Among the powerful barriers to making progress in patient safety is an attitude of complacency induced by the rarity of serious events and the general human bias toward assuming that things will work as they are supposed to. Although the overall incidence figures for accidental injuries and deaths in healthcare are horrendous—more than 1 million preventable injuries and 44,000–98,000 preventable deaths annually (1)—because they occur in >30 million patients and are spread out over the year, significant complications in medical diagnosis and treatment are not part of the everyday experience of doctors or nurses. They are even less likely to be so among laboratory personnel. Most of the time, the system works just fine. However, even small errors can have devastating effects, and for the victim the fact that it may happen to only 1 patient in 1000 is of little solace.

Two reports in this issue of Clinical Chemistry (2, 3) supply important evidence and insights on the contribution of defects in laboratory analyses that, although rare, can have serious effects.

Ismail et al. (2) found only 28 false results for immunoassays performed on 5310 patients, an error rate of 0.5%. Clinicians and laboratory physicians thus rarely see an incorrect test result. However, as a result of incorrect immunoassay results attributable to interference, one patient had 15 consultations, 77 laboratory tests, and an unneeded pituitary computed tomography scan. The authors stress the need for good communication between clinician and laboratory personnel, the importance of the clinical context, and the need for use of multiple methods for identifying erroneous test results. Heterophilic antibody blocking studies were most effective in identifying interference, but in 21% of patients with false results, dilution studies or alternative assays were necessary to identify the problem.

Marks (3), using a patient population selected to demonstrate false immunoassay results and enlisting participation from 74 laboratories in a broad international spectrum of settings, found that 6% of analyses gave “false-positive” results and that use of a heterophilic blocking reagent corrected approximately one-third of these. Interestingly, there was no consistent pattern for false results: errors were distributed across donors, laboratories, and systems of analysis. Marks stresses the need to ensure that clinicians are aware of the limitations of immunoassays.

What are we to make of these studies? Certainly, one implication is that however good our methods are, and they are very good indeed, we should not become complacent. Although the reported laboratory error rate of 5 incorrect results per 1000 tests seems commendable and is one-tenth that of clinical healthcare overall, it is also 10 to 100 times greater than is tolerated in almost any other industry. There is much room for improvement. We are far from a “six sigma” level of quality.

A second lesson is the value of teamwork and good communication. The cornerstone of identifying aberrant laboratory test results, noted in both reports, is clinical context and common sense. If the test result does not make sense, it may be wrong. Although medical students are taught this as a principle, in practice physicians are becoming ever more dependent on (and confident in) laboratory diagnosis of disease. Prolonged experience with tests that are seldom wrong can lead clinicians to put more faith in the test than their own judgment. The laboratory can help guard against this, but only if the clinician provides suitable clinical data with the requisition and if the principals talk with one another when there are questions. This is where teamwork comes in. An essential feature of a culture of safety is that all professionals and staff show mutual respect and value each others’ contributions. Communication is easy and welcomed. Each supports and is supported by the other. Sadly, this is not the norm in many hospitals.

Another characteristic of safe organizations is that every individual feels a personal responsibility for ensuring safety. In the hospital, that means not only the doctors and nurses, but technicians, secretaries, clerks, and maintenance personnel as well. In a safety-oriented laboratory, personnel have a healthy skepticism about everything they do—proud of high standards, but constantly on the lookout, because they are aware that they can, and will, make mistakes from time to time. Although a faulty analysis because of immunointerference is not a “mistake”, knowledge that it can lead others into error should lead to a special sense of awareness and a willingness to suggest further measures to clarify ambiguous findings. Noting in the patients’ records, as reported by Ismail et al. (2), that they have a problem with interference—and crucially, having a system that ensures that information comes up every time the patient is tested—is an excellent example of this sense of responsibility.

From the policy point of view, the question is whether multiple testing (dilution studies, heterophilic antibody blocking studies, and even alternative assays) should be performed on all assays to reduce the likelihood of interference errors. Although on the surface such an approach would seem to be forbiddingly expensive, the question could be answered by cost-effectiveness analysis provided that it includes not only the costs of test performance but also additional patient costs, such as lost wages, and the undocumented inefficiencies in the hospital care processes that escape the accountants’ eyes, e.g., time spent locating results and contacting physicians. Clearly, 12–13 extra consultations, as in case 1, would pay for several extra assays.

An alternative is to perform these studies “when indicated”, i.e., when the results do not fit the clinical picture. This was the tactic used by Ismail et al (2). The question that needs to be answered by further research is how many false results are still missed when this approach is used? If selection of a subset for reanalysis is to be used, then it is essential to use explicit laboratory criteria as
recommended by Ismail et al. (e.g., inconsistent profile, unexplained change, disproportionate increases in measured values) and to apply them consistently. In addition, as the authors make clear, personal review of all information should be carried out. Setting up a system that ensures that every assay is exposed to this type of rigorous review could be a major step forward in improving test validity. Every hospital clinical pathology department should seriously consider doing so.

References


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