

Final Report

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# REPORT

## **Evaluation of the Use of the Code “Probably Benign - Short-Term Follow-Up Suggested” to Classify Mammograms**

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**FINAL REPORT**

**for**

**Contract No. 200-96-0599**

**Task 9**

**EVALUATION OF THE USE OF THE CODE  
“PROBABLY BENIGN – SHORT-TERM FOLLOW-UP SUGGESTED”  
TO CLASSIFY MAMMOGRAMS**

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**TABLE OF CONTENTS**

	<i>Page</i>
EXECUTIVE SUMMARY .....	iv
1. BACKGROUND AND SIGNIFICANCE .....	1
2. STUDY DESIGN .....	3
3. SELECTION AND SAMPLE CHARACTERISTICS .....	5
4. DEVELOPMENT OF DISCUSSION GUIDE .....	9
5. FOCUS GROUP PROCEDURES .....	11
6. CONTENT ANALYSIS .....	12
7. RESULTS .....	13
8. CONCLUSIONS AND RECOMMENDATIONS .....	71
APPENDIX A    PHYSICIAN RECRUITMENT MATERIALS .....	A-1
APPENDIX B    FOCUS GROUP MODERATOR’S GUIDE .....	B-1

**LIST OF TABLES**

TABLE 1.    RADIOLOGISTS EXPRESSING INTEREST .....	6,
TABLE 2.    FOCUS GROUP PARTICIPATION .....	7
TABLE 3.    PARTICIPANT CHARACTERISTICS .....	7

## EXECUTIVE SUMMARY

**TITLE:** Evaluation of the Use of the Code  
“Probably Benign – Short-term Follow  
Up Suggested” to Classify  
Mammograms

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### **Purpose of the Study**

Many breast lesions detected by mammography show features that indicate that they have a high, but not absolute, likelihood of being benign. The American College of Radiology Breast Imaging Reporting and Data System (BI-RADS) classification includes “probably benign finding - short interval follow-up suggested” (code 3) for use in this circumstance. The Centers for Disease Control and Prevention (CDC) has determined that the use of this code varies widely across states enrolled in the National Breast and Cervical Cancer Early Detection Program (NBCCEDP), a program designed to provide breast and cervical cancer screening and follow-up services to low-income, uninsured women through state health departments.

To understand the factors affecting the use of code 3 by radiologists who read mammograms for the NBCCEDP, the CDC plans to conduct a national survey of these radiologists. The survey will measure the factors that may be affecting the use of code 3. In preparation for this survey, the CDC contracted Battelle Centers for Public Health Research and Evaluation to conduct a qualitative data collection effort comprised of focus groups with practicing radiologists who read mammograms for the NBCCEDP. The goal of this effort was to identify the range of factors which may impact

the use of code 3. A moderator's guide (Appendix B) was developed to promote discussion among physicians regarding these issues.

## **Methodology**

Focus groups were conducted with radiologists representing a broad range of practice settings, years of experience, and regions of the country (Section 5). Focus groups included male and female radiologists; radiologists who practice mammography exclusively and others for whom mammography is a smaller part of their practice; and radiologists who practice in a variety of settings, from rural to inner city. Seven focus groups with an average of eight participants per group were conducted by telephone. These groups of radiologists expressed a wide range of opinions regarding the use of code 3 and the factors that may relate to the use of this code.

Focus group discussions were audiotaped, transcribed and loaded into QSR NUD•IST to facilitate coding and extraction. Content analysis was conducted by two Battelle research personnel (Section 6). The results section provides a comprehensive listing of extracted comments made by participants (Section 7). Comments made by physician participants are organized into themes within the following topic areas:

- Background of Radiologist
- Patient-related Factors
- Practice-related Factors
- External Factors
- Understanding and Use of Code 3

Below we present the methods and results of our qualitative data collection effort focused on physicians. In addition, we present recommendations for the content of the survey. The report below is organized into eight sections: 1) Background and Significance; 2) Study Design; 3) Physician Selection Procedures and Sample Characteristics; 4) Development of Discussion Guide; 5) Focus Group Procedures; 6) Content Analysis; 7) Results; and 8) Conclusions and Recommendations.

## **Summary of Findings**

Section 7 presents the results of the content analysis around themes that emerged from the focus group data. Themes include the background of the radiologist, patient-related factors, practice-related factors, factors external to the clinical setting, and direct information on understanding and use of ACR code 3. Themes are

broken down into conceptual sub-themes and are presented as consensus themes, frequent themes and rare themes. Radiologists expressed a wide variety of opinions on many of the substantive topics. Areas of general agreement across groups are summarized below for each of the five key themes.

1. Background of Radiologist: All agreed that training and experience play a role in the use of code 3, although opinions varied as to the overall impact of these factors.
2. Patient-related Factors: Patient anxiety related to code 3 emerged as an important issue. Radiologists noted that, while patient reaction is widely variable, most patients agree to 6-month follow-up. Radiologists tend to offer biopsy to the minority of patients who are too anxious to wait 6 months. Radiologists agreed on the importance of interacting with the code 3 patients when possible; the approach they described was uniformly intended to be reassuring.
3. Practice-related Factors: It is clear that interaction with practice partners shapes the use of code 3. Radiologists also agreed that tracking systems, practice audits, and the availability of various types of equipment and technologies are important and impact the use of the code.
4. External Factors: Radiologists noted that prior personal or tangential experience with lawsuits can impact the use of code 3. Most radiologists opined that they do not consider insurance issues when assigning a code to a mammogram. Opinions regarding the impact of NBCCEDP participation varied widely.
5. Understanding and Use of Code 3: Many radiologists felt that code 3 is essential because it covers the “gray zone” in mammography. There was consensus that the terminology “probably benign” should be made less vague to avoid misinterpretation. Most radiologists interpret “short-term follow-up” to mean six-month follow-up, but many were unclear how long to continue following a probably benign finding.

## **Conclusions and Recommendations**

The purpose of this project was to develop an understanding of the use of Code 3 that will support a more extensive survey of radiologists. This research showed that these practicing radiologists perceived the use of code 3 to be influenced by a wide range of factors, including training and experience, patient characteristics, expectations of colleagues, availability of

technology, legal and cost implications, and their understanding of appropriate uses of code 3.

The product of this project is recommended content for the survey instrument. Based on the results of the project, we recommend that the survey capture as many of the identified influences as possible. In Section 8, we present recommended survey questions based on the results of the focus groups. Included are draft questions on the following topic areas:

1. Background of Radiologist: Education and training, experience
2. Patient-related Factors: Patient characteristics, interaction with patients
3. Practice-related Factors: Practice setting, colleagues, office practices, tracking and audits, equipment/technology
4. External Factors: Legal issues, financial issues, insurance, NBCCEDP, views of the ACR coding scheme
5. Understanding and Use of Code 3: Attitudes toward code 3, usage of code 3, diagnostic criteria, follow-up, most important factor in assigning code 3

## 1. BACKGROUND AND SIGNIFICANCE

Most benign breast lesions detected by mammography show features indicating that they have a high, but not absolute, likelihood of being benign. There is an increasing tendency for radiologists to recommend short-term follow-up with mammography, rather than immediate excision, for women with lesions of this type. The American College of Radiology created the Breast Imaging Reporting and Data System (BI-RADS) to provide a standardized lexicon and format for clear, concise mammography reports in order to eliminate the confusion created by lengthy and ambiguous mammography reports. The BI-RADS classification includes “probably benign finding - short interval follow-up suggested” (code 3) as one of the five allowable final interpretations of mammography. This category is meant only for lesions that have a very high probability of being benign. The radiologist does not expect the lesion to change over time, but would prefer to establish its stability before making a final recommendation to dismiss it.

The purpose of this study was to identify issues pertaining to the use of the code “probably benign finding – short interval follow-up suggested” (code 3) in the National Breast and Cervical Cancer Early Detection Program (NBCCEDP). The NBCCEDP was established by the Centers for Disease Control and Prevention (CDC) in order to provide breast and cervical cancer screening and follow-up services to low-income, uninsured women through state health departments. Many women are told that their mammograms indicate a breast lesion that is probably benign, and that they should return for follow-up in six months. A large percentage of these women either do not come back or come back after a long delay. The percentage of mammograms categorized as probably benign varies by state and enrollment site.

A recent study of use of the code 3 classification in the NBCCEDP identified a wide variation in the use of this code by state and by enrollment site. Variation among states varied from 2% to 16%. Variation among enrollment sites was even larger, ranging between 0% and 49%. There were no data for individual radiologists. It is possible that differences in training, experience, or personal characteristics, together with medical liability laws and malpractice precedents of the various states may account for this variation. The practice environment in which the individual radiologist works, the perceived likelihood that the patient will return for follow-up, and patient response may also potentially impact the use of code 3.

The purpose of this project was to identify issues related to the use of code 3 by conducting up to eight **90-minute** telephone focus groups of up to nine radiologists each. The data gathered through this study will inform the development of a quantitative survey to be administered to a random sample of radiologists who read mammograms for the NBCCEDP. The information gathered from this larger study will be used to help improve the quality of care given by the NBCCEDP.

Careful design of the national survey of radiologists is crucial to the success of this CDC initiative. A survey instrument that measured factors that are not perceived as relevant by practicing radiologists would likely have two consequences. First, it would likely result in low physician response rates as physicians read through the instrument and decided it

did not assess issues important to practicing radiologists. Second, it would fail to identify potentially important issues that could impact the use of code 3. In order to avoid these problems and to develop a comprehensive and relevant survey instrument, CDC determined the need to obtain qualitative data from radiologists who currently read mammograms for the NBCCEDP in preparation for developing the survey. This method of designing the survey is crucial because it obtains input directly from practicing radiologists who participate in the NBCCEDP, thus assuring that the survey development is based on empirical data and raises issues that are particularly relevant to these radiologists. It avoids potential biases or oversights by researchers who may not appreciate the broad range of issues affecting practicing radiologists.

Battelle Centers for Public Health Research and Evaluation worked with the CDC to design the data collection instrument and procedures to obtain this information. Battelle researchers collected, processed, and analyzed the qualitative data from the focus groups. The remainder of this document reports on the procedures and results of this important first phase to designing a national survey to assess issues that impact the use of code 3.

## 2. STUDY DESIGN

The goal of this research was to identify issues that may affect the use of code 3, “probably benign, short-term follow-up suggested,” by radiologists in the NBCCEDP. These issues were identified through the use of telephone focus groups with radiologists who read mammograms for the program. It was important to include radiologists who represented a broad range of opinions about the use of code 3. It was not possible to completely ensure a priori that we would select physicians with differing opinions about code 3. Thus we chose to select a sample based on characteristics that may be associated with different opinions. Such characteristics may include length of time in practice, physician demographic characteristics, type of practice, and urbanicity of practice location. Battelle and CDC identified the following characteristics as potentially important in ensuring adequate representation of different opinions and practices with regard to code 3:

- Length of time in practice of radiology
- Percentage of professional time spent reading mammograms
- Type of practice
- Urbanicity of practice
- Age of radiologist
- Gender of radiologist
- Geographic area: 12 states representing various regions of the U.S.

It was not possible or desirable to select physicians from all combinations of these characteristics since the total number of combinations is very high. However, an attempt was made to ensure that the final sample included physicians who represented each of the levels of each of the above characteristics.

Two methods of selecting and interviewing radiologists were initially considered: in-person focus groups and telephone focus groups. Each of these methods has important advantages and disadvantages to consider. The main disadvantages of in-person focus groups stem from the need for the participants to be physically present at the session or interview. Given budget constraints, in-person data collection methods must be limited to a small number of locations, each drawing participants from a small geographic area. If the focus groups are conducted in urban areas, it is difficult to include rural physicians who may need to take time away from their practice and travel a long distance to participate. By contrast, with telephone focus groups, there is no need to restrict the sample to a few small geographic areas. This allows for greater geographic diversity in the sample and reduces the logistic difficulties and costs of including physicians from across the country in the study.

The most important advantage of in-person over telephone focus groups is the greater ability of the moderator to maintain participant interaction, obtain participation from less verbal individuals and control dominant participants. Thus, in-person focus groups make it easier to obtain the rich information required for this project. By contrast, telephone focus groups make it more difficult to obtain this information primarily because the

moderator cannot attend to participant non-verbal cues and cannot use non-verbal cues to moderate the discussion.

A significant advantage of telephone over in-person focus groups is that respondents can keep their identities as private as they wish during the discussion, which can assist in achieving greater openness and willingness to discuss sensitive issues such as legal concerns or confusion regarding mammography guidelines.

After review of the options by CDC, the study design was finalized to include up to eight focus groups. It was agreed that the first two groups would be conducted by telephone. If CDC determined that the telephone groups were satisfactory, the remaining groups would also be conducted by telephone. If not, an alternative method would be pursued. After the first two groups were conducted by telephone, Battelle and CDC agreed that they were successful **and** these procedures were implemented for all remaining groups.

Participants were selected from twelve states. CDC selected the following states for participation: California, Colorado, Maryland, Massachusetts, Michigan, Minnesota, Missouri, New Mexico, New York, South Carolina, Texas, and West Virginia. These states were selected to represent the western, central, and eastern parts of the United States.

### 3. SELECTION AND SAMPLE CHARACTERISTICS

CDC provided Battelle with lists of radiology facilities that provide services to women in the NBCCEDP in 12 states: California, Colorado, Maryland, Massachusetts, Michigan, Minnesota, Missouri, New Mexico, New York, South Carolina, Texas, and West Virginia. Each included a list of NBCCEDP sites with an address and/or telephone number. Names of individual radiologists were included in most, but not all of the state lists. California, for example, listed only sites and department phone numbers. Michigan provided clinic names and addresses, but not names of radiologists. The roster for Colorado listed only clinic coordinators. Other lists occasionally omitted contact names or listed names of other employees (non-radiologists).

Initially, an attempt was made to reach each radiology site by telephone. For sites which provided the names of multiple radiologists, we chose a name at random and requested to speak with that person. If a radiologist was available when we called, we attempted to recruit that person. If no radiologist was available, we requested that any radiologist at the site return our call. When we spoke with a radiologist and found s/he was ineligible or declined to participate, we made an effort to speak with and screen another willing, eligible participant at the site. For states which did not provide the names of radiologists, Battelle called the site and requested to speak with any available radiologist who reads mammograms for the program. An effort was made to recruit only one radiologist at each site; however, this was not always possible to determine in advance, as many radiologists work at multiple sites.

When a radiologist expressed interest, we determined eligibility using the approved screener (Appendix A). In order to participate, radiologists must have read at least 50 mammograms for NBCCEDP in the previous year. Eligible candidates were then asked for the following information:

- Age;
- Gender;
- Length of time in practice;
- Percentage of time reading mammograms; and
- Type of practice/practice setting.

Each was **then** offered a choice of participation times and scheduled for one of the available focus groups. The focus groups were scheduled at various times of the afternoon and evening, giving each radiologist an opportunity to attend at a convenient time.

During the course of the study, sites that had not been contacted successfully by phone were mailed a study packet. The packet included an introductory letter explaining the study, a one-page screener, a postage-paid envelope and a fax return cover sheet with Battelle's toll-free fax number. **The** mail screener (Appendix B) determined eligibility and requested information identical to the phone screener. Each radiologist was asked to fill out the screener, indicate which of the scheduled focus group dates and times s/he

could attend, and return the completed screener to Battelle in the pre-paid envelope or by fax.

Focus groups were generally scheduled 4-6 weeks in advance. Eleven radiologists were scheduled for each group to provide an anticipated average attendance of 7-8 per group. In some cases, radiologists expressed interest but were unavailable at the scheduled times. These respondents were contacted again when new dates were scheduled and invited to attend. Although most interested radiologists were eventually scheduled, a few were unable to participate at any of the times scheduled. A number of potential participants were rescheduled several times before finally participating in a group. The following table shows the number of radiologists who expressed interest in the study, both scheduled and not scheduled.

**TABLE 1 . RADIOLOGISTS EXPRESSING INTEREST**

	<b>Agreed, Scheduled</b>	<b>Agreed, not scheduled</b>
<b>California</b>	4	2
<b>Colorado</b>	6	0
<b>Maryland</b>	4	1
<b>Massachusetts</b>	6	0
<b>Michigan</b>	15	2
<b>Minnesota</b>	6	1
<b>Missouri</b>	7	1
<b>New Mexico</b>	3	1
<b>New York</b>	3	1
<b>South Carolina</b>	4	3
<b>Texas</b>	6	2
<b>West Virginia</b>	3	1
<b>TOTAL SAMPLE</b>	<b>67</b>	<b>15</b>

After a radiologist was scheduled, a confirmation letter and consent form were mailed and/or faxed to him/her. Each letter contained the date and time of the focus group in which the individual was scheduled to participate. In addition, a reminder call was made to all participants one or two days before the session for which they were scheduled. If a radiologist had to cancel an appointment, an effort was made to replace that participant with another who had expressed interest. The following table lists the number of radiologists who participated in focus groups, along with those who agreed to participate but were unable to actually attend.

TABLE 2. FOCUS GROUP PARTICIPATION

	Agreed, participated	Agreed, did not participate
California	4	0
Colorado	6	0
Maryland	4	0
Massachusetts	3	3
Michigan	12	3
Minnesota	5	1
Missouri	5	2
New Mexico	2	1
New York	3	0
South Carolina	3	1
Texas	5	1
West Virginia	3	0
<b>TOTAL SAMPLE</b>	<b>55</b>	<b>12</b>

The final participants represented a broad range of experience, practice settings, and percentage of time spent reading mammograms. The characteristics of the final participants are detailed in Table 3.

TABLE 3. PARTICIPANT CHARACTERISTICS

<b>YEARS PRACTICING RADIOLOGY</b>		
Less than 1 year	0	0%
1 - 5 years	6	11%
6 - 10 years	11	20%
11 - 20 years	24	44%
21 - 30 years	13	23%
31 years or more	1	2%
<b>PERCENTAGE OF TIME READING MAMMOGRAMS</b>		
Less than 25 %	25	45%
25 - 50 %	12	22%
50 - 75 %	13	24%
75 - 100 %	5	9%

<b>PRACTICE SETTING</b>		
Hospital	5	9%
General	10	18%
Government	1	2%
Group Practice	1	2%
Imaging Center	2	3%
Private Practice	6	11%
University	5	9%
Single Specialty	18	33%
Multi Specialty	1	2%
Solo Practice	4	7%
Diagnostic	1	2%
Missing	1	2%
<b>URBANICITY</b>		
<b>Urban</b>	<b>26</b>	<b>47%</b>
Suburban	13	24%
Rural	7	13%
<b>Small City Town</b>	<b>9</b>	<b>16%</b>
<b>AGE</b>		
Under 35	4	7%
35 – 44	19	35%
45 – 54	25	45%
55 and up	7	13%
<b>SEX</b>		
<b>Male</b>	<b>41</b>	<b>75%</b>
Female	14	25%

#### 4. DEVELOPMENT OF DISCUSSION GUIDE

The focus group discussion guide was designed to elicit discussion on the topics identified by CDC as potentially related to the use of code 3, as well as any topics the participants raised in relation to the use of this code. Battelle developed the initial version of the discussion guide based on the list of topic areas provided by CDC, with additional questions designed to identify and explore additional issues which impact the use of code 3.

We presented the draft discussion guide to CDC to seek their input. Several conference calls were held to identify additional issues to include in the discussion guide and to modify the discussion questions. The final focus group discussion guide included the following questions designed to elicit comments on issues related to the use of code 3:

- Issues that impact the use of code 3
- Factors related to the use of code 3
- Use of code 3 and changes over time
- Outcomes resulting from the use of code 3
- Most important factor influencing the use of code 3

These general questions were followed by more specific questions to prompt response to the issues identified by the CDC as potentially important; these questions were used as needed to elicit comments on topics which had not been raised during discussion of the most general questions. These topics included:

- Education
- Experience
- Colleagues/social influence and support
- Extenuating circumstances
- Follow-up
- Patient reaction
- Legal implications
- Insurance
- Practice setting
- Practice environment
- NBCCEDP

The draft discussion guide was reviewed by a Battelle researcher, Dr. Daniel Montaiio, with extensive experience collecting qualitative data from practicing physicians, to ensure that the phrasing of questions was relevant and that appropriate terminology was

used. This final focus group moderator's guide was approved by CDC. The final moderator's guide is presented in Appendix A.

## 5. FOCUS GROUP PROCEDURES

Eleven participants were scheduled to participate in each of seven focus groups. The original plan called for eight groups; however, one group was canceled due to lack of available participants. CDC and Battelle agreed that sufficient data had been collected, and the group was not rescheduled. The focus groups were scheduled on weekdays, during the day and in the evenings at varying times to allow people across all time zones to participate at a convenient time. The sessions were organized like a conference call, with an operator connecting all parties several minutes before the discussion was scheduled to begin. The operator informed the moderator privately of which participants could not be reached before bringing all of the participants into the call.

At the scheduled time, the moderator began the session. She introduced herself, gave a brief description of the purpose of the focus groups, and provided guidelines on how the focus group would be conducted. Then the moderator asked each participant to give his/her first name, number of years in practice, and number of mammograms read in the past year. Participants were asked to use first names only to protect the privacy of the participants and encourage openness. This introductory question was used as an "icebreaker" to generate participant comfort with the telephone discussion format and to allow everyone to take a turn speaking. The moderator then proceeded to follow the focus group moderator's guide to generate discussion about the main discussion topics. Upon completion of the focus group, all participants were thanked and the call ended. Participants were sent a money order honorarium upon completion of each focus group.

A note taker attended each focus group session, and all sessions were audiotaped. After the sessions, a full set of notes was prepared for each focus group in preparation for the content analysis. These notes were prepared by listening to each focus group tape and filling in the notes taken during the sessions. The final notes were very thorough, approaching a full transcription.

## 6. CONTENT ANALYSIS

The goal of the analysis was to extract all issues or factors that focus group participants mentioned as possibly having an impact on the use of code 3. Content analysis of the focus group data involved two main phases: 1) coding and extraction of issues, 2) aggregation and conceptualization of issues. Below we describe the procedures for conducting this content analysis.

We used QSR **NUD•IST** in the coding and extraction phase. We have found that the use of this qualitative data analysis software is very efficient if it is used for coding, extraction and aggregation of text data rather than for lengthy exploration of the data. This is especially true in situations such as this, where many of the categories are predefined. Specifically, we have found that this software increases our efficiency of coding and extracting issues over extraction by hand or word processor. We began the extraction phase by designing a coding scheme in **NUD•IST** for recording and extracting relevant statements made by focus group participants. This coding scheme included the specific **items** addressed in the moderator's guide as well as additional categories that emerged during the analysis of the focus group text.

In order to check for coding consistency and to ensure comprehensive coding, two Battelle analysts coded the issues from each focus group. Each coder identified statements that were relevant to each of the identified codes. They coded each identified statement to the appropriate coding node. Once both analysts completed this process, they reviewed a printout of the focus group text with their codes, and compared their codes to identify any inconsistencies in decisions to extract a statement, or decisions about how to code the statement. They discussed key differences and reached consensus, erring on the side of including rather than excluding statements in order to ensure that comprehensive coding was obtained. Additional **NUD•IST** coding nodes were added to capture emergent themes which were not covered by the initial set of nodes. This process resulted in comprehensive coding of each transcript within **NUD•IST**. The statements coded to each model construct were then extracted by running a **NUD•IST** report on each coding node. This produced a comprehensive listing, across all focus group transcripts, of all statements associated with each coding node.

Next, Battelle analysts reviewed these lists to identify comments which address similar issues, in this way identifying conceptual themes. These comprehensive lists of issues and themes were organized by conceptual category and similarity.

## 7. RESULTS

The results of the content analysis of the focus group data are presented below. These results are organized by the main theme extraction topics identified. Below each topic we have listed the themes that were extracted, each followed by the comments that were extracted and grouped to make up the theme.

Our grouping of comments into themes is based on our professional judgement. The results presented below are based both on reading the transcripts and on overall impressions from listening to participants in the focus groups. In identifying themes, we tried to identify any differences in the meaning of comments, and tended to develop different themes to capture these, rather than to collapse themes. Comments were included as a new theme when judged to be unique.

The nature of focus groups, as well as the content analysis procedures used to collapse extracted comments into themes, does not allow quantifying the frequency with which a theme was elicited. However, the analysts assigned ratings to provide an indication of how commonly each theme was mentioned across focus groups. Thus, next to each theme, we have listed the following codes. These indicate whether the theme was mentioned by consensus across most focus groups, a frequent comment, or a relatively rare though probably important theme:

**C = Consensus Theme**  
**F = Frequent Theme**  
**R = Rare Theme**

### I. BACKGROUND OF THE RADIOLOGIST

#### A. EDUCATION AND TRAINING

##### 1. Level/source of training

###### Fellowships(R)

- I did the women's imaging fellowship, 6 months of mammography;
- Fellowship-trained by Sickles
- Someone new in our practice has had mammography fellowship training; being able to work with someone very conversant in all the ACR categories helped tremendously.

###### CMEs, conferences, lectures, literature (general)(C)

- All of us have to maintain our 15 CMES per 3 years. For those of us that BI-RADS came out after residency, you have to read journal articles or conferences.
- We certainly attend conferences and lectures, read journal articles and so forth.
- Most of us have learned it during courses and through the ACR, FTA, NQSA regulations.
- We all meet the requirements for CMEs.

- Conferences, articles and literature
- I attend about two seminars every year.
- Attended a number of conferences, articles in the literature
- Good descriptions through lectures at meetings you attend

#### No training in code 3 (R)

- No training in code 3.
- I continue to try and get educated, but I haven't addressed this specific issue.
- The probably benign category is just a couple years old, so wouldn't have learned about it in medical school.
- Finished residency in '82; the training was abysmal to say **the** least. Everything I've learned I've learned since then.

### **2. Importance of education/training**

#### Education is very important (C)

- It's a very dynamic process. We have to be open to new things that are going on, particularly our own education; really need to commit ourselves to constant education so we can get better at it.
- Education here is a key issue. The understanding of these categories really varies with the amount of education of the radiologists in breast imaging.
- I think the education of not just patients but of physicians, radiologists as well as family practice and surgeons, will be the great leveling factor to decrease those differences among states or regions.

#### Training doesn't guarantee correct practice (R)

- People seem to have CME credits up to date, yet the terminology they use is antiquated, not anywhere near lexicon. I find it hard to understand why if people are going to these courses all the time things aren't a little more uniform. That confuses and frustrates me.
- Theory and the practice are 2 different things. You can go to a lecture, but it requires quite a bit of doing to change your habits.
- It's like the old adage, you can bring a horse to water but you can't make him drink. You can make people have a certain amount of CME credits, but you can't make them really learn the material.

#### Training is only part of the equation (R)

- There is some importance for training and experience but that is not the only criteria to call something definitely benign.

### **3. Availability of training**

#### Hard to access training (R)

- Once you get into practice it's hard to get away to do a fellowship.
- Or even a conference.

- We're never going to have everyone fellowship trained and up-to-date and using the standards. Mammography is booming; just to keep people well-trained and making good decisions is really difficult.

#### Training in Code 3 is readily available (R)

- I think that the issue of "probably benign" comes up in every mammography course.

#### 4. Overall impact of training on practice

##### Training impacts mammography/use of code 3 (C)

- Percentage of code 3 varies for our group of readers w/ level of training.
- There's a wide range of training and experience and desire to be a participant in this field and it reflects in the recommendations that we give and the diagnostic ability that **comes** through.
- Had radiologists attend courses (Tabar and Logan) and showed that it affected the way mammograms were read.
- I attended a mammography conference and thought if I had read that case, I never would have called it cancer, yet it turned out to be.
- I agree you come back after a course and see all these subtle things that turn out to be cancer and say oh my gosh what have I been missing. I don't find that our category 3s go up, but our category Os, our callback rate, always takes a little jump up after a conference.
- Radiologists attended courses; it affected the way mammograms were read.
- Our practice has been heavily swayed by some of the top people internationally. We've gone to a lot of courses; they give outstanding courses and articles.

##### Training has increased/supported use of code 3 (F)

- Increased use of code 3 and positive predictive values after taking Mark Homer's course. There were lesions I would have sent for biopsy before taking his course, that turned out to be benign.
- I constantly try to decrease use of code 3, but when I hear leaders in the field, like Mark **Homer** course 4-5 years ago, encourages me to follow indeterminate lesions.
- More comfortable using that category more often after hearing Ed Sickles talk about it, with his criteria, with the idea that most of those we fit into that category seem to not be malignant in the long run and if they are, it's a low-grade malignancy.
- Sickles gives you pretty good confidence in that category.
- **Probably** everyone here has read Sickles' article -- 3200 probably benign, less than 1% turned out to be cancer. That's fairly convincing evidence, a lot of people who would have undergone a useless biopsy.
- After I go to a breast meeting or something for a week, it heightens your general anxiety level a little bit. They show you all these missed cases.

##### Training has decreased use of code 3 (F)

- Use code much less now because of CME and education.
- I started to use the code less after attending a Tabar training. Tabar's opinion is that you should make a decision one way or another right away.

- I follow Laslow Tabar, studied several times and worked with him for several weeks, both with his course and privately. His attitude is that it's not fair to follow a woman, you've got to come to a decision.
- Ed Sickles is a great resource. I was concerned a while back about my category 0, callback rate to be too high. I went out and spent a week reading mammograms with him in his practice and my rate dropped right down right away. My category 3s came down at the same time.

#### Leaders say different things (R)

- It gets confusing because national leaders do different things.
- It's nice to hear Sickles' take on it and some of the biggerwigs in the ACR just to get different perspectives.

### **5. Specific sources of information**

#### Sickles (F)

- Sickles' approach makes most sense to me.
- I also spent time in San Francisco with Sickles and found it very helpful too. They have those fellowship programs out there, you can spend some time, very very good.
- Sickles in San Francisco
- Brainwashed. Fellowship-trained by Sickles. (laughter) I have a bias.
- Sickles article on radiologic clinics 3 or 4 years ago: of women counseled appropriately and knowledgeable about it, only 2.5% elect to go to biopsy.
- Sickles published a very nice article on size vs risk in about 1994 Radiology.
- Certain individual lecturers come to mind, Ed Sickles giving talks on this very topic. I've certainly found that very instructional, very educational.
- Sickles is really the big guy who's known for the probably benign category.
- The person I trained with went to a Sickles' course and Tabar course.

#### Laslow Tabar (F)

- I urge everyone to go to Laslow Tabar's course on mammography. I went about five years ago and it really changed the way I read mammograms.
- Laslow Tabar's courses, I've gone to five of them and they're outstanding, that's heavily influenced me.
- I went to Laslow's last year.
- Laslow is a different style approach than the bigwigs in the ACR.
- I've avoided Laslow because everyone I've worked with who's a disciple has seemed more an acolyte than a scientist. I'm an American, and I believe in what works. From the little I know of Laslow, he's an apostle, and that's not American, that's all. He's very good, but
- Laslow's perspective is a little heretical when you compare it to the American radiologist.
- Laslow is a different style approach than the bigwigs in the ACR.
- The person I trained with went to a Sickles' course and Tabar course.
- I've been to Tabar's course too.

Parker/S tav(R)

- Trained with Steve Parker's first fellow
- I would recommend listening to Tom Stavros, who works with Steve Parker in Denver. He's the best ultrastenographer I've ever heard.
- I absolutely agree (Tom Stavros is good).

ACR (R)

- A C R
- The ACR bulletin has a lot of good information for mammo stuff almost every month.
- It's also nice to get the perspective of the people who are making all the ACR accreditation rules, and MQSA drawers.
- Info available from ACR

Others (R)

- Article out of Albuquerque (Joe's group) about reading mammograms.
- There was an ACS conference for family practice docs in a nearby city. I saw a tape of it.
- Homer

**6. Impact of training on specific practice issues**Audits (F)

- Been in practice 14 years, I don't think you can go anywhere without hearing Sickles speak. I've heard him speak so many times because he's on many programs, and he loves to give his talk about auditing your practice and talking about class 3 lesions. We're now convincing others; we've known it for years.
- We tend to learn not only from them but also taking their ideas about medical audits and learning that way.
- Homer didn't want to fill up his day by doing stereotactic biopsies, so he purposefully elected to do 6 month follow-up on indeterminate lesions instead. Brought that back to my practice and incorporated audits.

Follow-up (F)

- Tom Stavros and Steve Parker in Denver have a lot of influence in my general region. They say for cases in category 3, shorten the follow-up, lower the threshold for getting a biopsy.
- I think Sickles writes more extensively about this category than anyone else and of the 2000 patients he followed I think he had 17 cancers. Some of those were recognized after the 3 year follow up, so I wait 3 years before I say this particular lesion I've been following is benign.
- The study by Sickles has shown that 6 months is probably the soonest you'd want to repeat it.
- I remember 10 years ago going to a Mark Homer symposium where he had done a national survey of mammographers asking what is your short-term follow up and

found consensus of 6 months. I've never seen any data indicating what is the right follow up and I've just done 6-month follow up.

- A practical in-the-trench approach is you follow them successively through 2 years and if they show no appreciable change you drop them back into the yearly follow up. I'm not sure about literature; that's what **they** suggest at national conferences.

#### Standards for assigning code 3 (F)

- Key article on that (steps before assigning code 3) is Sickles' article.
- Literature says that these are 1% risk, these are after complete work-up, not off the screening.
- I think like the original Sickles article; he describes a probably benign lesion as one that has about a 98-99% chance of it being benign; I try to stick with those numbers as best I can.
- There are pretty rigid standards about what should be a code 3 in the literature.
- I think in the 3 years I've been practicing I've tried to adhere to the standards that are well-established in the literature.

#### Double-reading (R)

- These national experts, Sickles, Tabar, Homer, most of them I think all suggest that screening mammography is double read. I know Tabar does.

## **B. THE ROLE OF EXPERIENCE**

### **1. Impact of experience on use of code 3**

#### Use of code 3 increases with experience (F)

- Experience increases use of code 3.
- Use increases with experience, you downgrade from 4s.
- I see more and more lesions I would have biopsied 10 years ago but I don't, I follow them and they turn out to be benign.
- Use has gone up in our practice because we're willing to bite the bullet and watch instead of sending to biopsy, from experience.
- Comes with experience, having seen hundreds of these things that always **turn** out to be benign.
- With increasing skill and experience, I think we probably do a few more follow-ups, biopsy some less.
- The least experienced almost don't know enough **to** order a 6-month follow-up.

#### Use of code 3 decreases with experience (F)

- I see things people might call a 3 that against experience I'd call a 1 or a 2.
- Really use it a lot less as I become more comfortable with what **I'm** doing.
- Agree with experience; my use has gone down .
- My percentage has gone down because of experience, more comfortable with the process.

- Use has gone down quite a bit based on experience of radiologists; code 3s end up as code 4s and get biopsied; code 3s in the past turned out to be benign so more comfortable putting in code 2.
- Things that used to be code 3 for me have moved to code 2.
- Less experienced use it a lot more, as a safety mechanism, for things someone else might have put in category 2.
- Our use has gone down as radiologists get more comfortable with their readings, either calling something normal or being more aggressive in recommending diagnostic mammography or ultrasound, with a lower threshold than we used to.
- Audited our practice for the last 3-4 years, going back to each radiologist has really decreased some of the category 3s.
- The few of us in our group who spend the vast majority of our time doing mammograms tend to have a very low category 3 call rate. People who spend less time at the breast center tend to have higher rates.

#### Use hasn't changed with experience (R)

- Only been reading mammograms for 3 years; use has stayed the same.

#### Recent experience impacts use (F)

- [Recent cases] influence the next thing I do, whether that's right or wrong.
- Old rule, "it's the last one you saw."
- Bumps up when someone misses something, then comes back down again over time.
- When someone comes back from vacation they tend to read a lot more category 3s. Once they've been back in the saddle a few days that tends to drop back off.
- We had one code 3 that turned out to be cancer, it really shook us up, so we had a little blip and everything going up, calling things back.
- You retrain yourself, reset your thermostat based on recent and long-term experience.
- A way to adjust their reading levels when they saw by the numbers that they were out of sync with the rest of the readers

## **2. Importance of experience**

#### Experience is very important factor (C)

- Threshold (98% confident) develops with expertise and with time.
- Best teacher is experience.
- There's a wide range of experience and it reflects in the recommendations we give and the diagnostic ability that comes through.
- You just can't replace experience.
- Mammography is changing; we have to learn from experience.

#### Experience isn't the only factor (R)

- There is some importance for experience but that is not the only criteria.

## **3. Confidence/personality of radiologist**

Confidence/comfort level/personality of radiologist impacts use of code (F)

- Use of code 3 grows with level of confidence.
- Use of code 3 is due to lack of confidence; it's a way of **turfing** the case to someone else.
- There are some in our practice who are less decisive; it gives them a chance to be done with a case and not really have to make up their mind.
- People with less confidence give benign lesions a category 3 because they lack confidence to say it's benign and that's the end of it.
- Some people have to have such a high degree of certainty that something is totally normal that they order a lot of category 3s.
- Those who feel more confident with their diagnostic ability use it a lot less frequently.
- People with more comfort generate more "definitely benign, don't worry about it" code 2s.
- Some people are just insecure readers.

Confidence isn't the only factor (R)

- Someone like Sickles obviously is very confident, but when his article was written his percentage of 6-month follow-up was 11%. We're all less than that.
- It doesn't matter how confident I come across, they want a biopsy.

**II. PATIENT-RELATED FACTORS****A. PATIENT CHARACTERISTICS****1. Culture and socioeconomic status**Culture/socioeconomic status do not affect practice (F)

- I don't base my diagnosis on whether the patient is African American or Mexican or Native American; I base it on anatomy, and nothing else.
- I don't think it would matter about the patients' background; if we use the code, we assume the patient will come back.
- Socioeconomic status doesn't affect use of the code. Held to the same standard of care for everybody, no matter if rich, middle class, or lower socioeconomic standard.
- We have to hold to a set of standards. **If lesion** is very likely to be benign statistically based on our standards, trying to deviate because we don't think the patient will come back is probably not a good plan.

Culture impacts practice (R)

- I don't base my diagnosis on culture, but I would base my recommendation on culture.
- Navaho population you wouldn't want to string out.

## 2. Age

### Comfortable using code 3 with elderly patients (C)

- With older patients, if it were malignant it would be less biologically aggressive so I might let it go a year instead of 6 months.
- You don't want to send a woman in her 80s for a biopsy if it's unnecessary.
- Older women in their 70s and 80s I may choose to bring back because I don't think they're a great risk .
- If the patient's 80 years old and has a well-defined nodule at 8 mm she gets a **follow-up**.
- With **80+**, and particularly with over 85, I'm quite happy using this code.
- I agree entirely; I'm much more comfortable waiting on the older ones than on a 52-year-old.

### Use code 3 for younger patients (R)

- For a younger patient with a family history and **I'm** convinced after diagnostic maneuvers it's benign, I may be more inclined to go to 6-month.
- For a while I increased my category 3s when there was the controversy over 40-50 year olds, just so I could bring these people back, I didn't want her to go for two years.

### Don't use code 3 for patients under 40 (R)

- For young patients, under 40, we tend to biopsy because we don't want them at that age to have to come back at 6 months and then yearly.

## 3. Likelihood of return

### Summary of compliance rates

- Here we have 75% HMO penetration, we've found patients are extremely compliant; approximately 75% of the target population are screened on an appropriate basis.
- People I see are fairly conscientious doing their follow-up.
- In our practice only 80% of the women come back.
- Virtually 100% compliance for 6-month follow-up.
- 100%
- Very very likely that they'll return for follow-up after code 3.
- About 98%; a few people lost to follow-up because university community with transient population.
- I know it's high but not **100%**, must be over 90%.
- We **only** have about an 80% return rate in 6 months.
- We don't get anywhere close to 100% compliance.
- Our compliance is about **70-75%**. Not a very good record.
- We have about 90% compliance in the private practice, 75% in the hospital setting.
- We're around 90%. This is America. They have a right not to show, they may say 2%'s not even worth it, I'll come back in as year.
- If they don't come back, we're not a babysitter. They're big people; it's their decision.

Culture and compliance (R)

- Cultures are really quite different in their level of anxiety and compliance.
- **Spanish** speaking population here doesn't tend to come back if they're not sick – you told them it was probably benign.
- Ojibwi are more urbanized, higher anxiety, much higher probability of disease than Navaho women.
- Asians are no problem because they have such a tight community network
- Black and Hispanic populations are looser, but people are coming back.
- Underserved Hispanic community, the women are so happy anyone even cares about their mammography, they're very very agreeable, cooperative.

Age and compliance (R)

- Older women, 70s and 80s, are pretty reliable for follow-up.
- Elderly patients don't want to or can't come back, or have difficulty getting in.
- We get a lot of elderly patients who go to Florida for the winter and have their follow-up done somewhere else.

Urban/rural setting impacts compliance (F)

- In one city, they would truck them up 6 hours; hard to get them back, after 6 hours
- Some patients have to ride church bus or drive 2-3 hours.. . worried they'll never see them again.
- Work in urban area, losing them is not such an issue.
- I'm in an urban area, and I'm more confident that the patient will come back.
- Mine is a pretty rural practice; calling back for a diagnostic study is a big hassle, lots of times they won't come back.
- Agree it's hard for rural folks to come back for a diagnostic work-up. It's hard to do diagnostics on these screens, and it's hard to get them to come back for a 6 month follow-up.
- In a rural setting where a patient doesn't have opportunity to get back to the center for follow-up, I'd think use of code 3 would go up because I wouldn't have had an opportunity for complete assessment to sort out more carefully which are unequivocally benign and which should go to biopsy.
- If a patient is from 2-3 hours away, I'll explain the options and let the patient decide. I won't change what I recommend, but they certainly have the option to choose a more aggressive approach.
- I'm glad I live in a rural area with unsophisticated but compliant patients.
- Pretty good compliance, the ones we tend not to get back are from the corporate screening program (using a mobile van) at corporations maybe 60 miles away; they tend to go back to a closer hospital.

Socioeconomic status is related to compliance (C)

- Private patients seem to have better compliance.
- **Lower socioeconomic patients are more easily lost to follow-up, no matter how hard you try.**
- Agree compliance is lower among patients of lower socioeconomic status.

- The ones that are better educated tend to come back.
- Indigent and don't have to pay for their care, they don't come back that often.
- If you're doing outreach mammography in an indigent population in an inner city, you may not know who that follow-up physician is going to be. Sometimes patients fall through the cracks.
- I have a large indigent population and they seem to come back.

#### Follow more aggressive procedures for patients with poor compliance (F)

- My group likes me to biopsy because they may never see the patient again; so what I would call a category 3 in a reliable patient, I have to make a category 4.
- We have a lot of indigent patients that won't come back, so you have to be a little more aggressive.
- Lesion may be one you say to yourself is probably benign, but I'm going to do something more than follow for 6 months because I don't know where the person will be in 6 months; even though you call it the same thing, you're going to do something different with it over your fear that you're not going to get your follow-up.
- If you're in a setting where you think they'll come back in 6 months, you're much more comfortable using the probably benign category.

#### Negative effects of code 3 on compliance (R)

- If we scare her too much, in some of these communities, she won't seek further follow-up care.
- I've noticed after a short-term follow-up or a biopsy, she stops doing her yearly screening for a while; I'm wondering if the anxiety produced by the follow-up and biopsy has an effect on keeping the screening.
- Potential negative outcome of using category 3 a lot is that patients who are "bothered" too many times in the screening process will discontinue screening, especially if the outcome is always benign, which it normally will be for category 3.

#### Positive effects of code 3 on compliance (R)

- Giving them the information up front tends to scare them a little and they tend to come back for at least the 6-month and one year follow-up for a nodule.
- They still have an anxiety level about these things because you're not telling them it's just normal. I think that's why compliance is so high.

#### Patient/physician relationship impacts compliance (F)

- Patients who are well-connected with their physicians will return.
- Poorer women have poorer compliance, maybe due to lack of a primary care physician with whom they establish a relationship.
- Patients who are well-connected to their physician are more likely to stay on the protocol for follow-up.
- We've noticed some primary physicians have a lower level of compliance among their patients and we're addressing this personally with them.

#### Talking with patient improves compliance (R)

- Best compliance is with patients we actually talk to.

- I think talking to the patient at the time of initial recommendation will increase compliance.

#### 4. Hormone Replacement Therapy/Estrogen

##### Use category 3 for women on estrogen (F)

- Sometimes I put a woman in category 3 because on estrogen which causes increased density, it looks benign but I'm not totally sure.
- Estrogen is one reason people go into 6 month follow-up.
- Maybe on estrogen for 4-5 years, they have some asymmetry from estrogen; it doesn't look like a lesion, but I'm not penalized personally for bringing that patient back to be absolutely sure.
- 80-85% are on hormonal replacement, which makes you more nervous.
- I tend to follow some patients who are on estrogen therapy and an area of asymmetry develops that looks different from other areas of asymmetry.
- When a patient starts hormone therapy and has a dramatic change in the appearance of her breast, I use that as a reason for follow-up.
- If a patient's been stable for a long time and they start to get what look like benign changes from estrogen, I almost always follow it.
- Sometimes we'll follow that if they've started developing one or two nodules; more often we'll just ~~sono~~ them and say it's cyst and leave it alone.
- Anything I can't determine stability on because the patient's on estrogen, I follow.

##### Don't use category 3 for women on estrogen (R)

- I would not use code 3 in an estrogen replacement patient where you have a clear history there's been a change in dose; we'd use category 2.
- I don't use it for women who have been placed on hormone replacement unless there's a focal area that's become denser.

#### 5. History

##### Use code 3 for patients with history of risk (R)

- the other thing that might enter into whether I follow a lesion carefully might be the histology of a previous biopsy.
- when you put things together with the clinical history and the patient's and family history, I rather have them come back in 6 months because if I miss a cancer in that area, I'm going to feel bad for the rest of my career.

##### Biopsy patients with history of risk (C)

- offer biopsy as an option if there is some history, a close friend or family member
- patients who've had a family member with breast cancer who died are less willing to be put in a B-month protocol, more likely to have it removed.
- I had a case where the nodule looked benign on ultrasound and on the mammogram, but her sister, mother, and aunt had had cancer and she wanted a biopsy; we biopsied because of her anxiety and family history.

- We'll still put it in a category 2 or a category 3, but if there's a strong family history it's understandable that they would want things biopsied more readily.
- if someone has increased risk, like prior history of atypical hyperplasia, when they have a change on their mammogram they tend to get biopsied much quicker and don't go into 6 month follow-up.
- If we see an 8 mm well-defined nodule and the patients mother died of breast cancer that patient gets a biopsy.
- Patient who is very high risk, close personal history of breast cancer on one side, patient with a very strong family history; these are the ones that tend to move toward biopsy.
- In general I've found they don't want to follow anything if they have a prior history of breast cancer. They want you to biopsy or say it's okay.

## 6. **Other patient characteristics**

### Physical characteristics (R)

- It's very **multifactoral** why people go into a 6 month follow-up.. . loss or gain in weight.. .
- Density of underlying breast parenchyma is also a factor; fatty breast, easier to seem more confident one way or the other, or going to follow-up.

### Education (R)

- My patients are very educated and they quiz you about why do you want to do this. I end up doing biopsies even though I have all the confidence in the world it's a benign nodule.
- In some places you have patients that are very demanding and in other areas patients will do anything you tell them. I think it's related to education.
- They're not as well-educated as non-NBCCEDP patients and they don't mind going for the 6-month follow-up.

## **B. INTERACTION WITH PATIENTS**

### **1. Level of Interaction**

#### Talk to almost all patients in code 3 (F)

- Talk to almost all patients; interpret in real time.
- Very busy practice, but still find time to talk to any patient we're going to put in code 3 so they can be active in making that choice with us.
- I almost always see anyone that I give that recommendation to.
- I see the woman for diagnostic mammograms, which account for the large majority of code 3s I give. I see her and talk with her at some length about why I've come to this conclusion.
- Most of the time I'm willing to be there to talk to the patient.
- We personally meet with essentially all the women we bring back for diagnostic studies. If it's a code 3 and that's my decision I explain that to the woman.
- Any patient we see with a category 3 I talk to directly.

- I talk to all of these patients.
- We see all diagnostic mammogram patients.
- Any screening patient who's something other than category 1 or 2 I go in and talk to.

#### Do not routinely see code 3 patients (R)

- I like to see them, but I'm in a general practice, some I see and some I do not see.
- Diagnostics I don't always see either -- lots of residents, lots of fellows. If a patient ever requests to see me, certainly I will see them at any time.
- I'll talk to the patient if they want to or they're anxious or we think they don't understand, otherwise I'll often just let my tech tell them.
- If we do an ultrasound on someone and they get a code 3, I'll talk to them while I'm doing the ultrasound. If it's someone I'm not going to see I have the tech or the nurse let her know we think everything is fine but we do a 6-month follow-up.

#### Do not talk to screening patients (F)

- I wish I had time to do that, but it's a minority of patients I sit down with face-to-face and talk to about a probably benign lesion.
- Being at a county hospital, only talk to patients with ultrasound.
- We read screening mammograms in batch, so I won't have seen the woman.
- 80% start as screening patients and are batch read, I don't see those.
- We don't routinely talk to all our screening patients.
- We don't see them at all if they come in for screening, unless they ask to see the radiologist.
- We started out trying to tell every single screening patient the results, but it just got to be physically impossible with the volume of work we do.
- Our definition of a screening mammogram is they come in for 4 view and they go. The doctor's not even in the office.
- We sometimes code 3 from the screening, but we don't talk to the patients at that time.
- We don't see the screening patients.

#### Send letter to the woman (F)

- She gets her own letter with the report.
- We send out reminder cards to patients when their next mammogram is due.
- We send patients the letters telling them the likelihood that this is benign.
- Our patients get letters too; it's required by state law.
- Computerized reporting system sends a report to the physician and a letter for him/her to send to the patient with findings and recommendations.
- We send the letters out, but with no urgency.
- I think they're waiting for that letter to come in the mail to tell them everything's okay. To the patient it means a lot.
- The patient also gets a letter in the mail explaining what they have.

## 2. What the radiologist says to the woman (C)

- This looks like a benign lesion after ultrasound and cone compression, and there is a less than 2% probability of this being malignant.
- Take films to show the woman so she doesn't imagine some horrible alien thing in her breast, tell her what characteristics we look for in benign lesions, show her that her films meet the criteria, we believe it is benign and just because we're not perfect we'd like her to come back in 6 months to act as a safety net under our patients. Give them my name and card to call with questions.
- If I thought you had something I'd do a biopsy. I'm calling you back because I really don't believe there's anything.
- I explain that, statistically these are the chances, typically we'd watch if for 6 months, if you're not comfortable with that we can take additional steps and be more aggressive.
- I tell her I'm almost certain this is benign and I think it's reasonable to follow it in 6 months. I tell her if I saw anything on the mam that made me think this might be a cancer I would recommend biopsy. Try to reassure her that this is a good way to proceed.
- I talk to the women as if this is my breast, this is what I would do. They feel more comfortable about that.
- I let her know the statistics, that there's a 1% risk.

## 3. Importance of interaction with patient

### Good to speak with the woman (C)

- I find speaking with the individual patient is certainly helpful, if you have that luxury.
- Very important to get the woman on board, understanding what the reasons for follow-up are; we discuss it with the women, let them know what their options are.
- You can tell when you're talking to them if they're comfortable or not.
- Need to counsel the woman about what you're trying to say by that.
- From the standpoint of quality of care, I think it's best to see the patient.
- It's important to discuss it with the patient at the time of the diagnosis.
- Patients appreciate when you talk to them, your being forthright.
- When you meet with the patient you get a sense of the patient and that can help you decide which way to go.
- All patients in this code should be talked to by the physician and given options.
- You really have to talk with them and let them know that the odds are overwhelmingly benign, and not just probably benign.
- We have to take the initiative and talk to the patient.
- The key is talking to the patient at the time of categorizing.

### Approach impacts the woman's decision (R)

- So much depends on how it's presented to the woman; I think the number of biopsies can sometimes be an expression of how uncertain the information conveyer is.

- I think it goes back to the issue of how it's presented to them and who discusses it with them, to what level their anxiety soars.

#### Important to talk with patient so she can make the decision (F)

- The woman is the final determinant as to what happens; we **can** just recommend what we feel is a reasonable approach, but she makes the ultimate decision.
- I give her the choice many times.
- I encourage them to talk with their doctor, tell them it's a decision they and their doctor have to make, but this is my recommendation.
- I think the patient usually very readily understands what a 1% risk is and will decide right there whether she wants to biopsy it or follow it.
- You don't know up front which category that patient's going to be in – whether they want 6 month follow-up or biopsy right away.
- We also offer our patients the choice a lot of times of getting an answer right away.

#### **4. Anxiety, concern**

##### Category 3 causes patient anxiety (F)

- I don't like to use that category because I think it does cause some mental anguish in some patients.
- Code 3 probably causes a little more anxiety for the patient, but most of the times I'm willing to be there to talk with the patient, so in my opinion it doesn't matter how many times you use code 3.
- The key ramification of this category is that some patients, no matter how much you talk to them and reassure them, are going to spend the next six months wondering about this finding. It's really a problem with this particular category.
- One of the negative results of using this code is patient anxiety over the six month period.
- We've tried to minimize our amount of category 3s because so many women feel like they're hanging for 6 months.
- Patients really do have problems with this category. Patients tell me, "probably benign, that's not good enough."

##### Anxiety is unavoidable (R)

- The anxiety issue, although real, is a fact of life and anything we do in medicine.
- There is no way to eliminate the anxiety.

##### Patient anxiety is an important issue (C)

- If I had to pick one factor, it would be the patient's involvement and her level of comfort.
- Point that was raised about quality of life issue, patient anxiety, is a very valid point.
- There's the anxiety of the patient, and that's an important question.

## 5. Patient reaction

### Patient reaction varies widely (C)

- Reaction is really individual; there's a bell curve there.
- It's very dependent on the patient.
- Really variable how people react.
- People's comfort levels are really variable, and with the probably benign category I think they find it a little hard to comprehend how we decide when we're comfortable following something and how much they should trust our judgement.
- Response is across the board. Some are comfortable, some are not.
- Every patient is a little different, depends on their outlook on life, how positive or pessimistic they are and their anxiety level.
- Most of our people are rural and unsophisticated and I'm able to convince some of them, but it's a harder type.
- In our experience it breaks about **50/50**, half the patients are just happy they don't need a biopsy and are more than happy to come back in six months and half the patients get big eyes and say 2% is too much for me.

### Most patients agree to six month follow-up (C)

- Overwhelming majority say okay, that sounds reasonable to me, I trust you.
- For others 6 month follow-up is fine and they'll just leave.
- Most aren't worried.
- Most are okay with 6-month follow-up.
- Others say 6-month follow-up, fine; others say I'll be back in a year.
- If explain, most patients are fairly comfortable and will come back in 6 months.
- Many want to discuss it with their physician or may agree with follow-up but seek a second opinion from a breast surgeon. That increases their comfort with clinical follow-up as opposed to biopsy.
- Patients who've had 6 month follow up for something else (like a pap smear) and had no change will be more positive about follow-up because they had a positive experience before.
- Majority will opt for short-term follow-up and feel comfortable.
- Some patients are comforted by the six-month follow-up.
- I have very few patients that want a biopsy when we recommend category 3.

### Some patients are too anxious to wait six months (C)

- Sometimes they opt for not waiting; they can't tolerate waiting as much as we reassure them.
- Some are very nervous about their breasts and are just not going to be comfortable with it.
- We'll tell someone they have a cyst and you have to drain it in the office there or they're not functional.
- A few are very concerned, you can talk and talk and they're still concerned, have to handle the problem now.

- The woman who is waiting for 6 months wondering if she has cancer, she's too anxious and will tell her doctor she wants a biopsy anyway. That happens often.
- Some just need to have an answer.
- Sometimes you tell them it's a lymph node, it's nothing, and they still want it out.
- Some patients are anxious about the code; they want a definitive answer.
- Some of the patients are not comfortable.
- Patients are anxious even when doctors are not.
- Lot of anxiety about breast cancer; women don't want them followed; prefer to have lesions out.
- It's mostly nurses and people in the health profession that get really anxious and concerned about it.
- They seem to all have a friend or relative who was followed for 6 months and it turned out to be cancer, so there's a lot of patient anxiety associated with 6 month follow-up.

#### Biopsy because of high patient anxiety (C)

- Offer biopsy if patient's level of concern is higher.
- Sometimes it's better to take it out than to worry.
- If patient wants a biopsy, we'll see to it.
- A lot of pressure from the women to go on and do something; hard to say wait six months. I usually ask them, and if they want a biopsy we usually go ahead.
- We biopsy some category 3s because after talking with patients they want to eliminate even that 2% uncertainty.
- I find we do a lot of biopsies on code 3s because a lot of people are so anxious they want an answer before 6 months.
- You can eliminate anxiety in those patients if you do a biopsy.
- If they are anxious I will do a biopsy and be fully confident of the results.
- Every once in a while you get a patient who's really hyper and they absolutely want a biopsy, and we do the biopsy for them.
- Sometimes a patient is so stubborn about getting a biopsy, even though we're certain it's probably benign or even definitely benign; often after trying to talk them out of it for a while we will go ahead and do the biopsy.

### III. PRACTICE-RELATED FACTORS

#### A. PRACTICE SETTING

##### 1. Type of setting

#### Hospital (F)

- Our hospital patients are usually spoken to by a surgeon who reviews the mammogram.
- Being at a county hospital, only talk to patients with ultrasound.
- We have a 240-bed nursing home with our hospital.

- We also have some logistical problems caused by the stresses of a busy hospital; ultrasound department can't work in another patients, or mammo techs are behind and don't have time to do extra views.
- We're primarily hospital-based, and that's where they get all their care in rural America.
- We're county and we're hospital-based and we're salaried, and whether the hospital gets paid or not, we can't let that be a consideration; maybe if we were a private facility we'd have to pay more attention to that.
- I'm in a very large group resulting from mergers; the practice setting has impacted; putting radiologists together who read differently will have an impact on that rather than having a small tight setting where you can monitor closely the radiologists.
- County hospital, don't have a stereotactic machine; didn't have a good ultrasound machine until recently.

#### Office

- Mammography technicians in our off-ices tend to be better; I suspect that must have some affect on our code 3's.

#### Mobile Unit (R)

- I'm in a different environment, reading mobile stuff. I don't have access to magnification views or follow-up studies.

#### Practice in various settings (F)

- We have a varied setting, university setting and two private practices, I practice in all of them.
- We have two sites; one is main hospital with 4 radiologists on hand at all times; other is satellite site where basically screening is done and there's no radiologist on site.
- I practice in seven different mammography settings, everything from unsupervised to a small rural hospital where we pretty much check everything.

#### 2. **Setting is not a factor (F)**

- I don't think it's the setting.
- Hospital, private practice, whatever doesn't really necessarily make a difference, except economic status might differ.
- I practice in two different settings, an office and a hospital, and I don't find any difference.
- Variety of settings, no difference.
- Our practice is widespread – breast center, also outlying clinics. I think we're fairly consistent, as to place.
- We have 6 sites for mammography, as well as mammogram machines at **OB/GYN** offices, we read films for them.

### 3. Regional differences

#### Practice varies by region (R)

- I think different parts of the country practice different types of medicine as far as mammography. I think that's the way it got started and they're comfortable with that system, but there should be one standard.
- I think in different parts of the country, different cities, different places will be different. Once you get to the place where you feel you're recommending an appropriate number of biopsies and not missing cancers, that's the goal.

#### Practice does not vary by region (R)

- I disagree that area of the country is a factor. If you take the best standard of care it should be very similar nationwide.

## B. COLLEAGUES

### 1. Clinicians' understanding of code 3

#### Clinicians misinterpret/don't understand (F)

- Idea of quantifying high probability has great merit, b/c clinical colleagues may misinterpret it as well I'd better do something if you're 51/49% concerned.
- Could cause psychological trauma if clinician explains report to woman and doesn't understand that we're 98% sure it's benign when we say probably benign.
- There is confusion among the clinicians about what the terms may mean.
- Referring physicians do not or choose not to understand the code.
- At a conference, family practice physician said the ACR codes are meaningless to him; has no idea what they mean.
- Referring physicians/clinicians don't have an understanding of what "probably benign" is.

#### Clinicians need to learn that radiologists deal in probabilities (R)

- It would be educational to our clinical colleagues that we don't deal in certainties, we do deal in probabilities.
- We have to educate our colleagues that mammography's not 100%.
- I tell my docs that PPV is a batting average.

#### Important to talk with clinicians about individual cases (R)

- Frequently speak w/ clinician as well.
- For something other than normal, we call the physician the next day alerting them that there will be a report with a recommendation for follow-up.

#### Educating non-radiology colleagues is important (F)

- We print out what the codes mean on the report so physicians see what they mean; at first they asked about them, now they're used to it.
- It helps family practice docs to know that you're using some criteria and being consistent in your report.

- If you explain what the code means, most of our primary care physicians will go along with that.
- We've shared Sickles' data with numerous physicians, so it's accepted.
- It's important that clinicians who get the report understand that code 3 means 2% chance or less for malignancy. Need continuing education among clinicians.
- Education of all physicians, including family practice and surgeons, will decrease the differences among states or regions.

## 2. **Radiologists' understanding of code 3**

### Radiologists are confused (F)

- The term "probably benign" is confusing to some radiologists.
- I have no idea what criteria people are using in my town; not following ACR or Sickles criteria for coding something probably benign.
- My frustration is that there seem to be a lot of radiologists who don't understand or use the follow-up guidelines.
- Negative is radiologists using the code who don't fully understand the strict criteria of lesions which should be placed in that code; source of frustration.
- We've found that new radiologists coming into the practice don't understand the coding system, especially code 3.
- I guarantee it's not clear to all radiologists because I see a lot of folks who end up with a category 3 based only on a screening mammogram.

### Radiologists are not confused; fully understand code (F)

- The radiologists in my group fully understand the code.
- We seem to be in sync talking about comfort level of 95% or higher.
- I think radiologists as a rule have a good understanding of what "probably benign" is.

## 3. **Expectations clinicians have of radiologists regarding code 3**

### Radiologist should make recommendations (C)

- We find most clinicians prefer we make the call with regard to f/u recommendations.
- Clinicians really want a definitive recommendation from the radiologist.
- Clinicians look for, want, need that definite recommendation in the report.
- Clinicians ask us for a second opinion on reports from other radiologists that don't include a recommendation.

### Clinicians want radiologist to do follow-up (R)

- I've never had a clinician who wouldn't support that (talking with patient).
- Clinicians want you to be responsible for calling the patient back.
- Primary care physicians don't care if we use the code more often because we follow them up; if they don't make arrangements, we contact patients, so it doesn't add to their work.

Doctors want to inform patients themselves (R)

- Some doctors in outlying areas would rather explain the options to their patients themselves.
- Our physicians don't want the patients to get the letters before they (the physicians) hear.

**4. Responses of clinicians to code 3**Clinicians don't like code (R)

- Some primary care physicians are reluctant and anxious about the code; they want a definitive answer; don't want to wait 6 months.
- Several primary care physicians don't like that code; they're fearful, not comfortable waiting 6 months.

Clinicians don't mind the code (F)

- In our practice, most physicians are pretty comfortable with the code; we have a good reputation.
- We use code 3 so seldom that physicians are willing to accept it and go with follow-up.
- Some primary care doctors think code 3 is fine.
- Most of the physicians we deal with regularly feel comfortable about our diagnostic abilities and are reasonable about following our recommendations.
- We've used it long enough that physicians here are generally comfortable with it.
- All referring physicians know we're conservative, and they're comfortable following as we recommend.
- Our primary care physicians do exactly what we say without any question.
- Most are reasonable, they recognize your level of expertise and go along with your recommendations.
- The doctors, surgeons, GPs are quite comfortable because we're doing a good job [at my practice].
- When I say category 3, some surgeons say fine.
- We use it so rarely that most physicians know we really do think it's benign, and we get very little second-guessing.
- The primary care people that know us well are comfortable just sending the patient back.
- No problems on the 6-month code with anybody.
- I know all our primary care physicians very well and they're very receptive to 6 month follow-up.

Biopsy anyway; clinicians have lower comfort level (F)

- Many probably benign lesions are biopsied anyway because patients are instructed and educated by surgeons.
- Often when we recommend follow-up, surgeon will proceed with biopsy anyway because patient wishes it to be removed.
- Radiologist may feel comfortable, but some physicians or surgeons don't have that comfort level.

- Our comfort level may be greater than that of the clinicians.
- Outside-referred's that we don't communicate with as much, especially breast surgeons, may be more aggressive about biopsying lesions we think are benign.
- General surgeons do whatever they please despite what we recommend.
- We have a few older guys who do what they want no matter what.
- Report goes to clinician, sends patient to surgeon in spite of code 3 classification.
- Some surgeons want patients biopsied nevertheless.
- The biggest reaction we get is from surgeons, they come back and tell me all the time the patient doesn't want to wait, yet patients told me they're more than willing to wait.
- The general surgeons, but not the breast surgeons, push them more toward biopsy instead of waiting.
- With certain surgeons they'll end up with biopsy no matter what you recommend.
- If they're the kind of primary care physician that sends them to a surgeon any time there's something abnormal on a mammogram, we run into that problem (biopsy).
- If we think a lesion is benign but it's palpable, surgeon will usually biopsy it.
- Most of my patients have already seen a surgeon; I'm almost obligated to biopsy even though they would have been a category 3.

Clinician sends patient back after 6 months when radiologist recommended 1 year (R)

- Some less experience physicians will send patient for 6-month follow-up when we put it to annual follow-up.
- You don't recommend, but they send the patient in; doesn't occur that often.
- Sometimes not medically necessary, primary doctor wants an extra measure of something, maybe it's comfort.

Surgeons vary in acceptance of code (R)

- Surgeons vary in their acceptance of 6 month follow-up versus biopsy.
- Surgeons themselves can make a difference.

Non-radiology colleagues see radiologists as wishy-washy (R)

- Use of code '3 feeds into prejudices our clinician colleagues have that we're wishy washy and can't make a decision; that's why I use it very rarely.
- We understand what it means to try to instill in our referring physicians the sense that we are quite confident that the chance of benignancy is very high with these lesions.

Would like to know how non-radiologists see the code (R)

- Want to hear what our non-radiologic colleagues think of our category.

**5. Impact of physician response on use of code 3**

Direct impact (R)

- **A lot of my referring physicians were not sending them back every year, so** I'd say I want this lady back in 6 months because I wanted her back.

- We now put more palpable lumps in category 1 or 2, saying there's no sign of malignancy to try to deter the surgeon from biopsying what we know will just be fatty tissue.
- Anyone who's been in practice a long time adjusts themselves to their surgeons and primary care doctors and they get to a level that's comfortable for everyone.

#### No impact (R)

- Response of other doctors doesn't impact use of the code at all.

### C. OFFICE PRACTICES

#### 1. Double reading

##### Do double read (F)

- We double read all screening, but not diagnostic.
- We double-read all mammograms.
- We double-read randomly at various times.

##### Don't double read (F)

- We don't double read.
- We're too busy to do double reading.
- We used to double-read, but found the person who's doing the second reading knew who the first person was and it had a tremendous influence over which cases they would mark something off on or not.
- Tabar says double read gets 15% better sensitivity; that's not been our experience.

#### 2. Learning through established practices of the group

##### Interaction with practice partners shapes use of code (C)

- One of the things that's helped in my practice is double-reading mammograms. It's made our practice more uniform, more consistent in how we interpret mammograms.
- Use of code 3 within practice group becomes more consistent over time by reviewing cases.
- Practice has developed a style, melded together; tend to practice alike from working together.
- Among radiologists in our large practice there is some conformity coming.
- Read each other's reports on rotation, look at others' reports and see how they look at a case; lots of conferring, case discussions.. . this is what you'd do, this is how you'd give it a code 3.
- We do a medical audit across the practice; every radiologist gets his own data. Outliers really stand out in the group and work hard not to be an outlier in the future.
- In our practice we fall into two groups, one group uses code 3 rarely and the other **uses it often; each group is absolutely convinced they're doing the right thing.**
- We all see each other's cases in a weekly multidisciplinary conference.

- We have a mammogram conference once a month, discuss cases that have been biopsied, problem cases.

#### Radiologists should follow up to learn how things turn out (F)

- Need to make sure we follow up so we know what the fate of these patients is, what cancers really look like.
- One useful thing is to review all the positive cases, look at what we've coded them and try to learn from that.
- It would make a difference in the use of category 3 in our practice if radiologists who labeled someone as a category 3 had to read the 6-month follow-up themselves.
- Radiologists ought to be doing the biopsies and getting the feedback so they can adjust their suspiciometer accordingly.

### 3. **Technologist can impact the quality of mammographic readings**

#### Technologists do initial reading (F)

- **Techs** look at them and we read them once radiology wise directly guiding what happens next.
- We also try to screen all mammograms using pretty sophisticated technologists to look at the exams and check any of them with the radiologists if they see something in an unsuspected screening mammogram.
- I also work at other hospitals where we have technologists who are well-trained and competent and who we trust, and if they see an abnormal screening, they'll bring it to us.
- Other site is a satellite site where basically screening is done and there's no radiologist on site. At the primary site we essentially view mams as they drop out of the processor.

#### Radiologist sees every mammogram (F)

- We go in and scan every patient. The tech will take initial pictures, but we always go in and confirm.
- Half our cases are done with monitoring by radiologist at the time of the study.
- 80% of our studies are monitored.
- For screening patients I do review the exam while they're there.

#### Technologists provide a second opinion on screening mammograms (F)

- Mammography technicians in our offices tend to be better, do more spot films and more independent work on their own, and we have to call fewer people back if we're not there to monitor the exams. That must have some affect on our **code3s**.
- If my technologist sees anything of any question it's shown to me and we proceed from there with me.
- We use our techs to double-read basically.
- The techs look at as many mammograms as we do; we've had them pick some things up. Recently radiologist told the woman she could go, tech said "what's that?", picked up an asymmetry that turned out to be a cancer.

### Technologists do work-ups (R)

- If there's a palpable lump or if the technologist sees an added density or a nodule or whatever, we automatically do spot compressions and ultrasound.
- We've given permission to the technologists both at primary and secondary sites to do the spot compression views if they feel it would be warranted at the time.
- If I've got a good tech at a remote site I'll let her do spot compressions.

## **D. TRACKING AND AUDITS**

### **1. Relationship between tracking and use of codes**

#### Tracking/auditing helps shape the use of code 3 (C)

- When you go through stats for so-called false negatives the following year, you have some means of tracking – casting too many people in category 3, or not enough.
- If you have good statistics, and know what our false negatives are over a period of time, that will give us some direction with the use of the category.
- You can very confidently predict the odds of something being a malignancy after you collect and analyze that data over a period of time. We get all our statistics quarterly, our positive biopsy rates for each of the categories. That information is really valuable because you can detect any significant outlier immediately and hopefully modify their behavior.
- Every radiologist gets his own data – the way he read mammograms all year long, what his hit rate was, what categories he's using and so on. The outliers really stand out in the group, and they work hard not to be an outlier in the future.
- We've also audited our practice for the last 3-4 years so we keep control of what our positive predictive value is, how many biopsies we're doing in each category and that knowledge and education going back to each radiologist has really decreased some of the category 3s.
- We collected that data [use of code 3] and showed it to people and they could see that they were a clear outlier with the rest of the group, it gave them some pause to go back and look at the way they were reading.
- We sort of fall into two groups, low group and high group, and each group is absolutely convinced they're right. So there's no peer pressure forcing the people who say they're too high.. . they're convinced they're doing the right thing, and they're in a big enough group to support it.

### **2. Existence of tracking systems**

#### Have good tracking/auditing system (F)

- We have a good tracking program.
- I send my radiology reports to the state once a month, and once a month I get a report back collating my results. At the end of 6 months, I get a report showing number of false positives, true positives, and false negatives I have diagnosed. It's an excellent tracking system.
- We track everyone, except those lost to follow-up.
- For the past three years we've tracked the number of cancers detected.

- We do a medical audit across the practice.
- We have a coding system, a Penrad system and another code, so we have codes on all radiologists.
- I've been doing the audit for our group for the last 10-12 years. We've been monitoring our use of category 3 in our group.
- We've only been monitoring [positive biopsy rate and use of code 3] for the last 5 years.
- We do an audit in our practice.

#### Do not have good tracking system (R)

- Here in this state, I fill out these forms, they go off to the state, I have no idea what they're doing with the data.
- We do have a tracking system, but, to be practical, what we are following is our categories 4 and 5. We just cannot afford, nor can all the places we go be bothered with giving us responses on such a low likelihood group as category 3.
- I'm a site inspector for the ACR, and the places I've seen, the places with even rudimentarily satisfactory tracking systems are few and far between.

### 3. **Importance of tracking systems**

#### Computer system is helpful (F)

- The MRS system and Penrad system automatically generate letters to referring physicians that tell them the patient needs to come back in 6 months.
- We have a computer program, if you put in the ACR codes, it generates reminder letters for the 6-month follow-up. In addition to adhering to ACR recommendations, it really helps us because the code itself can be tied to a letter.
- Use computerized reporting system that sends a report to the physician and a letter for him or her to send to the patient with findings and recommendations.
- I think the folks most likely to use the ACR coding are the ones on some sort of automated reporting system.
- I'd urge all practices to have an automated data analysis system that would allow them to know, it's one thing to be educated about what the categories are and what to expect, it's another thing to know how you personally are performing.

#### Tracking is important (C)

- I'm trying to train all the other radiologists in our practice that do mammo to use those class 3, 4, 5 codes so we can track all kinds of different things.
- We've looked at our cancers, and of 200, 80% are 1.5 cm in diameter or less. So we know we're not ignoring cancers that turn out to be large cancers; we really believe that's another way to check how you're doing.
- We now have the Mammography Quality Standards Act so it's necessary to track all your patients that you say have abnormal findings on the mammogram.
- We have to make sure we follow-up so we know what the fate of these patients is, see what cancers really look like.

- I think the best thing that has come from all this bureaucratic imposition (ACR codes and accreditation) is the statistics. We can all say my PPV is this, my false negative rate is this, and that's good.
- The key to all this is what your predictive values are and how you're doing on your audit.

#### State registry is helpful (R)

- Any cancer in this state or a contiguous state is reported to the state database, so we have some handle on sensitivity.
- False negatives are hardest to follow; unless you have a state registry, it's hard to know if we're missing cancers.

## **E. EQUIPMENT/TECHNOLOGY**

### **1. Types of technology used by radiologists**

#### Technology for Mammography

- Mammography (C)
- New film for mammograms (F)
- CT mammography (R)
- Nuclear Medicine mammography (R)

#### Technology used for work-ups

- Diagnostic mammography (C)
- Ultrasound (C)
- Magnification views (F)
- Spot compression views (F)

#### Equipment for biopsy

- Stereotactic Guided Biopsy (C)
- Ultrasound Guided Core Biopsy (C)
- **Surgical/excisional** biopsy (C)
- Fine needle aspiration (R)
- Wire localization (R)
- Mammotome (R)

#### Tracking and Auditing systems

- Penrad system (R)
- MRS System (R)

### **2. How **the availability of technology/equipment impacts use of code 3****

The availability of ultrasound or stereotactic guided biopsies decreases the use of code 3 (C)

- I have access to ultrasound core biopsies and stereotactic guided biopsies in my office, and I'll go ahead and biopsy a mass I used to think was 99% benign to allay the fears of the patient and a little bit of myself.
- One thing that has helped me a lot is I now have a mammotome on my stereotactic machine, so I can go after smaller lesions.
- Nowadays it's great because we have stereotactic or ultrasound guided biopsy, so we don't have to do an open excision.
- Wire localization on those that are slightly more suspicious and can get a tissue diagnosis.
- We have biopsy techniques that are fairly non-invasive for when not sure.
- If it's suspicious, these days with stereotactic biopsies so easy to do you can get the answer and there's no worry.
- In the last five years my observation is that there are an increasing number of cases that are being sent for biopsy, whether by a radiologist or a surgeon.
- [National leaders] say shorten the follow-up, lower the threshold for getting a biopsy, especially because they are so much less invasive now.
- I think decreasing use of code over the years in our practice is directly related to how aggressively we've started to use ultrasound.
- If it's solid on ultrasound even if it looks benign, I would be loath to use number 3.
- The ATL study proves ultrasound can reduce the use of code 3.
- I use ultrasound ad liberatum, and I find it very effective at **determining** a benign nodule from on that is malignant.

The availability of old films can impact the use of code 3 (F)

- Suddenly a patient brings old film from three years ago, and every once in while it will go from a category 3 to a category 1.
- Availability of outside films reduce need to code 3. Old films generally allow you to code it 1 or 2, or code it 5, depending on the situation.
- Having previous mammogram is helpful . . . "yes, it was there last year." Allow us to gain confidence that nothing's going on that we should worry about.
- It's easy to get prior mammograms, get it, look at it, lesion is there, you already have your 3 year follow-up.
- A woman had a probably benign nodule on her old mammogram; before I saw her it was biopsied and was malignant. Developed a similar nodule that I would have called a 3 based on the image itself, but I moved it to a 4.
- Sometimes I put a woman in category 3 because.. . it looks benign but I'm not sure totally because of inadequacy of prior films to compare.

**3. How the lack of technology impacts the use of code 3**

The lack of availability of old films can increase the use of code 3 (R)

- I use it more if I don't have old films; looks like a benign finding but I don't have old films to confirm it.

- If no prior film or it's a baseline, and there is something there with a very low suspicion ... I might ask for a 6 month follow-up.

#### 4. **Negative aspects of technology**

##### Inappropriate uses of ultrasound or stereotactic biopsy (R)

- It's amazing how many cases get referred to us for stereotactic biopsy without a full work-up first . . . .You might as well flip a coin as to whether the things that radiologists are sending to us for stereotactic biopsy at other institutions are going to pan out or not.
- Smaller and smaller lesions are being sent to me for biopsy; I'm not sure that is the right thing.
- We bend over backwards to not use that biopsy technique for category 3 patients. We've monitored very carefully and we're only using that to biopsy people who would normally get an excisional biopsy with the criteria from before the days of stereocore biopsy.
- I don't think you should ever go to biopsy just because you have a machine that will do it.

##### Problems with ultrasound (R)

- Someone mentioned they were using a 5 megahertz ultrasound and that worried me because I've been doing biopsies that turned out to be cysts because the frequency was not appropriate.
- They had some 5 megahertz machines on some sites which we just thought were not appropriate for breast ultrasound.
- Bad ultrasound is worse than no ultrasound.
- People are terribly specific on sonography when they need to be more general and say this is likely a benign lesion .. rather than give a pathological diagnosis.

##### Negatives aspects of mammograms (R)

- The mammogram itself is the problem. It's not accurate to begin with. This probably benign category compensates for a test that has really low sensitivity and specificity.

#### 5. **Variability of quality of equipment.**

##### There is an increase in code 3 with new equipment and film (F)

- I've noticed that there's been a slight bump up of the probably benign category once we get new equipment and new film.
- After new equipment, bumps up for a couple of months, then people start getting comfortable with the changes and it goes back down.
- New film has really helped to show the edges of calcifications, some of the morphology better.
- We very rarely follow microcalcification. The only time is if we think the apparent difference is probably just due to the better film contrast on the newer film.

There is a great variability of film/equipment quality in different locations (F)

- I get mammograms from all over.. . the quality of the films varies considerably.
- Some [patients] come in and have a great difference in the quality of the mammographic exam from one year to the next.
- I think any recommendations from the ACR should recognize these regional differences in availability of different technologies within those communities.

Technology for reading mammograms has improved (F)

- Poorer quality mammograms in the past. Technology makes it easier now [to read a mammogram].

**6. Computer auditing systems make it easier to use the codes**

- The new computer systems have programs that require you to use these classes, and they tie them to letters that their computers are going to spit out.
- With the MRS system and Penrad system we have, it automatically generates letter to referring physician that tells them the patient needs to come back in 6 months.
- If I were on a computer system, I would absolutely use the digits (for the codes) as well.

**7. How patients are learning about options in breast biopsy**

- Often through a friend, word of mouth, magazines, and newspaper articles.
- It's not through their physician.
- Time Magazine seems to be a big one out there.
- Something will be on the morning national news show and that would really have a big effect.
- In our largest breast center we have an education room with a lot of different education materials.

**8. Level of work-up before assigning code 3**Code 3 is only used after a full work up (F)

- I would never recommend biopsy without further views unless it was overtly cancerous lesions with skin changes. So she would come back for a diagnostic mammogram, and then possibly go on for a biopsy.
- We always work up a lesion; never commit a woman to follow up without diagnostic views and a good reason for doing it.
- My training was that code 3 shouldn't be used until after some kind of work-up.
- Any patients read off-line we call back for biopsy or additional views; we do not recommend either short-term follow up or biopsy off a screening study.
- That's one thing that ought to be promulgated by the ACR that really a category 3 ought to be following a full work up rather than right off the screening mammogram I'm not sure that's understood, or even if it's official policy.
- In our practice, almost a rule that no one gets code 3 without a complete workup.

- If there has not been any work-up, we do recall patients before we put anything in the probably benign category.
- By the time a patient goes into a category 3 the ultrasound would have been done, magnification views, etc, before they get a category 3.

#### Code 3 can be assigned from a screening mammogram (R)

- I'm different from one of my partners, in that I'll code 3 based on a good screening mammogram, on something I think is probably benign and it's maybe her baseline exam and I want to look at it again in 6 months, and I'm not very suspicious of it.
- Significant minority of cases I've code 3 on the basis of what I see on a screening mammogram.

#### Examples of technologies included in a full work up

- You have to do your appropriate diagnostic work-up, whether that means spot compressions, magnification views, additional views, or an ultrasound, to work it up to fullest extent before you can call something probably benign .
- Don't think you should use code 3 until lesion is completely worked up with spot magnifications or spot views or ultrasounds.
- If my threshold of concern has not been exceeded after using additional views and ultrasound, it's code 3.
- I agree, bring back for additional views; spot compression for a mass, magnification views for calcifications, or spot views for asymmetric densities, or ultrasound if a mass, that would help me determine whether to go on to a follow-up vs. biopsy.

## **IV. EXTERNAL FACTORS**

### **A. LEGAL IMPLICATIONS**

#### **1. Malpractice is an issue in mammography**

##### Mammography is a litigious field (F)

- Mammograms are the biggest area for radiologists to be sued.
- This is a medically litigious field, nobody wants to miss a cancer.
- I like to study my mammography.. **because** I can be sued

##### The legal system does not understand that mammography is not black or white (F)

- We do deal in probabilities. Unfortunately the legal system doesn't understand it.
- The problem is that the public and the legal system do not understand that mammography is not 100%.

#### **2. Legal implications can affect how often code 3 is used**

##### Using code 3 can expose radiologist to malpractice (F).

- With a category 3, the probability of being sued is something you have to think about.
- Worry that if you follow it and it becomes cancer, malpractice exposure.

- The fear and frustration with using this category is that you know there is still a 2-3% change of malignancy that leaves an open door for lawyers or even the patient.
- If there's anything at all that makes us worry, we are not going to call it probably benign. The legal climate... our clientele wouldn't tolerate it if we started finding cancers six months later.
- Smaller and smaller lesions are being sent to us for biopsy. I think it's the malpractice climate; there's increasing apprehension.

#### Radiologist does not think about legal issues when assigning codes (F)

- I don't think it enters consciously into decision-making on a case-by-case basis.
- Legal issues have no importance to me.
- I don't believe in choosing the categories, that I'm influenced by the thought of malpractice.
- I never take the legal system into consideration.
- Can't practice defensively worrying about what some dirtball is going to do to me.
- I'll quit when I start worrying about getting sued.
- No lawsuits here; think it wouldn't change how we practice.
- When you practice mammography, you can't worry about being sued, because I think it does affect your practice.

#### Radiologists use code 3 so that they are not subject to malpractice (F)

- It may be a little bit of a hedge, but until there's some legal reform, in this situation I'll bring her back for follow-up.
- If the legal system changed, we would take the lesions we really believe are benign and not bring them back in 6 months.
- My use has gone down. But when moved to US from Canada bumped up because of legal implications.
- I think category 3 may have something to do with the legal system because you can bring the patients back in 6 months and not miss something for longer.
- I think [the legal system] has a lot to do with why some of my colleagues have a much higher percentage of cases they put in that probably benign category.

### **3. The result of follow up on lawsuits**

#### Radiologist has never been involved in lawsuit (R)

- Never been involved in a lawsuit in mammography.
- No lawsuits have arisen from code 3 use in our practice.

#### The radiologist has had probably benign lesions turn out to be malignant. No legal implication. (F)

- There are a lot of lesions we called definitely benign that turned out to be cancers.
- We have had lesions listed as probably benign by one reader that come back here and have developed a cancer.
- I didn't get in legal trouble, hopefully I didn't change her life by making her wait 6 months for the diagnosis.

- Know of several code 3s that turned out to be malignant. No legal spin-off at this point.
- I had one case, recommended 6 months, she came back in 4 months and found it to be malignant. No legal action.
- I had one where the small lesion had grown when they came back for 1 year.

#### 4. **Factors that will decrease the risk of malpractice even if a cancer does appear**

##### If radiologist follows the standards, it is easier to show that is was not malpractice (F)

- I don't know if that article will hold legal ground or not, but you're not going to get many radiologists to argue that you did the wrong thing.
- If you start changing the standard subjectively, you can't follow the national guidelines and that really makes it easy for the lawyers.
- Medically/Legally, they'll ask what your standards are.
- If you have statistics that show you've been following these things and 98% of them turn out to be nothing, at least you have a reason for doing what you're doing. Show your statistics.. .if you are sued at least you have this to show them that is why you did it even if you are wrong.

##### Talking with patients about code 3 will decrease chance they will sue(R)

- Goes back to talking with patient.. .then I don't think the patient is going to sue you.
- Patients appreciate when you talk to them.

#### 5. **Knowledge of malpractice affects perception of risk of using code 3**

##### Being sued or knowing someone sued affects use of code 3 (C1)

- I have a colleague who's been sued 2-3 times, definitely affects the way he reads.
- In the town where I practice, there was a malpractice against a surgeon where he elected to follow for 6 months, and it turned out to be cancer. A case like that shakes up the medical community and might lower the threshold for talking patients into having code 3 lesions biopsied rather than putting into follow-up.
- Prior personal history of litigation over missed breast cancer [affects use of code 3].
- It also makes a difference if you have a partner that is sued. All of a sudden they're going to be biopsying everything.
- We notice once a radiologist has experienced a lawsuit there's a big difference.
- You have variability throughout the year depending on whether somebody's been sued.
- The people who'd had experience with a lawyer.. . are just a little bit more defensive in the way they approach film reading.

##### Not knowing anyone sued makes radiologist more comfortable using code 3 (F)

- Everyone is paranoid, but never been a case I know of that resulted in legal trouble.
- No knowledge of any legal action, but I don't hear about that stuff.
- A radiologist has never gotten sued for suing a code 3 diagnosis., so one of the reasons I use it. I know many radiologists who were sued for not following up on a timely basis. Never heard of anyone who was sued because he got a x-ray too soon.

## B. FINANCIAL ISSUES

### 1. Cost impact of code 3

#### Code 3 reduces costs (R)

- The reason Sickles did this whole study was to show the difference in cost. ... And the difference between biopsying all these things as opposed to watching and proving that you can safely do that impacts on the cost factor.
- The reality is that with managed care and the pressures of the dollar, the pressure to keep good statistics and prevent needless biopsies is going to increase the likelihood of follow-up.
- That contributes to an overall reduction in the cost of screening if you can increase your positive biopsy rate by biopsying fewer lesions, that's certainly the goal.
- It's more cost-effective to follow up than to do a stereotactic right away. I haven't worked out the outcome, how good it is to go with follow up or biopsy, how many cancers detected.
- If [using code 3] reduces number of biopsies, could conceivably have a positive influence on cost.

#### Code 3 increases costs (R)

- Overall the impact of cost of life saved by screening mammography and how having too many callbacks or short-term follow-ups would raise that cost per life saved.
- If you're bringing back an inordinate number of patients who would hopefully never come to biopsy anyway, you may be increasing the overall cost of mammography.

### 2. Impact of cost issues on the use of code 3

#### Radiologists do not take cost considerations into account (F)

- I don't think anyone does anything with regards to mammography to make a buck because I think universally in radiology it is a money-losing venture to do mammography.
- We're county, and we're hospital-based, and we're salaried, so whether the hospital gets paid or not we can't let that be a consideration. Has to be what's in the patient's best interest. ... When you start letting cost affect how you manage your patients, that's a dangerous situation to get into.
- I select whatever views and whether we get paid or not, the county people who run the hospital do not care, and I never think about it one way or the other.

#### Radiologists do take cost considerations into account (R)

- I think money is the driving factor. We cannot dismiss that. If we suggest biopsy, we ... set up a chain of events causing money expenditure. So anything we say is really money-driven no matter how you slice it.
- We also take into consideration the cost-effectiveness, not referring everybody for biopsy, but making sure something is not a cancer.

- [For probably benign lymph nodes], I wouldn't work those patients up because I think the cost of doing the ultrasound and everything is more than just getting a follow up mammogram.

### 3. **Fee structure in mammography**

#### Radiologist charges one price for mammograms even if additional views are called for (R)

- If we have anyone we're going to do anything additional on (talking to them, additional views, that kind of stuff), all included. We charge a single price for mammogram and additional views on a return visit if necessary are included in that price.

#### Mammograms are almost always paid for (R)

- I think mammography is one area I can be confident I'll get at least ten bucks for reading a mammogram.

#### If additional views are needed radiologist charges for diagnostic mammogram (R)

- We don't charge them with screening and diagnostic, we just charge them with diagnostic.
- We do charge more if we do an ultrasound.

## C. **INSURANCE**

### 1. **Reimbursement in mammography**

#### In a managed care setting follow-up and biopsy are the same price (R)

- The amount of money difference Medicare and HMOs pay for ultrasound core biopsy and two extra follow ups is not very different.

#### Reimbursement is not good for mammography (R)

- Very much HMO, we lose money on [screening mammograms] sometimes.
- Reimbursements not that good for breast cancer screening.

#### Reimbursement is good for mammography (R)

- In the past many mammograms were not paid, but in the present situation at least we get paid something.

#### Managed care makes it more affordable for patients (R)

- We're talking quality medicine because it's clear they need to afford what we provide.
- If we have anyone we're going to do anything additional on it's all included.
- We charge a single price for a mammogram. Additional views on a return visit if necessary are included in that price.

## 2. The insurance scene does affect radiologist's practice

### Use of code 3 will increase with changes in insurance scene (R)

- The reality is with managed care and the pressures of the dollar, the pressure to keep good statistics and prevent needless biopsies is going to increase the likelihood of follow-up.
- I wonder if that has some impact on insurance reimbursement and if that's in the back of people's minds, that if they recommend follow-up the patient will come back and it will be covered.

### Insurance companies dictate practices (R)

- Some insurance programs won't allow our outpatient site to do extra views or breast ultrasounds, but they will allow screening only.

### Involvement in managed care increases patient return (R)

- Here we see good follow up mostly because of the high HMO requirements and the surveillance of primary care physicians.

## 3. The insurance scene does not affect radiologist's practice

### Insurance companies do not stand in the way of mammographic recommendations (R)

- I've never noticed an insurance company balk at anything having to do with follow-up.
- I've never had any of my recommendations questioned by local HMOs.
- No requests or directives from our business office to stop using the category.
- We haven't so far been limited by our insurance carriers in what we do.

### No change in use of code 3 based on changes in insurance (C)

- We are totally oblivious to the insurance scene.
- I don't worry too much about different insurance categories.
- Hasn't changed anything. We just do the same thing.
- Hasn't affected. Whether I do 6 month follow up doesn't depend on how I get reimbursed.
- I never check or know, and it doesn't enter in, in any fashion.
- We're fee for service and we do our studies, or follow ups with out regard to reimbursement.
- I'm presently salaried, I've been fee-for-service in the past, and I don't think it makes a bit of difference.

## D. NBCCEDP

### 1. Comments on the program itself

Positives about program (R)

- We rely on the NBCCEDP to get the patients in; the program is very good – they have a nurse I talk to all the time. The NBCCEDP is better funded than the radiology department at this county hospital.
- We've had excellent compliance too with the NBCCEDP because in this state they're very well-funded, they have excellent follow-up.
- We've had good compliance; we've not had anyone fall through the cracks yet.
- For the CDC screening program we get reimbursed for screening mammography, also if they come back for any additional views or ultrasound, core biopsies, visit to surgical clinic are reimbursed.

Problems with program restrictions (R)

- For a while they had to go to the university hospital if they needed diagnostic views, but we got the program changed so we can work them up and have them biopsied here if we need to, and that helped tremendously.
- Frustrating thing is can't do any extra views on some of these people and we'd like to. They have to come back for additional films, which is a little difficult because if I see something I'd like to work it up right away.
- Unfortunately program doesn't cover breast biopsies, so anyone who has a lesion that doesn't want to keep it in the breast even if it is a code 3 will end up getting a core biopsy because they don't have the money or the option of going to the operating room. In that way, that type of reimbursement has put more people in the code 4 category.

**2. Awareness of program participants**Not aware if in the program (F)

- We have no knowledge whatsoever of whether a patient's on one program or another.
- It's transparent to us.
- We don't know when a patient is in the program.
- No, I don't have prior knowledge of that.
- Our practice has 28 radiologists so we have a business office. We are totally oblivious to the insurance scene.
- It's there on the papers, but I don't have any reason to look and I'm not concerned with it, so I don't know or care how they're paid.
- There's no way to know.
- In our setting, I don't know which patients are NBCCEDP.
- I'm not aware; technologists may keep track.

Aware if in the program (F)

- They're clearly demarcated and we know who they are.
- Some patients have it on their request.
- Aware, because separate sheet to fill out.
- We do know.
- I am aware, have a separate sheet that comes through with those patients.

- We have time set up in our schedule for just NBCCEDP patients, so we do know.
- Aware, because have special forms to send in to the state program.

### 3. Impact of awareness

#### Awareness doesn't play a role (F)

- Don't pay attention to it.
- I don't know which patients are NBCCEDP; would need a red star on the patient information sheet, and they may not be the only ones who tend to be noncompliant.
- It doesn't impact how I interpret the mammogram or what I'll recommend.
- It doesn't influence the way we read their mammograms or what we do for them.
- It doesn't make any difference. We practice the same on everybody.

#### Provide more aggressive treatment for program participants (R)

- The clinic I work with has a very low threshold for biopsy because statistically they lose most of these patients (NBCCEDP patients) to follow up.
- Very very few in the NBCCEDP get code 3 with 6 month follow up; try to resolve, either benign or biopsy because we're concerned they're not going to follow up.
- Most are indigent, poor transportation, keep at hospital because bussed in or mass transit, we do go the extra mile with those people, push for work up.
- Because these patients are followed by clinics or ancillary practitioners, facility may not even be there in 6 months, so you have to be very thorough with these patients.

### 4. Characteristics of program participants

#### No prior mammograms (R)

- Lots of patients who come through the program have never had a mammogram and they're 60 years old.

#### Compliance problems (F)

- With the patients we have in this program, they sometimes aren't going to show up 6 months later (general agreement).
- There are compliance problems, financial or transportation problems.
- Patients in CDC screening programs have a poorer compliance in general.

## E. VIEWS OF THE ACR CODING SCHEME

### 1. Views and uses of the other codes

#### a. Category 0

#### Radiologist uses code 0 if a mammogram is not clear (F)

- I make liberal use of code 0 first, especially since I'm removed from the site, not on site where the mammograms are performed.
- Actually, when a mammogram is not clear, it goes into the ACR category 0.
- If not clear, on screening mammography it's either a clear negative or it's a callback.

Category 0 changes after training (R)

- Ed Sickles is a great resource. I was concerned a while back about my category 0, callback rate to be too high. I went out and spent a week reading mammograms with him in his practice and my rate dropped right down right away.
- I don't find that our category 3s go up, but our category 0s, our callback rate, always takes a little jump up after a conference.

With more experience, category 0 decreases (R)

- The few of us in our group who spend the vast majority of our time doing mammograms tend to have low callback rates, category 0s, where other people that spend less time at the breast center tend to have higher rates.

## b. Category 1 &amp; 2

Category 1 and 2 are used interchangeably (R)

- Category 1 and 2 are basically the same on my form.
- I use category 2 liberally, but mostly as a not to myself; 1 & 2 are interchangeable.

## c. Category 4 &amp; 5

Radiologists' understanding of the use of category 4 and 5 (F).

- With category 5 you've made a definite 100% diagnosis, category 4 you've made a 99% diagnosis.
- To me category 4 is not quite 99%. Category 5 is basically 100%.
- Chance of malignancy with code 4 is 20%, or code 5, 90%.
- Category 4 it's 23%, category 5, greater than 90% chance of malignancy.

The follow up for codes 4 and 5 are laid out (F)

- Code 4 must be biopsied. That's the definition in my opinion.
- By definition, those lesions [code 4] should go to biopsy.
- 4 or 5 are very straightforward about what you have to do. You use that category, you have to start being aggressive.

**2. The Mammography Quality Standards Act**The standards for mammography are strict (F)

- There's no question that there's a gross double standard in mammography where you even have this MQSA that states who is qualified to do mammography, where you don't have the same standard in reading chest x-rays.
- You don't have that standard in anything.

The MQSA is federal law (F)

- Important because now we have the Mammography Quality Standards Act. It's regulated by the FDA.
- Final regulations for MQSA have actually incorporated the BI-RADS lexicon, so it's federal law now.

### 3. Radiologists' views of ACR coding scheme

#### Codes are not obligatory (R).

- You don't have to give anyone a code. The ACR BIRAD codes are not obligatory.

#### The statistics are the best part of having the codes (R)

- I think the best thing that has come out of this bureaucratic imposition is the statistics.

#### Standardization of practice is the goal of the codes (R)

- I think when they came up with the BIRAD (Breast Imaging Reporting and Database System), their goal was to standardize the lexicon of findings and recommendations so anyone in the world could pick up the report and understand what you're saying.
- That's what the ACR is doing this for is to show that we're all trying to practice the same way.

### 4. Radiologists do not use the ACR codes or use it differently than ACR standards

- We read on a 4 point scale.
- I find that a lot of radiologists in this town aren't using the ACR categories at all.
- The whole state is divided into two large radiology groups. Both groups use ACR lexicon and categories, but the understanding of these categories varies with the amount of education.
- Everyone in our town uses the ACR categories, but I don't believe anybody has really formalized the use of the lexicon.
- Mixed bag in our city, whether or not radiologist use the ACR coding at all.

## V. UNDERSTANDING AND USE OF CODE 3

### A. ATTITUDES TOWARD CODE 3

#### 1. Positive aspects of Code 3

##### Reduce unnecessary biopsy (F)

- Positive - don't do biopsy for benign disease.
- The whole point of code 3 is to minimize the number of benign biopsies.
- I think the category has a useful purpose that is to decrease the number of biopsies that are most likely to be negative.
- Main reason is to avoid unnecessary biopsy.
- The reason you have a code 3 is to try to keep your false negative biopsy rate down.

##### Not miss cancer (F)

- The point of code 3 is to minimize number of false negatives, missed cancers.

- The positive result is if you didn't have this category, some findings you might just dismiss as being benign, you'll find turn out to be malignant.
- I rather have them come back and put it in because if I miss one cancer in that area, I'm going to feel bad for the rest of my career: "I should have called it probably benign, why did I call it definitely benign?"

#### Category 3 covers the "Grey Zone" in mammography (C)

- What happens if don't have code 3? Confined to benign vs. malignant, no in between, either black or white, no gray.
- The problem is that the public and the legal system do not understand that mammography is not 100%, not black or white - lots of gray.
- The fact that there is this big gray zone is what makes code 3 just crucial for us to have the prestige of our professional organization behind this as a standard nationwide, to have this category; it covers many sins.
- Helps us get away from the idea that you have to have a definite answer yes or no immediately, there is a little gray zone and you can feel comfortable in that gray zone for a while, you can make that comfortable for people.
- It would be dangerous not to have it because then it gives the illusion that mammography is either normal or not normal.
- Seems to work out pretty well from the standpoint of not wanting to call something definitely benign, because how do I know if it is or not?
- Category 3 lets us practice some of the art form that medicine is, nothing's 100%, have to use some subjective basis.

#### Code 3 gives radiologists the comfort to follow-up (F)

- It allows us a level of comfort that we can follow lesions that we think are probably benign without waiting a year or two.
- Psychologically, it's been very helpful - a formal recognition there are some lesions that are probably benign, and it's okay to follow them. For radiologists that I've talked to, helpful that there's something formalized that gives you support to follow something clinically.
- It gives me some support from my radiological colleagues that if you have that level of suspicion a follow-up is an appropriate thing to, and in a sense is supporting me for those 2% that I'm going to be wrong about.
- By the ACR guideline number 3 being stated the way it is and coupled with short-term follow-up, that's saying my colleagues in the ACR have reached a decision that those two things should be coupled. That makes it an appropriate course of action and in some ways relieves me of personal decision-making in this regard.

#### Code 3 gives radiologists flexibility (R)

- Code3 is nice because it gives radiologist a comfort zone and some flexibility; gives patient and PCP a comfort zone and options.
- Code 3 is my wishy-washy position.

Code 3 is a recommendation, not a diagnosis (R)

- I consider it a guessing game, not a definitive statement. My report includes a recommendation as to what action to take next, but it is not a definitive statement.

**2. Negative aspects of code 3**Excess use of code 3 will make the population stop screening (R)

- One of the problems is if you call them back the population for a lot of things they don't need to be called back for, and have an inordinate number of ACR category 3s you're following, that has a deleterious effect overall on the population and whether or not they'll continue screening.

Excess use of code 3 will make surgeons biopsy patients anyway (R)

- When you put them at 6 months you're going to have some of those patients go to the surgeon and the surgeon says maybe we'll biopsy so I think if we were to use it more it would increase patient anxiety and also increase the number slightly of benign biopsies.

**3. The terminology "probably benign" is confusing**"Probably benign" may be interpreted as over 50% (F)

- What does probably mean - 51% benign, or much higher, which is how I generally interpret it.
- The wording of the code itself doesn't say "high probability" or "95% probability" it just says "probably," which technically means more than 50%, just barely, more likely than not.
- When we use this terminology for our clinical colleagues they may misinterpret it, significant increase in community cost should they interpret it as well I'd better do something if you're 5 1/49% concerned.
- Patients tell me "probably benign, that's not good enough." You have to talk to them and let them know that the odds are overwhelmingly benign, and not just probably benign.
- Someone could interpret "probably benign" as a lesion I think is 5 1% benign and saying that's probably benign, but I don't think that's what most of us think.

The terminology is too vague (C)

- Terminology is haphazard.
- It's the verbiage that I think creates more uncertainty than is necessary.
- It's just such a nebulous term, and that's the crux of the problem.
- I've seen many mammograms interpreted "probably benign, recommend biopsy" because the term can be misinterpreted.
- I see confusion in radiologists. Indeed, most category 4 lesions are probably benign....that's where the confusion comes up.

The terminology "probably benign" should be changed (F)

- Maybe there's a better term.

- Although I agree in principle that the language should be changed I'm not sure how it should be changed.
- I vehemently disagree with the actual terminology they use for category 3, which is probably benign.

“Probably benign” should be changed to “high probability of benign”

- I personally think code3 should be changed to “high probability of benign”.
- I would support the idea of perhaps using the word high probability of.
- One of the things that has been expressed several times, is elevating probability to high probability.

The term “probably benign” should be quantified (F)

- The idea of quantifying for other consumption of high probability has great merit, b/c we seem to be in sync talking about comfort level of 95% or higher.
- I think it's much better to sit down and talk with a patient and let them know there's a less than 2% chance that this is malignant, rather than saying probably benign.
- I'd like to get away from the words “probably benign” and substitute the actual percentages.
- I think the idea of using the exact numbers is a wonderful idea.

The term “probably benign” should not be quantified (F)

- Would you go as far as quantifying the height? Greater than 90% or greater than 95%? I would be a little loath to see that as a national guideline.
- I have a little trouble with trying to specifically quantify the likelihood of 6-month follow-up as being malignant because I don't think that there's across-the-board consensus of what constitutes lesion requiring 6 month follow up.

**4. Views of the use of code 3**

Radiologists should minimize use of code 3, decide it is benign or needs biopsy (F)

- You need to get the magnification views, you need to decide, put it in category 2 or category 4.
- We try everything we can to keep things out of category 3 and either come to a decision they're benign and let it go for a year, or biopsy it.
- Agree with comments that the goal is to bring the patient back and make a more definitive follow-up, either biopsy or normal exam, rather than use category 3.
- I think it has to be almost certainly benign before you put it in the probably benign follow up. If it's questionable and you can't make up your mind that's not what goes into that category. If it's indeterminate and questionable you should biopsy.
- If something's suspicious you should be biopsying it, it's going to be suspicious 6 months from then. If it's benign you should call it benign you shouldn't put it in the short-term follow up category.
- If I can't say it's benign, and I'd rather say it's probably benign, I'll biopsy it.
- I try to characterize as benign or as suspicious enough to biopsy if I possibly can.
- We try to avoid it. If I don't feel a lesion can wait until the next screening in a year, I really look at it.

- Different from Ed Sickles, we either call it benign or biopsy it.
- Either the woman goes back to screening, or I'm going to do something about it. Very few women end up in a 6-month follow up for me.
- If you're going to say 6 months, why not just do a year and leave it as a routine follow up.
- Over the past couple years we've tried to minimize our amount of category 3s to even fewer because so many women feel like they're hanging for 6 months.
- Sounds from some of the comments that some of the radiologists defend a frequent use of this category. I think our goal should be to get use down to as little as possible.
- It would be great if radiologists could come to a consensus that the lesser the better use of this code.
- I don't like the category (probably) benign. It's meaningless to me. The only reason we do mammography is to look for cancer; it's pass/fail.

#### The goal should not be to eliminate code 3 (F)

- Very useful category. My goal wouldn't be to achieve 0% use of code.
- I think there may be some movement to eliminate the category entirely; I think that would be a big mistake also.
- If I'm at 1-2%, we better not use it less.
- If the ACR is considering doing away with the code in screening mammography, I'd be against that, even though I use it very infrequently.
- I like that category 3. I don't use it very much, but I don't want anybody taking it away from me.
- I have this ominous feeling that we'll be forced to have double-readings on these mammograms and cut back on these ones you're not sure about and that's setting a dangerous precedent.
- If the numbers are coming out right in the audit consistently, that we don't need to try to force down or force up category 3 to some magic number.

#### **5. Other factors are more important than use of code 3**

##### Improving your predictive value is more important than changing use of code 3 (F)

- I think you have to take it in the context of the whole audit, especially things like your positive predictive value, whether you have false negatives, that's more important.
- The key to all this is what your predictive values are and how you're doing on the audit. That should be your goal, what your real outcome is and what effect you're having on the population you're screening.
- Have to ask yourself, are you really good, or are you undercalling. Once you go into code 3 area, if your PPV is high, your 6-mo follow up is low, and vice versa.
- If you're going to increase your PPV, it's going to be at the expense of not biopsying and missing a lot of your slow-growing, better circumscribed, more indolent cancers. So you're going to be missing more cancers to increase your PPV.
- Once **you get to that place where you feel you're recommending an appropriate** number of biopsies and you're not missing cancers and people are happy and they're coming for their mammograms, that's **the goal**.

- Important number to look at would be your category 3s plus your callbacks.
- I'm much more concerned about not missing cancers and improving my false positive rate without missing small curable cancers. Code 3s are not as important an issue as doing that.

## 6. **Criteria for using code 3**

### Radiologists follow strict criteria before using code 3 (F)

- It has to be strict criteria for me before I'll put it in a 6-month category.
- That's the one category where you really have to follow the criteria to the letter before you should feel comfortable.

### Criteria for using code 3 are clear (F)

- We have here some good statistics and very rigid standards. We're lucky we have them, they're good for the patient and good for the physician; we already know what kinds of decisions we need to make.
- Category 3 gives us some very good guidelines so we can narrow our focus down.
- Criteria are straightforward enough, just stringent enough, that people aren't going to abuse the category for the most part.

## 7. **Basis for coding 3**

### Code 3 should only be used on the basis of the anatomy (R)

- I base it on what I look at, which is the anatomy, and nothing else.

### Code 3 can be assigned on the basis of variables other than anatomy (e.g culture, likelihood of follow-up) (F)

- I don't base my diagnosis on culture. But I would base my recommendation on culture and the patients' personal preferences.
- I think a code of 3 is critical when you're fairly sure it's a benign process but don't want to allow the woman to be lost to follow-up or come back for a one-year follow up or 2-year follow-up.

## B. USAGE OF **CODE 3**

### 1. **Percent of use code 3**

#### 0-2%

- I personally almost never use code 3.
- Either the woman goes back to screening, or I'm going to do something about it. Very few women end up in a **6/month** follow up for me.
- Almost never use, only 1-2% of time. We try to avoid it.
- Based on my callback rate, how many I put into code 3 after evaluation, closer to 2%.
- Looked at my stats: in last 10,000 screening cases, used it 2% of time.
- That's why is use it very rarely - 2.09% of my asymptomatic women.

**24%**

- Use has stayed the same at about 2-3%.
- I suspect ours is closer to 3-4% than to 8%.
- Our use of the code is not significant, probably 3-4% of time.

**4-6%**

- Probably code 3-5% of all mammograms as a 3, majority after having been called back for additional assessment.
- I use it maybe 4-5% of the time.
- Total percentage of all mammograms I read probably less than 5% in 6 month follow-up.
- About 10% of my diagnostic mammograms, my recalls, are code 3, so that comes to about 6% of everything, I follow 6% of everything with 6 month follow up for 2 years.
- I don't even think it is 10%. ..maybe 5% feels like I must use code 3 more often

**6-8%**

- 8% of time I use code 3.
- Probably in the 5-8% range.
- I use code 3 quite less than 10%.

**8-10%**

- I code very few mammograms as code 3, may be 5-10% of my mammograms.
- Use code 3 about 10%.

**2. Use of code 3 in group practice****Percent use**

- As a whole our 6-month follow up is about 8-9%.
- My partner and I have been talking more about using code3 vs. code4. We do an awful lot of 6-month follow ups.

**Use of code 3 is variable even within group practice**

- We've found that there are some radiologist that use it on a screening mammogram as much as 8% vs. a low number of .7% of the time.
- Our statistics are about the same, ranging from 1.6%-7%.
- Our percentages for code 3 are considerably higher ranging from 6% to high teens.
- So there's enough people at 8-10%, they're convince they're doing the right thing, and they are a big enough group to support it.

**3. Change****% use decreased (F)**

- 2-3% and maybe % has decreased over time.
- Past couple years, % of code 3 has gone down quite a bit based on experience of radiologists.

- We've monitored our use of category 3 over the years, and in 1990 we were using it 8% across the practice vs. about 2% now.
- I constantly try to decrease use of **code3**, but when I hear leaders in the field say they use it in that manner, encourages me to follow indeterminate lesions.
- My use of code 3 dropped a lot.

% use stayed the same (R)

- About 10% code 3 hasn't changed over past several years.
- Haven't changed use of code 3 over past year.
- If I had to, I'd say about the same or just slightly greater.

% use increased (R)

- Practice has changed so I think we've increased because we're seeing many more patients without a prior mammogram. Now like **5-8%**.

Incidence of code 3 is greater with baseline mammogram (F)

- Incidence of category 3 is generally less than 4% at our center. **Higher** for individuals who are getting their first mammogram without comparisons.
- We know the yield's higher in first mammogram than in any other.

Different rates for screening vs. diagnostic mammograms (R)

For us, only 2% get code 3 for screening, but up to 29% in **diagnostic** cases.

C. DIAGNOSTIC CRITERIA

**1. Dense breasts**

Breast density is a factor in using code 3 (R)

- Dense breast may have difficulty completely seeing margins on a mass lesion, may obscure calcifications; that's going to factor into whether you can classify as probably benign.
- We do have some mammographers who are very uncomfortable with reading dense breasts who routinely order breast ultrasounds just because a woman has dense breasts they can't just call it a dense breast negative. Again, that's a comfort level for them.
- I use code 3 most often in dense areas. Several times I think the cancers I detected were density related.

**2. Calcifications**

Never/rarely use code 3 on calcifications (F)

- We rarely follow calcifications.
- I wouldn't know how to tell there's been a change so I tend to even biopsy ones that look benign just because I don't feel comfortable following them. I don't in general follow up microcalcifications.

- I can go after smaller lesions. I've found some small cancers, too. So I tend not to follow them if there's any suspicion at all on calcifications that I would previously have said were code 3.
- I use it for indeterminate calcifications infrequently.
- Calcifications we decide at the time.
- Main reason code 3 is used less in our practice because we were less comfortable w/ microcalcifications before.
- We never put microcalcifications in 6-month follow-up

#### Follow calcifications (F)

- I also follow calcifications that are sedimentary in lateral view, particularly if it's the first time I see somebody and I don't know if they're developing or if they've been there for a long time.
- Calcifications, even if malignant, give you about a 3-year grace period before they're going to do any real harm. Even the ones I've followed over 2 years and have changed have turned out to be BCIS, so I'm much more comfortable calling these code3.
- Code 3 is more useful for calcifications.

#### Follow up is not helpful for calcifications because they don't change much (F)

- The fact that microcalcifications haven't changed over 6 months doesn't mean much; they can smolder along for 2-3 years and then a cancer develops, so we tend not to follow those.
- I also unfortunately find 6-month follow-up less helpful to me for calcifications than for masses.
- Frequently calcifications are at the same point as 6 months before.
- When you're sitting with the same decision 6 months later and this could go on forever, you have to bet off the fence, take your best shot the first time you see them.

#### Calcifications show up better on new film (don't know if they have changed) (F)

- We very rarely follow microcalcifications. The only time is if we think the apparent difference is probably just due to the better film contrast on the newer film.
- We recently changed equipment and I find that calcifications that were present on prior mammograms stand out a lot clearer now.

#### Calcifications are confusing (F)

- So you really have to be careful with calcifications, because some are definitely benign, some are malignant, and some you really don't know.
- I sometimes do put calcifications in a follow-up protocol, but when I do I'm more uneasy because I'm not real clear what it is I'm following.

#### Calcifications cause false positives (R)

- My biggest number of my false positives was for indeterminate microcalcifications.

### 3. Lymph nodes

#### There is confusion about how to code lymph nodes when they do not meet all of the criteria (R)

- Sometimes you can find them on ultrasound and they have characteristic ultrasonographic findings of lymph nodes and sometimes they don't.
- Intermammory lymph nodes that may be in an unusual location or don't quite meet the classic mammographic or sonographic criteria for such.
- I think a lot of people are comfortable just saying they're lymph nodes although they don't meet the strict criteria of lymph nodes.
- I've had a number come back six months later looking like a lymph node, and I couldn't get that projection six months before.

#### There is variability in the way other radiologists code lymph nodes (R)

- I also see things people might call a 3, particularly a benign looking lymph node, that against experience I would call a 1 or a 2.
- I see a lot of variability in reading of what to me are clearly benign intermammory lymph nodes; but they can also grow, and that's where I have my biggest headache.

#### Use code 3 for lymph nodes (F)

- In our group, we tend to use the code a lot when we see little nodules, which are probably benign lymph nodes. So we use the category 3 to follow those, although I guess it's very unlikely that they're going to change.
- When we would use the code tends to be on something that's likely a lymph node but does not have all the typical characteristic features that lets you know that for sure.
- There are some cases I don't bring back for more work-up; if it looks like a lymph node that looks benign and maybe 5-6 mm, I may do a 4-month follow-up rather than bring it back.
- A small lump or circumscribed nodule, upper quadrant of the breast, looks like a lymph node, it's a baseline mammogram, I'll 6 month it.
- We generally only use it for small nodules that aren't clearly a lymph node, but almost certainly a lymph node.

#### Do not follow lymph nodes (F)

- I agree with not working up those sort of things, but we'd assign those as code 2.
- I don't put lymph nodes in code 3.
- So if we do a mammogram and see what we think is a normal lymph node, maybe we'll do a magnification view. We wouldn't put that into category 3, we'd put it in category 2 and have her come back in a year.
- It might not have a lucent hylar area, but because of their small **SIZE** and their location we're quite confident they're a **LYMPH NODE** in a baseline situation.

#### 4. cysts

##### Will follow complex cyst (R)

- Sometimes we see a complex cyst that we think is a probably benign cyst. After having aspirated hundreds of these and never having had a single cancer, we tend to watch these things now, but we do like to follow them for 6 months to be sure they're not changing.

##### Will not follow complex cysts (F)

- If I have a complex cystic mass with irregular wall thickening and mural nodule or thickened septation, even if we do have diffuse level echoes we'll sample one to get some kind of an answer rather than throw it into the category.
- We often find cysts with echoes in them and so you can aspirate them without recommending biopsies, and then you save a biopsy and you've made a diagnosis. If it turns out to be a cyst, it gets a code 2.
- More often we'll just **sono** them and say it's a cyst and leave it alone.

##### Other radiologists misclassify cysts (R)

- We still have doctors calling fibroadenomas as cysts on a mammogram and from physical exams. They'll tell patients, "this is just a cyst, you don't need to do anything about it" on a physical exam.

#### 5. Fibroadenoma

##### Follow a fibroadenoma (code 3 used) (F)

- When I do, it's if I'm pretty sure something's a degenerating fibroadenoma, I just want to prove I called the woman back.
- For circumscribed lesions, if after ultrasound they really look **like** a fibroadenoma, cigar shaped, regular, we tell her we think it's benign and we'd like to follow up in 6 months.
- Something I really believe is fibroadenoma, we only bring the women back so we don't appear to be abandoning them, but we've not had one turn into something bad,
- If I'm not convinced they're benign, we'll biopsy them unless I **think** it's a degenerating fibroadenoma.
- I mainly use it for fibroadenomas. If the medical legal system changed and I had a cigar-shaped thing sitting there, I'd forget about it.
- When I often use this is when it's almost certainly a fibroadenoma, **w/** no malignant characteristics as well.

##### Do not follow a fibroadenoma (R)

- The fibroadenomas that are irregular and have shoddy margins, we biopsy, we don't leave those.

## 6. Masses/nodules

### Use code 3 for nodules/masses (F)

- Almost all category 3s go down nodule or mass avenue.
- I reserve it for small-mass lesions.

### Do not use code 3 for nodules/masses (F)

- Masses, get ultrasound, maybe try fine-needle aspirate (don't do many of those) prior to biopsy.
- A solid thing, a well-defined nodules you may decide to ultrasound and decide right away.
- Now that we have minimally invasive procedures where we can get an answer as to what a mass is, even if it's a well-circumscribed mass, if it's a new mass or something that's changing in terms of increasing prominence.

#### a. Solid

### Use code three for solid mass (F)

- If it's a solid, benign-appearing mass on ultrasound, it gets a code 3.

### Do not use code three for solid mass (F)

- If it's solid on ultrasound, even if it looks kind of benign I would be loath to use number 3.
- If it's morphologically a category 3, a well-circumscribed mass and stable, it goes to 2, if it's new I biopsy it.
- If it's round and solid and shadowing a little, maybe it's a small **spiculated** cancer.

#### b. Size

### Use code 3 for tiny nodules (F)

- I follow [tiny nodules].
- If low probability of malignancy, like well-defined lesion less than 1 cm, I'd code 3.
- Small lesions with very low suspicion of malignancy will get code 3.
- Likelihood that nodule less than a cm is benign, even when margins are not completely defined is higher than likelihood of malignancy, statistically.

### Do not use code 3 for tiny nodules (R)

- If it's less than 1 cm in size we'll either see them in a year or do a core biopsy.
- Not just borders, size is also a criterion we have to use. Even if well defined, if larger than 1.5 cm, obligated to go after it.
- I use 5 millimeters; it's not entirely scientific, but there seemed to be a myriad of **sub-5 mm** densities that I usually don't even comment upon.

## c. Margins

Use code 3 for smooth borders (F)

- If I see a nodule, well-circumscribed, 1 cm or less, I have them come back in 6 months.
- I tend to go with things that are well defined.
- I use the criteria that if it has perfectly smooth borders and it's not a new, non-cystic mass, we'll follow it.
- It's where I do feel something is probably benign, just a small nodule, less than 8 mm in diameter, smoothly marginated.

## d. Asymmetry

Use code 3 for asymmetries (F)

- Some asymmetries where they look less dominant in spot compression views, maybe only see them in one view not two, but don't completely go away when you press on them. Those are things you want to see in 6 months rather than waiting a whole year.
- We have an additional place where we use category 3 and that is definitive asymmetry of the breast in a baseline mammogram that is not palpable.
- It just looks like asymmetric glandular tissue but it's a baseline mammogram, I'll put those in 6-month follow-up.

Do not/rarely use code 3 for asymmetries (F)

- In terms of asymmetries, we don't put many in category 3, try to resolve with extra views or ultrasound, it's rare that we follow one.
- Most asymmetries are better served by coming back for diagnostic mammography to make them a benign finding (category 2), because if that is breast cancer presenting as an asymmetry it's going to be advanced and you hate to wait 6 months before you make that biopsy.
- I don't put nodes or asymmetrical densities, which I've worked up in category 3.

## e. In the literature

- I think most people for instance would reserve calling something a probably benign lesion for a round nodule, sharply marginated, proves solid by ultrasound or at least can't find a cyst so presume it's solid.
- I use code 3 mostly for a well-circumscribed, solid nodule with **no** architectural distortions, **spiculation**, no associated microcalcifications and **maybe** those cases with really uniform **punctate** microcalcifications. Those are the things listed in [Sickles'] landmark article.
- There are pretty rigid standards about what should be a code 3 in the literature. **Well-defined margins.**
- The literature is pretty straightforward, pretty clear. Sickles study shows well-defined <1cm has <5% (closer to 2%) of being cancer.

- I know Sickles says if it's a very well-circumscribed mass, whether its cystic or solid, and doesn't have any suspicious features, completely well-circumscribed, regardless of size he goes to 6 months.
- Sickles published a very nice article on size vs. risk in about 1994 Radiology. What they found was that as size went up there's a slight increase in risk, from about a 1% to a 2% risk, I think that was at 2 cm.

## 7. Estrogen therapy

### Follow patients on estrogen therapy (F)

- I tend to follow some patients who are on estrogen therapy and an area of asymmetry develops.
- When patient starts hormone therapy and has a dramatic change in the appearance of her breast, increase in density, I use that as a reason for follow up.
- We would never use it unless it were a focal abnormality that we were concerned about but sometimes if it's patchy like with hormone replacement.
- Patient's on estrogen, and there might be a change, I follow those patients.

### Do not follow patients on estrogen therapy (F)

- I would not use it in an estrogen replacement patient where you have a clear history that there's been a change in dose or new estrogen therapy in increased density; we'd use category 2.
- I don't use it for women who have been placed on hormone replacement unless there's a focal area that's become denser.
- Most of the time it's a diffuse change and you describe it as hormonal change. If it's something focal we tend to work it up and decide one way or the other.

## 8. Questions raised by radiologists

### How does patient's previous history affects use of code 3?

- If it were something like lobular carcinoma in situ, would you follow that more frequently?

### What are the criteria for coding 3 from ultrasound?

- No one's come up with criteria backed by statistics for sonographic category of probably benign. Is that what others understand?

### What are the criteria for coding 3 for calcifications?

- Is there a probably benign category for calcifications, is there not? Do you have to make a call one way or the other? What is the follow-up protocol if you say probably benign calcifications?

### What are the criteria for coding 3 for size?

- **Given a mass, is there any influence or agreement in** terms of size before putting it into category 3 or sending for biopsy?

## D. FOLLOW-UP

### 1. Time period indicated by “short-term follow-up”

#### Short-term follow-up is 6 months, not less (C)

- Short-term follow-up for us is 6 months.
- Occasionally not quite comfortable with 6 months; handle that by getting a second or third reading and coming up with a consensus.
- We ourselves define the interval as 6 months.
- Six months, based on what I’ve read through the years, seems to be what most people do.
- At times we were doing 3 months, at times 4 months, but generally speaking now we’re pretty much doing 6 months.
- When we started several years ago, 2 months, 4 months, just out of the blue moon. Now I think everyone’s doing 6 months.
- Sickles has shown 6 months is probably the soonest you’d want to repeat it.
- We do 6 months for everything.

#### Short-term follow-up can be less than 6 months (F)

- Mark Homer said if you really think it’s probably benign and want to establish stability, say 3-6 months and tend toward six months.
- If I’m a little worried, I go with 3-6 months, but that’s not more than 1-2% of the time; almost always say 6 months.
- One question that needs to be asked in the survey is how often people still see recommendations for mammograms every 3 months. I do, and I find it to be considerably inappropriate because it’s just too short to detect any significant change, but it still happens.
- One member of my practice was using 3-month follow-up quite a bit; his use has gone down, but people are clearly still using it and I have questions about the appropriateness.
- We do a 4-month follow-up on lymph nodes, 6 months on calcifications; that’s the standard of care in our community so we do the same as they do. I think 4 months or 6 months probably doesn’t make much difference.
- Until recently I did **4-month** follow-up on premenopausal women. I stopped that because nobody else seemed to be doing it, now I hear someone else is doing it.

### 2. Length of total follow-up period

#### Follow for 2-3 years (F)

- You should take it to 3 years to really determine stability (6 months, another 6 months, a year, another year). You and I know there are lesions that look benign, and two years later they start to grow. Three years is a good endpoint to say it’s stable, unchanged, no worry.
- I put them in follow-up protocol, I keep with it for 3 years at every 6 months.

- I wait three years before I say this particular lesion is benign, and after that I call it benign.
- I follow code 3s every 6 months for 2 years; hopefully they'll come back the next year too.
- Follow them successively through 2 years and if they show no appreciable change you drop them back into yearly follow-up.

#### Return to normal screening after 1 year (F)

- My recommendation after a no-change 6 months is bilateral mammograms in 6 months to return to yearly screening protocol.
- If you come back at 6 months and still the same, come back at another 6 months and do both sides, if still unchanged go back to a year.
- I'd code it a 1 or a 2 at the one-year mark.
- If stable at the 1-year mark, I'll code it a 2.

#### Return to normal screening after 6 month follow-up (R)

- Very often we'll put it in category 2 after 6 months, not always.
- I have some cases I feel very confident after 6 months that it's benign and I'll categorize it as benign at 6 months.
- We do one 6-month follow-up and then their yearly screening mammogram a year later.

#### Uncertain how long to follow (C)

- How long do you keep them coming back at 6 months when they fulfill all the criteria as a benign lesion?
- At 6 months unchanged, then what do you say? Come back in one year, or two years, or 6 months again?
- I'm unclear about whether to code it a 2 or a 3 after the bilateral at a year interval. I dictate it as stable, even more probably benign than originally thought. You could conceivably put it at a 2 at that point.
- I don't think we're clear on how far out you follow a probably benign to decide it's benign, unless it changes.
- I recently attended a course with Sickles and was surprised to hear when they talk about code 3 lesions, it's not really just a 6-month follow-up. They follow up to a period of 3 years.
- I've never seen any data whatsoever indicating what is the right follow-up and I've just done 6-month follow-up.
- If 6-month is stable, one year is stable, at what point do you swing to a definite benign? In our group our statistics may be skewed because some of us might swing this lesion into a benign lesion after 1 year, others after 2, others after 6 months.
- I often change to benign after a year; is that reasonable? I think you should follow it for more than a year, probably.
- Is six months really long enough to say something's stable? If you're going to say 6 months, why not just do a year and leave it as a routine follow-up.

## **E. THE MOST IMPORTANT FACTOR IN USING CODE 3**

### **1. The most important factor is lesion characteristics**

#### The most important factor in using code 3 is how the lesion looks (F)

- Lack of any malignant characteristics
- Finding that lacks any feature of malignancy but for some reason it's mysterious.
- It has to have morphologically benign features.
- The way the lesion looks
- Lesion characteristics

#### The most important factor in using code 3 is the work-up (F)

- If after best assessment possible, I feel that chance of it being malignant is minimal, that's when I use that category.
- A thorough work-up; make sure the lesion is fully evaluated and then make a decision.
- The work-up
- The work-up is paramount
- Previous studies are the single most important factor I think.
- How it looks on ultrasound

### **2. The most important factor is radiologist characteristics**

#### The most important factor in using code 3 radiologist judgment (F)

- Experience about what you think fits in this category.
- Good judgment
- I'm making the judgment based on my own experience.
- Basically people look at the mammogram and the ultrasound and ask their brain and soul whether they think this is malignant.

### **3. The most important factor is patient characteristics**

The most important factor in using code 3 is your patient population(R)

- Your patient population is a consideration. When I worked in Sweden, those people came back.

The most important factor in using code 3 is the patient's history (R)

- Looking at risk factors for the patient.

The most important factor in using code 3 the patient's wishes (R)

- The wishes of the patient; I would speak with the patient.

### **4. The most important factor is external characteristics**

The most important factor in using code 3 is the legal implications (F)

- The legal system
- Part of the equation is the legal system.
- I think category 3 may have something to do with the legal system.

The most important factor in using code 3 is cost (R)

- Part of this thing came out of costs.

## 8. CONCLUSIONS AND RECOMMENDATIONS

This research was conducted with the goal of identifying issues which may be related to the use of code 3 by radiologists who read mammograms for the NBCCEDP. To accomplish this goal, it was important to include radiologists who represented a broad range of practice experience and to engage them in a focused discussion of the use of code 3. The procedures we implemented to achieve these objectives were successful. Our final pool of participants represented a wide range of practice settings, years of experience, percentage of time spent reading mammograms, and urbanicity. Both male and female radiologists were included.

The comments listed in the results section (Section 7) were a comprehensive listing of all extracted comments. We felt that presenting the universe of comments was important in this phase of the research. The completeness of the extraction and reporting of the comments allows any amount of collapsing or reorganizing. Comments made by physician participants can be reorganized into additional themes, or similar themes can be merged. During the questionnaire development phase it may be desirable to combine themes in order to reduce the length of the questionnaire. Alternatively, it may be desirable to split themes in order to obtain more detailed information about physicians' perceptions that influence their use of code 3.

We recommend that the survey include questions on each of the topic areas identified through the focus group procedures. We have prepared an initial set of potential draft questions to address each of these topic areas; however, these draft questions are only a starting point. It will be very important to identify additional questions and to further develop and refine these questions after the research goals of the survey are more fully defined. Significant additional development will be required to incorporate these draft questions into a quantitative data collection instrument.

The draft questions we developed for each survey topic are listed below. The order of the topics mirrors that of Section 7, Results.

### I. BACKGROUND OF THE RADIOLOGIST

<b>A. Education and training</b>	
Question	Response categories
What type of training have you had on code 3?	None Literature Conferences/lectures Courses Fellowship training
How would you rate your understanding of the use of code 3? The understanding of your radiology colleagues? Of primary care physicians with whom you interact?	Scale of 1-10

Which leaders in the field do you follow most closely?	Sickles Tabar Parker/Stavros Other
How have leaders in the field affected your use of code 3?	Increased Decreased No impact
What is your primary source of updated information on the use of code 3?	Leaders in the field ACR Other radiologists in your practice

<b>B. The role of experience</b>	
In your opinion, how does experience impact the use of code 3?	Increases/decreases/stays the same
For each of the following, please indicate your response: My use of code 3 has gone down as I become more comfortable reading mammograms	Strongly agree.. . strongly disagree
Less experienced radiologists use code 3 as a safety mechanism for things that should be called benign	Strongly agree.. . strongly disagree
I now follow lesions that I would have biopsied 5 years ago	Strongly agree.. . strongly disagree
Radiologists who feel more confident with their diagnostic ability use code 3 less frequently	Strongly agree.. . strongly disagree
The confidence of the radiologist is not a factor in whether or not a finding is assigned a code 3	Strongly agree.. . strongly disagree

**II. PATIENT-RELATED FACTORS**

<b>A. Patient characteristics</b>	
What is your overall compliance rate for 6-month follow-up?	Percent categories
Overall, how do patients respond to the recommendation of 6-month follow-up?	Most are comfortable Half are comfortable, half are not Most are not comfortable, want p s y
Please indicate how much of a role each of these factors plays in your decision to assign a code 3.	(scale of 1-5 for each) prior history of cancer in patient prior history of cancer in patient's family patient anxiety patient age

<p>Please indicate your response to each statement:</p> <p>Follow-up should be more aggressive for patient populations with poor compliance rates</p> <p>Patients are more likely to return for follow-up if the radiologists speak with them when the code is assigned</p> <p>The cultural background of a patient should be considered in deciding what follow-up to recommend for a lesion that is probably benign</p> <p>In general, the majority of my patients are comfortable with short-term follow-up</p> <p>Code 3 causes an unnecessary degree of anxiety in patients.</p> <p>To reduce patient anxiety, I have tried to minimize my use of code 3.</p> <p>The anxiety of a patient should be considered when deciding what follow-up to recommend</p> <p>More than half of women with a code 3 lesion in my practice end up getting a biopsy.</p> <p>Very few patients request a biopsy when we recommend short-term follow-up.</p> <p>Patients who are highly educated tend to agree to follow-up more readily than those with less education.</p> <p>Patients who are highly educated are more likely to request a biopsy for probably benign lesions than less e-patients.</p>	<p>Strongly agree... strongly disagree</p>
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<p><b>B. Interaction with patients</b></p>	
<p>A negative aspect of code 3 is that it causes anxiety in patients</p>	<p>Strongly agree...strongly disagree</p>
<p>I try to minimize my use of code 3 to reduce patient anxiety</p>	<p>Strongly agree...strongly disagree</p>
<p>Code 3 is reassuring to most women</p>	<p>Strongly agree...strongly disagree</p>
<p>I lay out the options to my patients and let them decide how they wish to proceed.</p>	<p>Strongly agree...strongly disagree</p>
<p>I can usually convince women with a code 3 that 6-month follow-up is a reasonable way to proceed.</p>	<p>Strongly agree...strongly disagree</p>
<p>Most women are so anxious they request a biopsy.</p>	<p>Strongly agree...strongly disagree</p>

If I talk to the patients personally they are less likely to seek a biopsy when I recommend short-term follow-up (code 3)	Strongly agree.. .strongly disagree
I do not feel that the patient's level of anxiety should play a role in my decision about which category to assign	Strongly agree.. .strongly disagree
It's important to discuss the code with the patient when you assign it	Strongly agree.. .strongly disagree
It is unnecessary to talk with patients who are given a code 3.	Strongly agree.. .strongly disagree
I routinely see all screening patients	Strongly agree.. .strongly disagree
I routinely talk with all diagnostic patients with a finding other than category 1 or 2	Strongly agree.. .strongly disagree

### III. PRACTICE-RELATED FACTORS

<b>A. Practice setting</b>	
In which setting(s) do you practice?	Private hospital, government hospital, general private practice, mobile unit, breast center, etc.
Which is your primary practice setting, that is, the setting in which you spend the largest percentage of your professional time?	Private hospital, government hospital, general private practice, mobile unit, breast center. etc.
<b>B. Colleagues</b>	
How likely are the following to follow your recommendation for short-term follow-up (code 3)? Primary care physicians you work with routinely, other primary care physicians, general surgeons, breast surgeons	Very.. .not at all
How do your non-radiology colleagues respond to code 3? Primary care physicians you work with routinely, other primary care physicians, general surgeons, breast surgeons	Very comfortable.. .very uncomfortable
How do you communicate information regarding code 3 patients to their primary care physicians?	Phone, letter to physician, no contact, etc
Do you routinely provide information on code 3 to your non-radiology colleagues? If so, how?	Personal interaction, phone calls, reports with descriptions of codes, etc
Approximately what percentage of your referring physicians send patients over 40 in for regular annual mammograms?	% categories
<b>C. Office practices</b>	
In your primary practice setting, how often are mammograms double-read?	Routinely, periodically, occasionally, never
How have the practices of your current partners shaped your use of code 3?	Increased, decreased, have not impacted

Which of the following methods do you and your radiology colleagues use on a regular basis to share information on cases?	Informal interaction Weekly group review Monthly group review Double-reading Other None
For what percentage of your probably benign cases do you know the outcome of the 6-month follow-up?	<10%,10-25% etc
Which best describes your practice? Mammography technicians conduct an initial review of all screening mammograms One radiologist reviews each screening mammogram More than one radiologist reviews each screening mammogram Radiologists only review cases on which technicians find an abnormality Both a radiologist and a technician review all screening mammograms	
Double reading significantly increases sensitivity	Agree/disagree

<b>D. Tracking and audits</b>	
Does your practice use an automated reporting system to track mammography codes?	Yes/no
At your practice, do you track the following by radiologist: Use of category 3 Positive predictive value False negative rate Number of biopsies in each category	<b>Yes/no</b>
Please provide estimates of your: Use of category 3 Positive predictive value False negative rate Number of biopsies in each category	Percentages or ranges (respondents would be more likely to respond to ranges)
Radiologists should review statistics on their use of code 3 to ensure they do not use code 3 too little or too much	Strongly agree.. . strongly disagree
Tracking patient outcomes by radiologist for each ACR category provides <u>important information to radiologists.</u>	Strongly agree.. . strongly disagree

<b>E. Equipment/technology</b>	
What type of initial evaluation do you typically complete before assigning code 3? (may want to ask for various types of findings – lymph nodes, masses, etc.)	Screening mammogram Spot compression Spot magnifications Ultrasound Diagnostic mammogram
Which of the following technology do you utilize in your practice? (may offer scale -- not at all, occasionally, routinely)	Screening mammography CT mammography Nuclear Medicine mammography (SINTY or

	<p><b>MERRA-LUMA)</b>                  New film (specify)</p> <p>Diagnostic mammography                  Ultrasound                  Magnification views                  Spot compression views</p> <p>Stereotactic Guided Biopsy                  Ultrasound Guided Core Biopsy                  Fine needle aspiration                  Wire localization                  Mammotome</p> <p>Computer system for auditing/tracking                  Penrad system                  MRS System</p>
Age of equipment?	Models or year ranges
How have the following impacted your use of code 3? Availability of ultrasound Availability of noninvasive biopsy techniques Improved film	Increased/decreased/not impacted/not available in my setting
Approximately what percentage of patients coded 3 go on to biopsy?	% ranges
What types of biopsy are routinely available to your patients?	Stereotactic Guided Biopsy Ultrasound Guided Core Biopsy Fine needle aspiration Wire localization Surgical biopsy

**IV. EXTERNAL FACTORS**

<b>A. Legal issues</b>	
Has the current legal climate:	Increased your use of code 3 Decreased your use of code 3 Had no impact on your use of code 3
To what extent does prior history of litigation affect how a radiologist reads mammograms	Very much to not at <b>all</b>
Have you ever had a code 3 lesion turn out to be malignant If so, any legal action by patient	Yes/No
I use code 3 to decrease the chance of being sued. The use of code 3 exposes a radiologist to malpractice.	Very much to not at <b>all</b>
Radiologists should never allow the possibility of being sued	Strongly agree to strongly

affect their practice	disagree.
<b>B. Financial issues</b>	
To what extent do you consider cost when you review your use of code 3?	Very much to not at all
For indeterminate mammograms, rank the following procedures from most cost effective to least cost effective	Diagnostic mammogram Additional views Ultrasound 6 month follow-up Ultrasound guided or Stereotactic biopsy Surgical biopsy
In your view, how has the use of code 3 impacted cost-effectiveness in mammography?	Increased Decreased No impact
In your practice setting, who typically bears the cost of obtaining additional views for indeterminate mammograms?	Patient Provider Insurance NBCCEDP Hospital/Care facility
<b>C. Insurance</b>	
To what extent have changes in the insurance scene affected your use of code 3?	Very much – Not at all
Overall, how much have insurance companies limited your range of recommendations for indeterminate lesions?	Very much – not at all
Have insurance companies ever encouraged/discouraged the use of code 3.	Yes/No
How does insurance status affect likelihood of return for follow-up	Increases return No Difference Decreases return
<b>D. NBCCEDP</b>	
Are you aware of whether or not an individual patient participates in the NBCCEDP?	Yes, no, sometimes
Would you be more likely to recommend biopsy for a patient who participates in the NBCCEDP than for a non-participant?	Yes/no
Would you be as likely to assign a code 3 to a program participant as to a non-participant?	Yes/no
How does the compliance rate of NBCCEDP participants for 6-month follow-up compare to the compliance rate of non-participants? If better or poorer, to what is this due, in your view?	Better, same, poorer Level of program funding Patient characteristics Etc
<b>E. Views of ACR coding scheme</b>	
Do you routinely use the ACR BIRAD standard codes?	Yes / No

The ACR codes have improved mammography	Strongly agree -strongly disagree
The goal of the ACR codes is to standardize practice among radiologists	Strongly agree – strongly disagree
The MQSA has improved mammography	Strongly Agree – Strongly disagree
The MQSA is a burden for radiologists	Strongly Agree Strongly disagree
What percent of your screening mammograms do you give a code 0 (callback)?	Percent ranges

### V. UNDERSTANDING AND USE OF CODE 3

<b>A. Attitudes toward code 3</b>	
The primary purpose of code 3 is to: Reduce unnecessary biopsies Not miss cancers	Strongly agree to strongly disagree
A goal in my practice is to minimize the use of code 3	Strongly agree – strongly disagree
(or) Radiologists should try to minimize their use of code 3	Strongly agree – strongly disagree
Frequent use of code 3 is an acceptable practice	Strongly agree- Strongly disagree
I would support eliminating the use of code 3 for screening mammograms	Strongly agree – strongly disagree
The terminology “probably benign” is clear to radiologists To primary care physicians To surgeons To patients	Strongly agree – strongly disagree
I would like to change the terminology “probably benign”	Strongly agree – strongly disagree
The terminology of code 3 is confusing to radiologists To Primary care physicians To surgeons To patients	Strongly agree – strongly disagree
Category 3 is an important code	Strongly agree – strongly disagree

<b>B. Usage of code 3</b>	
What percent of your screening mammograms were code 3? in the past year? 3 years ago? 5 years ago?	% ranges
(or)Over time has your use of code 3:	Increased significantly Increased slightly Stayed the same Decreased slightly Decreased significantly

If changed, to what do you attribute this change?	Increased experience Change in practice setting Change in patient population Improved technology Changes in insurance Legal climate Etc. Other, specify
If you are in a group practice, what percent of the mammograms screened by your group are code 3?	% ranges
Subjective use of code 3: I use code 3 in screening mammograms:	Never Seldom Sometimes Often
Subjective use of code 3: I use code 3 in diagnostic mammograms:	Never Seldom Sometimes Often
In my practice use of code three ranges from ____ to ____	% ranges

<b>C. Diagnostic Criteria</b>	
A. How often do you use code three for the following types of conditions: Calcifications Lymph nodes Complex cysts Simple cysts Fibroadenomas Asymmetries Masses/nodules Size • Nodules (less than 5 mm) • Nodules (less than 1 cm) • Nodules (greater than 1 cm) Shape • Round • Oval • Cigar shaped • Spiculated Margins • Smooth borders Solid Patient on estrogen therapy with: • Focal density • Diffuse density	Always–Never
Or B. In most situations what would you do with the following conditions? Calcifications	Follow at 6 months Biopsy Use fine needle aspiration

<p>Lymph nodes Complex cysts Simple cysts Fibroadenomas Asymmetries Masses/nodules</p> <p>Size</p> <ul style="list-style-type: none"> <li>• Nodules (less than 5 mm)</li> <li>• Nodules (less than 1 cm)</li> <li>• Nodules (greater than 1 cm)</li> </ul> <p>Shape</p> <ul style="list-style-type: none"> <li>• Round</li> <li>• Oval</li> <li>• Cigar shaped</li> <li>• <b>Spiculated</b></li> </ul> <p>Margins</p> <ul style="list-style-type: none"> <li>• Smooth borders</li> </ul> <p>Solid</p> <p>Patient on estrogen therapy with:</p> <ul style="list-style-type: none"> <li>• Focal density</li> <li>• Diffuse density</li> </ul> <p>Breast Density</p> <ul style="list-style-type: none"> <li>• Dense breasts</li> <li>• Fatty breasts</li> </ul>	<p>Follow at 1 year Do additional views Ultrasound</p>
<b>D. Follow-up</b>	
<p>When you recommend short-term follow-up for a code 3, what length of time do you most often have in mind?</p>	<p>2 months 3 months 4 months 6 months 12 months it varies</p>
<p>If the short-term follow-up you recommend varies from case to case, which of the following do you consider when you decide on an appropriate length of time?</p>	<p>Baseline vs. non-baseline Type of finding (lesion, lymph node, etc) Your level of suspicion Patient anxiety</p>
<p>How long do you follow a no-change probably benign finding before moving it out of category 3?</p>	<p>I move it out of category 3 at: 6 months 1 year 2 years 3 years it varies unsure</p>
<p>6 months is the shortest follow-up period a radiologist should ever recommend for a probably benign finding</p> <p>3 month follow-up for a probably benign finding may be appropriate in some cases</p>	<p>Strongly agree... strongly disagree</p>

<p>Very few changes show up after only <b>6</b> months</p> <p>If there is no change after 6 months, you can be confident that the finding is benign.</p>	
<p><b>E. Most important factor in using code 3</b></p>	
<p>For me, the following are important factors in assigning code 3:</p> <p>Patient medical history  Patient anxiety  Likelihood of patient return  The radiologist's experience/judgement  The characteristics of the finding  The work up  Cost factors  Legal implications</p>	<p>Strongly agree to strongly disagree (or rank)</p>

i. Brenner, R.J., and Sickles, E.A. Acceptability of periodic follow-up as an alternative to biopsy for mammographically detected lesions interpreted as probably benign, Radiology, **171:645-646**, 1989.

ii. Sickles, E.A. Nonpalpable, circumscribed, noncalcified solid breast masses: Likelihood of malignancy based on lesion size and age of patient, Radiology, **192:439-442**, 1994.

iii. Hindle, WH: Screening mammography reports - Toward clear, concise clinical descriptions, Western Journal of Medicine, **157:152-153**, 1992.

iv. American College of Radiology. Breast imaging, reporting, and data systems" Reston, VA: American College of Radiology, 1993.

v. Hindle, W.H. Screening "mammography" reports: toward clear, concise clinical descriptions, Western Journal of Medicine, **157(2):152-153**, 1992.

APPENDIX A

PHYSICIAN RECRUITMENT MATERIALS

Focus Group:

Invitation letter  
Sign-up/Screening form  
Return fax cover sheet  
Confirmation letter  
Consent form

April 30, 1998

Dr. «FIRST\_NAME» «LAST\_NAME»  
<<ADDRESS\_1 >  
«ADDRESS\_2»  
«ADDRESS\_3»  
<<CITY>>, <<STATE>> «ZIP»

Dear Dr. «LAST\_NAME»:

The Centers for Disease Control and Prevention (CDC) has asked Battelle Memorial Institute to contact radiologists who read mammograms for the National Breast and Cervical Cancer Early Detection Program to learn about their opinions and practices related to the use of code 3, "probably benign, short-term follow-up suggested." Battelle is the oldest non-profit research institute in the U.S., and our group specializes in research on public health and health services.

You have been selected from a list of radiologists in 12 states who read mammograms for the program. We will schedule 11 physicians to participate in each of four discussion groups, which will be conducted by telephone. Your name was selected, and we are asking you to help with this important study.

Your input is critical to making this study valid, significant and influential. The CDC is seeking a better understanding of the knowledge, attitudes, and practices of radiologists related to the use of code 3. In particular, they are interested in your opinions about factors that may contribute to the variation in use of this code from state to state. Most of all, they need the input of practicing physicians. Your opinions would be compiled with those of the other physician participants and provided to the CDC so that they are able to better understand those factors that radiologists deal with on a daily basis that influence the use of code 3. In addition, your opinions and ideas also would be useful to help the CDC develop a nationwide survey of radiologists to further explore practice issues related to the use of code 3. Of course, your confidentiality would be protected, and your name would not be associated with any written report.

Your role would be to participate in a 90-minute group discussion with up to ten other radiologists across the country. We will convene this meeting by telephone, and will contact you at the number you tell us is most convenient for you. We realize that you seldom have extra time in your busy schedule. To help reduce this burden, we will provide you with an honorarium of \$100 for your help with this study.

We have scheduled four possible dates for these important group discussions (all times are Daylight Savings):

- 1) Wednesday, May 13, 9:15 p.m. Eastern (8:15 Central, 7:15 Mountain, 6:15 Pacific)
- 2) Thursday, May 14, 8:30 p.m. Eastern (7:30 Central, 6:30 Mountain, 5:30 Pacific)
- 3) Thursday, May 28, 1:00 p.m. Eastern (12:00 noon Central, 11:00 a.m. Mountain, 10:00 a.m. Pacific)
- 4) Wednesday, June 3, 9:15 p.m. Eastern (8:15 Central, 7:15 Mountain, 6:15 Pacific)

Please complete the enclosed response form to sign up for one of these groups. Since time is critical, please fax or mail us your response form right away. We hope you will help us with this important study.

If you have any questions concerning logistics, please contact Patrick Kiser at (800) 444-5234, ext. 142. If you have any questions about the study, please contact me at (800) 444-5234 ext. 141.

Sincerely,

Lisa V. John, MSW  
Senior Study Leader





Battelle Centers for Public Health  
Research and Evaluation  
1101 Olivette Executive Pkwy  
Suite 200  
St. Louis, MO 63 132

Date:

## *CDC Mammography Study*

# ***Fax*** Cover

To: Lisa V. John, MSW  
.....  
Fax No: 800-444-5234 ext. 105  
.....  
Alternate Fax No: 314-993-5163  
.....  
Phone No: 800-444-5234 ext. 141  
.....  
**Company:** Battelle  
.....

From: Dr. {FIRST NAME} {LAST NAME}  
.....  
Fax No:  
.....  
Phone No:  
.....  
Total **Pages:2** (Including Lead Sheet)  
.....

Comments: See completed Mammography Code 3 Discussion Sign-up  
Form attached.

<<DATE>>

Dr. <<FIRST>> <<LAST>>  
«ADDRESS\_1»  
«ADDRESS\_2»  
«ADDRESS\_3»  
<<CITY>>, <<STATE>> «ZIP\_CODE»

Dear Dr. «LAST»,

Thank you for agreeing to participate in a telephone focus group on the use of the code “probably benign – short-term follow-up suggested,” by radiologists who read mammograms for the National Breast and Cervical Cancer Early Detection Program, a screening program for low-income women. Your thoughts and experiences related to this code are very important to us.

You are scheduled to participate at «TIME» «TIME\_ZONE» Daylight Savings Time on «DAY», «DATE». According to our records, the phone number at which we will contact you is «PHONE\_». Please let me know if this number is incorrect or another number would be more suitable.

Enclosed is the informed consent for your review. As a token of appreciation for your time, we will mail you a money order for \$100 following the focus group discussion.

If for any reason you will be unable to participate as scheduled, or should you have any questions about the study, please contact me at 1-800-444-5234, ext. 141.

Sincerely,

Lisa V. John, MSW  
Senior Study Leader

## CONSENT TO PARTICIPATE IN DISCUSSION GROUP

The Centers for Disease Control and Prevention (CDC) is interested in learning more about the use of the code "probably benign -- short-term follow-up suggested" by radiologists. CDC, in collaboration with Battelle, is therefore conducting approximately eight discussion groups of approximately ten participants each. (Four groups have already been completed.) The purpose of this research study is to gather information to be used in the development of a questionnaire to be administered to random groups of radiologists participating in the National Breast and Cervical Cancer Early Detection Program (NBCCEDP).

You have been selected from a list of radiologists who read mammograms for the program to participate in one of the discussion groups. Your participation is entirely voluntary. Each discussion group will last approximately 90 minutes and will consist entirely of radiologists. You will be paid \$100 for your participation in one group. Risks associated with your participation are minimal. All data will be kept strictly confidential in accordance with federal laws, and any information you provide will not be associated with your name. Battelle researchers who are conducting the study will not reveal the names or other identifying information of individual radiologists to anyone. The sessions will be audiotaped; names and other identifying information will not be included in any transcriptions or reports. Battelle will permanently erase all tapes upon completion of the analysis. You have the right to refuse to answer any of the questions asked in your discussion group. You have the right to stop participating at any time during the discussion. There are no plans to contact participants again upon completion of the discussion groups.

If you have any questions about this study, please contact Lisa V. John, MSW, Task Leader, at 1-800-444-5234, ext. 141. If you have any questions about your rights as a study subject, please contact Margaret Pennybacker at (919) 544-3717.

APPENDIX B

FOCUS GROUP MODERATOR'S GUIDE

Task 9: Evaluation of the Use of the Code “Probably Benign – Short-term Follow-up Suggested” to Classify Mammograms

Introduction by moderator (5 minutes)

- I'd like to welcome you all and thank you for making time in your busy schedules to participate in this discussion of mammograms.
- I am Lisa John, task leader for this project and a senior study leader with Battelle Centers for Public Health Research and Evaluation. A few of my colleagues are also on the call tonight and will be taking notes to be sure we don't miss anything.
- We have been asked by the Centers for Disease Control and Prevention to identify issues related to the use of the code, “probably benign, short-term follow-up suggested,” in the National Breast and Cervical Cancer Early Detection Program. CDC has found that the use of this code varies across states and enrollment sites. We are gathering information on issues related to the use of this code. The results of our discussion will be used to develop a questionnaire to be completed by a random sample of radiologists who participate in the Breast and Cervical Cancer Early Detection Program in selected states nationwide. The overall goal of this project is to improve breast cancer screening among underserved women.
- You were invited to participate in this focus group today because you participate in the Breast and Cervical Cancer Early Detection Program and have conducted a significant number of mammograms during the past year.
- You may not have participated in a telephone focus group before, as this is a relatively new venue. Basically, the format of this discussion will be similar to a conference call. We have various topics we would like to cover related to the use of code 3, and I would like you all to feel free to contribute your ideas. We value your time, and we'll keep the discussion moving to be sure we end within 90 minutes as planned.
- I'd like to provide a few guidelines to make our time as productive as possible.
- First, there are no right or wrong answers, just varying points of view. We would like to hear from everyone; it's important that we hear the full spectrum of ideas, so please feel free to support, disagree with, or expand on one another's comments.
- Also, we'll be taping our discussion to be sure we don't miss anything; it would be helpful if you would speak one at a time.
- We'll be using first names only in our discussion today. Your comments will be kept confidential; no names will be used in any summaries or analyses. Since we're doing this by telephone, it would be helpful if you would preface your comments with your first name to help us with the note-taking.
- Finally, my role as moderator will be to ask questions and then listen. I won't be participating in the discussion, so please feel free to talk and respond to each other.

1. Opening question (5 minutes)

We have (number) people on our call tonight, from (number) states across the country. I'd like to start by asking each of you to tell us a little about your experience. If we were all in

one room, we would go around the table for these introductions, but since we can't see each other, I'd like you to just jump in, one after another.

- . Please tell us your first name, the number of years you've been in practice, and the approximate number of mammograms you've coded in the past year. (name), could we start with you?

2. Transition question (10 minutes)

- OK. To get started, I'd like to ask, When a mammogram is not completely clear, what might lead you to recommend an immediate biopsy vs. classify it as **code3**?

3. Key questions (20 minutes)

As I noted at the beginning of our discussion, there is considerable variation in the use of this code across states and program sites. We're interested in your thoughts about what might contribute to this variation. Let me briefly summarize what I've heard you say about how you interpret code 3 and what the code means to you. (summary) Is that right?

- . What issues do you feel impact the use of this code?
- What considerations or factors might lead you to decide to increase your use of the "probably benign" category? Decrease your use of this category?
- Which of these factors do you feel are most important?

*Based on the list at the end of this guide, moderator notes any topics which have not been mentioned. Before moving into **the final** questions:*

- I notice no one has mentioned (missed key topic). Is this at all important to you?

4. Follow-up questions (10 minutes).

Let's talk next about changes in the use of code 3.

- . I'd like to get a sense of approximately what percentage of the mammograms you've coded in the past year have been **code3**, and how has this percentage changed over time, if at all?
- To what do you attribute these changes?
- . Now I'd like to discuss what you see as the ramifications of code 3. I'd like you all to brainstorm for a few minutes on the ramifications of using code 3.
- . What various outcomes, both positive and negative, result from the use of this category?
- . What might result if you used the "probably benign" category more? What might result if you used this category less?

5. Ending questions (10 minutes)

- We're nearing the end of our discussion tonight. All things considered, what do you consider to be the most important factor influencing your use of this code?

***Approximately 5-10 minutes before the scheduled time is over, the assistant moderator gives a 2-3 minute summary of key points and asks:***

- Have we missed anything?

D. Thanks and dismissal (5 minutes)

Again, I'd like to thank you all for participating. We really appreciate your thoughtful comments on this topic.

E. Debriefing

Immediately following each focus group session, the moderator, assistant moderator, and CDC technical monitor will debrief. The debriefing will include discussion of:

- overall impressions;
- notable quotes;
- key insights or ideas presented;
- how this group compared to other groups;
- any potential revisions to the moderator's guide or procedures.

Education	What training, guidance, or instruction, if any, have you had regarding the "probably benign" category? This training could take a variety of forms, including participating in conferences, reading literature, or attending courses or seminars. Was that during school, your residency, continuing medical education, or some other channel?
Experience	Would you say that your use of the "probably benign" category has increased, decreased, or stayed the same over time? To what would you attribute this change?
Colleagues/social influence & support	How do your colleagues feel about the use of this code and what is their practice? How do the responses of your radiology colleagues impact your use of this category, if at all? The responses of primary care doctors?

Extenuating circumstances	If you felt that a mammogram should be classified as “probably benign,” could there be any extenuating circumstances or patient characteristics that might make you do an immediate biopsy instead?
Follow-up	When you classify a mammogram as “probably benign” and suggest to the patient that she receive “short-term follow-up,” what do you consider to be appropriate follow-up? Based on your experience, how likely is it that patients will return for follow-up after assignment of a code3?
Patient reaction	Do you have any interaction with the women? If so, when you classify a mammogram as “probably benign,” what do you tell the woman? How does she react to this information?
Legal implications	Has a lesion that you have classified as “probably benign” ever turned out to be malignant? What was the outcome for the patient? Did she take any legal actions against you?
Insurance	How have changes in the insurance scene impacted your use of code3, if at all?
Practice setting	What impact does the type of practice in which you work have on your use of this code? By type of practice I mean hospital practice, private group practice, HMO, or other practice setting.
Practice environment	How does the organizational culture of your practice impact your use of this code, if at all? Are there any underlying expectations which impact your decisions regarding this code?
NBCCEDP program	When you read a mammogram, are you aware of whether or not the patient participates in the Breast and cervical cancer early detection program? If so, are there any factors about the program itself that impact how you use this code?