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Patient and Provider Views on Informed Consent for Cardiac Catheterization: A Pilot Study

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PATIENT AND PROVIDER VIEWS ON INFORMED CONSENT FOR CARDIAC CATHETERIZATION: A PILOT STUDY

by

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ABSTRACT

Background: Patient provision of informed consent is foundational to medical decision-making. However, clinical informed consent is not as well studied as consent for research. Cardiac catheterization (CC) is a complex medical procedure with many potential variations, making informed consent challenging.

Objective: To determine patient and provider attitudes toward the informed consent process for CC and to test a new measure for measuring patient capacity to consent for CC.

Design: A mixed methods pilot study.

Setting: Academic medical center.

Participants: 8 patients who consented for non-emergent CC, cardiology fellows and faculty (21 surveyed, 7 interviewed).

Measurements: Patients and providers underwent semi-structured interviews, which were qualitatively coded for themes. Patients completed an instrument designed to measure capacity to consent for CC. Providers completed a survey to gauge attitudes about the consent process for CC.

Results: Most patients (75%) did not meet the 70% performance testing for capacity derived from a provider survey as a minimum for providing consent. Patients did not view the consent discussion as part of medical decision-making. In emergent situations, patients requested that providers apply pressure to convince patients to undergo necessary procedures. Providers believed proper informed consent was important, but admitted to less emphasis in emergencies, and they often used family to help patient consent in such situations. Patient and providers described common themes in informed consent.

Conclusions: The instrument developed herein for measuring capacity to consent for CC has promise for providing valid and reliable data. Most patients tested did not have capacity by criteria set by providers, suggesting that the informed consent process was inadequate. Patients and providers expressed a role for applying pressure to convince patients to consent to emergent procedures.

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Introduction

Acquiring informed consent prior to conducting medical procedures is an ethical and legal requirement of healthcare providers. Over the latter half-century, physicians have steadily supplanted the paternalistic model of physician-patient interaction with other models that emphasize patient autonomy, including active patient participation and shared decision-making (1, 2). Adequate informed consent for clinical procedures is a cornerstone of these other models, but it is a continual struggle to provide the appropriate amount of information at the appropriate level (3) and to ensure that patients appreciate complex medical information. However, the primary driving force behind much of the literature on informed consent concerns research trials, rather than clinical practice. This is likely a reflection of the impact of the Nuremburg Code, Declaration of Helsinki, and the Belmont Report, among others, on the growth of the field of biomedical ethics from human subjects research (4). Informed consent for medical treatments, on the other hand, originated more from case law with a focus on explication of risks (5). As such, the gathering of informed consent in practice for clinical procedures may have quite different requirements and implications (6). For instance, the threshold of capacity for informed consent for research may be higher, owing to the nature of experimentation and delineating as yet unknown risks in the context of little to no potential benefit to the individual subject (5). Further, as medical treatments by definition are designed to act to improve the condition of the patient, informed consent for clinical practice does not face the significant obstacle of therapeutic misconception (7).

A core precondition for informed consent is providing situation-specific information to the patient. Several methods with varying successes have attempted to bridge the information divide between patient and provider, owing to the difference between provider expertise and knowledge, and the patient's lack thereof. These methods include improved readability of forms, having extensive discussions, and using

multimedia programs (8-11). The visual communication of risk levels using images has also been shown to increase effectiveness of informed consent procedures (12). Attractive as advanced audiovisual multimedia may be, simpler aids were often found to be more effective than complex aids to decision-making (9). However, studies on improving the process informed consent, or improving patient understanding and appreciation of invasive medical procedures, have a high degree of methodological heterogeneity, making conclusions as to the most effective methods difficult (10, 11). That is, the studies differ by more than simply the method used, thus confounding the meaning of outcomes across studies.

Aside from the information proper, such as understanding the "facts" of what the procedure involves, achieving informed consent also means that patients must have the capacity to make an informed decision. Although differing legal nuances of capacity have been delineated, a consistent thread involves four domains: understanding, appreciation, reasoning, and expression of choice (13, 14). Gurrera *et al.* perhaps best distinguish these facets as (13):

1. Understanding—comprehension of diagnostic and treatment information.
2. Appreciation—personalization of information through integration with one's values, beliefs, and expectations.
3. Reasoning—evaluation of treatment alternatives in light of potential consequences for everyday life.
4. Expression of choice—communication of a treatment decision.

Assessment of these 4 domains can prove challenging. For instance, appreciation is harder to measure than is comprehension (15), and physicians often have difficulty assessing appreciation (16). Several instruments have attempted to measure patient capacity to consent (17) although practical application of these instruments has been limited. Shortcomings include: inadequate evaluation of validity and reliability of data from differing (nonspecialized) patient populations, time involved,

possible need for training (nonclinician) assessors, and relevance to clinical practice, among others (17).

Cardiac catheterization (CC) presents an excellent opportunity for evaluating the process of informed consent in the clinical setting. CC is a complex procedure with many possible variations, depending on the needs of the patient and what is found during the procedure. Although the primary indication is for diagnostic purposes, often patients are asked in advance to consent for additional (therapeutic) procedures to be done *in media res* depending on findings during the procedure. Generally, providers feel it more prudent to obtain consent for these possible secondary procedures up front (18). Moreover, many CCs are performed on an urgent or emergent basis, when informed consent is very difficult or impossible (19). Because of these issues, finding a simple method to improve patient understanding and appreciation for CC is important (20).

Few studies have examined informed consent in CC. Two were observational and showed patients grossly underestimated risks and overestimated benefits for coronary angioplasty (21), particularly when compared to cardiologists' judgments (22). One study found no difference in patient recall, satisfaction or anxiety comparing written, verbal or animated methods (23). Another study found that an interactive computer-based consent process for CC mildly increased patient understanding and appreciation compared to the standard consent process (24).

Finally, there is a paucity of studies that examine the provision of informed consent from the perspective of providers, especially in comparison to patient understanding and appreciation for the procedure. One study showed that patient beliefs regarding the benefits of percutaneous coronary intervention differed significantly from that of cardiologists (22). However, the authors did not measure cardiologist expectations of patient understanding, appreciation, or compare attitudes about the consent between the two groups. A disconnect between patient and provider

perspectives may have a great impact on the acquisition of legitimate informed consent itself, and presents ample opportunities for improvement of informed consent procedures. A comprehensive review of the literature found only one study directly comparing physician and patient attitudes toward informed consent, and it involved consent for blood transfusions. In this study, a majority of physicians and patients thought that the informed consent procedure was inadequate (25).

The purpose of the present study is to examine the process of informed consent for CC from the perspectives of both patient and provider. The specific aims of this study are as follows:

1. Identify current baseline for patient understanding and appreciation for CC at UNMH.
   a. Develop and test a new instrument for measuring patient capacity to consent for CC.
   b. Compare patient self-rating of understanding with objective measures on the instrument.
2. Identify current provider attitudes and expectations regarding informed consent for CC at UNMH.
   a. Derive a patient threshold for capacity to consent from provider views.
3. Compare UNM provider and patient attitudes toward the informed consent process for CC.

This study directly measures patient understanding and appreciation of the procedure, risks, benefits, and alternatives for diagnostic CC with the current informed consent process at the University of New Mexico Hospital (UNMH). Patient understanding and appreciation of the risks, benefits, and alternatives of cardiac catheterization is not well described for UNMH's unique population mix. UNMH serves a population similar to the state of New Mexico, dominated by about 47% Hispanics and 40% non-Hispanic whites (26). Nearly 20% of the population lives below the federal poverty level (26). Educational attainment in New Mexico is less than the United States

average, with approximately 83% of adults being high school graduates or having higher education, and nearly 26% obtaining a college bachelor's degree or higher (26). As such, UNMH's patient population largely fits the description of "vulnerable patients" who are at higher risk of providing inadequately informed consent (27). This study also will examine the relationship between patients' subjective views of their own understanding and their objectively measured understanding and appreciation. In addition, patients also describe their thoughts on the informed consent discussion during emergent situations.

Further, although there are several instruments in the literature to assess patient capacity to consent to treatment (17), none are specific for CC. To help address this gap in the literature, this study provides objective measurements of patient understanding and appreciation and develop an instrument specifically designed for CC. In a study of informed consent such as the present study, it is possible that a researcher might identify a patient with low level of understanding and appreciation of the risks, benefits, and alternatives of the clinical procedure of cardiac catheterization, as measured on the present study's instrument. This presents an ethical dilemma to the researcher: Should the researcher inform the provider who had just gained informed consent from the patient for CC, thus suggesting that the patient's previous given informed consent for CC be invalidated, or should the researcher not interfere with the clinical informed consent procedure that has already been completed? If the researcher informs the provider of the apparent lack of capacity to consent for the clinical procedure, the provider could then seek a legally authorized representative, such as a next-of-kin of the patient, to provide informed consent for CC. However, the provider is already assuming the patient has provided his/her informed consent for CC, and if the research on informed consent for CC had not been done in parallel to the clinical procedure of CC, then there would have been no indication to the provider of lack of capacity for informed consent for CC.

The latter is the case, presumably, in many clinical procedures in which formal assessments of capacity for informed consent are rarely conducted.

Although a known issue in research on informed consent (28), this situation is particularly challenging. Based on a review of the literature, one way to deal with this is to incorporate awareness of patient self-efficacy and empowerment, particularly in patients with low health literacy (29). Utilizing a prompt encouraging patients to contact their provider with additional questions may increase patient willingness to discuss confusing issues further and gain more information (29).

Last, this study examines the views of providers on the informed consent process for CC. This includes not only the minimal requirements providers believe are necessary to provide informed consent, but also gauges provider attitudes about what they see as challenging aspects of the informed consent process. Providers also explore their formative experiences for the process of informed consent, what expectations they have of patients during the process, and attempt to describe the process from the patients' perspectives. In addition, providers describe their thoughts on obtaining informed consent during emergent situations, and whether and how their expectations change compared to an elective procedure.

Methods

This is a mixed-methods preliminary study using both qualitative and quantitative data gathered from patients and providers regarding attitudes toward the informed consent process for cardiac catheterization (CC). Results from this study will be used to support future studies, including the seeking of external grant funding to further study informed consent for cardiac procedures in clinical practice. The Human Research Review Committee (HRRC, i.e., Institutional Review Board) at the University of New Mexico Health Sciences Center approved this study.

Participants

A convenience sample of patients was recruited from the UNMH cardiac catheterization laboratory. Inclusion criteria for patients in this study are as follows: ≥18 years old, have an indication for non-emergent cardiac catheterization, and have the capacity to provide informed consent according to the treating provider. Exclusion criteria included an indication for emergent cardiac catheterization (e.g., ST-elevation myocardial infarction, cardiogenic shock), or judged by treating providers to lack capacity for consent. Up to 12 patients were planned to be recruited, with an even mix among Hispanic, non-Hispanic white, men, and women.

All cardiology fellows (n = 12) and faculty (n = 19) at the University of New Mexico were eligible for inclusion in this study. All providers were eligible for completion of the survey. All fellows were eligible for participation in semi-structured interviews. Attendings that performed CC were specifically targeted for interviews.

Capacity to Consent Instrument

In the course of completing the semi-structured interviews, patients also completed a series of 11 questions to assess their capacity to provide informed consent for CC. This informed consent capacity instrument for the present study is based on assessment methods for capacity to consent recommended by our institution's Human

Research Protection Office (30), which in turn was influenced by the Human Research Protection Program at the University of California, San Diego (31). The original instrument, the *University of California, San Diego Brief Assessment of Capacity to Consent* (UBACC) (32) was modified to make it specific to CC procedures used at the University of New Mexico Hospital (the *Capacity to Consent for Cardiac Catheterization* instrument, or *C4* for short) (**Figure 1**). This new instrument has the advantage of addressing three of the domains of informed consent: understanding (items 1, 3, 7, 8, 11), appreciation (items 4, 5, 6, 9, 10), and reasoning (item 2). Patients demonstrated expression of choice by being willing to undergo CC and subsequently signing the consent form after discussion with their provider. Also as part of the completing the interviews, patients described their highest level of educational attainment. Education level was used as a proxy variable for health literacy in this preliminary study because other studies have suggested a strong predictive value of education for health literacy (33).

Figure 1. *Capacity to Consent for Cardiac Catheterization* Instrument Questions with Fully Correct Answers Shown.*

1.	*What are the symptoms you have that made your doctor recommend this procedure just described to you?* 2 = symptoms consistent with obstructive coronary artery disease (CAD) and/or valve disorder
2.	*What is your doctor trying to get done when he or she performs the catheterization just described to you?* (Overall purpose of the procedure—general descriptors, more open-ended) 2 = trying to figure out the cause of symptoms and/or need for coronary artery bypass surgery (CABG) concomitant with valve surgery
3.	*What is the main reason for your doctor to perform the catheterization?* Main reason for these non-emergent cases 2 = diagnose the presence of obstructive CAD
4.	*Do you have to have this procedure if you do not want to have it?* 2 = no
5.	*If you decide not to have this procedure, what are the other things you can choose to do to get diagnosed or treated?* Alternatives 2 = list one or more alternatives for either diagnosing or treating
6.	*Please describe what your doctor will actually do when he or she performs the catheterization.* 2 = involves tube going to heart from groin or wrist, use of dye to look for blockages in heart arteries
7.	*Please describe some serious harmful things that could happen to you if you have this procedure.* 2 = describes at least three complications/risks, including at least two of the following: death, stroke, heart attack
8.	*Please describe some ways that you might be helped if you have this procedure.* 2 = describes at least one appropriate benefit of the procedure (e.g., symptom relief, information regarding presence of blockages prior to valve replacement, etc.) Note: As all cases are non-emergent (not ST-elevation myocardial infarction or cardiogenic shock), life-saving would not be a correct answer.
9.	*If you have this procedure, is it possible that you will not be helped at all?* 2 = yes, it is possible that won't be "helped" as far as symptoms; would also accept gaining information as to presence/absence of obstructive CAD as part of diagnostic workup (explanation of symptoms, pre-operative evaluation for valve replacement, etc., if adequately reasoned)
10.	*If the results show you have blockage in an artery, what might be the next steps in your treatment?* 2 = stent placed if appropriate based on symptoms, CABG if valve replacement, possibly CABG if not valve replacement
11.	*After the procedure is over, what are some symptoms that you might have that you should call and tell your doctor about?* 2 = able to list at least three signs/symptoms concerning for a complication

* Fully complete answers from patient participants that convey the essential meaning of the response shown in the table are scored 2 points; partially correct answers scored are scored 1 point. A total score summing the points earned for all 11 items produce an overall score of 0 to 22.

At the end of the interview, the interviewer explicitly encouraged patients using language such as “Now that you have discussed this procedure and the process of learning about it in depth with me, think about whether you can state how serious the potential drawbacks and benefits of the procedure are, and consider whether you would like to know more about the risks and benefits. Please contact your nurse or provider if you have additional concerns.” As compensation for their time and effort, the investigator gave patients $20 in the form of an unrestricted Visa gift card.

Procedures

Recruitment of all patients occurred within 20 minutes of the CC consent discussion and the patient’s signing of the consent form. A diverse group of providers were involved in the consent discussions with patient participants in the present study (including at least one attending, fellow, and mid-level provider involved among the patient discussions). Due to the nature of the study in examining the role of informed consent *per se*, and that no changes in clinical treatment would be made, the present study’s informed consent was an abbreviated oral consent, as approved by the HRRC. A clear distinction was made to patients between consent for this study and informed consent for the clinical procedure of CC. The interaction with patients made it clear to them that their participation in this informed consent study would make no difference in their treatment for cardiac problems as previously determined by the patient and his or her provider.

An announcement at a fellows’ meeting served for recruitment of cardiology fellows for completion of the semi-structured interviews, and 4 fellows were interviewed on a first-come, first-serve basis, as well as 3 faculty cardiologists who perform cardiac catheterizations (2 interventional cardiologists, 1 invasive cardiologist). The survey (see **Appendix 1**) was distributed by email, directly at fellows’ conference, and by placing

physical copies in the mailboxes of fellows and attendings. Instructions for returning the survey anonymously were also provided.

Analysis

Patient and providers independently underwent semi-structured interviews. Interviews were transcribed for qualitative analysis using code structures that emerged from each set of interviews. After the completion of 8 patient interviews, a pre-specified interim analysis of codes was performed to assess for thematic saturation. If the analysis showed that thematic saturation had been reached, no further patient interviews would be performed. All target provider interviews were completed prior to analysis for coding (3 attending cardiologists, 4 fellows). The qualitative data software Dedoose (Dedoose version 4.5, Los Angeles, CA) was used to facilitate coding. For analysis, codes that emerged from a minimum of 2 participants in each group were considered to qualify for integration into a theme for further analysis. When appropriate, patient and provider themes were directly compared.

Two cardiologists independently scored completed the *C4* instrument according to the 0-2 scoring system as described in **Figure 1**, a scale recommended in the original instrument (32) and in other instruments measuring patient comprehension (34). A weighted κ was used to assess for inter-rater variability as well as calculation of Spearman's rank correlation coefficient. The raters settled disagreements in codes by discussion to determine the final scores for each item. Descriptive statistics for final patient scores, including mean and standard deviations, were calculated. To evaluate validity of the data, bivariate correlations among the *C4* items using Spearman's *r* were calculated. Final scores and subtotals for each consent domain (understanding, appreciation, and reasoning) were used to calculate Cronbach's α to measure internal consistency of the instrument. Patients rated their own level of understanding of the informed consent information for CC on a scale from 0 = not understand at all to 10 =

understand completely. Patient self-ratings were correlated with actual scores on the C4 informed consent assessment instrument using pairwise correlation. I also conducted a two-tailed paired *t*-test (α=0.05) to evaluate mean scores between patient self-ratings (transformed to a 0-100 score) and final scores as percentage of 22 maximum possible points. Spearman's r coefficient was used to assess correlations between total scores and gender, ethnicity, and education level, respectively, to look for potential associations informed consent understanding.

The survey asked providers what a patient should be expected to score on a test that measured patient understanding and appreciation of the risks and benefits of CC to then allow providers to conclude that patients had sufficient capacity to provide informed consent for CC. The initial version of this item asked how many questions correct out of 11 (the number of items on the C4 instrument). Based on provider feedback, this item was converted to ask for the "percent correct" response on the C4 assessment to qualify for patients to be considered having informed consent capacity. For providers that had previously answered out of 11, scores for this item were converted this to a percentage. A frequency histogram of the responses was used to determine a reasonable estimation of provider expectations of patient scoring. The minimum accepted score thus determined was compared with actual performance of patients, scored as mentioned above. Comparison to actual patient responses to analogous items was done with frequency counts for provider answers to the following survey items: main reason for CC, most common serious harmful effect, most serious harmful effects, medically concerning symptoms following procedure, diagnostic alternatives, and treatment alternatives. Because these questions were open-ended, providers may have listed multiple responses for each item.

The survey also asked providers to rate the ethicalness (on a 0-10 scale, 0 = not ethical at all and 10 = completely ethical) of applying pressure in the context of a patient

initially refusing CC, for whom the provider felt the patient would be best diagnosed or treated by CC. The survey asked this question in three scenarios: provider applying pressure to patient, family applying pressure to patient, and provider applying pressure to family. The initial version of the survey lacked the item concerning ethicalness of provider applying pressure to family, which was added after initial interviews highlighted the role of family in difficult situations. Descriptive statistics for these responses were calculated. Because the same provider rated the items on a single given survey, this violated the assumption of independence across samples, and answers to each of the items was compared using repeated measures analysis of variance (ANOVA). Based on Cohen's method (35) with data from the ANOVA table, η^2 was calculated as a measure of effect size for item and provider on the ethicalness score. Following repeated ANOVA, Tukey's honestly significant difference (HSD) test for repeated comparisons was used in determining whether the ratings for the three categories were significantly different from one another (family-wise α=0.05). Further, I calculated correlations between these answers and the following: fellow/attending status, number of consent procedures for CC in career, and number of consent procedures for CC in the past year. Spearman's rank correlation coefficients were calculated for all correlations because of the limited sample size and presumption of nonnormal data.

Results

Participant Characteristics

Patient and provider sample characteristics are shown in **Table 1**. Patient characteristics largely fit the state demographics, with 87.5% of patients obtaining a high school or equivalent education (25% with a bachelor's degree or higher). The patient sample represented gender and ethnicity equally. One provider abstained from the following survey items: level (fellow or attending), gender, and years in practice. A total of 21 providers responded to the survey, representing a response rate of 68%. Providers were split between fellows (52%) and attendings (43%). Women represented 19% of respondents (men 76%). Attendings were involved in a lower average number of consent processes in the previous year, but more over the course of their career. Attendings indicated spending 3-30 years in practice, averaging 14 years.

Table 1. Participating Patient and Provider Sample Characteristics.

PATIENT (n=8) Characteristics	*f*	*%*
Ethnicity		
Hispanic	4	50
White, non-Hispanic	4	50
Gender		
Woman	4	50
Man	4	50
Education		
Less than high school equivalent	1	13
High school or equivalent	4	50
Associate's degree	1	13
Bachelor's or Professional degree	2	25
Indication for procedure		
Chest pain	3	38
Preoperative coronary angiography prior to aortic valve replacement	4	50
Falls/syncope	1	13
Age in years	**Mean**	**Range**
Average	54.9	33-70
PROVIDER (survey) (n=21) Characteristics	*f*	%
Level		
Fellow	11	52
Attending	9	43
Not reported	1	5
Gender		
Woman	4 (19%)	19
Man	16 (76%)	76
Not reported	1 (5%)	5
Number of Consent Procedures*	**Mean**	**IQR**
Overall		
Previous year	101	35-140
Career	974	163-1000
Fellow		
Previous year	117	70-175
Career	198	130-250
Attending		
Previous year	81	12-50
Career*	1922	400-6000
	Mean	**Range**
Years in Practice	14	3-30

*Career numbers rounded to number given, e.g., ">1000" rounded to 1000 for calculation of mean and range.

Measurements of Patient Understanding and Appreciation

The distribution of patient answers for the *C4* instrument is shown in **Table 2**. Responses to items 6 (description of what the provider will actually do) and item 10 (next steps in the procedure) were open-ended and answers are listed separately in **Table 3** and **Table 4**. Patient summary statistics for correct responses to the 11 *C4* items are listed in **Table 5**. The average score among all patients was 13.75 (63%) (maximum possible score = 22). The highest score was 20 (91%), and the lowest 7 (32%). Initial inter-rater agreement by weighted κ averaged across the 11 *C4* assessment items was moderate (κ = 0.64), with a high correlation between the two ratings (r = 0.73).

Table 2. Distribution of Patient Responses for the *C4* Consent Assessment.

Patient Responses	*f*	%
Item 1: ***Symptoms***		
Chest pain/discomfort	3	38
Syncope/pre-syncope	3	38
Preoperative for valve replacement (no symptoms given)	2	25
Shortness of breath	1	13
Item 2: ***Purpose***		
Look for blockage*	4	50
Look at/check heart valve or pressures	2	25
Prevent heart attack	1	13
See damage to heart	1	13
I don't know	1	13
Item 3: ***Main reason***		
Diagnosis		
Find out where blockages are	6	75
Examine valve	1	13
Treatment ("to save my life")	1	13
Item 4: ***Have to have if not want***		
Yes	4	50
No	2	25
I don't know	2	25
Item 5: ***Alternatives (diagnosis or treatment)***		
I don't know	7	88
Ultrasounds	1	13
Item 7: ***Risks****		
Death	5	63
Stroke	4	50
Heart attack	4	50
Reaction to dye	1	13
Blood clot	2	25
I don't know	1	13
Item 8: ***Benefits***		
Symptom relief	3	38
Information†	2	25
Open blockage	1	13
Save life	1	13
I don't know	1	13
Item 9: ***Possible not to be helped***		
No	1	13
Yes	2	25
Information either way	4	50
I don't know/don't understand	1	13
Item 11: ***Post-procedure symptoms****		
Chest pain/heart attack	3	38
Access site (bleeding, swelling)	3	38
Stroke symptoms	2	25
Fever/infection	2	25
I don't know	2	25
Shortness of breath	1	13
Blood clot	1	13
High blood pressure	1	13

* Some patients gave >1 answer.
† Both valve patients.

Table 3. Patient responses to item 6: "*Please describe what your doctor will actually do when he or she performs the catheterization.*"

Patient	Response
1	**SUBJECT**: Well, she said they'll probably go in the wrist or the groin. And... the catheter... just look. As far as I know that's it. I don't know, I'm not familiar with it. ***INTERVIEWER**: That's ok. Any other parts of the process that was explained?* **SUBJECT**: I don't know.
2	Well... When they go, whether through the groin or the wrist, they, you know, they gonna see, you know, if there's any blockage, you know, they, they, they probably see--they will see all the other stents to see if they're working. If there's any blockage in them, you know. Things like that.
3	**SUBJECT**: Well, I think, I think they, before putting they put stents on my legs, and, uh, and I want--they want to put me to sleep, I guess. I mean, anesthesia. And, uh, they want to inject that thing through my groin up to, what do you call it, a catheter, I guess? And put the wire in there with a camera, I guess, with the arteries up into my heart. And inject some dye and check it out and see what's going on there. ***INTERVIEWER**: Ok* **SUBJECT**: And I don't know if they're going to go down my legs or not, for that part. I don't know if they're going to do that or not. Basically, I guess that's it.
4	Um, they'll be sticking a, uh, tube or a camera or whatever, into my--a tube into my main artery. Um, and putting dye into my heart so they can see how my heart is functioning on the screen.
5	**SUBJECT**: Um, well, we just talked about that. They're going to go... put an IV in a vein and an artery. And then they'll run a... thin wire in... and, uh, I'll be under x-ray. And they'll then check dye, and they will... look at the arteries and veins and see for narrowing. Um, then, I don't know how they're going to do it, but they said they'll take the pressures, look at the valve and take pressures in the heart and everything. So I assume that little wire has a, it's connected to instruments [laughs]. ***INTERVIEWER**: Ok.* **SUBJECT**: Probably a lot more technical than I did. But they want to look under x-ray, look at the dye to see if the arteries and veins are narrowed. Um... and get a better picture of the v--of the valve, how well it's working, and the pressures, and... I'm sure that y'all have charts that you go by and know exactly how good everything's going from getting all those readings.
6	He's going to put a... a tube, tinier than this one he said, into my leg. Well first they said in my arm, then they thought my leg was better. And then they're going to go up, and I'm going to feel a hot... flash or something. 'Til they get to wherever the blockage is.
7	Uh, I guess he's going into the groin, into the main artery, and they go in with a camera, and they use dye, uh, contrast that helps them, I guess, guide the camera to my heart, through the, through the main artery in my groin.
8	**SUBJECT**: From what I understand, they do a dye. ***INTERVIEWER**: Mmhmm.* **SUBJECT**: That shows that, if there's a blockage, any blockage. ***INTERVIEWER**: Ok. Um, so they use dye to see whether or not there's any blockages.* **SUBJECT**: Mmhmm, and god forbid there is, and they take care of that, fix it.

Table 4. Patient responses to item 10: "*If the results show you have blockage in an artery, what might be the next steps in your treatment?"*

Patient	Response
1	Whatever the doctor says [laughs]. I don't know. I don't know if it's surgery or not. I don't know all the steps to this.
2	Well, they could, they gonna put in a stent. Yeah.
3*	Well got back, I guess, and get a stent put in or something.
4	They'll probably put a stent in.
5*	Well, I guess, let's see, uh. I... That's up to the, you know, the doctors, but, uh, you know, there's always stents, uh... But more'n likely it'll be bypass surgery whenever they do the valve. When they do the valve they'll do bypass surgery. Just get it taken care of right then.
6*	Well they said if there is a blockage, they have to put a heart bypass.
7*	Well, I, uh, they said if there's a blockage then, and let them choose to try to do a stent. And if they can't fix it, if they didn't, then they would have to do bypass.
8	Well, a stent.

*Catheterization prior to aortic valve replacement, in which case "blockages" would be treated by coronary artery bypass grafting and not stent placement.

Table 5. Patient (n = 8) Summary Statistics for the *C4* Informed Consent Assessment Instrument.

Cardiac Catheterization Consent Assessment Question *	% Incorrect	% Partly Correct	% Correct	Mean (SD) Score
1. Symptoms you have for CC procedure	0	25.0	75.0	1.75 (0.46)
2. What doctor is trying to do with CC	25.0	37.5	37.5	1.13 (0.83)
3. Main reason doctor to perform CC	12.5	25.0	62.5	1.50 (0.76)
4. Do you have to have CC if you do not want	62.5	12.5	25.0	0.63 (0.92)
5. What are alternatives to having CC	87.5	0	12.5	0.25 (0.71)
6. What will doctor actually do when doing CC	0	50.0	50.0	1.50 (0.93)
7. Describe seriously harmful things could happen	12.5	50.0	37.5	1.25 (0.71)
8. Describe some ways you could be helped w/ CC	25	0	75.0	1.50 (0.93)
9. Possible your will not be helped by having CC	0	50.0	50.0	1.50 (0.53)
10. If artery blocked, what would be next steps	12.5	12.5	75.0	1.63 (0.74)
11. Post CC, for what symptoms should you call	25	37.5	37.5	1.13 (0.83)
Total Score **	23.9	27.2	48.9	13.75 (4.26)

* All questions scored 0 = fully incorrect; 1 = partly correct; 2 = fully correct.
See Figure 1 for fully worded questions.
** Total percent correct represents overall percent out of 22 possible points (SD).

Correlations of *C4* Items with *C4* Total Score and Subscale scores are in **Table 6**. Of these, most (9 of 11) items showed acceptable associations ($0.38 \leq r \leq 0.79$) with the overall 11 item score. Item 11 (concerning symptoms following procedure) was negatively correlated with both appreciation and reasoning subscales and C4 total score, and it was only lowly correlated with the understanding subscale. Item 3 (main reason

for your doctor to perform the catheterization) was correlated acceptably with the appreciation and understanding subscales but essentially not at all with the reasoning subscale and the overall score. However, one problem with the reasoning subscale is that is only a single item, and single items are well-known to typically have low reliability (36). Thus, correlations with the reasoning item are not necessarily good estimates of population values for this reason, which is compounded by the fact that the sample size is only 8 patients.

Calculation of Cronbach's α for the domains (**Table 7**) showed an acceptable level of internal consistency for measurements of understanding, and good consistency for appreciation (reasoning only had one item measuring the domain). Correlations for patient characteristics and total score are shown in **Table 8**. Of these, gender showed a very strong correlation with total score (r = 0.82), more so than education, ethnicity or age. Gender and education were modestly correlated (r = 0.47), but all women had a high school or equivalent education, and men represented both extremes of educational attainment (less than high school and bachelor's/professional degree).

Table 6. Correlations of *C4* Consent Assessment Items with C4 Total Score and C4 Subscales.

Domain	*C4* Assessment Question *	*C4* Total score	Understanding	Appreciation	Reasoning
Understanding	1. Symptoms you have for CC procedure	0.44	0.53	0.45	0.47
	3. Main reason doctor to perform CC	0.13	0.41	0.76*	-0.01
	7. Describe seriously harmful things could happen	0.72*	0.61	0.69	0.47
	8. Describe some ways you could be helped w/ CC	0.76*	0.78*	0.70	0.47
	11. Post CC, for what symptoms should you call	-0.38	0.27	-0.45	-0.65
Appreciation	4. Do you have to have CC if you do not want	0.79*	0.13	0.79*	0.87†
	5. What are alternatives to having CC	0.58	0.51	0.58	0.44
	6. What will doctor actually do when doing CC	0.66	0.51	0.66	0.46
	9. Possible your will not be helped by having CC	0.82*	0.28	0.83*	0.81*
	10. If artery blocked, what would be next steps	0.49	0.31	0.50	0.50
Reasoning	2. What doctor is trying to do with CC	0.89†	0.12	0.92†	1.00

*p<0.05 †p<0.01

Table 7. Internal Consistency of Total Score and Multi-item Subscales.

Domain	*Cronbach's α*
Understanding	0.66
Appreciation	0.76
Total 11-item Score	0.83

Table 8. Correlations Among Patient Characteristics and C4 Total Score.

Characteristic	*Total score*	*Education*
Education	0.39	--
Gender	0.82*	0.47
Ethnicity	-0.05	0.29
Age	-0.39	-0.31

*p<0.05

Patients rated their own understanding of CC on a scale from 0 = no understanding to 5 = moderate understanding to 10 = complete understanding). A comparison of patient self-rating their own understanding of CC and *C4* scores for patients is shown in **Table 9**. To facilitate comparison, *C4* scores are shown as percent correct, and patient self-ratings on the 0-10 scale were converted to a 0-100 scale to facilitate direct comparison to the % correct scale for *C4* objective scoring.

A moderate but not significant correlation (r = 0.37, p = 0.37) between patient self-scored understanding of CC and objective C4 score was found. A paired *t*-test of the mean self-score vs. objective C4 scores revealed that self-score was significantly higher than C4 score (t (7) = 2.88, p = 0.02; Cohen's d = 1.16).

Table 9. Comparison of Patient Self-ratings of CC Understanding with Objective C4 Scores for Understanding CC.

Patient	Self-score	C4 Score (%)	Difference
1	50	32	18
2	90	68	22
3	90	64	26
4	100	64	36
5	70	82	-12
6	85	41	44
7	85	91	-6
8	95	59	36
r = 0.37, p = 0.37			
Means* (SD)	83.13 (16.02)	62.62 (19.39)	20.50 (20.11)

*Cohen's d = 1.16, p < 0.02

Patient Semi-structured Interview

The themes resulting from qualitative analysis of the patient interviews are listed in the **Table 10**. Interviews with patients were ended after determining that thematic saturation had been reached.

Table 10. Themes from Patient Interviews (N = 8).

Theme	Codes
Communication	Communication difficulties Good communication Jargon use by doctors
Decision-making	Family involvement Freedom to decide Got to have it done Internet/prior reading Not really want procedure Pressure by others Prior experience/knowledge Trust in provider
Feelings	Discomfort Fear/anxiety Return to normalcy Unfamiliarity/uncertainty
Handling difficult situations	Physician emphasis of importance Physician obligation to patients Trust in provider
Purpose of consent discussion	Calming Information Legal Make sure patient wanted procedure
Suggestions for improvement	Better communication More information beforehand Visual aids

Communication did not emerge as a strong theme. Only one patient expressed communication difficulties with healthcare providers, and this mainly related to believing he received contradictory messages concerning the procedure. (This patient went for evaluation of CAD prior to valve surgery to see if bypass grafting would be performed with valve replacement.)

"[The first provider] told us they might put the stents in. And the doctor said they won't do that today. But it was pretty--there was something contradictory, you know?" (*Hispanic man, 64 years old)*

On the other hand, more patients mentioned good communication.

"He didn't try to use highly technical terms. And, uh, so uh, he did a very good job to try to make sure I knew what was going on." (*non-Hispanic white man, 52 years old*)

"He talked in language, uh, at my, my... education level or... medical education, I should say, you know?" (*non-Hispanic white man, 52 years old*)

"Well this one explained, I think, good." (*Hispanic woman, 70 years old*)

One patient in particular noted the use of medical jargon by providers in explaining CC:

> "And I think that's a lot of the problem, they don't explain it in English… They always throw in, it's a mixture of English and 'doctor.'" (*non-Hispanic white woman, 53 years old*)

Decision-making was a common theme in patient interviews, with several components. Regarding making the decision, however, few had done prior reading or Internet searching or had prior firsthand experience. A significant aspect of decision-making, which also overlapped with handling difficult situations, was trust in providers. Patients were explicitly asked: "Did you feel like you had a choice in deciding to be catheterized, or did you just go along with what the doctor recommended?" All patients indicated that they felt free to decide for themselves whether or not to undergo CC.

> "I mean, you can refuse any kind of treatment from a hospital. I mean, damn right, you know, which I have before." (*non-Hispanic white woman, 53 years old*).

However, even in stating they felt free to make their own decision regarding CC, most patients also said they "just went along with the doctor."

> "I went along with my doctor, but I did tell her I was afraid to have it done." (*Hispanic woman, 50 years old*)
>
> "I just went along with it. They said they want to, and I said 'ok.'" (*non-Hispanic white woman, 53 years old)*
>
> "I mean, the doctor recommended it, and I went along with it." (*non-Hispanic white man, 70 years old*)
>
> "The doctors know what's going on, so I'll go with that their opinion is. I'd trust the doctors." (*Hispanic man, 33 years old*)
>
> "I think that they know better than I do what's going on the heart…And I took their advice and here I am." (*Hispanic man, 64 years old*)

Several patients highlighted family involvement in the decision-making process, either directly or indirectly.

"[M]y family, all them insisted that I go through it to know... where the blockage, or whatever is wrong with my heart, or the artery, because they're afraid I might have a heart attack or something." (*Hispanic woman, 70 years old*)

"Well, my family, yes. They said, 'if you need it done, get it done so you can feel better.'" (*Hispanic woman, 50 years old*)

"I have my family with me, and they support me with it." (*non-Hispanic white woman, 50 years old*)

Although all patients explicitly denied feeling as though providers pressured them, several indicated family pressure played a role in the decision to undergo CC:

"They're the ones putting pressure on me. The doctors didn't. The two girls." (*non-Hispanic white man, 52 years old*)

"But my family are the ones that say, 'No, Mom, go through with it, go through with it.'" (*Hispanic woman, 70 years old*)

"My wife and kids, they're pushing me to do it." (*Hispanic man, 64 years old*)

Another component under the decision-making theme appeared to be that patients felt as though they had to have the procedure, for one reason or another (i.e., that there were not viable alternatives). This often went hand-in-hand with expressions of not really wanting the procedure, but not always. The latter primarily overlapped with family pressure mentioned above.

"How can I go on with those pains? I got to have it done, yeah." (*non-Hispanic white man, 70 years old*)

"I know I have to have [cardiac catheterization]." (*Hispanic man, 64 years old*)

"They know about the risk. I, and I gotta have the procedure anyway." (*non-Hispanic white man, 52 years old*)

"I'd rather them have a better look at my heart than not, you know? Yeah, so I think that it's a positive procedure prior to going into open heart surgery." (*Hispanic man, 33 years old*)

"If there are alternatives, I'd probably do that, because I don't want to do this. [laughs]" (*non-Hispanic white woman, 47 years old*)

"I didn't want it, to tell you the truth, because I feel ok." (*Hispanic woman, 70 years old*)

Patient feelings were also a significant theme during the interviews, and some degree of patient unfamiliarity/uncertainty was common among the codes, with five of eight patients (62.5%) expressing this emotion.

"Well, she said they'll probably go in the wrist or the groin. And... the catheter... just look. As far as I know that's it. I don't know, I'm not familiar with it." (*non-Hispanic white woman, 53 years old*)

"I don't know [laughs]. I'm not a doctor so I don't know [laughs]." (*non-Hispanic white woman, 53 years old*)

"I don't know anything about my heart." (*Hispanic man, 64 years old*)

"I probably should have questions, but probably my ignorance, or lack of knowledge, I should say, of medical procedures keep me from asking more questions." (*non-Hispanic white man, 52 years old*)

"Well, to tell you, like I said, I don't know what this is. And I can't explain what to expect." (*Hispanic woman, 70 years old*)

Patients also discussed fear and/or anxiety related to either the procedure itself, or the situations leading up to the procedure.

"Because to be left in a room, scared like that, it just builds up more fear and make the problem worse." (*non-Hispanic white woman, 53 years old*)

"And be where [I'm] fearful for passing out again somewhere else." (*Hispanic man, 64 years old*)

"I went along with my doctor, but I did tell her I was afraid to have it done." (*Hispanic woman, 50 years old*)

Two patients mentioned the hope for future symptom relief, in the form of a return to normalcy, which often influenced decision-making.

"I want to be able to do what I was doing, you know?" (*non-Hispanic white man, 70 years old*)

"[I want to] get back to my normal life again." (*Hispanic man, 64 years old*)

Regarding the purpose of the informed consent discussion and process, nearly all patients (7 of 8, 87.5%) stated that it was for the provision of information about the procedure to the patient.

"That they were letting me know what's going on, to happen, there, you know? That." (*Hispanic woman, 50 years old*)
"For me to know what they're gonna do." (*Hispanic woman, 70 years old*)
"To make sure that I really understood what was going on. Understood the risks. Um, and, was ready to, to go ahead with it." (*non-Hispanic white man, 52 years old*)
"To give me more knowledge." (*non-Hispanic white woman, 53 years old*)

Only one patient thought the purpose of the discussion was legal ("Liabilities, I imagine," Hispanic man, 64 years old). Two patients also said the purpose of the discussion was to ensure patient willingness to proceed with the procedure ("was ready to, to go ahead with it," non-Hispanic white man, 52 years old).

Patients were given the following scenario, and asked for responses:

> "Imagine you were in an emergency situation, and a provider thought that a given procedure would potentially be life-saving in your specific situation. You completely understood everything the provider said as far as benefits of the procedure, risks of the procedure, and so forth, but, for whatever reason, you said that you didn't want the procedure to be done. How OK is it, or is it OK at all, for the provider to apply pressure to you in order to get you to change your mind and let them do the procedure?"

Patient responses to this scenario, under the theme of handling difficult situations, fit under three main areas: physician emphasis of importance, physician obligation, and trust in providers.

> “Yeah, he, he would have to be... put pressure on then to have it done. Just so that he could, not-- to be clear with everyone that he did everything he could. I can't make 'em do it, but I tried. I did the best I could to make him, absolute clear to him, ‘you'd be a dead man if you don't.’” (*non-Hispanic man, 52 years old*)
>
> “And if it's a dangerous situation, then just be real with me, and, you know, how dangerous it is. If it's life-threatening or not. Or if I could go without it and then be fine or not.” (*Hispanic man, 33 years old*)
>
> “Well, I would appreciate them, I really would, explaining to me why it was, like, ‘you have to have this or you're gonna die.’” (*Hispanic woman, 50 years old*)

Interestingly, all patients (100%) expressed that providers should place pressure on patients in such a scenario, even invoking the Hippocratic oath:

> “If the doctor thinks there's concern it might kill me, then yeah, they should put on pressure to save a life.” (*non-Hispanic white woman, 53 years old*)
>
> “They take an oath for that. You know? And it kills them to lose a patient, I know that.” (*non-Hispanic white woman, 53 years old*)
>
> “That's the oath that they took and all in becoming a doctor. To help people.” (*non-Hispanic white man, 70 years old*)
>
> “I do believe they need to push the issue if it's a life-saving measure and you're not willing to do it.” (*non-Hispanic white woman, 47 years old*)
>
> “Yeah, he, he would have to be... put pressure on then to have it done. Just so that he could, not-- to be clear with everyone that he did everything he could. I can't make 'em do it, but I tried. I did the best I could to make him, absolute clear to him, ‘you'd be a dead man if you don't.’” (*non-Hispanic white man, 52 years old*)
>
> “[If] he firmly believes, he's obligated. Just for his own peace of mind.” (*non-Hispanic white man, 52 years old*)
>
> “I think that if something's going on, do everything you can.” (*Hispanic woman, 50 years old*)
>
> “And if it's a really, really bad, and they really, really think it's something that needs to be done, then they should, like, try to encourage me, at least let me know” (*Hispanic man, 33 years old*)

Trust in providers emerged as a theme in relation to both difficult situations (as the scenario above), as well as in the decision-making process for undergoing the present CC.

"Because if they have concerns then I should be concerned, because they're the ones that are knowledgeable about the medical field, not me." (*non-Hispanic white woman, 53 years old*)
"I think that they know better than I do what's going on the heart." (*Hispanic man, 64 years old*)
"The doctors know what's going on, so I'll go with that their opinion is." (*Hispanic man, 33 years old*)

Only a few patients made suggestions regarding improvement in the informed consent process, and their suggestions were: better communication (less jargon), more information beforehand, and using visual aids.

Provider Survey Data

The distribution of item responses for the provider is shown in **Table 11**. One respondent in the provider survey abstained from the following items: estimated probability of death due to CC, number of consent processes in the previous year and career, level (fellow or attending), gender, and years in practice. A different provider chose not to answer item 2 (most common harmful effects), but answered the other items listed.

Table 11. Provider (N=21) Survey Responses.

Provider Responses*	*f*	*%*
Total respondents	*21*	
Item 1: Main reason		
Diagnostic		
Diagnose CAD	12	57
Positive stress test	4	19
Cardiomyopathy	2	10
Therapeutic		
Chest pain/acute coronary syndrome	12	57
Explicitly for symptom relief	1	4.8
Item 2: Most common harmful effects†		
Bleeding/hematoma/vascular access	16	76
Renal damage	3	15
"Psychological stressor"	1	5
Item 3: Most serious harmful effect		
Stroke/embolic event	19	90
Bleeding	15	71
Renal damage	15	71
Myocardial infarction	10	48
Death	10	48
Vascular	6	29
Medication reaction (including dye)	4	19
Emergent surgery (including tamponade)	3	14
Infection	2	10
Radiation damage	2	10
In-stent restenosis	1	5
Item 5: Post CC concerning symptoms‡		
Access site (e.g., bruising, bleeding, pain, swelling)	29	
Chest pain or recurrent symptoms	18	
Shortness of breath	8	
Not urinating	3	
Back pain	3	
Fever/chills	2	
Hives/allergic reaction	1	
Nausea/vomiting	1	
Hypotension	1	
Neurologic symptoms		
"Stroke symptoms"	9	
Syncope/light-headed	3	
"Neuro dysfunction"	3	
Altered mental status	2	
Numbness/tingling	2	
Item 6: Diagnostic alternatives		
Non-invasive imaging without stress	12	
Coronary angiography via computed tomography	10	
Stress testing (treadmill, echocardiography, nuclear)	17	
Empiric medical management	4	
Item 7: Treatment alternatives		
Medical management	21	
Exercise/lifestyle modification	2	
Surgery	2	

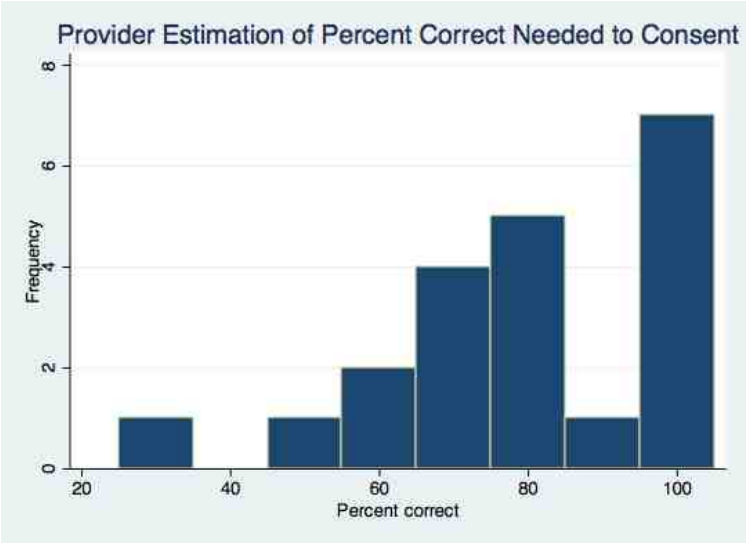
* Providers were able to provide ≥1 response.
† One provider did not answer item regarding most common harmful effects.
‡ Frequency only is shown because of overlapping answers given by the same provider (e.g., both bleeding and bruising listed as separate answers)

In item 4 of the survey, providers answered the following question:

> "If a patient was tested on his or her understanding of basic cardiac catheterization procedures and his or her appreciation of the related risks and benefits, what percent correct of informed consent-related questions should the patient answer correctly to be considered able to consent for the procedure?" [Underlines for emphasis included in the original survey.]

A frequency histogram of provider responses is shown in **Figure 2**. The mean percent correct was 79.1% (standard deviation 20.5, range 27-100%). Seventeen of 21 (81%) providers responded that the minimum percent correct in order to consent was 70% or higher.

Figure 2. Frequency Distribution of Provider Estimates of Percent Correct Questions that a Patient Must Answer to be Considered to have Capacity to Provide Consent for Cardiac Catheterization.



Items 8, 9, and 10 of the provider survey asked about the ethics of applying pressure in difficult situations on a 0-10 scale. Item 8 asked how ethical it was for providers to apply pressure to patients, item 9 about family applying pressure to patients, and item 9 about providers applying pressure to families. Summary statistics of these items are shown in **Table 12.**

Table 12. Mean (SD) Responses to Provider Questions Asking about Applying Pressure to Patients to Consent to Cardiac Catheterization.

Item	N	Mean*	SD
Provider to apply pressure to patient	21	5.24	3.53
Family to apply pressure to patient	18	5.94	3.28
Provider to apply pressure to family	21	3.29	3.78

*Higher mean values indicate greater ethical acceptability
*Maximum Cohen's *d* = 0.76

The means were subjected to a repeated measures ANOVA to compare the 3 items rating ethics of applying pressure to patients or family members by providers or by family members(see **Table 13**). The item itself had a modest effect on the score (η^2 = 0.078), representing providers as a whole may view these scenarios as different.

Table 13. Repeated Measures ANOVA Summary Table Comparing Mean Ratings of 3 Items Regarding Target (Patient vs. Family Member) of Pressure and Source (Provider vs. Family Member) of Providing Pressure on Patients to Consent to Cardiac Catheterization.

Effect	Partial SS	df	*F*	*p*	η^2
Question	62.26	2	7.69	0.002	0.08
Provider	569.29	20	7.03	<0.001	0.72
Model	644.99	22	7.24	<0.001	
Error	149.74	37			
Total	*794.73*	*59*			

Multiple comparisons among item ratings using Tukey's HSD post hoc tests are in **Table 14**. These show that mean ethical rating between the scenarios of provider applying pressure to patient is not significantly different from the ethical rating of family applying pressure to patient in order to convince a patient to have a procedure that the patient initially refused. However, providers consistently rated as less ethical the scenario of providers applying pressure to family members in order for patients to change their minds; this difference in rating was statistically significant both in comparison to the ethicalness of providers applying pressure directly to patients and family applying pressure directly to patients.

Table 14. Pairwise Contrasts Among the Items Rating the Ethics of Scenarios of Applying Pressure to Patients for Consenting to Cardiac Catheterization

Contrast	Means (pooled SD = 3.51)		Mean difference	Cohen's d	HSD t
Prov-pt vs Fam-pt	5.24	5.94	0.71	0.20	1.57
Prov-pt vs. Prov-fam	5.24	3.29	1.95	0.55	4.33*
Fam-pt vs. Prov-fam	5.94	3.29	2.66	0.76	5.89†

Prov-pt = provider pressures patient
Fam-pt = family pressures patient
Prov-fam = provider pressures family
*p=0.01 †p=0.001

Intercorrelations between the provider estimation of percent correct responses on a test of understanding and appreciation for a patient to be able to provide consent for CC, the number of consent processes performed in the provider's career and previous year, and the level of training (fellow or attending) are reported in **Table 15**. The number of consent processes conducted in the provider's career was correlated with the rated percent correct needed (r = 0.53), as did the provider level of training (r = 0.41), both indicating that attendings and more consent experienced providers expected patients to be able to answer more questions correctly to allow providing consent than did fellows or less experienced providers. The number of consent processes performed in the past year had a negative correlation with level of training (r = -0.52), indicating that fellows tend to perform more discussions in the previous year than attendings. This discrepancy may help explain the difference in correlation between expected percent correct between number of career discussions (r = 0.53), which may be more representative of attending views, and number of discussions in the past year (r = 0.07), which may represent the influence of fellow views.

Table 15. Intercorrelations Between Provider Rated Needed % Correct Responses on Consent Assessment Questions and Level of Provider Consent Experience and Level of Provider Training.

Measure	% Correct to Consent	Career	Last Year
Career consent processes	0.53	--	
Consent processes last year	0.07	-0.31	--
Level of training *	0.41	0.85	-0.52

*0 = fellow or 1 = attending; negative indicates more closely correlated with fellows

Provider Semi-structured Interview

Themes observed from the provider interviews are listed in **Table 16**.

Table 16. Themes from Provider Interviews.

Theme	Codes
Challenges	Applying pressure Emergent situations Refusing a procedure Time pressure
Expectations of patients	Ask questions Acknowledge right of refusal Be part of decision-making process Interest (in own health) Try not to expect much of patient Voice discomfort/not understanding
Feelings	Discomfort Superstition
Examining patient point of view	Confusion Legal purpose Patient expectations of providers Patient fear/anxiety Presumed to want treatment if sick Trust in provider
Pitfalls of informed consent	Information overload (Over)focusing on risks Using jargon
Purpose of informed consent	Medico-legal/*pro forma* Patient autonomy/patient decision-making Providing information
Technique	Big picture Empathy/understanding patient views Gauging patient Give time as possible Have patient explain I ask questions Imagery Plain language Role of family Tailoring to patient/scenario

Providers described their formative impressions of the informed consent process as during late medical school or during their intern year. All but one provider (86%) noted that the first exposure was practical, rather than a formalized lecture or didactics.

"Not...No formal, uh... No. It was sort of 'go consent Mr. S for a procedure.' Why? Some of the better residents, I think, did have me tag along when they would be doing that, but it certainly wasn't universal. It was never part of my training where I was actually taught how to obtain informed consent." (*Fellow*)

"I think I watched [as an intern], I was following my resident for one of them, then I started doing them by myself." (*Fellow*)

"But probably going in and anticipating doing or assisting with a procedure, an LP or a paracentesis. Ah, my intern or resident would tell me we need to do an informed consent and I would watch them do it." (*Attending*)

Commonly, providers described their initial impression of the purpose of informed consent as either medico-legal or *pro forma* in nature, but some also described an initial understanding of using the process as a method for information delivery.

"I felt like it was mostly legal… if something goes wrong, you agree to it, so it won't be my fault kind of thing." (*Fellow*)

"Focus was on you have to have a signature, a witness, a form. Or that was at least my feeling as a… junior medical student…[The] drive behind talking about an informed consent was driven, was sort of medico-legal." (*Fellow*)

"So it was explained to me as trying to get the patient to agree to do the procedure. And it's mainly trying to explain to them what we want to do." (*Fellow*)

"[The purpose] is that the patient should know what they're signing up for. Know the risks and benefits and be able to decide after hearing from the person that's going to do the procedure if they want to go through with it." (*Attending*)

"[The purpose is] so the patients can have as much, I guess, information to allay their fears, concerns, etc., in that peri-procedural period." (*Attending*)

Most providers indicated that they were uncomfortable during their first attempts at obtaining informed consent for procedures, driven in varying degrees by concern about lack of knowledge, or even guilt regarding a perceived lack of transparency in not explaining their newness as a trainee to patients.

"I never felt comfortable [when getting a consent from a patient]." (*Fellow*)

"I do remember a vague sense of dread." (*Fellow*)

"I think at least [during] those initial ones, there was certainly some anxiety." (*Attending*)

"I think I was bringing a lot of my 'hey, I'm a first-timer," and I never disclosed that to my patients. And I also felt guilty about that." (*Fellow*)

Providers who had several years' experience in obtaining consent for interventions and reported being more comfortable in their role, described a more nuanced purpose of the informed consent discussion. Fellows and attendings gave less attention to potential medico-legal reasons, but more emphasis on patient-centric ideals, such as providing information and allowing patient autonomy.

"I think now is to make sure that the patient, in broad terms, they know what their getting into. They know what to expect. Not just what to expect with the procedure. First we're going to be doing this. Next we're going to be doing that. But really understanding...why I think this procedure would be a good thing, certainly if we're recommending it to them. Um, as well as making sure they understand what the potential risks are. Not only, not only why we're doing it or why we think this is important, but what are the potential bad things that can happen. Make sure that they understand, specific to them, these are the things that might go wrong. What are the chances that's going to go wrong? And make sure they understand that there's always more than one way to do things. Make sure they understand what the alternatives are." (*Attending*)

"[The purpose] is that the patient should know what they're signing up for. Know the risks and benefits and be able to decide after hearing from the person that's going to do the procedure if they want to go through with it." (*Attending*)

"It's to provide the patient with...an adequate level of information for them to at least understand what a procedure involves, and why it's being recommended, and what could go wrong." (*Fellow*)

"I think informed consent, as it implies, the reason you get it is because you want to make sure your patient really understands what is going to be done to them, and why." (*Fellow*)

"But I think overall is...um, patient autonomy and us...you know, uh, doing our job in terms of telling them 'this is what we recommend. Here are your options.'" (*Fellow*)

Despite this, providers also frequently depicted the consent process as a *pro forma* maneuver. "As long as the [consent] form is signed" one may proceed with the

procedure, suggesting low concern for actually gaining true informed consent from patients. This attitude occurred more frequently in dealing with urgencies or emergencies, in which providers believed the benefits of CC significantly outweighed the risks.

> "These are the benefits, these are the things that can go wrong. You have questions? What do you think? You agree? Sign." (*Fellow*)
>
> "For a simple, straightforward, "Don't worry, you're risks are...I can't even see them, they're so low. You, know, your benefits are up here. I can save your life. Save your heart, it will go back to normal. You're going to go back to a normal life." I don't care if the guy understands what a catheter is, or, you know, who cares? Let me just take care of it. Sign right here, please." (*Fellow*)
>
> "But I think it depends on how indicated I think the procedure is. Somebody's coming in with a STEMI, you know, and I think that I can really impact their life. Um... You know, I'm probably going to take their face-value signature as consent." (*Attending*)

However, providers described mixed attitudes regarding the application of pressure on patients who had initially refused a procedure, even if the provider felt that procedure would be potentially life-saving. Providers frequently dealt with this by emphasizing the importance of the procedure, and by ensuring the patient gave a "hard no" (which was not necessarily seen as applying pressure). Some providers also described the role of having the patient's family apply pressure in these circumstances.

"You know, you don't, you try not to force something upon... that's not clear." (*Fellow*)

"I don't think it's OK to put pressure on the patient." (*Fellow*)

"I feel that it's really an abuse of our power to coerce people into doing something that they're apprehensive of. You know, as a result I've, you know, I've sat on some STEMIs, and I've watched people be medically managed through large MIs, and I've felt bad about it throughout." (*Fellow*)

"Pressure is, uh...meh...it's a difficult word, I think, to use in consenting process. Ah, but... I have to think of what you're trying to say. Um...[sigh] I think that pressure would equal...um... detailed explanation." (*Fellow*)

"I think I would put a moderate amount of pressure, but not because I would pressure them to say 'yes,' but because I just want to make sure that they understand what they're saying no to. So I would say that I probably do put a little bit of pressure on them." (*Attending*)

"I make sure the family knows and the patient knows that the patient is the boss. And we don't want to talk him into doing anything that he doesn't want to do. But they're ultimately the ones that make that decision." (*Attending*)

"If there's some dynamic there that a family member is able to convince a patient to do something that I pretty firmly believe in, as long as the patient agrees, I would call that consent." (*Attending*)

"I've... resorted to family members, or I have not interfered with family members pressuring patients." (*Fellow*)

"Honestly, we did. We try to do that [apply pressure]. We try to, to talk to them in a heart cath multiple times. It's, uh... I don't know if it's right or wrong, but in that situation when your clear medical judgment is cath, I think it's probably appropriate to try to convince the patient and show them, make sure they understand that they're probably making a wrong decision in refusing a heart cath. Unless they have a clear, you know, contraindication that's reasonable." (*Fellow*)

These notions dovetail with the abbreviated process of informed consent in emergent situations.

“I think that the informed consent receives a little bit of short shrift in that situation, because I think that, and this is probably a little paternalistic, but I think that I don't want them perseverating over potential complications, including renal insufficiency, contrast reaction, etc., because the risk of not opening up a proximal LAD is tremendous.” (*Fellow*)
“I could care less about getting a signature. And say, "You're having a heart attack, we need to take you to the cath lab right now, you're unstable. Can you sign here for me to help you?" (*Fellow*)
“When we're consenting, um, in a STEMI situation, I literally spend about 4 minutes doing in. I'm trying to do it as quickly as possible.” (*Fellow*)

Common shortcomings in the informed consent process, as depicted by providers, included “information overload” for the patients, which also went with over focusing on risks. This proved to be a uniform theme among providers. Most providers felt they performed well in avoiding use of medical jargon in discussing medical issues with patients, but they also acknowledged this as a potential cause for concern.

"I would imagine that it's extraordinarily difficult for a patient to grapple even with a relatively minor new diagnosis. And then, by the way, this minor new diagnosis means you need to have a major or minor medical procedure, and the procedure can cause 27 things, including heart attack, stroke, death." (*Fellow*)

"A lot. A lot. A great deal of information in a short period of time, especially in an urgent situation. But, you know, ah, it's a lot of information." (*Fellow*)

"They need to understand that I cannot give them the 100th possible side effect of a medication or the 100th possible poor outcome of a procedure. There is just not enough time in the year to be able to do that." (*Attending*)

"You know, do I need to tell every single person when I have a wire in their artery, or in their LV, they may have PVCs? You know, that's, I suspect that that's going to launch into--if they're really interested--that's going to launch into a side discussion of the importance of PVCs, right?" (*Attending*)

"Rate of information administration. If they're just...vomiting, uh, large amounts of, uh, information, giving the patient way too much information to handle all at once." (*Attending*)

"I don't know that it helps them any to go through a laundry list of possible complications that are very anatomic and very medical terminology-wise." (*Attending*)

"So more information is probably not as helpful as repetition and trying to simplify our message into a very concise thing that they could tell someone on the telephone in 3 minutes." (*Fellow*)

"But I think that it is important to tell people what the potential benefits are. Because we tend to get caught up in the all the risks, and I think that's why patients tend to think it's more of a legal document than a consent." (*Attending*)

Providers expressed expectations of the patient entering into the informed consent discussion. Most providers expected the patient to at least show some level of interest in the patient's own health. Many also expected the patient to ask questions during the process, and perhaps explicitly to acknowledge whether or not they understood what was being discussed. Two providers stated that they did not expect much of patients, in part because their experiences in previous consent situations had been disappointing regarding patient efforts to be actively involved.

"I think the most basic is that they will…listen, and be engaged. (*Fellow*)

"Some degree of interest. However minimal." (*Fellow*)

"We expect people to be interested in what's going on with them." (*Attending*)

"I mean, I'm expecting the patient to ask questions… Um, and I'm expecting patients to ask me about, uh, complications and alternatives." (*Fellow*)

"I want them to be understanding [*sic*], and try to ask questions if they don't understand it." (*Fellow*)

"They have the responsibility to ask questions or say 'no, I don't understand' when I ask them if they understand." (*Attending*)

"I don't expect them to [ask questions], just because a lot of the time they don't." (*Attending*)

"I'm trying not to have expectations, because most of the time they're just trashed [laughs]. It's like, yeah, well, I expect you to take your medications. I expect you to follow things." (*Fellow*)

Several providers described the technique they use in conducting the informed consent discussion. Common areas including discussing the "big picture" of what is to happen, asking questions of the patient and/or having the patient explain the procedure (and risks, benefits, etc.). Imagery and plain language (not medical jargon) were emphasized. Providers frequently depicted the ability to gauge patient understanding as being integral to the process, with methods such as observing patient body language (such as "just nodding along"), whether or not a patient asks questions at all, and eliciting patient explanations of the procedure.

To ascertain issues from the patient's point of view, providers outlined several areas. Among these was asking a patient about their understanding of the purpose of the informed consent discussion (information, legal) and the CC procedure itself. Other points of emphasis by providers were: (1) the role of the provider in explaining CC and

its risks and benefits well, (2) being sure always to have patient's best interest in mind, and (3) to carefully observe patients' possible confusion and/or fear or anxiety.

"They feel it's like, the doctors made the decision about what to do, or what's best for them, and they're just getting information about what's going to be done." (*Fellow*)

"[He or she] feels that we're just pretty much informing them that's what needs to be done." (*Fellow*)

"To give them an idea of what to expect." (*Attending*)

"Well, they just want me to sign this so I can't do anything if I have a bad outcome." (*Attending*)

"But I think if I was a patient, I would wonder why they are doing this. If I need this, why are they having me sign the piece of paper? It sounds like they're trying to protect themselves." (*Fellow*)

"I think they perceive it as another thing that I have to sign." (*Attending*)

"I would hope that patients' expectation would be that the doctor would be interested, compassionate, honest, and would convey the right amount of information for that situations about why something is being done, what could happen, and what the benefit would be." (*Fellow*)

"The other side of it is for any heart procedure, or any medical procedure, I think patients are at a huge disadvantage. They're scared, they're vulnerable, they're ill." (*Fellow*)

"Because sometimes they, you know, obviously it's a chaotic time, they're scared, they may only hear just about complications." (*Attending*)

Interestingly, some providers appeared to hold a somewhat superstitious outlook on the informed consent process. The underlying notion is that conducting a poor discussion, or taking a patient for a procedure who did not really understand or want it (but nonetheless "signed the form") may "set one up" to have a complication or bad outcome.

"Once you cross that line in which you're pulling [the patient into the procedure]...you know it's not 100%, you know that person didn't feel that the wanted to do it, and you're setting yourself up for bad outcomes." (*Fellow*)

"But, you know, those are the patients that I really want to make sure [laughs] that they want to do it. Because it seems like, coincidence or not, those are the patients that can have problems, or seem like they more frequently have problems." (*Attending*)

"Not necessarily that the patient is going to do poorly, because you might save that, you know, myocardium, but the patient is not going to be happy with it. Um... Things are going to come up, you know. Chest pain that's never going to go away and it was your fault because you put that stent in there. So...I don't know. Again, it hasn't happened to me very frequently because most people are just in need of getting something taken care of right away and are just agreeable, but I can see a situation like that going real bad." (*Fellow*)

Comparing Provider and Patient Perspectives

When providers gave the minimum percent score acceptable for a patient to be able to provide informed consent, over three-fourths (81%) gave 70% correct or above as the cutoff. A patient scoring less than this may not be considered adequately informed in order to provide the consent. Using 70% as the criterion, then, only two patients (25%) met the providers' level minimal acceptable level of understanding and appreciation on the C4 instrument.

Most patients (88%) described a diagnostic purpose as the main reason to undergo their cardiac catheterization, either to look for "blockages" or examine heart valves. Only one patient (13%) depicted the main reason as potentially therapeutic ("to save my life"). When asked the open-ended question of "what is(are) the main reason(s) for patients to undergo cardiac catheterization?", without any specific scenario delineated, most providers (86%) also chose diagnostic purposes, including diagnosing CAD (either directly listing this, or as a consequence of prior positive imaging or as an etiology of a cardiomyopathy). As this question was open, many providers listed more than one "main reason," and a majority (57%) also chose a therapeutic reason listed in

the context of a scenario (e.g., revascularization in the setting of acute coronary syndrome).

Table 17 shows a comparison of patient and provider responses for items on possible harmful effects.

Table 17. Comparison of Provider and Patient Responses for Harmful Effects of CC

Provider Response	**Frequency**	**Patient Response**	**Frequency (n=8)**
Most common (n=20)		Death	5 (63%)
Bleeding/hematoma/vascular access	16 (76%)	Stroke	4 (50%)
Renal damage	3 (15%)	Heart attack	4 (50%)
"Psychological stressor"	1 (5%)	Reaction to dye	1 (13%)
		Blood clot	2 (25%)
Most serious (n=21)		I don't know	1 (13%)
Stroke/embolic event	19 (90%)		
Bleeding	15 (71%)		
Renal damage	15 (71%)		
Myocardial infarction	10 (48%)		
Death	10 (48%)		
Vascular	6 (29%)		
Medication reaction	4 (19%)		
Emergent surgery	3 (14%)		
Infection	2 (10%)		
Radiation damage	2 (10%)		
In-stent restenosis	1 (5%)		

None of the providers' stated most common risks were patient stated risks of CC. However, half the patients listed stroke as a harmful effect of CC, which nearly all providers (90%) stated as one of the most serious risks. Nearly half of providers (48%) listed death and myocardial infarction as among the more serious risks of CC, and most patients also reported death (63%) and half heart attack (50%).

Symptoms that patients should watch for following CC are compared in **Table 18**. Patient and providers overlapped in the two most popular responses (access site complications and chest pain), although in both cases only a minority of patients described these symptoms. Although neurologic symptoms were popular among

providers, only a quarter of patients listed neurologic issues. Twenty-five percent of patients responded "I don't know."

Table 18. Comparison of Provider and Patient Responses for Concerning Symptoms after CC.

Provider Response (n=21)	**Frequency***	**Patient Response (n=8)**	**Frequency (%)**
Access site (e.g., bruising, bleeding, pain, swelling)	29	Chest pain/heart attack	3 (37.5%)
Chest pain or recurrent symptoms	18	Access site (bleeding, swelling)	3 (37.5%)
Shortness of breath	8	Stroke symptoms	2 (25%)
Not urinating	3	Fever/infection	2 (25%)
Back pain	3	I don't know	2 (25%)
Fever/chills	2	Shortness of breath	1 (12.5%)
Hives/allergic reaction	1	Blood clot	1 (12.5%)
Nausea/vomiting	1	High blood pressure	1 (12.5%)
Hypotension	1		
Neurologic symptoms			
"Stroke symptoms"	9		
Syncope/light-headed	3		
"Neuro dysfunction"	3		
Altered mental status	2		
Numbness/tingling	2		

*Frequency only is shown because of overlapping answers given by the same provider (e.g., both bleeding and bruising listed as separate answers).

Providers gave several alternatives to CC, both for diagnostic and treatment, whereas patients gave almost none (**Table 19**).

Table 19. Comparison of Provider and Patient Responses for Alternatives to CC.

Provider Response (n-21)	**Frequency**	**Patient Response (n=8)**	**Frequency**
Diagnostic alternatives		I don't know	7 (87.5%)
Non-invasive imaging without stress	12 (57%)	Ultrasounds	1 (12.5%)
Coronary angiography via CT	10 (48%)		
Stress testing (treadmill, echocardiogram, nuclear)	17 (81%)		
Empiric medical management	4 (19%)		
Treatment alternatives			
Medical management	21 (100%)		
Exercise/lifestyle modification	2 (10%)		
Surgery	2 (10%)		

Discussion

This study has elucidated several important aspects of the informed consent process for cardiac catheterization (CC) from the perspectives of both patients and providers. In doing so, it helps fill a gap in the literature, not only in directly comparing patient and provider views, but also in understanding a vulnerable patient population.

The new Capacity to Consent for Cardiac Catheterization (*C4*) instrument provides reliable data as evidenced by its internal consistency estimate. The *C4* also shows early evidence of validity as demonstrated by its correlations with educational level and patient age. Measures of the subdomains of informed consent tested (understanding, appreciation, and reasoning) and intercorrelations among these domains, also suggest the construct validity with the small sample of pilot data. This instrument thus has promise to provide objective measurements of patient understanding and appreciation of CC, which providers often have trouble measuring. The *C4* instrument now needs to be used to gather data with a larger sample of patients that will enable full psychometric evaluation of the reliability and validity of the measures.

Regarding patient demographics and performance on the C4, gender by far was the highest correlated measure ($r = 0.82$), which reached statistical significance even with this small sample size. However, a great deal of caution in interpreting this significance more broadly owes to the fact that all women in this sample had a high school education or equivalent, whereas men had education that stretched from not completing high school to a professional degree.

By the criterion identified by providers, most patients in this study (75%) did not qualify as meeting the minimal threshold of understanding and appreciation of CC to provide informed consent. By the time patients had completed the CC informed consent C4 assessment, the full CC informed consent discussion had already taken place, and all patients had formally signed consent for the procedure to continue. Nevertheless, all

studied patients subsequently underwent CC. This discrepancy may be due to differences in the clinical judgment of providers at the time of the consent discussion versus consideration of a more abstract scenario. Another interpretation may also be that providers consistently overestimate patients' understanding and appreciation of CC in practice. Still, this discrepancy within an institution is evidence of a more nuanced view of informed consent than is afforded by this study.

Regarding the application of pressure, providers rated applying pressure to families to influence a patient's decision to undergo CC as less ethical than providers applying pressure to patients directly, or family applying pressure to patients. Interestingly, this finding is in contradiction to what many providers described in interviews, which show more willingness to involve family in these difficult situations. Such inconsistency may owe to the idiosyncrasies among providers interviewed, a subsample of those surveyed who directly participate in performing CC. The contradictory attitudes seen from surveys with interviews also align with an issue elucidated during the interviews that, so long as the consent form is signed, providers are typically willing to perform CC, almost regardless of the circumstances of signing and lingering doubts. In contrast to providers, all patients thought that providers should apply pressure in such circumstances, should they initially refuse to undergo a procedure that providers feel would be beneficial. In fact, two patients invoked the Hippocratic oath in detailing providers' obligations to patients in emergent situations.

The literature specifically examining patient perspectives on CC is limited. One such study (21) showed patients underestimate the risks involved, and this study does similarly. This is also in keeping with clinical informed consent studies for other medical procedures, in which patients have difficulty enumerating risks of the procedure (37). Several providers described concern regarding "information overload," with a particular emphasis on "over focusing" on the risks, rather than the potential benefits of the

procedure. Providers must therefore maintain a careful balance in disclosure of the most germane “material risks” (38) necessary to be adequately informed about the procedure, without simply listing an inordinate number of risks that have been described in the literature (including case reports). In this survey providers consistently described similar “most common” and “most serious” potential risks as is found in wider patient information publications (39): bleeding/hematoma, damage from contrast, stroke, myocardial infarction, need for emergent surgery, and death. Although not listed, a description of common sensations (e.g., soreness at the access site) in addition to such a brief list of most common and most serious effects may give providers a consistent common starting ground on which to tailor individualized discussions.

In describing their decision-making process, patients made the contradictory claims to feel freedom of choice in deciding whether or not to undergo CC, while at the same time expressing a tendency to go along with the recommendations of the provider. Despite feeling free, the patients interviewed did not display a careful weighing of risks and benefits of the procedure in order to make the decision. Instead, they emphasized the recommendations of their providers in the context of personal goals (e.g., a return to normalcy), and they also portrayed a sizable influence of family members (often superseding their own personal interests), as well as often stating they felt as though they “had to have” the procedure. This type of decision-making appears to be more emotional than rational, and tied to the trust patients have in their providers. The informed consent discussion, as interpreted by patients, served as more of an information delivery construct than an attempt at actively involving patients in the decision-making process. Such an attitude may fit well with provider attitudes about the consent process in the emergent setting, when time pressure plays a large role in ensuring patients receive the best care possible. In these cases, providers describe

giving informed consent “a short shrift,” with the focus on getting patients to the catheterization laboratory as quickly as possible.

Furthermore, informed consent discussion itself appears to have a diminished role compared to other influences on decision-making (including apparent emotional rather than rational judgments). This may help explain the low scores on the C4 instrument, as well as the discrepancy between the high self-rated (subjective) scores by patients and their lower scores on the objectively scored C4. That is, because patients may have felt as though they had enough information to make a decision, the structured information provided during the consent discussion did not influence this significantly and the specific risks and so forth outlined in the discussion made less of an impression. In other words, because patients tend to feel the procedure is more a necessity than a choice, encouraged by family and trusting in their providers, the consent discussion before the procedure may have little influence on patient decisions. This finding is not unique to this study, as other qualitative studies on patient decision-making have also found similar reasoning (40).

Despite provider admissions of significantly abbreviating the consent process in emergencies, providers do express a commitment to ensuring that patients were adequately informed about CC. All providers described at least one technique for gauging how well patients understood the information being presented. These methods included asking patient questions and having them explain the procedure and associated benefits and risks, and paying close attention to patient body language. However, the finding that most patients did not qualify as being adequately informed, as judged by scores less than 70% on the *C4* instrument, is contradictory to the commitment to informed consent expressed by providers. Curiously, some providers had an almost superstitious outlook regarding adequately informing patients: that they are

more likely to have a “bad outcome” with a patient who does not give “appropriate” informed consent.

This study highlights several tensions inherent in the notion of informed consent in clinical practice as currently understood. Informed consent is predicated upon patients making a rational decision in the best interest of their health (2, 41). However, this consent paradigm may not be as valid in the clinical setting, where individual patient choices may be constrained by outside influences (5). Others have ascertained that the consent discussion does not necessarily play a large role in patient decisions to undergo a procedure (40). This study has similar implications, and the finding that trust in providers played a large factor in deciding to undergo CC has precedence in other medical fields (42-44). Based on these patient responses, this “entrustment model” of informed consent (42, 43), which also depends on providers being transparent in their thought processes (43, 45), may be more relevant to the population studied herein rather than the more rational patient autonomy model that is emphasized in informed consent in research situations. In addition, the entrustment model seems to offer a bridge in understanding the tension displayed between beneficence and autonomy in the emergent setting (46) with which providers interviewed consistently struggled.

The limitations of this study are several. First, this is a single-site pilot study looking at small samples of providers and patients served by the University of New Mexico Hospital, and although some findings of this study integrate well with the existing literature, applicability to other institutions or populations may be limited. The providers’ degree or composition of prior training in the process of informed consent is unknown, and may have had an impact on the quality of consent. Although this study did not investigate inter-provider variability, having a variety of providers involved attempted to mitigate this factor. At this institution, there is currently no method of validating the quality of those involved in obtaining consent or in training junior providers to do so.

Further, consent discussions were not recorded in this study, and thus their quality cannot be assessed. The length and quality of the provider-patient CC informed consent discussions may have varied widely. In previous studies, total consent time served as an important predictor of understanding (47), and time involved may have influenced patient understanding in this study. Specific providers involved in the consent process of the patients studied were not interviewed. Lastly, this study may have a selection bias in only interviewing patients who had provided consent. The current rate of refusal to undergo CC at this institution is unknown.

This study also provides the groundwork for additional investigations in on informed consent procedures and processes for cardiac catheterization. Extension of this method into non-English speaking populations might yield further insight into this very vulnerable patient population, including influences on decision-making as well as measuring capacity for consent. At the University of New Mexico, several providers have Spanish as their primary language, and the effects of this (versus use of interpreter) on capacity may also be assessed in future studies. Provider interviews to elicit comfort with non-English speakers and receiving informed consent may also prove useful in developing methods to overcome these obstacles. The information gathered from patient interviews in this study can be used to influence patient understanding and appreciation of the risks, benefits, and alternatives for cardiac catheterization and to inform providers to help them engage in improved informed consent procedures. For example, using methods geared more toward emotional understanding than a listing of rational facts may help providers better inform their CC patients. The Capacity to Consent for Cardiac Catheterization instrument developed for this study can serve as an objective measurement to evaluate methods of improving patient capacity specifically for CC.

List of Appendices

Appendix 1
Provider Survey of Knowledge and Beliefs
about Informed Consent for Cardiac Catheterization

Instructions: Please provide your best estimate to each question below. Please do not put your name or other identifiers on this survey. The survey should take about 5 to 10 minutes to complete.

1. What is(are) the main reason(s) for patients to undergo cardiac catheterization?

_____

2. What is the most common serious harmful effect on patients from cardiac catheterization?

_____

3. What are the 4 most serious harmful effects from cardiac catheterization that you want patients to know and appreciate?

a. _____

b. _____

c. _____

d. _____

4. If a patient was tested on his or her understanding of basic cardiac catheterization procedures and his or her appreciation of the related risks and benefits, what percent correct of informed consent-related questions should the patient answer correctly to be considered able to consent for the procedure?

_____ percent correct

5. After a patient undergoes cardiac catheterization, what are the 4 most medically concerning symptoms that should prompt the patient to call their doctor?

a. _____
b. _____
c. _____
d. _____

6. If the patient chooses not to undergo cardiac catheterization, what are the alternatives in diagnosing the patient's condition that you want to get across to the patients?

_____

7. If the patient chooses not to undergo cardiac catheterization, what are the alternatives in treating the patient's condition that you want the patient to know about?

Please go to page 2 for just a few more questions . . . .

Assume as the treating physician, you confidently believe that a specific patient would best be treated or diagnosed by cardiac catheterization:

8. How ethical is it for you to apply moderate pressure to convince a patient to consent for the procedure who initially declined consent for the procedure?

0	1	2	3	4	5	6	7	8	9	10
Not at all Ethical					Moderately ethical					Completely ethical

9. How ethical is it for the patient's family members to apply moderate pressure to convince a patient to consent for the procedure who initially declined consent for the procedure?

0	1	2	3	4	5	6	7	8	9	10
Not at all Ethical					Moderately ethical					Completely ethical

10. How ethical is it for you to apply moderate pressure to a patient's family members to convince the patient to consent for the procedure when the patient initially declined consent for the procedure?

0	1	2	3	4	5	6	7	8	9	10
Not at all Ethical					Moderately ethical					Completely ethical

11. In general, what is your best estimate of the probability that a patient will experience a serious adverse event when having a cardiac catheterization (we realize, of course, that the probability of serious adverse events is dependent on patient's specific medical condition)?

_____ % probability that a serious adverse event will occur

_____ % probability of death as a result

12. Please provide your best estimate of the number of patients for which YOU personally have conducted consent procedures for cardiac catheterization.

_____ number of patients during my career (best estimate please)

_____ number of patients in the past 12 months (best estimate please)

13. What is your current level of training?

__ attending cardiologist __ cardiology fellow __ resident physician

14. What is your gender? __ male __ female

15. How many years of clinical practice after training have you completed?
_____ years experience

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