REVIEW ARTICLE

REPORTING CLINICAL LABORATORY CRITICAL VALUES: A FOCUS ON THE RECOMMENDATIONS OF THE AMERICAN COLLEGE OF PATHOLOGISTS

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Background: Reporting critical values continues to receive a widespread attention from health care givers as it symbolizes a crucial clinic-laboratory link. This is because healthcare providers did realize the importance of prompt and timely communication of the critical results, which have positive implications on patient safety and treatment outcomes. In addition to physician and nurses, patients are also recipients of critical values, where they can make informed decisions prior to clinical intervention. The College of American Pathologists (CAP) requires stringent policies for reporting critical values in all laboratories, including adoption of a robust quality assurance system. Research studies have indicated that there still no universally accepted critical values list. This is because of various factors; such as differences in institutional organization, patient population, clinical demand, staffing, and instrumentation. However, through collaboration with other stakeholders involved in the delivery of healthcare, lab professionals may be able to come up with a realistic critical values list that reflects on the local needs and dynamics of patients' service.
Conclusion: This review offers an insight into the process of reporting critical values, some challenges encountered, as well as the policies and procedures of effective reporting with a particular focus on the guidelines of the College of American Pathologists. There should be a common global guideline introduced by the health care governing agencies to be adapted with some flexibility in clinical laboratories in different clinical settings.
Keywords: Critical values; Reporting; Guidelines; CAP

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INTRODUCTION

Reporting of critical values has continued to receive a widespread attention because of its importance in healthcare service. Timely and accurate reporting helps in supporting decision-making, improving patient safety and promoting positive treatment outcome.[1] Hanna, *et al*[2] define a critical value as a laboratory result suggesting a patient is in imminent danger unless the practitioners promptly initiate appropriate therapy. Bill Malone[3] gave a more comprehensive definition, stating that critical values signify a pathophysiologic state that is life threatening; or could result in irreversible harm, mortality or significant patient morbidity, and thus requires urgent medical attention.[3] In order to enhance the effectiveness of critical value reporting process, the laboratory and the health care organization need to understand and address all the variables involved during the process. Whereas regulatory, certification and accreditation bodies require laboratories to adhere to various procedures in order to ensure patient safety, guidance on best practices is limited.

The College of American Pathologists provides guidance on policies and procedures to follow during the reporting of critical lab values and results. These policies and procedures focus on the identification of critical values and the notification processes, including the use of telephone calls and call centres in reporting. They also call for the establishment of escalation policies to deal with situations where clinicians do not acknowledge receipt of the results. Apart from the policies and procedures, the CAP also has a critical values list that can guide practitioners to understand some tests that may require immediate attention. Nevertheless, some institutions continue to encounter problems in reporting of critical values. Addressing such problems can help improving patient outcomes. Moreover, providing some case scenarios will aid to create a better understanding of the real world critical values reporting.[4]

The process of critical test results communication is known to be so heterogeneous amongst clinical laboratories.[1] which requires establishment of generic policies and procedures that could be adopted globally. In this regard, the College of American Pathologists has set up various policies and procedures for reporting critical values. These policies cover a variety of areas including establishing critical values lists, escalation policies and notification procedures. Hanna, *et al*[2] confirmed

that the first step in communicating critical values is the identification of abnormal results by a laboratory specialist. For automated assays, the middleware instrument or LIS will alert the laboratory staff about the critical values. In most cases, the staff is the performing technologist. As the College of American Pathologists acknowledges, laboratory policies must indicate clearly whether the assay needs to be repeated and/or verified before reporting. If this is the case, the policies should indicate the timeframe for repeating or verifying the test results. Laboratory policies also need to indicate who reports the critical results and to whom.[2] In many laboratories and hospitals, the people charged with the responsibilities of receiving and acting upon critical values include any licensed caregiver, on-call physician, ordering physician or resident. However, other laboratories also permit administrative personnel such as ward clerks, unit secretaries and receptionists to receive critical results.[3]

According to Howanitz, *et al*[4], the CAP also acknowledged that policies should indicate the timeframe between the availability and the reporting of the critical results. Also, documentation of critical results is a crucial procedure in the reporting of critical values. The CAP specifies that information such as; date, time, person notified, and responsible laboratory specialist needs accurate documentation during the process. It is also important to mention that the CAP requires the establishment of an escalation policy particularly when dealing with automated solutions for reporting critical values.[4] As Campbell and Horvath, 2014[5] mentioned, the purpose of the escalation policy is to ensure communication of the critical results in instances where clinicians do not acknowledge receipt. The authors reported that such a policy can direct the lab technologist to contact a medical director, pathology resident and/or supervisor to assist in the critical value notification.

The CAP also provides some guidelines on reporting of critical values via telephone. It has been reported that the major advantage with the telephone call is that the individual receiving the critical test results can be able to read back the result to the lab specialist who can confirm and provide immediate explanation, if required.[6] The CAP requires all laboratory policies to comply with this requirement. Through the read-back policy, the practitioners can be in a better position to minimize errors. The approach that the CAP suggests for reporting critical laboratory results via telephone is stating the patient's name, time of sample collection, critical results, reference range and the units of measurement.[4] The next procedure is asking the recipient on the phone to repeat the name of the patient and the critical results, followed by verbally correcting any errors, and repeating the request for a read-back. The last procedure in telephone reporting is making a proper documentation. The flowchart (Figure-1) summarizes the overall process from identification of results to the reporting of critical values.

The College of American Pathologists provided a succinct list of critical values that many institutions identify as those results that require immediate attention. Some of the critical values identified by the College of American Pathologists include Hematocrit ≤21% or ≥65%, Hemoglobin ≤7 or >21.0 g/dL, Platelet Count ≤20 or ≥ 1000×10^3 /μL and white blood cell Count ≤20 or ≥ 40×10^3 /μL.[7] Other important critical values that the CAP identified included bacteria in bone marrow or cardiac fluid specimen, crescents in kidney biopsy, organisms in tissue specimen, transplant rejection, unexpected malignancy, acid-fast bacilli in any specimen, and bacteria in CSF.[7] The critical values list according to the CAP should also include tests, where there is a disagreement between the preliminary and final results.[8]

Although a widespread agreement exists on the need to include abnormal coagulation tests in the critical limit list of haematology, there is a wide variation in reporting coagulation tests and no uniformity is observed. The CAP also acknowledges that other common coagulation tests such as thrombin time, D-dimer and fibrinogen also do not find a consensus on inclusion in haematology critical values list.[7,9]

Dighe, *et al*[8] performed an extensive analysis to highlight the reporting of critical values at their institution, which is a large academic medical centre in an urban setting. The authors reported the analysis of 37, 503 successive laboratory critical values spanning a period of 12 months. They evaluated critical value reporting through a variety of parameters including: laboratory specialty; clinical care area; patient type; day time; test, and critical value limits. The researchers stated that the issue of patient safety has provided immense incentive for accurate and prompt critical value reporting.[8] According to the authors, many of the provisions governing critical value reporting, including those of the CAP, require health care centres to track and improve the receipt of critical test results by responsible and licensed caregivers. In addition, the CAP has expanded the definition of critical values to encompass, not only laboratory results, but also electrocardiograms and imaging studies. During the study period that spanned 12 months, the haematology and the chemistry laboratories at the medical centre reported 37, 503 critical values. In the same period, the laboratories reported over 14 million test results. Hence, the tests that had critical values

represented about 0.25% of the total results reported.[8] This research concluded that the outpatient critical values often present various challenges particularly those related to timely reporting to clinicians. The problems that the authors identified in this regard included missing or illegible ordering provider information, and heterogeneity of the outpatient population.[8] The researchers proposed that the implementation of appropriate communication technology can play an important role towards the challenges facing the reporting of the outpatient critical value.[8]

Campbell and Horvath[10] made a similar emphasis, stating that critical results must include diagnostic tests performed in the departments of cardiology, radiology and anatomic pathology.

Bill Malone[3] also identified some challenges associated with critical value reporting. According to the author, one major challenge that confronts lab professionals is the volume of forgotten call-backs and the volume of unanswered pagers from physicians. The author reiterates that in the rapidly changing IT environment, laboratory results now compete with a plenty of alarms that physicians encounter throughout their day. He concluded that a valid way of improving communication around the critical values reporting is for physicians and laboratory staff to work together in pushing for comprehensive and smarter IT solutions that close the gap on follow-up for abnormal results and critical values.[3] In agreement with this proposal, it has been reported that if lab professionals wish to enhance communication with physicians, they must adopt a broader approach of results reporting.[10]

In a similar context, Genzen and Tormey[11] also conducted an extensive review to ascertain best practices in critical value reporting. According to the authors, laboratory professionals and pathologists often face numerous obstacles in reporting critical values.[11] Some of the major challenges that the scholars identified included: establishing clinically relevant guidelines for critical values, and difficulties in locating order provider after obtaining a critical value, and ensuring that providers understand the implications or severity of a critical result. The researchers also narrated that information overload, and the resultant communication breakdown could have adverse effects on patient's care outcomes. Additionally, Singh and Vij[12] in their investigation of EMR-based notification system within the Veteran Affairs (VA) Department, have found out that 8% of abnormal imaging results, and 7% of abnormal laboratory results lacked timely follow-up, in spite of evidence of transmission to providers.[12] Failure to document the disclosure is thus another problem that many laboratories and hospitals face when reporting critical values.

Genzen and Tormey[11] in their extensive investigation, have provided some advice that might be helpful in enhancing the effectiveness of critical result reporting. The authors recommend that laboratories should work in harmony with physicians and other concerned stakeholders to develop holistic approaches for reporting of critical test results. They also mentioned that in order to boost the reliability and efficiency of critical test result reporting, it is essential to validate the list of critical values and use peer comparison during the process. In addition, it is necessary to make the reporting process more efficient through examining repeated testing, reducing false positives and improving middleware.[6]

From a different prospective, Campbell and Horvath[10] confirmed that the concerned stakeholders can make the process more reliable through decreasing handoffs, using a tier system of alerts and investigating "repeat calling policies". Furthermore, in order to make the reporting process much safer, it is crucial to link laboratories and pharmacy data, establish clear escalation policies, detect failures to acknowledge results, and share results with the patients. Campbell and Horvath have also highlighted the importance of harmonization in this respect. According to the authors, the first step towards successful harmonization is having a heightened understanding of the current laboratory practices.[10]

Various recommendations have been provided for practices and policies of communicating abnormal test results. Before proceeding to offer their proposals, the authors argued that policies and procedures for critical value reporting should be "evidence-based". The first recommendation by the researchers emphasized on the importance of clear definitions to ensure a common understanding among users.[12] Other recommendations provided by Singh and Vij[12] requested the need to develop policies to outline provider responsibilities clearly, specify acceptable length of time between reporting and ordering of critical values, specify the preferred patient notification mechanisms, write policies with input of key stakeholders, and establish responsibilities for evaluating communication procedures. Another study.[2] has reported that potential solutions to the problem of reporting would need to address information transfer, teamwork, improvement of interpersonal skills, and all other fundamental system factors associated with patients' safety.

It has been also reported that due to their increasing popularity and widespread usage, call centres and automated communication systems have become important tools that can aid in improving critical results reporting.[11] Call centres are also important for enhancing coordination between laboratory specialists and physicians, the authors added. Many studies favour the use of call centres over the automated notification

systems.[2,5,13] Of note, the automated notification systems are computerized reminders or alerting systems that use mobile phones, emails, pagers, or other personal electronic devices for alerting the responsible health care practitioner about critical results of laboratory tests. Upon receiving the automated notification, the concerned person acknowledges the receipt of the alert and confirms the critical test result receipt. Call centres, on the other hand, utilize a centralized communication unit for reporting critical lab test results through telephone calls to the responsible caregivers. In instances where the responsible caregivers are unreachable within a specified timeframe, the call centres will try to reach other alternative caregivers.

Quite recently, Piva and colleagues[14] conducted a comprehensive study to examine the effectiveness of computerized notification systems in enhancing critical values reporting. Many accreditation requirements including those advocated by the College of American Pathologists mandate clinical laboratories to undertake assessments and initiate appropriate measures for improving the timeliness of reporting and prompt receipt of critical values by responsible caregivers. The research by Piva and colleagues[14] revealed that computerized notification systems were, indeed, helpful in the reporting process. As the researchers admit, such systems bolster the timeline of reporting and mitigate potential errors related to the read-back of results. With respect to the above discussion, delay in reporting critical values was recently reported in a Turkish study[15] indicating the need to overcome this challenge to improve healthcare and patient's health expectancy.

In the same context, improving the effectiveness of call centres is a very important step. Hanna and colleagues[2], in their inquiry, came up with some recommendations for improving the effectiveness of these centres. The authors reported that it is essential to assign responsibility and accountability for the administrative control and accuracy of call schedules to the medical staff and the call centres. Another recommendation is that, in centralized systems, call schedules need to be input and sent by the call centres only. Campbell and Horvath[5] supported these assertions, adding that the call schedules must also be legible, typed using full names of the providers, and coordinated with answering services in order to validate accuracy. Monitoring the effectiveness of the system is yet another important aspect that can improve the efficiency of critical values reporting. When monitoring, it is necessary to validate that the call schedule list at the call centre is the most current, and that users assign coverage 100% of the time.[2] This should entail conducting periodic tests for validating acknowledgement process or "accepting coverage" process, for example, beeper/pager check. Murari[16] stated that validating the accuracy of contact information with the answering services of the physician as well as validating accuracy of the provider access information and gathering data about delays in the notification systems are also important components of effective monitoring.

Introducing standardized terminology for naming critical value categories (for example red, orange, yellow categories) to highlight the immediacy of the test result can also help in streamlining of automated systems and call centres to respond effectively.[2] Red zone values should indicate that the patient is in imminent danger of morbidity, serious adverse effects or death unless immediate treatment is initiated. The orange category values, on the other hand, should indicate significant abnormalities that need rapid, but not immediate, intervention by the responsible clinician. Whereas, the yellow category values should indicate significant abnormalities that are, nonetheless not life threatening. It has been also indicated that when using the automated systems, it is also important to take into account the patient privacy requirements. This is because data might conceivably be stored or transmitted in unencrypted devices.[11] Also, existing literature reveals that a number of personnel can receive critical results.

In a study investigating critical value reporting at laboratories in Egypt, Mosallam and Ibrahim[17] sought to determine the policies and practices governing the reporting of critical values. The design utilized by the researchers was a cross-sectional descriptive study, with subjects coming from inpatient divisions of laboratories in Alexandria hospitals.[17] The researchers collected data using a questionnaire that consisted of four sections. Section one explored laboratory and hospital characteristics, while section two assessed the procedures and policies of critical value reporting at the health care establishments. Section 3 explored the reporting process, and section 4 explored the ranges of critical values of selected common laboratory assays. The results of the study revealed very intriguing results. Essentially, there emerged some significant variations in the practices or policies of critical values reporting among the investigated laboratories.

For instance, Mosallam and Ibrahim[17] found out that a written procedure for critical value reporting was present in 77.5% of the laboratories and that 72.55% of the laboratories had a comprehensive critical values list. For the laboratories that had a list of critical values, the number of tests ranged from 7 to 40. Approximately 60% of the laboratories had policies for assessing reporting timeliness and 75% stated that their laboratory policies require a feedback on receipt. In 75% of the laboratories, the person responsible for reporting critical values was the hospital laboratory physician, followed by the lab technician. Nurses and physicians ordering the test mainly receive the tests,

with 67.5% and 55.0%, respectively, while the major channel of reporting was telephone (67.5%). Mosallam and Ibrahim reported that only 10% of hospitals utilized wireless technology in reporting of the critical values. In this study, the researchers came up with some practical recommendations.[17] The study revealed that hospitals and laboratories with clear policies or procedures for reporting registered high response time and improved patient outcomes. Therefore, the researchers proposed that it is important for hospitals and laboratories to adopt clear policies and assign responsibilities in order to enhance the effectiveness of the process. They also added that having comprehensive lists of critical values can be useful.

In another study, Howanitz and colleagues[4] examined the procedures governing the identification of critical values in laboratories. The objective of this study was to investigate critical values lists in the 623 institutions that were participating in the Q-Probes program at the College of American Pathologists.[4] The design was a multipart study, whereby the participants responded to information generated from pre-printed lists, completed a questionnaire, collected information on current practices, monitored critical values calls, reviewed medical records of patients, and surveyed nursing supervisors about critical values. The main outcome of the investigation by Howanitz and colleagues was the ability to define critical values systems, including: lists, processes, costs, personnel, usefulness, and other related medical outcomes. To obtain the results, the researchers determined the critical values lists for routine haematology and chemistry analytes. Findings revealed wide variations in the lists among the participant laboratories.[4]

Over 95% of the participants in the study[4] have reported positive cerebrospinal cultures, toxic therapeutic drug levels and positive blood cultures as critical values. Based on over 13,000 critical values, data from the participants revealed that persons who performed the test made the most critical values reports (92.8%). In addition, nurses received most of the reports for inpatients (65%), whereas for outpatients, physicians received the highest percentage (40%). On an alarming note, this study revealed that the vast majority of participants, representing about 71.4%, did not have a policy on how to handle repeat critical calls. Moreover, the percentage of unexpected critical values was substantially high, standing at 45%. The results also indicated that, whilst 94.9% of the 514 physicians who participated in the study found critical values lists useful, only 20.8% of the 2301 nursing supervisors who participated in the study found the lists valuable. In order to address the problems they found out in the study, the researchers proposed establishment of fool proof policies to report results from abandoned calls, and more efforts should be put towards automation widespread.[4]

McFarlane and colleagues[13] in their investigation also found some variations in the reporting of critical values. This investigation involved surveying Ontario laboratories in order to determine the current practice or procedures for reporting critical values in haematology.[13] The researchers sent the survey to 182 participants, questioning on various issues including sources and levels for establishing critical values, review frequency, reporting and delta checks. Some of the professionals who completed the survey included laboratory managers, technical specialists, supervisors, bench technologists and senior technologists working in haematology. The results were quite captivating; McFarlane and colleagues15 found that the majority of the participating laboratories had established comprehensive critical value limits for platelet counts, leukocytes count, and haemoglobin. Many laboratories also included the presence of blast cells and malaria parasites.[13]

From a different dimension, other laboratories in the study[13] reported, the presence of sickle cells, plasma cells, spherocytes and schistocytes as critical values. The research also confirmed that laboratories relied upon multiple sources to establish a critical value policy. However, variability was obvious in the review frequency of critical values, and the laboratories rarely used delta checks in determining whether a result warrants inclusion as a critical value or not. In conclusion, the researchers reported a lack of consensus on reporting critical values of haematology laboratory tests. In order to address this inconsistency, McFarlane and colleagues reported that standardization of the reporting practice would be significantly beneficial, in particular in haematology.[13]

Likewise, Murari[16] investigated reporting of critical values in haematology. This study, which followed a literature review approach, established finding that were consistent with those by McFarlane and colleagues.[13] The author begins by stating that there is no a universal critical values list. This was also reported by Genzen and Tormey[11] who added that factors; such as institutional organization, patient population, clinical demand, staffing and instrumentation have undermined development of universal standards across laboratories. In addition, Murari[16] mentioned that while the determination of critical values list falls under the mandate of the laboratory director, the process should be collaborative. It should involve input from the medical review board and clinicians who are directly engaged in laboratory services. According to Genzen and Tormey[11], when modifying or establishing a critical values list, the first place to begin is by comparing with practice parameters, previously published lists and consensus documents.

Just like Genzen and Tormey[11], Murari [16] also offered some practical recommendations for improving reporting of critical values. The researcher stated that some important issues requiring further deliberations including consensus regarding inpatient versus outpatient notification and response, acceptance of the critical value reports by clinicians, and response thereon, as well as proper documentation of reporting procedures and routine practice of critical values reporting.[16] The approval of critical values list needs to be done in consultation with the hospital board or clinician's panel.

In calling for harmonization of practices and policies, some researchers; such as Campbell and Horvath[5,10], and Genzen and Tormey[11] acknowledged that the system for communicating alert results should address various issues including the person responsible for defining the alert lists. The system and policies should also address a timeframe of communication and available communication channels for delivering alert results. In addition, research has revealed the pressing need for addressing the issues of who will receive and deliver the results, as well as mechanisms for acknowledging receipt of the results. In this respect, flexibility and a clear escalation procedure should be in place to guide results reporters.

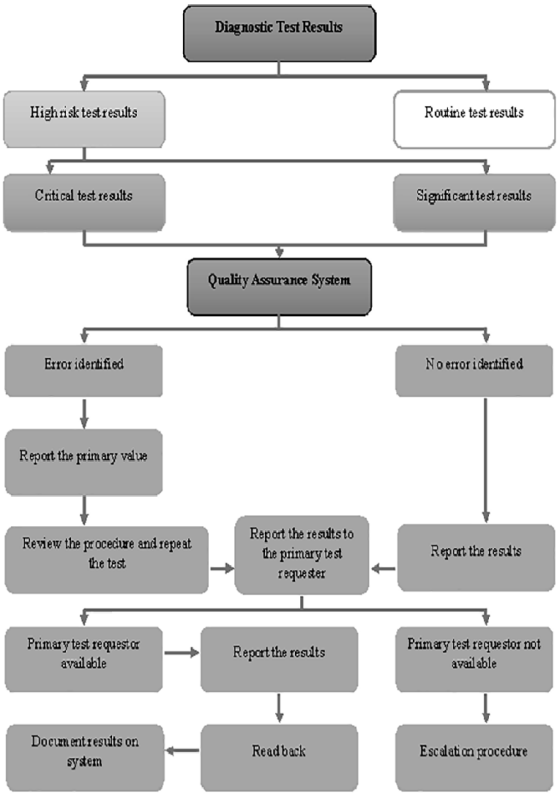

Figure-1: Flowchart of the main events in the process of reporting critical values

CONCLUSION

From the exhaustive review of literature, it is apparent that timely communication and release of critical test results can have significant impact on medical decisions and outcomes. Like many other hospital departments, laboratories have critical responsibilities towards patient safety and clinical decision making. Whilst regulatory, certification and accreditation bodies require laboratories to adhere to various procedures in order to ensure patient safety; guidance on best practices is limited. Reporting practices are mostly heterogeneous in many jurisdictions, a factor that might undermine the effectiveness of the reporting.

Hence, we recommend that the health care governing agencies; such as WHO should globalize common guidelines on reporting the critical test values allowing some flexibility to consider the differences in health care systems in different clinical settings. Also, in the future, handling of critical values should be an integrated effort that combines the entire team of laboratory staff, medical assistants, informaticists, doctors, nurses and cyber engineers working together to relate information bidirectionally from the laboratory to the respective physician, patient and medical department for timely clinical action. Having the information readily available and up-to-date can help shorten the time to diagnose, treat, and help doctors during urgent clinical situations.

We also suggest that reporting critical values should be done at multiple levels involving patient's representatives for keen and rapid communication of critical results.

Limitations:

The study could not provide comprehensive common guidelines on reporting clinical laboratory critical values due to the heterogeneous nature of procedures applied in clinical laboratories. Also, amongst the limitations of the current review is focusing only on the CAP guidelines.

The process starts with the identification of critical values and applying quality control checks beforehand reporting critical results. Primary reporting is always done to the principle test requester. Escalation procedure should be ready in place if the primary reporting failed.

AUTHORS' CONTRIBUTION

KAS: Data collection and writing up. OSM: Review rational/writing up. FA: Manuscript editing and revision. AA: Manuscript editing and revision. MAG: Revising clinical guidelines and final formatting

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