

Reciprocity for Patients With Head and Neck Cancer Participating in an Instrument Development Project

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Purpose/Objectives: To examine reciprocity (i.e., a mutual exchange of benefit) in study participation via a thematic analysis of field notes on study participation from a parent psychometric study.

Design: Qualitative.

Setting: Head and neck surgery clinic in an urban tertiary hospital.

Sample: Seven patients with head and neck cancer recruited to participate in an instrument development project.

Methods: Symbolic interactionism was employed to frame the examination of field notes from observations and interactions with patients, as well as participant notes accompanying returned retest questionnaires. Analysis relied on the constant comparative technique at the levels of open and axial coding.

Main Research Variables: Participation in an instrument development project.

Findings: Four content themes emerged in the analysis: Willingness to Help, Reassurance That the Deficits Patients Experience Are Common, Participation Provides Social Contact, and Confirmation of Clinically Significant Findings. A process theme, Unveiling the Experience, integrated the content themes in relation to participation itself. The role of the study nurse appears to be pivotal in this process.

Conclusions: A notion of reciprocity in research participation is apparent. The role of the study nurse is an important element in the process of reciprocity. This role should be explored to enhance study participation.

Implications for Nursing: Implications, particularly for clinical trial nurses, include recasting the benefits of participating in research, better addressing preparation for patients scheduled to receive treatment for head and neck cancer, and exploring and enhancing the role of the study nurse.

Key Points . . .

- ▶ The enrollment of subjects in clinical trials research results in investigator-participant relationships involving benefits to both parties, or reciprocity. Reciprocity for patients involved in observational, survey, or instrument development research has not been studied extensively and remains unclear.
- ▶ Benefits to patients participating in an instrument development project may include reassurance that their experiences with cancer are common, opportunities for social interaction, and contact with study nurses.
- ▶ Interaction with study nurses sometimes leads to the identification of clinically important information that warrants follow-up with a treating physician. It also may enable patients to better understand their experience with head and neck cancer.
- ▶ A study nurse can be a mediator of reciprocity in study participation; this aspect of the role should be explored further.

Faden, & Schoch-Spana, 1996). They often believe that the cure will affect them (Roberts, Warner, & Brody, 2000). Patients who participate in clinical research also have identified benefits of frequent testing and monitoring of disease (Mattson, Curb, & McArdle, 1985). However, benefits for those who participate in trials or projects that are not clinically

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Enrollment of subjects in clinical trials research is crucial to the success of any study. Enrollment in clinical trials results in the establishment of investigator-participant relationships that clearly involve reciprocity, or a mutual exchange of benefit. Investigators unmistakably benefit from patient participation, and participants in clinical trials often view study participation as a personal treatment option, as well as a means of contributing to a cure (Kass, Sugarman,

based are less clear. What can be gained by people who participate in observational, survey, or instrument development projects?

Several authors have suggested that patients participating in clinical research gain psychological and social benefits. Participation has been shown to enhance self-esteem (Ruzek & Zatzick, 2000; Seelig & Dobelle, 2001) and provide reassurance and peace of mind to subjects (Mattson et al., 1985; von Strauss, Fratiglioni, Jorm, Viitanen, & Winblad, 1998). These psychological benefits have been linked to the social interaction that occurs between subjects and research staff members during studies (von Strauss et al.).

This article reports a thematic analysis of field notes from an instrument development project. The purpose of the analysis was to examine study participation with a focus on describing the nature of any reciprocal benefit voiced by participants. The materials for the analysis included an audit trail maintained by the study nurse, as well as data contributed by participants in the form of notes and letters. Because of the character of the data, interaction between the nurse and participants was an initial trigger and focus for the analysis. The project was framed in symbolic interactionism, a social psychological theory aimed at understanding meaning derived from individuals' interaction with their environments, because of the interaction inherent in study participation (Blumer, 1969). The parent project, "Development of a Chemosensory Questionnaire for Patients Treated for Head and Neck Cancer," was reviewed and approved by the institutional review board of the University of Pennsylvania in Philadelphia.

When patients were asked whether they were interested in participating in the parent project to develop a chemosensory questionnaire for patients treated for head and neck cancer, they often answered with questions of uncertainty: "What will this mean?" "Will I have to come back?" "Will it hurt?" "How long will it take?" The literature suggests that inconvenience and personal cost are disadvantages of participating in clinical research (Mattson et al., 1985). Despite some patients' initial hesitance, at the time of data analysis, 97% of 120 invited patients agreed to participate. This high rate of acceptance poses the question of what perceived reciprocal benefits patients who participate in clinical research may have.

Theoretical Framework

Symbolic interactionism framed the exploration of communication around study participation to examine reciprocity. Symbolic interactionism is a social psychological theory that frames human communication in terms of symbols, meaning, and environment (Blumer, 1969). It relies on the notion of communication as an exchange of symbols and meaning in a particular environment. Symbolic interactionism then lends structure to understanding the phenomenon of nonclinical trials research participation when approached from the perspective of reciprocal exchange of benefit.

Methods

Parent Study's Design, Sample, and Setting

The study nurse for the parent study was a graduate nursing student with a clinical background of working with populations with HIV and cancer. She was responsible for subject

enrollment and data collection, which took place in the head and neck surgery clinic in an urban tertiary hospital. She approached eligible patients while they were in examining rooms waiting to be seen by their surgeons. To be eligible, patients had to be older than 18, fluent in English, available for retest within two weeks, able to participate by oral or nonoral means, able to complete a questionnaire independently, at least one month postdischarge from primary treatment for head and neck cancer, and able to take liquid or solid food by mouth.

Parent Study's Data Collection

The study nurse was present in the head and neck surgery clinic on days when physicians saw patients. Eligibility was determined by reviewing the charts of those patients who were to be seen on those days. After arrival of eligible patients to examining rooms, the study nurse approached them and inquired about their interest in participating in the parent study. She remained in the room with each patient and was available to answer questions while the study materials were completed (see Table 1). This process generally took 15–30 minutes. The study nurse asked patients if they would be willing to participate in a retest of one of the instruments by mail. If patients agreed, the study nurse sent the materials with return postage to the subjects about two weeks later. A handwritten note reminding patients of their willingness to fill out the retest questionnaire accompanied the survey. Many participants responded to this note with handwritten notes of their own. Participants often included personal comments that inquired about the study nurse and offered clinical information.

Procedures for Secondary Project

The study nurse was responsible for maintaining an audit trail of the research process. The purpose of the audit trail was to monitor the quality of enrollment and consent procedures and document comments from participants. It also tracked the numbers of patients who refused participation without including any identifying information about them.

Table 1. Study Materials

Questionnaire	Description
Chemosensory questionnaire (under development)	Assesses taste and smell changes in patients who have been treated for cancer of the head and neck.
Performance Status Scale for Head and Neck Cancer Patients (List, Ritter-Sterr, & Lansky, 1990)	Assesses the ability of patients with head and neck cancer to eat and speak.
University of Michigan Head and Neck Quality of Life Questionnaire (Terrell et al., 1997)	Assesses the impact of head and neck cancer on four dimensions of quality of life: communication, eating, emotions, and pain.
12-Item Short-Form Health Survey (Ware, Kosinski, & Keller, 1996)	Not specific to patients with head and neck cancer. Assesses health-related quality of life.

Data Analysis and Interpretation for the Secondary Project

Data for the secondary project consisted of 21 documents; 14 of these were field notes and 7 were notes written by patients. The data were from the first year of the parent study, during which time 120 of 200 participants (60%) were enrolled. To preserve confidentiality, specific demographic data were not associated with the audit trail. Documents were labeled only with subjects' numbers.

Data analysis procedures are outlined in Figure 1. Data were analyzed using a constant comparative technique at the level of open coding to identify themes (Strauss & Corbin, 1990). Open coding involves a process of examining data fragments for content. This first component of constant comparative analysis readies data for successive levels of abstraction that move toward axial or preliminary theoretical coding and inductive generation of concepts and theoretical frameworks. Analysis for the secondary project began with a review of all audit trail documents and patients' written notes, which were scanned for content related to participation. Twenty-one documents that commented on participation were culled. This set comprised the text sample for this analysis. Text from the field notes and materials written by participants were broken into phrases in open coding. These codes were sorted by content and compared with previous codes as data were accumulated. As themes became apparent, the open codes were reviewed and compared again. Variation in detail was excluded, and open codes were collapsed into axial codes (Strauss & Corbin). Axial codes were reported by the nature of the code itself. Codes that described content or information that participants expressed as important were labeled as content themes. The code that described process was labeled as such.

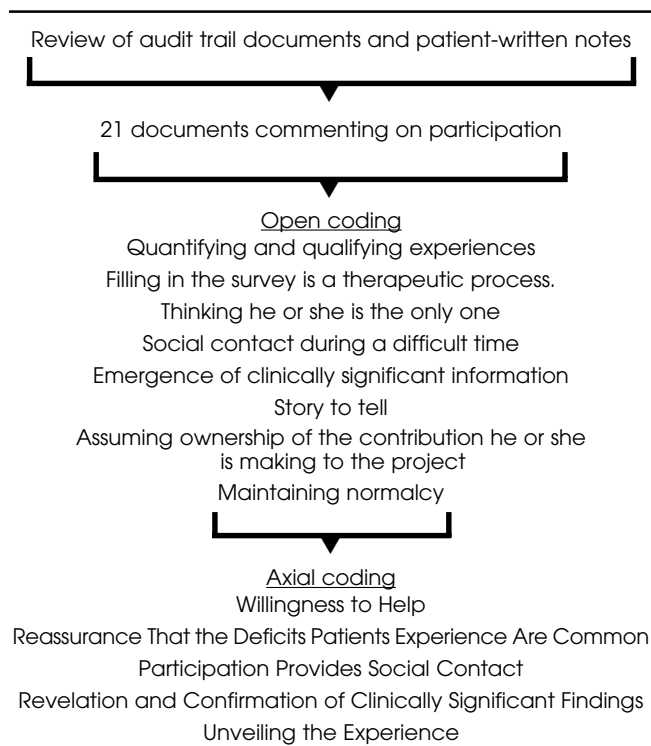


Figure 1. Data Analysis Procedures

Results

Five themes emerged from the analysis. Themes that reflected the content of the patients' experiences and the benefits of participating included Willingness to Help, Reassurance That the Deficits Patients Experience Are Common, Participation Provides Social Contact, and Confirmation of Clinically Significant Findings. The process theme was labeled Unveiling the Experience.

Willingness to Help

Many participants wrote statements indicating their desire to be helpful with the project. One man had been disease-free for more than five years when he completed the survey and said, "I would have liked to have filled this out when I had no taste. ... It would have been more helpful." Others offered this simple statement: "I hope I have been helpful." Patients seemed to take their agreement to participate seriously, often inconveniencing themselves to complete the study materials. When unable to finish the forms after their appointments, many participants asked, "Can I take it home to finish it?" If they did take the packet home, most (25 of 30, 83%) completed it and mailed it back to the study nurse. These participants appeared to want to make a substantive contribution to a project that would not benefit them directly but required a concerted effort to complete. This balance of contribution versus inconvenience was not, however, elucidated by the data available.

The commitment to help was additionally supported by the orientation of comments toward future research involvement: "Should you take this [area of inquiry] further, I would be willing to participate [in later studies]." One man had ideas about what should be investigated next: "I believe that we compensate for taste with sight and texture. Please let me know if you are going to carry [the chemosensory study] forward." These suggestions seemed to be an extension of helpfulness; participants held specific ideas that they appeared to express because involvement in the parent study provided an opportunity to do so.

This theme also was reflected in the inclusion of identifying data that patients wrote or attached to returned retest questionnaires. The participants were cautioned, in keeping with the protection of human subjects, not to include identifying information on study materials. Nonetheless, the patients who enrolled in this chemosensory project seemed not to want anonymity. Some apparently wanted to assume ownership of their contribution to the parent project.

Reassurance That the Deficits Patients Experience Are Common

Almost every participant, at some point while completing study materials, would grunt, sigh, or utter "hmmm." When asked whether everything was "OK," many replied with phrases such as, "I thought it was just me!" or "I thought I was the only one." One woman spoke at length about her struggle with nausea, vomiting, and eating, then commented, "When you fill out these things, you realize that what you're going through is normal." Completing the study materials appeared to confirm chemosensory and related symptom experiences for some participants, suggesting that they had limited confirmation of the commonality of that experience prior to participation.

Participation Provides Social Contact

The third theme reflects the social interaction provided by study participation. As participants talked to the study nurse, many described their experiences with head and neck cancer. Conversations that included exploration of chemosensory change often led to discussions of the cumulative loss inherent in the challenge of current treatment protocols for head and neck cancer. This theme was revealed by participants who expressed being unprepared and conveyed a sense of being taken aback by symptoms. "They told me all this stuff would happen to me, but they didn't tell me how bad it would be." This patient had undergone surgery and radiation and had lost more than 70 pounds with severe nausea, vomiting, and complications related to tube feedings. Although she had been informed that such complications could arise, encountering them stunned her.

One man, who had been cancer-free for more than four years, said the radiation oncologist told him that radiation to the neck would be a little like a burn. He reported that his experience was "like being sunburned from the inside out." Others described the toll that head and neck cancer and its treatment took on them. Several participants said, "I don't go out like I used to." Others made comments such as, "My energy isn't what it was before." Many participants said, "I cannot taste and smell like I used to. It's hard."

Although such comments are related to the commonality of symptom experience, these expressions of individual experiences seemed related to the presence of an educated listener, the study nurse. This social contact may have been important because of the study nurse's absence of a connection to family and friends (who might not want to hear the details of unpleasant experiences) or to the healthcare team (with whom it might be difficult to explore the experience because discussion takes extra time or requires extra attention).

Revelation and Confirmation of Clinically Significant Findings

The study protocol mandated that if the study nurse identified a clinically significant finding that a patient had not discussed with a treating clinician, she would solicit agreement to report the finding and communicate it immediately to the treating surgeon and nurse. Some participants identified nutritional deficits and inadequate pain control that were contributing to a depressed mood. One said, "Loss of taste and smell is devastating." The man who made this statement belonged to a family that valued mealtime. Another participant said that because he no longer enjoyed eating, he could not fully participate in an important family ritual, a loss that left him feeling isolated and downcast: "If it were not for my dog, I would have ended it a long time ago." As a result of his cancer treatment, he lost his voice and sense of taste. Despite the severity of these losses, their psychosocial impact was unknown to the treating surgeon. Study participation sometimes revealed clinically important findings that had been untreated. All participants with unreported symptoms had positive reactions to intervention by the study nurse with treating clinicians.

Unveiling the Experience

The process theme emerged as patients consistently qualified their answers to the survey questions orally and in writing. During analysis of the data for content, the process of

uncovering and confirming chemosensory issues and other aspects of the head and neck cancer experience seemed to be made clear by the communication of the content itself. In unveiling the participants' relevant experiences, the main content themes emerged. This process of unveiling connected the separate elements of benefit suggested in the content themes. These benefits to participants emerged during and as a result of interacting with the study nurse and the study materials.

Discussion

This analysis of audit trail documents to understand participation in nonclinical trial research and reciprocity for participants provokes several questions for the conduct of research and for investigation of research participation itself. The content themes imply specific benefit that is both altruistic and directed towards patients' own interests. The interactive process of research participation imparts specific benefits for individual participants. The participants in the parent psychometric project offered information for the secondary study that suggests they valued the process and found reciprocal benefit—in particular, content imbedded in the process.

These findings are congruent with conclusions offered by Napholz (1998) and von Strauss et al. (1998). Napholz's experiences accruing a sample of ethnic minorities for an intervention study revealed that subjects were more willing to participate when the interviewer created a safe environment and took time to develop a rapport with them. Furthermore, the relationship between subject and interviewer fostered the interviewer's legitimacy. Von Strauss and colleagues examined the benefits of participation to patients enrolled in epidemiology research. The authors alluded to the importance of the study personnel in successful study participation by older adults. The researchers explained that they intended to provide a pleasant and safe atmosphere for research and planned for additional time with subjects to develop a rapport.

Repeated literature searches found no nursing studies that specifically addressed participation in nonclinical trials research or the benefits associated with it. However, two nurse investigators have written methods papers that touch on some of the content reflected in this analysis. Neufeld, Harrison, Hughes, Spitzer, and Stewart (2001) emphasized the importance of study personnel (i.e., study nurses or research assistants) who are credible in participants' eyes and capable of effectively communicating and establishing trust with them. Smith (1999), in his article addressing the benefits of keeping a reflexive journal in phenomenologic studies, also acknowledged the importance of establishing a rapport with participants. Smith also noted that participating in his study seemed to be of therapeutic value and perhaps was part of the participants' healing from suffering.

Napholz (1998) and von Strauss et al. (1998) suggested that common concerns may exist in recruiting socially or physically vulnerable individuals for research participation and making the research process acceptable to such individuals. Neufeld et al. (2001) placed great emphasis on the role that study personnel play in the successful recruitment and retention of participants. Nurses who have clinical backgrounds may be particularly suited to serve as study personnel. Educated study personnel, time for interaction, and attention to clinically important but under-recognized phenomena all may

be of consequence in developing the benefit of participation in nonclinical trials research and creating reciprocity.

Achieving reciprocity by participating in clinical research is well acknowledged. African American, American Indian, and Latinas (Napholz, 1998), patients with schizophrenia (Roberts et al., 2000), elders in Sweden enrolled in a longitudinal study (von Strauss et al., 1998), and patients enrolled in cardiac-related clinical trials (Mattson et al., 1985) all showed evidence of some hopeful and altruistic motivation. However, reassurance is a concept that does not appear frequently in the literature related to study participation. Mattson and colleagues did note reassurance as a benefit of participation resulting from increased exposure to medical information.

The commonality of research participants' deficits and losses was not apparent in the research literature. Perhaps this finding arose from the nature of chemosensory loss as an understudied phenomenon or from some characteristic of the patient group studied. The theme of confirmation of clinically significant findings also did not appear in the research literature. These two areas of potential reciprocal benefit for patients participating in nonclinical trials research require confirmation through further investigation but imply that this area requires careful attention in the conduct of nonclinical trials projects, both to avoid neglect of clinical information and to retain participants by reducing physical or psychosocial distress.

This analysis is limited by the nature and volume of data and requires confirmation through replication of the aim in other research projects with diverse samples of vulnerable individuals. The findings would be strengthened by validation from participants who have completed nonclinical trials research.

Implications for Research and Practice

The content themes and notion of unveiling the experience imply some specific reciprocal benefit of participation in nonclinical trials research for these patients with head and neck cancer. This was corroborated by the work of other investigators who have analyzed research participation (Neufeld et al., 2001; Smith, 1999). However, the notion of reciprocal benefit to patients participating in nonclinical trials remains virtually unexplored within nursing. The research community currently is placing great emphasis on successful enrollment and retention of minority and other under-represented groups in research. Issues that emerged in this analysis may serve as a starting point for specific investigation of research participation and the benefits it may hold for patients.

The specific benefits described here suggest that interaction with study nurses may have therapeutic value beyond the ethical conduct of clinical research. Exploration of this role and its effects on patient outcomes and quality of life are underexplored and worthy of investigation. Attention to the interpersonal skills and clinical background of study personnel and time for interaction in excess of what may be required exclusively for completion of study materials are important elements of reciprocity in research participation. Development of training programs for study personnel is an important consideration as investigators strive to disclose all potential benefits of research participation and successfully recruit participants for their studies.

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For more information . . .

- ▶ Head and Neck Cancer Support and Information
www.hncancer.com
- ▶ Support for People with Oral and Head and Neck Cancer
www.spohnc.org
- ▶ Yul Brynner Head and Neck Cancer Foundation
www.headandneck.org

These Web sites are provided for information only. The hosts are responsible for their own content and availability. Links can be found using ONS Online at www.ons.org.