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Critical values in Hematology

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SUMMARY

Introduction: Critical values are life-threatening results that require immediate notification to the patient's healthcare provider. Accreditation bodies require laboratories to establish critical values. A survey of Ontario laboratories was conducted to determine current practice for critical values in hematology.
Methods: The survey was sent to 182 participants questioning sources for establishing critical values, levels, review frequency, delta checks, and reporting. The survey was completed by laboratory managers, supervisors, technical specialists, senior technologists, and bench technologists working in hematology.
Results: The majority of participating laboratories have established critical values limits for hemoglobin, leukocyte counts, and platelet counts. Most laboratories also include the presence of malaria parasites and blast cells. Some laboratories reported the presence of plasma cells, sickle cells, schistocytes, and spherocytes as critical values. Multiple sources are used for establishing a critical value policy. There was variability for the frequency of critical values review. Rules may differ for a first-time patient sample *vs.* a repeat patient sample. Delta checks are seldom used to determine whether a result should be called a critical value. Most participants require the individual taking the critical result(s) to read back and confirm that they are directly involved with the patient's care.
Conclusion: There is a lack of consensus for critical values reporting in hematology. As critical value reporting is crucial for patient safety, standardization of this practice would be beneficial.

INTRODUCTION

Critical values, as defined by Lundberg, are life-threatening results that require immediate notification to the patient's healthcare provider [1]. In hematology, a few laboratory test results may be considered critical, and when values are extremely high or low, that results indicate a condition of irreparable damage to a patient or even death if appropriate treatment is not initiated promptly [2]. Not reporting these values within a timely period or to the correct healthcare provider can potentially lead to adverse events such as prolonged bleeding episodes, prolongation of hospital stays, cerebrovascular accidents, cardiac injury, or

loss of life [2–4]. Even though appropriate critical value reporting is widely known to be a determinant of patient outcomes, there remains high variability between laboratories for which parameters should be reported and what levels are considered critical [2, 5, 6]. Besides the patient risks, laboratories have regulatory requirements to develop and implement critical value reporting policies. It remains the responsibility of each laboratory to establish critical values lists for the results that must be reported when they fall outside of defined limits [7–11]. Processes and procedures should be in place for communication of these results to the patient's healthcare provider in a timely manner including 'read back' of verbal results and appropriate documentation of the critical value reporting [12]. The reporting of critical values is not exclusive to laboratory results and may include other diagnostic services, for example, diagnostic imaging. Therefore, decisions for the critical reporting parameters and development of the processes may be implemented at a higher organizational level in healthcare facilities [13]. Although accreditation bodies require a laboratory to establish critical values, there is a lack of consensus on which parameters/tests and levels to include. There is a limited guidance for establishing critical values criteria in the hematology laboratory and how often a critical value should be reported on subsequent testing [7, 11]. The question that remains is 'Can universal critical value lists be developed or should it remain the responsibility of laboratory directors and healthcare administrators to making these decisions?' Medical decision points (MDPs) are generally based on reference intervals and recommendations from guidelines based on clinical evidence from studies or from expert clinical opinions [14, 15]. However, laboratory test results have been shown to have variability in both intralaboratory and interlaboratory comparisons through external quality assurance (EQA) programs [15, 16]. These issues highlight some of the problems for standardization and implementing universal MDP for critical values in hematology. To gather information on the current practice of critical value reporting in hematology, the Hematology Scientific Committee of the Quality Management Program —Laboratory Services (QMP–LS), an accredited EQA provider, distributed a patterns-of-practice survey to all Ontario laboratories. This paper presents and discusses the results of the survey.

METHODS

In October 2012, a web-based survey was distributed to 182 Ontario laboratories licensed to perform routine hematology analysis (see Appendix A for survey questions). The purpose of this patterns-of-practice survey was to gather information on their current practice for critical value reporting. The intent of the committee was to use this information for developing consensus practice recommendations for standardization and consistency between laboratories. The questionnaire asked laboratories about their reporting practices of critical values: the sources used for choosing parameters, setting criteria and critical levels, frequency of review, the use of delta checks, and reporting procedures. The coagulation tests were not included as part of this survey. The questions were specific to the quantitative hematology values and the morphology parameters reported in most routine hematology laboratories. For consistency and due to possible differences of age- or gender-related reference ranges, laboratories were asked to provide their limits for males ≥18 years old. Other questions inquired about the sources for establishing critical values, frequency of review of critical values, reporting practice of first-time patient *vs.* a repeat patient sample taken within a 24-h period, the use of delta checks before reporting, and the procedures for communication of a critical result.

RESULTS

Quantitative hematology parameters reported for critical values

All 182 participants, licensed to perform routine hematology analysis, were asked to submit their lower and upper critical values for leukocyte counts, hemoglobin, platelet counts, absolute neutrophil counts, absolute lymphocyte counts, and body fluid total nucleated cell counts. There were only a few submissions for the lower and upper critical limits for absolute lymphocyte and body fluid total nucleated cell counts, and these critical values demonstrated such wide variation that they were not included in our analysis. Of 182 participants, 154 (85%) provided lower critical values and 158 (87%) provided upper critical values for leukocyte counts, 179 (98%) provided lower critical values and 145 (80%) provided upper critical values for hemoglo-

bin, and 177 (97%) provided lower critical values and 143 (80%) provided upper critical values for platelet counts. Lastly, 161 (88%) laboratories provided lower critical values for absolute neutrophil counts. The range of the lower limits was 0.1–3.0 × 10^9/L for leukocytes, 50–90 g/L for hemoglobin, 9–100 × 10^9/L for platelet counts, and 0.4–2.0 × 10^9/L for absolute neutrophils. The ranges for the high limits were 20.0–100.0 × 10^9/L for leukocytes, 170–200 g/L for hemoglobin, 750–1500 × 10^9/L for platelet counts, and none were reported for absolute neutrophils (Table 1). Statistical analysis was performed to determine the median and range of values reported by Ontario laboratories for the leukocyte count, hemoglobin, and platelet count (Table 2). The information provided by laboratories was specific to males ≥18 years old. However, the majority (111 of 180 [62%]) of laboratories only have one level for reporting critical values, whereas 68 (38%) did have multiple levels that were patient population dependent (i.e., age or gender). In this survey, laboratories were not asked to provide the critical levels established in these patient population groups.

Morphology parameters reported for critical values

One hundred seventy-four of 182 (95.6%) participants are laboratories licensed to perform peripheral blood film morphology. Of these, 94% reported diagnostic morphology critical values for malaria, 84% for parasites other than malaria, 74% for blast cells, 48% for sickle cells, 39% for schistocytes, 37% for plasma cells, and 22% for spherocytes. The morphologic parameters, which were reported as critical values, are presented in Figure 1.

Sources used for establishing critical values

The sources used to determine critical values vary, and many institutions use a combination of more than one method. The medical director's recommendation is the most frequently cited method (149 [82%]) followed by the published literature (84 [46%]), Medical Advisory Committee (62 [34%]), another institution (59 [32%]), Ontario Association of Medical Laboratories Guideline (54[30%]), textbook (24 [13%]), and laboratory manager (22 [12%]). Thirty-four (19%) laboratories also reported other comments, including the following: consultation with other physicians – hematopathologist or designated, published literature from ISLH, QMP-LS broadsheets, CAP Q-probes, AACC guidelines, committees for regionalization of laboratory programs, through comparison with peer hospitals, designated hospital committees, and from patient clinical outcomes.

Frequency of review of critical values

The frequency of review of critical values was variable with laboratories reporting the following: annually (91 [50%]), every 2 years (17 [9%]), not sure when last reviewed (33 [18%]), and other time frames such as every 3 years and when replacing instrumentation (41 [23%]).

First-time patient sample *vs.* a repeat patient sample

One hundred and nine (60%) of the laboratories reported that different rules are used for a first-time patient sample *vs.* a repeat patient sample, taken within a 24-h period, whereas 72 (40%) laboratories did not.

Do laboratories perform delta checks to determine whether a result should be called a critical value?

Only 33 (18%) reported they use delta checks to determine whether a result should be called a critical value.

Communication of critical values

Laboratory personnel communicate critical values in various ways. The majority (90%) of participants require the individual recording the critical value result(s) to read back the results; 10% of laboratories do not have policies to read back verbal results. Most (79%) laboratories confirm that the person taking the critical result(s) is directly involved with the patient's care, while 21% do not. Information for which healthcare personnel received the critical values was not obtained in this survey.

DISCUSSION

Almost all (98%) laboratories completing the survey had established critical values for at least one hematology test. There was a high level of consensus from Ontario laboratories that the parameters hemoglobin, leukocyte count, platelet count, and neutrophil count

Table 1. Critical value limits reported by hematology laboratories

Lower leukocyte critical value (n = 154)

$\times 10^9$/L	No. of aboratories	% of laboratories
0.1	1	1
0.4	1	1
0.5	17	11
1	40	26
1.5	6	4
2	80	52
2.5	7	5
3	2	1

Upper leukocyte critical value (n = 158)

$\times 10^9$/L	No. of laboratories	% of laboratories
20	6	4
25	12	8
30	23	15
40	57	36
50	54	34
100	6	4

Lower hemoglobin critical value (n = 179)

g/L	No. of laboratories	% of laboratories
50	30	17
60	61	34
70	48	27
75	13	7
80	15	8
85	2	1
90	10	6

Upper hemoglobin critical value (n = 145)

g/L	No. of laboratories	% of laboratories
170	1	1
180	18	12
190	20	14
200	106	73

Lower platelet critical value (n = 177)

$\times 10^9$/L	No. of laboratories	% of laboratories
9	1	1
15	1	1
20	43	24
25	2	1
30	33	19
40	1	1
50	88	50
60	5	3
100	3	2

Upper platelet critical value (n = 143)

$\times 10^9$/L	No. of laboratories	% of laboratories
750	9	6
800	8	6
900	2	1
1000	119	83
1500	5	3

Lower neutrophil critical value (n = 161)

$\times 10^9$/L	No. of laboratories	% of laboratories
0.4	1	1
0.5	134	83
1.0	21	13
1.5	3	2
2.0	2	1

had lower and upper ranges for defining critical values. However, there was wide variability as to the critical ranges established. These findings follow what has been previously published, and variability may be due to differences of expert opinions, the sources used for setting critical levels, specific patient populations,

Table 2. Summary of the critical values for common hematology parameters

Parameter	Lower limit	Upper limit
Leukocyte count ($\times 10^9$/L)		
Median	2.0	40
5–95th percentile	0.5–2.5	20–50
N	154	158
Hemoglobin (g/L)		
Median	69	200
5–95th percentile	50–90	180–200
N	179	145
Platelet count ($\times 10^9$/L)		
Median	50	1000
5th–95th percentile	20–70	750–1000
N	177	143

or differences due to analysis methodology [3, 4, 13, 17–21]. Critical levels of hematology parameters may be affected by age, gender, or disease condition, which impacts on efforts to harmonize critical results [19, 22].

With peripheral blood morphology, it was agreed by most laboratories that the presence of malaria and parasites, other than malaria, should be reported as a critical value. Approximately 75% of laboratories also included the presence of blasts as a critical value. Less than half of the laboratories consider plasma cells or red cell abnormalities such as sickle cells, schistocytes, and spherocytes critical.

The literature does not provide much in the way of guidance for how laboratories should establish critical values. It has been suggested that thresholds should be the level where clinical actions are needed to reduce risks to a patient [19]. For the most part, these decisions are left to the laboratory director in consultation with organizational committees, other professionals, and clinicians. Recommendations based on guidelines and published literature or clinical evidence play a lesser role in clinical value decision making, which may be due to the limited number of these resources [19]. Setting appropriate levels is important. If upper limits are established too high or lower limits too low, there may be a significant increase to workload for reporting and also at the other end, for those receiving an inappropriate critical result. At the other extreme, if a true critical result is not reported, it puts a patient at a risk for poor outcome or even death [19]. There are limited resources for recommendations of when it is appropriate to review and potentially make changes to critical limits. Ontario laboratories are required to perform an annual review of their laboratory procedures and processes to meet the QMP-LS accreditation requirements. Fifty percent of the survey participants responded that critical values were reviewed annually. There is still the question of once a critical result has been reported to the patient's healthcare provider and if the test is repeated within a 24-h period, is it necessary to communicate the repeated result? The data from this survey showed a lack of uniformity in laboratory practice, and little information is available in the published liter-

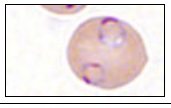
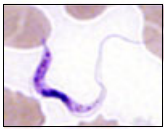
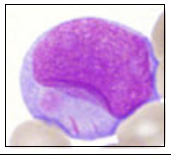
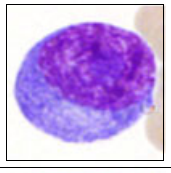
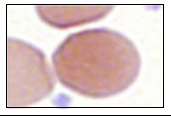
Morphology	Percent of labs reporting results as critical (n = 174)
	Malaria: 94%
	Parasites other than malaria: 84%
	Blast cells: 74%
	Sickle cells: 48%
	Schistocytes: 39%
	Plasma cells: 37%
	Spherocytes: 22%

Figure 1. The morphologic parameters which were reported as critical values (photographed by the author R.P, using Olympus BX51 microscope and DP71 camera, Wright–Giemsa, original magnification 100× oil immersion).

ature for these decisions, leaving it up to each laboratory to set their own policies.

As expected, delta checks are not used to determine whether a result should be considered a critical result by the majority (82%) of laboratories. Delta check refers to the comparison of a patient's current test result with a previous result to look for pre-analytical laboratory errors primarily due to specimen mislabeling or dilution with IV fluid [21]. The survey did not specifically address whether laboratories routinely perform repeat testing on the same sample in the case of critical results [23].

It is essential for critical values notification be done in a timely manner to the correct healthcare provider so that appropriate action can be taken for the patient. Effective communication of critical values is crucial for maximizing the clinical benefit. The majority of laboratories ensure that critical values reach the personnel directly involved with the patient's care and results verification of correct results using a read-back method [12].

CONCLUSIONS

The implementation of a reporting system for critical values is a good laboratory practice. It increases safety and reduces the risk of harm to a patient, and is required by most laboratory accreditation organizations. In the responses, some laboratories did not have critical values for hematology parameters included in this study. Determination and implementation of critical values are strongly encouraged to ensure patient safety. A considerable variation was observed in the critical limits used by different organizations. This might arise from the differences in patient groups and healthcare services provided in these organizations, and/or lack of standardization in defining these critical values. Using published critical values as a benchmark and developing an organization's critical values based on the medical need arising from specific patient populations and services provided may be a good approach. Regular review of critical values in predefined time frames helps to ensure that critical values meet the clinicians' needs, and will aid the laboratory to ensure that resources are used efficiently to increase clinical benefit. Effective communication of critical values is crucial for maximizing the clinical benefit. Laboratories should ensure that critical values reach the personnel directly involved with the patient's care and that service personnel record results correctly by using a read-back method.

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APPENDIX A
QMP-LS Survey Questions

Section D **Critical Values**

16. For the following parameters please provide your laboratory's limits for critical values. Please provide the limits for males ≥ 18-years-old.

Parameter/Test	Units	Males ≥ 18-years-old	
		Lower limit	Upper limit
Leukocyte	x 10^9/L		
Hemoglobin	g/L		
Thrombocyte	x 10^9/L		
Absolute Neutrophil	x 10^9/L		
Absolute Lymphocyte	x 10^9/L		
Body fluid Total Nucleated Cell Count	x 10^6/L		

17. For the following morphology findings please provide your laboratory's limits for critical values. Please provide the limits for males ≥ 18-years-old.

Morphology	Males ≥ 18-years-old
Malaria	
Parasites other than malaria	
Blast cells	
Plasma cells	
Sickle cells	
Schistocytes	
Spherocytes	

18. Do you have multiple levels for critical values? ◯Yes ◯No

19. How were your laboratory's critical values determined? Select all that apply.

- ☐ Determined by medical director
- ☐ Determined by laboratory manager
- ☐ Adopted from another institution
- ☐ Adopted from literature
- ☐ Adopted from textbook
- ☐ Medical Advisory Committee
- ☐ Ontario Association of Medical Laboratories Guideline
- ☐ Other, specify: _____

20. How often does your laboratory review the critical values?

- ◯ Annually
- ◯ Every 2 years
- ◯ Not sure when last reviewed
- ◯ Never reviewed
- ◯ Other, specify: _____

21. Does your protocol have different rules for first time patient sample versus repeat patient sample, taken within a 24-hour-period? ◯ Yes ◯ No

22. Does your laboratory perform delta checks to determine if a result should be called a critical value? ◯ Yes ◯ No

23. If you answered "Yes" to Question 22, please provide the parameter/test delta check limits for males ≥ 18-years-old.

Parameter/Test	Units	Males ≥ 18-years-old	
		For low cell counts	For high cell counts
Leukocyte	x 10^9/L		
Hemoglobin	g/L		
Thrombocyte	x 10^9/L		
Absolute Neutrophil	x 10^9/L		
Absolute Lymphocyte	x 10^9/L		
Body fluid Total Nucleated Cell Count	x 10^6/L		

24. If you answered "Yes" to Question 22, please provide the morphology delta check limits for males ≥ 18-years-old.

Morphology	Males ≥ 18-years-old
Malaria	
Parasites other than malaria	
Blast cells	
Plasma cells	
Sickle cells	
Schistocytes	
Spherocytes	

25. Does your protocol require the person taking the critical value result to read back the results? ◯ Yes ◯ No

26. Does your laboratory confirm the person taking the critical value result is directly involved with the patient's care? ◯ Yes ◯ No