ABSTRACT

- **Objective:** To improve patient safety through identification, communication, and documentation of perceived contaminated specimen results.
- **Methods:** Representatives from the departments of emergency medicine, pathology and laboratory medicine, and performance improvement met to conduct a systematic review of a critical event and review associated policies and procedures. A new communication protocol was initiated to improve processes and patient safety.
- **Results:** Between November 2011 and March 2013, there was a 3% to 4% increase in the number of patient sample results proven to be not contaminated and truly reflecting the patient’s condition compared with the period before implementation of the protocol. 96% to 97% of suspected inaccurate results from sample contamination were shown to be true indicators of sampling error. Anecdotal clinician evaluation of the new communication protocol revealed high satisfaction in the joint decision-making with medical laboratory scientists.
- **Conclusion:** The project has resulted in improved communication with clinicians, enhanced documentation of suspected contaminated results, increased patient safety, and increased interdepartmental understanding and cooperation.

Diagnostic laboratory testing has been reported to be critical in 60% to 70% of diagnosis and treatment decisions [1,2]. Unfortunately, errors can occur within the total testing process, commonly divided into preanalytic, analytic, and postanalytic phases of testing [3]. The preanalytic phase includes clinician test selection, test ordering, patient preparation, patient and specimen identification, and specimen collection and transport [3] and is the phase in which the greatest number of errors occur [4]. The postanalytic phase includes turnaround time, critical value reporting, report formatting, general results reporting, clinician interpretation and follow-up, laboratory interpretive consultation services, and specimen storage [3]. In the postanalytic phase, good communication between clinicians and medical laboratory professionals is necessary to ensure quality of care [5]. However, a national status report on laboratory medicine in 2009 reported a lack of formal training of clinicians or laboratory professionals in effective communication [3]. Further, Simundic noted a wide variability in the criteria and method for rejecting sample results due to suspected errors occurring in the preanalytic phase of testing and no standardized policies [4].

Medical laboratory scientists are required to watch for patterns that can suggest a compromise in the integrity of a patient sample, thus affecting the accuracy of those test results. Four possible scenarios may occur every time a patient sample is analyzed and evaluated by the laboratory scientist: (1) contamination present but unrec-
COMMUNICATING TEST RESULTS

Table. Criteria Used to Assess Patient Samples for Possible Contamination

<table>
<thead>
<tr>
<th>Contaminant</th>
<th>Detection and/or Correction</th>
</tr>
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<tbody>
<tr>
<td>EDTA*</td>
<td>No K result or very high K result, eg, K &gt; 14.5 mmol/L</td>
</tr>
<tr>
<td></td>
<td>Very low Ca and ALP</td>
</tr>
<tr>
<td>Dextrose IV*</td>
<td>Very high glucose result when all previous glucose results are normal or consistent</td>
</tr>
<tr>
<td>Saline IV*</td>
<td>Increased Cl, normal Na, low or critical low K</td>
</tr>
<tr>
<td></td>
<td>Hematology/coagulation also may be affected</td>
</tr>
<tr>
<td>Dobutamine IV</td>
<td>Creatinine &lt; 0.1 mg/dL</td>
</tr>
<tr>
<td></td>
<td>Request a recollected specimen after dobutamine infusion is completed</td>
</tr>
<tr>
<td>HA fluid*</td>
<td>Specimen lipemic and cannot be cleared by airfuge</td>
</tr>
<tr>
<td></td>
<td>Increased glucose, K when previous levels were normal</td>
</tr>
<tr>
<td></td>
<td>Hematology may be affected with increased MCV and decreased MCHC</td>
</tr>
<tr>
<td>Sodium citrate*</td>
<td>Calcium decreased by 50% and critically low, sodium increased by 5 mmol/L, chloride decreased by 10 mmol/L from previous, and AGP increasing to ≥ 30-40 mmol/L in absence of DKA</td>
</tr>
</tbody>
</table>

Note: Check to see if the specimen was collected by a nurse or was collected from an IV line. AGP = anion gap; ALP = alkaline phosphatase; Ca = calcium; Cl = chloride; DKA = diabetic ketoacidosis; EDTA = ethylenediaminetetraacetic acid; HA = hyperalimentation; K = potassium; MCHC = mean cell hemoglobin concentration; MCV = mean cell volume; Na = sodium.

*Check for second red-top tube. If yes and not affected, repeat results and send corrected report. Otherwise, report contamination to nurse or physician and request a recollected specimen.

recognized (false-negative), (2) contamination present and identified (true-positive), (3) no contamination present but suspected (false-positive), and (4) no contamination present and recognized as a quality sample (true-negative). The first and third scenarios can result in error and potential patient harm. In our institution, investigation of a critical result led to important system changes in our laboratory and communication practices. This article reports on our root cause analysis, methodology, and outcomes.

PREVIOUS LABORATORY PROTOCOL

Delta checks are a technique in which a patient’s test results are compared to his previous results within a predefined length of time [6]; if the differences are significant, then the newer specimen is “flagged” [6]. Delta checks can be used to identify changes in a patient’s condition and to identify sample quality issues, including wrong order of draw, wrong specimen submitted, delay in transport, heme concentration/dilution and mislabeling. The laboratory staff at this institution utilized a checklist to assess for the presence of possible contaminants (Table). If the criteria for suspected contamination was met, the laboratory staff could request a specimen recollection without disclosing the actual results to the clinician. The policy was based on the concern that patient care could be compromised and harm result if treatment was initiated based on an erroneous contaminated result. In such cases they entered the word “Canceled” into the EMR.

CASE REVIEW

Our quality assurance officer is tasked with reviewing critical results. As a result of a patient’s critically high potassium level upon readmission, she investigated the history:

A middle-aged chronically ill male with diabetes and dialysis-dependent renal failure presented to the ED from a residential long-term care facility with complaints of altered mental status, lethargy, and vomiting. Admission laboratory samples (day 1, 22:49) were obtained, and the initial metabolic panel revealed potassium 4.7 mmol/L, bicarbonate within normal limits, glucose 132 mg/dL, and an anion gap of 22 mmol/L. The patient had a 12-hour stay in the ED as his altered mental status was determined to be secondary to the side effects of sedating pain medications, and overnight observation was indicated.

The patient gradually improved to baseline status but subsequently began vomiting again. With the emesis being positive for blood, the differential diagnosis was expanded to include gastrointestinal bleeding versus a less serious gastritis. A pre-discharge metabolic panel was ordered, drawn by a phlebotomist and sent to the lab for analysis (day 2, 14:32). The test results were deemed by the medical laboratory scientist to be significantly abnormal, and most likely contaminated by an external agent. Per the laboratory policy, the laboratory staff determined the results to be neither valid nor reportable, and all tests on those specimens were marked as
"canceled" and a sample redraw request was noted in the electronic medical record (EMR). A call was made to the unit clerk with the expectation that the “canceled” status would be communicated to the clinician in charge of the patient’s care. The status was posted in the EMR, with no explanation given for cancellation. Multiple attempts by the clinician to recollect the samples were unsuccessful due to poor venous access and patient refusal.

The patient’s condition significantly stabilized, his mental status returned to baseline level of function, and the patient was discharged to the long-term care facility. Within 2 hours of discharge, the patient was transported back to the ED with increasing lethargy and diabetic ketoacidosis. The patient suffered a brief cardiopulmonary arrest after arrival and had successful return of spontaneous circulation with prompt and aggressive resuscitation by the ED team. An intraosseous line was established. Blood samples from this site (day 2, 22:40) revealed glucose 664 mg/dL and potassium 5.7 mmol/L. The patient remained hypotensive despite resuscitation with 7 L of intravenous fluids. He was subsequently transferred to an intensive care unit on a ventilator. He subsequently required tracheostomy, but slowly improved and was later able to return to the long-term care facility.

**EVENT ANALYSIS**

Members of the departments of emergency medicine, pathology and laboratory medicine, and performance improvement met to conduct a systematic review of the event and associated relevant policies and procedures. A root cause analysis was conducted (Figure 1), and the root cause was identified as the laboratory policy which directed the laboratory staff to request a redraw for samples yielding highly abnormal results, presumed to be secondary to contamination. No direct communication of the suspected contamination results to the provider was required. Contributing factors included (1) the laboratory label “canceled” in the EMR did not have the same meaning to the bedside clinician as it did to the laboratory staff; (2) a lack of knowledge by the laboratory staff regarding whether a specimen was obtained by a phlebotomist or an ED clinician, with the assumption that the latter was more likely in the ED, and would be associated with a higher rate of sampling error [7,8]; and (3) no documentation of the phlebotomy site, preventing a rule out of a common source of collection contamination (downstream intravenous site, A-line, central line) [9].

A comparison of the pre-ED discharge results with those from the “contaminated” metabolic panel showed the “contaminated” metabolic panel to have been congruent with the patient’s condition at the time: glucose 610 mg/dL, bicarbonate 8 mmol/L, potassium 7.0 mmol/L. These results would have led the provider to suspect DKA and would have prompted more aggressive efforts to redraw blood, place a central line, provide insulin therapy, administer fluids, and admit the patient to the hospital. However, results were not made available to the clinical provider, per laboratory protocol, secondary to the belief that the specimen was contaminated. The medical laboratory scientist independently made the determination based upon test result patterns that were markedly different from those previously available. In the EMR, the clinician could only see that the specimen was “canceled,” but not the reason.

The bedside clinicians interpreted “canceled” as indicating “no testing was done,” “no sample arrived,” “specimen was lost,” “we could not obtain a result,” “someone else canceled it,” “it was clotted,” or “it was grossly hemolyzed.” The clinicians did not realize that actual specimen results were, in fact, being generated and interpreted by medical laboratory scientists for specimen validity but they were not discussing it with them. A further historical barrier was that even in the case of a true critical result, the lab staff often found it difficult to identify the patient’s ED clinician to effectively deliver the questionable result in a timely fashion. Only the need for a specimen recollect was communicated to an ED clerk, rather than discussion of any results with the clinician responsible for patient care.

**NEW PROTOCOL**

The major transformational change that resulted from this review was to remove the unit clerk from the line of communication, and the additional requirement of direct communication between the laboratory scientists generating the lab test results and the clinicians in immediate need of those results. ED Tracker software application (Awarepoint, San Diego CA) was added to 4 computers in the core laboratory. This, plus wireless phone technol-
Figure 1. Ishikawa (fishbone) diagram of root cause analysis.

Communication Test Results

**Environment**
- Production pressures
- Discharge plan
  - LTC accepted patient
- Patient return to baseline
- Lengthy LOS in ED
- Complex environment

**Discharge Process**
- Lab tests cancelled
  - No patient advocate
  - Lab redraw not ordered
- ED treats acute condition
- ED not manage chronic illness

**Episodes of Care**
- Complex medical Hx
- Unable to participate in care
- Refused IV access
- Chronic illness
- ESRD DM
- Lack of patient focus
- Difficult to manage

**Culture**
- Bias in lab communicating contaminated results
- Bias in ED regarding substance abuse
- Bias ED labs less pure

**Personnel**
- Staff not aware of lab process
- Lack of initiation of IV therapy

**Process**
- Inadequate plan of care
- Human error

**Handoff Variations**
- Multiple provider handoffs
- Incomplete handoffs

**Handoff**
- Complex process
- High risk area
- Numerous redraws
- Patient dissatisfier

**Technoogy**
- Lack of flag/alerts for the providers
- Assumptions: a canceled lab means no results/specimen hemolyzed

**Power Chart**
- Documented as canceled
- Lab terminology
- POC and metabolic panel 5 hrs apart

**Failure to communicate contaminated lab test results**
- No order for RTC POC glucose

*Assumptions:* a canceled lab means no results/specimen hemolyzed

- Lab tests cancelled
- Lab redraw not ordered
- ED treats acute condition
- ED not manage chronic illness

- Complex medical Hx
- Unable to participate in care
- Refused IV access
- Chronic illness
- ESRD DM
- Lack of patient focus
- Difficult to manage
ogy (Vocera, San Jose CA), allowed the laboratory staff to identify the ED clinician caring for each individual patient, enabling rapid and direct lab staff-to-clinician interaction. The laboratory scientist now verbally provides preliminary results, articulates concern that the specimen may be contaminated, and requests consideration of re-collecting a new specimen to the clinician who is at the bedside caring for the patient. Software changes were also implemented to document contaminated specimens in the laboratory computer system and the EMR as “ALERT” rather than “Canceled.” Figure 2 shows the EMR view available to the clinician, with the ability to review the specific results found, information regarding possible specimen contamination, and the request to consider repeating the test if clinically indicated. The EMR also includes documentation of the name, time, and date of the clinician consultation. Laboratory policy and standardized processes were revised to integrate the laboratory staff’s new responsibilities for management of contaminated specimen results and direct communication of those results to assigned clinicians (Figure 3). The hospital’s system-wide clinical staff were educated regarding the revised communication and documentation methods utilized by the laboratory staff regarding contaminated specimens. Tours of the laboratory and ED were conducted by leadership from both departments for staff to enhance interdepartmental understanding.

**MEASUREMENT**

This event raised the question of the accuracy of the criteria used to assess patient sample integrity, as well as the unilateral protocol exercised by the laboratory staff in cancelling all testing when the patient sample is suspicious for contamination. From implementation of the new ALERT system on 16 Nov 2011 to 31 Mar 2013, there were 307 perceived contaminated specimens identified by the lab staff: 282 were determined by clinician and lab staff to be contaminated and 25 specimen results were requested to be posted by the consulting clinician. Sixteen of these 25 specimens were confirmed to be contaminated upon subsequent testing. Nine of the 25 specimens were proven to be not contaminated but due to the patient’s condition (including 3 where the patient died). Therefore, 96% to 97% of samples suspected as being contaminated were confirmed as such.
thus affirming the accuracy of the criteria being used by the laboratory scientists (Table 1). Three percent to 4% of samples were proven not to be contaminated but were due to the patient’s condition. No adverse events related to contaminated specimens were recorded during this time period. The leadership of the ED reported improved physician satisfaction with the new process, as the providers appreciated being informed earlier and having the opportunity to share in the decision-making with the laboratory scientists.

**DISCUSSION**

Rapid and accurate communication of critical laboratory test values is of critical importance and is an important safety goal [10–15]. Christiana Care Health System’s “Focus on Excellence” program has patient safety as a
This collaboration leads to better patient care when the appropriate and changes are appreciated and evaluated in being directly communicated to the treating clinician as of the evaluation criteria used to assess patient samples for and mitigating harm to patients. The accuracy and utility ing process, ultimately leading to the safest possible care evaluating that data, completes the circle of the total test care. Directly involving the medical laboratory profes more than ever as leading to the most effective patient results in the light of the patient’s condition is appreciated pret them using established objective criteria. Viewing the testing on all patient specimens, review results, and inter now realize that the laboratory staff routinely perform of one another’s work environments. The ED clinicians tion’s laboratory and ED staffs have a better understanding erate” for call center systems of notification [23].

Based on his review of ED cases, Cosby recommended a framework for establishing patient safety practices that included focusing on teamwork and communication to reduce diagnostic errors [16]. In a systematic review of 94 studies of patient safety practices involving improvements for patient diagnosis, McDonald et al [17] found 29% of studies utilized interventions with additional steps for interpreting/reporting test results. A change in feedback systems and/or technology-based systems was completed in 44% of studies, and 9% of studies involved implementation of educational strategies to achieve improved patient care. Specifically, McDonald et al cited 4 studies that included an evaluation of real-time notification of ED staff concerning critical laboratory testing results [18–21]. Evidence from another systematic review of 11 eligible studies (of 196 publications dealing with critical value communication), done using laboratory medicine best practices review methods [22], summarized the overall strength of evidence as “moderate” for call center systems of notification [23].

As a result of the steps taken in this case, this institute’s laboratory and ED staffs have a better understanding of one another’s work environments. The ED clinicians now realize that the laboratory staff routinely perform testing on all patient specimens, review results, and interpret them using established objective criteria. Viewing the results in the light of the patient’s condition is appreciated more than ever as leading to the most effective patient care. Directly involving the medical laboratory professionals in this process, who are generating and initially evaluating that data, completes the circle of the total testing process, ultimately leading to the safest possible care and mitigating harm to patients. The accuracy and utility of the evaluation criteria used to assess patient samples for possible contamination has been confirmed. Results are being directly communicated to the treating clinician as appropriate and changes are appreciated and evaluated in the clinical context. Treatments are implemented sooner, leading to improved patient outcomes and reduced harm. This collaboration leads to better patient care when the bedside clinician and laboratory scientist communicate and make a shared decision (“sharing the worry”) regarding the validity of questionable laboratory tests.

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REFERENCES
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