

Failure to Track and Follow Up on Abnormal Test Results Leads to More Extensive Surgery

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Introduction

A critical function in any physician practice is to promptly follow up on abnormal test results. Failure to do so can result in dire consequences for the patient and greatly increase professional liability exposure for the doctor. This interesting case from the Southeast illustrates what can happen when the follow-up system fails.

Facts

The patient was a 42-year-old female with a history of HPV, infertility, yeast infections, and abnormal Pap smears. She presented to her OB/GYN's clinic for a routine Pap smear. It had been a little more than 2 years since her last Pap smear, which had been negative. The tissue sample was taken and, for reasons not known, was sent out to a private diagnostic laboratory, rather than the hospital laboratory (as was the normal practice). The laboratory returned findings of endocervical adenocarcinoma in situ.

Dr. A reviewed the test results and entered the findings into the electronic health record (EHR). He then gave the results to a nurse and instructed her to contact the patient to arrange an appointment as soon as possible. Unfortunately, no one from the clinic contacted the patient about the abnormal results.

The patient returned to the clinic for her routine checkup 2 years later, and it was discovered that no one had followed up on the previous abnormal results. A thorough examination was done at that time, including a colposcopy.

The results from the colposcopy indicated endocervical adenocarcinoma in situ, and a prompt referral was made to Dr. B, a GYN-oncologist. A CT of the patient's pelvis and abdomen indicated a cervical mass extending from her upper vagina to the lower uterine segment, as well as a cyst on her liver (which turned out to be benign).

Because of the extent of the cancer, Dr. B promptly performed a robotic radical hysterectomy, bilateral salpingo-oophorectomy, complete pelvic node dissection, and low para-aortic lymph node sampling (this was one of Dr. B's first uses of the robot for this procedure). The final staging of the adenocarcinoma was T1B2, NO, MX.

Initially, the patient did well following surgery; however, she later developed complications, including bilateral pulmonary emboli and pleural effusions, abdominal infection and ileus, and a large abdominal hematoma. Multiple hospital admissions followed (including some to the ICU) before she fully recovered. Fortunately, she did fully recover, and has had no recurrence of the cancer.

The patient filed a medical malpractice lawsuit against Dr. A and his clinic only. The case was settled by a payment to the patient in the midrange, with defense costs also in the midrange.

Discussion

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Dr. James Reason, a psychologist and human factors researcher, has studied the healthcare delivery process for many years. He is the architect of Failure Mode and Effects Analysis, an analytical approach that reframes the question “What happens *if* someone makes a mistake?”

to “What happens *when* someone makes a mistake?” Some of Dr. Reason's conclusions regarding healthcare delivery (as well as similar systems) include:

- Humans are inherently flawed and can be expected to make mistakes.
- The more complex a process, the more opportunities there are for human error to interfere with the correct functioning of the process.
- Processes can be designed to minimize the potential for inevitable human error that may cause harm.
- Processes designed to minimize error are most effective when they are used consistently (i.e., variation from the normal process increases the risk of error).

The value of these principles is clear when we apply them to the particular facts of this case. The first risk issue relates to how the initial tissue sample was handled. The clinic's normal process was to send all specimens to the local hospital for analysis.

The local hospital had implemented two very beneficial safety procedures to minimize the risk of tests “falling through the cracks.” The first safeguard was a “check-back” system. After notifying a physician of an abnormal test result, the hospital would follow up with the physician within a given timeframe (such as 30 days) if no further specimens from that particular patient were received.

The second safety procedure was a quarterly report to the physician, which listed all of the abnormal results that had been reported to him or her in the preceding quarter. This would give the physician an opportunity to check the report against the patient record to verify that appropriate action had been taken in each case.

Unfortunately, in this case, the clinic's normal procedure was not followed, and the patient's specimen was sent to an outside laboratory that did not use similar safety procedures.

Further, the clinic missed another important opportunity by not utilizing the patient as part of the follow-up process. Although a typical practice may handle thousands of specimens per month, a patient rarely has more than one or two test results pending. The practice can easily tell a patient "We will contact you within 2 weeks with the results of your test. If, by chance, you do not hear from us by then, please call us and inquire about your results." By using this approach, rather than the "no news is good news" approach, the practice adds an additional level of scrutiny and redundancy to the reporting process.

Another important issue is the "learning curve" associated with the use of new equipment of any sort. In this case, Dr. A's clinic had just transitioned to an EHR system, and Dr. A was still adjusting to it. Experience has shown that the period of transition to an EHR system is a

time of significantly elevated risk for the loss of information, failure to follow up, etc. Exercising special caution during this transitional time is very important.

The learning curve also applies to equipment used in the actual treatment of patients. There was some thought that Dr. B's limited experience with robotic surgery may have contributed to some of the patient's complications following surgery. Further, complications may have been avoided if a simple, rather than a radical, hysterectomy had been performed. (Radical hysterectomies have a greater risk of complications than simple hysterectomies.) However, because a simple hysterectomy would have been indicated if the diagnosis had been made on the earlier date, any problems with the eventual surgery could not be used in the defense of this case.

Summary Suggestions

The following suggestions may be helpful to physicians wishing to minimize failures in tracking tests, following up with patients, or adjusting to new equipment:

- Whenever variation occurs in normal test-tracking procedures, special attention should be given to ensure that test results are properly received and communicated to patients.
- Practices should include patients in the tracking process by asking them to follow up if they do not receive their test results within a specified timeframe.

- Any transition in record-keeping systems, especially from a paper-based system to an EHR, should be recognized as a time of increased vulnerability to error.
- Increased vulnerability also occurs during the implementation of new equipment for treatment. Physicians using new equipment should exercise exceptional caution, both during treatment and during posttreatment follow-up.

Conclusion

To err is human. Systems that take into account the potential for human error and are specifically designed to minimize this potential can maximize the safe delivery of patient care and reduce professional liability exposure.

Physician Perspective

*The Medical Protective Obstetrics/
Gynecology Advisory Board*

As the practice of medicine continues to evolve on many fronts, it is incumbent on physicians to be vigilant in identifying circumstances in which error is possible, and to use special caution in those circumstances. Implementation of, and rigid adherence to, established protocols will help physicians and their staffs avoid procedural errors. Similarly, careful attention to all details of performance will be beneficial when acclimating to new equipment of any type.

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