

Research Methods Priorities in Geriatric Palliative Medicine

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Abstract

Continuing the momentum of geriatric palliative medicine research achieved during the past decade requires a focus on research methods priorities that span the continuum of research from small pilot studies testing new interventions to large multisite studies evaluating implementation of proven interventions and models of care. Each phase of this continuum presents unique challenges for investigators who are designing, conducting, and reporting results of these scientific endeavors. The goal of this article is to describe the top priorities in research methods for the field of geriatric palliative medicine that will enable the field to rapidly respond to the changing landscape of health care policy and quality improvement initiatives.

Introduction

RESEARCH IN GERIATRIC PALLIATIVE MEDICINE spans the continuum from small pilot studies testing new interventions to large multisite studies evaluating implementation of proven interventions and models of care (see Table 1). Each phase of this continuum presents unique challenges for investigators who are designing, conducting, and reporting results of these scientific endeavors. The goal of this article is to describe the top priorities in research methods for the field of geriatric palliative medicine across that research continuum. In identifying research priorities, we have given weight to the speed with which policy initiatives are moving forward and preferred practices and clinical guidelines are being established. Given this momentum, it is critical to build the evidence base for palliative medicine and geriatrics using existing innovative analytic techniques as well as developing new techniques for studying this population.

We have identified three research methods priority areas, one at each stage of the research continuum, for research and funding to enhance care for older adults living with serious illness and their families. The first research priority is to employ with greater frequency rigorous analytic techniques for observational and quasi-experimental research studies. The second priority is to enhance collaborations across centers and encourage multisite studies that build on evidence from single-site study designs. This second priority includes the development of infrastructure for uniform clinical data collection across sites for research purposes. Third, in conjunction with these first two priorities there is a pressing need to apply the tools of dissemination and implementation science in a focused and methodologically sound manner to re-

search in geriatric palliative medicine that is evidence based and has already been established by rigorous research. These three complementary research priorities represent the next wave of critical work that needs to be conducted to continue the momentum of scientific research in palliative medicine and aging that have been achieved in the past decade.

Research Priority: Employ rigorous analytic approaches to quasi-experimental and observational studies including greater use of analytic methods for addressing selection bias, modeling health care cost data, and other research methods challenges.

This research priority is focused on observational and quasi-experimental study designs because these types of studies have the greatest potential to leverage existing data and rapidly move the field forward relative to experimental studies. Despite the strengths of experimental study designs (e.g., randomized controlled trials (RCTs)), there are certain research questions, particularly in palliative medicine, for which an RCT may be unnecessary (because the question has been clearly answered by observational studies); inappropriate (because the very act of randomization may reduce the intervention's effectiveness); impossible (because physicians or patients may refuse to be randomized or the sample size required may not be attainable); or inadequate (because the external validity or "generalizability" of RCTs may be low, particularly for studies with stringent inclusion/exclusion criteria).^{1,2} In these situations the use of observational or quasi-experimental designs has become increasingly necessary to study the complex aspects of aging and palliative medicine delivery.^{3,4}

One of the greatest barrier to the legitimacy of much of the observational and quasi-experimental work currently being

TABLE 1. RESEARCH CONTINUUM FOR GERIATRIC PALLIATIVE MEDICINE RESEARCH

	<i>Early</i>	<i>Middle</i>	<i>Late</i>
Setting	Single site	Multisite or multisetting	Single or multisite/setting
Sample size	Small	Large	Small or large
Objective	* Evaluate feasibility of an intervention * Provide initial evidence of the effectiveness of an intervention or identification of a "problem" (e.g., access to care, disparities in outcomes)	* Build the evidence base for the effectiveness of interventions across settings and populations * Evaluate the mechanisms contributing to issues such as access to care and disparities in health care outcomes	* Evaluate the transition from scientific knowledge to clinical practice * Provide evidence of the implementation experience across regional and national health care systems and community organizations
Research methods priority	Employ more rigorous analytical approaches to observational and quasi-experimental research	Greater support for infrastructure and funding of multisite collaborations and uniform clinical data collection	Utilization of the framework and tools of dissemination and implementation science

conducted in palliative medicine and aging is the critique that selection bias has not been adequately addressed.⁵ Although investigators are well versed in the limitation posed by selection bias, sophisticated methods for addressing it are not widely used. One such method for reducing the effects of selection bias on the estimation of treatment effects on outcomes in observational studies that is gaining popularity in palliative medicine and aging research is propensity score matching.⁶⁻⁸ Recent studies across a range of topics have employed propensity scores to more closely match intervention subjects (or "cases") with control subjects, including studies evaluating (1) the impact of palliative care consultation teams on hospital costs,⁹⁻¹¹ (2) family perceptions of care from palliative care consult teams versus inpatient units,¹² (3) the impact of hospice enrollment on Medicare expenditures,¹³ and (4) the impact of feeding tubes on pressure ulcers in a cohort of nursing home residents.¹⁴

In short, a propensity score is a summary measure of multiple characteristics (usually patient characteristics) associated with both the study intervention and outcome of interest. The investigator computes a propensity score for each subject that reflects the probability of that subject being a member of the intervention group. The investigator then matches intervention and control subjects on their propensity score using various matching strategies. The objective is that analyses using the resultant dataset of matched intervention and control subjects will be less subject to selection bias and will allow for a more unbiased estimate of the intervention's effect. Although the use of propensity score matching is increasing, it is not yet a standard technique, and studies employing propensity score matching remain concentrated among a relatively small group of investigators.

Going forward, in addition to greater use of propensity score matching to address selection bias or missing data, we need investigators to think creatively about new applications of tools such as propensity scores for addressing other complexities of geriatric palliative medicine research. For example, missing data is a major challenge in palliative medicine and aging research, given the vulnerability of the patient population and high prevalence of conditions such as dementia.¹⁵ Data can be

missing because patients with serious illness die during studies or are unable to report directly about their symptoms, concerns, or attitudes because their illness or treatment have left them confused, weak, or unconscious. Propensity scores could be used to match intervention and control subjects and then impute missing values within the pair or matched group. Although limitations exist, greater use of propensity scores may enable researchers to better address the issue of nonrandom missing data that often impedes our work. We also need investigators who can explore if propensity score matching can be used to identify controls from administrative databases or national studies to be used in studies that have been conducted without controls (i.e., intervention-only studies). This methodology has been employed in the fields of education and economics and has tremendous potential for palliative care and aging. It enables investigators to use existing data on interventions that may not have a control and publish and disseminate results without waiting to conduct additional larger studies. Future work could also include applying propensity score matching to hierarchical data (e.g., patients nested within physicians nested within hospitals) and weighted survey data (Health and Retirement Study: A longitudinal study of health, retirement, and aging. Sponsored by the National Institute on Aging. Available at hrsonline.isr.umich.edu) that are increasingly used for larger-scale studies in health policy and health services research.

In conjunction with building the evidence base for the effectiveness of geriatric palliative medicine interventions, it is becoming imperative to also examine the cost and potential cost savings of health care interventions. A key reason for conducting rigorous research is to build the evidence base for practices that improve patient outcomes but also to argue that such interventions should be covered by insurance programs and thus are able to be implemented on a large scale. Further, the growing understanding that many palliative care interventions not only improve patients' quality of life but also reduce costs needs to be reinforced by rigorous analyses, which are often not conducted. Although the problems of skewed data, nonnegative outcomes, and censoring that are inherent in cost analyses are well documented and there exist methods to

address these challenges, rigorous costs studies should be more frequently employed in palliative medicine and aging research.

Research Priority: Support midcareer and senior investigators in developing and conducting multisite collaborative geriatric palliative medicine research by identifying common research interests across institutions, supporting networking and project start-up meetings, and investing in infrastructure for multisite trials and uniform clinical data collection to enhance the efficiency of research endeavors.

A major barrier to the conduct of collaborative research is the lack of funding to support the required infrastructure for multisite studies—particularly for studies in palliative medicine in which a large number of sites, each recruiting a handful of patients, are often required to conduct meaningful research. Therefore, a critical research priority is supporting the development of collaborative research networks by supporting planning meetings and facilitating grant applications to the National Institutes of Health (NIH) and major foundations to establish collaborative research networks.

The successful creation of the nation's first palliative care research cooperative group, the Palliative Care Research Cooperative (PCRC), is an example of how such support can work. The PCRC originated with a meeting in 2010 sponsored and funded by the National Palliative Care Research Center (NPCRC). The goal was to plan an NIH application to support a multisite collaborative palliative care study.¹⁶ The plan was successful and as a result of this meeting the investigators received a three-year \$7.1 million American Recovery and Reinvestment Act grant from the National Institute for Nursing Research (NINR) to create the PCRC. The cooperative, composed of 15 academic and community-based sites, is now supporting a multisite study examining the effect of statin discontinuation on outcomes in patients at the end of life. Although the cooperative is currently not focused on the needs of seriously ill older adults, it could be expanded to include a focus on geriatric palliative medicine issues.

Similarly, the NPCRC supported and funded a one-day conference in June 2011 of the nation's foremost experts in dementia research. The goal of the meeting was to bring together leading senior scientists from across the nation conducting research in palliative care and advanced dementia to establish a research agenda for this population. A paper summarizing the conference entitled, "Research in Advanced Dementia: State-of-the-Art and Priorities for the Next Decade," was recently published in the *Annals of Internal Medicine*.¹⁷ As a follow-up to this highly successful meeting, the NPCRC recently funded a second conference in June 2012 whose focus was the development of a research network to improve palliative care for persons with advanced dementia. The group also plans to utilize the meeting to develop one or more R01 applications to address the research priorities identified in the *Annals* manuscript. Although successful, these efforts to support multisite studies need to be implemented on a larger scale and at a faster pace to continue the momentum and branch out into both the geriatric and palliative care communities.

In conjunction with the support of multisite studies to increase the efficiency of research in geriatric palliative care, there is a need to develop infrastructure for the collection of uniform clinical data on geriatric palliative care patients across institutions. The establishment of a mechanism by which uniform clinical data could be collected across sites for geriatric patients receiving palliative care consults has the

potential to rapidly move the field forward in answering pressing questions regarding the treatment and outcomes of this patient population.

Research Priority: Apply the framework and tools of dissemination and implementation science to palliative medicine and aging research.

The field of palliative medicine and aging is in the advantageous position of considering dissemination and implementation research as a research priority. Despite significant gaps in the evidence base for many aspects of health care for this population, there are a number of areas for which sound evidence of preferred practices exist. A challenge, however, is that the field lacks corresponding expertise in the most effective ways for these findings to be integrated into the care of patients. Equally important, innovative approaches to overcoming barriers in the adoption of evidence based interventions are generally not widely disseminated and understood.

Although many definitions exist, implementation research has been defined as "scientific investigations that support the movement of evidence based, effective health care approaches (e.g., as embodied in guidelines) from the clinical knowledge base into routine use. These investigations form the basis for health care implementation science. Implementation science consists of a body of knowledge on methods to promote the systematic uptake of new or underused scientific findings into the usual activities of regional and national health care and community organizations, including individual practice sites."¹⁸

A recent article¹⁹ highlights the need for the field of palliative medicine to become more trained in dissemination and implementation science. The article describes the frequent disconnect between our knowledge of best practices and their use to produce high quality patient outcomes. An example is the disconnect between statistics regarding the persistence of ineffectively treated pain and evidence of effective pain treatments. The author calls for palliative care researchers to (1) identify palliative care issues with sufficient evidence to be disseminated and implemented, (2) test the implementation of these interventions, (3) adapt interventions to the context in which the intervention is being tested, and (4) describe or report on the implementation components and effectiveness.

It is reasonable to assume that existing implementation science conceptual frameworks and dissemination strategies will need to be modified and adapted to the specific unique components of palliative medicine and aging health care. Potential issues to be considered include lack of standardization in the settings in which palliative medicine and geriatric care are delivered; variation across settings and regions in the practitioners and teams that provide health care to patients; inherent difficulty standardizing interventions such as communication skills; and current lack of uniformity in the documentation of interventions, discussions, and treatments for this patient population.

Implementation and dissemination research is also crucial in the context of health policy research. The field of palliative medicine is rapidly evolving with the adoption and endorsement of preferred practices and quality guidelines. The ability to effectively and equitably implement these policies and guidelines requires attention to a broad range of issues related to practice setting and population served. A research imperative is for investigators to write about their implementation experiences within a scientific framework and with a common language in order to maximize learning from

current and past initiatives. For example, the National Quality Forum (NQF) has endorsed 11 quality measures for palliative care focused on older adults including measures from RAND's Acute Care of Vulnerable Elders (ACOVE) project²⁰ and the Centers for Medicare & Medicaid Services sponsored PEACE project.²¹ These measures now serve as quality measures for new health care payment systems (i.e., bundled payments, patient-centered medical homes, accountable care organizations) under the provisions of the Affordable Care Act. Understanding the experience of health care organizations in successfully or unsuccessfully implementing these measures would be a valuable contribution to the field.

To encourage such research, investigators need funding and there are mechanisms in place to support researchers in implementation and dissemination work. The NIH's R21 initiative, "Dissemination and Implementation Research in Health,"²² has a stated objective to "support innovative approaches to identifying, understanding, and overcoming barriers to the adoption, adaptation, integration, scaleup and sustainability of evidence based interventions, tools, policies, and guidelines."²³ There is a significant amount of work in aging and palliative medicine that is relevant to such a mechanism. Similarly, researchers in geriatric palliative medicine interested in implementation research can apply to the National Institute on Aging's (NIA) T2 translational research mechanism.²⁴ Specifically, this funding opportunity encourages research directed towards development of health care practices, community programs, and policies, including monitoring and quality improvement for approaches for preventing and treating key health issues affecting the elderly. The focus is on funding research to gather information to develop or evaluate methods of translating results from clinical studies into clinical practice and health decision making. Although this funding mechanism has existed at the NIA for many years, it is not widely accessed by geriatric palliative care researchers.

Dissemination and implementation research, however, does not need to be the entire focus of a research grant. Rather, it could be integrated, when possible, into the aims of studies evaluating interventions. It is thus critical that grant review committees and journal editorial boards and reviewers include individuals with expertise in dissemination and implementation science research, so that attempts to include such analyses in research proposals and manuscripts are given appropriate consideration. In doing so, the palliative medicine and aging community can begin to emphasize, through publications, conference discussions, and strategic planning initiatives, the critically important role of implementation and dissemination research at this phase in the field.

In summary, continuing the momentum of geriatric palliative medicine research requires a focus on research methods priorities that span the continuum of research from building the evidence base to implementation and dissemination. The first priority, to employ more rigorous analytic approaches for addressing methodological weaknesses of observational research, is needed to bolster the evidence base in a timely manner as health care policy and coverage decisions are being made. The second research priority, to support both the infrastructure and conduct of multisite studies across the United States, allows us to evaluate the effect of interventions across different settings and to learn from variations that are identified. At the other end of the spectrum is our third research priority—to employ implementation and dissemination research to interventions with

strong evidence based support. These objectives may be best achieved through more extensive training of both current and future investigators, access to expertise and knowledge, and increased funding of studies developing and employing these methods within the fields of palliative medicine and aging. Through greater training there will not only be greater use of these methods, but also greater understanding and acceptance of these methods by grant and publication reviewers. Demand for training in these types of research methods is evident: the annual scientific meeting of the American Academy of Hospice and Palliative Medicine has had increasing numbers of research methods focused presentations that are consistently well attended. As the evidence base for palliative medicine and aging builds, it is imperative that our field be an informed and engaged community with broad-based understanding and willingness to utilize advanced research methods adapted to the complexities of our research population and settings.

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