Point-of-Care Testing Error

Sources and Amplifiers, Taxonomy, Prevention Strategies, and Detection Monitors

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- **Context.**—In a survey performed 4 years ago, testing venues doing only point-of-care testing (POCT) made up 78% of sites for patient testing licensed under federal regulations.

**Objectives.**—To identify sources of POCT error, to present a classification of such errors, to suggest strategies to prevent errors, and to describe monitors that assess and reduce the frequency of errors.

**Design.**—To identify sources of POCT error, large studies of error among US Federal Certificate of Waiver laboratories (CoWs) and practitioner-performed microscopy certificate holders were reviewed. To facilitate investigation and management of POCT error, a taxonomy of such errors (modified from a classification previously published by Gerald Kost) was used to identify 4 steps with error potential in each of the 3 phases (ie, preanalytic, analytic, and postanalytic) of the POCT process. To prevent observed POCT errors, 4 strategies are suggested: direct observation of instrument/method functionality, structured observation of method performance, proficiency testing/use of relevant test scenarios, and autonomation. To assess frequency of errors, a quartet of indices are introduced as detection monitors: order documentation, patient identification, specimen adequacy, and result integrity.

**Results.**—Three sources of POCT error were identified: operator incompetence, nonadherence to test procedures, and use of uncontrolled reagents and equipment. Three other characteristics of many point-of-care tests amplify their risk of error: incoherent regulation, rapid availability of results, and the results' immediate therapeutic implications. Two members of the quartet of detection monitors, order documentation and specimen adequacy, are relatively difficult to measure and are controversial, but the other 2, patient identification and result integrity, are easier to assess and are relatively widely accepted.

**Conclusions.**—Point-of-care testing errors are relatively common, their frequency is amplified by incoherent regulation, and their likelihood of affecting patient care is amplified by the rapid availability of POCT results and the results' immediate therapeutic implications. The modified Kost taxonomy offers a reasonable approach to the identification of POCT errors. Direct observation of test functionality, structured observation of test performance, and testing the competence of POCT operators, as well as autonomation of devices, are strategies to prevent such errors. In this context, we suggest monitoring POCT order documentation, patient identification, specimen integrity, and result reporting to detect errors in this sort of testing.

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**DEFINITIONS**

To identify sources and amplifiers of point-of-care testing (POCT) error, categorize this sort of medical error, and suggest strategies to prevent and indices to monitor such errors, we start from Price and Hicks'1 4-part definition of POCT. Such tests are, primarily, assays of blood and other body fluids or examinations of suspensions and smears of cells, crystals, etc. They are, negatively, not undertaken in central or satellite clinical laboratories. Positively, they are tests undertaken close to the tested patient. Finally, and most importantly in relation to medical error, they are tests performed so that their results can rapidly lead to changes in patient care.1 We also need to work from a definition of error. The influential Institute of Medicine report, To Err Is Human, defines medical error as either failure of a planned activity or choice of a wrong plan. An adverse event is an injury caused by medical management, rather than by underlying patient conditions. Closing the circle of definitions, a preventable adverse event is an adverse event due to medical error.2 Medical errors in clinical laboratory testing, including POCT, are mostly failures of planned testing actions.

**SOURCES AND AMPLIFIERS OF POCT ERROR**

The industrial psychologist James Reason has identified organizational and local workplace factors as latent conditions that are the sources for such failures. These latent conditions include shortfalls in training, undetected manufacturing defects or maintenance failures, and unworkable procedures.3 Three latent conditions are sources of POCT error, namely, test operator incompetence, operators' nonadherence to test procedures, and their use of uncontrolled reagents and testing equipment (Table 1).
Other conditions of POCT amplify either the frequency of error or increase the likelihood that these errors become preventable adverse events. An amplifier that increases the frequency of error events is incoherent regulation of this sort of testing. Rapid availability of POCT results and the immediate therapeutic implications of many point-of-care tests amplify the likelihood that erroneous results from these tests will cause preventable adverse events.

**Operator Incompetence**

In 2000–2001, the federal agency charged with regulating laboratory testing, the Centers for Medicare and Medicaid Services (CMS), undertook a national survey of laboratories performing “waived” POCT, the largest regulatory category of such testing. In this survey, CMS observers examined test performance in 436 laboratories with certificates of waiver (CoWs) in 8 states. Regarding operator incompetence, the CMS examiners found that 19% of testing personnel had been neither trained nor evaluated in the performance of the assays that they carried out, while 32% of the observed test operators could not locate test instructions when the observers asked the operators to refer to them.4

**Nonadherence to Procedure**

In the CMS study, 25% of test operators failed to follow manufacturer’s directions, and 7% of operators did not perform required calibrations.4

**Uncontrolled Reagents and Equipment**

Thirty-two percent of test operators failed to perform quality control (QC), and 20% physically separated (against the manufacturer’s directions) internal QC test fields from patient test fields in card format tests; 6% also used expired reagents and kits, for whose integrity manufacturers would vouch no longer.4

**Sources and Amplifiers of Error in Practitioner-Performed Microscopy**

The CMS national survey also examined the second largest regulatory subcategory of POCT, practitioner-performed microscopy, and turned up similar levels of testing deviance. Among practitioner-performed microscopy certificate holders, regarding operator incompetence, 25% of certificate holders did not document practitioners’ ability to carry out the microscopic examinations indicated. Regarding nonadherence to procedure, 28% of certificate holders had no written operating procedures to which they could adhere. Regarding uncontrolled equipment, 36% did not perform required maintenance of the microscopes and centrifuges that they used.4

**EXTENT OF THESE PROBLEMS**

The results of the CMS survey were drawn from a representative 2.5% sample of the certified testing venues (in the case of the CoWs), spread over 10 states. The study showed operator incompetence, nonadherence to procedure, and absent procedural reagent controls in a fifth to a third of these laboratories.

At the time of the 2000–2001 survey, CoWs made up 56% of the 174,500 laboratories registered with CMS, as mandated by the Clinical Laboratory Improvement Act (CLIA) of 1988. Laboratories with a certificate of waiver can perform any of more than 56 waived tests.3 Waived tests are point-of-care tests performed without direct oversight and for which test operators need not participate in proficiency testing programs. At the time of the practitioner-performed microscopy survey, practitioner-performed microscopists held another 22% of CLIA certificates. Taken together, CoWs and practitioner-performed microscopists made up 78% of venues for patient testing licensed by CMS under the CLIA regulations.

**INCOHERENT REGULATION**

Regarding waived tests, regulatory incoherence is a contributing latent condition conducive to POCT errors. Statutory attributes applied to waived POCT assays in the 1988 CLIA law and incorporated into the pursuant regulations are counterfactual. The 3 statutory attributes are “cleared by FDA (Food and Drug Administration) for home use,” “so simple and accurate to perform that the likelihood of erroneous results could be negligible,” and “not posing reasonable risk to patients (even) if performed incorrectly.”6 The 3 attributes can be contrasted, by pertinent counterexamples, to the waived point-of-care tests’ real characteristics. Regarding clearance for home use, the majority of current waived analytes are not cleared for home use.7 Regarding the demonstration of simplicity and accuracy, such that the likelihood of result error would be negligible, in a multi-institution study we found 13% of warfarin patients misclassified by POCT prothrombin times.8 In a similar study, a decade ago, of POCT blood glucose determinations, one of us demonstrated that 9% of these determinations were more than 25% different from simultaneous reference laboratory blood glucose test results.9 Immunity from reasonable risk to patients, due to incorrect performance, does not appear to be assured when POCT prothrombin times guide medical management of inpatients beginning, changing dosage, or discontinuing warfarin therapy,10 nor is such immunity assured when POCT blood glucose determinations guide tight control of blood glucose among patients in intensive care units.11

Regulatory incoherence extends to the application of QC in waived POCT. Around the turn of the millennium, a second federal agency, the Centers for Disease Control and Prevention (CDC), studied the application of QC in the actual performance of waived testing. The CDC formed sentinel monitoring networks of laboratories doing waived tests and studied the use of QC procedures among the network participants.12

In one such study, CDC surveyors asked 205 volunteer CoWs, from among 439 facilities participating in one of these collaboratives, the US Pacific Northwest Laboratory Medicine Monitoring Network, to characterize the patterns of use for external (liquid) QC materials.12

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**Table 1. Sources and Amplifiers of Point-of-Care Testing Error**

<table>
<thead>
<tr>
<th>Sources</th>
<th>Amplifiers</th>
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</thead>
<tbody>
<tr>
<td>Operator incompetence</td>
<td>Incoherent regulation</td>
</tr>
<tr>
<td>Nonadherence to procedures</td>
<td>Rapid result availability</td>
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<tr>
<td>Use of uncontrolled reagent/equipment</td>
<td>Immediate therapeutic</td>
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The CDC surveyors documented 3 major variations in the use of external QC. First, use of liquid control materials varied, not with test setting or patient acuity, but with who did the test; 59% of respondents from test settings in which medical technologists/medical laboratory technicians performed tests reported using liquid QC, but only 39% of testing personnel in other laboratories reported doing so \( (P = .05) \). Second, use of these controls varied among laboratories that by regulatory categories and complexity of testing attributes should have been similar. Neither regulatory category nor accreditation program predicted whether a laboratory used liquid QC for the specific tests about which the surveyors inquired. Third, and most strikingly, use varied among sites using the same manufacturer’s kit of procedures and reagents. The procedures varied, not with test setting or patient acuity, but with who did the test; 59% of respondents from test settings in which medical technologists/medical laboratory technologists performed tests reported using liquid QC, but only 39% of testing personnel in other laboratories reported doing so \( (P = .05) \).

**RAPID RESULT AVAILABILITY**

In the absence of published investigations correlating the speed with which POCT results are made available to their potential for bringing medical errors “closer to the patient,” study of the clinical consequences of stat laboratory errors is of interest as a surrogate for the missing publications. Stat tests, like POCT assays, differ from other laboratory tests in being rapidly available. On this basis, one can hypothesize, these 2 types of testing have similar influence on medical decision making. In a study of stat test errors published in 1997, of 189 clinician-discovered errors, Italian investigators found that three quarters of the errors \( (140 [70\%]) \) had no effect on patient care, but that about a fifth \( (37 [19.6\%]) \) stimulated (further) inappropriate investigation, and that 1 in 16 \( (12 [6.3\%]) \) led to inappropriate initiation or modification of therapy. \( \text{13} \)

An objection can be raised to the comparison of stat with POCT assays. Point-of-care testing results, at least of waived tests, are often deployed as screening devices, and errors would be checked by less defect-prone confirmatory tests before they reached the patient. The CDC Pacific Northwest Monitoring Network survey offers data that reduce the force of this objection. \( \text{12} \)

<table>
<thead>
<tr>
<th>Phases/Steps in POCT Process</th>
<th>Step-by-Step Defects</th>
</tr>
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<tbody>
<tr>
<td>1. Preanalytic phase</td>
<td></td>
</tr>
<tr>
<td>a. Test ordering</td>
<td>Excessive/mistimed orders</td>
</tr>
<tr>
<td>b. Patient/specimen identication</td>
<td>Wrong patient/wrong specimen; erroneous patient/specimen information entry</td>
</tr>
<tr>
<td>c. Specimen collection</td>
<td>Inappropriate/inconsistent specimen type, volume, or application to testing surface/chamber</td>
</tr>
<tr>
<td>d. Specimen evaluation</td>
<td>Attributes degrading patient ID/collection quality not recognized</td>
</tr>
<tr>
<td>2. Analytic phase</td>
<td></td>
</tr>
<tr>
<td>a. Method calibration</td>
<td>Omitted, nonprotocol, or miscentered calibration</td>
</tr>
<tr>
<td>b. Specimen/reagent interacation</td>
<td>Patient-related native interference, specimen-related nontarget influences, specimen-reagent matrix effects</td>
</tr>
<tr>
<td>c. Result generation</td>
<td>Results outside method’s validated range</td>
</tr>
<tr>
<td>d. Result validation</td>
<td>Lack of quality control and/or other performance monitors</td>
</tr>
<tr>
<td>3. Postanalytic phase</td>
<td></td>
</tr>
<tr>
<td>a. Report formatting</td>
<td>Absent/inappropriate units, reference intervals, machine output; mistaken human transmission/transcription</td>
</tr>
<tr>
<td>b. Critical value reporting</td>
<td>Criticality not recognized, not brought to decision maker’s attention, not documented for retrieval</td>
</tr>
<tr>
<td>c. Other result reporting</td>
<td>Report communication failed/delayed; lost to retrieval</td>
</tr>
<tr>
<td>d. Report recording/retrieval</td>
<td>Lack of correlation between initially generated/final recorded result</td>
</tr>
</tbody>
</table>

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**TAXONOMY OF POCT ERRORS**

We present a modified version of the Kost error classification (Table 2). \( \text{15} \) As in the original classification, the POCT process is divided into preanalytic, analytic, and postanalytic phases. In the preanalytic phase, however, we add an initial step with error potential, namely, test order indication and frequency. With this addition, the modified taxonomy now consists of 4 steps with error potential in each of the 3 phases.

In each phase, particular aspects of the process are especially salient latent conditions for POCT error. In the primary, preanalytic phase, patient and specimen variables are of overriding importance. In the central, analytic phase, the key aspect is the opacity of automated analysis in the typical “black-box” POCT test device. For the final, postanalytic phase, the most pertinent latent condition for error is the potential—paradoxical at first glance—for both immediate and subsequent miscommunication (or noncommunication) of POCT results. In the following paragraphs, we examine the elements of the error taxonomy phase by phase.

**Preanalytic Phase**

In the first step of the preanalytic phase, test ordering, the first latent condition for error is excessive ordering,
which can lead test interpreters to be confused (overwhelmed) by the plethora of laboratory results. The second opportunity for error at the order step is mistimed testing, in which test results lose temporal connection with therapeutic interventions during dynamic treatment situations. Examples of this sort of uncoupling of test result from patient condition are POCT pH and bicarbonate determinations obtained during bicarbonate infusions in the course of cardiopulmonary resuscitations or POCT blood glucose levels measured during insulin administration as part of the treatment of diabetic ketoacidosis. In such situations, result interpreters end up “chasing their own tails,” reacting to transient or recent pathophysiologic states, rather than to a patient’s current pathophysiologic status.

In the second step of the preanalytic phase, patient and specimen identification, POCT error patterns are different from those in laboratory-based testing. They can, however, have similar outcomes in preventable adverse events. An example of POCT patient misidentification is a emergency department staff member dispatched to perform POCT electrolytes on the “patient in bay 10,” who turns out (in the emergency department fog of war) to be a different person from the patient on whose encounter sheet the tests results are written.

Another latent condition for error in POCT situations is the practice of batching specimens in outpatient settings. This occurs most often with urine tests and rapid tests for group A streptococcal antigen left on the counter. If containers or swabs are not labeled on collection, examples of consequent errors are a pregnant woman being told that she is not pregnant and a nonpregnant woman told that she is, or a child with group A streptococcal pharyngitis not receiving penicillin therapy, while a child with a non-streptococcal sore throat embarks on the antibiotic course.

A third identification problem regards the preservation of POCT results for comparison with previous and subsequent determinations. Wrong or absent patient identification leads to upload failure, in which these results fail to reach the permanent record or reach the wrong record. This error can trouble, for example, busy clinics managing many patients with diabetes mellitus, recording many thousands of blood glucose determinations in a month.

In the third step of the preanalytic phase, specimen collection, defects include inappropriate or inconsistent specimen type, volume, or application to the POCT device’s testing surface or reaction chamber. “The learning curve” is jargon used by POCT coordinators, medical technologists who manage POCT programs in practice settings subject to accreditation by the Joint Commission for the Accreditation of Healthcare Organization or the College of American Pathologists. It refers to a frequent cause of interoperator variability in POCT specimen collection: only with practice do operators adjust to differences between venous and capillary (fingerstick) blood samples and only with practice do they deliver reasonably consistent amounts of specimen to the POCT device’s testing surface or intake chamber. In the context of the learning curve, both the extent and effectiveness of operator training and the frequency with which POCT operators perform specific tests influence specimen quality as a potential cause of error.

The fourth, and last, of the preanalytic phase steps is assessment of specimen attributes other than those which point-of-care tests attempt to detect or measure. Some of these attributes may cause errors in test results. Kost distinguished between attributes influential in whole blood assays that are patient related (like anemia or leukocytosis) and those which are collection related (mostly hemolysis and clotting). In usual POCT situations, 3 obstacles interfere with detection of these influences. The first obstacle is the serial acquisition of patient data without real-time review of trends and deviations in the sequence of test results that make up the series. An example of a lost opportunity for real-time review in POCT is the inability to perform delta checks on POCT test results. Delta checks of routine (and stat) central laboratory testing discover whether an individual patient’s result is significantly different from the same patient’s results reported during previous encounters with the assay. Point-of-care test operators often lack automatic access both to previous results and to the automated statistical analysis, which together make delta checks possible. The second obstacle is the small sample volumes in most POCT assays. The specimen quality (specifically, evidence of hemolysis or clot) in such small volumes is hard to assess. Finally, most POCT devices’ reaction sites are opaque, that is, hidden from the operator’s view, so any quality assessment of how the reaction is going is quite literally obstructed.

Analytic Phase

In this central phase of the test process, a POCT method may require calibration. If it does, then that is the first step with an opportunity for error; not calibrating, deviating from the calibration protocol, or misrecording calibration data are the types of error at this step.

Defects may next develop in specimen/reagent interactions. These error-inducing interactions divide into 3 subtypes: patient-related native interferences (eg, nonspecific agglutinins in precipitation slide tests), specimen-related nontarget influences (eg, drugs causing spurious results in electrolyte channels of handheld chemistry POCT devices), or specimen-reagent combination-related matrix effects. In most POCT devices, however, it is difficult or impossible to separate native, nontarget, and matrix sources of error inside the devices’ black-box designs.

At the third analytic step, result generation, errors can occur when results are produced outside a POCT method’s validated range. Such results may not be reliable, for example, when different ranges are operative for adult and neonate tests and cartridges incorporating these differences become confused. The fourth error-relevant analytic step is result validation. Lack of any QC in waived POCT, operator failure to recognize out-of-control QC, and the absence of other performance-control monitors (eg, lockout devices) can all lead to uncontrolled acceptance of invalid results. Quality monitors of the analytic phase can, however, bring along an additional quandary; when a back-up method is periodically deployed to monitor a POCT assay, separating signal (evidence of POCT error) from noise (random variation or error in the back-up method) can be very difficult.

Postanalytic Phase

In the final phase of the testing process, defects can occur at steps of report formatting, critical value reporting, other result reporting, and lastly, the ultimate step of report management. The latter, ultimate step combines report verification, preservation, storage, and retrieval.

When a report is formatted, it may lack units of mea-
and recording QC, along with quizzing operators on sce-

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record the performance of 3 activities. The ®rst involves, 

pervisor familiar with the POCT operations perform and 

Rightly, critical value reporting has become a focus of 

medical error prevention.16 Regarding POCT critical value 

report error, a POCT result's criticality may not initially 

be recognized. Second, this criticality may not reach the 

attention of the effective clinical decision maker. Third, the 

critical value may not be documented for subsequent re-

trieve. These same, potentially error-engendering fates 

may also await noncritical value results. An industry now 

exists to respond to the error-provoking circumstance in 

which without the electronic connectivity (transfer of 

POCT information stored or entered into an electronic de-

vice directly into a laboratory computer system), POCT 

results often disappear from the patient record into the 

well of human forgetfulness.17 The error potential in the 

last postanalytic step, report management, has not been 

so clearly acknowledged and dealt with as successfully 

(for a price) as connectivity has dealt with result report-

ing. Failure to correlate initially generated results with 

subsequently preserved reports leaves users unaware of 

discrepancies between, for example, a handheld machine's 

output and the patient record, or, in another example, re-

garding results on which clinical users acted, but which 

have subsequently disappeared from the record. The clin-

ical user may also be greeted in retrospect by results of 

whose generation they were not previously aware. Com-

parison of initially generated and subsequently recorded 

results also occasions another kind of “quality moment” 

that detects error; at such times, the temporal drifts, for 

example, of prothrombin results, due to reagent variation, 

or temporal shifts in glucose levels, due to a day out of 

QC, rise above the horizon of consciousness.

**ERROR PREVENTION**

The first strategy for resolution of operator, procedural, 

and quality control problems uses the well-tried means of 

competence assessment—checking and testing (Table 3).18

### Checking

Checking requires that both POCT operators and a su-

ervisor familiar with the POCT operations perform and 

record the performance of 3 activities. The first involves, 

for the test operator, direct observation of instrument or 

method functionality by performing and recording QC 

each day of method use. For the supervisor of POCT op-

eration, it involves observation of operators performing 

and recording QC, along withquizzing operators on sce-

arios of QC failure. The second activity is, for both the 

operators and supervisors, structured observation of 

method performance, using checklists. Checklists are valu-

able to test operators, who need to be sure that they are 

adhering to the POCT procedures consistently. Checklists 

are further valuable to POCT supervisors, who need to 

detect variation from procedure during observed testing. 

Finally, checking involves, for both operators entering re-

sults and supervisors confirming result entry, comparison 

of instrument or worksheet records with patient or main-

tenance records to detect inconsistencies in information 

transfer.

### Testing

Testing involves both operators doing proficiency tests 

and supervisors reviewing their results. It includes oper-

ators testing unknowns and supervisors assessing opera-

tors’ knowledge of POCT error prevention and detection 

by evaluating operators’ responses to relevant test scenar-

ios.

Checking and testing are educational strategies. Like all 

good teaching, they aim to impart both good information 

and good behavior. Effective education, however, requires 

effort and attention to detail. The use of proficiency testing 

is an example in which application to detail is important. 

For this element of the testing function to have its intended 

effect, the survey material should appear in the course of 

routine testing; it should be handled, as far as practicable, 

in the usual routine from start to finish; it should be pro-

cessed by the same mix of test operators who carry out 

routine testing; it should be handled, as far as practicable, 

for this element of the testing function to have its intended 

effect, the survey material should appear in the course of 

routine discussion, comparison, or repetition of generation 

of results. These proficiency test results should further be 

reported with the same care for transcriptions accuracy as 

patient results (no more, no less). If these details are at-

tended to, when the statistically valid assessment of the 

survey results return, they then offer an essential teachable 

moment about opportunities for both nonerror variation 

and error in POCT.

### Autonomation

An axiom of research into the human factors involved 

in error and its prevention is that good active educational 

efforts, checking and testing, are necessary but not suffi-

cient conditions for safe operations. One further necessary 

condition is what the Toyota Motor Company calls “au-

tonomation,” that is, designing devices and procedures so 

that the right (and safe) thing to do is the easiest thing to 

do and so that foreseeable violations of right (and safe) 

procedure can be countered by forcing functions and lock-

outs.19 Point-of-care testing device manufacturers and the 

Food and Drug Administration have pursued the actual-

ization of POCT autonomation in ways beyond the scope 

of this brief overview.

### Error Monitoring

A further necessary condition is one which, along with 

pedagogical responsibility, the certificate of waiver cate-

gory of POCT sought to evade, namely, ongoing monitor-

ing.20 On the reasonable hypothesis that their application 

will reduce the frequency of the errors that we have cat-

ergorized, we urge that 4 ongoing monitors be applied to 

POCT.

The first of these proposed monitors is the most diffi-

cult: monitoring of POCT order documentation. Point-of-

| Table 3. Prevention Strategies and Error Monitors in Point-of-Care Testing |
|--------------------------------|--------------------------------|
| Prevention strategies         | Error monitors                |
| Direct observation of instrument/method functionality (QC) | Order documentation |
| Structured observation of method performance (checklists) | Identification validity |
| Proficiency testing/relevant test scenarios (evaluations) | Specimen acceptability |
| Autonomation (lockout and forcing functions) | Result report accuracy |

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care testing orders are more difficult to document than any other type of laboratory order. However, without such documentation, the defects of excessive/mistimed testing and wrong patient and specimen identification cannot be adequately addressed. Fortunately, the presence of a valid order is a prerequisite for POCT to be legally billed as laboratory testing. This requirement is a helpful conjunction of good safety monitoring and good accounting practice.

The second monitor is the least controversial, monitoring the presence/absence of valid patient and specimen identification at each POCT event.16

The third proposed monitor, monitoring of specimen acceptability, takes more effort. In the authors’ practice, it consists of detecting local unit variation in POCT versus laboratory method discrepancies, then finding which operators, in the high-variation unit, suffer from the most “noise” or are “on the early segment of the learning curve.”

Easier, and second to patient identification monitoring, is the high degree of consensus as being of value, is monitoring of result reporting; measurement of the completeness of connectivity, whether electronic or not, in the authors experience also demonstrates significant error reduction over time.15

SUMMARY

At present, we offer 8 take-home messages about medical error in POCT. First, 3 sources of POCT error turned up in large CMS surveys: operator incompetence, nonadherence to procedure, and uncontrolled reagents and equipment.4 Second, these 3 sources of error are amplified by 3 other factors: incoherent regulation (waived testing), rapid result availability, and immediate therapeutic implications of, at least, a substantial fraction of POCT. Third, incoherent regulation has rendered QC standards for safe performance of POCT uncertain.12 Fourth, immediate application of POCT results for definitive diagnosis and therapeutic monitoring is the fate of a substantial fraction (we estimate on the basis of one large study about a half) of POCT results.12 Fifth, we urge the adoption, with a modification of the preanalytic testing phase’s taxonomy, of Kost’s error classification, which locates POCT errors in steps within each of the preanalytic, analytic, and postanalytic phases of the total testing process.14,15 With our modification, there are 4 potential error steps per each of 3 test process phases. Sixth, within this taxonomy, POCT errors arise from patient and specimen misidentification and nonidentification, poor quality POCT specimens, opacity of many device-based POCT methods, and miscommunication/misrecording or noncommunication/nonrecording of POCT results. Seventh, we advocate pedagogic antierror prevention strategies that counter operator incompetence, procedural nonadherence, and failure to control reagents and methods. This entails structured supervision of test operators’ performance, assessment of their competence, and demonstration of their proficiency (ie, checking and testing). Lastly, we advocate monitoring 4 ongoing indices of POCT safety: test order integrity, patient identification, specimen acceptability, and report accuracy.


References