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Original Article

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Critical Values Analysis of Biochemical Parameters in A Tertiary Care Hospital: A Retrospective Study

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ABSTRACT

Critical value reporting is one of the requirements for laboratory accreditation and is an important aspect of quality assurance regarding reporting of results. This reporting of patient results specially critical values should be clear, accurate and rapidly communicated to clinicians.

Methods: Biochemical parameter results of one year (January 2020 to December 2020) were retrospectively evaluated in terms of identification of critical values generated from the testing of samples on siemenes analyser and their association with entries in the call back register in a biochemistry lab situated in a tertiary care hospital. Statistical analysis was conducted using Microsoft Excel 2016 program.

Result: A data of 79773 tests were analysed, and 2658(3.3%) critical alerts were generated by the Siemens auto analyzer. of these only 1649(2%) were recorded in the call back register of critical alert.

Key Words: *Biochemistry, Critical Value, Emergency Laboratory, Pre-Analytical Errors*

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INTRODUCTION

There is an important role of Clinical lab in promoting patient safety by timely release of report and communication of critical results to doctor which have significant role in medical decisions and subsequent patient outcomes.

Critical result concept was introduced by Lundberg more than 46 years ago [1, 2]. It is defined as a result which is abnormal and considered life threatening or that could result in significant morbidity and which, therefore, requires urgent action [3].

The Critical limit refers to the upper and/or lower range of a result or the change of a result within a critical time scale beyond which the finding needs medically urgent prompt action [4]. In the current era accreditation agencies related to clinical laboratories have enlisted critical ranges, formulated notification procedures, documentation of critical results, and notification to physician as a requirement for certification [5]. Critical value reporting has been considered vital as it reflects an increase in the clinical usefulness, patient safety and operational fitness and designing data based system for timely notification of laboratory results.

With this perspective, we designed to analyse the critical values data in terms of data obtained through the analyser and data entered in the call back register at a tertiary care hospital in laboratory setting for a period of one year and match up to the frequencies for different parameters with the available data from previous studies

Material and method

The current retrospective study was conducted at the Biochemistry laboratory of NKP Salve Institute of Medical Sciences & Research Centre and Lata Mangeshkar Hospital, Nagpur after approval from IEC. The blood samples in the laboratory are received from all the wards of the hospital as well as outpatient department of the hospital.

The biochemistry parameters that are done on blood samples in our tertiary care hospital laboratory includes odium (Na) , potassium (K), chloride(cl), creatinekinase (CK), lipase, glucose, urea, creatinine, total bilirubin, direct bilirubin, Alkaline Phosphatase (ALP), Alanine Transaminase (ALT), Aspartate Transaminase (AST), amylase, D-dimer, Ferritin , Lactate , HbA1c etc. All the samples which are received in the laboratory are run on Siemens auto analyzer. Data was collected from call back registers and Health management information system(HMIS) which are maintained in the laboratory.

Biochemical parameter results of one year (January 2020 to December 2020) were retrospectively evaluated and total of 154287tests were done in our lab during this period .The protocol which is followed in our laboratory for critical value notification is as follows :During the testing of samples, after checking for the analytical reliability of the critical tests and ruling out the pre- analytical errors as a potential cause of critical values the samples are run again. Once the result is validated, the result is measured as a true critical value and it is notified by the doctor on duty telephonically to the physician in the respective wards and the same is recorded in a register. The list of critical values and their biological limits used for this study are presented in table 1. Among all the parameter done in lab only few parameter (table .1) analysed because they are most commonly critical found in our lab. So 79773 test were analysed.

Table 1: Critical call back list for clinical chemistry used during study

Test	Critical value
Glucose (mg/dl)	>450 <40
Creatinine(mg/dl)	>5
Urea (mg/dl)	>214
Sodium (mEq/L)	<120 >160
Potassium (mEq/L)	<2.8 >6.2
Calcium (mg/dl)	<6 >13
Phosphorus (mg/dl)	<1 >8.9
Albumin (gm/dl)	<1.7

Statistical Analysis

Microsoft Excel 2016 program was used. The values obtained were entered in this program and Calculations of critical values of was presented as number and percentage.

RESULTS

The biochemistry sample results of one year were evaluated retrospectively. During this period, 154287biochemical tests were performed in the biochemistry section of the central clinical laboratory. of these considering the parameters in which maximum number of critical alerts were noticed 79773(51%) tests were analysed for the study. 2658(3.3%) critical alerts were generated by Siemens auto analyser instrument which is used for measurement during this period meaning that a flag was generated by the instrument. of these only 1649(2%) were recorded in the call back register of critical alert. The details of the same is depicted in table 2.

Table 2			
Parameter	Total test analysed	Total Critical values From HMIS	From Call back register
Glucose (mg/dl)	7935	301(3.7%)	107(1.3%)
Creatinine (mg/dl)	15599	555(3.5%)	433(2.7%)
Urea (mg/dl)	14378	503(3.4%)	401(2.7%)
Sodium (mEq/L)	14911	301(2.0%)	201(1.3%)
Potassium (mEq/L)	14911	371(2.4%)	255(1.7%)
Calcium (mg/dl)	1670	128(7.6%)	26 (1.5%)
Phosphorus (mg/dl)	362	32(8.8%)	12(3.3%)
Albumin (gm/dl)	10007	467(4.6%)	214(2.1%)
Total	79773	2658 (3.3%)	1649(2%)

As in table 3 the distribution of critical alert of the parameters during routine hours (10 am -5pm) states that 1446(54%) were reflected in the HMIS and (50%)in the call back register from the total as shown in table 2. we observed that glucose (81%) is more reported in routine hours than emergency(18%). While KFT parameter are almost equally reported in routine and emergency hours.

Table 3		
Parameter	Critical values in Routine ((10am-5pm)	
	From HMIS	From Call back register
Glucose (mg/dl)	244(81%)	80(74%)
Creatinine (mg/dl)	241(43%)	201(46%)
Urea (mg/dl)	232(46%)	152(37%)
Sodium (mEq/L)	146(48%)	99(49%)
Potassium (mEq/L)	172(46%)	101(39%)
Calcium (mg/dl)	70(54%)	15(57%)
Phosphorus (mg/dl)	20(62%)	9(75%)
Albumin (gm/dl)	321(68%)	170(79%)
	1446(54%)	827 (50%)

As in table 4 the distribution of critical alert of the parameters during emergency hours (6pm – 9 am) states that (45%) were reflected in the HMIS and (49%) in the call back register from the total as shown in table 2. As depicted in table 2, 3 and 4 the percentage of critical call back is comparitively less through the register than actually seen in the HMIS.

Table 4

Parameter	Critical values in Emergency (6pm -9am)	
	From HMIS	From Call back register
Glucose (mg/dl)	57(18%)	27(25%)
Creatinine (mg/dl)	314(56%)	232(53%)
Urea (mg/dl)	271(53%)	249(62%)
Sodium (mEq/L)	155(51%)	102(50%)
Potassium (mEq/L)	199(53%)	154(60%)
Calcium (mg/dl)	58(45%)	11(42%)
Phosphorus (mg/dl)	12(37%)	3(25%)
Albumin (gm/dl)	146(31%)	44(20%)
	1212(45%)	822(49%)

DISCUSSION

Each and Every laboratory must establish their Critical limits, since sample types, analytical platforms, patient population and clinician's perception may differ in different laboratory. Our study has a sample size of 79773 while studies from other laboratories had sample size ranging from 548786 done by Sarita et al [7] to 51,05,336 studied by Anand Dighe et al. [6]. The of critical values incidences in our lab varies from as low as 2% to as high as 81%.

In previous studies Sarita et al [7] have reported that the critical values frequencies of creatinine and urea was observed to be 6.59 % and 28.78 % respectively. Thus, there is a wide range of this frequency. Also it was seen that the frequency of critical value notification for serum creatinine was 3.5% and it was 3.4% for blood Urea in total.

As is depicted by this data, the frequency of critical values of renal function in routine is are much lower in our laboratory. Also it is evident from the present comparative study that the critical values of electrolytes are lower than study of Sarita et al[7] and Dighe [6] and AA-Rocha et al. [8]

We observed that the percentage of critical values from HMIS is more than call back register. A focussed group discussion was taken with the technicians and the major reasons identified for less entries in the call back register was the presumption that values are directly transferred from the machine to the end user i.e the wards and hence can be visualized by the clinicians directly and hence there was no need for communication of the same. Also previous experience that in some cases notification of critical alert was not of significance since the patient had been transferred to Ward or ICU from the primary admitted placetelephonic communication was not conveyed since the phone was engaged or phone not picked up by care giver were the major hinderances in writing the critical alerts in the call back register. The OPD patients were routinely not informed about critical results which was a major chunk.

The important aspect for quality assurance is to train all laboratory staff including technicians and doctors on duty for the protocol of the laboratory regarding critical value notification and record the same in the respective registers. This is because this small efforts towards patient care can help modify clinical management of the patients and thus can be very useful for both clinicians and patients. This will also help in establishing a healthy interaction with the clinicical doctors and laboratory specialist which will be beneficial in the long run. This underscores the importance of the notification of critical results and the need to have acontinuous improvement process in each laboratory.

CONCLUSION

Critical value reporting is an important phase of the clinical laboratory testing process and The final aim should be that these values must be with the right person, as fast as possible, so that the doctors give immediate treatment to the patient and improve the final outcome of the patient.

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