

Confirmatory testing reduces risk

Q We recently had a physician tell us that we need to do a confirmatory culture on all negative rapid strep tests. Do we put the lab at risk if we do not?

A The risk here is more likely to fall on the physician who chooses not to follow up the screening test by ordering a culture. The example, however, is a good one for examining the need for second-level confirmatory testing in the lab setting, because the principles are the same.

From a risk-management standpoint, determining whether to do a second-level test when a screening test is negative hinges primarily on two points: 1) the sensitivity and specificity of the screening test (and the confirmatory test) and 2) the seriousness of a false positive. Develop a policy with these points in mind.

The effectiveness of a screening test in sorting out positive results from negative results is critical. Some screening tests have a high incidence of false positives, making them less useful for initiating treatment, especially if the treatment is expensive or potentially toxic. The incidence of false-positive results in HIV testing, for example, has been an issue since the earliest tests were designed and, for some methods such as the oral rapid-screening test, remains an issue. The higher the incidence of false positives, the greater the need for confirmatory testing before instituting treatment.

Similarly, the ability of a test to definitively *rule out* a diagnosis becomes important when the risk of failing to make a diagnosis is greater. Troponin testing, for example, has proven valuable because its false-negative rate is low. Fewer than 1.5% of patients with a negative troponin go on to have a myocardial infarction within 30 days of testing — a pretty good track record. When determining policy about follow-up testing, performing an assessment of a screening test as part of the overall risk analysis is an important step.

The ultimate danger to the patient of a false result is also essential to the risk assessment. Often, a rare result is dismissed from consideration because it *is* rare. If the result is devastating, however, the balance of risks changes. Remember the Challenger explosion? Physicist Richard Feynman pointed out in the hearings that the risks of O-ring deformity were dismissed because they were rare — but the results were catastrophic. Rare does not mean insignificant.

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A problem arises when a variance exists between the standards advocated by experts and those actually followed in the community. There may be good reasons for deviating from the recommendations of a professional body, but there are also legal risks. An institution that deviates from the published standard gives an attorney a foothold in filing suits and makes it easier for him to find an expert in support of a lawsuit.

Part of the decision-making process is to balance all the risks, including the risks to patients, individually and as a group, of failing to follow up with a confirmatory test. In the case of strep testing, rheumatic fever may be rare, but its incidence is 100% for the patient who experiences it. Rheumatic fever is a serious medical problem and is the sort of complication that is likely to give rise to a lawsuit. Once that happens, the “battle of experts” will actually end up determining what standard actually applies.

The issue of performing follow-up tests came up in a lawsuit against a family practitioner who did not order a confirmatory culture on a child with a negative strep test. The child later developed rheu-

matic fever, and his family sued the doctor — but lost. The physician’s medical expert, Paul Fischer, MD, wrote an article about the experience and gave a convincing medical argument for *not* performing a confirmatory culture in these circumstances. The article, “Defending the Real Standard of Care,” can be found in *Family Practice Management*; 2008;15(2):48 or online through Medscape.

Making an argument about the sensitivity of tests, the costs and risks of antibiotics, the relative difficulty and unreliability of cultures themselves, and the community standard of practice carried the day in Dr. Fischer’s case, but the outcome is never guaranteed when a jury is involved. Some institutions put more weight on avoiding the potential for litigation when weighing the costs and risks of not doing additional testing. The costs to the institution of doing additional tests to back up a false-negative test may not be much greater than the costs of a single lawsuit, even if the institution prevails in court.

If your practice is to vary from published expert standards, do your homework and make a clear, detailed case for why the standard is not applicable to your particular situation. Document a basis for developing a more reasonable policy for your institution. Regularly assess the policies to make certain they take into account changes in recommended practices and available technology. Sound decisions based on good science and good sense can keep the case out of court or be the basis for a winning argument if it does go to court. □



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