Two articles in this issue of Clinical Chemistry provide additional evidence of the potential benefits of applying modern quality theory to clinical medicine. Though understandably focused on laboratory process, these papers nevertheless suggest lessons that are widely applicable to reducing error rates and improving quality of care throughout medical practice.

The manuscripts complement each other nicely. Witte et al. [1] concentrate on rates of error within the analytical process of the laboratory, and find that widely discrepant values (>7 SD from expected) are relatively rare, occurring in 98 of 219 353 analyses they conducted. To compare error rates in the laboratory with error rates in other settings, they translate the figure 98 of 219 353 into a standard metric for error measurement: errors per million episodes (parts per million in industry jargon). Their data suggest an error rate of 447 ppm. They note, for example, that mishaps in anesthesia include 2.5 deaths per million cases, and aviation deaths are 0.18 per million passenger enplanements. Though their finding is seemingly much higher than for these other fields, the error rate in laboratory analyses is not really comparable, since the outcomes measured by Witte et al. are so different. Only 9 of the 98 laboratory errors were judged likely to have affected clinical decision-making, and whether any serious harm was likely to have resulted is unclear.

Plebani and Carraro [2] provide valuable perspective on error rates in laboratory medicine by exploring a somewhat different question: What proportion of laboratory errors are attributable to problems outside the analytical process itself? Their conclusion is that the great majority of errors result from problems in the preanalytical or postanalytical “phases.” These problems include erroneous specification of the hospital unit, collection of the specimen from an infusion route, or failure to notify the physician of the laboratory finding. They conclude that improving the quality of the clinical chemistry system requires increased focus on error in the pre- and postanalytical phases of testing. Correcting such problems, they argue, depends on increased cooperation between laboratory and nonlaboratory personnel.

From the standpoint of laboratory practice, several points about these two studies stand out. First, there is room for improvement in the analytical phase of the clinical chemistry process. Second, however, the quantitatively largest reductions in laboratory error are likely to result from interdepartmental cooperation designed to improve the quality of specimen collection and data dissemination. These observations provide valuable guidance for laboratory directors and medical administrators, who must deploy scarce resources to reduce medical error.

From the standpoint of quality improvement more generally, other lessons emerge from these papers. First, it is clear that modern quality theory and practice—based on methods pioneered in industrial settings over the last 80 years—are gaining ground in medicine. Both papers liberally use standard industrial quality methods, including the concepts of special and common causes of error and the use of benchmarking across industries to provide perspective on error rates. The diffusion of such ideas and tools is gratifying evidence that quality management is coming of age in medicine, not only in the US but around the world.

Second, the papers demonstrate the applicability of modern quality theories and tools to the job of improving medical processes. The relevance of these theories and tools will strike some observers as self-evident. When the jargon of quality management is stripped away, all that Witte et al. and Plebani and Carraro have done is to apply the scientific method to understanding the causes and (inferentially) the solutions of flaws in a clinical process. They developed methods of error detection, counted the errors, formulated and tested hypotheses about the sources of error, and reported the results. What could be less remarkable in a discipline (medicine) that prides itself on its roots in biomedical science?

The point, however, is not that the methods themselves are innovative (they are not), but that they have thus far been so erratically applied in the daily work of medical practice. Medicine has done a remarkable job of using science to improve the technologies available for diagnosing and curing illness. The healthcare system has been much less diligent about applying the scientific method to improving the performance of the increasingly complex processes in which those technologies are embedded: the processes, for example, of deciding which laboratory tests to order, collecting the specimens, moving them to the laboratory, organizing the information that results, communicating it to physicians, and acting on the results. If a system is no better than its weakest link, then many of our most exciting new diagnostic and treatment methods have been hobbled by failures in the human systems they depend on.

For decades, other sectors of society have been perfecting approaches to reducing errors that result from human and system failures. Out of insularity or defensiveness, health professionals and institutions have shown little interest in these approaches. Now, at long last, this situation is changing. The result is likely to be healthcare that is not only better but cheaper, and much more satisfying to practice.

References

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