

Cytology workload limits: For adequacy assessments, it's time, not slides

Valerie Neff Newitt

August 2018—The CAP and the Centers for Medicare and Medicaid Services reached an understanding earlier this year on how adequacy assessments and rapid on-site evaluations in cytology can be accounted for without causing undue impact on workload limits. The agreement, communicated to state survey agency directors in a March 16 CMS memorandum, is reflected in the updated CAP accreditation program cytopathology checklist released this month.

"I would not even call it a compromise, but rather an excellent conclusion to a situation that had become problematic," Diane Davis Davey, MD, a member of the CAP Cytopathology Committee and a professor of pathology at the University of Central Florida, Orlando, says of the agreement.



Dr. Davey

The problem arose in 2017 when the CMS, in its concern about manageable workloads for pathologists, said adequacy assessments and rapid on-site evaluations, or ROSE, must be counted toward the primary screening workload limit for each individual of 100 slides per 24 hours. (That limit is capped at 80 in California.)

"The stress associated with finding a few abnormal cells buried in a sea of normal cells on a Pap smear—the reason workloads were established in the first place—is quite different from assessing if there are adequate cells [for diagnosis] on a slide resulting from a fine needle aspiration. It is like comparing apples and oranges," Dr. Davey says.

Bharati Jhaveri, MD, chair of the CAP Council on Accreditation and past medical director of laboratory and staff pathologist at St. John's Hospital, Springfield, Ill., agrees the two procedures are entirely different. "Adequacy assessment has no diagnostic purpose. It is simply a way of telling whoever is doing the biopsy—pathologist, radiologist, ENT surgeon, interventional gastroenterologist, etc.—that, 'Yes, you have enough material,' or 'No, you need more.' It is a very rapid check to make sure material is retrieved from the correct area or lesion."



Dr. Jhaveri

The CAP's cytopathology checklist, prior to 2017, permitted adequacy assessments and ROSEs to be excluded from the total number of slides counted toward an individual's primary screening workload. But when the CMS insisted during its review of, and just before the release of, the CAP's 2017 accreditation program checklists that they must be counted, the language that excluded rapid assessments from the workload count had to be removed.

"Just imagine if all those slides had to be counted," Dr. Jhaveri says, adding that counting the quick checks toward a total count would leave individuals without enough workload balance to do primary screening. "We would not be able to do the rest of our work. After all, we do need time to screen Pap smears and all the rest," she says. "We could have faced a situation where we simply would have to stop doing the adequacy assessments. That would send health care backward to a time when patients faced multiple operations, multiple rounds of anesthesia, etc., just to get adequate biopsy tissue for a diagnosis. That is not an acceptable option." But there was insufficient time before the 2017 checklists were released, she says, to iron out the differences between the CAP and the CMS interpretations and opinions.

The result was "concern and confusion," says Harris S. Goodman, MD, vice chair of the CAP Checklists Committee and medical director of the clinical laboratory at Saint Francis Memorial Hospital, San Francisco. "CMS threw a monkey wrench into the works at the last minute. Some of our lab professionals were angry, thinking the CAP had not stood up for them. But that wasn't the case. Lack of time was the immediate problem."

The CMS originally missed the point that rapid assessments are exactly that, Dr. Goodman says. "We don't have the luxury of time when doing these evaluations. A patient may be under anesthesia while the operator is waiting to find out if more specimen is required. Furthermore, some tumors are very bloody and can generate a lot of slides—10, 20, or more. You may see blood, normal cells, or abnormal cells, but you don't take the time to characterize them."

Representatives from various CAP committees gathered evidence of their contention that some slides need not and should not be counted toward the primary screening workload. Evidentiary slides and statements were sent to the CMS, after which opinions and positions were exchanged over many months. "At first we couldn't come up with an agreement," Dr. Goodman says, "which is why we had to publish the 2017 checklists without the previous exception language. We had nothing to replace it with at the time, causing people to ask, 'Do we count these slides or don't we?' And we didn't really have an answer. But we had a breakthrough following the CAP's efforts to educate CMS about the difference between the rapid evaluations and primary screenings."

That breakthrough came in a phone call during which Dr. Jhaveri and Emily Volk, MD, MBA, vice chair of the CAP Council on Government and Professional Affairs, and other CAP representatives, explained to the CMS that requiring the rapid assessments to be counted toward workload totals would negatively affect patient care.

"Originally, CMS saw these as diagnostic procedures, and we educated them to the fact that they are not," Dr. Jhaveri says. She and the others explained the brevity of the assessments and their value to the patient. "We explained that in the past these biopsies were done as multiple surgical procedures and that the patients suffered through more surgery if additional material was needed. We explained that time was needed for true primary screening and stressed that we must not take medicine back to a time when patient access to care was less than it is today with the advent of fine needle aspirations."

After much discussion, Dr. Jhaveri says, a CMS representative said, "'We are suggesting that you do not count them [adequacy assessment and ROSE] as slides, but that you do count the time it takes to do them.' Since it is usually only a few minutes at most, it seemed fair, and it certainly is better than having people refuse to do assessments for fear of running out of workload allowance."

Dr. Volk, senior VP of clinical services, University Health System, San Antonio, agrees with the fairness of the outcome. "It maintains optimal patient care by having the adequacy determined rapidly and then proceeding with triage of the specimen to minimize anesthesia and the likelihood of complications."

The result of the new accord is found in the CAP's 2018 cytopathology checklist, in cytology workload requirement CYP.08500. New language clarifies that adequacy assessments and ROSEs will not be counted toward the total number of primary cytology screened slides allowed in a 24-hour period. The requirement reads: "For all screening personnel, adequacy assessment of fine needle aspiration (FNA) smears or rapid on-site evaluation (ROSE) is not considered primary cytology screening; however, the time spent performing adequacy assessments must be used to prorate the maximum number of slides the individual can screen in a 24-hour period."

Therefore, the time spent doing those quick assessments must be counted, recorded, and deducted from the total time in a day on which allowable slide count is computed. This will in turn result in a prorated number of allowable slides, found by using a simple formula: number of hours spent screening (minus the time for rapid assessments) × 100/8.

The new language prompts little change in laboratory behavior, in Dr. Goodman's view. "When I read it, I thought to myself, 'There's been no substantive change.' The new CYP.08500 also includes a comment that the number of slides seen in a 24-hour period should be 'reduced proportionately based on other duties performed.' To me, that line suggests that doing a rapid on-site evaluation is just an 'other duty,' like staining slides, cleaning the cytology lab, or prepping nongyn fluids." He sees the situation now as an acceptable one. "I know some people are saying, 'Now I need a spreadsheet for the number of hours spent doing ROSEs and other activities, in addition to screening slides.' But I suggest that people just include ROSE in 'other duties.' In my mind, that should meet the spirit and essence of the requirement."



Dr. Goodman

Although the new checklist is out this month, and electronic notifications of changes have been sent out on listservs, "Some people are probably not aware of the change in language yet," Dr. Davey says. "They need to be updated so they can determine the best, easiest, and most accurate way for them to remain in compliance with their workload monitoring."

Dr. Davey says members of the Cytopathology Committee, which includes cytopathologists in private practices, large commercial labs, academic settings, and the Veterans Affairs, discussed the new stipulation, "and everyone was very pleased. We actually had very little discussion after that because it was such a satisfactory conclusion. It makes sense, and it is fair." Cytopathologists want to be able to take care of patients and to look at the slides rapidly and carefully, she says. "We were very concerned that if we exceeded workload limits, we might not have been able to offer adequacy assessments, and for patient care that would not have been a satisfactory result. Instead, we have an excellent solution that reflects high-quality patient care."

Workload limits continue to be important, Dr. Davey says. "But it is just as important that we apply them to the proper specimens. Now we are all on the same page."□

Valerie Neff Newitt is a writer in Audubon, Pa.