As I climbed into my neighbor’s car, I nearly sat on his daughter’s “Speak and Spell” toy; but it was, in fact, a portable automated external defibrillator (AED) his company sells. Would it shock me if I pushed the wrong button? “No” he retorted, “unless it senses that it needs to, no matter what the user does. Sixth-graders given the AED took 90 seconds to learn to administer a proper charge to a training dummy after reading a quick-reference guide. EMS-trained professionals took 60 seconds.”

“Does everyone train on it, even though it is ‘idiot-proof?’” I asked. “Yes. Incidentally,” he said, “it needs a physician’s prescription.”

This exchange got me thinking about the concerns brewing over waived testing. Remember, waived tests are considered so simple and accurate that erroneous results are negligible; chances of causing harm or death to a person are minimal. Available data, however, suggest 2% to 3% (of some 102,000 waived labs) have problems that create an imminent and serious risk to human health.1

A number of groups — CLIAC, FDA, CMS, AdvaMed — looking at the data are concerned with what analytes get waived, how they will be used, and how to reduce the propensity for error through test design and development. Like the AED, waived tests will not work if not operated properly. Users have to know what to do. The AED is a “complex” device, one part of a first-response care continuum. The manufacturer provides AED training, which is required by the same FDA that approves laboratory test systems.

Does your test system manufacturer/distributor provide training? Many do on complex test systems, but not on simple tests. Some 3% (an estimated 3,000 waived labs*) are considered “immediate jeopardy.”1 While these numbers are relatively small, the data suggests something is seriously wrong in training and in the total test system in those labs.

Recommendations are plentiful: “… we will institute an educational program for waived laboratories” notes CMS and accrediting organizations;1(p3,8,9) “… we should standardize the format for test system labeling … and include a quick-reference guide for newly waived test systems,” advise others. “In lieu of fail-safe mechanisms, failure-alert mechanisms could be used to notify the operator of test system problems” — like attributes of the AED I saw!

Manufacturers, recognizing the importance of training, are employing new models to provide not only a good laboratory-diagnostic product but also the know-how to make it work properly. Web-based training can meet the needs of compliance, continuing education on clinical science-related topics, and test system-specific training. Training and education, however, are just part of the total testing system. The recommendations — for analytic, pre-analytic and post-analytic phases of waived testing to improve the total test performance — offered by a confluence of laboratory interests address the total system for these tests.

In all aspects of lab operation, system thinking provides a mechanism for breakthrough improvement. Can system thinking apply to waived testing? CMS, FDA, and CDC considered the total test system and educational programming for Waived Rapid HIV testing developed by OraSure. Time was spent on educating users on practical pre- and post-analytic counseling. While the education and application of such counseling may not directly affect the accuracy of the test per se, because the paradigm includes a user’s understanding of the lab system and post-test implications of the results, he is more likely to understand and perform the test with more attention and diligence.

A sixth-grader does not fully appreciate the first-response system in which the AED is used, nor is he the intended user. The analogy demonstrates that with a combination of design, training, and acknowledgement of its uses and limitations, a device can be effectively and safely used by the unskilled. This paradigm is at the heart of how we should think about waived testing. Yes, it can be simple, and it is “intricate” and “multifaceted” — both synonyms for “complex.”

Three thousand labs with testing problems purported to be of immediate jeopardy to patient health are a serious concern. When the tests in those labs are categorized as having insignificant risk to patients when erroneous, the thought is frightening.

If a 12-year-old with 90 seconds of AED training can shock my heart back into rhythm, should we not expect better from our lab testing system? □

*Note: In 2003, CMS visited a sample of 1,756 waived labs in all 50 states: 94% were operating safely, 3% were considered “immediate jeopardy.”

References

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