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CUSTOMISED CRITICAL LIMITS HELP TO ACHIEVE EFFICIENT USE OF THE LABORATORY'S RESOURCES

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ABSTRACT

Background: Customisation of critical value policies in laboratories with increasing workloads helps to achieve efficient use of laboratory's resources.

Methods: The critical value policy at an academic hospital was customised with the introduction of a new middleware (Sysmex Corporation, Kobe, Japan). The number of notifications over a one-month period was reviewed in order to determine the impact of customisation on laboratory resources and patient safety.

Results: 1891 haematology critical values were identified. 1195 (63%) results did not require notification according to the customised policy. Of these, 1034 (55%) had a previous critical result, 89 (5%) were not phoned as per customer request and in 72 (4%) the critical result was already viewed by the clinician.

Conclusion: Customisation resulted in a marked reduction in the critical results requiring notification. Laboratory information system middleware can be developed to consider factors such as, a change in the current result from previous results, patient location and requesting doctor to customise notification.

KEYWORDS

critical limits; haematology; patient safety, laboratory management, delta checks

BACKGROUND

Critical limits were first defined by Lundberg in 1972 as life threatening results that require urgent notification.[1] He advised laboratories to develop a critical value policy to contact clinicians with critical results so that immediate treatment could be administered. Subsequently, studies have confirmed the effectiveness of critical value reporting in relation to patient management.[2] The timely and accurate reporting of critical limits has become an important post-analytical quality indicator, that most laboratories in South Africa have implemented critical value policies.

Since 1970, advances in information technology (IT) and laboratory analytical processes have made it possible to design customised critical value policies tailored to each laboratory's requirements. Regulatory guidelines permit laboratories to redefine critical limits with regards to patient information and their previous laboratory results.[3] Several laboratory surveys have demonstrated that a number of institutions have modified their critical value policies for specific wards, clinician requests and repeat critical values within a specific time frame without compromising patient safety.[4-10] In a 2015 survey of the practices of 666 laboratories worldwide, Keng et al.,[5] found that almost half (45.30% n=174) of the respondents used delta checks (a change in the current test result from that of the previous result) to decide whether a result should be considered critical with a few allowed exceptions for specific wards (18.00%, n=69) and clinician requests (14.10%, n=54). The customisation of critical value policies in laboratories with increasing workloads has helped in achieving a more efficient use of laboratory resources.[11,12] For example, repeat notification of neutropenia in a patient on chemotherapy may be considered an ineffective use of the laboratory's time, with uncertain benefits to patient care. Furthermore the frequent interruptions for the oncology clinician may result in negative feedback towards the laboratory services. It is therefore important for laboratories to review their critical value policies in conjunction with requesting clinicians. The resultant review will balance providing information that requires urgent action, thereby avoiding information overload with expected results.

A study was designed to evaluate the critical value reporting at the Charlotte Maxeke Johannesburg Academic Hospital (CMJAH) Haematology Laboratory Complex in South Africa (SA). The critical value policy at this academic hospital was developed in conjunction with local clinicians, regulatory guidelines and laboratory surveys.[5,13,14] In order to optimise the use of the laboratory's resources and to avoid overloading the requesting clinicians with information the critical value policy at CMJAH has recently been customised with the introduction of a new middleware (Extended information processing unit, Sysmex Corporation, Kobe, Japan). The study aimed to determine the impact of this customised critical value policy on laboratory resources.

METHODS

Study setting

The critical value reporting at the National Health Laboratory Service Haematology Laboratory at the CMJAH was reviewed. The CMJAH is the second largest academic hospital in Africa. The hospital offers specialist medical, surgical, paediatric, obstetrics/gynaecology and haematology/oncology inpatient and outpatient treatment. The haematology laboratory is certified to ISO 15189 standards.

Critical value policy

The critical tests and limits that were in use at the time of the evaluation were as follows: haemoglobin <7g/dL or <10g/dL in neonates (age <28 days); platelet count <20 × 10^9/l or >1000 × 10^9/l; white cell count (WCC) <2 or >100 × 10^9/l; partial thromboplastin time (PTT) >120 seconds; international normalised ratio (INR) >5 and the presence of microangiopathic haemolysis; leukaemia or bacteria or parasites on morphologic analysis (Table 1).

The critical value policy was customised and the following modifications were then applied to the middleware: identification of first time critical results. The use of delta checks to decide whether a repeat result should be considered critical with exceptions allowed for specific wards or clinician requests, which have immediate access to authorised results (Table 2). All critical results were flagged by the laboratory information system (LIS) to trigger a phone comment. The phone comment referred to as "PHONH" captured the date and time of the call, the patient's demographics, the laboratory staff communicating the critical value and the recipient of the information. According to the laboratory's critical value policy, notification was performed telephonically by the laboratory staff, namely technologists and pathologists, on duty. The laboratory required that the person notified of the critical value preferably be a nurse or doctor directly involved in the patient's care, and/or the person who ordered the test. In addition, the laboratory has implemented an automated message notification system for critical value reporting. Critical values transmitted from the LIS triggered the generation of text messages to the requesting doctor's mobile phone. In the event that the caregiver could not be reached, there was an algorithm that needed to be followed. The steps in the algorithm included contacting the doctor on call, or delivering the critical values by a messenger or an automated message notification. The laboratory had no set time limits for delivery of a critical result. However, a time lapse of >2 hours from the authorisation of the critical value, was regarded as an unsuccessful notification.

Data collection and statistical analysis

Critical values reported between 15th May and 15th June, 2017 was reviewed. The critical values were generated from the LIS and compared to the customised critical values list generated by the middleware. The critical value data analysed included: the critical test and limit, site and turnaround time (TAT). The TAT was defined from the audit trail as the time interval between authorisation of the critical result and communication of the critical result or viewing of the critical result by the caregiver. For repeat critical results, the proportion of repeat results at the critical limit and the time frame per patient were collected. Data was exported to Microsoft Excel (Microsoft, Redmond 2010, WA, USA). Descriptive statistics were then applied to the collected data.

RESULTS

During the study period, 1891 haematology critical values were identified from the LIS, which represented 12% of the total tests reported. According to the customised critical value policy, the laboratory reported 695 (37%) critical values while there were 1195 (63%) results which did not require notification (Table 3). There were 9 (0.5%) critical values which were inaccurately reported. There were 1034 (55%) critical values with a previous critical result which were not communicated. The frequency of repeat critical values was collected: 13% were repeated within 12 hours of the previous critical test, 65% within 24 hours, 10% within 48 hours and 11% within >48 hours. Specifically, a review of patients with critical results from the oncology department showed a median of 11 (range, 2-43) repeat critical WCC results, 5 (range, 2-22) repeat critical haemoglobin results and 7 (range, 2-25) repeat critical platelet count results per oncology patient during the study period. There were 89 (5%) critical values which were also not communicated where clinicians/

Table 1: Critical value list at the CMJAH

TEST	CRITICAL LIMIT
Platelet count (PLT)	First time PLT<20 x 10^9/L or >1000 x 10^9/L or failed delta check (50% / 90 days)
Haemoglobin (Hb)	First time Hb <7g/dL or failed delta check (25% / 90 days) First time Hb <10g/dL and age<28 days or failed delta check (25% / 90 days)
White cell count (WCC)	First time WCC<2 x 10^9/L or >100 x 10^9/L or failed delta check (50% / 90 days)
Partial thromboplastin time (PTT)	PTT>120 seconds
International normalised ratio (INR)	INR>5
Morphologic analysis	First time leukaemia or microangiopathic haemolysis or bacteria or parasites including malaria

Table 2: Customised critical value reporting at the CMJAH

COMMENT	EXCEPTIONS
Results not phoned as result was already viewed by clinician	If there was a time lapse of >2hours from authorisation of the critical value, the audit trail was checked to see if the result had been viewed by the clinician.
Results not phoned as per customer request	Exceptions allowed for specific requesting outpatient departments which have immediate access to authorised results.
Results not phoned as previously communicated	Use of delta checks (90 days) to decide whether a repeat result should be considered critical.

wards had requested to have immediate access to authorised results. In comparison to the laboratory inpatient turnaround time of 37 minutes (0-533 minutes) to communicate critical results (P<0.0001), these critical results were viewed at a significantly longer median time of 120 minutes (range, 18-1320 minutes) from authorisation. A further 72 (4%) critical results were viewed by the clinician prior to the laboratory communicating the result.

Of the 695 critical results which were reported, 625 (90%) represented first time critical results and 70 (10%) represented critical results with a failed delta check (Table 3). The majority of these critical values were from the inpatient departments (n=509, 73%), Specifically, 25% from the medicine department, 31% from the haematology and oncology department, 10% from the intensive care units, 9% from the emergency department, 13% from the surgical department, 7% from the paediatric department and 5% from the obstetrics and gynaecology department respectively (Table 4).

The laboratory TAT was collected for the reported critical results to assess the timeliness of the customised critical value reporting. The majority of the caregivers were reached within the laboratory's acceptable notification period of 2 hours with a median TAT of 30 (range, 0-120) minutes. The median TAT for inpatients was 37 (range, 0-533) minutes and for outpatients was 60 (0-2700) minutes. For 97 (14%) critical results, the caregiver could not be reached and the algorithm was followed. Identifiable reasons for the caregiver not being contacted included: testing performed after hours (n=43), outpatient clinics contacted outside of operating hours (n=21), testing ordered on requisitions lacking the contact details of the clinician (n=2) and the incorrect patient location (n=8).

Table 5 illustrates the critical results that were reported. Approximately half of the critical values were for the lower limit for haemoglobin for adults. The potential effect of changing the threshold for critical tests was examined. Adjusting the haemoglobin threshold from less than 7g/dL to less than 6g/dL, would result in a reduction of 250 (61%) of the 407 customised critical haemoglobin values. The resultant effect would be an overall reduction of the critical result volumes (n=695) by 36% during the study period.

Table 3: Customised critical value reporting (n=1891)

REASON	CRITICAL RESULTS (n)	CRITICAL RESULTS (%)
Results not communicated as result was already viewed by clinician	72	4
Results not communicated as previously communicated	1034	55
Results not communicated as per customer request	89	5
First time critical results communicated	625	33
Critical results with a failed delta check	70	4

Table 4: Customised critical values by location

LOCATION	CRITICAL RESULTS (n)	CRITICAL RESULTS (%)
Inpatient	509	73
Outpatient	186	27

DISCUSSION

At the CMJAH, there are a large number of critical values to report each day. Communication of critical results by technologists or pathologists is a costly practice as extensive time is required by skilled laboratory staff to handle such reporting. In the last few years, the workload in our laboratory has increased resulting in the need for review and modification of our critical value policy. The newly introduced middleware has allowed for the development of a customised critical value policy which considers a change in the current test result from that of the previous results, the patient location and the requesting doctor. Similarly, this middleware/software platform from Sysmex has enhanced the reliability and efficiency of several other large sized laboratories in South Africa. The challenge, however, is to design cost-effective platforms for small and medium-sized laboratories, also faced with staff shortages.

Customisation of the critical value policy with regards to repeat critical values resulted in a marked reduction in the volume of critical results requiring notification. In this way we were able to alleviate the workload on the laboratory staff without increasing the risk of information overload on the clinicians. For example, a median of 11 (range, 2-43) critical WCC results were repeated per oncology patient receiving chemotherapy.

Table 5: Customised critical results reported; 15th May - 15th June 2017 (n=695)

TEST	CRITICAL RESULTS (n)	% OF CRITICAL RESULTS	TEST VOLUMES (n)	% OF TEST VOLUME WITH A CRITICAL RESULT
Platelet count	93	13	18628	0.5
Haemoglobin	407	59	21612	1.9
White cell count	116	16.7	18794	0.6
Partial thromboplastin time	4	0.58	1588	0.3
International normalised ratio	67	9.64	11028	0.6
Morphologic analysis	8	1.15	529	1.5

The majority (74%) of these critical values were repeated within 24 hours of the previous critical test. In this context, according to our local clinicians, repeat critical results do not qualify as life threatening results and lead to unnecessary interruption for clinicians. Customisation of the critical value policy had further advantages in that it helped to ensure the value of critical value reporting over time while still addressing the clinicians' requirements. This practice of reporting repeat critical results within a specified time period has recently received much interest. However, there is little consensus in the published literature. Each laboratory should be responsible for establishing policies that are their own. It is interesting to note that in a survey of 182 laboratories in Ontario, Canada the majority of laboratories had implemented a customised policy for repeat critical results within a 24 hour period.[4] Notifying clinicians of each repeat critical value for specific laboratory parameters may contribute to improved patient care and safety and should be strongly considered in such cases. For example, a repeated outpatient INR>5 on follow-up may not be an expected result and as such requires intervention and ongoing urgent management, including further investigation. It is therefore important for policies on repeat critical values to be established in conjunction with local clinicians.

Salinas et al., demonstrated that critical value policies can also be individualised in laboratories without advanced IT solutions by active participation from pathologists in those laboratories.[10] In this study, pathologists were able to reduce the volume of reported critical results by taking into consideration the requesting clinician, the patient characteristics and the nature (stat' or routine) of each critical result. Stat' results are 'expected' by the clinician and as such are timely viewed, as they may be required for immediate patient treatment. A limitation however, of such a customised method is human error in decision making. In our study, we identified that 0.5% of the critical results were incorrectly reported according to the customised critical value policy. However, in a larger study statistical significance may be achieved. This requires investigation and implementation of corrective and preventative measures and is an area of further research.

The critical value policy was also modified for specific wards and clinician requests. In the group which requested an 'opt out' (n=89, 5%). First time critical results were viewed by the clinicians at a significantly longer median time of 120 minutes (range, 18-1320 minutes) from authorisation when compared to the laboratory inpatient turnaround time of 37 minutes (0-533 minutes) to communicate critical results (P<0.0001). Timely reporting of critical results has a significant impact on time to treatment and subsequently on patient outcomes. As such we concur with the consensus that exceptions for specific wards or clinicians should be discouraged.

Another strategy to reduce critical call volumes is to examine the impact of changing thresholds for critical tests. As patient populations differ, the critical test list should be tailored to accommodate these differences. The most common critical value in this study was a haemoglobin of less than 7g/dL. In a previous survey of the critical value policies of South African laboratories, we identified considerable variation in critical limits among different laboratories, especially regarding the lower threshold values for haemoglobin.[14] Published critical limits from international laboratory surveys are available.[5,15] These recommendations are a benchmark against which laboratories can compare and adjust critical values lists in order to address local patient populations and clinical requirements. According to World Health Organization (WHO) estimates, Africa has one of the highest prevalence of anaemia owing to the high burden of chronic infections such as HIV and tuberculosis.[16]

In a patient context such as this, a haemoglobin of 6g/dL in the absence of cardiac risk factors has been suggested by clinical consensus to be a more relevant threshold.[17] A change in the lower limit for haemoglobin from less than 7g/dL to less than 6g/dL would result in an overall reduction of the number of phone calls (36%) for the laboratory staff thereby improving overall laboratory efficiency. A limitation of this study however, is how the lowering of thresholds impacts patient safety. Unfortunately this could not be determined as patient outcomes were not collected.

In addition to efficiency, another important laboratory quality indicator is TAT, as it directly impacts on patient care and safety. In this study (24%), the TAT to reporting the critical result was unacceptably delayed. For the purpose of this study this was defined as more than 2 hours. However other studies indicate a wide variability.[7] In a survey of intensive care unit specialists in South Africa (SA), most clinicians designated the traditionally accepted time frame of 30-60 minutes as an acceptable length of time for notification of critical results.[13] Several causes for delayed critical value notification were identified in this study, including specimens from outpatients, requisitions without contact details of the clinician and testing performed after hours. Reaching caregivers with critical results after hours represents a challenge. In addition, critical value notification took a median of 60 minutes for outpatients, whereas for inpatients it took 37 minutes. This concurs with a previous study which also found that it takes more than twice as long to communicate critical results for outpatients than for inpatients.[18] In response to the findings of this study, we are presently working with our clinicians to formulate policies for critical value reporting after hours and for outpatient and referral clinics. We are further trying to ensure all requisitions have proper contact details and the LIS has the updated details of the doctors on call.

CONCLUSION

This study illustrates the safe and efficient reporting of a customised critical value policy at an academic hospital. Use of a customised critical value list eliminated a large number of unnecessary critical value calls. Each laboratory needs to customise its critical values list according to its 'clinicians' needs, local patient population and laboratory resources. This study provides clinically relevant data for laboratories establishing or reviewing critical value lists in order to improve current practice. LIS middleware can be developed to consider factors such as, a change in the current test result from the previous results, patient location, requesting doctor as well as other parameters to customise notification.

CONFLICT OF INTEREST

The author(s) declare no conflicts of interest with respect to the authorship and/or publication of this article.

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