

Challenges of doing research that involves patients

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Abstract. Several influential groups (e.g. Institute of Medicine) have emphasized the importance of capturing patients' perspectives, as they are encouraged to become more actively engaged in their healthcare. Likewise, human factors researchers are increasingly focusing on the role of the patient. Doing research that involves patients can be challenging. Based on the literature and our own experience we illustrate some of these challenges. We also emphasize the benefits of directly involving patients in human factors research.

Keywords. Healthcare, patients, chronic conditions, care coordination, challenges.

1. Introduction

Considering that healthcare is all about taking care of patients, it is surprising that the role of patients in healthcare processes has received so little attention (Vincent & Coulter, 2002). The US Institute of Medicine (IOM) has acknowledged the importance of patients in healthcare delivery, and described patient-centered care as one of 6 pillars of quality (IOM, 2001). The IOM defines patient-centered care as: "Providing care that is respectful of and responsive to individual patient preferences, needs, and values, and ensuring that patient values guide all clinical decisions" (IOM, 2001). There is increased recognition that patients and their families must be engaged in health-related activities and not be seen as passive recipients of medical care (Unruh & Pratt, 2007). Some authors suggest that greater patient involvement in healthcare processes could have more benefit than pharmaceutical interventions. Patient involvement could be considered "the blockbuster drug of the century" (Dentzer, 2013) and a key component in the redesign of health care processes (Longtin et al., 2010). Yet, doing research with (and on) patients can be difficult (Gueldner & Hanner, 1989; Harris & Dyson, 2001; Uman & Urman, 1990).

1.1 *The potential research participants are patients*

A patient (the original meaning is: "one who suffers") is by definition a person who is under medical care or treatment for a disease or medical condition. This inherently means that physical access to patients may be limited. Patients are sick, tired, (re-)hospitalized, or otherwise not able to answer a researcher's questions. Doing research with patients also requires that researchers have to deal with unforeseen consequences of their medical condition. For example, severe chronic obstructive pulmonary disease (COPD) patients often use an oxygen tank to facilitate breathing. These tanks make noise; therefore,

making it difficult for the patient and researchers to hear each other. The sound quality of audio-records can be poor. Likewise, patients can tire easily; their medical condition must be respected. This means that patients must be allowed to interrupt an interview because they are tired or do not feel well.

1.2 Patients and aging

Many patients are elderly. Aging is a multidimensional process of physical, psychological and social change and comes with a decrease in some physical and mental capacities (Johnson & Wolinsky, 1993). For example, one's hearing and vision regress after age 30, as well as muscles, muscle power, contraction speed and endurance; also there is a decrease in maximum oxygen intake and heart rate (Marquié, Cau-Bareille, & Volkoff, 1998). Mental capacities also decrease, in areas such as speed of information processing, short-term memory, concentration, speed of learning, and an increase in time needed for problem solving and decision-making (Akatsu & Miki, 2004; Botwinick, 1967; Salthouse, 1990, 2000). A researcher must deal with many of these consequences of aging when doing research that involves patients. For example, patients may have problems understanding the researcher due to hearing problems or may not remember their medical course and interactions with the healthcare system.

1.3 Patients and complex medical conditions

One important aspect that researchers need to consider is that many patients do not have a single condition. For example, many patients with COPD or congestive heart failure (CHF) also have arthritis, diabetes, hypertension, etc. This makes it difficult to focus on one medical condition; the symptoms overlap. These patients take numerous medications for different conditions and yet may be hospitalized for another condition. Therefore, if a researcher is interested in asking the patient about his/her care coordination related to a specific condition, that may be a difficult question for the patient to address.

1.4 Patients and privacy

Research, by definition, requires collecting data. In the USA collecting data from patients is protected by the by Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy and Security Rules. The HIPAA Privacy Rule establishes the circumstances under which protected health information may be used or disclosed for research purposes. Research is defined in the Privacy Rule as, "a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge" (HIPAA, 2011). When data are shared, they must be de-identified, i.e. stripped of protected health information (PHI). PHI is any information that can be used to identify, contact or locate an individual, and includes a wide range of information. HIPAA poses challenges for researchers interested in interacting with patients. It requires that any information being released to researchers must be stripped of identifiers; this often involves taking extra steps to protect patient privacy. For example, in our study on care coordination, a "third party" not involved in research and data collection had to arrange interviews and focus groups. Patients were asked to pick an alias (e.g., John Doe) and the research team was provided the alias rather than the patient's real name. Practically, that also means that research conducted over the phone requires that the patient be referred to by the alias. Patients do not always remember that they chose an alias and are sometimes confused about who is calling them and for what reason when they are called by the alias.

1.5 Summary

Doing research with older chronically ill patients can be challenging, but it can also be

rewarding for the patients and the researchers. In this paper we provide some examples of the challenges based on our research in the Keystone Beacon Community (KBC) project.

2. Backgrounds

2.1 Care management

Patients are particularly vulnerable during transitions of care, such as after hospital discharge, when returning home, or going to a nursing home (Jencks, Williams, & Coleman, 2009; van Walraven et al., 2011) (see Figure 1). Care management involves highly trained and experienced nurses who are in charge of the patient’s clinical trajectory, and has been proposed as one solution to the multiple problems of care transitions.

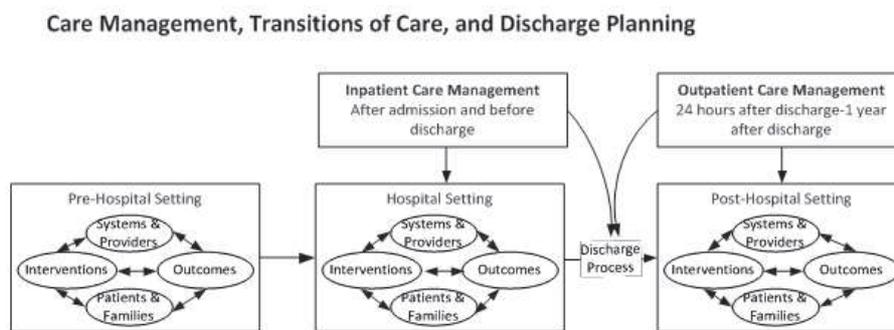


Figure 1: Care management, transitions of care and discharge planning (adapted from Holland & Harris, 2007)

2.2 The Keystone Beacon Community (KBC)

The KBC project is a community-wide intervention that uses health IT-supported care management to help CHF and COPD patients manage their condition and, in turn, reduce admissions, readmissions and emergency department visits. In the KBC project both inpatient (hospital) and outpatient (clinic) care managers were deployed to help patients manage their medical condition(s). We used focus groups, interviews and a survey to ask patients about their experiences with KBC care management.

3. Methods

3.1 Patient Focus Groups and Interviews

KBC clerical staff sent recruitment flyers to a pool of 378 eligible patients and followed up via telephone to recruit participants. Four focus groups were organized with 17 patients scheduled to participate. Nine of the 17 patients participated in the focus groups. Likewise, 11 face-to-face interviews were scheduled; 4 of them had to be conducted via telephone.

3.2 Patient Survey

To examine patient satisfaction with various aspects of KBC care management, we drew from the literature to develop a survey. It was sent to 200 patients in an Intervention Group (IG) and 200 patients in a Control Group (CG). The patients in the IG were recently discharged from one of 4 participating KBC hospitals and had received KBC care management. The patients in the CG were discharged from a hospital that did not participate in the KBC project and therefore did not receive KBC care management. Response rates for the IG and CG were respectively 41% and 46%.

3.3 Institutional Review Board

Institutional Review Board (IRB) approval was obtained for this study. We also needed

data use agreements with the healthcare organization to obtain information such as gender and age of the patients. This was a lengthy and challenging process.

4. Results

4.1 Focus Groups and Interviews

We identified potential participants for the focus groups and interviews from a population of over 1,500 patients who had received inpatient KBC care management. The initial inclusion criteria applied to this population were: admitted with a diagnosis of COPD or CHF; discharged from one of the participating hospitals in the last 90 days; discharged to home; patient/family understanding of the patient's discharge plan was not coded as "reviewed but not understood"; no altered mental status; caregiver close by (in order to drive them to focus group meeting); patient did not have a certain type of health insurance; and patient had no problems with independent activities of daily living. By applying these criteria, the population was reduced to 15 (!) patients. We then relaxed the criteria and had a pool of 378 eligible patients. Focus groups and interviews were then scheduled with 28 participants of which only 19 (68%) actually participated in the study (see Table 1). Four interviews were conducted over the phone because the patient was not home at the time of the interview, was re-admitted to the hospital, or experienced other problems.

Table 1. Participants scheduled vs. actual attendance at focus group or interview

	Participants scheduled	Actual Participants	No shows
Interviews	11	10	1 (9%)
Focus groups	17	9	8 (47%)
Total	28	19	9 (32%)

4.2 Survey

The intervention group consisted of patients who were recently discharged from one of the 4 participating KBC hospitals and received KBC inpatient and outpatient care management. The patients in the control group were discharged from a hospital that did not participate in the project and therefore had not received KBC care management.

Table 2. Survey respondents by medical condition

	Control % [n]	Intervention % [n]	Total % [n]
Chronic Obstructive Pulmonary Disease (COPD)	14% [12]	23% [17]	18% [29]
Congestive Heart failure (CHF)	14% [12]	20% [15]	17% [17]
Diabetes	6% [5]	4% [3]	5% [8]
None	7% [6]	4% [3]	5% [8]
Combination	59% [50]	49% [37]	61% [98]
Total	100% [85]	100% [75]	100% [160]

Results in Table 2 show that, although the target population of the survey consisted of patients with COPD or CHF, the majority of respondents had multiple medical conditions. In the survey, patients were asked whether they talked to a KBC inpatient care manager during their hospital visit and whether they currently had a KBC outpatient care manager. Table 3 summarizes the results.

Table 3. Percent of patients in control and intervention group who indicated that they received KBC in- and outpatient care management

	Control Group			Intervention Group		
	Yes	No	DNR	Yes	No	DNR
During your stay at the hospital, did you talk to a Keystone Beacon Community (KBC) care manager?	25%	23%	53%	29%	14%	57%
Do you currently have a care manager who helps you manage your condition?	36%	44%	20%	54%	28%	19%

Results in table 3 show that the majority of the respondents did not remember (DNR) whether they received KBC inpatient care management. Further, there are no differences between the control and intervention group in patients who indicated that they talked to a KBC inpatient care manager ($\chi^2=1.39$, $df=1$, $p =0.24$). There were significant differences between patients in the control and intervention group who indicated that they had an outpatient care manager ($\chi^2=4.81$, $df=1$, $p =0.03$), but the differences are small.

5. Discussion and Conclusion

The literature and our own experience in this study demonstrate how difficult it can be to conduct research that involves patients. Because these research participants are *patients*, access to them may be restricted. Results of our recruitment process for the interviews and focus group make this clear. By loosening our initial inclusion criteria to only two criteria: requiring that the patient had CHF or COPD and was cognitively alert, the number of potential participants from the pool of 1,500 increased from 15 patients to 378 eligible patients. From the 28 patients who were scheduled to participate, 19 (68%) participated. The other 32% were not present at the interview or focus group for various reasons; some of the interviews were rescheduled to telephone interviews. This, along with HIPAA requirements, demonstrates how difficult it is to recruit and involve patients in research.

One aspect of doing research with patients that researchers often do not consider is that many patients have more than one disease or medical condition (see Table 2). This complexity makes it difficult to do research focusing on one medical condition. Often symptoms overlap, patients take different kinds of medication for different conditions and, although patients may have one over-riding condition they are hospitalized for another condition.

Similarly, many chronically ill patients are elderly and researchers have to deal with the consequences of aging along with the complexity of the patient’s condition. Results in Table 3 demonstrate this. More than half of the patients in both the intervention and control group did not remember whether they talked to a KBC inpatient care manager. Many patients (not only elderly patients), due to their medical condition, forget who they talk with during their hospital stay as they are attended to by many clinicians and staff.

Research, by definition, means collecting data. However, in the US (and many other countries) collecting data from patients is protected by privacy and security rules, and it is difficult to conduct research without collecting personal information. In our case, we used hospital and insurance company staff to recruit patients who then used alias names (e.g., Marilyn Monroe, John Doe).

In this paper, while we present challenges of doing human factors research that involves patients, we do not want to discourage others to conduct similar research that involves patients. On the contrary! We strongly encourage researchers to actively involve

patients in their research. Our interviews and focus groups provided us with rich, qualitative information that we otherwise would not have been able to collect.

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