

Ragini Vilavali adorning herself for her lover. Deccani, circa 1790 A.D. Reproduced by the courtesy of Mrs. Meenakshi R. Virani.

*Incorporating visual aids  
enhances the informed consent  
process for some people.*

## Educational Intervention for Women Undergoing Image-Guided Breast Biopsy: Results of a Randomized Clinical Trial

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**Background:** *The process of informed consent has been examined for patients undergoing various procedures but not breast biopsy. Our study was a randomized trial that examined the effect of an educational flip chart as part of the informed consent.*

**Methods:** *A total of 122 patients referred for stereotactic or ultrasound-guided core breast biopsy were randomly assigned to receive an informed consent discussion with or without an illustrated flip chart. The chart included information about breast anatomy, pathology, and diagnostic procedures. Outcome measures included objective knowledge, subjective knowledge, anxiety, and satisfaction.*

**Results:** *Analysis showed few significant main effects of the intervention. However, results showed interactions between experimental condition and race/ethnicity, indicating that the intervention was effective in enhancing objective and subjective knowledge for African American but not Caucasian patients. Anxiety after consultation was higher among patients assigned to the flip chart condition, possibly because they were better informed about the risks of the procedure. Patients who underwent biopsy sooner after learning they needed one were more satisfied with their care.*

**Conclusions:** *The usual care consent process is effective for many but not all patients. Informed consent that employs visual aids may help overcome characteristics of the consent process that are ineffective for some patients.*

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**Abbreviations used in this paper:** Group 1 = patients assigned to flip chart educational intervention, Group 2 = patients assigned to usual care control condition.

## Introduction

For many women, the experience of breast cancer begins with suspicious findings on a standard screening procedure and, if the suspicions are not ruled out, with a biopsy.<sup>1</sup> The results of most breast biopsies are benign,<sup>2,3</sup> but the procedure can be emotionally distressing,<sup>4,8</sup> not only because of the possibility of a cancer diagnosis,<sup>4,5</sup> but also because the biopsy itself is a potentially painful, invasive medical procedure.<sup>4</sup> Also, patients undergoing biopsy are presented with new medical information to assimilate.<sup>4,8</sup> This information includes description of the procedure and its associated risks, and it may include terms or medical concepts that are unfamiliar to some patients.

This information is typically presented during an unstructured verbal encounter between the provider and the patient, and it is documented with a signed consent statement. This traditional method of consenting patients has been examined for patients undergoing adjuvant cancer treatment,<sup>9,10</sup> cancer research,<sup>11,12</sup> and cancer-related screening procedures.<sup>13-15</sup> However, we identified no studies that examined informed consent for patients undergoing breast biopsy, despite the prevalence of the procedures.

In general, studies of consent have revealed deficiencies in the consent process, including poor understanding of the consent form,<sup>9</sup> poor recall of discussion of side effects of treatment,<sup>10</sup> and inadequate discussion of the limits of medical testing.<sup>13</sup> Research has also shown that patients may have literacy levels below that at which consent forms are written.<sup>14,16-18</sup> This problem of low literacy is exacerbated by the fact that health literacy may be lower than an individual's general literacy level.<sup>19</sup> This is especially important to the issue of health disparities because lack of adequate literacy is twice as high among inner-city minorities.<sup>19</sup>

Ensuring that patients understand the risks and benefits of breast biopsy is important for ethical reasons,<sup>20</sup> especially given recent emphasis on reducing the interval between detection and diagnosis.<sup>21-23</sup> This interval is a period of severe anxiety for some patients,<sup>24</sup> and reducing it might alleviate their distress.<sup>25</sup> However, it might also infringe on the patient's right to a thorough discussion of options regarding biopsy, a discussion necessary to informed consent.<sup>25</sup>

The current study examined the effect of an educational intervention used during the informed consent discussion for women referred for breast biopsy. The study fits within the framework of the Donabedian model of quality of care assessment, in which "quality assessment is a judgment on the process of care delivered by practitioners" and in which *process* is most easily inferred by examining relevant patient outcomes.<sup>26</sup> For the current study, the relevant outcomes are patients' understanding of the procedure, anxiety, and

satisfaction with care. We hypothesized that patients assigned to receive the educational intervention would demonstrate better objective and subjective knowledge, less anxiety, and better satisfaction with their care. Based on previous research regarding education interventions in this population, we also speculated that the intervention might be differentially effective for Caucasian and African American patients.<sup>27</sup>

## Methods

### Setting and Participants

Data were collected in the Breast Health Center at the Alvin J. Siteman Cancer Center at Barnes-Jewish Hospital and Washington University School of Medicine, St. Louis, Missouri. Participants included women 18 years of age and older who underwent evaluation at the Breast Health Center and were referred for an image-guided core biopsy (stereotactic or ultrasound-guided). Women were excluded if they had a history of breast cancer, if they lived more than 2 hours away from the center, or if they were unable to understand conversational English. Participants were recruited between February and October 2003.

### Procedure

Eligible patients were recruited by mammography clinic staff. Consent was obtained in writing by the study research assistant. Because of staffing limitations, patients were recruited 3 days per week rather than daily.

Assessments were conducted by a study research assistant at three time points and involved completion of written measures assessing the patients' knowledge, anxiety, and satisfaction regarding their care. Each assessment took about 10 minutes to complete. The assessments occurred between specific elements of the patient's medical care, in the following sequence: (1) indication for biopsy, (2) first assessment (baseline), which took place immediately before the medical consultation, (3) the medical consultation during which informed consent for the biopsy was obtained; this consultation was provided by one of seven board-certified radiologists in practice at the breast health center, six of whom were Caucasian, (4) second assessment (postconsultation), which took place immediately after the medical consultation, (5) biopsy, generally 0 to 7 days after the medical consultation, (6) third assessment (follow-up), immediately after the biopsy, and (7) further medical care as needed.

After the baseline assessment, the research assistant opened an envelope coded with the patient's identification number. The contents indicated the patient's assignment to receive either a medical consultation structured to include use of an extensively illustrated educational flip chart or a standard medical consulta-

tion that did not include the flip chart. Assignment was random, in equal proportions, and was based on a computer-generated allocation sequence developed by the first author (M.S.W.). Assignment was unknown to the patient and to study staff until after the baseline assessment. Once assignment was revealed, the patient's consulting radiologist was told of the assignment, and it was known by the research assistant and other study personnel. Patients were not explicitly informed of their assignment but are assumed to have inferred it, given the stated purpose of the research. Their knowledge of their assignment may have influenced outcomes such as anxiety and patient satisfaction, but this knowledge is assumed not to have affected objective knowledge. The Protocol Review and Monitoring Committee at Siteman Cancer Center and the Institutional Review Board at Washington University School of Medicine approved all study procedures.

### Educational Intervention

The educational intervention consisted of a 47-page flip chart developed in consultation with the Cancer Communication Research Laboratory at Saint Louis University. The information contained in the chart was presented at an introductory level, included colorful graphics, was designed to be culturally sensitive, and was suitable for high- and low-literacy patients and family members. Artwork in the flip chart included photos and line drawings. The cover art depicted people of different races and ages, and illustrations within it showed women with an olive or light tan complexion so that a very broad segment of the patient population would relate to the models. A sample page showing a core biopsy is presented in Fig 1.

Key topics covered in the flip chart included breast anatomy, common breast abnormalities, diagnostic procedures, treatment, reconstruction, and clinical trials. The section on breast anatomy and pathology included a basic explanation of breast masses, calcifications, cysts, and cancer. Discussion of diagnostic procedures included fine-needle aspiration, core biopsies, needle localization, excisional biopsy, and ductography. Basic information for treatment decision making was also included, such as lay explanations of tumor staging and lumpectomy vs mastectomy. In addition, to facilitate the healthcare professional's discussion with the patient, simplified treatment algorithms and introductory explanations of surgical and nonsurgical treatments were included.

The flip chart was intended to supplement discussions during informed consent for procedures or discussions regarding procedure options in the clinic setting. It was not intended to present new material that was not already covered during a standard consultation. It was designed for use with patients scheduled to undergo a breast imaging diagnostic procedure or a

breast biopsy and also for patients with a newly diagnosed breast cancer. For purposes of this study, however, only the portion of the flip chart relevant to breast biopsy was used in the informed consent discussion.

The content of the flip chart was developed to address three of the five elements of consent for medical treatment: voluntarism, disclosure, and understanding.<sup>28</sup> The remaining two, capacity and decision, are elements of the informed consent medical consultation itself and are not addressed by the educational intervention. The content addressed voluntarism by balancing the presentation regarding risks and benefits of having a biopsy and by avoiding a level of explicitness that might unduly engender fear. The content addressed disclosure by identifying and describing risks of the biopsy procedure. The content

#### Core Biopsy for Lumps Easily Felt

**definition** A needle removes pieces of tissue from a breast lump to check for cancer.

**key points**


- Usually done by a surgeon in the office
- Takes about 10-20 minutes
- Local anesthetic
- Results usually in 2-3 days

**pros**

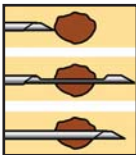
- Can often be scheduled quickly
- Tiny scar
- High accuracy without surgery
- Gives detailed information about the lump
- If cancer, can plan one-step operation for treatment

**cons**

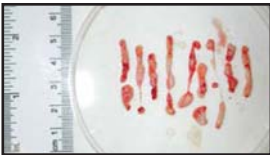
- Does not remove entire lesion
- May have bruising, bleeding and rarely infection
- May still need surgery




*The surgeon performs the biopsy in the office*



*A special needle removes small pieces of tissue*



*Several samples are removed*



*Tiny scar after core biopsy*

Fig 1. — Sample page from educational flip chart showing core biopsy.

addressed understanding by presenting information in a structured, multimodal format that would increase understanding among participants.

Before implementing the flip chart in this study, the second author (D.F.) reviewed its use with the radiologists conducting medical consultations and instructed them about its intended use as an adjunct to the usual informed consent discussion of standard length. No additional instruction or supervision was provided, and to enhance the ecological validity of our findings, no additional constraint on use of the flip chart was

imposed. Because the chart was developed for this study and was not previously used by the providers, we assumed there was no provider allegiance regarding the intervention conditions.

Use of the chart was not intended to systematically lengthen consultations. It might have lengthened some consultations by prompting questions and shortened others by structuring the coverage of topics. To the extent that consultations using the chart differed in length from those that did not, they were within the usual range, and such variation is construed as reflect-

**Table 1. — Objective and Subjective Knowledge Measures**

<p><b>Objective Knowledge (Baseline)<sup>a</sup></b>          Which of the following choices is a risk of this breast biopsy procedure? Blood clots; <i>Bleeding</i>; Diarrhea; Deformity of the breast.          After this breast biopsy, how long will I need to stay in bed? 24 hours; 3 days; 1 week; <i>I will not need to stay in bed.</i>          During this biopsy procedure, what will the doctor remove? A few tiny cells; <i>Small thin pieces of tissue</i>; Fluid only; The entire lesion; My entire breast.          What type of anesthesia, if any, is used for this biopsy? No anesthesia is used; <i>Local anesthesia</i>; Diazepam (Valium); General anesthesia.          Because I am having this biopsy, I definitely will not need to have surgery at a later date. True; <i>False.</i>          Where is this procedure performed? <i>Here in the Breast Health Center</i>; In my regular doctor's office; In the surgeon's office; In the operating room.          What does this breast biopsy involve? The breast is removed; <i>A sample of the lesion is removed</i>; A few cells are removed.          Who will perform this procedure? Surgeon; <i>Radiologist</i>; Pathologist; Technologist.          What will I feel during the procedure? Nothing, because I will be asleep during the biopsy; Sharp pains, like a cut to the skin; <i>A needle stick then pressure only.</i></p> <p><b>Objective Knowledge (Postconsultation)<sup>a</sup></b>          Which of the following choices is a risk of this biopsy procedure? Stroke; Hot flashes; Numbness and swelling of your arm; <i>Bruising.</i>          When can I expect to get my biopsy results? Immediately after the biopsy; In 4–6 hours; <i>In 2–4 days</i>; In 2–3 weeks.          I will be able to resume normal activity right away. True; False.          For this biopsy, I will: <i>Lie on my back</i>; <i>Lie on my stomach</i>; Stand; Sit.<sup>b</sup>          What are other ways that I can have this lesion biopsied? Skin biopsy; <i>Surgical biopsy</i>; Blood test; There are no other ways that I can have this lesion biopsied.          What kind of scar will I have after this procedure? It will go halfway across my breast; 3-inch scar around the nipple; <i>Less than 1/2-inch scar in the breast.</i>          How long does the core biopsy procedure take? 5 minutes; <i>15–45 minutes</i>; 3 hours.          How is the tissue removed from the lesion during the core biopsy? Individual cells are sucked out and smeared on a slide; <i>Small pieces of tissue are removed with a needle</i>; The entire lesion is removed.          How will the doctor find the lesion to guide the biopsy? The doctor uses his/her fingers to find the lesion; <i>The doctor uses a mammogram to find the lesion</i>; <i>The doctor uses an ultrasound picture to find the lesion.</i><sup>c</sup></p> <p><b>Subjective Knowledge (Postconsultation)<sup>d</sup></b>          I understand what I need to know before having my biopsy.          I am ready to have my biopsy.          I need more information before my biopsy.          I know what to expect regarding my biopsy.          I need more time to think about things before my biopsy.          I have enough information to make any decisions that I need to make about my biopsy.</p> <p><b>Subjective Knowledge (Follow-up)</b>          I understood what I needed to know before having my biopsy.          I was ready to have my biopsy.          I needed more information before my biopsy.          I knew what to expect regarding my biopsy.          I needed more time to think about things before my biopsy.          I had enough information to make any decisions that I needed to make about my biopsy.</p> <hr/> <p><sup>a</sup> Items in italics scored as correct.  <sup>b</sup> Correct answer is on back for ultrasound-guided biopsy, on stomach for stereotactic biopsy.  <sup>c</sup> Correct answer is mammogram for stereotactic biopsy and ultrasound for ultrasound-guided biopsy.  <sup>d</sup> Items were rated on a 5-point Likert-type scale, with higher scores indicating greater subjective knowledge.</p>
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**Table 2. — Factor Pattern Coefficients for Satisfaction Measure**

How satisfied are you with: <sup>a</sup>	Factor 1 <sup>b</sup>	Factor 2 <sup>b</sup>
The personal attention you received	.232	<u>.250</u>
The usefulness of the information you received	<u>.656</u>	.233
The ability of health providers to answer your questions	<u>.974</u>	-.088
The knowledge and skill of the health providers	.045	<u>.497</u>
The comfort of the physical environment	.148	<u>.488</u>
The length of time for your appointment	-.085	<u>.538</u>
Your medical consultation prior to your biopsy	<u>.724</u>	-.055
Your overall biopsy experience	-.059	<u>.728</u>

<sup>a</sup> Items were rated on a 7-point Likert-type scale, with higher scores indicating greater satisfaction.

<sup>b</sup> Underlined loadings indicate item assignment

ing intrinsic characteristics of the intervention and not as a confound to be controlled.

Patients assigned to usual care in this study received the standard informed consent discussion delivered by the radiologists in practice at the Breast Health Center, without use of the educational flip chart.

**Measures**

The outcomes for this study were selected based on their relevance to the subjective experience of patients undergoing medical evaluation (anxiety, subjective understanding), relevance to the issue of informed consent (subjective understanding, objective knowledge), and as a broad marker of quality of care (patient satisfaction).

Objective knowledge was assessed with a 9-item multiple choice test of biopsy knowledge at baseline and a comparable 9-item test administered after the medical consultation. Comparable but distinct items were used at baseline and postconsultation to minimize testing effects.

Subjective knowledge was assessed with a 6-item measure at the postconsultation assessment and a comparable 6-item test administered at follow-up. Items for each measure were developed for this study by the investigators and were piloted and refined before use. Table 1 presents sample items from the objective and subjective knowledge measures.

Patient satisfaction was assessed at follow-up with an 8-item measure developed for this study. Patients rated each item on a 7-point scale, indicating their satisfaction with various characteristics of medical care. Table 2 presents a list of the items included in this measure.

State anxiety was assessed with the 20-item state section of the State-Trait Anxiety Inventory (STAI).<sup>29</sup> The STAI was administered at baseline and at the post-consultation assessment to evaluate the extent to which the intervention reduced anxiety before the biopsy was performed.

The primary independent variable for the analysis was assignment to the flip chart educational interven-

tion (Group 1) or to the usual care control condition (Group 2). Additional variables examined for inclusion were demographic characteristics (age, race/ethnicity, education), whether the patient was accompanied to the appointment, first vs second medical opinion, type of biopsy performed (ultrasound-guided vs stereotactic), and biopsy wait time (0 to 3 days vs 4 days or more).

**Statistical Analysis**

For sample size considerations, we assumed a moderate effect (Cohen’s *d* = .50) of the intervention on the primary outcome variables.

Assuming this effect, our planned sample of 125 provided power of .79 for simple tests of the main effect of the intervention.

We used maximum likelihood factor analysis with oblique rotation to examine the structure of the patient satisfaction and subjective knowledge measures. Analysis of covariance was used to evaluate the effects of the educational intervention, controlling for demographic and other variables. Model development was hierarchical and examined main effects of the intervention first, then interactions with age, education, and race. Mann-Whitney *U* tests and *t* tests were conducted to examine simple tests of group mean differences. All tests were two-tailed, with alpha set at .05.

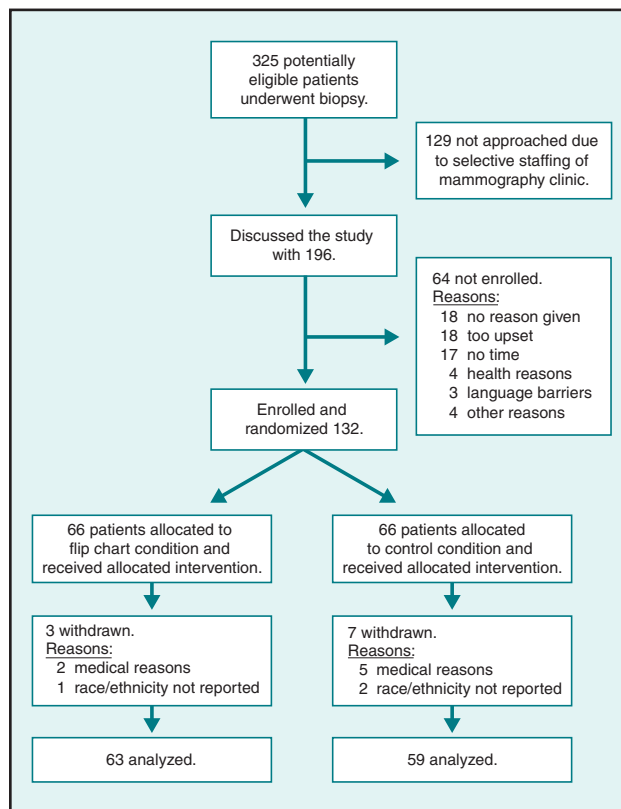


Fig 2. — Diagram of patient participation in study of educational intervention for breast biopsy patients.

## Results

### Sample Characteristics

As shown in Fig 2, 325 potentially eligible patients were referred for biopsy based on diagnostic procedures performed in the Breast Health Center mammography clinic between February and October 2003. Of these, 196 were approached and were invited to participate in the study, and 132 enrolled. As a proportion of those invited to participate, this represents a recruitment rate of 67%. Seven patients were withdrawn from the study for medical reasons before completing data collection and 3 patients were excluded due to unknown or "other" race/ethnicity status, leaving 122 patients as the final sample for analysis. As noted, 6 of 7 radiologists who provided medical consultations to patients as part of this study were Caucasian, and greater than 95% of the consultations were provided by these physicians. As a result, it was not possible to evaluate the effect of physician race or of race matching between patient and physician. Characteristics of the sample are reported by treatment condition in Table 3.

### Factor Analyses

Factor analysis of the patient satisfaction measure led to a two-factor solution that explained 44% of total item variance. The first factor reflected satisfaction with patient-physician communication. The second factor reflected satisfaction with other characteristics of the medical visit. Unit-weighted factor scores were com-

puted and used as dependent variables in analyses of patient satisfaction. Factor pattern coefficients for this measure are reported in Table 2.

Factor analysis of the subjective knowledge measures (postconsultation and follow-up), also indicated the presence of two factors. However, assignment to factor clearly broke on positively vs negatively worded items, suggesting a single underlying dimension. Therefore, a single composite score for each measure was computed and used in analyses involving subjective knowledge.

### Knowledge, Subjective Knowledge, Anxiety, and Satisfaction

The main effect of the intervention on postconsultation objective knowledge, controlling for age, education, race/ethnicity, biopsy type, first vs second opinion, baseline anxiety, and baseline objective knowledge was non-significant,  $F(1, 109) = 1.749, P = .189$  (Group 1 mean = 91.9, SD = 7.39; Group 2 mean = 90.0, SD = 10.5). However, controlling for baseline objective knowledge, the educational intervention interacted with race/ethnicity in predicting postconsultation objective knowledge,  $F(1, 117) = 5.632, P = .019$ . Means and standard deviations for each group are shown in Table 4. The pattern of the interaction indicates that African Americans in Group 2 scored significantly lower than African Americans in Group 1 and Caucasians in Group 2. The pattern suggests that the intervention did not affect postconsultation knowledge among Caucasians but was effective among African Americans.

The main effect of the educational intervention on postconsultation subjective knowledge, controlling for age, education, race/ethnicity, biopsy type, first vs second opinion, baseline anxiety and baseline objective knowledge was significant,  $F(1, 109) = 4.343, P = .04$ . After receiving the intervention, patients in Group 1 reported better subjective knowledge than patients in Group 2 (Group 1 mean = 4.64, SD = 0.57; Group 2 mean = 4.44, SD = 0.74).

We also tested the effect of the educational intervention on follow-up subjective knowledge — the sense among patients after the biopsy that they had understood the procedure prior to the biopsy. Controlling for baseline anxiety and race/ethnicity, the main effect of the intervention was significant,  $F(1, 118) = 5.642, P = .019$ . As with postconsultation subjective knowledge, patients in Group 1 reported better subjective knowledge than patients in Group 2 (Group 1 mean = 4.73, SD = 0.37; Group 2 mean = 4.52, SD = 0.69). However, the educational intervention also interacted with race/ethnicity. Controlling for

Table 3. — Characteristics of Sample, by Experimental Condition

Patient Characteristics	Flip Chart (n = 63)	Control (n = 59)	P <sup>a</sup>
Age (yrs)	56.6 (12.1) <sup>b</sup>	53.3 (11.9)	.13
High school or less (vs some college)	33%	34%	.95
African American (vs Caucasian)	30%	27%	.71
Obtaining second opinion	61%	51%	.25
Accompanied at appointment	62%	59%	.77
Ultrasound-guided (vs stereotactic) biopsy	64%	63%	.59
Biopsy wait time (days)	4 (0 – 7) <sup>c</sup>	3 (0 – 7)	.39
<b>Study measures</b>			
Baseline objective knowledge	70.9 (16.3) <sup>b</sup>	72.7 (15.2)	.53
Postconsultation objective knowledge	92.1 (7.3)	90.0 (10.5)	.21
Postconsultation subjective knowledge	4.61 (0.60)	4.44 (0.74)	.18
Follow-up subjective knowledge	4.73 (0.37)	4.52 (0.69)	.05*
Satisfaction with patient/doctor communication	6.93 (0.16)	6.81 (0.47)	.09
Satisfaction with other factors	6.75 (0.40)	6.77 (0.37)	.81
Baseline anxiety (STAI)	46.3 (13.4)	45.1 (12.8)	.63
Postconsultation anxiety (STAI)	41.6 (11.8)	38.3 (13.3)	.15

<sup>a</sup> Tests of significance were Mann-Whitney *U* test for biopsy wait time, Pearson Chi-square for variables reported as percentages, and *t* test for the remaining variables.  
<sup>b</sup> Mean (SD).  
<sup>c</sup> Median (1st–3rd quartile).  
 STAI = State-Trait Anxiety Inventory  
 \* Significant at  $P < .05$ .

baseline anxiety, this interaction was significant,  $F(1, 117) = 6.000, P = .016$ . Means and standard deviations for each group are shown in Table 4. As with postconsultation objective knowledge, the pattern shows that African Americans in Group 2 scored significantly lower on follow-up subjective knowledge than African Americans in Group 1 and Caucasians in Group 2. As above, the pattern suggests that the intervention did not affect follow-up subjective knowledge among Caucasians but was effective among African Americans.

The main effect of the intervention on postconsultation anxiety, controlling for baseline anxiety, approached significance,  $F(1, 118) = 3.132, P = .079$ . However, the effect was that those in Group 2 tended to have lower postconsultation anxiety than those in Group 1 (Group 1 mean = 41.6, SD = 11.8; Group 2 mean = 38.3, SD = 13.3). Although this suggests that the intervention may increase anxiety relative to usual care, it should be noted that these represent mild elevations of anxiety relative to healthy adult norms.<sup>29</sup>

Because of skew in the distribution of the satisfaction variables, Mann-Whitney  $U$  tests were utilized to examine the effect of the educational intervention. Test results regarding satisfaction with patient-physician communication were nonsignificant ( $z = .425, P = .671$ ). Test results regarding patient satisfaction with characteristics of the medical visit were also nonsignificant ( $z = .394, P = .694$ ). However, test results showed a significant main effect of biopsy wait time ( $z = 2.715, P = .007$ ), indicating that patients who waited 4 days or more for a biopsy procedure were less satisfied than patients who waited 3 days or less (means = 6.86 vs 6.66, respectively).

## Discussion

Our findings did not support hypotheses regarding broad, main effects of the intervention on knowledge, anxiety, and satisfaction. However, results did show interaction effects regarding objective and subjective knowledge. In these interactions, the intervention appeared helpful to African Americans but not Caucasians.

These findings add to the literature regarding patient-physician communication in several ways. They suggest that providers might not always inform patients as fully as possible during the usual consent process for breast biopsy and that the pattern of patients underserved by the typical verbal consultation is not random. Although the typical consent process appeared to work well overall, it worked much better for Caucasians than for African Americans. The results also show that simple measures, such as the use

Table 4. — Objective and Subjective Knowledge According to Experimental Condition and Race/Ethnicity

Postconsultation Objective Knowledge	Flip Chart Condition Mean (SD) (n = 44)	Control Condition Mean (SD) (n = 43)
Caucasian	92.4 (7.87)	92.5 (8.65)
African American	91.2 (5.95)	83.3 (12.17)
<b>Follow-Up Subjective Knowledge</b>		
Caucasian	4.71 (0.34) (n = 44)	4.66 (0.52) (n = 43)
African American	4.75 (0.42) (n = 19)	4.15 (0.95) (n = 16)

of a well-designed visual aid, can strengthen the presentation of information to patients and reduce or eliminate racial/ethnic disparities in patients' understanding of their care.

It is unclear why the usual consent process was less effective for African Americans than for Caucasians. It is possible that health literacy differed across race/ethnicity groups and that the flip chart intervention relied less on health literacy than the usual care consent process. It is also possible that cultural and language barriers played a role. Because the consulting radiologists were primarily Caucasian, Caucasian patients typically met with a race-matched physician but African American patients did not. This may have influenced the quality of the patient-physician communication.

In addition, these findings do not tell us what characteristics of the intervention were effective. However, they do suggest that modest interventions can improve the effectiveness of medical consultations delivered to African American patients in certain circumstances. Such interventions permit all groups of patients to be and feel well informed regarding their care.

Contrary to our expectations, the results suggest that the flip chart intervention might have been less effective in reducing anxiety compared with the usual care approach. This unexpected finding may be due to the graphical content of the intervention, making it more difficult for patients to avoid thinking about the medical issues. Consistent with this, several comments suggested that some patients preferred not to think about why they needed a biopsy.

These analyses showed that most patients were satisfied with the quality of patient-physician communication and with other aspects of their medical care visit. However, they also showed that patients whose biopsies were done sooner were more satisfied with other factors related to their biopsy than were patients who had to wait longer for a biopsy. Although there were exceptions, this generally accords with patient comments, in which most patients expressed either gratitude that they obtained a biopsy quickly or frustration that they did not.

This study is limited in several ways. First, our sample size was modest and thus limited the power and complexity of our statistical tests. Second, the manner in which the flip chart was used by physicians was not constrained and might have varied from physician to physician. Third, our assessment of the intervention effects did not include objective indicators of patient behaviors during the consultation, such as tracking the number of questions patients asked. Fourth, the statistical analysis did examine several possible interactions, and some level of alpha inflation might have occurred. Finally, the intervention was delivered at an NCI-designated comprehensive cancer center and addressed one type of medical procedure. A study of patients treated in other settings, with different standard consent processes or with disparate medical procedures, might show different effects.

## Conclusions

Despite study limitations, findings from this study support the conclusion that medical consultations with patients undergoing breast biopsy generally lead to informed consent. Findings also suggest that when such consultations involve primarily Caucasian physicians and African American patients, consent might be less fully informed than it could be. However, use of visual or other aids to supplement the informed consent discussion might effectively compensate for barriers to informed consent that arise in such contexts.

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