

Engaging Patients with Heart Failure into the Design of Health System Interventions: Impact on Research Methods

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Abstract

Purpose: 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.

Design: A qualitative structured interview was conducted.

Method: Eight patients from two rural hospitals participated in an interview prior to discharge.

Results: Patients validated the study design, measures and outcomes, but identified one area that should be added to the study protocol, symptom experience.

Conclusion: Patient interviews validated that the intervention, methods and outcomes were important, but modifications to the study protocol resulted. Patient engagement in the conceptualization of patient centered outcome research is essential to guide the investigator approach to studies.

Key words: heart failure; patient engagement; rural hospital; research design

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 all patient 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 to 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 vary 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 and interviews are now more commonly used to elicit patient input into study design and engage patients.⁷⁻⁹ Investigators then can redesign and refine the protocol based on the results.¹⁰⁻¹²

Identifying health care processes and patient outcomes most important for patients with HF is essential to developing 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.¹³ 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.¹⁴

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. Sing 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.¹⁵ 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 care¹⁶ 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 hours 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-minute structured interview in the patient's hospital room (see interview questions in Figure 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 Figure 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 Figure 1 questions 3 and 5). Responses to each question were entered in a Microsoft Excel spread sheet, 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. Interviews 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.

Guideline-based care. Most (63%) felt teaching patients and families about diet, exercise, medications and safety is most helpful to prepare them to go home. Six out of the eight patients (75%) felt it is important to learn about and understand their illness. Five out of the eight patients (63%) felt it is very important to have an appointment with health care providers after leaving the hospital. Six patients (75%) reported it is important to or would like to have a post discharge call. Two patients felt it is important to know what they can or cannot do.

Outcomes of importance. Seven out of the eight patients (88%) described asking them about their general health and management (medications, diet, breathing, working, walking, and traveling) is important. All patients (100%) felt asking them about staying out of the hospital over the next month is very important or important. Asking about symptoms is very important or important for seven patients (88%). All patients (100%) described it is very important or important to ask about their breathing. The primary worry of the six patients (75%) is about how to manage disease and symptoms at home.

The patient interviews validated the intervention, methods and outcomes used in our prior study in urban and community hospitals were consistent with and important to people with HF in rural settings. Patient interviews supported all changes suggested by the clinicians in development of the protocol, and added the importance of asking about symptoms experiences as an outcome measure. Changes to the study are summarized in Table 2.

Discussion

Patients with HF from rural hospitals supported the guideline-based intervention, design, methods and outcomes used in our prior study in urban/community hospitals aligned well with what is most important to them. They suggested we add symptom experience as an outcome measure.

For respondents, asking about symptoms is very important - which is consistent with other studies have found in terms of symptom burden. Patients with HF reported an average of 9 -15 symptoms¹⁷⁻¹⁹ with dyspnea (54- 85%),^{19,20} lack of energy/fatigue (55-75%)^{20,21} and a decreased feeling of wellbeing (84%).²¹ Older patients with HF experience severe and frequent symptoms of fatigue and dyspnea making them dependent on others for survival.²² In this study, most patients reported it is very important to ask about their symptoms, especially breathing.

Patients worried about disease management at home and readmission. Readmission is a quality metric for hospital performance, but it is clearly important to patients too. Patients with HF stated readmission to the hospital happens when they are not able to manage their symptoms at home, making it a proxy measure for distressful symptoms.²³

It was interesting no respondents described depressive symptoms as a potential issue. Depression is related to symptoms such as dyspnea, fatigue, sleep difficulty, pain and adherence.^{11,24,25} However, in a review of 13 qualitative studies, financial burdens are an important factor associated with depressive symptoms, which may result in a patients'

decreased ability to engage in HF self-care.¹⁹ In this study, patients reported disease management and education were most important to HF patients, with only one respondent identifying financial issues as their major concern.

Although the planned study outcomes were thought to be important to people with HF, a premise of PCOR is studies should use interventions and outcomes patients themselves care about. Patients clearly support the use of guideline based care. Engaging patients however, identified an area (symptoms) that was added to the protocol before implementation.

Limitations

The limitations of this qualitative study include the representativeness of the HF patients and the limited sample size. It is not known if the subjects included in this study were representative of all people with HF or if they represent those living in rural settings. The participants were recruited in two rural hospitals using convenience sampling. Subjects included were recovering from an acute episode of care, and may not have provided the same responses they would have if they were interviewed after discharge from the hospital. The intent of this study was not to identify themes from the qualitative data or test for statistical significance, but to engage patients to assess if the design, methods and outcomes used in a prior multi-site urban/community hospital setting can be applied in a rural setting.

Conclusion

Patient engagement validated the design, methods and relevant outcomes used in a prior urban/community hospital multi-site study are appropriate for future rural hospital studies to improve care for people with HF. Patients also suggested symptom experience should be included. Patient engagement in the conceptualization of patient-centered outcome research is essential to guide the investigator approach to studies. Engagement improves the credibility of results and their applicability to the HF patients.⁷ Credible and clinically relevant results will also foster better adoption of results by both clinicians and patients.

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Figure 1. Structured Interview

Directions: After discussing the study purpose, design and data to be collected using the Patient Interview Information, read the following script to ask the subject the following questions. Record the subject's answers on this form.

Who answered the questions to this interview?

- Patient
 Significant Other
 Both

"In this study we are asking questions about heart failure (HF) care and results that are important to you after you leave the hospital. Your answers to these questions will help us learn about what is most important to you."

1. What is the most important thing that we can do for you and your family to prepare you to go home?
2. What can we teach you that will help you most when you go home?
3. We have found that there are ways to help you do better at home. I am going to ask you about three things that might help and would like to hear if you think that they are important.
 - a) How important is it that you understand HF?
 - b) How important is it that you have an appointment scheduled with your provider after you leave the hospital?
 - c) How important is it that we call you to see how you are doing a couple days after you are home?
 - d) Are there other things that are important to you that I did not ask you about?
4. If we want to know how well you are doing at home- what would should we ask about?
5. I am going to ask you about some areas that may be important to you.
 - a) How important is it for us to ask you about staying out of the hospital or emergency department over the next month?
 - b) How important is it for us to ask you about symptoms that keep you from what you need and want to do?
 - c) How important is it for us to ask you about your breathing?
 - d) How important is it for us to ask you about feeling tired?
6. What are you worried about when you go home?

Table 1. Patients' Responses to the Interviews (N=8)

Interview guidelines	Patients' responses (N)
1. What is the most important thing that we can do for you and your family to prepare you to go home?	<ul style="list-style-type: none"> • Improve health status (4) • Disease education (2) • Need money (1) • Just want to go home (1)
2. What can we teach you that will help you most when you go home?	<ul style="list-style-type: none"> • Diet, exercise, medications and safety (5) • Disease education (2)
3. We have found that there are ways to help you do better at home. I am going to ask you about three things that might help and would like to hear if you think that they are important.	
a) How important is it that you understand HF?	<ul style="list-style-type: none"> • Important (6), Not important (1), Diet, no money (1)
b) How important is it that you have an appointment scheduled with your provider after you leave the hospital?	<ul style="list-style-type: none"> • Very important (7), Hard to make an appointment (1)
c) How important is it that we call you to see how you are doing a couple days after you are home?	<ul style="list-style-type: none"> • Important (6), Not important (2)
d) Are there other things that are important to you that I did not ask you about?	<ul style="list-style-type: none"> • Nothing (3), What can or can't I do (2), Medication education (1), Diet (1)
4. If we want to know how well you are doing at home- what would should we ask about?	<ul style="list-style-type: none"> • General health and management (medications , diet, breathing, working, walking, traveling) (7)
5. I am going to ask you about some areas that may be important to you.	
a) How important is it for us to ask you about staying out of the hospital or emergency department over the next month?	<ul style="list-style-type: none"> • Important (8)
b) How important is it for us to ask you about symptoms that keep you from what you need and want to do?	<ul style="list-style-type: none"> • Important (7)
c) How important is it for us to ask you about your breathing?	<ul style="list-style-type: none"> • Important (8)
d) How important is it for us to ask you about feeling tired?	<ul style="list-style-type: none"> • Important (4), Not important (3)
6. What are you worried about when you go home?	<ul style="list-style-type: none"> • How to manage at home (6), Living alone (1) and need resources (1)

Table 2. Protocol Changes

Original protocol	Provider engagement recommendations	Patient engagement recommendations
Intervention		
1) Standardized patient education	Providers support	Patient interviews support
2) A post discharge appointment with the patient's provider		
3) Phone call 48 hours after discharge to reinforce the patient education		
4) Phone call 7 days after discharge to assess patient' self-care, complications, and satisfaction with instruction		
Measures		
Levels of education	Add literacy assessment	
Depression	Providers support	
Readiness for hospital discharge	Providers support	
	Add medication adherence	
Outcomes		
Knowledge	Delete knowledge post test	Patient interviews support
Self-care	Providers support	Patient interviews support Added symptom experience
Readmission	Providers support	Patient interviews support
Cost	Providers support	Patient interviews support