Qualitative Research in Palliative Care: Applications to Clinical Trials Work

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Abstract

Background: While vast opportunities for using qualitative methods exist within palliative care research, few studies provide practical advice for researchers and clinicians as a roadmap to identify and utilize such opportunities.

Objective: To provide palliative care clinicians and researchers descriptions of qualitative methodology applied to innovative research questions relative to palliative care research and define basic concepts in qualitative research.

Body: We describe three qualitative projects as exemplars to describe major concepts in qualitative analysis of early palliative care: (1) a descriptive analysis of clinician documentation in the electronic health record, (2) a thematic content analysis of palliative care clinician focus groups, and (3) a framework analysis of audio-recorded encounters between patients and clinicians as part of a clinical trial.

Conclusions: This study provides a foundation for undertaking qualitative research within palliative care and serves as a framework for use by other palliative care researchers interested in qualitative methodologies.

Keywords: clinical trials work; palliative care; qualitative research

Background

QUALITATIVE RESEARCH is “any type of research that produces findings not arrived at by statistical procedures or other means of quantification.”¹ While subject to distinct but equally demanding sets of rigor, qualitative methods are ideal for exploring phenomena and experiences not easily captured through quantitative or objective measures, such as patient–clinician interactions and patients’ perceptions of prognosis. Such analyses result in deep, rich results that can explore reasons or associations between phenomena.²⁻⁴

Palliative care is a field ripe for the application of qualitative analysis; palliative care practice patterns are evolving rapidly, new patient populations are being treated, and there is a recent trend to integrate palliative care earlier into care.^{5,6} Several randomized controlled trials (RCTs), including one performed by our team at the Massachusetts General Hospital (MGH), have demonstrated that palliative care integrated early into the course of cancer care leads to improved patient outcomes.⁷⁻¹¹ Since early integration represents a new paradigm of palliative care,¹²⁻¹⁴ clinicians in our trial received

only general guidelines about how to translate principles of palliative care into their clinical practice.^{7,15} Therefore, exploring the components of early palliative care, their use among clinicians, and their impact on patients remain critical, yet, understudied aspects of palliative care, which qualitative analyses are uniquely capable of illuminating.¹⁶

This study describes a step-by-step approach to undertaking qualitative research by detailing its use in identifying the components of early palliative care as practiced in two RCTs at MGH. We illustrate the key concepts integral to doing this work and show how they are the foundation of the iterative, descriptive qualitative research process. Our aim is to present key principles and define concepts in qualitative research to facilitate its use in palliative care research settings.

Context for Three Qualitative Projects

Patients with incurable cancer at MGH were randomized to receive either oncology care alone or oncology care with early palliative care in two RCTs; one study was conducted in patients with nonsmall-cell lung cancer and the second, in

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Accepted March 6, 2017.

patients with lung and gastrointestinal cancers.⁷ Within both studies, patients randomized to receive early palliative care received a coordinated model of care, in which their oncology team and palliative care team worked together to manage their patient's care. Both of these trials supported the efficacy of early palliative care in improving mood and quality of life.^{7,10} However, the "syringe" of the content of early palliative care itself has never been delineated, in other words. Thus, our three qualitative projects were conducted to elucidate the content and timing of this intervention. This investigation thus would uncover critical information as to why and how early palliative care makes a difference. Within these trials, we conducted complementary qualitative analyses, including (1) descriptive analysis of palliative care clinician documentation,¹⁷ (2) thematic content analysis of palliative care clinician focus groups,¹⁸ and (3) framework analysis of audio-recorded encounters between patients and palliative care clinicians.

Descriptive analysis of clinician documentation

Since our trial work did not use a structured, protocolized palliative care intervention, our first step was to identify the components of the early palliative care intervention. We conducted an analysis of palliative care clinician documentation in the electronic health record from the first RCT.⁷

First, we formulated a sampling plan. Investigators must identify the parent population from which the sample is to be drawn.¹⁹ Since qualitative analysis uses written text or other nonnumerical data as its source, investigators must decide what to sample: people, interviews, documents, events, or settings. Samples should reflect the research purpose and may be homogenous, stratified purposeful (distinct subgroups that can be compared), snowball (sampled individuals identifying other individuals to sample), criterion based, or random.^{20,21} Qualitative sample sizes are typically small, as only needed to achieve a state of saturation, the point at which no new information is culled. Qualitative research aims to describe phenomena rather than report statistics, and each analyzed item provides a wealth of data.¹⁹

In the first study, we drew from the set of all clinician documentation of palliative care visits with the 77 patients randomized to receive early palliative care in the first RCT. We stratified patients into four groups by duration of survival after enrollment (less than 3 months, 3–6 months, 6–12 months, and 12–24 months) to best capture the range of clinical courses and the content that clinicians addressed. Five patients were randomly selected from each group. We studied the clinician documentation of every palliative care visit with these selected patients.

The process of thematic identification begins with familiarization. A highly experienced and trained team of clinical experts in medical oncology, palliative care, psychiatry, and psychology and an investigator with expertise in qualitative methods became familiar with the data to identify recurring themes.^{22,23} We read the clinician documentation for each patient in our sample, and we discussed our findings over several meetings. Three investigators then undertook multiple readings of the documents to finalize the set of seven themes by ensuring thematic saturation (Table 1).

Next, we used the seven themes as a coding scheme to label segments of the raw data (Table 1). We coded the clinician documents in QSR International's NVivo analytical Software, although this process can be performed manually.

Multiple investigators code the same data, and their analyses are compared for consistency; we used two independent coders. NVivo can generate a numerical assessment of interrater reliability called Cohen's kappa. A kappa value of at least of 0.80 is considered an indication of high concordance.

Our group quantified the frequency of the codes within our data set, thus adding a quantitative element to the analysis. Mixed methods studies combine both qualitative and quantitative methods; they may be convergent (comparison of separate quantitative and qualitative data and analyses), explanatory (quantitative analysis followed by explanatory qualitative study), or exploratory (qualitative results used to generate quantitative data collection procedure).^{4,24} Using an exploratory approach, we identified the frequency of each of the seven elements throughout different phases of patients' clinical courses: initial visits, middle visits, and final visits. These results demonstrated the longitudinal differences between palliative care elements across time.

Thematic content analysis of clinician focus groups

After the descriptive analysis of clinician documentation, we wanted to directly explore clinicians' perspectives of these seven elements to validate their role within early palliative care. By conducting a focus group, we could both confirm our previous findings and yield a deeper understanding of each element. We were also interested in exploring clinicians' perceptions of these elements serving an explanatory function by describing the potential mediators of improved outcomes in our early palliative care study.

In this second study, we validated the themes identified in our first study by analyzing focus group data. Triangulation is the use of different data or analytical methods to support findings.^{25,26} Building on a single analysis, applying multiple approaches increases the validity of findings.²⁶ There are several forms of triangulation, including triangulation by method (different methods of analysis for the same research question), by data type (analyses of different data types), by researcher (different researchers analyzing the same data with the same methods), and by theory (different theoretical perspectives).^{20,21}

We created an interview guide to direct our focus group sessions in a focused but open manner. Interview guides may be structured, semistructured, or unstructured. Whereas structured interview guides have specifically worded probes to address several topics in a specific order, unstructured guides allow the interview or focus group to address a limited number of broad, open-ended topics as guided by the conversation.²⁷ Our guide was semistructured and included questions and suggested probes about broader perspectives and goals of early palliative care, how to initiate early palliative care, and each of the seven elements (Table 1).

Focus groups and individual interviews are two means of generating qualitative data that include textured experiences and insightful perspectives beyond that typically captured in quantitative analyses. Whereas individual interviews allow for privacy and detailed attention to each participant, focus groups allow participants to hear one another's perspectives and enrich their understanding of complex topics. We expected that a focus group setting would help clinicians share their perspectives on this novel care paradigm.

TABLE 1. EXAMPLES OF TOOLS, DATA, AND RESULTS USED TO ANSWER THREE QUALITATIVE RESEARCH QUESTIONS

Original source	Research question	Methodology	Tools, data, and results	Examples
Clinician documentation	What are the key elements of early palliative care?	Thematic content analysis	Data: sample clinician documentation ¹⁷ Results: major themes emerging from clinician documentation ¹⁷	<p>“Married for 10 years, have known each other for 15 years. Patient has 2 children from a previous marriage with whom they are very close, also has 2 grandchildren.”</p> <p>“Her back pain has improved moderately...since she underwent radiation therapy...she is still having some pain...increasing in her right hip and right anterior lateral lower rib...consider use of ibuprofen which she found very helpful in the past...”</p> <ol style="list-style-type: none"> 1. Relationship and rapport building 2. Addressing symptoms 3. Addressing coping 4. Establishing illness understanding 5. Discussing cancer treatments 6. End-of-life planning 7. Engaging family members <ul style="list-style-type: none"> • How do you think early PC helps patients? • To build a relationship with the patient and family, what do you ask about? How do you ask about it? • What are your strategies for building rapport with the patient? <p>“Our focus is on quality of life. And we do that in several different ways. We talk about physical symptoms. We talk about emotional symptoms. Sometimes people are sad and worried. And we think sometimes about decisions that are coming up in the future.”</p> <p>“It helps in terms of consistent messages that we’re really talking and understanding what the oncologist and the oncology team is thinking before we go in and suggest something that would be either a conflict with what they said or seem divisive.”</p> <p>“When someone has prognostic awareness and illness understanding, what it looks like is they can talk about what the likely future holds, they have some affect that seems appropriate, that they’re coping with, that they’re not completely undone by but they’re able to sort of emotive and still have some containment, and not get washed over by it.”</p>
Palliative care clinician interviews	How do palliative care clinicians conceptualize and practice early palliative care?	Focus group analysis	Tool: Interview guide sample Data: Sample quotes from interviews	<ol style="list-style-type: none"> 1. Symptom assessment and treatment <ol style="list-style-type: none"> a. Preparing for anticipated symptoms b. Assessing symptoms <ol style="list-style-type: none"> i. General symptoms ii. Appetite iii. Dyspnea and cough iv. Edema v. Fatigue vi. Etc. c. Evaluating symptom management <ol style="list-style-type: none"> i. Asking if symptom management strategies are effective ii. Making changes to previous symptom management strategies iii. Discussing future evaluation of new symptom management strategies d. Encouraging and empowering patient and caregiver to self-manage symptoms e. Coordinating symptom management f. Discussing and providing referral for symptom management g. Encouraging disclosure of symptoms now and in the future <p>“[CLINICIAN]: If somebody like you—they’re not having bad pain and they don’t need to take their pain meds, the question is, the breakthrough pain meds. Are you on more long-acting than you really need? And so, one thing we could do is just take you down.”</p> <p>“[CLINICIAN]: Does it feel better with the idea of being at home, or being somewhere like rehab? It doesn’t really matter?”</p> <p>“[CLINICIAN]: Given how you’re feeling with the anxiety and everything, having this whole tribe of people come in, did that feel overwhelming?”</p>
Patient–clinician conversations in the clinic setting	What are the components and subcomponents of the key elements of early palliative care?	Framework analysis	Results/Tool: Framework sample Data: Clinician quotes from patient–clinician conversations	

Our group held two focus group interviews and one individual interview, for a respondent unable to attend a group session, with the eight palliative care clinicians (board-certified palliative care physicians and advanced-practice nurses)¹⁸ who had participated in the first randomized trial of early palliative care. Interviews were ~60–90 minutes in length, and were audio recorded, transcribed, and reviewed for accuracy before analyses¹⁸ (Table 1).

We performed thematic content analysis of the focus group interview transcripts, beginning with familiarization. Using the seven preidentified elements to serve as an initial set of themes, we established a framework, in which the seven themes served as larger elements into which new concepts were categorized.¹⁸ Next, multiple investigators coded the focus group transcripts to validate the framework. As Ritchie, Spencer, and O'Connor note, there is a wide range of approaches to categorizing themes in analysis, whether they are “attitudes, behaviors [sic], motivations, or views” or even “the general atmosphere of an interview or the ease of difficulty of exploring particular subjects.”²² The constant comparative method, in which analysis from one subset of data is applied to other data, allowed for the framework to be iteratively modified, maintaining consistency in analysis.²⁵

Framework analysis of clinic audio recordings

Patients receiving early palliative care in the current RCT were invited to consent to having every palliative care clinic visit audio recorded. A group of investigators used the results from the clinician documentation and focus group analyses to develop a preliminary three-tiered framework consisting of categories, subcategories, and sub-subcategories to code the entirety of the clinic visits (Table 1). The categories mirrored the seven key elements identified in the first two analyses, and the subcategories and sub-subcategories included details such as organ system-specific symptoms and the types of nonmedical issues with which patients described coping. The purpose of the framework analysis was to validate and deepen the findings from the first two qualitative projects. Then, as part of the familiarization process, we read transcripts of participants' palliative care clinic visits. We are collecting and analyzing audio recordings of patient–clinician conversations in the clinic setting.

Familiarization and saturation do not require investigators to review the entire data set first, as long as representative data are selected.²² We used the following sampling strategy: one clinic visit was selected each from early, middle, and late in every patient's disease course,¹⁷ and visits were only selected if the clinician had noted them as covering meaningful content on postvisit surveys. Audio recordings of visits were transcribed and deidentified by an external transcription company.

We initiated the coding process in NVivo. Coding provides the opportunity to revisit the framework; a researcher may add or subdivide a category, or combine multiple categories into one²² (Table 1). Palliative care clinicians were excluded from the coding process as they were clinicians during the study and their analysis would be prone to bias.²³ The framework was accordingly revised through the coding process. However, the ultimate structure of the framework remained largely the same, with the same major concepts from the first two analyses reflected in categories of the final framework.

Discussion

Qualitative methods served as a versatile set of tools and a necessary complement to quantitative analysis in this series of studies of early palliative care. This article shows how qualitative research is uniquely positioned to contribute to ongoing clinical trial development and analysis and provides a demystifying introduction to qualitative methods for interested palliative care clinicians and investigators. Our group used triangulation by data method, with naturally occurring data in the form of documents and patient–clinician conversations as well as generated data in the form of focus groups. In addition, we used triangulation by researcher within each step of the analysis, by having at least two investigators code the data and compare the results. Furthermore, to ensure the validity of the coding framework and minimize bias, we employed an interdisciplinary team for each study, consisting of oncologists, nurses, and psychologists, and research trainees from varied medical disciplines. In addition, the findings were reviewed by investigators who did not participate in the trials.

There is a rich history of qualitative methods in academic palliative care, as palliative care continues to emerge as a field.^{26,28} Prior studies have examined complex elements of communication outside the scope of the present study such as wording, conversational flow, and nonverbal techniques applied in end-of-life patient–clinician interactions.²⁹ Yet, for researchers who are unfamiliar with qualitative methods, such procedures may appear overwhelming to conduct.

We close with recommendations of next steps for palliative care providers interested in a qualitative research pursuit. First, we would recommend collaborating with an investigator who has experience in qualitative methods. Second, there are several excellent resources that provide a comprehensive overview of qualitative methods; we recommend *Qualitative Research Practice* by Ritchie and Lewis.³⁰ Finally, while designing a qualitative analysis, reviewing validated qualitative reporting criteria such as the 32-item COREQ (Consolidated Criteria for Reporting Qualitative Research) assists researchers in ensuring the best qualitative methods are applied to their research question.²³

Acknowledgments

Funding received from National Institute of Nursing Research (R01 NR012735), National Cancer Institute (K24 CA181253), and MGH Clinical Research Program Qualitative Core. National Institutes of Health (R01 NR012735 (J.S.T.). National Institutes of Health R01 NCI (1K24CA197382 (E.R.P.). Faculty Committee on Scholarship in Medicine, Harvard Medical School fellowship.

Author Disclosure Statement

No competing financial interests exist.

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