of the study may be the key to successful data collection. As a data collection site, the subject's home setting may be more desirable and convenient for a subject than a complex facility or institution, and response rates may improve. The disadvantage is that home visits are time intensive for the researcher, and the subject may not be home at the agreed appointment time despite confirmed appointments and reminder calls.

Event Problems

Unpredictable events can be a source of frustration during a study. Research tools ordered from a testing company may be lost in the mail. The printer may break down just before 500 data collection forms are to be printed, or a machine to be used in data collection may break down and require 6 weeks for repair. A computer ordered for data collection may not arrive when promised or may malfunction. Data collection forms may be misplaced, misfiled, or lost.

Local, national, or world events can also influence a subject's response to a questionnaire or ability to enroll in a study. For example, a researcher conducting a study of the effects of fatigue on the health of air traffic controllers encounters a rash of national media reports about controllers falling asleep while on duty. This event could be expected to modify subjects' responses. In attempting to deal with the impact of the event on the study, the researcher could obtain IRB approval for a modification that would allow for continued data collection from the intended sample but to examine the impact of news such as this on subjects' responses rather than the original purpose. However, the emotional climate of the airports participating in the study may not be conducive to this option. The researcher may choose to wait 3 months before collecting additional data and examine the data before and after the event for statistically significant differences in responses. If no differences are found, the researcher could justify using all the data for analysis.

Other, less dramatic events can also have an impact on data collection. If data collection for the entire sample is planned for a single time, a snowstorm or a flood may require that the researcher cancel the session. Weather may decrease attendance far below that expected at a support group or series of teaching sessions. A bus strike can disrupt transportation systems to such an extent that subjects can no longer get to the data collection site. A new health agency may open in the city, which may decrease demand for the care activities being studied. Conversely, an external event can also increase attendance at clinics to such an extent that existing resources are stretched and data collection is no longer possible. These events are also outside the researcher's control and are impossible to anticipate. In most cases, however, restructuring the data collection period can salvage the study. To do so, it is necessary to examine all possible alternatives for collecting the study data. In some cases, data collection can simply be rescheduled; in other situations, the changes may need to be more complex. For example, recruiting women to participate in a study that requires an hour or longer of their time may necessitate that the researcher provide childcare. Providing childcare would be more costly and add complexity to the process, but it may be the best alternative for increasing participation.

Serendipity

Serendipity is the accidental discovery of something useful or valuable. During the data collection phase of studies, researchers often become aware of elements or relationships that they had not previously identified. These aspects may be closely related to the study being conducted or have little connection with it. They come from increased awareness and close observation of the study situation. Because the researcher is focused on close observation, other elements in the situation can come into clearer focus and take on new meaning. Serendipitous findings are important to the development of new insights in nursing theory. They can be important for understanding the totality of the phenomenon being examined. Additionally, they lead to areas of research that generate new knowledge. A relatively easy way to capture these insights as they occur is to keep a research journal. These events must be carefully recorded, even if their impact or meaning is not understood at the time.

Serendipitous findings can also lead the researcher astray. Sometimes researchers forget the original plan and redirect their attention to the newly discovered dimensions. Although modifying data collection to include data related to the new discovery may be valid, there has not been time to plan carefully a study related to the new findings. The study's approval by the IRB covers only information included in the submitted study proposal. Examination of the new data should be an offshoot only of the initial study and would require seeking additional IRB approval.

Having Access to Support Systems

The researcher must have access to individuals or groups who can provide mentorship, support, and consultation during the data collection period. Support can usually be obtained from academic committees, from IRB staff, and from colleagues on your research team.

Support of Academic Committees

Although thesis and dissertation committees are basically seen as stern keepers of the sanctity of the research process, they also serve as support systems for novice researchers. Committee members must be selected from faculty who are willing and able to provide the needed expertise and support. Experienced academic researchers are usually more knowledgeable about the types of support needed. Because they are directly involved in research, they tend to be sensitive to the needs of a novice researcher and more realistic about what can be accomplished in the designated time frame.

Institutional Support

A support system within the institution where the study is being conducted is also important. Support might come from people serving on the institutional research committee or from nurses working on the unit where the study is conducted. These people may have knowledge of how the institution functions, and their closeness to the study can increase their understanding of the problems experienced by the researcher and subjects. Do not overlook their ability to provide useful suggestions and assistance. Your ability to resolve some of the problems encountered during data collection may depend on having someone within the power structure of the institution who can intervene.

Colleague Support

In addition to professional support, having at least one peer in your research world with whom to share the joys, frustrations, and current problems of data collection is important. This colleague can often serve as a mirror to allow you to see the situation clearly and perhaps more objectively. With this type of support, the researcher can share and release feelings and gain some distance from the data collection situation. Alternatives for resolving the problem can be discussed in a less emotional context. Data collection is demanding but rewarding. With time, confidence and expertise of the novice researcher increase.

Data Safety and Monitoring Board as Source of Support

If you are conducting an intervention study that is deemed to be of low risk to the patient, such as a behavioral intervention to improve sleep quality, a data safety and monitoring plan will suffice. In these situations, less support for you as a researcher is needed. This plan is deemed adequate when it conforms to the IRB requirements for reporting any adverse event and includes annual progress reports. It requires that the researcher explicitly states the plan to review the data from each set number of subjects or from each 3-month or 6-month batch of recruited subjects, depending on the extent of the study.

If the study involves an intervention protocol that is higher risk to patient safety, a data safety and monitoring board is required. This board includes members who are not directly involved in the study and who can be objective about the findings to date. This board should meet at regular intervals and discuss whether the study should continue or be stopped based on the data collected to date. The board should consist of very experienced researchers and clinical experts. See Chapter 14 for more information on conducting intervention studies.

Managing Data

Once data collection begins, you have to be prepared to handle large quantities of data. To avoid a state of total confusion, make careful plans before data collection begins. Plans are needed to keep all data from a single subject together until analysis is initiated. Write the subject code number on each form, and check the forms for each subject to ensure that they all are present. Researchers have been known to sort their data by form, such as putting all the scales of one kind together, only to realize afterward that they had failed to code the forms with subject identification numbers first. They then had no idea which scale belonged to which subject, and valuable data were lost.

Allot space as needed for storing forms. Purchase file folders, and design a labeling method to allow easy access to data; color coding is often useful. If you are using multiple forms, the subject's demographic sheet could be one light color, with a different pastel color for the pain questionnaire and a contrasting light color for all the physiological data sheets used to record blood pressure, pulse, and respiration readings. Use envelopes to hold small pieces of paper or note cards that might fall out of a file folder. Plan to code data and enter them into the computer as soon as possible after data collection to reduce the loss or disorganization of data. If data are collected on a computer, make sure the data are backed up and stored in a separate space so that they are not lost if the computer fails.

Preparing Data for Computer Entry

Data must be carefully checked and problems corrected before you initiate the data entry phase. The data entry process should be essentially automatic and require no decisions regarding the data. Anything that alters the rhythm of data entry increases errors. For example, the subject's entry should be coded as it appears, and any reverse coding that may be needed should be done at a later time by computer manipulation in a consistent manner rather than trying to have the data entry person recode during data entry.

Such simplicity in data entry reduces the number of data entry errors and markedly decreases the time required for entry. It is not sufficient to establish general rules for individuals entering data such as "in this case always do X." This action still requires the person who is entering data to recognize a problem, refer to a general rule, and correct the data before entry. Correcting the data requires using a different

color ink from the subject's mark, and the correction should be initialed by the researcher making the correction.

1. *Missing data*. Provide the data if possible or determine the impact of the missing data on your analysis. In some cases, the subject must be excluded from at least some of the analyses, so you must determine what data are essential.
2. *Items in which the subject provided two responses when only one was requested*. For example, if the question asked the subject to mark the most important item in a list of 10 items and the subject selected 2 items, you must decide how to resolve this problem; do not leave the decision to an assistant who is entering the data. In the codebook and on the form itself, indicate how that particular datum is to be coded and entered.
3. *Items in which the subject has marked a response between two options*. This problem commonly occurs with Likert-type scales, particularly scales using forced choice options. Given four options, the subject places a mark on the line between response 2 and response 3. In the codebook and on the form, indicate how the datum is to be coded. This is often best coded as a missing value, but coding rules should be consistent. A rationale can be made to take the highest value, the lowest value, or code toward the center value.
4. *Items that ask the subject to write in some information such as occupation or diagnosis*. Such items are a data enterer's nightmare. Develop a list of codes for entering such data. Rather than leaving it up to the assistant to determine which code matches the subject's written response, the researcher should enter this code in a different color and initial that change before turning the data over for entry. After the data have been checked and needed codes written in, it is prudent to make a copy rather than turning over the only set of your data to an assistant.

Data Entry Period

If you are entering your own data, develop a rhythm to your data entry process. Avoid distractions while entering data, and limit your data entry periods to 2-hour intervals to reduce fatigue, errors, and repetitive wrist strain or injury. Backup the database after each data entry period, and store it on an encrypted flash drive, on a secure website, or in a fireproof safe. It is possible for the computer to crash and lose all of your data. If an assistant is entering your data, make yourself as available as possible to respond to questions and address problems. After entry, the data should be randomly checked for accuracy. Data checking is discussed in Chapter 21.

Storage and Retrieval of Data

In this time of flash drives and thumb drives, it is relatively easy to store data. The original data forms and database must be stored for a specified number of years dictated by the funding source or by the journal publisher. There are several reasons to store data. The data can be used for secondary analyses. For example, researchers participating in a project related to a particular research focus may pool data from various studies for access by all members of the group. Data should be available to document the validity of your analyses and the published results of your study. Because of nationally publicized incidents of scientific misconduct, where researchers fabricated data and published multiple manuscripts, you would be wise to preserve documentation that your data were obtained as you claim. Issues that have been raised include how long data should be stored, the need for institutional policy regarding data storage, and whether graduate students who conduct a study should leave a copy of their data at the university. Some researchers store their data for 5 years after publication, whereas others store their data until they retire from a research career. Researchers should check with their funding sponsors and publishers for guidelines on how long to keep the data. Most researchers store data in their office or laboratory; others archive their data in a central location with storage fees or retrieval fees. Graduate students do have a responsibility to keep and securely store data from their studies.

KEY POINTS

- Careful planning is needed before collecting and managing data.
- The researcher may need to develop data collection forms and format these forms to promote accuracy and ease of data entry.
- The researcher must determine exactly how and in what sequence data will be collected and the timing of the process. Information about the procedures to be used must be described in the subject's informed consent.
- The researcher must decide who will collect the data.
- If data collectors are used, they must be provided information about the research project, the instruments, and data collection protocol.

- Consistency in data collection across subjects is critical, and training is required to promote consistency among data collectors if more than one data collector is used.
- After training, data collectors must be evaluated periodically and randomly to determine their consistency.
- Decision points that occur during data collection must be identified, and all options must be considered.
- Data collection also involves maintaining research controls and solving problems that threaten to disrupt the study.
- Problems that arise during data collection involve recruitment and attrition issues, treatment of the subject as an object, external influences on subject responses, passive resistance from staff members or family, researcher interactions, lack of skill in data collection techniques, and researcher role conflicts.
- A successful study requires support that is often obtained from academic committees, healthcare agencies, and work colleagues.
- Data collected during a study must be accurately entered in an encrypted computer and safely stored in either a data repository or on an encrypted flash drive.

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