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Occupy Call Street? Reconsidering a Microbiology Critical Action Value Policy

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Abstract

Critical action value (CAV) policies for microbiology test results are regulated by the same mandates that govern critical values for other laboratory testing. Policy revisions and updates are left to the discretion of laboratory directors, in conjunction with their clinical communities. The published literature on CAV policy has limited discussion of infectious disease testing, necessitating the use of other information as a guide. The reconsideration of one's CAV policy benefits from an organized approach and the recognition and reconciliation of different perspectives and resources. A recent experience and considerations for the future are presented.

Introduction

Does your critical action value (CAV) list seem like it should be subtitled "legacy"? Does it no longer reflect all the methods and the menu of your laboratory? Do policies from benchmark institutions look like Mars to your Venus? Does laboratory call volume feel like the "99 percent" instead of the "1 percent"? Any of the above is a good reason to rethink your CAV policy. Here, a recent effort at policy revision is presented against the backdrop of current considerations and challenges. The setting is a microbiology laboratory within a not-for-profit, 496-bed, urban academic medical center caring for adult and pediatric patients. In 2012, the microbiology laboratory reported an estimated 2,000 CAVs, reflecting a 6.9% CAV rate and 5 to 6 calls per day distributed among staff calculated as 30 full-time equivalents. Regardless of inter-laboratory differences, it is hoped that our approach and lessons learned can serve as a helpful primer for others. As a prelude to policy review, some "CAV basics" are summarized below.

Who Has a Say in a CAV Policy?

Several legal and regulatory entities mandate aspects of CAV policy, including the International Organization for Standardization, the Clinical Laboratory Improvement Amendments, the Joint Commission, and the College of American Pathologists (CAP) Laboratory Accreditation Program. Individual states and municipalities may also have mandates or guidelines (1).

In general, laboratories are expected to have a CAV policy that defines critical results and a procedure for defining, executing, and documenting timely reporting. Details can be found in original source documents on organization websites (2-7). They also are cited and summarized in an excellent recent review (1). Before diving into microbiology, it is prudent to check matters of basic compliance, that is, that you have a policy and that it defines by whom and to whom results are reported; the manner and time frame for reporting, readback, and documentation; and the minimum duration of record storage. Notification should also include escalation and fail-safe pro-

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tocols for difficult-to-complete and unsuccessful call attempts, respectively. These basics may be covered by a general institutional policy, your departmental policy, or both, if they are not already one and the same. Also, laboratories should have policies governing quality assurance audits to track and improve performance and compliance and to assess the impact of CAV policy (8,9).

How Often Should a CAV Policy be Reviewed?

Obviously, a CAV policy should be updated in real time as warranted, regardless of the frequency of routine review. For example, the recent CDC guideline (10) for carbapenem-resistant *Enterobacteriaceae* (CREs) may have prompted mid-term consideration for policy amendment. Changes that are required between routine reviews can be a challenge to implement efficiently. It is prudent to have an established process for these ad hoc considerations in order to facilitate effective communication with stakeholders at departmental and institutional levels. For routine policy review, annual or biannual (every 2 years) frequency is usual. For example, laboratories accredited by CAP can infer from current requirements (11) that at a minimum a biannual review of CAV policy is necessary. Of note, a 2007 survey (12) found that only 56% of respondents had an existing policy for establishing, revising, or updating a CAV policy. We should do better than that, given the current regulatory environment and the dynamic effect on critical values imposed by changing clinical care, test menus, resources, and technology.

Thinking About What Critical *is* Before Thinking About *What* is Critical

Does your policy actually say what critical *is*? Having a definition right up front can be a helpful reality check during difficult revision decisions. Including a definition remedies a lack of policy clarity that invites unwanted liability. The origins of critical value reporting (circa 1972) and the contributions of George Lundberg are well summarized elsewhere (1,13). Lundberg defined critical values as a laboratory result value representing "a pathophysiological state at such variance with normal as to be life-threatening unless something is done promptly and for which some corrective action could be taken" (14). Current definitions of critical values mirror the spirit of the original, for example: "Laboratory results that indicate a life-threatening situation for the patient. Because of their critical nature, urgent notification of a critical value to the appropriate healthcare professional is necessary" (1). The CAP All Common checklist (11) notes: "Alert or critical results are those results that may require rapid clinical attention to avert significant patient morbidity or mortality. The laboratory may establish different critical results for specific patient subpopulations (for example, dialysis clinic patients). Critical results should be defined by the laboratory director, in consultation with the clinicians served. Allowing clinicians to 'opt out' of receiving critical results is strongly discouraged."

Which Test Results are "Critical"?

Published literature on CAV policy often excludes microbiology testing (8) or has only a limited discussion of it. The latter option usually involves a table that highlights familiar qualitative common denominators: positive smears for blood cultures, cerebrospinal fluid (CSF), sterile body fluids, acid-fast bacillus (AFB) smears and cultures. Sometimes included, in addition, are positive antigen and molecular tests for CSF, sterile fluids, and surgical tissue and possibly selected enteric pathogens (1,12,14). The establishment of a universal standard is undermined by the great variety of laboratory practices, clinical settings, staffing and call resources, preferences and precedents, and the scarcity of outcome-based data (1,14,15). Individual policies are left to the discretion of laboratory directors, in conjunction with their clinical community, and they serve as useful but variable benchmarks. We are left to re-evaluate and reconcile different and competing interests, opinions, and resources, including changes in diagnostic methods, new pathogens, more vulnerable outpatient populations, limited laboratory call resources, and the risks versus benefits of "de-escalating" existing critical values. In addition, laboratories typically have limited access to clinical information for interpretive context. The clinical perspective can be at odds with that of the laboratory. Finally, there is the ongoing responsibility debate, i.e., to what extent is a provider responsible for checking the results of tests ordered?

Getting Organized

Against this backdrop, one can build, revise, or limit a policy based on several considerations. What is "everyone else" thinking? Previously published lists, practice parameters, and consensus documents have the benefit of having been "refined with the benefit of time, institutional comparison, and clinical performance" (1). However, as mentioned above, they have limited utility for infectious disease testing. Therefore, in addition to polling colleagues by e-mail and on the members-only ASM listserv Clinmicronet (16), I searched the Internet and found several policies (17-19), some from institutions similar to my own. I borrowed a template in which test values were formatted in a chart that, at least for the first draft, included a column noting additional context for each entry, as shown below. (Note that in the following account some examples have been updated to include more recent considerations.) Specific critical values were then reviewed in the context of CAV definition and with regard to the following:

- Clinical pathogenicity
- Infection control or public health concerns (including pan-resistant pathogens)
- Potential biothreat agents (i.e., those on the CDC select agent list) (20)
- Regulatory requirements and important practice guidelines
- Extensive delay between specimen acquisition and final result (i.e., slow-growing pathogens)
- A vulnerable patient population, specific clinical setting, or location
- A finding that implies specific vulnerability (e.g., *Nocardia* spp. or *Pneumocystis jirovecii*)

Based on a first round of review, there was additional scrutiny of the current policy, for example:

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