Data Management and Security in Qualitative Research

Li-Chen Lin, RN, MSN

Qualitative research provides rich data on phenomena important to nursing and may offer in-depth information for critical care nurses in providing care to their patients. Data management, which encompasses topics such as human subjects’ protection, confidentiality, data storage and record keeping, data ownership, and data sharing, is a critical process in qualitative research that deserves researchers’ attention. Thus, the purpose of this article is to synthesize existing research studies on qualitative data management.

Keywords: Confidentiality, Data management, Data sharing, Ownership, Qualitative research, Record keeping

Qualitative approach can be used for research studies in many clinical settings, including critical care units. Thus, it is useful for critical care nurses to become familiar with qualitative research and data management. Data management is important in both quantitative and qualitative research because it ensures the truthfulness of the data and protects research participants. Qualitative research provides a profound representation of a phenomenon that communicates the richness of a study. Data in qualitative research might include field notes, audiotapes/videotapes, transcriptions, memos, and analyses. Data management in qualitative research is defined as a designed structure for systematizing, categorizing, and filing the materials to make them efficiently retrievable and duplicable. Converting data representing human interactions into written reports is part of managing qualitative data. Proper data management allows researchers to accumulate information in various forms or locations for different research purposes, while maintaining the security of the data. There is little published information about managing data generated in qualitative research studies.

BACKGROUND

Data management has become more complicated and requires that researchers develop a plan before collecting data. By providing a “road map,” organized qualitative data allow researchers to answer specific research questions. Researchers can use a reflective process to manage data generated in qualitative research to better systematize their data. This process involves interviews with concurrent note taking, reflective journaling, revising field notes, and listening to audiotapes. Qualitative data might include various forms of records, such as notes and audiotapes. Depending on what a researcher intends to achieve or what research questions he/she wishes to answer, varied approaches may be needed to manage his/her data. Many computer tools are available to assist in managing qualitative data; however, a detailed discussion is beyond the scope of this article.
Qualitative researchers may use various software packages to help with data analysis. Researchers can use a reflective process to manage data generated in qualitative research to better synthesize their data.

Topics in qualitative data management include, but are not limited to (1) confidentiality, (2) human subjects’ protection, and (3) data storage, sharing, and ownership. Confidentiality is one of the responsibilities of a researcher and professional commitment to the participants. The privacy of information gathered on each research participant must be respected and maintained. Confidentiality is defined as the responsibility for information obtained in the interaction between the professional and the client. Protecting information is part of a professional commitment; the obligation to maintain confidentiality is rooted in the clients’ right to privacy and control of information.

In addition to confidentiality, human subjects’ protection is another area discussed broadly in qualitative research studies. Human subjects or research participants are the most important part of a research study. Researchers must protect study participants in all possible ways. Building rapport with the participants is also important because it helps develop a nonhierarchical relationship between the researcher and the participant. Researchers must show the participants that the researcher will treat their data with respect and maintain privacy. If handled improperly or not adequately protected, information divulged in an interview in a qualitative study could be harmful to the participants. Potential harm might include negative psychological impacts and feelings of regret for a story shared. Properly storing research records ensures that researchers maintain the integrity of the collected data. The characteristics of a good data book are legible, well organized, accurate, complete, replicable, and accessible to authorized persons only. Researchers should keep their data notebooks in a safe place with backups or in secure computer files.

Many of the articles reviewed addressed the pertinent issues regarding confidentiality and human subjects’ protection in various populations using the qualitative research method as in all research. However, few studies have addressed the other critical elements of qualitative data management, such as data storage, sharing, and ownership. Hence, the purpose of this article was to synthesize the existing literature specific to managing data generated in qualitative research to provide future research direction.

**LITERATURE SEARCH METHOD**

Qualitative data management articles were located from a search of various databases. Many articles were located, but only the ones written in English and published after 1992 were reviewed for a total of 6 articles. Because of the dearth of information available on managing qualitative data, I also incorporated information drawn from quantitative research, and in addition, other relevant information from the National Institutes of Health’s (NIH’s) Web site was also reviewed. In addition to the literature, the Web sites of 3 major research universities located in various regions of the United States were reviewed to compare descriptions of data management in research. These descriptions provided a general idea about how research data were managed in practice.

**RESULTS**

Most selected articles were qualitative research studies that addressed various issues in managing qualitative data (Table 1). Methods used in the selected articles were oral history, grounded theory, ethnography, and qualitative interviews using a biographical approach.

Using a semistructured interview approach, Boschma et al. conducted an oral history with psychiatric mental health nurses to discover these nurses’ work experience and the changes in nursing practice over time. They clearly expressed concerns about protecting the participants. Ownership of the data was clearly stated as shared between the researcher and the interviewee. Brown’s grounded theory study of 20 counselors touched areas of concern, including confidentiality, record keeping, child protection, and data sharing. Although the counselors performed their job by relating information sharing, record keeping, and their beliefs and relationships to the external environment, there was a lack of or problematic information about record keeping and information sharing. In an ethnographic study, Hofman used multisided project interviews with female intravenous drug users and focused on human subjects’ protection. The author suggested that extra safeguards be used when interviewing members of high-risk populations to avoid unnecessary harm to them. Similarly, Langford’s grounded study of battered women also touched on confidentiality and data protection. If handled inappropriately, women may feel further victimized by being involved in a research study. Woogara used
ethnographic techniques to address confidentiality by evaluating patients’ privacy in the wards. The author interviewed 18 patients, 6 doctors, and 16 nurses, in addition to making direct observations of patient care on the wards, to add variation and richness to the data.

All 6 studies selected for this review addressed confidentiality, and 5 of the 6 studies addressed issues on human subjects’ protection. Two articles discussed data ownership, and 1 concentrated on data sharing. Empirical research on issues in qualitative data management, other than human subjects’ protection and confidentiality, is scarce, and these topics require more attention.

Although there were some differences among the Web sites of the 3 universities, the major contents on confidentiality, data sharing, data ownership, and human subjects’ protection were similar. For instance, the Web sites of all 3 universities stressed the importance of confidentiality and suggested that researchers protect their research subjects’ identity and information. All 3 Web sites required a scientific review before conducting any research project involving human subjects. Research data were accessible to sponsors, university officials, and other authorized agencies such as the Food and Drug Administration for a reasonable period under reasonable rules. All research records should be kept for a specified period after the completion of a research study and properly maintained by the principal investigator(s) or project director(s). The concept and importance of data sharing, storage, and ownership were emphasized by all 3 universities, although they organized and presented the information differently.

**DISCUSSION**

The 6 articles selected for this review addressed various topics in qualitative data management; however, most of these studies only addressed confidentiality and human subjects’ protection broadly. Confidentiality and human subjects’ protection are the most commonly discussed topics in qualitative data management because most qualitative research involves human participants. Principal investigators have the ultimate responsibility for protecting their research participants. In addition, they are responsible for recording, storing, and sharing data appropriately. Principal investigators should become familiar with policies, procedures, and related rules when conducting a research study to make clear how their data will be documented, stored, and shared.

**Confidentiality**

Simply stated, confidentiality is the protection of data collected by a researcher. A rigorous procedure should be put into place to protect any personal information that is used for research purposes. For instance, social security numbers should not be used to categorize data. According to NIH, investigators, their institutional review boards, and institutions must take the responsibility for protecting participants’ privacy and confidentiality by preparing the data in a way that reduces the
possibility of identifying individual participants. The researcher who collects the data has the primary responsibility for protecting confidentiality. Possible ways to achieve this goal include altering the forms of documentation, removing personal identifiers, and encoding data elements. In addition, noticeable personal identifiers, such as names, addresses, driver’s license number, places of birth, and contact information must be permanently destroyed. Researchers should also avoid collecting any data that are not necessary for the study.

Confidentiality is the protection of data collected by a researcher.

Researchers commonly use audiotapes or videotapes to collect qualitative data, which may include personal information, such as names and locations, which could compromise participants’ privacy and confidentiality.2 Strict precautions should be put into place to prevent this information from being disclosed inappropriately. Audiotapes and videotapes should be kept in a secure, locked location where only authorized persons have access to them. In addition, transcriptions, notes, and other related records should be treated in the same way. Protecting the confidentiality of study participants is especially important for vulnerable populations or ethnic minorities.3,12,17 Confidentiality should be maintained for these research participants and the third parties involved in their descriptions to avoid potential negative consequences after the study or interview.11

Protection of Human Subjects
Investigators are responsible for encouraging participants to share information and preventing them from sharing information they might regret later. They should be made aware that they should not talk about anything that might place themselves or others in danger.11,15 Researchers might use a “reflective diary” to help refine their qualitative work.10 For instance, researchers may learn from previous studies or interviews by reviewing their diary, thus preventing the same mistakes from happening again. This also helps researchers to clear their minds and make informed decisions about their research project.

Participants should be made aware of the potential risks involved in participating in the study, including negative feelings and other possible parities.11,19 They should also be provided with options, such as withdrawal from the study, in case undesired events occur. Research participants, especially those from vulnerable populations, might have negative feelings such as feeling further battered by being involved in the research process.12 Researchers should be honest and open-minded when conducting a qualitative study, to be respectful and sensitive to potential problems and then to handle them appropriately.

Data Storage and Record Keeping
Enormous amounts of data may accumulate during the course of a qualitative research study. Data might be stored in many forms, such as original hard paper copies, computer files, or photocopies. Researchers should specify in their research proposals what data management methods they will use and their involvement in data analysis.2 In addition, researchers should be familiar with policies related to record keeping before conducting a study.16 Data should be transformed into a retrievable form as soon as possible to prevent its loss or deterioration. Two rules might be useful to researchers: (1) a numbered hard copy bound in a notebook would provide for easy follow-up in the event of future questions, and (2) an electronic copy would provide a way to validate the date when data were entered.5

The required length of time that data should be retained varies by facilities and funding agencies, ranging from 3 to 10 years.5 Importantly, researchers should clearly understand the data storage and retention policies of their funding agency or sponsoring facility. A verbatim record is often used to demonstrate the existence of data in the case of an audit, as well as for data confirmation. Data should be protected for possible future use in verifying research findings, setting priorities, or reanalyzing.5

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Data Sharing
Research data are shared in many ways to advance knowledge in many fields. According to the NIH, the mode for sharing data may depend on the sensitivity and ownership of the data, the complexity of the data set, and other reasons such as the researcher’s preference.14 Data sharing is necessary because it can potentially help researchers validate, broaden, and generalize findings, as well as build new theories.4 Today, researchers are encouraged to access and share data; thus, data are becoming widely and internationally available.3 Researchers
should raise questions regarding when, who, and how to share data before actually sharing their data.\(^5\) Research data should be finalized before releasing it to the public, unless the preliminary data are crucial to the public, such as the discovery of a severe side effect in a medicine.\(^3\) Unless there is a persuasive reason for confidentiality, data should be available to the public under the Freedom of Information Act after they are published.\(^13\)

Investigators might share their data by copying it to a diskette or transforming it into a data archive. A data-sharing agreement should be made at the earliest possible time, when appropriate. Obtaining the Certificates of Confidentiality is one way researchers can protect identifiable research information from compelled disclosure. The certificate, issued by the NIH, allows investigators and others who have access to research records to refuse to disclose or share identifying information on research participants in federal, state, or local proceedings.

Many universities or other research facilities may have various ways of handling data sharing. Once data are available, researchers decide with whom they will share their data.\(^16\) Consequently, it is best for researchers to check the policies of their institution, as well as those of state and federal agencies, when appropriate, before collecting data, to avoid improper sharing of research data and findings. A checklist or guideline may also be useful for researchers. Although it is becoming more common to share scientific data, qualitative researchers may not share their data as readily because they are not comfortable with sharing their data or have a lack of knowledge about how and to whom they may share their data.\(^4,16\) Hence, proper training is necessary to maximize the potential sharing of qualitative data to augment knowledge in a specific field.

### Data Ownership

It is essential that researchers be clear about data ownership. Data could be owned by the research funders, research institutions, research participants (in some cases), or investigators. In qualitative research, research participants are often very involved with the data collected, which may make them feel that they own part of the data.\(^5\) Because of the nature of qualitative research, data are usually a result of a shared effort between the participant and the researcher.\(^3\) In addition, when researchers present the raw data or summary to the participants, they have the right to remove or change the data. Thus, it is essential for the researcher to clarify any concerns before and during the interview process to avoid any potential conflict.

In general, the researcher has the right to use and manage the data for analysis. However, the owner of the data could be any one of the parties involved as mentioned above. The institution usually has the greatest legal claim to a data set.\(^3\) It is wise for researchers to be aware of their obligations and rights in the use of data before collecting data to avoid any unnecessary conflict. Indeed, the principal investigator should take charge in clarifying the ownership of the data collected and the results generated from research to the entire research team to avoid possible confusion or conflicts. It may be more difficult in qualitative research to have a clear data ownership agreement, especially where data ownership is split between 2 or more parties. Nonetheless, an unambiguous statement of ownership made in

<table>
<thead>
<tr>
<th>TABLE 2</th>
<th>Proposed Checklist for Researchers Managing Qualitative Data</th>
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<tbody>
<tr>
<td><strong>Components</strong></td>
<td><strong>Take-Home Messages and Checklist Items</strong></td>
</tr>
<tr>
<td>Confidentiality</td>
<td>Researchers should take the responsibility to protect their data.</td>
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<tr>
<td></td>
<td>A rigorous procedure should be put in place throughout the research study.</td>
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<tr>
<td></td>
<td>Participants’ personal information should be encoded or removed from public view.</td>
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<tr>
<td>Human subjects’ protection</td>
<td>Researchers have the primary responsibility for protecting participants in their research studies.</td>
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<td></td>
<td>Researchers should be honest, respectful, and sensitive to potential problems.</td>
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<td></td>
<td>Building rapport and trust is important in conducting qualitative research.</td>
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<tr>
<td>Data storage and record keeping</td>
<td>Data should be backed up and accessible as soon as possible.</td>
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<td></td>
<td>Data may be stored in many forms and should be well organized, accurate, complete, and accessible to authorized persons only.</td>
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<td>Researchers should know the policies of the facility where they work or the agencies that funded their research.</td>
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<tr>
<td>Data sharing</td>
<td>Data sharing is required to advance knowledge and science.</td>
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<tr>
<td></td>
<td>The mode of data sharing depends on the ownership, sensitivity, and complexity of the data set.</td>
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<tr>
<td></td>
<td>Researchers should be familiar with policies related to data sharing.</td>
</tr>
<tr>
<td>Data ownership</td>
<td>Funding agencies, research institutions, participants, or researchers might own the data, which should be made clear before beginning the research.</td>
</tr>
<tr>
<td></td>
<td>Researchers should be aware of the issues surrounding the ownership of data and their obligations to the data in the process of research planning and implementation.</td>
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writing before the beginning of a research study may be useful.

CONCLUSIONS
The qualitative approach to research may provide nurses a unique way of obtaining in-depth information in critical care settings. Data management, both in quantitative and qualitative research, is a complex undertaking that all researchers will face during their research career. Qualitative data management is fundamentally different from quantitative methods because qualitative data encompass additional types of information, although there are some common rules in terms of data management. Confidentiality, protection of human subjects, data sharing, storage, and ownership are all pertinent areas of interest in qualitative and quantitative research. Qualitative researchers deal with these areas in diverse ways because of the nature of the methods and the greater involvement of participants in the research process. Different facilities or agencies may have different approaches and regulations to handle research data. The proposed checklist may be useful in ensuring that all pertinent topics are considered in qualitative data management (Table 2). Researchers should be familiar with the available resources for their research study. The principal investigator should take responsibility for ensuring that everyone on the research team is aware of the policies and rules applicable to the research project. Data management, as well as other potentially related issues, should be considered throughout the research process, including planning, hiring personnel, and collecting, maintaining, analyzing, and presenting data.

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