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Editorial

Advances in Palliative Care Research Methodology

Scientific advances often rely on the invention of new tools and methods for seeing the world. The path towards discovery is marked with methodological inventions such as the telescope, the electron microscope, computed tomography, biostatistics, or randomized controlled trials. The papers in this volume help to prove this point in our own small neck of the clinical woods. How do we know what works and what does not in palliative care? We know by applying new methods of inquiry to our subject, and by deploying old methods in new ways. The papers in this volume therefore illustrate a range of solutions investigators have developed to the peculiar and distinctive challenges to clinical research in our field. Existing methods have been applied in a varied and creative way to make it possible to draw causal inferences about the effect of numerous aspects of palliative care.

The object of inquiry in palliative medicine is complex, which makes attention to methodology all the more acute. Our population of patients is heterogeneous and evanescent. Our interest in these patients is diverse, and ranges over clinical, physiological, psychological, and social aspects of the phenomena in question. And we are interested not just in the patient, but also in the patient's family and even in the medical providers caring for the patient. And, finally, our interest includes longitudinal changes across time in all of the foregoing.

The papers in this volume, from investigators in the US, Canada, Australia, the UK, and Norway, provide an outstanding illustration of ways to engage our object of inquiry, and they illuminate state-of-the-art palliative medicine research methods. They highlight several emerging trends in the best such research, including the increased use of population-based samples, the increased use of longitudinal designs, the increased focus on individuals beyond the patient, and the increasing inroads that RCT designs are making into palliative care.

First, palliative medicine research is increasingly focused on drawing systematic, population-based samples in an effort to move beyond either convenience samples or clinic-based studies that often (but certainly not always) can limit both sample size and generalizablity. In some cases, such as the impressive undertaking by Currow and colleagues, large samples of patients are surveyed and impaneled. In others, administrative data are used for case finding (such as in the study by Steinhasuer *et al*.) or for assessment (Grunfeld *et al*.).

Second, new work often involves longitudinal designs, obtaining repeated observations on subjects. Such studies have at least two compelling strengths: they can allow us to study a temporally unfolding process, and they can permit superior statistical control for unobserved heterogeneity. That is, when subjects are repeatedly measured across time, variation in one variable can more plausibly be ascribed to variation in another – since all time-invariant attributes of an individual (whether measured, or indeed unmeasured) can be ignored since they cannot explain why an event occurs at one point in time as opposed to another point.

Third, studies in palliative medicine are increasingly focusing not just on the patient, but also on the patient's family. The papers by Steinhauser *et al*., Cohen *et al*., and Hynson *et al*. are all centered on the role of families in terminal illness. Such studies explicitly acknowledge the critical importance in palliative care of the family – not only as an actor that influences what happens to the patient, but also as an object of care themselves. And such studies privilege the important idea that illness and medical care can have collateral health effects on others.[1,2] A related design involves impaneling paired samples of professional care providers (e.g. doctors, nurses) along with their patients (such as the Koropchak *et al*. study of communication involving 59 doctors and 281 of their patients).

Finally, creative RCT's are increasingly being conducted in palliative care. RCT's, as Kaasa *et al*. point out, have been used in palliative medicine at least since the pathbreaking work of Geoff Hanks *et al*. regarding oral morphine published in 1981.[3] But RCT's are increasingly finding their way into the armamentarium of investigators conducting assessments of the effect of non-pharmaceutical interventions, as illustrated by the research of Currow *et al*. (involving a complex, factorial RCT of a health services intervention) and Koropchak (involving a complex, three-phase intervention involving both patients and doctors).

In some ways, in its progressive adoption of a broader variety of methods of increasing sophistication with larger or more representative samples, palliative medicine is re-capitulating the developments seen 20 years ago in other fields of patient-oriented clinical research, such as

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general internal medicine or cardiology. This is a natural and healthy evolution, and there is much reason to be optimistic that the knowledge base in palliative medicine 20 years from now will be much broader and sounder than it already is today. Many of these advances will, of course, rely on investigators overcoming the well known barriers to research at the end of life.

These barriers include the difficulties in identifying a target population (e.g. in knowing who is dying), retaining this terminally ill population in a study (where loss to death is not just the outcome being studied, but an obstacle to retention), obtaining informed consent from exhausted patients and their families, and so on. The studies in this volume describe a variety of clever way of surmounting these obstacles, or of making more efficient use of available patients and data.

For example, Currow et al. fielded a complex randomized controlled trial over two years involving 461 patients chosen from a source population of 2,261 people. The objective was to evaluate the impact of various service-based interventions on numerous outcomes, including patient function and pain. They rightly point out that a factorial design, such as the one they implement, is very efficient in that it allows for numerous interventions to be evaluated simultaneously in the *same population*, saving time and money and avoiding the necessity of several samples. This substantial undertaking provides proof of this concept in palliative care.

The investigative study by Steinhauser *et al*. was equally ambitious, and involved the longitudinal study of 240 patients and carers (out of a planned, eventual target of 480). The investigators itemize numerous barriers to palliative care research and the ways they were able, successfully, to surmount them. Notably, roughly ten times as many patients as were ultimately enrolled needed to be identified, highlighting again the complexity of case finding in palliative medicine research.

The paper by Fowell *et al*. asks whether it makes a difference to sample recruitment if one uses one of two different approaches to obtaining subject consent: cluster randomization (in which there is, initially, group-level consent) versus so-called 'randomized consent' (in which only the arm randomized to the treatment is consented). Fowell *et al*. use an RCT (of a very small sample of patients) to evaluate these two approaches to subject recruitment, and they conclude that cluster randomization is a more efficient means to obtain subject consent. This is a valuable contribution.

Hynson *et al*. elegantly outline a variety of techniques that would be useful to others in approaching patients and their families struggling at difficult times. Among other clever ideas, they mention the simple expedient of providing an answering machine on which candidate research subjects could leave (deliberately impersonally) a message refusing to participate.

Finally, other papers in this volume provide useful reviews of other common problems in conducting palliative medicine research, including problems of measuring psychological distress (Kelly *et al*.), handling missing data (Fielding *et al*.), and involving patients in the conduct of research (Wright *et al*.). Other reviews examine the place of action research in palliative care (Hockley *et al*.) and discourse analysis (O'Connor *et al*.).

Kaasa *et al*. provide an important overview of all these helpful developments in palliative care research and call for more international, collaborative, multi-center trials, with all the benefits this might confer, including the benefits of standardization, applicability, and large sample accumulation. We do not yet have many examples of such trials, though there has been, Kaasa argues, much progress over the last decade. I agree. The work that is emerging, and the methods that are exemplified by the papers in this special issue, provide substantial grounds for optimism. I am certain that we will improve the evidence base required to care for people who are seriously ill or dying and who are therefore worthy of the finest and best informed care we can provide.

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