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FOLLOW UP OF ABNORMAL CLINICAL AND IMAGING FINDINGS OF THE BREAST: FIVE SELF-STUDY MODULES FOR PRIMARY CARE CLINICIANS

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Breast Cancer Module V: Risk Management

Primary care clinicians can help ensure that women receive timely and appropriate follow-up by practicing risk management strategies developed from common causes of delay of diagnosis of breast cancer. In Module V of this Clinical Update, we discuss the most common reasons for a delayed diagnosis of breast cancer and present algorithms and practice guidelines that can be used to help avoid a missed diagnosis of breast cancer. Clinicians must determine an appropriate plan of action for following up with their patients after assessing their breast cancer screening results, and must identify those patients who are at risk for noncompliance with follow-up or incomplete follow-up.

Module V Objectives

Upon completion of this activity, participants will be able to:

1. List the most common reasons for a delay of diagnosis of breast cancer
2. Recognize that the use of algorithms and practice guidelines can help avoid a missed diagnosis of breast cancer
3. Determine an appropriate plan of action for breast cancer screening results
4. Identify patients at risk for incomplete follow-up and strategies to maximize patient compliance with clinician recommendations
5. Utilize clinical tracking systems to promote patient compliance with recommended follow-up

Delay of Diagnosis - Lessons Learned

The leading cause of physician delay in diagnosis of breast cancer continues to be inappropriate reassurance that a mass is benign without biopsy. Reducing delay in diagnosis will require less willingness to rely on CBE to decide that a mass is benign, less reliance on negative mammography reports to decide not to biopsy a mass, and a requirement that fine-needle aspiration biopsy be done by persons with demonstrated competence for the procedure.^[1]

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Only 1 in 10 women with a delayed diagnosis of breast cancer files claims. Delay is 10 times more common if there is a negative mammogram and 3 times more common if the woman finds her own breast mass. In a sample of 454 breast cancers,^[1] Goodson and Moore found the following factors related to delay of diagnosis of breast cancer:

- Misinterpretation of clinical breast examination (CBE) is the most common cause of delayed diagnosis of breast cancer. Stated another way, assuring a patient that a mass is benign is the most common cause of delayed diagnosis of breast cancer, affecting 5% of all women diagnosed with breast cancer.
- Most women who are inappropriately reassured that a mass is benign have a negative mammogram.
- Women with breast cancer who had a negative mammogram were 10.8 times more likely to have a delayed diagnosis than those with an abnormal mammogram.
- A woman with breast cancer who finds a mass herself is 3.3 times more likely to have a delayed diagnosis.
- Use of menopausal hormone therapy increases the risk of delayed diagnosis of breast cancer - *even after a mass has been identified* -- by a relative risk of 3.3. (This is *not* a problem of the mass being obscured by changes from the hormone therapy; this is for masses that had already been discovered. Presumably, clinicians attributed changes in the breast to effects of the hormone therapy rather than doing further work-up.)
- Delay is just as common in women over 50 years of age as in women under 50 years of age. However, most lawsuits are initiated by women younger than 50 years of age.
- Other causes of delayed diagnosis are misinterpreted mammograms (3%), misinterpreted pathology (1%), and poorly performed needle biopsies by person without adequate training (1%).

- Follow up to be sure that all patients for whom you recommend imaging or consultation get evaluated.

Successfully Litigated Claims

The Physicians Insurers Association of America (PIAA) Data Sharing Reports indicate that the most prevalent and second-most expensive condition resulting in claims against physicians is malignant neoplasm of the female breast^[2] The 2002 PIAA Breast Cancer Study focused on 450 paid cases that specifically involved a delay in the diagnosis of breast cancer reported by PIAA member companies. The results were compared to previous studies published by the PIAA in 1990 and 1995.

Major Findings: of the 2002 PIAA Breast Cancer

- Study Seventy-four percent of the claims involved pre- and perimenopausal women, who are considered less likely to get the disease and in whom detection is more difficult due to denser breast tissue. These 2 factors alone result in providers being less impressed by a patient's reported symptoms or by a finding on CBE.
- More than 68% of the women filing claims were under age 50, accounting for 78% of reported indemnity.
- Radiologists were most frequently claimed against (> 33%). Patients in this study reportedly had at least 1 mammogram in more than 88% of the cases.
- The patient most commonly found the lesion (59% of the cases) and was younger on average than when the lesion was discovered by the physician (42.4 vs 46.8 years).
- In almost 80% of cases, the results of the first mammogram were reported as negative or equivocal. Patients who received a second mammogram also received negative or equivocal results in 61% of cases.
- In the 2002 study, the average delay in diagnosis rose to 16.3 months from 14 months in the 1995 study and 12.7 months in the 1990 study.

Communication has been shown to be a major determinant of patient satisfaction and perceptions of quality care; miscommunication and lack of patient understanding and agreement can result in noncompliance with recommendations, delayed diagnoses, and subsequent litigation.^[3]

What can I do to reduce the likelihood of a delay of diagnosis of breast cancer?

The PIAA makes recommendations based on the most prevalent problems described in narrative summaries prepared for each of the 450 cases. The intent of the risk management suggestions is to improve patient care and minimize professional liability losses. The following is by no means an all-inclusive list; however, if followed, these suggestions may reduce liability risks. ^[1] The PIAA clearly states that they are not to be interpreted as standards of care.

- All patient-reported breast symptoms relative to the breast should be documented.
- Personal and family history of breast cancer should be recorded.
- Inquire and request the results of any previous mammograms.
- Follow up with consultants regarding test results, etc.
- Pregnancy should not cause a delay in use of appropriate diagnostic studies.
- A unilateral discrete palpable mass with a negative mammogram unequivocally requires tissue diagnosis.
- Perform a thorough breast examination on each female patient as part of a physical exam, regardless of age or reported symptoms.
- Do not abandon further diagnostic studies because you are unimpressed with the physical finding.
- Be sure the patient understands the need for subsequent studies (her summary of what she understands) and document this fact.
- Perform regular follow-up examinations on patients who present with breast-related symptoms.

In a separate review of 124 malpractice cases for delayed diagnosis of breast cancer, women's health clinicians (i.e., obstetricians/gynecologists, family practitioners, and internists) were the largest group of defendants aside from radiologists. ^[3] The most common complaints specified in these cases were failure to refer for surgery or ultrasound, failure to perform CBE, and failure to order a diagnostic mammogram (Table V-A). ^[4] Alarmingly, radiologists did not communicate (no phone call and/or no report) mammography results to the referring provider in nearly half of the cases. Similar to the PIAA study, patients initially discovered the lesion in a vast majority (77%) of cases. ^[3]

Table V-A: Common Allegations for Failure to Diagnose Breast Cancer and Recommended Steps in Risk Management ^[4]

Allegation	Recommendation
Failure to screen	<p>Document each step below</p> <ul style="list-style-type: none"> • Perform clinical breast exam according to guidelines • Order mammography according to guidelines • Communicate recommendations

Failure to have knowledge of abnormal mammogram results	<p>Document each step below</p> <ul style="list-style-type: none"> • Track results of tests • Communicate abnormal results and recommendations to patient
Failure to follow up on patient symptoms; failure to take patient symptoms seriously; failure to verify a patient symptom on physical exam	<p>Document each step below</p> <ul style="list-style-type: none"> • Perform careful history and clinical breast exam • Compare and confirm results of clinical breast exam with results of breast self-exam, if any • Repeat exam at best phase of menstrual cycle if ovulating (Days 5-10 of menses) • Follow symptoms to resolution or refer • Communicate findings/recommendations • Track patient follow-up appointments
Failure to follow up on a physical exam with abnormal findings	<p>Document each step below</p> <ul style="list-style-type: none"> • Follow physical finding to resolution or refer • Communicate findings/recommendations • Track patient follow-up appointments • If referred, establish follow-up responsibility with referring provider and patient
Failure to refer	<p>Document each step below</p> <ul style="list-style-type: none"> • Refer any persistent clinical breast abnormality to a specialist, no matter what the mammogram result • Communicate area of concern to patient and specialist • Establish follow-up responsibility • If surgical intervention is deferred, establish clear follow-up plan

Modified from Osuch JR, Bonham VL. The timely diagnosis of breast cancer. Cancer. 1994; 74:271-278.

All of the following guidelines are important for risk management except which one?

- Perform a thorough breast examination on each female patient as part of a physical exam, regardless of age or reported symptoms.

- Follow up with consultants regarding test results, etc. Be sure the patient understands the need for subsequent studies (her summary of what she understands) and document this fact.
- Perform regular follow-up examinations on patients who present with breast-related symptoms.
- Document that no further tests are necessary if a negative mammogram is issued with an asymmetrical clinical finding.

Breast Diagnostic Algorithms

What is the value of using diagnostic algorithms to adjunct clinical decisions for timely and appropriate follow-up?

Primary care clinicians who perform CBE and refer women for mammography may have questions about the sequence of steps to perform when breast abnormalities are detected.

Breast diagnostic algorithms are systematically developed decision points based on scientific data and professional consensus, and visually guide the clinician toward referral to a breast specialist for definitive diagnosis when indicated.

Clinical algorithms define consensus guidelines, allowing for practice variation based on a clinician's clinical judgment and patient circumstances. Typically, algorithms:

- Use a stepwise, branching approach to guide practice that is based on screening and diagnostic results and patient characteristics;
- Promote "if, then" decision-making so that the clinical pathway can adapt to a variety of test results;
- Allow for clinician assessment to affect decision points along a "branching logic" tree; and
- Are useful when clinical judgments determine different choices in clinical pathways.

Benefits of Algorithms

By using consensus-driven clinical pathways, clinicians minimize their professional liability. The overall benefits include:

- An efficient way to incorporate accumulated scientific knowledge into daily practice;
- Adherence to standard guidelines by using algorithms that are kept current through regular revision;
- Improvement of quality of care by reducing missed diagnoses; and
- Efficient use of valuable health resources.

Although the benefits of using algorithms appear straightforward, not all clinicians use them regularly. Some perceived barriers are related to clinic management systems and others are related to clinician attitudes and historical practice. Examples of some common barriers and proposed strategies to overcome them are outlined in Table V-B.

Table V-B: Common Barriers to the Use of Algorithms* in Primary Care

Barrier	Strategy
Clinician time constraints	<ul style="list-style-type: none"> • Make algorithms readily available (e.g., print algorithms directly off Web sites) • Place a copy of the algorithm directly into the patient chart • Familiarize yourself with the key elements of the algorithms you use most commonly
Organizational problems	<ul style="list-style-type: none"> • Gain administrative support when needed • Educate support staff to assist with follow-up • Implement tickler and other efficient tracking systems
Resistance and lack of agreement among peer clinicians	<ul style="list-style-type: none"> • Identify peer "champion" with high credibility to promote use of algorithms • Promote "buy-in" by involving peer clinicians in implementation plans • Use case studies to train peer clinicians • Emphasize "guideline" nature of algorithm • Encourage discussion to promote consensus • Develop networks with other local providers to share experience with the use of the algorithms
Legal fears: worry that if all steps of algorithms are not followed, may expose clinician to malpractice accusations	<ul style="list-style-type: none"> • Explain any decisions that do not follow algorithms • Involve patients in decision-making process with sensitivity to ethnic and cultural barriers • If there are multiple breast lesions, work up every finding individually • Any variation or disagreement among specialists should be discussed and documented *For

*For access to breast diagnostic algorithms, go to <http://www.sdsu.edu/qap>.

Practice Guidelines

Practice guidelines assist primary care providers in identifying the absolute ("must do") and relative ("highly suggested to do") indications for clinical action. (See Table V-C, below.) These guidelines can assist in standardizing care within a practice.

Table V-C: Absolute and Relative Indications for Referral to a Breast Specialist ^[4]

Absolute Indications for Referral
<ul style="list-style-type: none">• Nonpalpable mammographic abnormality read as suspicious• Discrete palpable abnormality that is not cystic by ultrasound or fine-needle aspiration (Note: This is true even if an associated mammogram is read as normal.)• Any discrete abnormality that is not evaluated further by the primary clinician• Aspirated cysts that are grossly bloody• Aspirated cyst with residual palpable mass or thickening after aspiration• Rapidly recurring breast cyst (within 6 weeks)• Asymmetrical thickening that persists after a menstrual cycle in an ovulating woman• Any asymmetrical thickening in a nonovulating woman• Spontaneous unilateral nipple discharge• Nipple scaling that does not respond to topical steroid treatment within 10 days• Skin retraction• Skin erythema that does not respond to antibiotic treatment within ten days
Relative Indications for Referral
<ul style="list-style-type: none">• Nonpalpable mammographic abnormalities read as BI-RADS Category 3• Bilateral multiple duct spontaneous nipple discharge• Woman with difficult breast examinations (i.e., extreme breast tenderness, density, or nodularity)• Women at high risk for the development of breast cancer• Worried patient with a negative work-up• Evidence of lack of an effective provider-patient relationship (for risk management purposes)

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In summary, the intent of the algorithms and guidelines provided in these modules is to give providers a consistent framework for evaluating a spectrum of breast lesions. If the clinical examination, radiologic imaging, and pathologic findings are not concordant, the clinician should consider resampling of the lesion or that the patient needs a full assessment using open surgical biopsy. Incorporating the patient into the health care team's decision-making empowers the patient to determine the level of breast cancer risk that is personally acceptable in the follow-up recommendation.

Use of diagnostic algorithms are useful for all but which one of the following?

- Understanding what the current scientific evidence says about the usefulness and application of diagnostic procedures.
- Promote "if-then" decision making based on consensus agreement among breast experts.
- Can save time and resources in redundant research at the individual clinical practice level.
- Application of clinical practice policy to each and every woman in your clinical practice, regardless of unique patient circumstances.

Improving Patient Adherence to Follow-up

Both patients and clinicians contribute to delays in the follow-up of abnormal findings. Most clinicians would agree that it would be useful if there were a way to identify patients who are most likely to have incomplete follow-up.

Numerous studies have shown the motivating effect that clinician recommendation(s) can have on adherence to preventive health behaviors. Clinicians often underestimate how important their advice is in enhancing patient compliance with follow-up plans. It has long been known that the most important reason women have not had screening is that their clinician did not recommend the procedure(s).^[5]

Patients who are most likely to have incomplete follow-up can be identified based on:

- Behavior characteristics (e.g., screening history); and
- Barriers (e.g., lack of transportation, inadequate insurance coverage, lack of child care, inconvenient clinic hours).
- Current literature indicates that racial and ethnic minorities (e.g., African American, American Indian, Asian, and Hispanic/Latina women) have significantly less timely follow-up after an abnormal mammogram.^[6,7]

Acknowledging and addressing factors that can be changed may increase your ability to provide timely and adequate follow-up to women with abnormal results. Clinicians should be aware of local resources that can assist women (e.g., financial, transportation support, etc.). Becoming more aware of the cultural beliefs that relate to patients' decision-making will improve their adherence to follow-up recommendations. One way of doing this is to listen to each patient talk about her thoughts and feelings during patient-clinician encounters.

Characteristics of Patients Most Likely to Have Incomplete Follow-up

- Have never had a mammogram, or very few compared to screening standards;
- Are age 65 and older;
- Have had fewer mammograms in the past 5 years based on appropriate screening recommendations;
- Have lower socioeconomic status; Lack insurance coverage; Are less educated; Report their own health as "fair" or "poor" (coexisting morbidity);
- Feel they are "too old" for treatment or desire "not to know if something is wrong";
- Receive services from a clinician who is not the patient's primary care clinician;
- Have a test result "probably benign," with 3- to 6-month follow-up recommended; Report difficulty in obtaining an appointment; and/or
- Have transportation problems.

Multivariate analysis show that rural women, those with abnormal CBE findings but normal or equivocal findings on mammograms, and those who self-discovered a mass are less likely to receive adequate follow-up than are their counterparts.^[8]

Steps to Increase Adherence to Follow-up

Taking the time to conduct a careful patient assessment for barriers to follow-up will provide useful information to help navigate the patient through a timely and appropriate follow-up. The following steps are targeted to increase adherence with patient-specific action plans for the work-up of abnormal breast screening results:

- Communicate mammography results as soon as possible (5 business days is optimal, less than 30 days is more practical) and prepare women by informing them when and how they will receive these results (radiologist may call primary care clinician who then calls the patient).
- Schedule appointments, provide reminders, and shorten the waiting time for diagnostic work-up.

This interim waiting time after an abnormal finding is an emotionally stressful period for the patient, due to the uncertainty of the diagnosis. The uncertainty of the diagnosis can be more stressful than knowing one has cancer. ^[9]

- Write a prescription for the follow-up procedure (this is the recommended procedure to reinforce a patient's ability to adhere to the advice).
- Identify potential barriers and help the patient find solutions to the problems.
- Develop a relationship with the patient that conveys confidence and credibility in the abnormal finding and recommended follow-up; acknowledge her spouse/partner and family through education.
- Provide educational materials early and ensure access to one-to-one communication, if desired by the patient, to decrease the fears and uncertainties of the abnormality and/or diagnosis.
- Deliver patient education using appropriate language, with sensitivity to cultural and ethnic diversity.
- Acknowledge her spouse/partner and/or family.

Patient noncompliance is generally not detected unless specific efforts are made to determine adherence. Many clinicians are unaware of the problem or its magnitude. ^[10]

- Understand the patient's perspective. This can be particularly challenging when the patient is from a different culture. Culturally sensitive clinician/staff-patient communication will increase the chances that her follow-up will be completed.
- When any distressing information is shared, ask the patient for her understanding of your explanation. This will help you find out what information was actually heard and what misconceptions may have developed.
- Establish and sustain a clinician-patient relationship by warmth, caring, positive regard, and nonverbal expressions.
- Spend time on patient education, both listening and responding. Patient education ultimately results in better adherence.
- Maintain a callback system. There are many mechanisms that can improve adherence to mammography and follow-up. Consider a navigator program approach where a designated person checks on every report when there is an abnormality. This person then tracks the patient to a final diagnosis and through treatment.
- Provide patients with adequate time to ask questions and express concerns, as efforts to counsel women may not improve compliance with recommendations until anxiety is addressed and reduced. ^[11]

- Ensure confidentiality;
- Encourage the patient to be involved in decision-making.
- Assess your practice/clinic management systems to ensure that they promote screening and follow-up.

Making Referrals

How can I ensure that making a referral to another provider of care will be effective and efficient?

The primary care clinician assumes an important clinical, ethical, and legal responsibility when making a referral since he/she is enlisting a specialist's assistance. ACOG has outlined the following responsibilities for the referring clinician ^[12]:

- Request consultation in a timely manner by having a formal consultation protocol developed for your practice.
- Prepare the patient with an explanation of the reasons for consultation, the steps involved, and the names of qualified consultants.
- Provide the consulting clinician with a summary of the history, physical examination, laboratory findings, and any other information that may facilitate the consultant's evaluation and recommendations.
- Whenever possible, document in the medical record the indications for the consultation and specific issues to be addressed by the consultant.
- Mutually agree upon the level of consultation, which can vary from single-visit consultation, to continuing collaborative care and/or transfer of primary clinical responsibility.
- Track that the referral consultant reported back the results of the referral.

Clinic Management Systems

How can I improve office systems to track and monitor my patient over time?

Efficient and effective clinic management systems are an important part of healthcare practice, especially for continuity of care, risk management, and reimbursement. Whether the systems are manual, automated, or both, you are encouraged to assess your office systems for referral, tracking, and follow-up features, such as:

- Appointments scheduled, kept, missed, rescheduled;
- Dates and results of in-office exams and tests (include correlation of clinical findings and other tests);
- Exam forms to note both normal and abnormal findings;
- Dates patient notified of results;
- Dates when reports from referral clinicians or consultations were received in the office;

- Dates and the outcomes of discussing test results with patients;
- Documentation of recommendations made and counseling/health education provided—also note materials given;
- Follow-up on referrals needed, when appointments are made and if they are kept; and
- Recall for rescreening exams and dates scheduled.

The likelihood of a woman receiving all needed cancer follow-up tests was 4 times higher after receiving a reminder letter and a telephone call. ^[13]

For purposes of accuracy, respect, and confidentiality, it is important to ask each patient how she prefers to receive appointment reminders and results of exams or tests, (e.g., at home or work, by confidential phone message or letter). By providing options, a woman is more apt to receive the notification and respond to it.

Types of Tracking and Patient Notification Systems

- Chart flags on patient medical records to indicate recommended screening dates or appointments for follow-up;
- Practice flowcharts determining rescreening appointments;
- Checklists for follow-up phone calls or letters;
- Manual "tickler" systems using self-addressed envelopes (post cards are no longer HIPAA compliant) filled out by the patient, filed by chronological dates;
- Computerized tracking systems that generate lists of patients due for appointments and accompanying form letters;
- Automated patient confirmation/reminder systems; and
- Periodic chart audits.

Information to Include in Patient Reminders

Keys to effective office prompt systems are: (1) only 1 or 2 specific tasks per prompt, regardless of who in the office is responsible), (2) there is an efficient system in place to generate the notices and to place them in the chart, and (3) the prompts are timed so that the task is completed immediately upon notification. ^[13]

- Reason why the woman is being notified—what the appointment is for;
- How to schedule or change an appointment; best times of the day to call;
- How long the appointment will take and if she will need to arrive early for any reason;
- Who the appointment is with;

- What exams or tests may be performed;
- How to prepare for the exam (e.g., for mammography -- what to wear, not to use deodorants or underarm powders);
- What forms, medical records, previous films/reports, medication lists, or eligibility information to bring;
- Directions to the office and information on transportation or parking availability/costs; and
- Patient education information related to the upcoming procedure.

Other Activities to Improve Follow-up by Patients

- Arrange timing of callbacks to share an abnormal result so that the patient receives the message directly, not by answering-machine messages left for her during work hours, which may cause great anxiety;
- Immediately attempt to arrange follow-up appointments, and utilize referrals with capacity to accommodate quick turnaround times;
- Ask the patient to notify your office if she is unable to keep a scheduled appointment or if the appointment is canceled or rescheduled by the referred specialist office;
- Assist patients with financial concerns or eligibility; and
- Identify community resource agencies (e.g., grassroots, voluntary, and community action agencies) that provide services such as transportation, elder care, or translation can help to remove these barriers and increase adherence for individual women.

Cultural Competency

The healthcare provider system can be a barrier itself. Behaviors by clinicians that promote communication and understanding with patients include, but are not limited to:

- Provide adequate time for patient to ask questions;
- Acquire the services of a licensed interpreter if indicated;
- Acknowledge and provide guidance on use of alternative health practices;
- Assure respect for family member(s);
- Verify patient understanding of recommendations communicated;
- Avoid questions of personal nature perceived as private, unless related to medical history;
- Assure that information related to citizenship will not be reported to authorities; and
- Address of all patient concerns and/or questions.

The attitudes of the staff toward the patient can have a significant impact on adherence to a diagnostic follow-up plan. Patients who feel and perceive genuine warmth, encouragement, support, and concern for their well-being have been shown to significantly improve their adherence to recommended follow-up. ^[14-17]

Recommendations

- Provide opportunities for staff to attend cultural sensitivity training.
- Provide comfortable settings for patients (e.g., waiting room, exam room, etc.).

Communicating Abnormal Results

When a woman is notified of an abnormal result from a cancer-screening exam, she may experience anxiety, fear, depression, and may not comply with the advised diagnostic work-up. Researchers have stressed the importance of improving communication of abnormal results for both cervical cancer screening and mammograms. As there are strengths and weaknesses associated with written, phone, and in-person communications, ideally a combination of these methods should be used. ^[9]

Interactive telephone counseling is more effective than mailed reminders in improving follow-up compliance. ^[18]

Documentation Protocols

What key documentation practices will ensure continuity of care and enhance risk management?

Because delays in diagnosis exact a heavy toll—for patients and clinicians -- documentation protocols can promote quality care and minimize clinician risk. These protocols may include, but are not limited to, the following ^[4, 19-21]:

- Document the date the patient last received a mammogram, the findings, and how often the patient obtains mammograms.
- Document whether the patient has been counseled about the benefits and limitations of BSE.

- Document a patient's personal and family medical histories, including family history of other cancers (e.g., prostate, colon, ovarian), as well as a detailed risk factor profile for the patient. The profile should incorporate a history of previous breast surgeries or procedures and previous lesions and their outcomes.
- Document women who are at high risk for getting breast cancer (see Module II).
- Document risk counseling for high-risk women or refer to a specialist in risk counseling.
- Document in word and diagrammatic form the location of any mass detected by a patient, the date the mass was detected, and any associated changes in the breast (e.g., nipple discharge, dimpling, retraction, etc.). The record should also include documentation of areas where the clinician found no palpable mass upon physical examination.
- Document any problems in physical examination for women with a history of fibrocystic problems, lumpy breasts, cysts, diffuse nodularity, firm breasts, or any other condition (e.g. breast implants) that makes clinical examination difficult.
- Document, when appropriate, the consistency, color, and volume of any fluid removed from the breasts, whether it was sent for analysis, and a description of the findings.
- When referral is initiated, document that the patient was informed of the findings and recommendations of the referral clinician.
- When a follow-up plan is developed, document the plan along with a note specifying the communication of this plan to the patient.
- If, for any reason, a delay in diagnosis occurs, document the cause of the delay. If patient non-compliance or resistance is the reason, document this and note that the patient was informed of the possible adverse side effects of her action or inaction. All attempts to communicate with the patient to obtain the needed health services must also be noted in the patient's medical record.

Lost to Follow-up

After 2 to 3 unsuccessful attempts to contact the patient about an abnormal test result, send a certified letter (return receipt requested) to the patient notifying her of the result and the importance of contacting the clinician. All of these actions need to be documented in the medical record.

Little is gained beyond 3 attempts to arrange follow up. ^[21]

Medical Refusal

Informed refusal is a fundamental component of the informed consent process. According to the ACOG Committee on Professional Liability, ". . . must disclose to the patient the risks, benefits, and alternatives that a reasonable person in the patient's position would want to know to make an informed decision. The subsequent election by the patient to forgo an intervention that has been recommended constitutes informed refusal. Documentation of the informed refusal process is essential. It should include a notation that the need for the intervention, as well as risks, benefits, and alternatives to the intervention, and possible consequences of refusal, has been explained. The patient's reason for refusal also should be documented." ^[22]

Having the patient sign a medical refusal form that outlines the recommended follow-up and the consequences of refusal is not only legally prudent, it may convince some women to change their minds and agree to follow-up.

Health Insurance Portability and Accountability Act (HIPAA)

Effective April 14, 2003, clinicians are required to comply with the privacy rule released under the Health Insurance Portability and Accountability Act of 1996. Essentially, this compliance effort directs how protected health information flows inside and outside the clinical practice of providers.

A clinical practice is permitted to use and disclose protected health information without authorization for related treatment activities to be performed by another health care clinician for a patient in common. *For example, referral for diagnostic work-up in response to an abnormal breast screening is a permitted disclosure.*

The minimum necessary standard will require practices to make reasonable efforts to limit uses, disclosures, and requests for patient information to the minimum necessary to complete the task or satisfy a request. This minimum necessary standard does NOT apply in the following circumstances:

- Disclosures or requests by health care clinicians for treatment (including your office). Under these circumstances, the entire medical record can (technically) be disclosed. Practically, only the relevant documentation and related reports are generally disclosed.

- Disclosures to the patient who is the subject of the information. This information is a combination of verbal and written depending on the needs of the patient involved.

A clinical practice may use or disclose protected health information to other people involved in the patient's care for notification purposes if the patient is informed in advance of the use or disclosure and has the opportunity to agree, restrict, or prohibit the use or disclosure. ***For example***, if a woman requests that her husband be allowed in the exam room during her office visit, a provider can infer that the woman agrees to the disclosure of health information to her husband during the office visit, but the provider also should ask whether this is the case. If so, the provider may disclose such information during the visit only (does not imply permission outside the context of that office visit).

For more information on HIPAA, go to <http://www.cms.hhs.gov/HIPAAGenInfo/>.

Plan of Action to Manage and/or Reduce Patient Risk for Delay of Diagnosis

Plan of Action to Manage and/or Reduce Patient Risk for Delay of Diagnosis

A complete screening includes a breast health history, CBE, and screening mammography, with subsequent correlation of the results. The breast cancer screening guidelines have been the center of consensus as well as considerable controversy (see Table V-D4). The controversy involves age at initiation, breast cancer risk status, sensitivity and specificity of the procedures, intervals between screening and the strength of language used to recommend CBE and screening mammography. Clinicians are encouraged to have written protocols for the screening/rescreening guidelines to be used in their clinical practice.

Table V-D4: Breast Cancer Screening Guidelines -- Asymptomatic Women/Average Risk

Organization	Clinical Breast Examination (CBE)	Mammography
American Academy of Family Physicians	Every 1-3 yrs. at ages 30-39; annually after age 40	Every 1-2 yrs. beginning at age 40
American College of Radiology	Every 3 yrs. at ages 20-39; annually after age 40	Annually beginning at age 40
American College of Preventive Medicine	No recommendation	Every 1-2 yrs. beginning at age 50
American Cancer Society (ACS)	CBE with periodic health maintenance visit, every 3 yrs. at ages 20-39; annually after age 40	Annually beginning at age 40 y
American College of Obstetricians and Gynecologists	Annually or as appropriate starting at age 20	Every 1-2 yrs. at ages 40-49, annually at age 50+
American Medical Association		Annually beginning at age 40
American College of Surgeons		Annually beginning at age 40
American College of Physicians	No recommendation	Every 2 y at ages 50-74;
American Medical Women's Association	Annually by age 40	Every 1-2 yrs. beginning at age 40
National Cancer Institute	Every 1-2 yrs. beginning at age 50	Every 1-2 yrs. Beginning at age 40
US Preventive Services Task Force	Says evidence is inconclusive to recommend for or against CBE	Every 1-2 yrs. for women 40 and older

Controversy remains about the efficacy of instructing women to perform breast self-examination (BSE) as part of an early detection triad. Careful assessment of a woman's desire and ability

toward self-empowerment for the early detection of breast cancer may help the clinician determine for whom the instruction is most useful.

Plan of Action: Screening for Women at Higher Than Average Risk

Screening guidelines for women at high risk have not been published by national organizations like routine screening guidelines. The high-risk guidelines are published textbook guidelines, hence may be modified for variant settings, regions and clinical practices. ^[23]

Management of Special Populations

Women with Implants

These women still receive regular CBE and mammography according to accepted screening guidelines. CBE technique is the same as for women without implants. Imaging evaluation using specialized views in addition to the 2 views used in normal screening is standard practice. Special positioning techniques are also used to maximize visualization of breast glandular tissue. The presence of breast implants should be noted on the radiology request form. An MRI scan is the current recommendation to rule out silicone implant leakage or rupture if the patient has signs or symptoms to suggest this. Patients with saline implants or intact double lumen implants (where the outer bag is saline) do not need MRI evaluation. MRI is not routinely recommended for implant evaluation. MRI of implants is different from MRI for breast cancer. Contrast is not injected and the imaging sequences are different. High-resolution ultrasound and MRI will indicate a leak or rupture with a characteristic "linguini" sign which are linear artifacts created on the image by the envelope of a disrupted breast implant. Women should sign consent prior to imaging regarding liability of rupturing the existing implant during the procedure.

Pregnant or Lactating Women

About 1 in 3000 pregnant women will develop invasive breast cancer. At the initial obstetric visit, a thorough CBE is important as the exam becomes more difficult to interpret as pregnancy progresses. Because of age, physiology issues and the radiation exposure of mammography pregnant patients do not typically undergo screening mammography. Furthermore, mammography of women who are pregnant and or lactating is more difficult to interpret. However, dominant masses noted on BSE or CBE can be evaluated with ultrasound (to determine cystic or solid) or the "triple test," realizing that diagnostic mammography is safe during the first 10-12 weeks (and preferable with a lead shield used) as pelvic radiation from mammography is nonmeasurable. Lactating women should pump breasts immediately prior to mammogram to reduce discomfort, improve tissue visualization and reduce the radiation exposure. There is no restriction to breast feeding after a mammogram.

Young Women

Women younger than 30 years frequently present with new breast lumps; however, benign breast disease is more common than in older women.

Ultrasound is the first line of investigation to evaluate a questionable or indeterminate CBE finding. If this is negative, a mammogram should be ordered. FNA biopsy or core needle biopsy to confirm the presence of a benign lesion can be a useful approach. Some, but not all, data evidence suggests that, stage-for-stage, prognosis of breast cancer is slightly worse for younger women compared to patients older than age 40. ^[24]

Males

The male breast is normally only a small disk of ductal tissue behind the nipple-areolar complex. Enlargement of this tissue, either unilateral or bilateral, especially when soft or firm (not hard) and tender, is most commonly due to gynecomastia, a benign enlargement of male breast tissue with many causes (including any condition causing relative hyperestrogens and several medications). It is most often benign and peaks in 2 age groups: the adolescent and those over age 50 years. Breast cancer in males is most often unilateral and painful.

Males should be evaluated with physical examination initially. Breast cancer in males is rare (approximately 1500 cases per year in the United States or less than 1% of all breast cancers). Males can have mammograms and ultrasounds to evaluate a breast mass when indicated.

Suggested Reading

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