

Does routine repeat testing of critical laboratory values improve their accuracy?

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Abstract

Background: Routine repeat testing of critical laboratory values is very common these days to increase their accuracy and to avoid reporting false or infeasible results. We figure that repeat testing of critical laboratory values has any benefits or not.

Methods: We examined 2233 repeated critical laboratory values in 13 different hematology and chemistry tests including: hemoglobin, white blood cell, platelet, international normalized ratio, partial thromboplastin time, glucose, potassium, sodium, phosphorus, magnesium, calcium, total bilirubin and direct bilirubin. The absolute difference and the percentage of change between the two tests for each critical value were calculated and then compared with the College of American Pathologists/Clinical Laboratory Improvement Amendments allowable error.

Results: Repeat testing yielded results that were within the allowable error on 2213 of 2233 specimens (99.1%). There was only one outlier (0.2%) in the white blood cell test category, 9 (2.9%) in the platelet test category, 5 (4%) in the partial thromboplastin time test category, 5 (4.8%) in the international normalized ratio test category and none in other test categories.

Conclusion: Routine, repeat testing of critical hemoglobin, white blood cell, platelet, international normalized ratio, partial thromboplastin time, glucose, potassium, sodium, phosphorus, magnesium, calcium, total bilirubin and direct bilirubin results does not have any benefits to increase their accuracy.

Keywords: Critical values, Laboratory, Accuracy, Allowable error.

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Introduction

Nowadays, laboratory services play a major role in optimizing patient care. In some circumstances, increased laboratory use is allowed such as: 1. Correct and prompt diagnoses can be made. 2. Suitable treatments can be selected and achieved. 3. Better prognoses can be established and 4. The duration of the patient's hospitalization can be shortened (1-4).

Repeat testing usually occurs for the following reasons: 1. Previous test results are not available or the physician does not know about them (5-8), nevertheless, information technology can display previous

test results and reduce useless repeat testing (9,10). 2. A performed test, repeats again for the patient after admission to hospital (11). 3. Pre-analytic errors occur and there is a need for re-sampling the specimen (12,13). 4. The patient asks physicians to repeat a test again (14,15).

In the early decades of 1970, Lundberg and his colleagues at the Los Angeles County/University of Southern California Medical Center introduced the term "panic values" for those kinds of laboratory results that can predict high risk danger for the patients and be life-threatening unless the physicians do some immediate possible in-

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tervention. After some criticism that physicians should not be panic for any cause, they changed it to "critical values" (12,13,16).

In time, reporting of critical laboratory test values became an important operation of clinical laboratory utilization and has been adapted worldwide including some laboratory accreditation agencies, such as the College of American Pathologists (CAP) and the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) that have made it part of the requirements for laboratory accreditation (17,18). They require laboratories to define their own list of critical test values according to their national safety conditions and an authentic system to report of such results to patient's caregivers (18-20).

The JCAHO announced improving the process of critical value reporting a National Patient Safety Goal for the years 2004 through 2006. Also it has defined critical test results as not only laboratory tests but also imaging, electrocardiograms, and other diagnostic proceedings (17).

In the early years of automatic laboratory procedures, there were no advanced Laboratory information system (LIS) technology and instruments with sensitive level sensors and clot detectors. Therefore, it was acceptable to repeat critical test values to prevent inaccurate results created due to common problems such as misidentification of the sample, fibrin clots, or insufficient samples. But nowadays repeating them is necessary only when we have uncertain results otherwise it is an unnecessary work to do (21). As a recent summary of data from a College of American Pathologists (CAP) Q-Probes survey shows that pre-analytic and post analytic errors representing 85% to 92% of all clinical laboratory related errors, while analytic issues include only 8% to 15% of them (22,23). It also approved that 60.8 percent of laboratories still repeat critical values in chemistry, and 52.6 percent always repeat critical values in hematology (24).

On the other hand, unnecessary tests may

have some disadvantages such as: 1. Performing inappropriate treatments. 2. Causing fear and anxiety in patients by false positive results, or inducing a large number of further unnecessary testing (25,26). 3. Increased costs for the patients and health care system which could lead to other incompetencies in health care delivery (27-31). 4. Delay reporting to caregiver for example, The CAP Q-Probes survey expressed that laboratory routine repeat testing can delay reporting by 10 to 14 minutes without increasing the accuracy of the results (24,31,32).

So far, several studies have been conducted recently about the routine repeat testing of critical values in laboratories and its possible effect on increasing accuracy of the results, such as: 1. Chima et al's study in 2007 on 580 repeated tests in hematology, coagulation, and chemistry testing (21). 2. Toll et al's study in 2010 on 500 consecutive critical results in 5 different hematology and coagulation tests (31). 3. Deetz et al's study in 2011 on 3162 critical results (33). They all reported that routine repeating critical test values did not offer any advantage over single testing in improving results accuracy.

There has not been any study about determining the effect of routine repeat testing of critical values in laboratory tests in Iran. Moreover, the international studies on this subject mostly cover a limited range of laboratory tests. Therefore, we conducted our research in a way that covers various tests to overcome this shortcoming of existing literature. Another incentive for our research is the fact that the majority of laboratories in Iran, especially the ones in educational hospitals apply routine repeat testing of critical values as their regular method. This method is time consuming and expensive, so unless they add significant prognostic information they can be avoided. Our goal was to determine the effect of routine repeat testing of critical values in 13 different hematology, coagulation, and routine chemistry tests.

Methods

Hazrat Rasoul-e-Akram Hospital is a 426-bed Hospital in Tehran. Specialty services at our hospital include internal medicine, cardiology, neurology, neurosurgery, pediatrics, ophthalmology, ENT, gynecology and obstetrics and emergency. In our hospital we repeat critical laboratory test values routinely to verifying them to ensure their accuracy before reporting them to the physician. This repeating can be performed on the same collected specimen or on the re-collected one.

Tests examined were Hemoglobin (HGB), white blood cell count (WBC), platelet count (PLT), international normalized ratio (INR), partial thromboplastin time (PTT) for hematology laboratory and glucose (Glc), potassium (K), sodium (Na), phosphorus (P), magnesium (Mg), calcium (Ca), total bilirubin (total bil) and direct bilirubin (direct bil) for chemistry laboratory. Hematology tests were performed on ethylenediaminetetraacetic acid (EDTA) - anticoagulated blood specimens on the Sysmex KX 21 analyzer. For sodium and potassium tests we used Ion Selective Electrode (ISE) method on Microlyte analyzer. Chemistry tests were performed on serum specimens on the Hitachi 902 analyzer, and coagulation tests were performed on citrated blood specimens and analyzed by manual method. Repeat runs were performed on the same analyzer. All analyzers were placed under calibration and quality control constantly. We created a report to retrieve only the repeated critical values tests not any repeated testing. The data captured in these reports included date, patient ID, age and gender of patients, initial result, repeated result, repeated test was performed in which sample: the same collected specimen or on the re-collected one. We collect these data for over a year from August 22, 2011 to August 22, 2012.

Medical laboratory staff was highly qualified and they have had over five years of experience. We also directed them on the way that the tests results should be collected and reported.

The critical laboratory test values were collected from patients with a wide variety of clinical complaints including malignancies, infections, autoimmune disorders, traumas, etc. The absolute value and the percentage of change between the 2 test runs for each critical value were calculated and averaged for each test category and then compared to the College of American Pathologists/Clinical Laboratory Improvement Amendments (CAP/CLIA) allowable errors. If the absolute difference or the percentage of change between the repeated value and the initial result was greater than CAP/CLIA allowable error, it was assumed an outlier. The CAP/CLIA allowable errors and critical values for the tests are shown in Table 1.

Statistical analysis

All statistical analysis was done by SPSS19. Absolute Difference, Mean, and Percentage of change were calculated as follows:

$$\text{Absolute Difference} = |\text{Initial test value} - \text{Repeated test value}|$$

$$\text{Mean} = \frac{\text{Initial test value} + \text{Repeated test value}}{2}$$

$$\text{Percentage of Change} = \frac{\text{Absolute Difference}}{\text{Initial test value}} \times 100$$

Results

Hemoglobin (HGB): Among the 348 HGB critical values, the repeat values of 122 specimens (35.06%) had equal results to the initial test run.

White Blood Cell Count (WBC): Among the 469 WBC critical values, the repeat values of 171 specimens (36.46%) had equal results to the initial test run.

Platelet Count (PLT): Among the 309 PLT critical values, the repeat values of 95 specimens (30.74%) had equal results to the initial test run.

International Normalized Ratio (INR)

International Normalized Ratio (INR):

Table 1. The CAP/ CLIA allowable errors and critical values

Test	Critical value	Allowable Error
Hemoglobin	< 7 or > 20 g/dL	+/- 7%
Platelet	< 30000 or > 950000 per/mL	+/- 25%
White Blood Cell	< 2000 or > 25000 per/mL	+/- 15%
Partial Thromboplastin Time	< 20 or > 106 sec	+/- 15%
International Normalized Ratio	> 5	+/- 15%
Glucose	< 50 or > 450 mg/dL	+/- 6 mg/dL or 10%
Sodium	< 125 or > 150 mmol/L	+/- 4 mmol/L
Potassium	< 3 or > 5/9 mmol/L	+/- 0/5 mmol/L
Calcium	< 6 or > 14 mg/dL	+/- 1 mg/dL
Magnesium	< 1 or > 4/5 mg/dL	+/- 25%
Total Bilirubin	>18 mg/dL	+/- 0/4 mg/dL or 20%
Direct Bilirubin	> 1/8 mg/dL	+/- 0/4 mg/dL or 20%
Phosphorus	< 1 mg/dL	+/- 0/3 mg/dL

Among the 104 INR critical values, the repeat values of 27 specimens (25.96%) had equal results to the initial test run. In this category, 69 repeating tests (66.35%) were performed on the re-collected sample.

Partial Thromboplastin Time (PTT):

Among the 126 PTT critical values, the repeat values of 13 specimens (10.32%) had equal results to the initial test run. In this category, 86 repeating tests (68.25%) were performed on the same collected sample, and 40 repeating tests (31.75%) were per-

Table 2. The Mean Absolute Difference And Percentage of Change Between 2 Testing Runs For Each Test Category

Test	Subgroups	No. of specimens	Result Range	Result Mean	Mean Absolute Difference	Mean Percentage of Change
HGB (g/dL)	All specimens	348	-	-	0.16	2.3%
	HGB < 7	329	2.4-6.9	6.08	0.13	2.26%
	HGB > 20	19	20.1-25	22.1	0.62	2.84%
WBC (per/mL)	All specimens	469	-	-	152.45	2.25%
	WBC < 2000	223	200-1950	1243.5	52.47	3.91%
	WBC>25000	246	25100-123000	30761.8	243.09	0.75%
PLT (per/mL)	All specimens	309	-	-	1747.57	7.15%
	PLT < 30000	285	1000-29000	16977.19	1126.3	7.68%
	PLT>950000	24	952000-1310000	1001104.2	9125	0.84%
INR	All specimens	104	5.1-7	5.56	0.22	3.87%
	same sample	69	5.1-7	5.59	0.26	4.63%
	re-collected sample	35	5.1-6.5	5.5	0.13	2.37%
PTT (sec)	All specimens	126	107-136	116.83	3.87	3.34%
	same sample	86	107-136	116.8	3.83	3.3%
	re-collected sample	40	107-130	116.91	3.98	3.42%
P (mg/dL)	All specimens	82	0.3-0.9	0.76	0.05	7.99%
Glc (mg/dL)	All specimens	109	-	-	2.04	1.62%
	Glc < 50	38	29-49	42.91	1.5	3.73%
	Glc > 450	71	451-513	467.49	2.32	0.49%
K (mmol/L)	All specimens	118	-	-	0.06	1.81%
	K < 3	90	2.5-2.9	2.8	0.06	2.13%
	K > 5.9	28	6-6.2	6.05	0.05	0.77%
Mg (mg/dL)	All specimens	87	-	-	0.05	3.03%
	Mg < 1	60	0.6-0.9	0.83	0.03	3.34%
	Mg > 4.5	27	4.6-5.4	4.89	0.11	2.35%
Na (mmol/L)	All specimens	124	-	-	0.46	0.37%
	Na < 125	102	120-124	122.99	0.49	0.4%
	Na > 150	22	151-153	151.25	0.32	0.21%
Ca (mg/dL)	All specimens	106	-	-	0.12	1.63%
	Ca < 6	63	5-5.9	5.53	0.12	2.15%
	Ca > 14	43	14.1-16.1	14.74	0.13	0.88%
Total bil (mg/dL)	All specimens	131	18.5- 40.5	26.71	0.19	0.74%
Direct bil (mg/dL)	All specimens	120	1.9-4.5	2.93	0.19	6.49%

HGB, Hemoglobin; WBC, White Blood Cell; PLT, Platelet; INR, International Normalized Ratio; PTT, Partial Thromboplastin Time; P, Phosphorus; Glc, Glucose; K, Potassium; Mg, Magnesium; Na, Sodium; Ca, Calcium; bil, Bilirubin; sec, seconds.

formed on the re-collected sample.

Phosphorus (P): Among the 82 P critical values, the repeat values of 52 specimens (63.4%) had equal results to the initial test run.

Glucose (Glc): Among the 109 Glc critical values, the repeat values of 17 specimens (15.6%) had equal results to the initial test run.

Potassium (K): Among the 118 K critical values, the repeat values of 62 specimens (52.5%) had equal results to the initial test run.

Magnesium (Mg): Among the 87 Mg critical values, the repeat values of 56 specimens (64.37%) had equal results to the initial test run

Sodium (Na): Among the 124 Na critical values, the repeat values of 76 specimens (61.29%) had equal results to the initial test run.

Calcium (Ca): Among the 106 Ca critical values, the repeat values of 36 specimens (33.96%) had equal results to the initial test run.

Total Bilirubin: Among the 131 Bil total critical values, the repeat values of 22 specimens (16.8%) had equal results to the initial test run.

Direct Bilirubin: Among the 120 Bil direct critical values, the repeat values of 20

specimens (16.67%) had equal results to the initial test run.

The mean absolute difference and percentage of change between two testing runs for each test category and subgroups of them are tabulated in Table 2.

The lowest absolute difference was 0.05 mg/dL, obtained for the Mg and P results, and the highest absolute difference was 1747.57 per/mL, obtained for the PLT results. Among the subgroups the lowest absolute difference was 0.03 mg/dL, obtained for the Mg<1 mg/dL results, and the highest absolute difference was 9125 per/mL, obtained for the PLT>950000 results.

The lowest percentage of change was 0.37%, obtained for the Na results, and the highest percentage of change was 7.99%, obtained for the P results. Among the subgroups the lowest percentage of change was 0.21%, obtained for the Na>150 mmol/L results and the highest absolute difference was 7.99%, obtained for the P results.

The specifics of outliers are shown in Table 3. There was 1 outlier (0.2%) in the WBC test category with the absolute difference of 200 per/mL, and a mean value of 1400 per/mL, 9 (2.9%) in the PLT test category with the absolute differences in the range of 1000 to 4000 per/mL, and the mean values in the range of 3500 to 18000

Table 3. Specifics of Outliers

Test	Total Specimens, No	Outliers, No. (%)	Allowable Error	Run 1	Run 2	Mean	Absolute Difference	Percentage of Change	Same or recollected sample
White Blood Cell (per/mL)	469	1(0.2%)	+/-15%	1300	1500	1400	200	15.38%	Same
Platelet (per/mL)	309	9(2.9%)	+/-25%	8000	10000	9000	2000	25%	Same
				7000	9000	8000	2000	28.57%	Same
				4000	5000	4500	1000	25%	Same
				7000	11000	9000	4000	57.14%	Same
				3000	4000	3500	1000	33.33%	Same
				4000	5000	4500	1000	25%	Same
				5000	7000	6000	2000	40%	Same
				16000	20000	18000	4000	25%	Same
				7000	9000	8000	2000	28.57%	Same
International Normalized Ratio	104	5(4.8%)	+/-15%	5.2	6.2	5.7	1	19.23%	Same
				6	7	6.5	1	16.67%	Same
				5.2	6	5.6	0.8	15.38%	Same
				5.3	6.1	5.7	0.8	15.09%	Same
				5.2	6.2	5.7	1	19.23%	Same
Partial Thromboplastin Time (sec)	126	5(4%)	+/-15%	118	136	127	18	15.25%	Same
				108	125	116.5	17	15.74%	Same
				107	124	115.5	17	15.89%	Same
				107	124	115.5	17	15.89%	Recollected
				113	130	121.5	17	15.04%	Recollected

per/mL. 5 (4.8%) in the INR test category with the absolute differences in the range of 0.8 to 1, and the mean values in the range of 5.6 to 6.5. 5 (4%) in the PTT test category with the absolute differences in the range of 17 to 18 seconds, and the mean values in the range of 115.5 to 127 seconds, and none in other 9 test categories.

Out of 20 (100%) samples with significant difference (outlier) only two (10%) of them were among the tests performed on recollected samples, the rest were performed on the same samples. Both of these cases belong to PTT test which means two of 126 tests (1.6%) and two of 40 recollected samples of this test (5%) showed significant differences. Recollected samples were only available for PTT and INR. Therefore, we do not have enough evidence to conclude whether recollected samples have significant effects on the results.

Discussion

As we mentioned before, recent studies showed that the routine repeat testing of critical test values does not have any advantage with recent year's laboratory automated equipments (21,31). In a recent study, Chima et al collected a total of 580 repeated tests for potassium, glucose, platelet count, and activated partial thromboplastin time and expressed that 95.3% of repeated testing for critical values was within their acceptable difference (21). Another study examined 500 consecutive critical results for 5 different hematology/coagulation tests. By using their laboratory's acceptable tolerance limits for reruns (ATLR), Toll et al expressed that 0% to 2.2% of the repeated values for these tests were outside of their acceptable range (31). Also, in 2011 Deetz et al examined 2162 critical results in chemistry laboratory and they found that 2.8% of the repeated values were outside of the CAP/CLIA Total allowable errors (33). They all concluded that repeated testing for critical values did not offer an advantage in hematology, chemistry, and coagulation settings. To determine the effect of routine repeat test-

ing of critical values, we examined 2233 specimens from 13 different hematology, coagulation, and chemistry tests (348 HGB critical results, 469 WBC critical results, 309 PLT critical results, 104 INR critical results, 126 PTT critical results, 82 P critical results, 109 Glc critical results, 118 K critical results, 87 Mg critical results, 124 Na critical results, 106 Ca critical results, 131 total Bilirubin critical results, and 120 direct Bilirubin critical results). We calculated the absolute difference and the percentage of change between the initial and repeated value for each of them and then compared with CAP/CLIA Total allowable errors. If the absolute difference or the percentage of change between the repeated value and the initial result was greater than CAP/CLIA allowable error, it was assumed an outlier.

From 2233 repeated test values, a total of 20 outliers were detected (99.1%) in which the difference between 2 testing runs exceeded the CAP/CLIA limits for allowable error. The test results outside this range included: There was only one outlier (0.2%) in the WBC test category, 9 (2.9%) in the PLT test category, 5 (4%) in the PTT test category, 5 (4.8%) in the INR test category and none in other test categories. None of the critical test values became noncritical on repeat testing.

The significant difference between the initial result and the repeated result in the PTT test category might be attributed to instability of specimens from patients on heparin therapy. Sometimes, heparin inhibition by platelet factor 4 (released by activated platelets in the specimen) makes these patient's results poor reproducible (34). In the PLT test category, it might be attributed to clot formation in the testing process, and that would decrease the count initially, but because of the poor strength of the clot, it will get a higher count the second time. Another problem with platelet counting is when you get down to really low levels; debris in the sample (e.g. ruptured cells, membranes, etc.) become a significant problem and Interferes with the

measurement system (24). On the other hand, hemolysis due to the breakdown of red blood cells is important to the laboratory because it can have an effect on laboratory results by increasing them falsely.

Despite our effort, our research faces some shortcomings which can be improved in future studies. First of all, the fact that all of our samples were collected from a single medical laboratory means that our results could be affected by the quality of its instruments, kits and reagents. Secondly, collected data for some tests such as Phosphorus and Magnesium were limited which could have made some biasness in our results. Finally, recollected samples were not available for all of our tests (they were only available for PTT and INR). Therefore, we are not able to make a comprehensive comparison between initial samples and recollected ones.

As a result of limited time and resources we were unable to collect data from various laboratories. It will be beneficial for further studies to collect data from different laboratories, which would be more representative.

Conclusion

At the end, we can say that the result of our observations is similar to previous studies. Nowadays, with advanced laboratory equipments, the routine repeat testing of critical values has no effect on increasing the accuracy of the results of these tests. Repeat testing may be helpful in some situations, such as when the physician doubts about the accuracy of a result, or when the test result is not consistent with the patient's condition. By ignoring the routine repeat testing of critical values we can accelerate the result reporting to caregiver, in addition to, we can reduce the additional test costs.

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