

Special Article

Exploring Generalizability in a Study of Costs for Community-Based Palliative Care

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Abstract

Context. Palliative care researchers face challenges recruiting and retaining study subjects.

Objectives. This article investigates selection, study site, and participation biases to assess generalizability of a cost analysis of palliative care program (PCP) clients receiving care at home.

Methods. Study subjects' sociodemographic, geographic, survival, disease, and treatment characteristics were compared for the same year and region with those of three populations. Comparison I was with nonstudy subjects enrolled in the PCP to assess selection bias. Comparison II was with adults who died of cancer to assess study site bias. Comparison III was with study-eligible persons who declined to participate in order to assess participation bias.

Results. Comparison I: When compared with the other 1010 PCP clients, the 50 study subjects were on average 3.6 years younger ($P = 0.03$), enrolled 70 days longer in the PCP ($P < 0.001$), lived 6.7 km closer to the PCP ($P < 0.0001$), and were more likely to have cancer (96.0% vs. 86.4%, $P = 0.05$). Comparison II: Compared with all cancer decedents, the 45 study subjects who died of cancer were on average 7.0 years younger ($P < 0.001$), lived 2.7 km closer to the PCP ($P < 0.001$), and were more likely to have had radiotherapy (62.2% vs. 33.8%, $P < 0.0001$) and medical oncology (28.9% vs. 14.8%, $P = 0.01$) consultations. Comparison III: The 50 study subjects lived on average 42 days longer after their diagnosis ($P = 0.03$) and 2.6 km closer to the PCP ($P = 0.01$) than the 110 eligible persons who declined to participate.

Conclusion. If the study findings are applied to populations that differ from the study subjects, inaccurate conclusions are possible. *J Pain Symptom Manage* 2011;41:779–787. © 2011 U.S. Cancer Pain Relief Committee. Published by Elsevier Inc. All rights reserved.

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Key Words

Palliative care, sample, research methods, sampling issues, bias, validity, generalizability

Introduction

Palliative care researchers face challenges recruiting and retaining study subjects. However, the generalizability (external validity) of study findings is dependent on being able to obtain an unbiased and representative sample of the population to which one wishes to apply the findings.¹⁻⁸ Restrictive or overly broad eligibility criteria may make it difficult to discern the groups to which the results can be generalized.^{2,3} A lack of clarity in defining the target populations also has been identified as a key problem limiting the translation of palliative care evidence into practice.⁹

This study investigates the potential impact of selection, study site, and participation biases on the generalizability of findings. Selection bias was assessed in relation to the study subject eligibility criteria. Study site bias was investigated in relation to place of recruitment. Participation bias was examined by comparing those who participated in the study with those who were eligible but chose not to participate. This study was carried out by examining the study subjects from a city (Halifax, Nova Scotia) included in a Canadian palliative care cost analysis.¹⁰ The palliative care program (PCP) clients interviewed for the study were compared on sociodemographic, geographic, survival, disease, and treatment characteristics to three potential target populations for the planning of community-based palliative care.

Methods

From February 7, 2005 to November 29, 2005, all persons newly referred to the PCP located in Halifax, Nova Scotia, Canada, were assessed for inclusion in a cost analysis during their palliative phase of care. The study eligibility criteria are listed in Table 1. Accrual continued until the target of 50 study subjects was attained. A total of 160 subjects were determined to be eligible and were approached, with 110 declining to participate.

Three comparisons were made to assess the generalizability of the cost analysis findings. To assess selection bias, the 50 study subjects

were compared with the 1010 clients enrolled in the PCP in 2005 who were not study subjects (Comparison I). To investigate study site bias, the 45 study subjects with cancer on their death certificate were compared with all adult residents (older than 18 years) of Halifax County who had cancer as their cause of death in the study year (Comparison II). To assess participation bias, the 50 study subjects were compared with the 110 PCP clients who were eligible for the study but declined to participate (Comparison III).

Comparison I investigated the impact of the study eligibility criteria in relation to all other persons enrolled in the PCP from which the study subjects were recruited. This comparison is important if people attempt to use the cost findings to estimate the costs for all persons enrolled in the PCP.

Comparison II goes beyond the service from which the subjects were recruited and asks whether the study subjects who died of cancer differ from all other persons who died of cancer. Thus, this comparison explored using the PCP as a recruitment source. This comparison is important for people who may try to use the cost findings to estimate costs for persons not currently being served by the PCP.

Comparison III addresses the question of whether there appears to be a participation (refusal or response) bias. It explores whether

Table 1
Eligibility Criteria

Participants were deemed eligible for inclusion if they were:
<ul style="list-style-type: none"> • a new client in the PCP • older than 18 years • a resident of Halifax County • able to understand and speak English or French • affected by a terminal disease • not a nursing home resident • without a serious mental disorder or cognitive impairment • living at home or returning to home after time in hospital • receiving care and assistance from an informal caregiver (spouse, parent, child, sibling, or friend) who was able and willing to provide information about the study subject's health services utilization, personal expenses related to care, and loss of income

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