Hospice, HIPAA, and Hope:
Survey Research with the Terminally Ill

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Abstract

Quantitative studies have provided insight into the needs and desires of those who are dying as well as those who care for the dying. Yet survey research with the terminally ill is particularly challenging. There are a number of ways for error or bias to occur while researching this population. This is a narrative description of the experience of developing and administering a theoretically-based survey instrument to measure suffering in terminally ill patients. The setting is a Veterans Administration hospital and outpatient clinic.

This paper will describe issues involved in instrument development and sampling in relation to population definition, sampling decisions in the Health Insurance Portability and Accountability Act environment, interviewer characteristics, item order, and protections for this highly vulnerable population. It also argues that participation in research protocols offers the terminally ill an opportunity for personal growth and contribution to the larger community. Research into quality of life and suffering at end of life is developing more sophisticated quantitative strategies. Understanding the specific challenges involved in survey development and administration with the terminally ill will further the research agenda for end-of-life studies.

Keywords: research subjects; terminally ill; end of life; vulnerable populations

1. Introduction

Increased sensitivities to the needs of the dying are accompanied by a greater focus on survey research used to assess the quality of life of the terminally ill. This paper describes methodological issues of particular interest in developing and implementing a survey instrument intended to assess suffering at end of life. The project described is the "Assessment of Veterans' Suffering in Late and Terminal Illness: A Pilot Study" conducted at Wayne State University School of Medicine and the John D. Dingell Veteran Administration Medical Center. This paper focuses specifically on population definition, Health Insurance Portability and Accountability Act (HIPAA) requirements in a clinical setting, interviewer characteristics, and item order. It then suggests that the terminally ill have the right to be recruited for research and that participation in research affords them the opportunity for contribution and personal growth.

Najman and Levine (1981) concluded that poor research design called into question the results of most of the quality of life studies related to illness that had been done in the 1970's. Most of the work that was reviewed involved analysis of the effectiveness of high-technology medical interventions. They suggested that since these interventions late in life often do not prolong life, then quality of life must be measured in other ways. These could include symptom relief and improved mental health, among others. Since the 1980's, improved research designs have resulted in substantial progress toward understanding the experiences of the dying and their caregivers. Central to this progress is the tenet that proxy reports may not be adequate to measure the experience of dying patients (Mount & Scott, 1983). To understand patients' experiences, patients must be asked.

Broader views of what constitutes suffering continued to emerge. Cicely Saunders, a pioneer of hospice work in the 1970's in England, spoke of the "total pain" of the patient, pain which encompassed physical, psychological, social, and spiritual elements (Saunders, 1964). Cassell (1982, 1991) argued that while pain and suffering are most often considered as a whole, suffering is a dimension in itself and maintains an existence even after pain has been controlled. He also refers to social relationships as the foundation of an integrated "personhood," suggesting that once pain is under control, suffering continues as the patient experiences personal disintegration or the fear of personal disintegration. This is not the suffering of physical pain, but rather the suffering of faltering social relationships. Cassell, too, argues that the only way to know whether suffering is present is to ask the patient. This focus on patient input is echoed by Wanzer et al. (1989) who recommended that doctors make the effort to understand patient values and wishes by employing the same strategies that are used to take medical and family histories.

Research in the 1990s and beyond was marked by the development of qualitative and quantitative strategies

to understand the experiences of the terminally ill. The focus was not on the success or failure rate of treatment regimens, but on the quality of life at end of life—essentially the quality of dying. Byock (1996) suggested that the central responsibility of clinicians is to support patients as they strive to discover their own answers. Byock describes the dying period as a developmental opportunity with landmarks and tasks to be completed: a sense of completion with worldly affairs and relationships with community; sense of meaning about a person's life; the experience of love of self and of others; completion in relationships; acceptance of the finality of life and a new self; meaning about life; and surrendering or "letting go."

Qualitative studies included Chochinov's (2002) work that focused on "meaning" for dying patients and their caregivers. He argues that caregivers who conserve the dignity of patients experience a kind of dignity themselves. While acknowledging that this very small-scale work cannot be generalized, Chochinov emphasizes that the model emerged from earlier empirical work with 50 cancer patients. In a qualitative study involving interviews with 126 patients with advanced disease (Singer, Martin, & Kelner, 1999) researchers identified five domains of quality care at end of life: adequate pain and symptom management; avoiding inappropriate prolongation of dying; achieving a sense of control; relieving burden on loved ones; and strengthening relationships with loved ones. By maintaining a primary focus on medical issues, clinicians run the risk of excluding these important dimensions.

A series of 12 focus groups of physicians, nurses, social workers, chaplains, hospice volunteers, patients, and recently bereaved families explored the characteristics of a "good death" and found six domains which were valued across groups: the control of pain; clear decision making; preparation for death; sense of completion; contributing to others; affirmation of the whole person by health care professionals (Steinhauser, Bosworth, et al., 2002). While people may fear that acknowledgement and acceptance of dying may result in a loss of hope for the patient, these researchers suggest that "bad dying" is characterized as the failure to fulfill those social obligations such as planning ahead, making personal arrangements, decreasing family burden, or saying goodbye.

2. Defining the Population: What Is 'Terminal Illness'?

The development phase of the survey took place within a new program in palliative care in a major metropolitan Veterans Administration medical center. A series of qualitative interviews with terminally ill patients were conducted to explore their understanding of their experiences of terminal illness. Hospice benefits are typically available to those with a terminal illness and prognosis of less than six months. Prognostication is an inexact science at best (Christakis, 1999), so using the definition of "hospice eligible" was judged inadequate. Palliative care programs have emerged in the last few years in recognition that the six-month standard may be inadequate, not in length, but rather in scope. The purpose of these programs is to

> …relieve suffering and to support the best possible quality of life for patients with *advanced chronic* and *life-threatening illnesses* [italics added] and their families. It focuses on treating pain, symptoms and stress, providing support for daily living, helping patients and families make difficult medical decision and insuring that patient and family wishes for care are followed. (National Consensus Project, 2004)

According to the guidelines of the University's Human Investigations Committee, the terminally ill fall into two categories:
1. "imminent death" where survival is likely ≤ 1 week
2. "shortened life expectancy" where survival is likely greater than one week but less than six months (Wayne State University, 1999).

With the multiple and increasingly broader understanding of "terminally ill," the study protocol described here was written such that hospice and palliative care patients with a terminal illness as identified by the Palliative Care consult team at the medical center would be eligible to be recruited. This placed the selection judgment within the expertise of the medical team and outside the judgment of the researcher. Cognitively impaired patients were not included in the research protocol.

3. Vulnerable Populations: Protected or Patronized?

While there are specific federal regulations that address the status of children and prisoners as "vulnerable" populations in research, those guidelines are absent for the terminally ill. Absent these federal regulations, the university identifies the terminally ill as vulnerable and pays particular attention to the "risks" and "benefits" sections of the research protocol. Coercion of patients is guarded against. In this case, the patient's attending physician was allowed to screen for possible recruitment for the study, but not allowed to gain informed consent. This approach

addresses the concern that a terminally ill patient might feel desperate and thus agree to participate when he/she might not otherwise. Additionally, respondents who, in the judgment of the researcher, appeared to be disturbed or upset by the experience were to be referred to the palliative care clinical team for assessment and follow-up.

This placed a unique responsibility on the shoulders of the researcher. These respondents were competent and able to consent to the interview. The protocol required that original copies of the signed consent be placed in their charts. Thus, while answers are kept confidential, participation in the research itself is kept confidential only to the extent that patient charts are confidential. Additionally, researchers are required to make judgments concerning the emotional response to the interview process and make clinical referrals. These mechanisms are in place to protect vulnerable populations, and fall outside the normal expectation of privacy in survey research.

While the later portion of the survey schedule included closed-ended questions, the early sections were made up of a series of open-ended questions. The combination of these open questions with the conversational approach to the interview brought with it a certain unpredictability in results. This process is akin to qualitative research methods of grounded theory, ethnography, or observational research. Koenig, Back, and Crawley (2003) argue that qualitative methods may be less stressful for terminally ill respondents, whose moods and energy levels can be more readily gauged by an experienced qualitative interviewer. They also suggest that the use of a more structured instrument, whose completion is critical to the quality of the data, may not make allowances for patient frailty. As a result of pretesting on this project, printed response sheets in large type were given to the respondents to view as they answered the questions. This was an effort to facilitate responses on the closed-question section of the survey schedule by lessening the strain of patients who were short of breath or fatigued.

The issue of equal rights emerges in these research processes. The university's IRB recognizes that these patients, while considered "vulnerable," also have the right to participate in research. Phipps (2002) warns against developing an "overly protective and paternalistic stance toward patients and families…" (pg. 107). Just as medical providers gain consent for treatment from the patient, so must clinicians and researchers recognize the right and the authority of the patient to make the decision about participation in research. Clinicians should not bar access, either

overtly or covertly, to potential study participants in the name of "protection."

4. HIPAA: Privacy Gates

Any research that involves access to patient charts also must comply with health care privacy guidelines. In this case, the Veterans Administration health care system had additional safeguards in place. Specifically, the human subjects review board required a two-part consent: a 3-page research consent form and a separate, 2-page release for access to health care information. Patients had to sign both documents before any interviewing could commence. Upon renewal of the study protocol, the consent form was blended into one 4-page document that only needed to be signed once, but had to be initialed on each page. The originals still remain in patient records, with copies to the patient and to the office of record for the study.

In addition to the requirements involved in developing the consent forms, HIPAA guidelines determine who can recruit patients. These guidelines accommodate hospital quality-assurance programs and educational access to patients (medical students, interns across a number of disciplines, nursing students, and the like); they are less accommodating to survey researchers. Researchers are not authorized to approach patients to recruit them for participation unless the researchers already have some professional relationship in place with the patient. Thus the researcher cannot have access to patient lists or to meetings in which patient care is discussed. Accordingly, it becomes necessary for clinicians, e.g., social workers, nurses, doctors, spiritual care givers, or the like, to be involved in a research project, participate in training, and be approved by the institutional review board.

As discussed by Raudonis (1992), there may be an "inherent role conflict" (p. 242) in clinical settings. Researchers must be cautious to recognize the potential for confusion of roles, both on the part of the patient and the researcher/caregiver. Care must be taken to clarify the role of the researcher and to gather only that data which has been approved as part of the protocol. Clinicians may also vary in their commitment and enthusiasm for research in the clinical environment. A non-clinician researcher, who, because of HIPAA, is dependent upon the clinical staff for access to patients may need to assure the staff of the importance of the research protocol. Researchers may also find themselves facing clinicians who want to protect patients from the burden of participation in research.

5. Item Order: The Structure of Compassion

Recognizing that questions involving life events and loss can be upsetting in any interview, the survey questions were patterned specifically to address this possibility. The first two questions in the schedule asked about patients' lives before they became ill and then asked which activities were the most important to them. The final question of the interview refers back to those first responses and asks if there are any favorite memories or stories about that time of the respondents' lives. With one exception, all respondents had at least one funny or happy story to tell about themselves. This technique allows the interview to conclude with the recollection of an enjoyable memory for the patient. It was not unusual for a respondent to thank the interviewer at this point, with comments such as "I hadn't thought about that in a long time," or "This is the first I'd thought about that since I got sick."

Survey instruments themselves have an ebb and flow: an introductory, framing section; a middle segment that may explore some of the more difficult issues; and a concluding segment that wraps up the survey. Interruptions in the interview can interfere with the rhythm of the survey instrument. Of the surveys that were administered, only one had unanswered questions. In this case, the interview had been interrupted three times, with one of those interruptions lasting for more than 15 minutes. The final interruption was the arrival of the patient's dinner tray and a brief conversation with the food service worker. With such a small respondent pool, missing data is particularly problematic. In retrospect, these unanswered questions were the result of the loss of the rhythm of the interview. Without the multiple interruptions, the lapse in the rhythm and pacing of the interview would have been noticed. This suggests that in any environment where interruptions are likely, researchers must be particularly careful about examining the survey document page by page before concluding the interview.

Those who care for the terminally ill are subject to a particular kind of workplace stress. Conducting survey research with this population is stressful for the researcher as well. These respondents were genuinely frail. The survey instrument specifically explored the patient's sense of loss and social relationships. Researchers must acknowledge their own responses to this work and recognize their own emotional strengths and limitations. The "favorite memories or stories" portion of the interview, described above, was designed specifically to refocus the respondents'

thoughts at the conclusion of the interview to enjoyable memories. What was unexpected was that these stories also became a way for the interviewer to be refreshed at the conclusion of the interview.

6. Interviewer Characteristics: Must I Be Dying?

There is a fairly large body of experience and literature on the appropriate characteristics of interviewers and focus group leaders with regard to respondent comfort and the accuracy of results. How then to determine the most appropriate characteristics of those who interview the terminally ill? In this project the interviewer was an experienced hospice trainer and volunteer with substantial personal experience in a hospital environment. Thus the pace of the hospital day and the sights and sounds and organization of the clinical environment came as no surprise.

But age, race, and gender may serve as barriers or facilitators of interviewer/ respondent relationships. The hospice-experienced interviewer was also a middle-aged white female. Since the research setting was a VA hospital in a metropolitan area, the population base was primarily male and reflected a high proportion of African Americans. The age range of respondents was 43 to 83, with an average age of 59.5. Anecdotally, respondents appeared to be more sensitive to age over race and gender. In the early stages of the recruiting and consent process, respondents often asked about the interviewer's status as a student and her family circumstances. The appropriateness of this interaction is discussed more thoroughly below. But it became clear that patients relaxed upon realizing that the researcher had significant life experiences involving children and work. This suggests that in the absence of other characteristics in common, respondents were more comfortable discussing their illness and social relationships with someone closer in age to themselves.

Researchers must guard against their own biases in how they regard and treat patients. Failure to recognize the nature of the relationship between the researcher and patient could result in an inappropriate influence upon the patient's response or an inaccurate interpretation of the data. A change in tone of voice or a gesture of kindness by the researcher may influence a patient's response to questions. Affection, admiration, or dislike for a patient may influence the recording and interpretation of a response, particularly in open-ended questions. Frank (2001) suggests that research on suffering increases the suffering of patients and that only by recognizing their own suffering experiences can researchers hope to understand and appreciate the

suffering of those they are trying to study.

7. Hope and Growth

During the recruiting and informal conversations before the interviews commenced, it was not unusual for patients to ask about the interviewer's family. Interestingly, they occasionally asked whether the interviewer's parents were alive; that question was asked more frequently than any other, including whether the interviewer had children. This suggests that patients may be thinking about their own losses in life (the losses that patients most often mentioned in response to survey questions were their own family members). Conventional practice in survey research is for the interviewer to deflect these questions, specifically to lessen interaction with and influence upon the respondent. Yet in the hospice setting, a compassionate and respectful response warrants at least some modest level of conversation. These respondents are aware that their lives are limited, and social interaction is often critical to their sense of well-being. Offering respondents even the most basic human interaction of answering a personal question affords them dignity and a kind of "normal" conversation that they may not frequently enjoy. It also increases rapport between the interviewer and respondent, an important element that facilitates the interview process. This approach to responding to patient conversational questions echoes to some degree the findings of Steinhauser, Bosworth, et al. (2002). They suggest that affirmation of the whole person is one of six domains which people value at end of life. One affirming behavior may include something as simple as a conversation with a patient about a personal, rather than medical, matter. This reaffirms their position as a social human being, not merely a patient. When interviewers share a relevant and appropriate element of their lives, they are creating respect, empathy, and connection.

The most common response at the conclusion of an interview was "I hope I've been able to help." One of the in-patients had actually sought out the researcher. He was aware of the developing project and expressed his desire to help; he eventually served as a pre-tester of the questionnaire. He wanted to contribute to the palliative care service that he felt was helping him in his last months of life, and said as much. These experiences reiterate that the terminally ill may need to feel that they have some legacy to leave to the world. This coincides with Erikson and Erikson's view of the "grand-generativity" (1997, p. 63) in old age, a component of the integrity and wisdom stage. Particularly for inpatients, who may be isolated from normal social interaction, this is an opportunity for contributing to the larger social world and for personal growth.

8. Limitations

This paper has not addressed one of the most methodologically challenging elements of survey research with the terminally ill: reliability efforts through test-retest strategies. Often, patients approach or are referred to hospice services once they are very far along in their disease trajectories; they may be quite frail and within weeks, days, or even hours of death. Any test-retest strategies are confounded by timing, out-patient transportation, patient symptoms, drug effects, and patient death. Additionally, sample size in research with the terminally ill, particularly in a pilot project, will tend to be quite small, which influences the strength of any statistical analyses. Even in a fairly large hospital setting, the underlying requirement of cognitive function coupled with the realities of disease trajectories result in a small sampling frame. The difficulty of recruiting respondents within that environment is particularly challenging. The conceptualization and operationalization of suffering at end of life is itself a difficult and subtle effort, requiring familiarity with literature in spirituality, medicine, sociology, psychology, philosophy, and nursing.

9. Conclusion

None of the elements that have been outlined above—population definition, protections for vulnerable populations, HIPAA requirements, interviewer characteristics, item order, or opportunities for patient growth and hope—are isolated one from another. There is a complex interplay of these elements as they determine who will be successfully interviewed for a study. Even with clear agreement on patient eligibility, HIPAA regulations demand that non-clinical researchers rely upon clinicians to contact and recruit potential study participants. Support for the project may vary within members of the clinical team, whose professional commitment and responsibility is to provide care for the patient, not for the research protocol. While privacy for the patient is guarded, it is also balanced against the need to protect a vulnerable population base. Researchers who are working in this environment must be particularly attuned to respondent manifestations of distress—which behaviors are appropriately referred to the palliative or hospice care team, and which could be considered to be within the boundaries of normal patient behavior. Experience counts in this setting, and strong communication between the clinical team and researchers is central to successful application of protocols.

Importantly, research participation can provide the terminally ill an opportunity for personal development and growth. The terminally ill often have something that they want to share, perhaps need to share, in order to feel that they have made a contribution at the end of their lives. A research protocol that is developed around the special circumstances of those who are approaching death can do two things: first, further the science concerning end-of-life experiences; and second, provide a safe space for the terminally ill to share their experiences and have their lives affirmed in a respectful and caring environment.

Some of these elements of survey research with the terminally ill will come as no surprise to researchers who work in hospital settings. Familiarity with hospital procedures and protocols will always facilitate predictability, which enhances the quality of results. What this also suggests is that there is no "efficient" way to do this research, given the challenges of recruitment and the fluidity of patient symptoms.

As the needs of the dying are recognized and the clinical and research communities embrace a model that includes the patient as a research subject, survey research is increasingly being used to assess the quality of life of the terminally ill. This paper described some of the challenges encountered in the development and implementation of a pilot project to assess suffering in late and terminal illness in a Veterans Administration health setting. It focused on population definition, IRB designation of the terminally ill as a vulnerable population, HIPAA requirements in a clinical setting, interviewer characteristics, and item order. The terminally ill have the right to be recruited for research. Their participation may tell us something about a life process that everyone will experience, no matter what race, gender, socio-economic level, education, sexual orientation, or culture. Their participation also affords the terminally ill some hope of contribution as they face the end stage of life.

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References

Byock, I.R. (2003). Four things that matter most. Retrieved February 26, 2005, from http://www.dyingwell.org/ 4things.htm

Cassel, E.J. (1982). The nature of suffering and the goals of medicine. *The New England Journal of Medicine*, *306*, 639-645.

Cassell, E.J. (1991). Recognizing suffering. *The Hastings Center Report*, *21*, 24-32. Retrieved May 20, 2003, from GaleGroup Health & Wellness Resource Center database.

Chochinov, H.M. (2002). Dignity-conserving care—a new model for palliative care: helping the patient feel valued. *JAMA, 287*, 2253-3360.

Christakis, N.A. (1999). *Death foretold: Prophecy and prognosis in medical care*. Chicago: University of Chicago.

Erikson, E.H. & Erikson, J.M (1997). *The life cycle completed: Extended version*. New York: W.W. Norton.

Frank, A. W. (2001). Can we research suffering? *Qualitative Health Research*, *11*, 353-362.

Koenig, B.A., Back, A.L., Crawley, L.M. (2003). Qualitative methods in end-of-life research: recommendations to enhance the protection of human subject. *Journal of Pain and Symptom Management*, *25*, S43-S52.

Mount, B.M., & Scott, J.F. (1983). Whither hospice evaluation. *Journal of Chronic Disease, 36*, 731-736.

Najman, J.M. & Levine, S. (1981). Evaluating the impact of medical care and technologies on the quality of life: a review and critique. *Social Science and Medicine, 15F*, 107-115.

National Consensus Project. (2004). Introducing Clinical Practice Guidelines for Quality Palliative Care. Retrieved November 14, 2005, from http://www.aahpm.org/NCPfactsheet.pdf

Phipps, E.J. (2002). What's end of life got to do with it? Research ethics with populations at life's end. *The Gerontologist, 42* (Special Issue III), 104-108.

Raudonis, B.M. (1992). Ethical considerations in qualitative research with hospice patients. *Qualitative Health Research*, *2*, 238-249.

Saunders, C. (1964). The symptomatic treatment of incurable malignant disease. *Prescribers Journal, 4*, 68-73.

Singer, P.A., Martin, D.K., & Kelner, M. (1999) Quality end-of-life care: patients' perspectives. *JAMA, 281*, 163-168.

Steinhauser, K.E., Bosworth, H.B., Clipp, E.C., McNeilly, M., Christakis, N.A., Parker, J., et al. (2002). Initial assessment of a new instrument to measure quality of life at the end of life. *Journal of Palliative Medicine*, *5*, 829-841.

Wanzer, S.H., Federman, D.D., Adelstein, S.J., Cassel, C.K., Cassem, E.H., Cranford, R.E., et al. (1989). The physician's responsibility toward hopelessly ill patients: A second look. *The New England Journal of Medicine, 320*, 844-849.

Wayne State University. (1999). HIC Policy: Vulnerable subjects: terminally ill. Retrieved February 15, 2005 from http://www.hic.wayne.edu/hicpol/terminal.htm