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Original Research Article

Evaluation of critical value and urgent sample notification at clinical biochemistry laboratory in a tertiary care hospital

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ABSTRACT

Background: Critical value and urgent sample result notification is widely accepted in the diagnostic fraternity as an important factor, as it may affect patient care and safety. Timely release and notification of these test result as per the individual laboratory protocol becomes an internal part of quality reporting system. The present study was aimed at evaluating the effective implementation of the existing protocol of urgent clinical notification (UCN) in the clinical biochemistry laboratory of tertiary care hospital and evaluating the turnaround time for urgent samples and critical results listed under UCN protocol in the clinical biochemistry laboratory.
Methods: A prospective, observational study was conducted in clinical biochemistry laboratory of a tertiary care hospital. Descriptive statistics was calculated for all the data by Mann-Whitney and Wilcoxon test.
Results: Majority of the critical results were informed to the clinical personnel by the clinical laboratory. Out of 4687 critical results, 25.41% critical results were informed directly to the ward through telephonic communication. Documentation of critical values in the dedicated register and lab information system (LIS) was 25.41% and 40.28% respectively. 421 (9%) out of 4687 critical results were not notified. The median turnaround time for all urgent tests and critical results was found to be 72.33 minutes and 76.00 minutes respectively.
Conclusions: This study highlighted various approaches to improve the critical value notification and its turnaround time and status of UCN in laboratory

Keywords: Alert value, Urgent sample, Critical value notification

INTRODUCTION

The term critical value is frequently used in medical laboratory setup. It is a value that is above or below the normal biological reference interval of an analyte. It is also called alert value as the clinician has to be notified of the same for immediate treatment action. Critical value notification comes under the post analytical phase. Informing the critical values to the clinician helps in early and better patient care of critical patients, thus critical value notification becomes an important tool for assessing the quality of laboratory.

The laboratory test results support the clinical decision-making in the majority of clinical interventions.[1-2] It is estimated that around 70% of treatment decisions are taken based on laboratory results.[3] Thus, when critical results are identified in the laboratory after investigation or when there is a urgent sample request from the clinician, it is imperative that the clinician is informed about the results, so that appropriate action can be taken to improve patient care and subsequent clinical outcomes.[4]

Even with the current technology and automation in laboratory, the labs are not able to communicate all the critical results and the results of urgent sample, to the clinician or care giver due to several errors in the process of notification of results. Hence, this study carried out to evaluate the existing protocol for notification of critical results, and to enable us to identify areas of the protocol requiring correction and preventive action.

METHODS

The prospective, observational study for the period October 2016 to December 2017 was conducted at the laboratory services of a tertiary care hospital, Bangalore, Karnataka, India.

Selection criteria of the patients/results/tests

All the analytical values that came under critical results as per the protocol of the laboratory and all the test requests that were received in clinical biochemistry which were labelled as urgent by the clinician during the study period were included in the study.

Procedure

As per the laboratory protocol, the urgent samples were prioritized for the analysis. Upon receiving urgent samples with a clear indication of the status by the clinician, the personnel at the Biochemistry sample receiving counter, color code the samples to enable easy identification by all related personnel. The color-coded samples are handed over to the technician for sample preparation and analysis on a priority basis. The results are informed to the clinician or the care giver and these details are entered in the dedicated register and in the LIS. The critical results identified during the results recall from the instrument for the routine samples also follow the same protocol of notifying the results. Since the protocol involved timelines and the TAT for those samples were also calculated.

In the present study, the necessary from sample receipt to notification of the above test results were recorded. This involved time of receipt of sample, time of completion of sample analysis, time of verification and time of notification of results, were collected.

In view of large sample size, the test parameters under the study were divided into groups and each of these groups were evaluated for a period of three months as given below-1st group: Ammonia, lipase, magnesium, albumin, uric acid and bilirubin, 2nd group: Chloride, urea, glucose, CSF glucose, calcium and sodium, 3rd group: Phosphate, creatinine, potassium, ionised calcium, arterial blood gas analysis-pH and pCO_2, 4th group: Troponin I, carbamazepine, phenytoin, phenobarbital, valproic acid, cortisol.

The necessary data was documented in Microsoft excel sheet for further statistical analysis.

Ethical approval

Ethical approval was obtained from Institutional ethical clearance-355/2016.

Statistical analysis

Descriptive statistics was calculated for all the data collected during the study period. To compare the turnaround time (TAT) of urgent samples and samples with critical results, the median time taken from the sample receipt till verification for each of the analytes was calculated and compared by Mann-Whitney and Wilcoxon test using SPSS 23.

RESULTS

As per CLIA (clinical laboratory improvement amendments) definition, critical values, formerly known as panic values or alert values, are abnormal laboratory results that constitute a life-threatening condition for the patient, which must be informed to the clinician or also to the care giver or patients as early as possible. Any delay in reporting can result in adverse outcomes for patients.[5] Thus, critical value notification is an integral part of clinical laboratory.

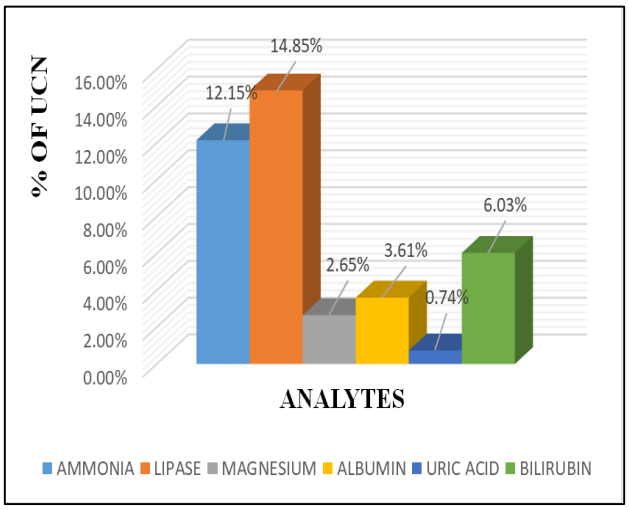

Figure 1: Percentage of UCN from October-December-2016.
UCN: Urgent Clinical Notification.

The present study recorded 4687 critical values. Table 1 shows the total number of tests analyzed in the respective months during the study period. It was observed that, the test count was highest for albumin, glucose, creatinine and cortisol and lowest for ammonia, cerebrospinal fluid glucose, calcium and phenobarbital.

All parameters under UCN were analysed on a fully automated analyser. The parameters were grouped into four groups and are shown below in the Table 1.

Figures 1-4 shows the percentage of critical values for the analytes evaluated in the respective months.

In 1st group (Figure 1), lipase showed the highest percentage of critical results (140 / 943; 14.85%) as well as the lowest for uric acid (15/2038; 0.74%).

In the 2nd group (Figure 2), chloride (11.06%) was highest, followed by sodium (8.11%).

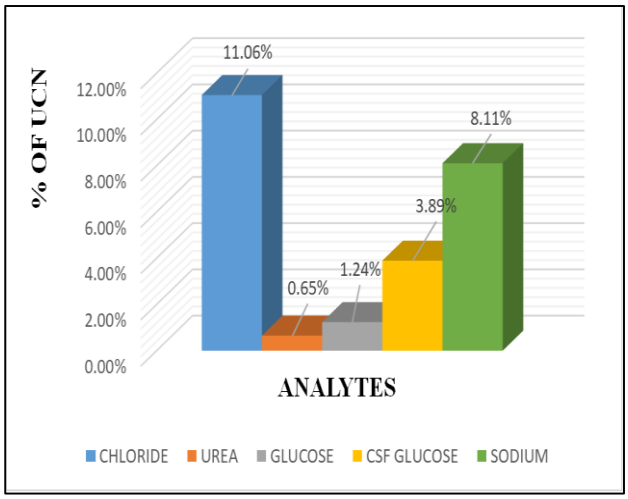

Figure 2: Percentage of UCN from January-March-2017.

In the 3rd group (Figure 3), ABG-pO_2 (18.32%) was highest and lowest for phosphate (0.81%).

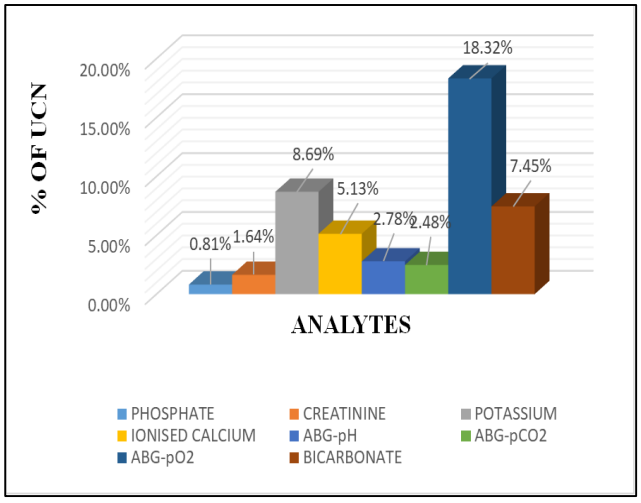

Figure 3: Percentage of UCN from April-June-2017.

In the 4th group (Figure 4), it was observed that phenytoin (35/99; 35.35%) had the highest percentage of critical results with respect to total volume during July to October- 2017.

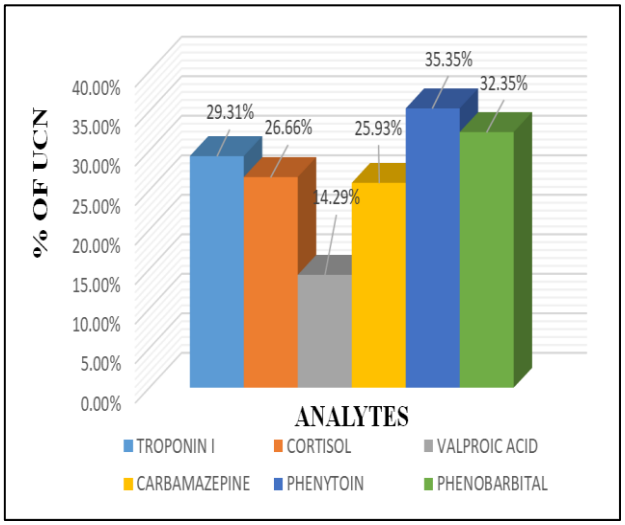

Figure 4: Percentage of UCN from July-October-2017.

The median time taken for the sample from the time it was identified as critical after analysis, to the time of verification is shown in Figure 5. The time taken for carbamazepine was 46.5 minutes and for ABG analytes was 7 minutes. The average time duration from the time of completion of analysis by instrument to verification was 63.83 minutes.

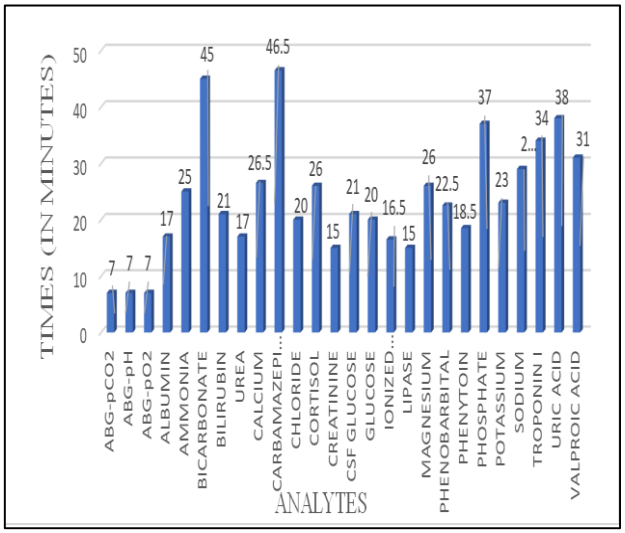

Figure 5: Time duration between analysis completed time and verification time of critical results.

Evaluation of effective communication of results of urgent samples and critical results notified after analysis through telephone showed that troponin I (85.16%) followed by potassium (64.24%) as the most commonly informed analytes. CSF glucose, ionized calcium, cortisol, phenobarbital, carbamazepine were not at all notified during the study period. Implementation of documentation of UCN in Table 2 shows that notification of calcium (92.24%) and chloride (95.45%) was documented successfully in LIS but the entry of the same

in the record book was only 30.17% and 27.27% respectively. There was no documentation of CSF glucose, cortisol, phenobarbital and carbamazepine in both dedicated register and LIS.

Out of 4687 critical results, 91% of the results were informed by calls and other forms of notification. 25.41% (1191) critical results were informed directly to the inpatient ward through telephonic communication which was recorded in the dedicated register and 40.23% of total critical results was entered in LIS. No telephonic communication or other forms of records were present for 421 (9%) results which included CSF glucose, blood gases, phenobarbital and carbamazepine.

Table 1: List of number of tests under UCN with their percentage.

Groups	Duration	Analytes	Total no. of tests analyzed by the lab	Critical results notified by the lab	
				N	%
1	Oct-Dec 2016	Ammonia	395	48	12.15
		Lipase	943	140	14.85
		Magnesium	1809	48	2.65
		Albumin	11864	428	3.61
		Uric Acid	2038	15	0.74
		Bilirubin	4126	249	6.03
2	Jan-Mar 2017	Chloride	199	22	11.06
		Urea	9076	59	0.65
		Glucose	18540	229	1.24
		CSF Glucose	334	13	3.89
		Calcium	6048	116	1.92
		Sodium	4700	381	8.11
3	April-June 2017	Phosphate	4057	33	0.81
		Creatinine	28043	461	1.64
		Potassium	8075	702	8.69
		Ionised Calcium	156	8	5.13
		ABG-pH	1616	45	2.78
		ABG- pCO2	1616	40	2.48
		ABG- pO2	1616	296	18.32
		Bicarbonate	792	59	7.45
4	July-Oct 2017	Troponin I	2023	593	29.31
		Cortisol	2303	614	26.66
		Valproic Acid	196	28	14.29
		Carbamazepine	54	14	25.93
		Phenytoin	99	35	35.35
		Phenobarbital	34	11	32.35

UCN: Urgent Clinical Notification.

Table 2: Percentage of UCN informed.

Analytes	Critical results	(5a) information via telephonic communication (%)	(5b) Documentation in the dedicated register (%)	(5c) entry in LIS (%)
ABG-pH	48	0	0	0
ABG-pCO_2	140	0	0	0
ABG-pO_2	48	0	0	0
Albumin	428	3.27	3.27	14.01
Ammonia	15	4.16	4.16	25
Bicarbonate	249	0	0	11.86
Bilirubin	22	20.08	20.08	60.24
Urea	59	15.25	15.25	64.40
Calcium	229	30.17	30.17	92.24
Carbamazepine	13	0	0	0
Chloride	116	27.27	27.27	95.45
Cortisol	381	0	0	0.32
Creatinine	33	6.94	6.94	14.53
CSF Glucose	461	0	0	0

Continued.

Analytes	Critical results	(5a) information via telephonic communication (%)	(5b) Documentation in the dedicated register (%)	(5c) entry in LIS (%)
Glucose	702	6.55	6.55	12.66
Ionized calcium	8	0	0	12.50
Lipase	45	0.71	0.71	38.57
Magnesium	40	14.58	14.58	58.33
Phenobarbital	296	0	0	0
Phenytoin	59	5.71	5.71	2.85
Phosphorus	593	33.33	33.33	78.78
Potassium	614	64.24	64.24	63.96
Sodium	28	12.86	12.86	77.42
Troponin I	14	85.16	85.16	83.30
Uric acid	35	6.66	6.66	93.33
Valproic acid	11	3.57	3.57	3.57

UCN: Urgent Clinical Notification.

Table 3: Comparison of TAT between critical results and urgent samples.

Analytes	No: of samples found as critical after analysis	TAT-critical results (min)	No: of urgent samples	TAT-Urgent samples (min)	P value
Albumin	167	74.00	2	78.00	-
Ammonia	67	77.00	99	67.00	0.017*
Bicarbonate	23	60.00	85	53.00	0.428
Bilirubin	322	80.00	24	73.50	0.432
Calcium	163	80.00	30	77.50	0.572
Chloride	39	87.00	47	49.00	0.001*
Cortisol	698	109.00	1	54.00	-
Creatinine	635	68.00	37	62.00	0.232
Glucose	198	93.00	13	43.00	<0.001*
Ionized calcium	36	61.50	1	90.00	-
Lipase	92	74.50	48	62.00	0.066
Magnesium	41	62.00	10	65.00	0.794
Phosphorus	64	84.00	7	80.00	-
Potassium	303	73.00	24	54.00	0.006*
Sodium	257	75.00	15	54.00	0.019*
Troponin I	574	74.00	751	74.00	0.999
Urea	24	69.50	1	167.00	-
Uric acid	22	66.50	5	99.00	-

TAT: Turnaround time, *****Statistically significant ($p<0.05$)

The number of urgent samples and samples reported as critical after analysis were 1200 and 3725 respectively during October 2017-December 2017. Table 3 gives the distribution of turnaround time (from sample reception to verification) for all urgent tests and critical results and, it was found to be 72.33 minutes and 76.00 minutes respectively. Among the samples that notified as urgent after analysis, cortisol was found to have highest TAT (109 min) and TAT for bicarbonate was 60 min which was least. In the group of urgent samples, calcium took more time to report (77 min) and the TAT was less for glucose (43 min) followed by chloride (49 min).

DISCUSSION

Critical result and urgent sample results notification is very important for critical treatment decision. Monitoring the notification of the same has become a part of guidelines for accreditation agencies and as a part of quality indicator. Direct notification of results to the caregiver is another major aspect of handling critical sample, which is the next step after verification by the verifier (technician). The reports are handed over to sample receiving area (receptionist) to inform the care giver. As per the protocol all the UCN must be informed to the care giver (100%) and the same should be documented in record book or LIS.

In this study, 9% of the critical results were either not informed or informed and not documented in the LIS. Failure to inform the caregiver or failure to document the notification, appears to be relatively common. A recent study also described that failures to inform patients were relatively common, occurring every 1 in 14 tests.[6] Similar study conducted by Valenstein et al shows that no call or

other form of rapid notification took place for 10 of the 3545 critical results.[7]

Agarwal et al reported that there is a poor awareness among nursing and lab staff regarding urgent sample and critical value reporting.[8] After intervention they found an improvement in reporting and recording of urgent samples in separate register from point of sample receiving area.

Increase in sample load in lab has also been found to be another cause of delay or failure in reporting. This must be addressed by increasing the number of counter staff with appropriate training or dedicated technician to handle these notifications to improve quality of reporting/ adopt innovative methods using information technology. Hawkins study on 'laboratory turnaround time' noted that training of laboratory staff to expedite handling of urgent laboratory samples, improves services.[9]

In the present study, other reasons include shifting patients to other location in the hospital and phone call not attended by caregivers. This could be reduced by sending an SMS alert to registered phone number and to the mobile number of the caregiver. However, form of communication has its own pros and cons, where the care giver may not attend to it, if there are many notifications informed to him. Similarly, Plebani et al explained one of the ways to notify the critical results is by mailing or to generate an SMS to the cell phone of the referring physician and to the respective care area.[10] Mangukiya et al found that major reasons for failure of notification of critical alert were incomplete detail on request form, which include patient location, phone not picked up by caregiver or phone engaged, OPD patients that are routinely not informed.[11]

The fruitfulness of the UCN can only be assessed by knowing the number of results which actually reached the concerned physician and effective measures were taken for the same. Assessment of this is extremely difficult, however.

TAT for all the analytes were within the time frame as per the protocol in the laboratory which shows the effective handling of urgent samples and critical results by the technician.

ABG analysis was always considered as an urgent sample, where the sample is processed and verified immediately without delay and printout of results from the instrument is handover to the caregiver or attender. So, the turnaround time is always negligible. The effectiveness of the ABG reporting process depends on the timely information that is handed over from caregiver or attender to the treating physician.

In a national survey, 11% of patients stated that they had experienced delays during the previous year in receiving abnormal test results.[12] Tate and Gardner show that fewer than 10% of critical value were reported in their institution.[13] Many researchers have reported about the handling and notification of urgent or critical samples. Agarwal et al also found that the average TAT for critical value notification in their laboratory was 60 min.[8]

TAT between urgent samples and routine samples with critical results was compared using Mann-Whitney and Wilcoxon test. Statistically significant difference ($p<0.05$) in turnaround time between urgent sample and sample with critical results was found for the analytes viz., ammonia, chloride, glucose, potassium and sodium. For these analytes urgent sample results were informed much faster than the critical results, as urgent samples are continuously followed. The delay for critical results may be due to technician not able to recall results immediately after analysis. To overcome this, enabling settings in the instrument for highlighting critical results or alarm for those results soon after analysis or more frequent recall of the results from instrument would be of great benefit.

The p value was not calculated for the analytes such as albumin, cortisol, ionised calcium, phosphorus, urea, uric acid as the number of urgent samples were less during the study period and for drugs such as valproic acid, carbamazepine, phenytoin, phenobarbital and CSF glucose as they were not received as an urgent sample.

Wski et al reported that TAT can be shortened by running a satellite laboratory.[14] Fernandes et al reported that the time taken to convey specimens to the laboratory can be shortened by using a pneumatic tube system.[15] TAT can also be decreased by laying down the protocol for type of sample required for urgent samples. Using plasma sample as choice of specimen would certainly decrease TAT. TAT can also be decreased if the analyte can be estimated in whole blood by point of care devices without compromising the quality of results.

Limitations

Follow up after notification of critical values were not done in the study and OPD samples were not considered in this study.

CONCLUSION

This study highlighted that the laboratories could have various approaches to improve the critical value notification and its turnaround time. First, the critical value notification procedure must be laid down by the laboratory. Second, increase in awareness among laboratory personnel and caregiver about the UCN protocol will lead to improvement in communication of critical value and its timely notification. Third, review of the process of UCN to identify the deficiencies in the steps / workflow involved. Fourth, effective use of LIS and alert value flagging to the technician. Fifth, sample type required and the methodology for the urgent samples can be changed to improve the turnaround time.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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