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Feature Article

Engaging patients with heart failure into the design of health system interventions: Impact on research methods

Robin P. Newhouse, PhD, RN, NEA-BC, FAAN^{a,*}, Meg Johantgen, PhD, RN^b,
Sue A. Thomas, PhD, RN^b, Nina M. Trocky, DNP, RN, NE-BC, CNE^b,
Cheryl Dennison-Himmelfarb, RN, PhD, FAAN^c, Jooyoung Cheon, RN, PhD^d,
Wanda Miller, DNP, RN, CENP^e, Tracy Gray, BS, RN^e, Robin Pruitt, RN^f

^a Indiana University School of Nursing, 610 Barnhill Drive, Indianapolis, IN 46202, USA

^b University of Maryland Baltimore, School of Nursing, 655 West Lombard Street, Baltimore, MD 21201, USA

^c John Hopkins School of Nursing, 525 N. Wolfe Street, Baltimore, MD 21205-2110, USA

^d Department of Nursing, Wonju College of Medicine, Yonsei University, 20 Ilsan-ro, Wonju, 26426, Republic of Korea

^e Riverside Tappahannock Hospital, 618 Hospital Road, Tappahannock, VA 22560, USA

^f Riverside Shore Memorial Hospital, 9507 Hospital Avenue, Nassawadox, VA 23413, USA

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ABSTRACT

The purpose of this study was to engage patients with heart failure (HF) to assess if changes are needed in a research study design, methods and outcomes when transferring interventions used in urban/community hospitals to rural hospital settings. A qualitative structured interview was conducted with eight patients with a diagnosis of HF admitted to two rural hospitals. Patients validated the study design, measures and outcomes, but identified one area that should be added to the study protocol, symptom experience. Results validated that the intervention, methods and outcomes for the planned study were important, but modifications to the study protocol resulted. Patient engagement in the conceptualization of research is essential to guide patient-centered studies.

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Introduction

Heart failure (HF) affects 5.1 million people in the U.S. with 825,000 new cases annually.¹ Improving care for patients with HF is a major focus for healthcare systems because of its high estimated total costs of \$31 billion per year² and 30-day readmission rates post discharge of 24%.^{3,4}

Guidelines for caring for people with HF are widely available.⁵ Evidence-based guidelines are important because they provide recommendations for the interprofessional team who care for people with HF (including nursing care). Recommendations range

from those of high benefit (should always be used) to recommendations with no benefit or may cause harm (are not recommended for use). For example, before discharge: 1) all patients should receive assessment of barriers to care and limitations of support, and 2) education should include self-care, emergency plans and adherence to recommendations [high benefit recommendations supported from a single randomized trial or nonrandomized studies (Class I Level B evidence)].⁵ An appointment for a follow up visit within 7–14 days and/or a telephone follow up within 3 days is reasonable for patients to receive [some benefit has been established supported from a single randomized trial or nonrandomized studies (Class IIa Level B evidence)].⁵ The issue is the adoption of guidelines/evidence-based practices varies widely – which means not all patients receive the care they deserve.

Implementation of evidence-based practices can be enhanced through patient engagement.^{6–8} Qualitative methods such as focus groups, surveys and interviews are now more commonly used to elicit patient input into study design and engage patients.^{7–13} Investigators then can redesign and refine the protocol based on the results.^{14–16}

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* Corresponding author.

E-mail address: newhouse@iu.edu (R.P. Newhouse).

Identifying health care processes and patient outcomes that are most important for patients with HF is essential to develop appropriate strategies to help them (and their family members) care for themselves after discharge from the hospital. To be helpful to patients, healthcare processes must be aligned with the patients' goals and outcomes important to them. Patient centered outcomes research (PCOR) helps people and their caregivers communicate and make informed healthcare decisions, allowing their voices to be heard in assessing the value of healthcare options.¹⁷ Engagement of patients in generating the research questions, selection of the design, methods and outcomes is one of the first steps in the process.⁸ There are multiple ways to engage patients in the research continuum – and the methods should be selected based on factors such as the study purpose, characteristics and investigator stakeholder and patient partnerships. A summary of patient engagement methods across the continuum of research process is available describing engagement in planning and conducting a study, as well as disseminating study results.¹⁸

Our team has conducted two multi-site studies to test interventions to improve care for people with HF. The first was a phased cluster-randomized trial testing a quality collaborative that included HF resources (toolkit) with 23 rural hospitals in the eastern United States. The toolkit was investigator developed and included evidence-based resources [fact sheet, relevant scientific articles, nurse education modules, HF admission order set, HF discharge checklist, standardized patient education booklet (moderate-low literacy)], and HF patient education. Smoking cessation counseling materials that were publicly available through Agency for Healthcare Research and Quality were also included. Results indicate rural hospitals with lower HF core measures improved care over time, and nurse turnover over time was associated with better HF core measures.¹⁹ The second was a quasi-experimental study testing a guideline based toolkit with 40 Magnet hospitals nationally, finding the toolkit effective to improve processes of care²⁰ and patient's ability to care for themselves at home. Based on these two studies revisions were made to the toolkit by the research team and clinical partners.

The purpose of the study reported in this paper was to engage patients with HF to inform the research study design, methods and outcomes when transferring the intervention from an urban/community hospital setting to rural hospitals. Patient engagement was used to assess if there were changes needed in the design, intervention (HF toolkit), methods or outcomes when implementing the study in two rural hospitals. The first step, common in all of our multi-site studies, was to work with our clinical partners at the rural hospitals to validate the appropriateness of the design, methods and outcomes planned for their rural hospital acute care setting. Based on the recommendations from our clinical partners, a literacy assessment was added at baseline, evaluation of medication adherence was added 48 h post discharge, and the post-test patient knowledge measures were deleted. After tailoring the health system intervention to the clinical site, we then engaged patients.

In phase 1 of the study, patients with HF admitted to the rural hospitals were interviewed to inform the design, methods and outcomes planned in implementing the HF toolkit. After incorporating the patient's suggestions, phase 2 (not reported in this paper) tested the feasibility and effect of guideline-based care (i.e., the toolkit). This study was reviewed and approved by the University of Maryland Institutional Review Board (IRB) with an IRB Authorization Agreement from participating hospitals' health system IRB.

Methodology

Study design

In phase 1, a structured interview was used to collect narrative data. The structured interview guide was developed by the investigators

based on national guidelines for HF care (education and follow up) and outcomes (knowledge, self-management, and readmission).

Sample and recruitment

Patients admitted from the community with a diagnosis of HF from two acute care rural hospitals were included in this study. The inclusion criteria were: English speaking patients with a diagnosis of HF ages of 21 or older who are cognitively intact with a discharge to home, assisted living or intermediate care planned from study units. Patients were excluded if they were enrolled in another research study to test interventions for HF, transferred to another unit in the hospital and would be discharged from the study unit, or who underwent or had a planned surgical intervention during their hospital stay. Potential patient subjects were informed about the study by their nurses, in their hospital room using a scripted invitation. If patients expressed interest, the nurse notified the study team who introduced the study and completed an informed consent in the patient's hospital room. Confirmation of informed consent was validated by asking the following questions:

1. What are some of the reasons that we are doing this study?
2. What will you need to do to be part of this study?
3. Do you think that this study has been explained to you clearly?
4. Do you have additional questions?
5. Do you think that you (by yourself) can make the decision to be part of this study?

Interviews

After informed consent was completed, the study team member conducted a 15-min structured interview in the patient's hospital room (see interview questions in Fig. 1). Responses were recorded on the structure interview form and validated with the patient.

Patients received a \$25 gift card for participating.

Data analysis

Qualitative content analysis was used to summarize responses to the four short answer open ended questions from the structured interview (see Fig. 1 questions 1, 2, 4 and 6). The nurses documented the patients' response to each item.

Categorical responses were categorized by the associated item response format (see Fig. 1 questions 3 and 5). Responses to each question were entered in a Microsoft Excel spreadsheet, and summarized by responses and frequency. Responses from the open ended questions were categorized and coded to identify themes of patterns.

The study team then reviewed, discussed and agreed upon the results. Rigor was accomplished through multiple techniques including a dual-coder review of the patient responses, team meetings to review data collection and analysis procedures, use of a structured interview, site protocol, and audit trails.

Findings

A total of eight patients (of 19 approached) participated in the interview. Most were male (6/8, 75%), African American (5/8, 63% with 3 Caucasian participants, 38%), and above the age of 58. Interview responses will be summarized below (see Table 1 for summary of patient responses).

Preparing to go home

Half of the patients indicated the most important thing on their mind was to feel better prior to going home with one quarter stating disease related education was important.

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