



HEALTHCARE

RISK MANAGER

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Correcting Errors in the Electronic Medical Record

By: Georgette Samaritan, RN, Senior Risk Management Consultant

Despite all of the benefits that electronic health records (EHR) offer, there remain opportunities for incorrect data entry due to problems with system design and or user error. Errors caused by system problems (e.g., a confusing screen design, etc.) can be prevented by working with your vendor to reset user preferences as needed. In order to preserve data quality and protect patient safety, it is essential to set an office policy to funnel all errors to necessary staff and physicians in a timely manner. The case study below illustrates why establishing a sound system is very important.

Suppose that a physician orders a pregnancy test on a patient before administering a variety of drugs known to cause birth defects in the fetus. An incorrect result is recorded in the patient's record, but subsequently discovered. The patient might well have begun treatment prior to the correction of the lab report. In such a situation, it would be important to the physician to be able to prove that the initial (incorrect) report on which he relied, existed. It is also important that a corrected report be brought to the immediate attention of the physician.

In the case of electronic records, the problem is that the correction of the lab report may potentially eliminate information that the physician relied on for a period of time. Also, the correction might be made without the physician ever being aware

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Prostate Cancer Screening: Reducing Professional Liability Exposure

By: Georgette Samaritan, RN, Senior Risk Management Consultant

According to the American Cancer Society, prostate cancer is the most common type of cancer found in American men except for skin cancer. The ACS estimates that over 232,000 new cases of prostate cancer will be diagnosed this year in the United States, and more than 30,000 men will die of this disease. One man in 5 will be diagnosed with prostate cancer during his lifetime. But only 1 in 33 will die of this disease. Major risk factors are age, family history, race, and possibly dietary fat.¹

In an analysis of claims involving allegations of the failure to diagnose prostate cancer, the Physician Insurers Association of America (PIAA) identified the three medical specialties most often involved in a claim. Of 162 study cases, urologists were named in 65, or approximately 40 percent of cases. General and family practice physicians were named in 42, or approximately 26 percent of cases, and internists were among the named defendants in 36 or 22 percent of cases.² (Table 1)

The PIAA data reflect the respective levels of involvement of the primary physicians as well as urologists in the diagnosis of prostate cancer. In a 2004 report of urologists and medical malpractice claims, the PIAA reported that diagnostic error was the most common medical misadventure in claims when the patient expired (24.5%). The most common patient condition was prostate cancer which made up 22.7% of closed claims when the patient died. More than 31% of these claims resulted in indemnity payments totaling over \$3.9 million.³

Table 1

1995 PIAA STUDY: Prostate Cancer Claim Defendants (n=162)

Defendants	Number	Percentage
*Urologists	65	40%
GP/FP	42	26%
Internists	36	22%
Other	9	12%

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Common Factors Identified in Prostate Cancer Claims

1. Failure to follow up after an abnormal prostate-specific antigen (PSA) results
2. Failure to notify the patient of an elevated PSA test
3. Failure to perform a digital rectal exam (DRE)
4. Failure to order a PSA test

Early Detection

Currently measurement of PSA is the most sensitive noninvasive test available for early detection of prostate cancer, and its use may lead to earlier diagnosis of aggressive disease. The shifts in age at diagnosis and in the stage of cancer detected, the changing pattern of prostate cancer incidence, and mortality are perhaps early signs of the success of PSA screening, although alternate explanations do exist.

Combining the use of PSA with DRE increases the early-detection rate in asymptomatic individuals. Indirect measures such as a higher survival rate for patients with early-stage disease, types of tumors detected by PSA more likely to be early-stage disease, or PSA-detected tumors that seem to have features associated with increased risk for progression, suggest a possible benefit to PSA screening. Evidence suggests that most cases of prostate cancer that are being detected with current methods are not fatal. However, the decline in the incidence of distant-stage disease suggests that use of PSA testing may lead to a sustained decline in prostate cancer mortality.

On an individual basis, testing offers an uncertain hope. Some individuals who undergo screening with DRE and PSA

will likely benefit; others will not, and still others may experience harm. The relatively long doubling time (on average) of early prostate cancer of 3 to 4 years or more indicates a relatively good prognosis for many men with this cancer, even without early detection and treatment. The old notion that “any PSA value under 4.0 is normal” is still prevalent among patients and unfortunately many practitioners. The following table documents the American Urological Association’s (AUA) Best Practices Policy on PSA Testing.

Table 2

American Urological Association (AUA) Best Practice Policy on PSA Testing.

Age Range	Asian	Caucasian	African-American
40-49	0-2.0 ng/mL	0-2.5 ng/mL	0-2.0 ng/mL
50-59	0-3.0 ng/mL	0-3.5 ng/mL	0-4.0 ng/mL
60-69	0-4.0 ng/mL	0-4.5 ng/mL	0-4.5 ng/mL
70-79	0-5.0 ng/mL	0-6.5 ng/mL	0-5.5 ng/mL

Men who have baseline values above these numbers should be referred to a Urologist immediately

Guidelines on Prostate Cancer Screening

Although no consensus regarding screening exists, the medical literature suggests certain measures the practitioner can follow to best deal with a request for screening, and to reduce the potential for liability. The current conflicting recommendations reflect “differences in the level of evidence required to make a positive recommendation rather than different interpretations of the results of existing studies.”⁴ (Table 3)

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*Note that this CME activity requires review of both the newsletter article and screening algorithms in order to complete the posttest.

Table 3. Current Guidelines on Prostate Cancer Screening

Organization	Year	Guideline
Canadian Task Force on the Periodic Health Examination	1994	Recommends excluding PSA as a routine screening measure based on poor predictive value and uncertain balance of harms and benefits.
US Preventive Services Task Force	1995	Routine screening for prostate cancer with DRE, serum tumor markers or transrectal ultrasound is not recommended.
American Cancer Society	1997	Both prostate-specific antigen (PSA) and digital rectal examination (DRE) should be offered annually, beginning at age 50 years, to men who have at least a 10-year life expectancy and to younger men who are at high risk.
American Urological Association	1997	Both PSA and DRE should be offered annually, beginning at age 50 years, to men who have at least a 10-year life expectancy, and to younger men who are at high risk.
American College of Radiology	1997	Both PSA and DRE should be offered annually, beginning at age 50 years, to men who have at least a 10-year life expectancy and to younger men who are at high risk. Information should be provided to patients regarding potential risks and benefits.
American College of Physicians	1997	Rather than screening all men for prostate cancer as a matter of routine, physicians should describe the potential benefits and known harms of screening, diagnosis, and treatment; listen to the patient's concerns; and then individualize the decision to screen. The College strongly recommends that physicians help enroll eligible men in ongoing clinical studies.
American College of Preventive Medicine	1998	Recommends against routine population screening with DRE and PSA. Men aged 50 or older with a life expectancy of greater than 10 years should be given information about the potential benefits and harms of screening and limits of current evidence and should be allowed to make their own choice about screening, in consultation with their physician, based on personal preferences.
National Cancer Control Network	2006	All men in high risk groups (men with a family history of prostate cancer and African-American men) should receive a full prostate examination (PSA & DRE) annually beginning at age 40. By age 50, all men are considered high risk and should be receiving a full prostate examination annually.

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Informed Consent

Which are better: general or procedure-specific forms?

While both the general and procedure-specific consent forms are useful, a procedure-specific form is better when the proposed treatment or procedure is more complex. A properly developed, patient-signed consent form is compelling evidence that a patient was adequately informed before a medical procedure. Evidence reveals it also helps patients make smarter decisions about their healthcare—prompting less anxiety and fewer days in the hospital. Patients also seem to acquiesce with post-procedural treatment, requiring fewer analgesics, prompting quicker recuperation.

What Men Need to Know in Order Make an Informed Decision about Prostate Cancer Screening

Lack of proof of net benefits from early detection with DRE and PSA and the potential for serious attendant harm mandate a higher level of informed consent than exists for most “simple” diagnostic tests. Concepts that must be explored with the patient include: 1) the long-term ramifications of screening; 2) the relatively high probability of further evaluation and biopsy with positive results; 3) potentially difficult decisions that may

arise about using treatments with a high morbidity rate and uncertain benefits (at this time) if cancer is discovered; and 4) no age is specified for stopping the test, although a ten-year life expectancy of the person in question is sometimes cited as an end point. Physicians should be aware of the uncertainties in the key variables that influence early detection decisions and the tradeoff of potential benefits for known risks before they and their patients make a screening decision.

Table 4. Current Recommendations – Informed Consent for Prostate Screening

Organization	Year	Recommendation
American College of Physicians	1997	The physician should describe the potential benefits and known harms of prostate screening, listen to the patient’s concerns, and then individualize the decision to screen.
American College of Preventive Medicine	1998	Further research should be conducted in optimizing the process of patient education and informed consent.
American Urological Association	2000	The decision to use prostate-specific antigen (PSA) testing for the early detection of prostate cancer should be individualized. Patients should be informed of the know risks and the potential benefits.
American Cancer Society	2001	Prior to testing, men should have an opportunity to learn about the benefits and limitations of testing for early prostate cancer detection and treatment.
US Preventive Services Task Force	2002	Clinicians should not order the PSA test without first discussing with the patient the potential benefits.
National Cancer Control Network	2006	NCCN publishes a Resource Kit For Making Prostate Cancer Decisions (costs \$18.95 from UsToo! International) http://www.pccnc.org/patient_resources/

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Ask A Risk Manager

How do we respond to medical records requests from the Coroner?

Coroners or medical examiners often have the responsibility to investigate a person’s death, thus, such investigations may require a person’s medical records. HIPAA specifically provides an exception to patient authorization and permits a physician to provide such information at the coroner’s request. Similarly, many states allow physicians to provide such records to a coroner, although some states only permit such disclosures under a subpoena. Check with your state’s privacy laws before releasing patient information to coroners or medical examiners.

Detailed Policy to Correct Errors in Electronic Medical Records Essential *(continued from page one)*

that a reporting error was made. State laws vary on how medical records can be amended. Generally the law frowns on erasing relevant information so that it cannot be recovered. That's why opaque correction fluid should not be used in correcting paper records, and why incorrect entries in the written medical record be lined out and rewritten rather than obscured.

The possibility exists that over-writing the initial EHR, even though the information is incorrect, could be construed as improper alteration of the historical medical record. In general, states merely require that electronic records be maintained "to the same standards" as paper copies. Also, the amended EHR should be flagged to indicate that it has been corrected, and some mechanism be put in place to retain and easily access copies of the original, if incorrect, data. A comment field in the amended report may suffice. In general, a narrative entry in the medical record statement indicating that an error has been made, and is being corrected, is the best procedure. When a lab or diagnostic report is involved, the facility director or pathologist should assume the responsibility for insuring that such an entry is made. Both the original error and the correction should be well documented for future reference.

Personal contact between the laboratory/diagnostic facility and the involved physician is always desirable, and should occur whenever an erroneous report must be corrected. Keep in mind that the report may be critical and time may be of the essence. Most importantly, whenever an error in lab/diagnostic test reporting is made, it is essential for the laboratory/facility to retrace the handling of the specimens, films etc., and determine how erroneous results were released. The facility should then institute appropriate policy and procedure changes to prevent recurrence of such errors.

In summary, correcting errors in EHR systems should follow the same basic principles as correcting paper copies. These specific considerations apply:

- Work with your vendor to confirm that your EHR system allows error correction and whether or not the vendor has established a process.
- The system must have the ability to track corrections or changes once the original entry has been entered or authenticated.
- When correcting or making a change to an entry, the original entry should be viewable, the current date and time should be entered, the person making the change should be identified, and the reason should be noted.
- In situations where there is a hard copy printed from the electronic record, the hard copy must also be corrected.
- The process should permit the author of the error to identify, and time/date stamp, whether it is an error.
- The process should offer the ability to suppress viewing of the actual error but ensure that a flag exists to notify other users of the newly corrected error.
- The location of the error should also point to a correction. The correction may be in a different location from the error if there is narrative data entered, but there must be a mechanism to reflect the correction.
- Develop a practice policy to ensure that your facility corrects and reports errors in a consistent and timely manner.

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Prostate Cancer Closed Claim

A 55-year old man was seen by his internist for a routine physical. During the exam, the physician performed a digital rectal exam and made a note that the exam was normal. Blood work was ordered, including a PSA. The patient received a letter from the internist indicating that all of his blood work was within normal limits. The PSA result was above 8.0, but was not reviewed by the physician or reported to the patient. Two years later at the patient's scheduled physical exam, blood work showed an elevated PSA at 18.0. A subsequent needle biopsy was positive for adenocarcinoma. The patient filed suit against the physician for delay in diagnosis. The suit was settled in a high range.

Comments:

The patient's PSA results were not included in the letter because the results had not yet been received by the physician's office at the time the letter was sent to the patient. The patient was not specifically informed that the PSA test result was still pending when he received the results of the other test. The outside laboratory used in this case did not have a protocol to notify the ordering physician of significantly abnormal test results. A failure in the office system to track and review all ordered tests resulted in the PSA test result being overlooked.

Summary

Until there is reliable scientific evidence against screening, a practitioner must decide to screen or to document in detail why he or she did not perform a DRE and PSA. It may be more expedient in many instances to simply order the test than to counsel the patient in detail, and carefully document the reason for the decision whether or not to test. Nonetheless, the better practice is to exercise good judgment, engage in full patient

communication, and carefully advise the patient on the implications of such tests. Although there are diverse recommendations and factors to be considered, it is usually prudent to perform a DRE and PSA in patients falling within the recommended guidelines and provide individualized procedure-specific informed consent.

Other Risk Management Strategies to Reduce Prostate Cancer Claims Include:

1. Follow and individualize established prostate screening guidelines.
2. Discuss the risks and benefits of a routine PSA test with the patient and include the patient in the decision making process.
3. Document this discussion in the medical record and any informed refusals.
4. Develop a tracking system for all ordered PSA tests.
5. Significantly elevated PSA test results should be reported directly by the lab to the physician's office and to the patient.

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¹ Pienta KJ, Esper PS, Risk Factors for Prostate Cancer. *Ann Intern Med.* 1993;118:793-803

² PIAA Data-Sharing Reports 1995

³ PIAA Data-Sharing Reports, Urologic Surgery, 2004

⁴ Coley CM, Barry MJ, Fleming C, Mulley AG. Early detection of prostate cancer. I. Prior probability and effectiveness of tests. *Ann Intern Med.* 1997;126: 394-406

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