rent insights on functional sensitivity is not so much whether the 15%, 20%, or 30% interassay CV should have been chosen, but rather concerns the necessity for manufacturers and laboratories to use the same clinically relevant protocol for establishing interassay precision when comparing assays [3]. Further, because functional sensitivity varies across laboratories that are using the same manufacturer’s platform, perhaps as a reflection of instrument differences, it is essential that laboratories establish their functional sensitivity limit independent of the manufacturer’s claims and monitor it on an on-going basis [3].

Impact of Point-of-Care Testing on Healthcare Delivery

To the Editor:

In their recent article [1], Parvin et al. concluded that “use of i-STAT results in the ED [Emergency Department] for clinical decisions failed to shorten emergency department patient length-of-stay, regardless of final disposition, presenting symptoms, or the presence or absence of other central laboratory testing.” The conclusion might more accurately have been stated (italics mine), “use of selected i-STAT results (Na, K, Cl, BUN, and glucose) in the ED for clinical decisions in the absence of an effort to address other work flow process issues in our department failed to shorten emergency department patient length-of-stay.”

The authors contrasted their results to a study performed in the Stanford University ED [2], in which it was concluded that “earlier results might have reduced the length of stay in the ED for 17.3% of patients studied.” The Stanford conclusions were based on retrospective judgments offered by the treating physicians, who were also offered a hematocrit (Hct) determination along with the parameters included by Parvin et al. The aggregate percentage comprised two decisions that were to initiate a therapeutic intervention and (or) to discharge or admit a patient. In the “Limitations and Future Questions” section of the Stanford study, the authors stated clearly that further investigations would be necessary to elucidate the specific applicabilities and benefits of point-of-care testing.

Both studies should help frame future investigations to unravel the work flow complexities associated with determining the most cost-effective and clinically appropriate testing method in any particular medical situation. The technologies will be developed and improved quickly—changing human behavior is more difficult.

Even assuming that a point-of-care blood testing device can deliver a reliable measurement at the bedside—and that having that result eliminates 30–120 minutes of time that can be attributed to blood draw, sample handling, transportation of the sample, and result reporting—other factors must still be addressed to convert the time savings into economic benefit:

- The point-of-care results must be reported to the provider who controls the relevant decisions (clinical or “traffic”) as soon as the results are available.
- Other information factors that impact the provider’s decision-making process (e.g., test results such as X-rays, physiological parameters such as pulmonary function in an asthmatic) must be controlled in the analysis.
- Other procedural factors that impact the work flow process (e.g., bed availability, patient transportation, time to consultation, key provider access) must be controlled.

For example, a nurse manager in the ED can have a patient ready for transfer to an inpatient unit, only to have to wait two hours for the “bed upstairs to be cleaned” or for the completion of “change of shift.” If a trauma patient is to be discharged postobservation if the repeated Hct is reported at a certain level, then the physician must be available to interpret the results. If an anxious congestive heart failure patient, taking digoxin and a diuretic, must wait an hour for the X-ray technician to process a film, the time benefit of a normal bedside potassium determination is negated. Before anyone concludes that shortening time to laboratory results cannot have a positive impact upon the overall process, the overall process must be addressed.

It is difficult to imagine that near-immediate access to certain laboratory values, particularly as test panels expand, could not be translated into more rapid decisions and more efficient work flow. To determine which factors, alone and in combination, are influential in improving clinical patient outcomes (short and long term) and improving the work flow process from a cost-benefit perspective, future investigations will have to analyze all of the performance issues, and the population studied will have to be large and

References

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Editor’s Note: The term “sensitivity” has come to have two meanings: the slope of the calibration curve (International Union of Pure and Applied Chemistry) and the lower limit of detection (immunoassay workers). This Journal reserves the term “sensitivity” for the IUPAC meaning. We call the lower limit of detection the “lower limit of detection.” Widespread use of the term “functional sensitivity” has created a semantic difficulty, because the term could mean the “functional” slope of the calibration curve” (whatever that might mean), whereas as introduced by Spencer, it refers to the lowest concentration at which an interassay CV of 20% can be achieved. None of the august bodies that address definitions has (to our knowledge) blessed this term and this usage.

Until Solomon (or perhaps New York Times wordsmith William Safire) resolves the issue, we will continue to include Spencer’s definition of “functional sensitivity” in each article where the term appears.
statistically significant. When the process of delivering care to a patient is maximized for efficiency from all relevant perspectives, we will be able to definitively understand the impact of the time savings generated by point-of-care testing. This is an exciting time in medicine because we have the opportunity to challenge basic assumptions in an effort to improve the delivery of healthcare.

References

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Three of the authors of the article referred to above reply:

To the Editor:
We enjoyed reading Dr. Auerbach's letter and fully agree with the points he makes. He is correct in his restatement of our conclusions. For instance, "...use of selected i-STAT results. ..." was done for medical reasons because the results of the hematocrit values were not reliable in the hands of nonlaboratory operators in our setting. This was likely due to preanalytical error by personnel for whom generating accurate laboratory values is not a primary responsibility. All other available i-STAT tests were performed, and we state in our discussion that as point-of-care testing (POCT) menus expand, it may be necessary to reexamine this issue.

We also completely agree with Dr. Auerbach's addition of "...in the absence of an effort to address other workflow processes. ..." As Dr. Auerbach points out, many factors influence patient length-of-stay (LOS) in an ED, and laboratory turnaround time (TAT) plays only a small part. Our study clearly demonstrated that in our current ED setting, improvement in this part (TAT) of the overall process did not, by itself, improve patient LOS. Improving other workflow and patient flow is outside the purview of the laboratories and of our study. Obviously, improvements in all aspects of the ED process would be ideal, and as these occur the contribution of POCT may need to be reexamined.

We again emphasize that the factors affecting both LOS and TAT will vary considerably in different settings, so the impact of POCT may differ among institutions. Thus, we believe it very important that the impact of POCT be examined directly in the setting where it is hypothesized that it will solve a problem. We hope that our study will provide a footing upon which other studies can address these important questions.

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Serum Transferrin (Total Iron-Binding Capacity) in Evaluation of Iron Status

To the Editor:
The recent review by Hastka et al. of laboratory tests of iron status focused on three tests of iron metabolism—serum iron, the percent saturation of transferrin with iron, and serum ferritin—but failed to discuss the information content of the serum transferrin concentration [total iron-binding capacity (TIBC)] [1]. In addition, the authors paid insufficient attention to the lability of serum iron and, therefore, to the lability of the percent saturation of transferrin with iron.

Serum iron is highly labile—normally varying over a 24-h period by as much as 20 μmol/L—in the absence of disease. Moreover, an acute injury can within hours drop the serum iron concentration to below normal. In contrast, serum concentrations of transferrin (TIBC) are relatively stable over days and weeks. Therefore, the percent saturation of transferrin with iron can vary without a change in iron stores [2-4].

Next, when looking for iron deficiency, the information content of transferrin (TIBC) is essentially identical to that of ferritin. In a classic study carried out at McMaster University, the area under the ROC curve for transferrin was 0.92 and for ferritin 0.93—when the gold standard was presence or absence of bone marrow iron [5]. This fact has practical importance because the chemical assay for TIBC is far less expensive than the immunoassay for ferritin.

Moreover, transferrin (TIBC) and ferritin are affected in different ways by medical conditions other than disorders of iron metabolism. For example, transferrin (TIBC) is a sensitive marker of protein malnutrition—it decreases during negative nitrogen balance. Ferritin, in contrast, is a positive acute-phase reactant and is increased in patients with acute or chronic diseases in the absence of an increase in iron stores. Therefore, measurement of both provides more information than either alone. For example, a patient with iron deficiency may have a normal concentration of apoferritin, but a high TIBC concentration consistent with iron deficiency. Conversely, another patient with iron deficiency may have a high-normal TIBC concentration but a very low serum concentration of apoferritin that is diagnostic of iron deficiency.

The serum transferrin (TIBC) concentration is an essential component of any laboratory evaluation of iron status. Patients are ill served when this test is neglected or misunderstood.

References

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