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Janci A. Demyun Date

THE IMPACT OF A TABLET-BASED GRAPHICS APPLICATION ON PATIENTS' EXPERIENCES AND ENGAGEMENT DURING THE CONSENT PROCESS FOR INPATIENT CARDIAC CATHETERIZATION

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M.P.H., Emory University, 2014
B.A., Pennsylvania State University, 1987
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Thesis Committee Chair: Iris E. Smith, Ph.D., M.P.H.

An abstract of
A Thesis submitted to the Faculty of the
Rollins School of Public Health of Emory University
in partial fulfillment of the requirements of the degree of
Master of Public Health in the Executive MPH program
2014

Abstract

THE IMPACT OF A TABLET-BASED GRAPHICS APPLICATION ON PATIENTS' EXPERIENCES AND ENGAGEMENT DURING THE CONSENT PROCESS FOR INPATIENT CARDIAC CATHETERIZATION

BY
Janci A. Demyun

Objective: The objective of this exploratory study was to assess the impact of an interactive, tablet-based graphics application on patients' experiences with the consent process and decision-making for inpatient cardiac catheterization.

Methods: We employed a modified pre-post design. Eighteen patients underwent a consent process incorporating the tablet-based graphics application; 22 patients underwent a standard consent process. Outcomes were assessed via structured interview and included procedural knowledge, satisfaction with the consent process, and perceptions of the intervention.

Results: Patients from both groups reported high satisfaction with the consent process. No significant differences were appreciated between groups regarding procedural understanding or treatment decisions. Many intervention patients valued seeing the procedure beforehand. In particular, patients reported that pictorial representations created a sense of reassurance and comfort.

Conclusion: Significant differential impact on objective outcome measures was not appreciated but was difficult to assess given high background satisfaction. However, patients' responses were very positive toward the intervention. Applications like this may enhance patients' experiences of consent and reduce procedural anxiety. These goals have practical and ethical importance independent of procedural knowledge or decisions.

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This thesis is dedicated in loving memory of my father, Myron Demyun, for his strength, love and devotion to his family. Without his healthcare experiences, I may never have been led to pursue this important topic for my thesis. I am hopeful that the findings from this project encourages additional research to further explore the importance of providing reassurance and comfort to patients when they are in need of cardiac procedures.

I also wish to thank the following people for their role in my successful completion of this thesis project:

My husband, Alan Fishman, for his continual encouragement and support throughout my pursuit of my Master of Public Health.

My field advisor, Dr. Neal Dickert, for his support, and thorough explanations and answers to all of my questions throughout my practicum and resulting thesis.

My chair, Dr. Iris Smith, for her expertise and experience, which helped me through the thesis process.

My mother, JoAnne R. Demyun, for her inspiration resulting from her tireless efforts working on and completing her Master of Science in Nursing, while my brother and I were in elementary school.

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Chapter One: Introduction

Overview of problem

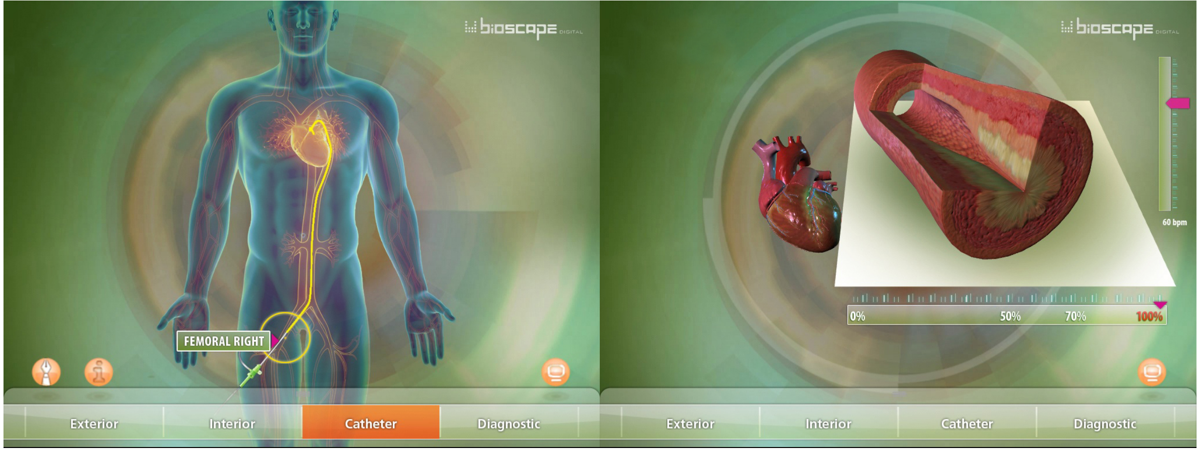
At the turn of the century, the Institute of Medicine (IOM), the health arm of the National Academy of Sciences, challenged the United States Healthcare system to be “more patient-centered, evidence-based, and transparent.” This directive has encouraged patients to play a more active role in their health care decisions (Medicine, 2001) and increased physicians’ awareness of the importance of matching treatment decisions with patients’ preferences. (Decker, 2008). Since, physicians have explored various technology tools to assist in communicating medical information to patients. Often, these tools are used to help patients gain an understanding of a specific procedure (A. H. Pieterse, de Vries, M., Kunneman, M., Stiggelbout, A. M., Feldman-Stewart, D. , 2013); however, they have also been used to improve provider communications skills with their patients (Weiner, 2006). The use of technology tools to enhance patient experiences through engagement contributes to nurturing the continued growth and development of the physician-patient relationship, and influences positive patient experiences (Weiner, 2006). The tablet-based software tool used in this study is designed to enhance patient engagement through improved communication during the consent process for cardiac catheterization and possible percutaneous coronary intervention (PCI), or the insertion of a stent to unblock an artery.

Background

Cardiac catheterization and PCI are fundamental therapies in the medical management of coronary artery disease (CAD) and myocardial infarction (MI). For CAD, multiple treatment options exist, including the use of different types of stents, resulting in varied individualized risks, including bleeding or restenosis, stroke, or even death. Multiple choices with varied risks versus benefits necessitate that patient preferences or goals guide therapy (M. Coylewright, Montori, V., Ting, H. H., 2012; M. Coylewright et al., 2012). Patient involvement in treatment decisions is particularly important in the case of PCI, where evidence has indicated that patients overestimate the benefits. This overestimation could lead patients to make decisions based on misconceptions, resulting in treatments that are inconsistent with their values (Rothberg et al., 2010). Overall, better provider-to-patient communication may improve patients' awareness of their condition, could result in improved adherence to treatment recommendations, and might increase confidence in their provider, and even in their satisfaction with the healthcare system (Burton, Blundell, Jones, Fraser, & Elwyn, 2010).

The Bioscape Digital (http://bioscapedigital.com/products.html) tool used in this study is tablet-based software designed to improve patient engagement, education, and communication for making cardiac catheterization and PCI decisions. A three-dimensional, interactive anatomic illustration (Figure 1) is the focal point, allowing physicians to demonstrate coronary anatomy, and the processes of atherosclerosis, catheterization and PCI. It also contains an educational component that highlights the pathophysiology of CAD, providing physicians with the ability to demonstrate patients' coronary lesions. For the purposes of this study, the tool does not contain any language regarding risks, benefits or alternative treatment approaches, though such capabilities exist.

Figure 1. Sample graphics from the intervention demonstrating:



A) Cardiac catheterization and access B) Intracoronary stenosis

Primary research questions

The principal objectives of this pilot study: "Enhancing Patient Education and Communication for Cardiac Catheterization," were to incorporate a tablet-based tool by Bioscape Digital into cardiac catheterization consent discussions in order to:

1. Assess the impact of this tool on patient understanding, level of engagement, and general experience with the consent process for catheterization.

- Hypothesis – The tool will be associated with improved patient understanding of the procedure and its attendant risks and benefits.

- Hypothesis – The tool will be associated with a higher level of patient engagement and satisfaction with the consent experience.

2. Assess providers' perspectives regarding the utility of this tool to facilitate patient education and shared decision-making in this context.

- Hypothesis – The tool will be easily integrated into consent conversations without impeding workflow.

- Hypothesis – The tool will be associated with physicians' perceptions of patients being more engaged in consent discussions and decision-making.

3. Identify potential improvements to the format and content of the tool.
4. Assess the feasibility of implementing this tool in clinical practice.

Purpose of study

This project is designed to advance the goal of improving communication in order to promote shared decision-making and patient-centered care, with significant emphasis on enhancing patients' experiences and satisfaction. Such experiences include emotional preparation and comfort. The latter, often considered second-order goals, are ethically important. Such goals are key to providing patients with respect and facilitating the physician-patient relationship—important components of patient-centered care (Beach, Duggan, Cassel, & Geller, 2007). Informed consent processes that advance these goals, independent of their effects on understanding of treatment options or specific treatment decisions, may be valuable and warrant exploration.

Chapter Two: Literature review

Patient-centered medical care

Patient-centered medicine developed as an outgrowth of the biopsychosocial model under the direction of the late Dr. George Engel. Dr. Engel criticized the then prevailing biomedical model as being "disease-oriented versus patient-oriented" (Engel, 1978), and urged medical schools to adopt a more humanistic approach to caring for the sick. Thus, his biopsychosocial model of clinical treatment emerged as an important alternative to the centuries-old clinical approach to patient care.

Despite the growing popularity of patient-centered care (PCC), many definitions of this concept have evolved over the last 30 years. Although most definitions are similarly phrased, the meaning and approaches vary (Mead, 2000b). PCC can be described in terms of consultation behaviors, a base of knowledge, or as a professional attitude (Mead, 2000a); however, one consistently recognized definition of PCC remains popular as being "care that is closely congruent with and responsive to patients' wants, needs and preferences" (Gerteis, 1993).

Five dimensions of PCC. 1) Adopting the biopsychosocial approach versus purely biomedical, 2) Understanding the patient as person versus a body with an illness, 3) Sharing power and responsibility between the physician and the patient, 4) Building a therapeutic alliance and 5) Understanding the physician as a person, not merely as a skilled technician (Mead, 2000b).

Under the biopsychosocial approach, the patient's subjective experience cannot be ignored as a primary contributor to accurate diagnosis, health outcomes, and humane care

(Borrell-Carrió, 2004). The physician role is that of decisional priority, typically being the first to recommend a treatment path, with the competent adult patient having final decisional authority (S. N. Whitney, McGuire, A. L., McCullough, L. B., 2003). The physician must shift the balance of power from him/herself to the patient, and seek to understand the patient's treatment preferences, thus being caring not merely curing. PCC is dependent on respectful communication between both physician and patient, with both parties valuing each other's contribution to making health care decisions (Engel, 1978).

Shared decision-making and relationship-centered care

Shared decision-making (SDM) and relationship-centered care (RCC) are two ways of facilitating PCC where technology tools may be particularly beneficial to effectively communicate complex information (Weiner, 2006), thereby leading to successful consultation (Pearce, 2011). In RCC, the physician and patient share information, intuitions and the actual making of health care decisions, with the physician's focus on that of active listening to the patient to determine his/her treatment goals. Unfortunately, patients and physicians do not always communicate using the same language. Nor do all physicians possess the same comfort level in communicating. In physician-patient relationships, effective information exchange is the key to determining patient preferences, regardless of chosen communication method (visual, verbal, etc.), and whether at levels of objectivity or subjectivity (Weiner, 2006).

Evidence indicates that SDM between physicians and their patients is often lacking in decisions regarding cardiac catheterization and PCI (Burton et al., 2010). One study suggested, that SDM was significantly less common regarding management of CAD than in choosing prostate cancer screening/management strategies (Fowler et al., 2012).

Barriers

Barriers to PCC, SDM and RCC for cardiac catheterization and PCI include: time limitations of physicians; patient intimidation due to power asymmetry; patient expectations, which may be unrealistic; fear of bad outcomes and the patient's lack of familiarity with procedures. Also, structural barriers exist, such as rushed discharges and tight scheduling with brief in-patient stays. In addition, multiple layers of providers are involved in patient care, which can be confusing for patients. The physician directing catheterization may not be the same who conducts the informed consent nor who discusses the details of treatment options. Moreover, in a teaching hospital, residents and fellows may provide care in addition to or in lieu of the patient's usual physician. Finally, patients' coronary anatomy is often not defined until the time of catheterization, and PCI is frequently performed concurrently. Thus, consent for catheterization frequently involves provisional consent for PCI.

Barriers resulting from the health illiteracy of patients and complexity of information can impede information transfer between physician and patient. Information patients should receive includes: the nature of coronary disease, the different risks and benefits associated with different management plans, and the implications of medical and interventional therapies in terms of need for follow-up treatment, need for future procedures, and interference with other medical needs due to differing needs for antiplatelet therapy.

IT and informed consent

Informed consent (IC) is a legal requirement designed to protect prospective human subjects by providing them information about a research study prior to their agreed participation. Also, IC minimizes a physician's liability through a patient's documented authorization of a medical procedure. IC takes place through the physician-patient discussion of the patient's medical problem and mutual decision to choose a particular intervention. If only one choice is truly predominant, then the IC process serves as an opportunity to educate the patient about the necessary procedure (S. N. Whitney, McGuire, A. L., McCullough, L. B., 2003). Such can be the case with coronary catheterization, which could result in reduced levels of patient engagement. (S. N. Whitney, McGuire, A. L., McCullough, L. B., 2003).

Generally, decision aids (DAs) can help patients feel better informed; however, DAs used during the IC process may have less effective results than those used for purposes other than IC. The Cochrane Collaboration's systematic review of 86 randomized trials of decision aids in health care indicated that, in general, decision aids "increase patient knowledge, decrease patient uncertainty related to feeling uninformed, increase patient engagement in decision making, and improve patient-provider communication" (O'Connor, 2009). The Collaboration found the benefits of decision aids used during the IC process to be unclear, indicating that previously decided-upon treatments could be the cause for possible ineffectiveness (D. Stacey et al., 2011).

Power asymmetry can also contribute to lack of patient engagement. In the last several years, research investigating the routine use of computers in physician-patient interactions found physician computer use to help reduce (Pearce, 2011), or at least balance out power asymmetry by assisting in the physician in communicating information and saving time in the consultation process (Pearce, 2011).

Knowledge. The Internet-based program PREDICT, Patient Refined Expectations for Deciding Invasive Cardiac Treatments, was designed to embed patient-specific estimates of risk, such as death, bleeding and restenosis, into customized, individual PCI IC documents. It is the first IC program of its kind (S. V. Arnold et al., 2008).

To build PREDICT, information compiled from focus groups and patient interviews determined the best presentation method. In addition to the individualized risk factors, the IC document also worked to increase patient understanding of the procedure through the use of innovative educational initiatives. Educational pictures accompanied descriptions of coronary catheterization, angioplasty and stents. Also, consideration toward the patient target audience led the study team to reduce the reading level to be at a more appropriate level based on the Flesh-Kincaid grade level readability statistic. Then, comparisons between patients' experience with IC before and after implementation of PREDICT found nearly two times the amount of patients recalled reading the PREDICT consent form versus the original consent form (Decker, 2008).

Technology maximizing the use of the patient experience created an information system and user interface that focused on customizing IC for risk. This IC document then provided the opportunity for interventional cardiologists, who perform PCI, to focus on having an informed dialogue with their individual patients. Prior to PREDICT, standard consent forms resulted in extremely variable communication between patients and physicians (S. V. Arnold, Decker, C., Ahmad, H., Olabiyi, O., Mundluru, S., Reid, K. J., . . . Spertus, J. A. & 2008). The PREDICT study focused on a transparency model that viewed IC as a "conversational process" designed to enhance good clinical practice and patient autonomy without sacrificing the legal requirements of IC (Decker, 2008).

While most clinicians found the PREDICT tool did provide clarity and educational value for patients, study authors concluded that a randomized trial of PREDICT consent, leveraging the accumulated knowledge from this first experience, is necessary for further evaluation of its impact on medical decision-making, patient compliance, and clinical outcomes (Decker, 2008).

Communication. Recent findings have revealed that patients who are more actively involved in their healthcare experiences have better outcomes than those who remain uninvolved (A. H. Pieterse, de Vries, M., Kunneman, M., Stiggelbout, A. M., Feldman-Stewart, D. , 2013). The Chest Pain Choice DA is an example of successful communication of complex information for IC, which increased both patient knowledge and engagement. The DA also led to the reduction of false positive cardiac imaging and/or stress test results. This DA included a 100-person pictograph depicting the pretest probability of acute coronary syndrome for patients presenting in the hospital emergency room, and presented available options for management (E. P. Hess, Knoedler, M. A., Shah, N. D., Kline, J. A., Breslin, M., Branda, M. E. ... Montori, V. M., 2012). As a result of this graphical technology, patients were able to appreciate differences in risks versus benefits between different available diagnostic strategies, and make better-informed personal health care decisions.

Recent research has demonstrated that values clarification tools have led to DAs that improve study participants' knowledge and/or provide a reduction in decisional conflict, when compared to DAs without values clarification tools. For example, one recent trial investigating prostate cancer screening DAs found that among eighteen PCa screenings only five included a values clarification component to assist in integrating relevant information and elucidating patient preferences. This lack of values clarification methods (VCM) appears to explain the reason for no greater than a modest improvement in study participants' knowledge or modest reduction in decisional conflict (Dorfman, 2010). The DAs with VCMs contain components to help clarify values to determine patient preferences. VCM support patient decision-making and patient preferences by seeking to clarify patient preferences that are either pre-existing or constructed from basic values (A. H. Pieterse, de Vries, M., Kunneman, M., Stiggelbout, A. M., Feldman-Stewart, D. , 2013).

Summary of findings

The principal focus of most interventions outcomes assessment has been on decision and understanding. Since patients have begun to play a more active role in their health care decisions, physicians have explored various technology tools to assist in communicating increasingly complex medical information to patients. Historically, these tools have been used to help patients gain an understanding of a specific procedure (A. H. Pieterse, de Vries, M., Kunneman, M., Stiggelbout, A. M., Feldman-Stewart, D. , 2013), and/or to improve provider communication skills with their patients. Recently, progress is being made toward enhancing patient experiences and engagement through the effective use of technology tools that nurture the continued growth and development of the physician-patient relationship.

Chapter Three: Methods

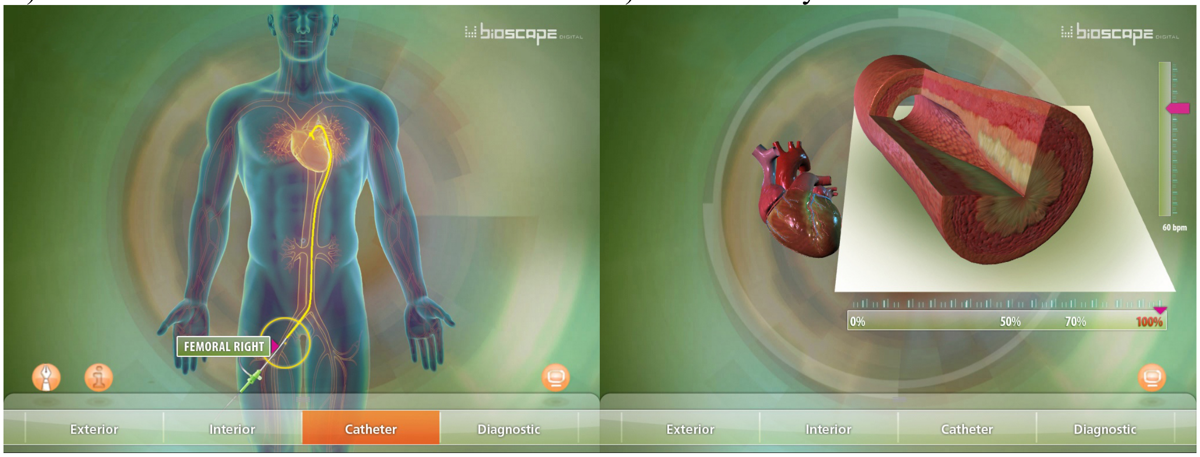
Purpose of study

This project is designed to advance the goal of improving communication in order to promote shared decision-making and patient-centered care, with significant emphasis on enhancing patients' experiences and satisfaction. Such experiences include emotional preparation and comfort. The latter, often considered second-order goals, are ethically important. Such goals are key to providing patients with respect and facilitating the physician-patient relationship—important components of patient-centered care (Beach et al., 2007). Informed consent processes that advance these goals, independent of their effects on understanding of treatment options or specific treatment decisions, may be valuable and warrant exploration.

The study intervention was a tablet-based, three-dimensional, interactive software tool designed by Bioscape Digital, which displayed cardiac and coronary artery anatomy, the cardiac catheterization procedure, and degrees of intracoronary stenosis (Figure 1). This study was designed to encompass two phases occurring over approximately one year, with the pilot to provide preliminary experience with the tool, assess feasibility of its implementation, and provide data to be used in developing the survey tool for the second phase. The project for this thesis is the first phase of the study.

There were no inherent risks under this study; however, interviewers communicated to patients their right to opt out of the study at any time for any reason, prior to receiving patients' consent. The Emory University Institutional Review Board approved this study on May 13, 2013 (Appendix A).

Figure 1. Sample graphics from the intervention demonstrating:



A) Cardiac catheterization and access

B) Intracoronary stenosis

Study design

A modified pre-post-design was developed in order to minimize the Hawthorne effect associated with a standard pre-post design. Four physicians, current Emory University Cardiovascular Disease Fellows, alternated between their standard consent process and the same consent process aided by the use of this technology tool, utilizing identical consent forms, in blocks of approximately five patients. After five patients had been interviewed per each physician, each physician was trained in using the tablet tool, allowing for a “break-in period” of approximately one week to allow physicians to become familiar with the tablet. This design gave each participant multiple periods of time to be on and off of the intervention. Structured interviews prior to discharge provided data for outcomes assessment. All participants provided written consent for interviews.

Study population

The study population included adult inpatients at Emory University Hospital Main Campus location, undergoing diagnostic cardiac catheterization for suspected coronary disease with potential for percutaneous coronary intervention. Patients were excluded if they had a planned coronary intervention, were undergoing catheterization for another indication, were visually impaired, did not speak English, or did not make their own medical decisions.

Recruitment

Each day, co-investigator, Janci Demyun checked-in via text messaging with physicians to receive notification of patients approached for consent for catheterization with possible PCI. Ms. Demyun and Kristen Douglas, a research staff colleague, then approached the patients in the hospital to ask if they were willing to be interviewed either in-hospital or over the telephone after discharge. Total interviewing time consisted of approximately eight-to-ten weeks.

Sampling

Total recruitment time for both phases consists of a four-to-six-month period with an estimated eight weeks of interview data for each phase of the study. This pilot was designed to provide data to guide the larger, second phase; therefore, given the then-current catheterization lab volume, each phase recruits approximately 40 patients. This sample size, consistent with the hypothesis-generating goals of the study, was sufficiently large to generate reasonable confidence intervals around point estimates of most of the primary outcome measures, and to gather meaningful qualitative information about the potential impact of the tool, to guide development of a closed-ended survey for the second phase.

Physicians in focus groups consisted of the four physicians, who were current Emory University Cardiovascular Disease Fellows.

Questionnaire/interview guide

Ms. Demyun assisted in the initial development of the interview guide for the project. The structured interview guide focused on major domains, as follows: level of knowledge about the procedure, perceptions of involvement in decision, satisfaction with consent process, views on the tablet tool and suggestions for improvements in consent/decision-making process. Five-point Likert scale questions were used to assess satisfaction with consent and the intervention, where applicable, and health literacy (Appendix B).

Specifically, the sections of the interview guide are:

- **Part A: Introduction and Consent**
- **Part B: Demographic Information**
- **Part C: Knowledge of Catheterization and PCI**
- **Part D: Perceptions of Involvement in Decision Making**
- **Part E: Satisfaction with the Consent Process**
- **Part F: Views on the Tablet Tool and Improvements in Consent and Decision (*only for patients with iPad)***
- **Part G: Suggestions for Improvements in Consent and Decision-making Process *(only for patients with NO iPad)***
- **Part H: Health Literacy**

Physician Focus Groups

Neal Dickert, M.D., Ph.D., principal investigator, and Ms. Alexandra Fehr, Dr. Dickert's qualitative research assistant, conducted the two focus groups with the four participating physicians. Ms. Demyun participated in the second. The first focus group discussion took place prior to study implementation for purposes of pre-assessment. The second was to ascertain the four participating physicians' perceptions of the intervention's effects on patient engagement, facility of use, and possible areas for improvement. The physician focus group guide for the second focus group focused on three major domains: the impact of the tablet on conversations with patients; the impact of the tablet on patients' understanding; and the feasibility and ease of use, with suggestions for improvement.

Data collection and management

All interviews took place in-person, in the patient's hospital room, prior to discharge. Interviews lasted approximately 20 minutes. The interviews were recorded using a digital audio recorder. Ms. Demyun and Ms. Douglas each conducted half of the interviews, and divided transcriptions one-third-to-two-thirds, respectively—each transcribed verbatim and individually corrected for errors. Ms. Fehr entered directly into a spreadsheet for quantitative analysis closed-ended questions.

Data analysis

Ms. Demyun and Ms. Douglas each coded half of the transcriptions using a qualitative data management software package (MAXQDA) to manage textual data for qualitative analysis.

Ms. Demyun created the original codebook with a priori codes, based on the expected responses and major domains, (Cassell, 2008), and developed additional codes inductively with Dr. Dickert and Ms. Fehr. Ms. Demyun and Ms. Douglas divided equally the primary and secondary coding for all interviews, using the final codebook. Each alternated per interview as primary and secondary coder. Ms. Demyun, Ms. Douglas, Dr. Dickert and Ms. Fehr discussed and resolved discrepancies by consensus. Then, the four ensured thematic integrity by reviewing instances of major codes.

Data analysis for this study was based primarily on an analytic goal of qualitative description. Dr. Dickert and Ms. Fehr examined relationships between primary outcome measures and patient characteristics, such as race, age and sex, using simple statistical methods, such as chi square analysis for proportions, utilizing Microsoft Excel.

The team of four correlated patients’ responses to interview questions with other data already available from the project, including: demographic information, prior cardiac disease, and procedures and treatment received—medical management, surgery and stent type, if PCI.

Results

There were no substantial demographic differences between groups (Table 1).

Table 1. Demographic information

Demographic Characteristic		Intervention N=18	Non-Intervention N=22
Gender	Men	9	8
	Women	9	14
Race	White/Caucasian	10	15
	Black/African	6	7
	American	2	0
	Other		
Age	Median (Range)	65 (47-88)	59.5 (36-94)
Education	Less than college	6	7
	At least some college	12	15
Use computer at home*	Yes	11	16
	No	6	6
‘‘How confident	“Extremely;” or	13	13
are you filling out medical	“Quite a bit”		8
forms by yourself?’’**	“Somewhat;”	4	
	“A little bit;” or		
	“Not at all”		
	Yes	7	10
Past catheterization	No	11	12

*1 missing from Intervention group
**1 missing from Intervention group and Non-Intervention group

Patients exposed to the intervention all reacted positively through comments; however, four patients did not recall its use, although they had received exposure. Three among them felt certain their catheterization was in the context of a “life-or-death” situation. All patients who recalled the intervention “strongly agreed” that the intervention made the procedure easier to comprehend and appreciated having physicians use it to explain the procedure. Most patients focused more on their sense of comfort than on direct provision of information or their decision-making process. A common theme was that it was reassuring to see the procedure on the tablet before it happened (Table 2).

Table 2. Relevant themes

Overall Theme	Sub-theme	Supporting Quote
Perceptions of Process	Time spent	- "They were patient; they took their time, and I think, made sure that I had an understanding of what exactly was going on."
	Plain language	- "And for me as a patient, I just need bottom line, plain black and white, plain English. None of that medical stuff…"
	Decision was obvious	- "Whether I live or die, simple as that." - "… they kind of put the facts out there… there was no alternative."
Perceptions of Tablet	Reassurance	- "It (the tablet) reassured me, showed me exactly what was going to be done."
	Importance of visual information	- "At least I know what he was going to do. I don't like when doctors say something and they don't show me. Show me something. Show me how you're going to do it. As long as you show me how to do it."

Also, the intervention did not notably affect patients with varied levels of health literacy or computer exposure differently. Nor did it have a considerable effect on the patients' knowledge, overall satisfaction, or decision-making; however, it did appear to enhance patients' experiences with the consent process and individual treatment, particularly in providing comfort and reassurance.

Physicians also responded positively to the intervention. They found implementation simple and felt patients consistently reacted positively. One physician noted older patients were more often “impressed” by the intervention’s graphics whereas younger patients seemed more engaged by the intervention. The physicians’ only suggestion for improvement was to incorporate the intervention into existing devices, such as their smartphones, to eliminate carrying an extra device.

Chapter Four: Discussion and conclusion

Discussion

Although the intervention did not have a considerable effect on the patients' knowledge, overall satisfaction, nor decision-making it did appear to enhance patients' experience with the consent process and individual treatment, particularly in providing comfort and reassurance by being able to visualize the procedure in advance.

As expected, the impact of the intervention on treatment decisions was limited, as the patient normally meets with the treating physician and makes the decision to proceed prior to receiving consent for catheterization. Surprisingly, there were no observed differences in recall of information. Possibly, the intervention had unmeasured effects, because the interview guide assessed only spontaneous recall of procedural information. Further work could elucidate any such effects by assessing the impact of the intervention on specific procedural detail, risks, and benefits.

The high level of overall satisfaction made delineating the effects of the intervention challenging. The Hawthorne effect could have been a factor; however, the four physicians in the study also seem to possess excellent communication skills on a variety of levels. Each was comfortable drawing pictures and/or explaining in "plain language" to the patients what the cardiac catheterization procedure would involve. Overall, patients in the study appreciated their visual and/or verbal explanations independent of the intervention.

Regardless, there are several areas where the intervention appeared to have an impact. First, when asked what distinguished this consent process from previous processes, many patients exposed to the intervention spontaneously mentioned the use of the tablet intervention. Second, all patients who remembered the intervention described it positively, and many specifically stated that it provided them with reassurance and comfort. Finally, the intervention was well received across the population. Though its effects among older and younger patients appeared to vary, the intervention did not notably affect patients with varied levels of health literacy or computer exposure differently.

The principal goals of many tools designed to promote shared decision-making are to improve understanding, clarify values, and affect decisions. Yet outcomes derived from assessing patients' experiences of their care and treatment decisions, and emotional preparation for invasive procedures is ethically valuable, and critical to patient-centered care (*Crossing the Quality Chasm: A New Health System for the 21st Century*, 2001; Dickert & Kass, 2009; Medicine, 2001; Rowbotham, Astin, Greene, & Cummings, 2013). Technology tools such as this intervention may help to increase the extent to which patients feel respected by their providers, reduce procedural anxiety, and facilitate cooperative physician-patient relationships. These outcomes are the central focus of RCC; however, they can be difficult to measure and thus, are often ignored. Further development of tools to assess domains such as respectfulness of care is important.

This graphics intervention is easy to implement, particularly if physicians are already using mobile devices. Additional content to enhance communication, such as structured copy and additional graphics could easily be incorporated into the existing program. Moreover, as a pre-learning component, patients could receive individualized pictorial representations of coronary anatomy to facilitate continuity.

Limitations to this study are important to consider. First, as an exploratory study, the sample size was small. Second, variability among physicians in their conversations with patients is possible, as this observation was not part of the study. Finally, the interview guide assessed spontaneous recall of information disclosed during consent, which did not provide the opportunity to capture data regarding patient understanding of specific procedural elements.

Conclusion

A number of patients who received this intervention felt reassured and comforted by the graphical depiction of the cardiac catheterization process prior to having the procedure during consent. The ethical value of this, and potentially other similar interventions, may advance the goals of respecting patients by enhancing their experiences rather than simply directly informing or altering treatment decisions. Further attention is needed in the development of metrics for assessing these domains, which represent an important component of PCC.

Chapter Five: Journal article

Title

Moving beyond consent: the impact of a tablet-based graphics intervention on patients' experiences of consent for cardiac catheterization

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ABSTRACT

Objective: The objective of this exploratory study was to assess the impact of an interactive, tablet-based graphics application on patients' experiences with the consent process and decision-making for inpatient cardiac catheterization.

Methods: We employed a modified pre-post design. Eighteen patients underwent a consent process incorporating the tablet-based graphics application; 22 patients underwent a standard consent process. Outcomes were assessed via structured interview and included procedural knowledge, satisfaction with the consent process, and perceptions of the intervention.

Results: Patients from both groups reported high satisfaction with the consent process. No significant differences were appreciated between groups regarding procedural understanding or treatment decisions. Many intervention patients valued seeing the procedure beforehand. In particular, patients reported that pictorial representations created a sense of reassurance and comfort.

Conclusion: Significant differential impact on objective outcome measures was not appreciated but was difficult to assess given high background satisfaction. However, patients' responses were very positive toward the intervention. Applications like this may enhance patients' experiences of consent and reduce procedural anxiety. These goals have practical and ethical importance independent of procedural knowledge or decisions.

INTRODUCTION

Patient-centered strategies for promoting shared decision-making incorporate a heterogeneous set of goals. Individualized risk estimates,(S. V. Arnold et al., 2008) for example, or graphical displays of numerical concepts(E. P. Hess et al., 2012) help transmit complex information. Other tools clarify patients' values(A. H. Pieterse, de Vries, Kunneman, Stiggelbout, & Feldman-Stewart, 2013) and emphasize their role as principal decision-makers.(D. Stacey et al., 2011) All of these tools have the potential to improve communication, enhance confidence in decisions, and maximize the extent to which decisions advance patient's own goals.(Burton et al., 2010; D. Stacey et al., 2011; S. N. Whitney, McGuire, & McCullough, 2004) These strategies may also affect satisfaction with care and patients' sense of being respected and engaged.

Enhancing patients' experience and satisfaction, as well as their emotional preparation and comfort, are often considered second-order goals; greater emphasis has generally been placed on decision-related outcomes. However, these goals are ethically important; they are central to respecting patients and facilitating relationships and thus important components of patient-centered care.(Beach et al., 2007) Elements of consent processes that advance these goals - independent of their effects on understanding of treatment options or concrete treatment decisions- are thus worthy of exploration.

We conducted a pilot study utilizing an interactive, tablet-based graphics application during consent for cardiac catheterization. The aim was to evaluate the impact of this tool on multiple dimensions of patients' experiences with the consent process and decision-making regarding catheterization.

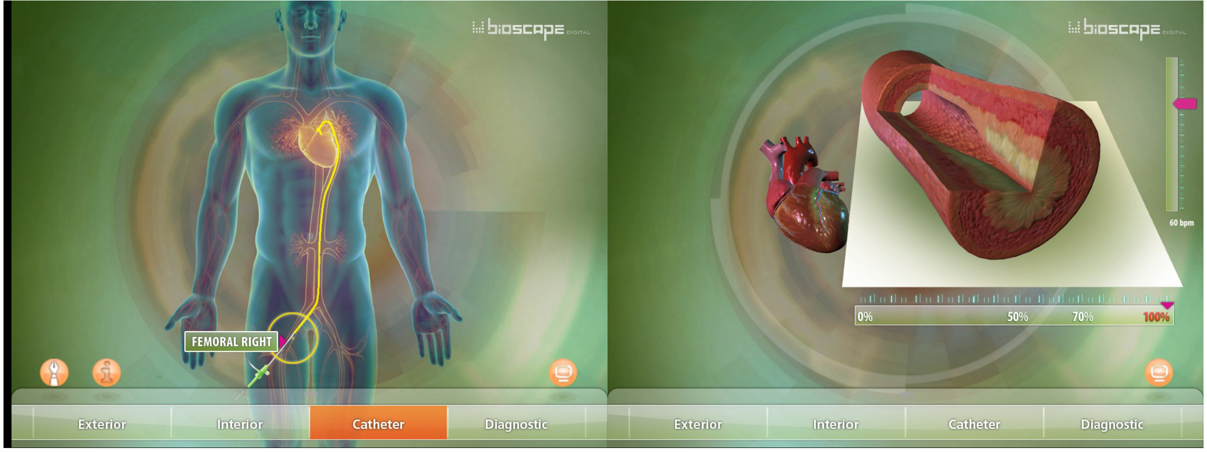
METHODS

Study Design

The study intervention (Bioscape Digital) was a tablet-based interactive graphics application displaying cardiac and coronary artery anatomy, the cardiac catheterization procedure, and degrees of intracoronary stenosis (Figure 1). Four physicians (cardiology fellows) alternated between a consent process supplemented with this application and their standard consent process (consent forms were identical) in blocks of approximately five patients. This modified pre-post design was created in order to minimize the Hawthorne effect associated with pre-post designs. Outcomes were assessed through structured interviews prior to discharge. All participants provided written consent for interviews. The Emory University Institutional Review Board approved this study.

Figure 1. Sample graphics from the intervention demonstrating:

A) Cardiac catheterization and access B) Intracoronary stenosis



Study Population

The study included adult inpatients undergoing diagnostic cardiac catheterization for suspected coronary disease with potential for percutaneous coronary intervention. Patients were excluded if they had a planned coronary intervention, were undergoing catheterization for another indication, were visually impaired, did not speak English, or did not make their own medical decisions.

The study team was notified daily of eligible patients. Interviews were conducted by JD and KD and were recorded and transcribed for analysis. The structured interview guide focused on 4 major domains: recall of procedural details and consent process; overall experience and satisfaction; involvement in decision making; and opinions of the intervention. Five-point Likert scale questions assessed satisfaction with consent, the intervention (where applicable), and health literacy.(Wallace, Rogers, Roskos, Holiday, & Weiss, 2006)

Participating physicians were also interviewed. These interviews focused on their perceptions of the intervention's effects on patient interaction, ease of use, and potential areas of improvement.

Data Analysis

Descriptive statistics were calculated using Microsoft Excel. MAXQDA was used to manage textual data for qualitative analysis. An original codebook was created with a priori codes; additional codes were developed inductively.(Cassell, 2008) All interviews were coded with the final codebook by a primary and secondary coder. Discrepancies were discussed and resolved by four authors. Instances of major codes were reviewed to ensure thematic integrity.

RESULTS

Forty interviews were completed (response rate 89%), 18 with the intervention and 22 without. There were no substantial demographic differences between groups (Table 1).

Table 1. Demographic information

Demographic Characteristic		Intervention N=18	Non-Intervention N=22
Gender	Men	9	8
	Women	9	14
Race	White/Caucasian	10	15
	Black/African	6	7
	American	2	0
	Other		
Age	Median (Range)	65 (47-88)	59.5 (36-94)
Education	Less than college	6	7
	At least some college	12	15
Use computer at home*	Yes	11	16
	No	6	6
''How confident	"Extremely;" or	13	13
are you filling out medical	"Quite a bit"		8
forms by yourself?''**	"Somewhat;"	4	
	"A little bit;" or		
	"Not at all"		
	Yes	7	10
Past catheterization	No	11	12

*1 missing from Intervention group
**1 missing from Intervention group and Non-Intervention group

Patients in both groups were very satisfied with the way the procedure was explained to them and the way they were asked for consent. Without being prompted, several in the intervention group mentioned the tablet as a key difference in the consent process when compared to previous experiences. There was no obvious difference in recall of procedural details between groups; both had similar descriptions of the decision-making process, including weighing the benefits and risks of the procedure. There were also no discernable differences based on patient-level health literacy. Many patients felt the catheterization decision was obvious or straightforward, especially those who believed it was a “life-or-death” situation.

All comments from patients exposed to the intervention were positive regarding the intervention. Four patients exposed to the intervention did not recall its use, three of whom felt their catheterization was in the context of a “life-or-death” situation. All patients who recalled the intervention “strongly agreed” that it made the procedure easier to understand and liked having physicians use it to explain the procedure. Most patients focused more on their sense of comfort than on direct provision of information or their decision-making process. A common theme was that it was reassuring to see the procedure on the tablet before it happened (Table 2).

Table 2. Relevant themes

Overall Theme	Sub-theme	Supporting Quote
Perceptions of Process	Time spent	- “They were patient; they took their time, and I think, made sure that I had an understanding of what exactly was going on.”
	Plain language	- “And for me as a patient, I just need bottom line, plain black and white, plain English. None of that medical stuff…”
	Decision was obvious	- “Whether I live or die, simple as that.” - “… they kind of put the facts out there… there was no alternative.”
Perceptions of Tablet	Reassurance	- “It (the tablet) reassured me, showed me exactly what was going to be done.”
	Importance of visual information	- “At least I know what he was going to do. I don't like when doctors say something and they don't show me. Show me something. Show me how you're going to do it. As long as you show me how to do it.”

Providers were also positive regarding the intervention. They found it easy to implement and felt patients uniformly had a positive reaction. One provider noted older patients more often seemed “impressed,” while younger patients seemed more engaged when using the intervention. The providers’ only complaint was carrying an extra device; they suggested incorporating the intervention into devices they already carry such as smartphones.

DISCUSSION

This study assessed the effect of an interactive graphics application for displaying cardiac catheterization and coronary anatomy on patient’s experiences of the consent process for catheterization in the inpatient setting. Although the intervention did not have a demonstrable effect on patients’ knowledge, overall satisfaction, or decision-making, it did appear to enhance patients’ experience of the consent process and their treatment. In particular, the intervention appeared to provide some patients with comfort and reassurance.

The limited impact of the intervention on concrete treatment decisions was not surprising. By the time a consent process takes place for catheterization, the decision to proceed has largely already been made. In contrast, the absence of observed differences in recall of information was surprising. It is possible that the intervention had unmeasured effects, because the interview guide assessed only spontaneous recall of procedural information. Further work assessing its impact on specific procedural details, risks, and benefits could elucidate any such effects.

The high level of overall satisfaction made delineating the effects of the intervention challenging, but there are several areas where the intervention appeared to have an impact. First, when asked what distinguished this consent process from previous processes, many patients exposed to the intervention spontaneously mentioned the use of the tablet intervention. Second, all patients who remembered the intervention described it positively, and many specifically stated that it provided them with reassurance and comfort. Finally, the application was well-received across the population. Though its effects among older and younger patients may have been interestingly different, the intervention did not differentially affect patients with overtly different levels of health literacy or computer exposure.

While the principal goals of many tools to promote shared decision-making are to improve understanding, clarify values, and affect decisions, it is important to recognize that enhancing patients' experiences of care and treatment decisions, as well as their emotional preparation for invasive procedures, is an ethically valuable outcome that is an indispensable element of patient-centered care (*Crossing the Quality Chasm: A New Health System for the 21st Century*, 2001; Dickert & Kass, 2009; Rowbotham et al., 2013). Tools such as this intervention may help to increase the extent to which patients feel respected by their providers, reduce procedural anxiety, and facilitate cooperative provider-patient relationships. These outcomes are at the core of what it means to respect patients. They can, however, be difficult to measure and are often ignored. Further development of tools to assess domains such as respectfulness of care is warranted.

This graphics intervention is easy to implement, particularly if physicians are already using mobile devices. Structured content employing additional tools to enhance communication, for example, could also easily be added. And individualized pictorial representations of coronary anatomy could be sent to patients, referring providers, or others to enhance communication and facilitate continuity.

Several limitations warrant mention. As an exploratory study, the sample size was small. Second, actual conversations were not observed, and there may have been variability among practitioners. Finally, because the interview guide assessed spontaneous recall of information disclosed during consent, robust comparisons regarding understanding of specific procedural elements were not possible.

CONCLUSION

Patients valued this tablet-based graphics intervention as a component of the consent process for cardiac catheterization, principally because it provided reassurance and comfort. These findings serve as a reminder of the ethical value of interventions that may advance the goal of respecting patients by enhancing patients' experiences and not by directly informing or altering treatment decisions. Further attention is needed to development of metrics for assessing these domains, which represent an important component of patient-centered care.

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COMPETING INTERESTS

No authors have any relevant financial conflicts to disclose

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Janci Demyun 37

Appendix A

IRB > Bioscape Consent Study

< Prev **10 / 22** Next >

Activity Details (Study : *Approved*)

Author:	Michael Arenson (Med School)
Logged For (IRB Study):	Bioscape Consent Study
Activity Date:	5/29/2013 3:47 PM EDT

Activity Form Property Changes Documents / Tasks / Notifications

Documents:

fromString.html

Interview Guide V 4/10

Catheterization Consent Study Consent Form V 4/10/13

Request for waiver of consent documentation (for phone interviews)

Catheterization Consent Study V 4/10/13

Project Task Assignments:

Name	Priority	User	Activity	Due Date

E-mail Notifications:

Job Name	Subject	Recipients
Decision Notice: Expedited Approved	Decision Notice: Expedited Approved	Arun Mohan (MedHospitalMed) email:arun.mohan@emory.edu Azizul Hoque (MedCardio) email:azizul.hoque@emoryhealthcare.org Habib Samady (MedCardio) email:hsamady@emory.edu Janci Demyun (MedCardio) email:djanci@emory.edu Michael Arenson (IRB) email:michael.arenson@emory.edu Mihir Kanitkar (RTP) email:mkanitk@emory.edu Neal Dickert Jr (MedCardio) email:njr@emory.edu

Exit

Appendix B
Enhancing Patient Education and Communication for Cardiac Catheterization
Patient Interview Guide

Study ID:______________ Date:__________________

Interviewer:________________ Recording Number:__________ Doctor:_____________

Part A: Introduction and Consent

Hello! My name is _______ and I am part of a research team at Emory University. (*Get patient's name)* I'm here to talk to you today about an interview study that we're doing on how doctors communicate with patients about things like heart catheterization. If you decide to participate, the study would just involve this one brief interview about your experience in the hospital. This is not a treatment study and we do not ask any sensitive questions. With your permission, I would like to interview you for this study and if you're interested I can give you more information. Do you think this is something that you might want to participate in or learn more about?
Assuming yes…

Great, thank you. Again, my name is _______. As a first step, I will go over this form with you that we need you to sign that shows you agree to be interviewed. Here are two copies: one for me to keep as record, and one for you to keep so that you have all the information you may need about this study. We'll go over this together now.

The document begins with basic information about the study. As I mentioned, we are interviewing people to find out how doctors communicate with them about procedures like heart catheterization. This form also gives more details we are required to provide. I'll highlight the important parts. So you know, there are no risks for participating in this study, nor are there any direct benefits or compensation. There is also a section about confidentiality and privacy that basically confirms your rights and states that we are going to protect your information.

I do plan to record this interview. However, this is only so I do not have to write down everything you say. Recordings will be transcribed and then destroyed. No one outside the research team will hear the recordings or read the transcripts. All information that could be used to identify you will be removed from the transcripts.

Again, your personal information or anything you say during the interview will not be seen by anyone outside the research team until all identifying information is removed.
Things you say will also not be directly reported to your medical treatment team. For example, if you discuss the way your doctor communicated with you, I – or anyone on the research team - will not directly report that information to the doctor.

Lastly, it is important for you to know that you can change your mind about participating at any time. If there are any questions you do not want to answer, you do not have to. If you change your mind and do not want to participate at all – even after we have completed the interview and I have left – you can withdraw. Here is the phone number for Dr. Dickert, the head doctor on this project. And here is my phone number (give number). Feel free to call either of us if you have any questions.

Before we move on to the interview, what questions do you have for me about the interview or the form?

Assuming no…

Great, then please sign these two copies, and I will as well. *(Sign consent forms – make sure you each have a copy!)*

Now, let's get started on the interview. The interview is made up of a series of questions that will ask for your thoughts and experience regarding your time in the hospital, specifically about the procedure you had done for your heart. There are no right or wrong answers to these questions; we only want to learn about your experience and thoughts. I will start by asking some basic background questions, and then we'll move on to questions about communication.

If at any time you do not understand a question, or want to ask a question of your own, please just let me know.

Part B: Demographic Information

Great, thank you. To begin, I am going to ask you some basic information about yourself.

B.1.	*For interviewer: Is the respondent male or female?*	1) Female 2) Male
B.2.	What year were you born?	
B.3.	Which of the following best describes your marital status?	1) Single 2) Married 3) Divorced or Separated 4) Unmarried living with partner 5) Widow or Widower
B.4.	Do you consider yourself Hispanic?	0) No 1) Yes
B.5.	Which of the following best describes you?	1) Asian, Hawaiian, or Pacific Islander 2) Black or African American

		3) Native American/Aboriginal 4) White 5) Other (specify):
B.6.	What is the last grade or year that you completed in school?	1) Less than high school 2) Some high school 3) High school or GED 4) Some college 5) College graduate 6) Some post-graduate 7) Post-graduate or Professional degree 8) Other (specify):
B.7.	Which of the following describes your employment status?	1) Employed, full-time 2) Employed, part-time 3) Unemployed 4) Retired 5) Disabled 6) Other:
B.8.	Do you use a computer at home?	0) No 1) Yes

Part C: Knowledge of Catheterization and PCI

For the next few parts of the interview I am going to ask you questions about the procedure you had and the way your doctor discussed this procedure with you. I will also ask you questions about how you made your decisions about this procedure. If you have any questions along the way, please feel free to ask.

C.1. Can you tell me about the heart catheterization procedure you had done (today/yesterday)?

Probe: What did this procedure involve?

C.2. Have you ever had that procedure before?

Probe: How many times have you had this procedure?
Have you had stents placed or other heart procedures done?

C.3. What were the results of this most recent catheterization?

Probe: Did they find anything that needed to be fixed?

What did your doctor tell you about the procedure they did?

C.4. From what you have been told, what were the ways that having a heart catheterization procedure could help you?

C.5. What were the risks your doctor discussed with you about the procedure?

Part D: Perceptions of Involvement in Decision Making

D.1. How did you make the decision to have this procedure done?

Probe: What were the most important factors to you when deciding? (*only if patient needs clarification – be careful not to lead* - e.g. the benefits of the procedure, how your health may improve, the risks, time in the hospital, recovery, etc.)

D.2. As a patient, did you feel like you were able to make this decision on your own about whether to have this procedure done?

Probe: Did you feel like someone else made the decision for you? (If yes, good or bad?) Did you feel pressured when making this decision? (If yes, by whom?)

Part E: Satisfaction with the Consent Process

E.1. Were you asked for permission or consent to have this procedure done?

By whom?

E.2. Please tell me about the conversation when they asked you for permission or consent to have the procedure done.

E.3. Do you feel like the procedure was explained clearly?

E.4. Did you have questions about the procedure when it was discussed with you?

If NO → Skip to E.6.

Probe: What were those questions?

E.5. Did you feel like your questions were answered?

Probe: If not, in what way were they not answered? What was still unclear to you?

E.6. How was this process the same or different from other times you have been asked for permission or for consent to a medical procedure?

Probe: (*If different*) Can you give a specific example?

I am now going to read you two statements, and for each one, please tell me on a scale of 1 to 5 how much you agree, with 1 being strongly agree and 5 being strongly disagree.

E.6. I was satisfied with the way that this procedure was explained to me.

1: Strongly agree 2: Agree 3: Neutral 4: Disagree 5: Strongly disagree

NOTE: *repeat back response to patient*

E.7. Again, tell me on a scale of one to five how much you agree with the following statement: I was satisfied with the way that I was asked for permission to do this procedure.

1: Strongly agree 2: Agree 3: Neutral 4: Disagree 5: Strongly disagree

NOTE: *repeat back response to patient*

E.8. When explaining this procedure, did the doctor use an iPad or tablet computer with pictures of the heart and blood vessels?

0) No → ***If no, skip to Part G***
1) Yes → ***If yes, go to Part F, then skip Part H***

Part F: Views on the Tablet Tool and Improvements in Consent and Decision-making Process

Note: iPad users only

F.1. Please tell me how the doctor used the tablet computer.

Probe: What did the doctor show you using the tablet computer?
What did they explain using the tablet computer?

F.2. What did you like about the doctor using the pictures on the tablet?

F.3. What did you not like about the doctor using the pictures on the tablet?

I am now going to read you two statements, and for each one, please tell me on a scale of 1 to 5 how much you agree, with 1 being strongly agree and 5 being strongly disagree

F.4. Being shown the pictures on the tablet helped me to understand the procedure better.

1: Strongly agree 2: Agree 3: Neutral 4: Disagree 5: Strongly disagree

NOTE: *repeat back response to patient*

F.5. I liked being shown the pictures on the tablet to explain the procedure to me.

1: Strongly agree 2: Agree 3: Neutral 4: Disagree 5: Strongly disagree

NOTE: *repeat back response to patient*

F.6. Do you feel like looking at these pictures made it easier or more difficult for you to make a decision regarding this procedure?

Probe: How so?

F.7. If something like the pictures you saw on the tablet were available to you at home to learn more about the procedure that you had, do you think you would use it?

Probe: How so?
Would you look at it if you had access to it after you leave?
Would it have helped to see these pictures before the doctor came to talk to you?

F.8. In what ways do you think the pictures and tablet computer could be used to be more helpful to you and other patients?

Probe: Do you have any specific examples?

F.9. In general (not just with the tablet), what are some things your doctor could have done differently to help you better understand this procedure?

Probe: Is there anything that would help you understand this procedure better?
Is there anything the doctor did that made the procedure more difficult to understand?

Note: Now skip to Part H

Part G: Suggestions for Improvements in Consent and Decision-making Process

Note: only for patients with NO iPad

G.1. How did your doctor explain the procedure to you?

Probe: Did they draw pictures or show you any pictures related to the procedure when they explained the procedure?

G.2. What did you like about the way your doctor explained the catheterization procedure to you?

G.3. What did you not like about the way your doctor explained the procedure to you?

G.4. What are some things your doctor could have done differently to help you better understand this procedure?

Probe: Is there anything that would help you understand this procedure better?
Is there anything the doctor did that made the procedure more difficult to understand?

Part H: Health Literacy

Thank you for your responses so far. We are almost done with the interview. For the last part, I am going to ask you some questions regarding medical information in general. I will ask you a question, and you will respond with how this applies to you, according to a scale that I will give you.

H.1.	How often do you have someone (like a family member, friend, hospital/clinic worker, or caregiver) help you read hospital materials?	1) All of the time 2) Most of the time 3) Some of the time 4) A little of the time 5) None of the time
H.2.	How often do you have problems learning about your medical condition because of the difficulty understanding written information?	1) All of the time 2) Most of the time 3) Some of the time 4) A little of the time 5) None of the time
H.3.	How confident are you filling out medical forms by yourself?	1) Extremely 2) Quite a bit 3) Somewhat 4) A little bit 5) Not at all

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Part I: Conclusion

We have now completed today's interview. Thank you so much again for your time! Your answers will help us to better understand how we can best work with patients to explain procedures and help patients make decisions about procedures. Again, if you have any questions or concerns after I leave, please feel free to use the contact information on the sheet I have given you.

Before we depart, do you have any final questions or anything you would like to add?

Thank you and goodbye!

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