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PATIENT SAFETY NETWORK

Critical Opportunity Lost

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The Case

A 55-year-old woman presented to the emergency department (ED) with new onset chest pain. She reported eating a heavy dinner the previous night in celebration of her anniversary. She initially attributed her chest pain to acid reflux, but when the pain persisted, she arrived at the ED for further evaluation. During her ED visit, her symptoms resolved with sublingual nitroglycerine and a "GI cocktail" (an oral antacid/anesthetic combination sometimes used to treat possible reflux), and her electrocardiogram was unremarkable. She felt back to "normal" so the clinicians caring for her in an observation unit arranged for a stress test the following morning.

When the patient arrived for her stress test, she reported feeling well with no further chest pain. Approximately 3 minutes into her stress test, she collapsed and went into cardiac arrest. Resuscitation attempts were unsuccessful. The case was reviewed by the hospital's quality committee, whose members noted that the providers in the observation unit failed to note an elevated troponin prior to discharge. The facility recently transitioned to a new electronic health record and questions were raised about how critical or panic lab values should be managed. Providers felt that a lack of such a system had contributed to the error in this patient's care.

The Commentary

Poor management and workflows in handling important lab results can lead to significant adverse outcomes, particularly when the system fails to quickly identify and notify providers of such results. Critical values are a defined subset of important lab results. Sometimes going under the names of panic values or alert values, they were originally described as "values which reflect pathophysiological derangements at such variance with normal as to be life threatening if therapy is not instituted immediately."(1) Given the importance of such test results, critical values are a topic of great consideration—and often contention—in both laboratory medicine and clinical practice. This case provides an opportunity to review the historical context for defining critical values, available guidelines about best practices, and practical considerations in designing safe systems to manage them.

In the United States, the Clinical Laboratory Improvement Amendments (CLIA) of 1988 require that a clinical laboratory's procedure manual must include a section on "imminently life-threatening test results" when applicable.(2) Additionally, the laboratory must have a protocol for reporting such values to "the individual or entity requesting the test and if applicable, the individual responsible for using the test results."(2) Both the College of American Pathologists Laboratory Accreditation Program and the International Organization for Standardization include specific requirements for critical value policies, communication, and documentation.(3,4) Furthermore, in an effort to improve overall patient safety, The Joint Commission incorporated critical value communications into their National Patient Safety Goal to enhance the effectiveness of communication among caregivers.(5)

CLIA's inclusion of the words "if applicable" may seem peculiar at first. When would having critical values not be applicable in a clinical laboratory setting? How should a laboratory differentiate an individual requesting a test from an individual responsible for using a test's result? Although the regulations mentioned above delineate specific requirements, this language allows the necessary flexibility to optimize a laboratory's policies to an institution's structure, clinical focus, and most importantly, its patient population. Due to patient care, safety, and liability concerns, virtually all clinical laboratories do have critical value policies in place. The content of these policies, however, can differ markedly.

Indeed, there are no national requirements for which specific tests or limits need to be incorporated into a laboratory's critical values list. Many laboratories rely on prior lists that have been revised in practice over time or have developed them around those found in the literature.(6-8) Surveys of clinician knowledge of critical values can help to ensure that the laboratory policies are properly aligned with patient care and operational efficiency.(9) The prospect of developing national standards for critical values is intriguing, but in reality would be difficult to implement effectively across all laboratory settings. For example, many laboratory assays are not standardized across instruments. There is also a dearth of outcomes data for specific critical value thresholds.

With this background in mind, there are several issues from the present case that merit further discussion. While many (if not most) laboratories do have critical value limits for troponin, some may communicate only the first elevated result for a patient within a defined period of time (say, 24 or 48 hours). Such policies help to decrease both the call burden on the laboratory and call fatigue by providers. While it may initially seem surprising, some laboratories have chosen to *not* include troponin on their critical values lists. This is not because elevated troponin results aren't important—obviously they are—but rather because some health systems expect that *every* troponin result should be actively monitored by the ordering clinician in settings in which troponins are ordered. Paradoxically, adding a test to a critical values list can also prolong the turnaround time of result availability, as critical results may enter an electronic queue pending verbal communication versus simply being auto-verified (i.e., released automatically from the laboratory information system [LIS]).(10)

In the present case, the quality committee should review the lists, policies, and procedures that were in place at the time of the incident and then evaluate whether they were followed appropriately. These foundational steps should be completed before suggesting system-wide changes. If troponin was not on that laboratory's critical values list, and relevant stakeholders decided that it should be added, policy changes can be made with appropriate consideration for staffing, resources, and call frequency.

Can electronic strategies be used to improve critical value notification? Current regulations permit the communication of critical values electronically, although confirmation of receipt is still required. Such confirmation may be electronic (e.g., clicking a button that documents the provider accepted results upon receipt) or by completing a telephone call-back to the laboratory. Several such customized systems have been described in the literature.(11,12) Broader implementation will depend on the development of modules that integrate this process into commercially available LIS and/or electronic health record (EHR) distributions.

In theory, a well-designed EHR with automated communication capabilities could augment, or even replace, the traditional system of phone calls for critical results. The success of such systems in managing critical value communications will be contingent on their ability to identify and alert the *correct* provider. This will depend on the maintenance of up-to-date databases of provider contact information, as well as an automated way to identify the *responsible clinical provider* for patients at any given moment. Such mechanisms may differ between inpatient and outpatient settings.

From an end-user perspective, EHRs could then be designed to include displays that automatically alert providers of critical test results if they are currently logged into the system. For example, a pop-up screen might notify a user that a critical result for one of their patients is ready for review, even if the provider is not currently viewing that patient's specific chart. The provider could then review and acknowledge receipt of the critical value. If the provider does not believe that they are presently responsible for the patient's clinical care, they could alert the system that an alternative provider should be reached. Such a system could help track responsible providers in the context of care transitions. It could also be customizable for different user types. Perhaps a charge nurse may want to receive critical alerts for an entire inpatient unit, while a medical resident may want to receive alerts for all patients directly under their care, regardless of location. Additional specificity, including population-specific critical value rules, recommendations for follow-up testing, and benchmarking of communication efficiency could also be incorporated.

For providers who are not logged into the EHR, systems could be designed such that a critical value alert would be automatically sent electronically (via pager or smartphone) using contact information in the provider database. The widespread use of smartphones suggests that secure, electronic critical value communication and acknowledgement can and should be integrated into future EHR distributions. Obviously, backup systems to those described above would need to be in place to trigger traditional phone calls if electronic communications are not completed in a timely manner.

Take-Home Points

- Critical values are potentially life-threatening laboratory results that should be communicated promptly so that appropriate care can be initiated when clinically necessary.
- Institutions should have policies and procedures in place to identify, communicate, and document critical values.
- Customized electronic systems for critical value communication have been developed but are not yet in widespread use.
- Users of electronic health record systems should request that their vendors develop modules for critical result communication.

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