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CLINICAL & RISK MANAGEMENT PERSPECTIVES
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Breast Cancer — Reducing the Risk of Delayed Diagnosis

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LEARNING OBJECTIVES

By reviewing medical professional liability claims and/or emerging topics in healthcare risk management, this enduring material series will support your ability to:

- Assess your practice for risk exposures.
- Apply risk management best practices that increase patient safety and reduce medical professional liability claims.

TARGET AUDIENCE

All physicians, clinicians, staff and healthcare administrators.

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INTRODUCTION

In women, breast cancer is the most commonly diagnosed cancer and the second leading cause of death in the U.S. It accounts for 30 percent of all new cases of cancer diagnosed in women in the U.S.[1,2]

In 2013, the PIAA (now known as the Medical Professional Liability Association) issued a comprehensive study of breast cancer claims, which revealed errors in diagnosis as the most common chief medical factor.[3] The study also indicated that most patients who developed breast cancer were over age 50, but the majority of lawsuits were filed by patients under age 50, because the disease tends to be more aggressive in younger patients.[4] In NORCAL diagnostic error claims closed between 2013 and 2017, malignant neoplasm of the female breast was the most frequently misdiagnosed condition. The average indemnity payment on NORCAL's breast cancer diagnostic error claims is 5.5% higher than the average payment for all NORCAL diagnostic error claims, and 20.5% higher than the average indemnity paid on all NORCAL claims.

Most of NORCAL's breast cancer diagnostic error claims were against radiologists; however, about one-third of these claims were against physicians in a medical specialty such as internal medicine, family medicine, or obstetrics/gynecology. As such, this article will focus primarily on how breast cancer diagnosis errors impact medical specialties outside of radiology. The November *Claims Rx* will address diagnostic error claims against radiologists.

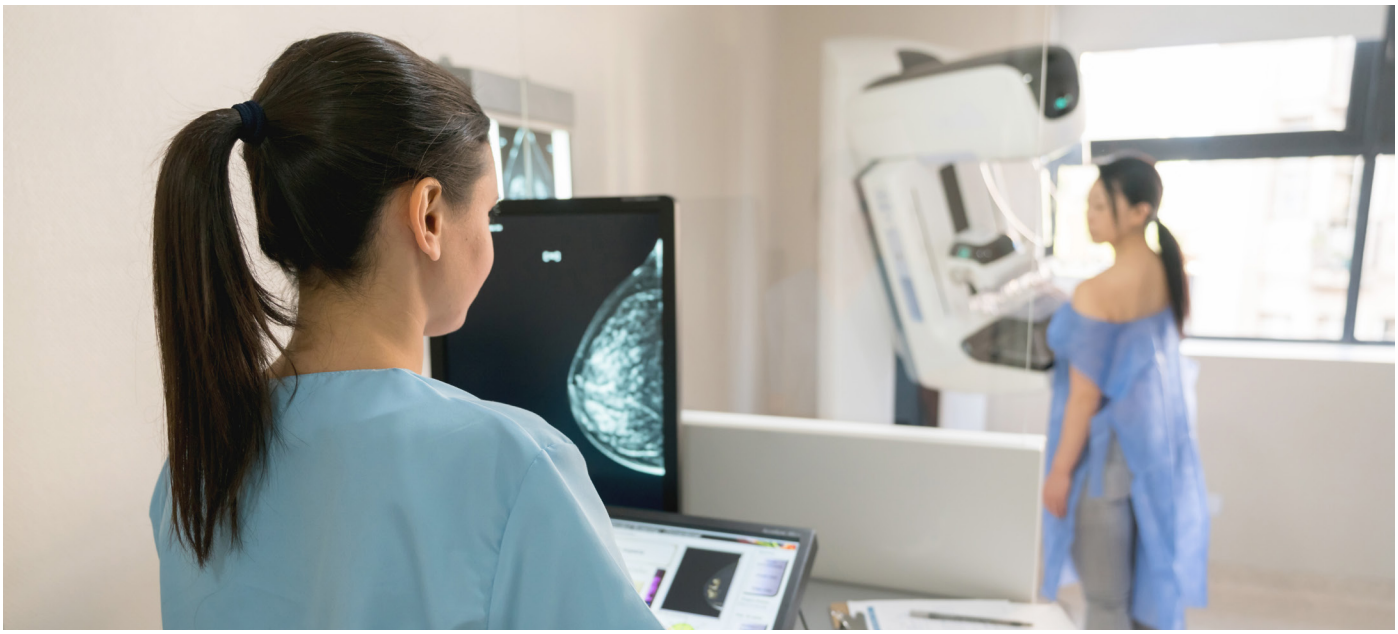
Non-radiology issues that contributed to diagnostic error in NORCAL claims include lab errors; problems with patient history, exam or work-up; failure to follow up; and communication problems between healthcare providers. In addition, Ward and Green's review of breast cancer claims data echo this.[5] Their 2016 article spotlights documentation and communication as issues of concern, specifically lack of documentation of patient complaint of a breast lump and failure to document a breast exam.

These data support the need to integrate a risk management approach to breast health — particularly one that emphasizes communication, documentation, and follow-up — to improve patient care and reduce medical professional liability exposure.

Screening for Breast Cancer

Breast cancer screening guidelines differ among professional organizations. For example, the 2017 American College of Obstetricians and Gynecologists (ACOG) recommendations state that women of average risk for breast cancer should be offered screening mammograms starting at age 40, and no later than age 50, continuing to at least age 75. The ACOG recommendations stress "shared decision-making," to include discussion of the potential benefits and harms of mammography.[1]

Regarding the time to stop mammograms in women over age 75, ACOG states that the decision to continue mammograms should be based on shared decision-making that considers the patient's health status and longevity. This guidance takes into account the recommendations of the U.S. Preventive Services Task Force, American Cancer Society, and National Comprehensive Cancer Network, each of which focuses on a different aspect of patient health.[1]



The differences in guidelines — regarding what ages to start and stop screening and how frequently to recommend screening — can create anxiety among healthcare professionals about potential liability associated with not following a particular recommendation, as well as confusion for patients. Consider implementing the following risk management practices to mitigate such exposure:

- Maintain a current awareness of various guidelines in order to have productive discussions with patients.
  - American Cancer Society. Available at: ***cancer.org/healthy/find-cancer-early/cancer-screening-guidelines/american-cancer-society-guidelines-for-the-early-detection-of-cancer.html*** (accessed 8/13/18)
  - U.S. Preventive Services Task Force. Available at: ***uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/breast-cancer-screening1*** (accessed 8/13/18)
  - National Comprehensive Cancer Network. Available at: ***nccn.org/professionals/physician_gls/default.aspx#breast*** (accessed 8/13/18)
- Document the guidelines you are using for decision making.
- Document your reasoning for following a specific screening recommendation over another.[5]
- Discuss screening in an informed consent context, balancing the benefits (e.g., decreased risk of dying from breast cancer) and potential harms (e.g., potential false-positive results, additional testing, benign breast biopsies) associated with screening.[1] Key to this discussion is managing patient expectations about the limitations of screening and detection.[5]
- Document discussions and patient decisions, including refusal of screening modalities.

The Importance of History

Taking the Time to Look at the Individual Patient

Assessing risk factors for the individual patient helps to determine whether a patient is at average or increased risk of developing breast cancer, further helping to identify women who might benefit from genetic counseling, screening that includes MRIs, or more frequent clinical breast exams (CBEs). Consider the following factors that could indicate increased risk of breast cancer:[i]

- Family history of breast, ovarian, prostate, and pancreatic cancer
  - First-, second-, and possible third-degree relative
  - Age at diagnosis
- Known gene mutation
- Prior breast biopsy with specific pathology (e.g., atypical hyperplasia (lobular or ductal), lobular carcinoma in situ)
- Early onset of menstruation
- Late menopause
- Nulliparity
- Prolonged interval between menarche and first pregnancy
- Menopausal hormone therapy with estrogen and progestin (decreased risk with estrogen only)
- Not breastfeeding
- Increasing age
- Ethnicity (specifically increased risk of BRCA mutation in women with Ashkenazi Jewish ancestry)
- Higher BMI
- Alcohol use
- Smoking
- Dense breast findings on mammography
  - When evaluating next steps for women with dense breasts whose mammograms show negative findings, remember that these women have a higher risk of false-negative findings.
- Prior exposure to high-dose therapeutic chest irradiation (between the ages of 10-30)

Some risk factors are modifiable, which presents opportunities for physicians to engage in discussions with patients about lifestyle changes and preventive care. For example:[ii]

- Weight
- Physical inactivity
- Alcohol consumption
- Long-term, heavy smoking
- Sleep disruption
- Postmenopausal hormone use (combined progestin and estrogen)

i. American College of Obstetricians and Gynecologists (ACOG). Practice Bulletin. Breast cancer risk assessment and screening in average-risk women. *Obstet Gynecol.* 2017 Jul;130(1):241-243. Available at: ***acog.org/-/media/Practice-Bulletins/Committee-on-Practice-Bulletins----Gynecology/Public/pb179.pdf?dmc=1&ts=20180204T1824108792*** (accessed 7/5/18)

ii. American Cancer Society. Cancer Facts & Figures. 2017. Available at: ***cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2017/cancer-facts-and-figures-2017.pdf*** (accessed 7/11/18)

BRCA Test Result Communication

The following case illustrates how a BRCA-1 mutation can impact development of another type of cancer, as well as the importance of involving specialists in the care of patients who are candidates for BRCA-1 genetic testing.

CASE ONE

Allegation: Delayed diagnosis of ovarian cancer resulted in increased risk of recurrence and diminished prognosis.

A 48-year-old female with a strong family history of breast cancer (mother and maternal aunt) presented to her primary care physician and requested to be tested for the BRCA-1 mutation. The patient's insurance would not pay for the test, but she was willing to pay for it herself. The physician received the results two months after the blood draw, read them as normal, and documented her review in the patient's chart. She created a reminder in her task list in the electronic health record (EHR) to contact the patient with the results. The EHR was set up to place non-urgent items at the bottom of the task list. The physician's nurse contacted the patient to inform her that her results were negative.

Over the course of the year, the patient was seen in her primary care physician's office with complaints of nausea, fatigue, and urgency when urinating. The physician suspected urinary tract infections, but the symptoms were not resolving with antibiotics. The physician referred the patient for imaging to investigate the symptoms. A CT scan showed lesions throughout the uterus, originating from the right ovary. The patient underwent a hysterectomy and bilateral salpingo-oophorectomy. Cancer was present in both ovaries, and it had metastasized to the lymph nodes. The patient underwent multiple rounds of chemotherapy. Her oncologist reviewed the BRCA-1 results, which had been provided with records from the primary care physician, and informed the patient that she had, instead, tested positive for the BRCA-1 mutation. As a result, the patient additionally underwent a bilateral mastectomy. She filed a suit against the primary care physician.

DISCUSSION

The physician in this case assumed responsibility for a type of testing with which she did not have much experience, and did not appreciate the potential complexity of the results. Experts who reviewed the case thought the patient should have been referred to a genetic counselor or OB/GYN to order and manage the results of the BRCA mutation test. The reviewers felt the delay in diagnosis caused the patient's survival rate to drop significantly, and that she could have been referred to a specialist earlier to have a prophylactic oophorectomy.

RISK MANAGEMENT **RECOMMENDATIONS**

- Consider referring management of genetic testing to a specialist (e.g., a gynecologist or medical oncologist) who has the expertise to interpret results and is familiar with coordinating care (i.e., a genetic counselor).
- Develop a process to ensure that tests you order are returned to the office in a timely manner.
- When patients present with new complaints that are seemingly unrelated to prior concerns, such as the patient in this case did (i.e., nausea, fatigue, and urgency with urination that had followed her request to be tested for the BRCA-1 mutation), consider stepping back and revisiting those concerns.
  - Review the patient's chart to re-familiarize yourself with history, complaints, and whether/how those complaints were resolved.

Genetic Testing for BRCA Mutation

BRCA-1 and BRCA-2 are genes that suppress tumor growth. Testing patients for mutations in these genes helps clinicians identify at-risk patients and direct their care appropriately. One in 300 people carry the BRCA-1 mutation, while one in 800 carry the BRCA-2 mutation. Mutations are more prevalent in individuals of Eastern or Central European Jewish ancestry, as well as French Canadian and Icelandic ancestry.[6] Those who test positive for the BRCA mutation have a 50% chance of developing breast cancer by age 50, and a 45 to 85% chance of developing the disease by age 70.[4,7] Patients with a BRCA mutation also have an increased risk of developing cancer of the ovary (with the fallopian tube as the site of origin), peritoneum, pancreas and skin.[5,7]

Recommendations for testing of BRCA mutations are based on the following criteria:[7]

- One first- or second-degree relative diagnosed with breast cancer at or under age 45
- One first- or second-degree relative diagnosed with ovarian cancer
- Two breast cancers on the same side of the family, one diagnosed in a person younger than age 50
- Three breast cancers on the same side of the family, diagnosed at any age
- One first- or second-degree relative diagnosed with triple-negative breast cancer at or under age 60
- Three relatives on the same side of the family with any combination of breast, ovarian, pancreatic, or prostate cancer
- Known BRCA mutation within the family
- A close relative with male breast cancer

RISK MANAGEMENT **RECOMMENDATIONS**

- Obtain a complete, current personal and family history to determine if genetic testing is appropriate.
- In taking a family history, inquire about the type of primary cancer, the age of onset, the lineage (female or male), which family member and the family member's ethnic background.
- Keep in mind that the criteria for testing are intended to guide non-genetic specialists in providing patients with more specialized evaluation;[7] therefore, documentation of your communication with patients and coordination of referrals is key to promoting continuity of care and avoiding potential liability for failure to refer.
- Counsel the patient, including referral to a genetic counselor (or gynecologic or medical oncologist),[7] as appropriate. An individual specializing in genetic counseling will be able to explain to the patient:[6]
  - How testing is done
  - What the results could indicate
  - Choices depending on the results
- Ask if the patient has a relative who is available to test.

Challenges with Genetic Testing

Two primary challenges with genetic testing are absence of FDA regulation of testing[4] and lack of insurance coverage for testing. Lab results are not required to be validated against any external standard, which means that results can vary depending on where the patient is tested. The insurance issue is one that is most familiar to providers and patients; either the insurance carrier does not cover the test or, if it does cover it, it might dictate which lab will perform it.[4] In the foregoing case, the patient was willing to pay for the test, so this was not an issue; however, it was unclear why it took the lab eight weeks to return results to the ordering physician (i.e., was this the lab's standard turnaround time, or did the physician need to follow up with the lab?).

RISK MANAGEMENT **RECOMMENDATIONS**

LAB FACTORS

- Be aware of what to look for in lab quality; for example:[4]
  - Analytical sensitivity and specificity
  - Quality control measures
  - Lab commitment to reclassifying variants when in receipt of new information
  - Processes for communicating initial and follow-up results
- Consider alternatives to labs that might not meet certain quality standards (e.g., inquire about the patient's ability to pay, or whether insurance will approve of the patient going to a lab of your choosing).[4]

These factors highlight the specialized nature of genetic testing, and why it benefits physicians to be knowledgeable in current practices.

PAYMENT FACTORS

- Advocate for the patient if there are restrictions; you might not succeed in your appeal, but documenting your efforts can help diminish allegations of negligent referral or failure to obtain appropriate studies.

PATIENT REFUSAL OF TREATMENT

- If the patient refuses treatment because of the cost, you confront a unique dilemma with various unsatisfactory options, including: encouraging the patient to proceed despite the cost; recommending care that is less expensive, but substandard; or refusing to care for the patient. Uncomfortable negotiations can follow, with the healthcare provider striving for an appropriate quality of care and the patient striving for care at the lowest cost. Striking a balance and achieving the best possible results for both the physician and patient requires planning, excellent patient-physician rapport, a commitment to the patient's well-being and thorough documentation.
  - Patients have a right to refuse treatment because they cannot afford it or do not want to pay for it. When a patient refuses recommended treatment for financial reasons, documentation of the patient's informed refusal is particularly important.

What Happens after Testing for the BRCA Mutuation?

POSITIVE RESULT

This means the patient has the mutation and carries an increased risk; however, it does not necessarily mean the patient will get cancer.[iii] Recommendations for patients with a positive result include the following:

- Breast cancer screening
  - Clinical breast exam every 6-12 months
  - Annual imaging starting at age 25; MRI starting between 25 and 29 years of age; and annual MRI and mammogram beginning at age 30
- Ovarian cancer screening
- Medications
  - Tamoxifen (for BRCA-2 mutation)
  - Combined hormonal birth control pills may reduce the risk of ovarian cancer
- Surgery
  - Bilateral mastectomy
  - Bilateral salpingo-oophorectomy

NEGATIVE RESULT

This result could mean that the patient has not inherited the mutation, which puts her in the same category as the general population; therefore, it can be helpful to have a family member tested.[iii]

iii. American College of Obstetricians and Gynecologists (ACOG). Patient Education Fact Sheet. PFS007: BRCA1 and BRCA2 Mutations. October 2017. Available at: ***acog.org/Patients/FAQs/BRCA1-and-BRCA2-Mutations*** (accessed 7/13/18)

Failure to Review Pathology Report Thoroughly

The following case illustrates the consequences of not reviewing information thoroughly.

CASE TWO

Allegation: Delayed diagnosis of breast cancer resulted in diminished prognosis.

A 35-year-old female presented to a family practice physician to establish care. The physician ordered a routine screening mammogram, which identified calcifications. The physician ordered a magnified mammogram, which was classified as BI-RADS IV. He then ordered a stereotactic biopsy. The introductory section of the pathology report indicated no evidence of invasive carcinoma, which led to the physician documenting a negative result in the patient's chart. He discussed the result with the patient and recommended a mammogram in one year. Further in the report, the pathologist had actually noted the presence of ductal carcinoma in situ with lobular extension and high-grade comedo type, and recommended that the patient obtain a surgical consult.

The patient saw her family physician several more times for various issues over the next few months. One year after the patient's last appointment with the family physician, she discovered a lump by self-exam. She made an appointment with a plastic surgeon because he had performed a breast augmentation for her some years earlier, and she wondered if the lump might be related to that procedure. The surgeon referred her for testing, which revealed an aggressive tumor with metastasis into the patient's lymph nodes. The patient underwent a bilateral mastectomy.

DISCUSSION

Experts could not support the family physician's failure to review the entire pathology report; had he done so, the patient may have stayed ahead of the cancer, undergoing lumpectomy and adjuvant chemotherapy.

RISK MANAGEMENT **RECOMMENDATIONS**

- Review reports completely, as relevant findings and recommendations may be contained further within the report.
- Contact pathologists or radiologists when impressions or recommendations are ambiguous.
- Evaluate discordant findings (such as a BI-RADS IV mammogram and a negative biopsy) further until diagnostic concordance is achieved.
- When analyzing discordant findings, consider patient breast cancer risk factors.

Examination and Work-Up

Patient History and Physical

Ward and Green (2016)[5] recommend implementing a checklist to capture patient reports of breast symptoms. The authors present the following types of patient breast findings/symptoms in their checklist:

- Lump
- Nipple discharge
- Inverted nipple
- Skin retraction
- Rash, itching
- Changes in appearance
- Pain
- Previous breast surgery

For each of the findings listed above, the physician documents the location (e.g., right or left breast; under arm) and description (e.g., for nipple discharge: clear/bloody/cloudy), as well as the date.

If a patient has focal breast pain (i.e., she can point to it with her finger), the physician accurately describes the pain location by breast side, position (clock face) and distance from the nipple in the diagnostic mammogram order.

Clinical Breast Examinations (CBEs)

Provenchar *et al*[8] studied breast cancers that were diagnosed between 1999 and 2010 and concluded that "a significant number of cancers would have been missed" without a CBE:

- 39% of breast cancers were detected by mammography alone
- 54.8% of breast cancers were detected by mammogram and CBE
- 8.7% of breast cancers were detected by CBE alone

The cancers detected with CBE had more aggressive features compared with those found by mammogram alone. This suggests that a combination of screening methods may yield more useful information to aid in diagnosis and decision making.

Features of abnormal CBEs included:

- Presence of a mass
- Nipple discharge
- Skin or nipple retraction
- Edema
- Erythema
- Pitted or dimpled appearance
- Ulcers

RISK MANAGEMENT **RECOMMENDATIONS**[5,9]

- Ensure that you are performing thorough exams (e.g., from different patient positions), addressing such features as:
  - Asymmetry
  - Tenderness
  - Nodules
  - Skin dimpling
  - Edema
  - Discoloration
  - Nipple discharge
  - Nipple retraction
  - Palpable nodes and lumps
- Take patient risk factors into account during your exam.
- Document accurately. Rather than making a vague statement such as, "breasts normal," use clear, descriptive, precise language to document clinical breast exam findings. For example:

PALPABLE LYMPH NODE – NOTE:

- Location
- Size (cm)
- Texture (e.g., soft, rubbery, hard)
- Mobility
- Tenderness

PALPABLE BREAST LUMP – NOTE:

- Location (quadrant/subareolar)
- Size (cm)
- Mobility
- Texture (e.g., soft, hard, smooth, irregular)
- Associated skin changes

From a risk management perspective, this kind of documentation demonstrates attention to detail that not only furthers patient care, but can aid in the defense of a malpractice action.

Communication Problems between Healthcare Providers

Reliance on another clinician to accomplish follow-up, particularly when a malignancy is suspected or diagnosed, is risky for any physician involved in the diagnostic process, and dangerous for the patient.

CASE THREE

Allegation: Delay in diagnosing breast cancer resulted in advanced-stage cancer, bilateral mastectomies and increased risk of harm.

A 40-year-old female was referred by her primary care physician to a general surgeon following discovery of a lump under her left armpit. The surgeon palpated a 3x4 cm mobile left axillary mass. The patient reported a family history of breast cancer (maternal aunt). The surgeon did not ask the patient when she had last undergone a breast exam or mammogram, nor did he perform a bilateral breast exam. The surgeon performed a core needle biopsy, which showed fat necrosis and no malignancy. The surgeon told the patient she did not need to have the mass removed unless she wanted to do so. The patient felt reassured and chose not to undergo an excision. The surgeon recommended that the patient return if the size of the mass increased.

One month later, the patient presented to her gynecologist for an annual exam. The gynecologist noted a normal breast examination, with no mass or nodes palpated. The patient told the gynecologist that she was under the care of a surgeon for the axillary lump, so the gynecologist did not pursue it. The gynecologist recommended that the patient obtain a screening mammogram; however, she did not indicate a timeframe for obtaining it, only that the patient should obtain it before her next annual appointment. The patient did not follow up with the mammogram. Ten months later, the patient felt the axillary mass was larger. She was diagnosed with metastatic breast cancer and underwent bilateral mastectomy, radiation and chemotherapy.

DISCUSSION

Experts who reviewed this case thought that the surgeon should have had more of a follow-up plan after the biopsy. The aggressiveness of the cancer at the time of diagnosis the following year indicated that it was likely present when the patient saw the surgeon. Reviewers were also critical of the gynecologist for: not documenting that the surgeon had evaluated the patient's axillary lump; documenting "normal breast" when it was not normal; not appreciating the patient's family history; ordering a screening, rather than a diagnostic, mammogram; and not making a connection between the presence of the axillary lump and the potential for imaging to yield additional information, which may have prompted the gynecologist to emphasize to the patient that she should have the mammogram sooner rather than later. Other weaknesses included lack of communication between the physicians (gynecologist, surgeon, and referring primary care physician) and review of the patient's medical records, particularly when all three physicians used the same electronic health record system.

RISK MANAGEMENT **RECOMMENDATIONS**

- Evaluate the degree of patient monitoring needed following a benign biopsy. Options might include:[10]
  - Ordering an initial mammogram (or ultrasound) and conducting an initial CBE as a baseline
  - Having the patient return in six months for a mammogram (or ultrasound) and a CBE
- Confirm and document which physician on the healthcare team will manage follow-up.
  - Clarify the roles and responsibilities of all members of the patient's breast health team and document this information in the chart.
    - Coordinate with other clinician offices to ensure receipt of test results and documentation of consultations.
    - Do not delegate breast health responsibility to a different clinician unless the arrangement has been specifically discussed and documented.
- When there is doubt about a patient management situation, pick up the telephone and speak with other physicians involved in the patient's care, then reiterate this information with the patient.
- Review information in the patient's chart, including other physicians' records, to better evaluate patient health and make prudent and appropriate decisions.
- Document all patient complaints relative to breast health.
- Rather than documenting with a vague statement such as "breasts normal," use clear, descriptive, precise language to document clinical breast exam findings.

Follow-Up

Physicians have a duty to follow up with their patients and other healthcare providers in order to coordinate and maintain medically indicated care. It is a fundamental responsibility in the practice of medicine.

Failure to follow up is a common associated issue in diagnostic error claims, such as those having to do with breast cancer. The case examples in this article show how failure to follow up typically manifests:

- Inadequate communication and follow-up with patients
- Poor communication and follow-up between healthcare professionals
- Problems with documentation and test result handling

RISK MANAGEMENT **RECOMMENDATIONS**

Prioritizing follow-up in your medical practice can help you provide more effective and safer patient care, while minimizing the kind of harm that often results in professional liability claims.

- Establish office policies and procedures for tracking, follow-up and referral. These include systems to ensure the following:
  - All ordered tests and reports are completed and results are returned to the office in a timely manner.
  - All results are reviewed by the clinician and authenticated prior to being filed in the medical record.
  - Patients are notified of all test results and notification is documented in the medical record.
  - Create a process for communicating critical test results when the ordering physician is not available in the timeframe indicated.
- Review office policies and procedures to ensure that information is being transferred between patient and physician, between physician and physician, and within the office in a format that is consistent, clear and organized.
- Document when and what information was relayed to the patient (include date, time and the person charting).
- Create and document a follow-up plan for results of concern.

CONCLUSION

Breast cancer is a public health issue, which means that patients have a heightened awareness of it and corresponding expectations of their healthcare providers. The availability of genetic testing and varying guidelines for breast cancer screening require physicians to maintain a high level of knowledge and to stay current as developments change. Clinicians also encounter a great amount of data in electronic health records; the challenge lies in accessing and evaluating that information effectively in order to manage patient care appropriately.

Incorporating risk management practices into clinical management can enhance patient care and protect physicians from allegations of negligence. Clear communication with patients and other healthcare professionals, thorough and patient-specific documentation and solid follow-up systems are key areas to consider. In managing breast health, physicians should exercise vigilance in the areas of history, exam and work-up: implement a system that utilizes standardized breast health assessments, including a comprehensive breast health history, a clinical breast exam, and standardized algorithms for the work-up and follow-up of any new breast finding.

Special thanks to Jane Mock, Risk Management Specialist, for authoring this article.

ENDNOTES

The NORCAL documents referenced in this article, along with many other Risk Management Resource documents and past editions of the *Claims Rx*, are available in the Risk Solutions area of MyACCOUNT, or by policyholder request at 855.882.3412.

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