88172 Is More Than Counting Cells

Ensuring the Quality of Immediate Assessment of Fine-Needle Aspiration Material

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Cytologic examination is highly complex requiring significant training and expertise as well as integration into the clinical presentation of the patient. Cytologic analysis has always been restricted to laboratories certified by the Clinical Laboratory Improvement Amendments (CLIA) of 1988, similar to all other highly complex testing. Cytologic interpretation requires not only extensive training and expertise but also a quality assessment program (as mandated by CLIA) to ensure an accurate result.

Recently, the Center for Medicaid and Medicare Services (CMS) changed its guidelines to allow medical professionals to use Current Procedural Terminology (CPT) billing codes 88172 and 88177 without a CLIA license. CPT codes 88172 and 88177 are professional cytology billing codes that are used for rapid assessment of fine-needle aspiration (FNA) samples. In effect, disconnecting this code from the oversight of a CLIA-certified laboratory allows this high-complexity test to be performed by physicians with no specific training in cytology and without a quality assessment program as mandated by CLIA. To my knowledge, this change was made without any pathology organization being aware that the topic was being seriously considered. It seems likely that the driving force behind this decision was the desire of endocrinologists to perform thyroid FNA and bill for immediate assessment to improve adequacy.

There is no denying that immediate evaluation may be useful for clinicians collecting aspirates of thyroid nodules in their offices, and most often, in this setting, a pathologist is not available to perform this service. It is also true that some endocrinologists have been performing this service for years without reimbursement precisely because it can improve the care of their patients. Although the evaluation of adequacy in this setting has certain pitfalls (lymphocytes, macrophages), some endocrinologists can perform this service successfully. Nevertheless, there are good reasons to resist this change.

First is the obvious fact that this change allows individuals with no specific training in microscopy to perform a microscopic service that is currently only performed by those with formal training in this area. Even among pathologists with formal training in microscopy, significant differences of opinion are common in thyroid FNA, and this includes the seemingly easier area of determining adequacy. In practice, this change will pit the will and desire of the endocrinologist, who is performing and assessing the adequacy of the aspirate, against the will and desire of the pathologist, who must subsequently make a final interpretation. I am aware of situations in which slides that have been found to be adequate after immediate assessment by a clinician are subsequently found to exhibit cells unidentifiable by the pathologist. Interestingly, in some cases, once these slides were stained “again” in the pathologist’s laboratory, the pathologist was able to identify cells on the slide. Obviously, such a result raises serious concerns about the interpretation of adequacy.

Second, although it is true that endocrinologists can be trained to count cells for adequacy assessment, immediate assessment is more than this. In many if not most settings, immediate assessment is not just counting cells but involves rendering a preliminary diagnosis and collecting triage material for culture and flow cytometric analysis, as well as molecular studies. A simple audit of the last 100 cases in which CPT code 88172 was billed at my hospital showed 17 cases in which the specimen was sent for flow cytometric analysis and 19 cases in which the material was sent for culture. Even with years of experience, this may be a difficult task, and in cases
with scant tissue samples, triage is not always done ideally. There is no doubt that this task requires a diagnostic skill that involves much more than simply counting cells.

Third, the number of biotechnology companies trying to obtain tissue samples for molecular studies has increased substantially. These companies are able to persuade clinicians to submit tissue samples for their ventures. In contrast, pathologists seem to be less easily persuaded by these requests, especially when the test is investigational and of no clear clinical benefit. In this scenario, the pathologist can serve as a useful gatekeeper to prevent tissue samples from being allocated based on criteria that may not be in the best interest of the patient. If the process of immediate assessment is performed by clinicians other than pathologists, it is highly likely that the biotechnology companies will recognize this as a window of opportunity to persuade clinicians to send FNA tissue samples directly for testing, without any further assessment of the quality or appropriateness of these tests.

Fourth, to be CLIA certified, a laboratory must have a quality assessment program. The specimens that use the CPT code 88172 are part of a much larger CLIA-mandated quality assessment program that has significant positive effect on patient care quality. For example, thyroid FNA has been performed at my hospital for more than 13 years. During that time, more than 40 radiology fellows have rotated through the department. In almost every case, the combination of greater experience at FNA and the feedback provided by immediate evaluation has led to a consistent improvement in the adequacy rates of individual fellows over the year of their fellowship. Nevertheless, in the beginning, our adequacy rate was lower than we would like it to have been, even with extensive use of immediate evaluation. It was only by examining the entire process, including preanalytic, analytic, and postanalytic issues, that we were able to identify our practice of immersing process, including preanalytic, analytic, and postanalytic of immediate evaluation. It was only by examining the entire process, including preanalytic, analytic, and postanalytic issues, that we were able to identify our practice of immersing process, including preanalytic, analytic, and postanalytic of immediate evaluation. It was only by examining the entire process, including preanalytic, analytic, and postanalytic issues, that we were able to identify our practice of immersing process, including preanalytic, analytic, and postanalytic issues, that we were able to identify our practice of immersing process, including preanalytic, analytic, and postanalytic issues, that we were able to identify our practice of immersing slides in ethanol rather than spray fixing as a cause of cell loss directly for testing, without any further assessment of the quality or appropriateness of these tests.

By following the quality assurance program mandated by CLIA, we were able to improve our performance. Our experience clearly demonstrates that even in the hands of very good aspirators, immediate assessment is not by itself a guarantee of an acceptable adequacy rate.

Some may argue that clinicians can establish and run quality assessment programs as well as pathologists. Although this is true, I have had the experience, on more than one occasion, of assuming responsibility for a clinician’s laboratory that had been performing waived testing for years, only to discover that the controls for the waived tests had never been opened and that no documentation existed of performance of quality assessment. It seems highly unlikely that the routine quality assessment steps taken in every CLIA-certified laboratory will be followed as thoroughly or consistently by a laboratory that is not subject to routine CLIA inspection.

In addition, unlike waived testing, quality assessment in cytologic analysis does not only involve running controls. It also includes patient identification and proper labeling of specimens, procedures to ensure that slides do not become contaminated from case to case, checking stains daily, and microscope maintenance. Every pathologist knows how easily a good test in the hands of a good technologist can go awry because of a failed electrode or improper reagents, and how hard it can be to even identify that there is a problem. Indeed, problems can continue for a long time without being identified, and a whole series of mistakes can be made that can require significant effort and difficulty to rectify. It seems highly unlikely that a clinician’s office will have safeguards in place to avoid, identify, and correct problems. Indeed, the College of American Pathologists checklist in nongynecologic cytologic analysis is a list of multiple checks and safeguards to ensure that the highest quality end result is obtained for the patient. This includes specific technical questions including the quality of staining and fixation that are likely to be much more difficult to address when the ultimate control of these factors is in someone else’s hands. Allowing immediate assessment to be performed outside a CLIA-certified laboratory will allow physicians to circumvent these safeguards, and decreases in the quality of the FNA specimen, final diagnosis, and patient safety are likely.

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References

2. Center for Medicare & Medicaid Services, MLN Matters Medicare Learning Network 2011; # MM7277:3.