Make no mistake — PT referral not allowed

Anne Ford

October 2015—No one *plans* to screw up.Take the worker carrying out maintenance duties at a Damascus, Ark., U.S. Air Force base one evening in 1980. Surely the only thing on his mind was doing a decent job and going home.

Unfortunately, his good intentions didn't prevent him from accidentally dropping a socket from a socket wrench. Or the socket from falling 80 feet onto a missile tipped with a nuclear warhead, piercing its fuel tank. Or the fuel from exploding. Or the entire launch complex from being destroyed. Or one person dying and 21 being injured.

Fortunately, few of us will ever be in a position to nearly eradicate Arkansas. But the point remains: Even completely innocent mistakes can have severe repercussions.

That's why Amy Daniels, MT(ASCP), senior manager of investigations for CAP accreditation programs, is determined to put an end to the problem of proficiency testing referrals. "These incidents of PT referral that are occurring—they're not caused by people trying to cheat," she says. "That is not at all what's driving this. What's driving it is misconceptions on how PT is handled within the laboratory. No one means to screw up. No one's trying to cause problems in the lab. These are honest, innocent mistakes. But they have serious consequences," such as laboratories being put on probation, Medicare payments being canceled, and CLIA certificates being revoked.

Daniels

Daniels says that laboratories have become better at identifying when PT referral has occurred. Then, too, the actual number of PT referral incidents is quite low. Says Beth Chmara, CT(ASCP), CAP technical director of proficiency testing: "The vast majority of our labs adhere to the CLIA recommendations and CLIA requirements, and we do not see this [PT referral] as being a pervasive issue. Overall, the CAP has observed extremely high compliance."

Still, Daniels and Chmara are frustrated that the number of PT referral incidents they see persists in remaining any more than zero. "I think laboratories are aware they're not supposed to do this," Daniels says. "But the problem is, it's still happening."

To go back to basics briefly: Per the Centers for Medicare and Medicaid Services and the CAP, laboratories are not permitted to communicate about proficiency testing samples with each other, refer PT samples to each other, or accept PT samples from each other. In Daniels' words, "A CLIA number is issued to a laboratory with a physical address, and all of the laboratory's proficiency testing has to be done within those four walls. Once PT leaves that CLIA number, then you've broken the rules."

This rule applies even if the main laboratory's CLIA number differs from the CLIA number of one or more point-of-care testing sites elsewhere in the institution, such as in the ER or ICU. "And if you decide, 'Well, I'm going to share my PT with them and have them do this one,' you can't do that. They have to order a PT under their own number, do their own testing, and report it. You can't bring their results to the main lab and report it for them because you're a different lab," Daniels says.

It’s not complicated, but it’s worth reviewing given that some laboratory directors, in Daniels’ experience, aren’t aware of how seriously they should be taking the possibility of a PT referral: “Maybe they’ve been a lab director for a long time and this has never happened in their laboratory before, so they’re just not aware this could happen and what the effect of it is.”

Dr. Sharkey

Why, despite potentially severe sanctions, does PT referral continue to happen? CAP Accreditation Committee member and Laboratory Accreditation Program state commissioner Francis E. Sharkey, MD, says that more often than not, a laboratory that mistakenly refers a PT specimen does so because it knows it is supposed to process PT samples in exactly the same way it processes patient samples, which entails sending at least part of its testing to another laboratory for further exam.
For example, “If a small stat lab gets a CBC, they may normally refer the visual differential to the main laboratory for review, or if they identify something atypical in the cells, they’ll refer it to the pathologist in the main laboratory for further review,” says Dr. Sharkey, a professor of pathology at the University of Texas Health Science Center at San Antonio.

But that’s no excuse, given how clearly the CAP’s prohibition against PT referral is worded. “It does say, ‘This prohibition takes precedence over the requirement that proficiency testing specimens be handled in the same way as patient specimens,’” Dr. Sharkey points out. “I think that’s pretty clear.”

For her part, Daniels speculates that staff turnover and the need for testing efficiency may be contributing factors. “Maybe someone at the lab hired someone new, and they didn’t realize they couldn’t do this [PT referral],” she says. “Or they trained people, but didn’t retrain them, so someone forgot. And laboratory testing happens quickly. Specimens are moving from place to place, and you want to report things in a timely way. Proficiency testing samples go through that same process, so the testing and the reporting occur quickly, and then you realize, ‘Oh, that was proficiency testing.’ And then you have a problem.”

If there’s a bright spot in all this, it’s that laboratories appear to have gotten better at recognizing when PT referral has occurred and reporting it to the CAP, she says. Unfortunately, sometimes the offending laboratory doesn’t recognize that PT referral has taken place until after it’s received the report from the other laboratory. “At that point, it’s too late,” she says. “And now two labs are involved in this—the lab that sent them something and the lab that reported something. At that point, both labs are problems, because one referred the result for interpretation and the other one interpreted it and sent out the report.”

Of course, sometimes the laboratory that receives the PT sample realizes it before testing takes place. “That’s a key step, to realize that if anything looks suspicious, like it might be proficiency testing, you need to stop the process, do a time-out, and figure out: ‘Is this a PT sample? Is this not a PT sample?’” Daniels says.

“Let’s say you receive a sample labeled ‘Marilyn Monroe,’ and you have no idea it has been relabeled, and it’s proficiency testing. You would be innocent,” she continues. “But if it’s labeled ‘CAP Survey D PT Specimen 1,’ it’s pretty obvious that’s a CAP proficiency testing sample, and if you accept it into your lab and do testing on it and then report, you’re guilty too.”

Once a laboratory realizes that PT referral has happened and alerted the CAP, a complaint investigation is opened. “There’s a lot of information we ask for, because we need to understand: Was this the first occurrence? Has this happened at all within the past two years, during their accreditation cycle? We ask for their proficiency testing

procedures, their policies. If it happened with a specific proficiency testing challenge, we will ask to see their worksheets for that challenge, what they reported to the College, how did they figure out what happened. We want to understand: How did this accident happen, and at what point in time did you realize it?"

Three of the PT-related incidents that have taken place within the past year may serve as warnings to other laboratories. The first represents the only instance of PT referral to date in which Daniels has seen evidence of deliberate cheating. "They took a PT sample, and someone in the laboratory took it upon themselves to put an identifier on the sample so it didn't look like proficiency testing. They sent it to another lab for testing, and then when they received those results, that's what they reported to the proficiency testing provider," she explains. "It just looked suspicious. I hate that that happened, but it did. And that laboratory did end up on probation."

The second outstanding instance of PT-related misconduct took place in a cytology laboratory and involved not referral but inappropriate consultation among cytotechnologists.

Dr. Henry

Michael Ross Henry, MD, a member of the CAP Checklists Committee and director of cytopathology at the Mayo Clinic, explains how gynecologic cytology PT should be performed: "The slides are sent to the laboratory, and if your laboratory uses cytotechnologists to screen, then the slides are screened by a cytotechnologist and their answers are recorded on an answer sheet. They're not allowed to ask any questions or get help with any of those slides from any individuals. Then the slides are also interpreted by the pathologists who sign out gyn cytology, and they get slides that have been screened by a cytotechnologist, and they have that cytotechnologist's answers. Again, the pathologist is not allowed to show those slides to anybody else; they just have that cytotechnologist's answers. And they're not allowed to share. And then you're not allowed to talk about any of the answers within the laboratory during the PT testing period."

A proctor oversees the process, and here's where the laboratory in question went wrong, says Daniels: "The person proctoring the test didn't follow the rules. Unfortunately, a lot of laboratories will assign the proctoring role to someone who is in more of an administrative support role within the laboratory, someone who understands how the laboratory works but who may not understand how important it is to follow all the rules for the proctoring. In retrospect, I wonder if they should have brought in, say, a supervisor from chemistry to do the proctoring, because that person would have understood proficiency testing.

"What happened in this event was, the proctor let people collaborate about their results, and that's what was submitted," she continues. "It's supposed to be an exercise completed independently by each person, and basically, it became a group project. The rules weren't followed. Someone complained to the College, and there were serious problems. CMS also investigated it. Several people aren't at that laboratory anymore, and there was a large fine, but it could have been worse. I mean, they didn't close the lab."

In Chmara's view, the error may have stemmed from the fact that "in practice, a pathologist and a cytotechnologist will often consult each other on a challenging case," she says. Still, "all the information that the CAP offers as guidance for labs, of which there's plenty, indicates that consulting on PT cases is breaking those requirements, which are set up by the government. All of our documentation strongly indicates you cannot discuss cases."

Daniels sees a clue in the fact that proctoring generally happens only annually. "The proctoring instructions aren't

excessively complicated, but you do it only once a year," she says. "And if, let's say, the proctor who's been doing it for 10 years in your laboratory has retired, and now you have someone new doing it, you really need to make sure that person understands all the rules and instructions, so they handle the PT appropriately."

The third instance, too, took place in a cytology laboratory. "Typically you have a cytology person who screens the slides, and they will mark suspicious-looking slides with a Sharpie marker, and that slide gets referred to a pathologist to take a look at," Daniels explains. "Well, a lot of times the pathologist won't screen that slide; the cytotech will screen it, and the pathologist will look at it. If both of those people are in the same building, that's fine."

You know what's coming next: "We had an event where a laboratory screened the slides at one location, and then they sent the slides to a secondary location to have the pathologist look at them, and you can't do that. You can't send marked slides from one location to another, and that's what this lab did, and that's not allowed."

That said, "CMS does allow for off-site courtesy screening, if approved by the CAP. Completing the alternative site courtesy screening form is required prior to off-site testing. If approved, the proctor from the main laboratory cleans the slide set between testing and secures the slide set for transport between labs. The main laboratory proctor and a randomly chosen cytotechnologist will travel to the alternative lab with the secured Pap PT material, where the cytotechnologist will perform a courtesy screen."

In their ongoing efforts to prevent inappropriate PT-related incidents, Daniels and Chmara are making slight changes in the wording of the CAP's instructions. For example, the PT-related requirements in the CAP's All Common checklist have been revised slightly. Daniels reports, "We tried to add clarifying text just so that people are aware of what you can't do and what you need to have procedures for. The goal is to try to figure out what the magic words are that we need to share with laboratories to get them to make sure that everyone in their lab really does understand the effect of referring a proficiency testing sample."

Chmara

Chmara is rearranging content within the proctoring kit instructions for cytology PT. "A lot of times, if people are really familiar with PT, they may not be as diligent with reviewing the kit instructions," she says. "So we're revising the language and calling attention to it. The new language will also speak to the civil money penalties that laboratories are susceptible to if they don't adhere to the regulations."

Those penalties are no longer as severe as they once were for laboratories that unknowingly or unintentionally refer PT specimens. "Once the CAP saw that some of these penalties were quite draconian and varied from one region to another, it got together with CMS and came to an agreement about at least grading the penalties according to intent and things of that nature," Dr. Sharkey says. "Previously, the penalties had been extremely severe, even for completely inadvertent referral or discussion of PT. They were over the top. And they were decidedly inconsistent from one CMS region to another, which also was not fair. I believe now there is greater consistency in this respect."

But, of course, that doesn't mean laboratories can relax their vigilance in this regard. Nor can Daniels. "CMS has made it a much improved process, and I think the laboratory community appreciates it," she says. "The problem is that the way the regulations are written, the laboratory gets a break the first time, but if it has an accident a second time, the regulations are not as favorable. We don't know what would happen with round two. We're going to see some of those eventually. And I'm afraid of what could happen to the facility."

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