

# The critical value concept in clinical laboratory

## *O conceito de valores críticos no laboratório clínico*

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### ABSTRACT

The critical value is a laboratory result representing a pathophysiological state that offers risk to a patient's life. The communication of these results is a laboratory responsibility and, according to the literature, 95% of physicians consider it useful in decision-making and patient management. Two-thirds of critical results lead to some change in therapeutic approach. The communication of critical results is a requirement for laboratory accreditation programs. Thus laboratories should establish a list of tests, their critical values, and the procedure describing the communication flow. The performance indicator for this activity should consider the time between results release and their effective communication, and the percentage of successful communication. There is no standardization of laboratory parameters that need to have critical values established, not even the ranges to be considered for notification purposes. The frequent update of test lists and critical value ranges based on literature reviews and on experience exchange among clinical laboratories ensure the continuous improvement process for this procedure and patient safety.

**Key words:** hospital laboratories; patient safety; quality indicators in health care; patient care management; total quality management.

### INTRODUCTION

The importance of clinical laboratories is currently acknowledged in medical activity; around 70% of decisions are taken based on laboratory tests<sup>(1)</sup>. One of the most important functions of a clinical laboratory is the clear, accurate, and rapid communication of a critical value to patient care providers<sup>(2)</sup>.

Most laboratory test results have diagnostic and therapeutical implications that do not require immediate action. However, laboratory findings are sometimes much altered, and may indicate a potentially fatal situation to the patient<sup>(3)</sup>.

The term "critical laboratory value", also known as critical result, panic value, or alert value, was defined by George D. Lundberg in 1972 as a result that represents a pathophysiological state different from normal, which poses risk to a patient's life, unless an immediate action is taken<sup>(1, 4, 5)</sup>. Currently, the use of the term panic value is discouraged, because it suggests emotional stress, and because it runs against the process of communicating information clearly<sup>(2)</sup>.

Critical values generally represent less than 2% of test results at a clinical laboratory<sup>(6)</sup>.

A study comprising 623 health institutions revealed that 95% of physicians consider communication of critical results useful in the management of patients, and 75% document the values in medical records. Two-thirds of critical results lead to some change in the therapeutic approach<sup>(7)</sup>.

The reporting of critical values became a mandatory quality practice in laboratory medicine procedures, especially after the introduction of accreditation and certification programs to clinical laboratories<sup>(8)</sup>.

The communication of critical values is required by several laws, regulations and accreditation programs, as, for example, the International Organization for Standardization (ISO) 15189 of 2007, The Joint Commission (TJC) at the National Patient Safety Goals (NPSG) 02.03.01, the College of American Pathologists (CAP), Organização Nacional de Acreditação (ONA), the clinical laboratory accreditation program of Sociedade Brasileira de Patologia Clínica/Medicina Laboratorial (PALC-SBPC/ML), among others<sup>(9-12)</sup>. And because so far there is not a standardized list of critical values in the medical literature, each institution is expected to draw up its own list<sup>(1)</sup>.

## THE PROCESS OF DEFINING A CRITICAL VALUE POLICY

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The formulation of a list of exams and their respective critical values must be coordinated by the director or the person in charge of the laboratory, based on the type of patient seen by the service, the most prevalent diseases and their pathophysiology, by consensus among the clinical team<sup>(1, 4, 13)</sup>. Thus, it is necessary to conduct meetings with the heads and members of the different clinical and surgical departments, with the hospital administration and with the nursing staff, to define the critical value notification policy, choose the tests to be included in the list, as well as the values that must be reported<sup>(4)</sup>.

It is important to have in mind that very extensive lists or inappropriate critical values – with thresholds requiring excessive notification – may result in information overload, unnecessary work by laboratory staff and a negative attitude towards this important laboratory function by doctors. In their turn, very reduced and exclusive lists – with too high or too low thresholds – might not prevent an adverse clinical outcome and delay decision taking. These situations can be avoided by revision and periodical updating of the critical value list<sup>(4, 13)</sup>.

For the establishment of a list, it is fundamental to consult review articles, previously published lists, or lists available on the internet, from some reference health services, such as the Mayo Clinic (<http://www.mayomedicallaboratories.com/articles/criticalvalues/view.php?name=Critical+Values%2FCritical+Results+List>) and Mount Sinai Hospital ([http://icahn.mssm.edu/static\\_files/MSSM/Files/Research/Labs/Clinical%20Pathology%20Laboratory/CriticalValuesTable.pdf](http://icahn.mssm.edu/static_files/MSSM/Files/Research/Labs/Clinical%20Pathology%20Laboratory/CriticalValuesTable.pdf))<sup>(1, 4, 14-17)</sup>. It is important to highlight that the differences in the cut-off values and the analytes chosen by the different institutions are related to the characteristics of the treated patients – risk levels – and the employed laboratory methods<sup>(6, 14)</sup>.

In general, the lists comprise biochemistry, hematology, toxicology and microbiology tests, both from adult and pediatric patients<sup>(2)</sup>.

## THE REPORTING PROCEDURE

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After establishing the critical value list, it is necessary to describe the conduct for critical values reporting. Currently,

procedures are not well standardized, with great variability among institutions<sup>(5)</sup>.

The first step is the identification of a critical value by the laboratory analyst, either from a pre-programmed warning signal in the equipment or from the laboratory information system itself. In the written procedure, it must be clearly indicated if there will be repetitions or some type of result verification before reporting, including the actions that should be taken in manual tests that cannot be repeated, as, for instance, in culture tests – area of microbiology<sup>(2)</sup>.

Pre-analytical problems that may cause false critical results must be of general knowledge. Some of them include sample contamination, inadequate transport conditions, incorrect timing of sample collection (for example, for toxicological testing) and delay in sample processing<sup>(1)</sup>.

The following step will be the communication of this result, which may be carried out by telephone or a computerized alerting system<sup>(14)</sup>. Controversy exists regarding the best reporting method. In several institutions, the standard model for notification of critical values includes the manual process of contacting, either by phone or personally, the attending physician. This is a time-consuming task, which delays the conduction of other laboratory activities, besides resulting in the handoff of information to an intermediary, and increasing the probability of errors and delays in the process of critical value communication<sup>(18)</sup>. Some defend that the use of a computerized alerting system would avoid the potential communication errors, increasing the rate of success and shortening notification time<sup>(14)</sup>.

It is important to define who will be in charge of reporting results. The ideal is that notification is given by the clinical pathologist, because there will be a more rational opportunity to analyze and discuss the case<sup>(1)</sup>. Although it is established that critical values must be reported to a professional capable of acting according to the received information, the lack of general consensus on the professional to be directly informed (doctor, nurse) causes significant variation in the procedures of critical value reporting in the diverse institutions<sup>(19)</sup>.

## REPEAT TESTING OF CRITICAL VALUES

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There are few works in the literature about repeating a critical result for each analyte or for the same patient. According

to Howanitz *et al.* (2006, 2007)<sup>(20, 21)</sup>, analytes as sodium and calcium may be repeated more than once for the same patient. However, there is no consensus on which laboratory tests are prone to repetition of critical values, and there is little data on the distribution of these values. Besides, there is no data comparing clinical outcomes between patients that have more reported critical values and those with just one reported critical value. Yang *et al.* (2013)<sup>(22)</sup> investigated the occurrence, the distribution of repeat critical values, and the relationship between the frequency of these values and patient outcomes, in order to provide hospitals with information on improving policies of repeat result. They verified that all the assessed items were prone to repetition; on average each patient had two occurrences of repeat value, with median interval time of 8 hours. For patients with repeat critical values of potassium and platelets, a longer period of hospitalization was verified, with a worse outcome<sup>(22)</sup>.

According to the norm ISO 15189:2007 and the College of American Pathologists (CAP) accreditation program (GEN 41330), reported critical values must be documented, with date, hour, laboratory analyst, professional notified and the reported result. Any difficulty to fill these data must be recorded and revised during audits<sup>(9)</sup>. At the end of each month, a report must be produced with the respective critical analysis and possible improvement actions to maintain or increase the performance level of critical result communication.

Another important requirement, according to the Joint Commission on Accreditation of Healthcare Organizations, is about the receiving healthcare professional: this person must read back the test result, that is, confirm the received result and inform the patient's identification. At last, critical value reporting time must be measured<sup>(5)</sup>.

## REPORTING ASSESSMENT

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Laboratories are responsible for detecting life-threatening results, reporting them to healthcare providers, as well as monitoring and improving the time of reporting and receiving critical values<sup>(8)</sup>.

The indicator in the critical value policy is the response time, defined as the time elapsed between the moment a professional identifies the test with a critical value and the moment he or she

contacts the ordering physician or the team in charge of taking the appropriate measures to reduce or avoid adverse events, evidenced by the increased morbidity or mortality, in case there is no timely intervention<sup>(1)</sup>.

Each laboratory should determine its own reporting time, because variation exists both among institutions and in the literature. A CAP Q-Track study of 180 institutions, conducted in 2007, obtained a mean time for report a critical value around 6.1 minutes for inpatients and 13.7 minutes for outpatients<sup>(5)</sup>. Another study by CAP, carried out in 2008 with 121 institutions, obtained a median time of 4 minutes for reporting of a critical value, and 96% of them included the read-back<sup>(6)</sup>. However, a study comparing effectiveness of the reporting process between telephone call and the computerized alerting system demonstrated a larger variation, reaching approximately 30 minutes in the telephone call system and 11 minutes in the computerized notification, with 50.9% and 10.9% of unsuccessful notifications (more than one hour), respectively<sup>(14)</sup>. According to CAP, critical value reporting within 15-30 minutes after testing would be a reasonable target for most inpatient settings<sup>(6)</sup>.

In order to decrease the rate of unsuccessful notifications it will be necessary to ensure the control of reporting time, enable faster procedures, avoid communication errors (absence of read-back), and decrease reporting obstacles and difficulties in finding the responsible clinician<sup>(6, 14)</sup>.

## CONCLUSION

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Establishing an effective policy of critical value reporting, besides being fundamental for patients treatment and safety, must be considered an opportunity for closer cooperation between pathologists and the medical staff. It should not be seen as just another requirement of accreditation programs, but a way for the laboratory to ensure patient-centered care.

With the development of new computerized reporting methods, new communication procedures will appear, and notification time will decrease. For the moment, a standardization of the procedures for reporting critical values is necessary to enable comparison among clinical laboratories, and the creation of international quality norms.

## RESUMO

*O valor crítico é um resultado laboratorial que representa um estado fisiopatológico de risco à vida do paciente. A comunicação desses resultados é de responsabilidade do laboratório e, segundo a literatura, 95% dos médicos a considera útil na adoção de condutas e no manuseio dos pacientes. Dois terços dos resultados críticos resultam em alguma mudança na conduta terapêutica. A comunicação dos resultados críticos é um procedimento previsto nas listas de verificação dos programas de acreditação laboratorial, portanto o laboratório deve estabelecer a lista dos exames, os respectivos valores críticos e o procedimento, descrevendo o fluxo de comunicação. O indicador de desempenho para esta atividade deve considerar o tempo decorrido entre a liberação do resultado e a sua efetiva comunicação e o percentual de sucesso na comunicação. Não existe padronização acerca dos parâmetros laboratoriais que necessitam ter valores críticos estabelecidos, nem mesmo os intervalos a serem considerados para fins de notificação. A atualização frequente da lista de exames e dos intervalos de valores críticos com base na revisão da literatura e na troca de experiências entre os laboratórios clínicos garante o processo de melhoria contínua para esse procedimento e a segurança do paciente.*

*Unitermos: laboratórios hospitalares; segurança do paciente; indicadores de qualidade em assistência à saúde; administração dos cuidados ao paciente; gestão de qualidade total.*

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