Utility of Repeat Testing of Critical Values

A Q-Probes Analysis of 86 Clinical Laboratories

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• ***Context.***—**A common laboratory practice is to repeat critical values before reporting the test results to the clinical care provider. This may be an unnecessary step that delays the reporting of critical test results without adding value to the accuracy of the test result.**

Objectives.—**To determine the proportions of repeated chemistry and hematology critical values that differ significantly from the original value as defined by the participating laboratory, to determine the threshold differences defined by the laboratory as clinically significant, and to determine the additional time required to analyze the repeat test.**

Design.—**Participants prospectively reviewed critical test results for 4 laboratory tests: glucose, potassium, white blood cell count, and platelet count. Participants reported the following information: initial and repeated test result; time initial and repeat results were first known to laboratory staff; critical result notification time; if the repeat result was still a critical result; if the repeat result was significantly different from the initial result, as judged by the laboratory professional or policy; significant difference threshold, as defined by the laboratory; the make and model of the instrument used for primary and repeat testing.**

Results.—**Routine, repeat analysis of critical values is a common practice. Most laboratories did not formally define a significant difference between repeat results. Repeated results were rarely considered significantly different. Median repeated times were at least 17 to 21 minutes for 10% of laboratories. Twenty percent of laboratories reported at least 1 incident in the last calendar year of delayed result reporting that clinicians indicated had adversely affected patient care.**

Conclusion.—**Routine repeat analysis of automated chemistry and hematology critical values is unlikely to be clinically useful and may adversely affect patient care.**

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The College of American Pathologists (CAP) and The Joint Commission require laboratories to have mechanisms in place to communicate critical values in a timely and accurate manner to clinical care providers. To verify that a result is truly critical, laboratories frequently repeat critical values before reporting the test results to the clinical care provider. Given the sophistication of many of the chemistry and hematology instruments currently in use, repeating a result may be an unnecessary step that delays the reporting of critical test results without adding value to the accuracy of the test result. Toll et al[1] concluded that routine, repeat testing of critical hemoglobin, platelet and white blood cell count, prothrombin time, and partial thromboplastin time results was not indicated. Munoz[2] also concluded that repeating critical hematology results was not warranted if the analyzer did not flag the result. Chima et al[3] discontinued repeat analysis of critical results produced by automated chemistry, hematology, and coagulation results, based on an analysis of their repeat data. Deetz et al[4] concluded that automated chemistry results that lie within the verified analytic measurement range do not need to be repeated.

Although it is assumed that repeat analysis of critical values is common, published information about the practice is scant. Munoz[2] reported on the practices of 340 laboratories for repeating critical values and delta check values, from a 2007 survey. Seventy percent of respondents always repeated, 29% sometimes repeated, and 0.9% never repeated hematology critical values. Forty percent always repeated, 56% sometimes repeated, and 3.3% never repeated delta check values. Comparable repeat rates were found for critical and delta check values for chemistry and coagulation testing, respectively (O. Muñoz, MS, written communication, March 2008). Information about how repeat values are interpreted and acted upon, and how repeat testing affects clinical practice has not been reported in the peer-reviewed literature; and only 1 center has reported the effect of repeat testing on turnaround times.[4]

This Q-Probes study was designed to determine the proportion of repeated critical results, the proportion of

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repeated results that still met the criteria for a critical result, the proportion of repeated results that were significantly different from the original result, and the median time between the initial and repeated test result for multiple laboratories that repeat at least some critical values.

MATERIALS AND METHODS

Definitions of Terms

Time of Critical Result.—The time a result was first known by the laboratory staff to be critical. This is generally the time the test instrument first made the critical result available to laboratory staff. This time is not necessarily the time of result verification in the computer, unless the laboratory staff member verifies results as soon as testing is complete.

Critical Result Notification Time.—The time a laboratory staff member or client services staff member first attempted to reach someone to accept the critical result.

Significant Difference Threshold.—The difference between repeat values that your laboratory defines as significant for that test.

Study Design

Participants prospectively reviewed critical test results for 4 laboratory tests: glucose, potassium, white blood cell count, and platelet count until 40 initial critical results of each test type that were subsequently repeated were identified. A maximum of 5 repeat critical results of each test type per day were included in the study to ensure a survey of practice across multiple days, particularly for laboratories that report more than 5 critical results per test per day. Point-of-care testing was excluded from the study. For each repeated critical test result, participants reported the following information: initial and repeat test result; time initial and repeat results were first known to laboratory staff; critical result notification time; if the repeat result was still a critical result; if the repeat result was significantly different from the initial result, as judged by the laboratory professional; significant difference threshold, as defined by the laboratory; and which instrument was used for initial and repeat testing (primary versus secondary instrument). Participants were also asked a number of questions about their critical repeat policies and practices.

Calculation of Quality Indicators

Proportion of Repeated Results That Met Criteria for a Critical Result = (No. of Repeated Tests That Were Still Critical Values/Total No. of Repeated Critical Tests) × 100.

Proportion of Repeated Results Significantly Different From the Original Result = (No. of Repeated Tests That Were Significantly Different From the Original Result/Total No. of Repeated Critical Tests) × 100.

Proportion of Critical Values Repeated = (No. of Repeated Critical Tests/Total No. of Critical Results Reviewed to Meet Sampling Criteria) × 100.

Median Time to Repeat Test (minutes) = Median Elapsed Time Between Initial and Repeat Analysis.

Statistical Analyses

The distributions of the Quality Indicator proportions were skewed so a log transformation was performed to normalize the data. For each of the 4 laboratory tests, the 4 Quality Indicators were tested for statistical association against all demographic and practice variables by using Kruskal-Wallis tests for discrete-valued variables and simple regression analysis for continuous variables. Variables with significant associations ($P < .10$) were entered into a forward selection multivariate regression model using a significance level of .05. All statistical analyses were performed with SAS v9.1 (SAS Institute, Cary, North Carolina).

RESULTS

Participant Characteristics

Most of the 86 participating institutions (94%) were located in the United States, with the remaining located in Saudi Arabia (3), Australia (1), and Canada (1). Of the participating institutions, 29.1% are teaching hospitals and 18.1% have pathology residency programs. Within the past 2 years, the CAP inspected 85.5% of the participating laboratories. Laboratory inspections were conducted by the Joint Commission at 19.3% of institutions within the last 2 years. Institution demographics are provided in Table 1.

Laboratory Policies and Practices of Repeat Results

Seventy-three percent (hematology section) and 78% (chemistry section) of participants did not have a policy defining a "significant" difference between repeated results, and for those that did have a policy, nonlaboratory personnel had reviewed the policy at 46% of the institutions. Of those that did not have a policy, 93% left it to the employee verifying the result to define a "significant" difference on a case-by-case basis. With the exception of potassium, difference thresholds were more often defined as a percentage difference, and 10% was the most common difference considered significant (Table 2). If a repeat value is not considered significantly different, approximately 60% of laboratories would report the first result. If a repeat value is judged significantly different, most laboratories would run the test for a third time. If the repeat value is not significantly different, but no longer a critical result, 40% of laboratories would report the original critical value to the clinician. If the repeat value is significantly different, but no longer a critical result, only 14% of laboratories would report the original critical value to the ordering clinician (Table 3).

Participants performed chemistry measurements on 16 analyzer models from 7 different manufacturers using hexokinase, glucose oxidase, or glucose dehydrogenase methods. Hematology measurements were performed with 21 analyzer models from 5 different manufacturers. By design, all participants repeated at least some critical results. In approximately 61% of chemistry sections and 53% of hematology sections, critical results were repeated routinely (Table 4). There was no significant statistical association between testing methodology or instrument make or model and the proportion of critical values that were repeated. Reasons for not repeating critical results included prior report of a critical value for that patient; critical result not a delta check; and institutional policy precluding a repeat owing to patient type, clinical service, or patient location. Ninety-one percent of laboratories reported having a backup chemistry analyzer and 94% a backup hematology analyzer. Repeat analysis was performed predominantly on the same analyzer that was used for the initial analysis. This was done automatically on most chemistry analyzers, but rarely on hematology instruments. If the initial analysis was performed on an aliquot, the repeat was always performed on the primary sample 37% of the time for chemistry specimens and 52% of the time for hematology specimens (Table 4).

Critical Repeat Data

There was excellent agreement between initial and repeat test results (Table 5). Greater than 99% of repeated glucose results were still critical, and only 0.3% were considered significantly different. Ninety-nine percent of repeat potas-

Table 1. Institution Demographics		
	No. of Institutions	Percentage
Institution type		
Voluntary, nonprofit hospital	48	57.8
Proprietary hospital	8	9.6
County hospital	5	6.0
Private, independent laboratory	3	3.6
Nongovernmental, university hospital	3	3.6
Other, governmental, nonfederal	3	3.6
System/integrated delivery network	2	2.4
Other, nongovernmental	2	2.4
Governmental, nonfederal university hospital	2	2.4
Indian Health Service	2	2.4
Group practice	1	1.2
Children's hospital	1	1.2
State acute hospital	1	1.2
Veterans hospital	1	1.2
Other, governmental, federal	1	1.2
Occupied bed size		
0–150	36	49.3
151–300	19	26.0
301–450	10	13.7
451–600	4	5.5
>600	4	5.5
Institution location		
City	35	42.2
Suburban	23	27.7
Rural	25	30.1
Government affiliation		
Nongovernmental	68	81.9
Governmental, nonfederal	11	13.3
Governmental, federal	4	4.8

sium results were still critical, and only 0.2% were considered significantly different. Ninety-nine percent of repeat white blood cell counts were still critical and only 0.2% were considered significantly different. Ninety-eight percent of repeat platelet counts were still critical, and 1.7% were considered significantly different (Table 5). However, 24 of the 37 platelet results considered different originated from only 2 institutions. This most likely reflects either a problem with their analyzer(s) or a problem with specimen preparation. Excluding these 2 laboratories from the analysis produces an incidence of significantly different results of 0.6%, a value consistent with results for the other 3 tests. Review of the data for all 4 tests demonstrated that some laboratories are expecting result repeatability that is not within the capability of contemporary hematology and chemistry analyzers. This is consistent with the distributions of stated thresholds for significant differences (Table 2). There was no significant statistical association between testing methodology or instrument make or model and the proportion of repeat results that were either no longer critical, or were significantly different.

One quarter of laboratories had median repeat times of at least 10 to 14 minutes, while 10% of laboratories had median repeat times of at least 17 to 21 minutes (Table 6). Test repeat times were the only quality indicators that had statistically significant associations with laboratory practices in the final multiple regression model. Laboratories that always repeat critical glucose ($P < .001$) or potassium ($P = .04$) results had significantly lower median repeat times. Laboratories that had policies that precluded repeat analysis of critical white blood cell ($P = .007$) and platelet ($P = .005$) counts, based on patient type, clinical service, or ward location, had significantly lower proportions of repeat analyses. There was no significant association between testing methodology or instrument make or model and median repeat times. Twenty percent of laboratories had at least 1 instance in the last calendar year where clinicians reported that a delay due to repeat testing had adversely affected patient care.

COMMENT

Little is known either about the practices of laboratories that have a policy of repeating critical values, or about the utility of repeat analysis (reproducibility). The limited studies that are available that compare repeated results cover a very limited number of hematology and chemistry analyzers.[1–4] This Q-Probes study was designed to provide some insight into laboratory practices for repeating test results and to collect repeat data for 2 chemistry and 2 hematology tests performed on a variety of primary and secondary analyzers.

Table 2. Significant Difference Thresholds for Each Test Type			
Threshold	Frequency	Threshold Expressed as a Percentage	Frequency
Glucose[a]			
3	2	4	1
4	2	5	3
6	8	5.6	1
12	1	10	19
		50	1
Potassium[b]			
0	1	4	1
0.1	1	5	2
0.2	4	6.2	1
0.4	1	7	1
0.5	11	10	5
0.8	1	12.3	1
1.0	1	25	1
WBC count[c]			
0	1	1.4	1
0.1	1	5	2
0.3	1	9	1
0.4	2	10	7
1	1	15	2
3	1	20	2
		25	1
		30	1
Platelet count[c]			
1	1	0	1
3	1	7	1
5	1	10	5
6	1	15	2
9	1	20	3
15	1	25	2
20	2	50	1

Abbreviation: WBC, white blood cell.

[a] Threshold expressed as mg/dL.
[b] Threshold expressed as mEq/L.
[c] Threshold expressed as $\times 10^3/\mu L$.

Table 3. Chemistry and Hematology Practices Relating to Significantly Different Repeat Critical Values				
	Chemistry Laboratory Section		Hematology Laboratory Section	
	No. of Institutions	Percentage	No. of Institutions	Percentage
If the repeat value is not significantly different, which value is reported?[a] (chemistry: N = 76; hematology: N = 74)				
First result	46	60.5	46	62.2
Second result	27	35.5	22	29.7
Average of results	0	0.0	0	0.0
Other	7	9.2	9	12.2
Other category, submitted text responses	Tech decision (3) Either result reported Repeat test again		Tech decision (4) Either result reported Repeat test again Depends on initial result Depends on instrument flags	
If the repeat value is NOT significantly different but no longer classifies as a critical value, is the critical value still reported to the clinician?				
Yes	30	40.0	31	41.9
No	45	60.0	43	58.1
If the repeat value is significantly different but no longer classifies as a critical value, is the critical value still reported to the clinician?				
Yes	10	13.9	11	15.5
No	62	86.1	60	84.5
How does the laboratory proceed if the repeat value is significantly different from the first?				
Run the test a third time	58	74.3	50	66.7
Not run the test a third time	1	1.3	2	2.7
Other	19	24.3	23	30.7
Other category, submitted text responses	Recollect (8) Troubleshoot (5) Run QC, repeat on second specimen Review previous Check sample for fibrin		Recollect (9) Troubleshoot (4) Investigate sample (3) Check sample for clots (2) Run QC, repeat on second specimen Confirm by smear review Slide estimate Review previous	

Abbreviations: QC, quality control; Tech, technician or technologist.

[a] Multiple responses allowed.

Three quarters of laboratories did not have a written policy defining a significantly different repeat result. Instead, determination of a critical difference was left to the person verifying the results. This will inevitably lead to unwanted practice variation. For laboratories that define a significant difference between repeat results, 10% was the most common difference cited. The reasons laboratories selected their respective cutoffs were not solicited, so it is unclear if 10% was selected because of expected performance of the tests, of clinical significance, or for some other reason.

Routine, repeat analysis of all chemistry critical values (60.8% of laboratories) was more common than for hematology critical results (52.6% of laboratories). This may be due to the fact that, unlike hematology analyzers, chemistry analyzers can be programmed to automatically repeat samples. Automatic repeats would also explain the shorter median repeat time for laboratories that always repeat chemistry critical results.

Based on the repeat data from this study, and others, the clinical value of routinely repeating critical results appears suspect. Greater than 99% of the time a repeated potassium, glucose or white blood cell result was still critical and not considered significantly different by the laboratory. While repeat platelet counts appeared more variable (1.9% no longer critical and 1.7% considered significantly different), the increase in discrepant results was the result of a disproportionate contribution from only 2 participating laboratories. The adjusted incidence of discordant platelet pairs was comparable to those for the other tests (<1%). The incidence of results that are truly clinically different for any of the 4 tests is actually lower, since many test result pairs identified as significantly different by the participants could not be differentiated, based on the reproducibility of current hematology or chemistry analyzers.

Routine repeat of critical values had a significant impact on the provision of clinical care. Median repeat times were at least 17 to 21 minutes for 10% of laboratories. More importantly, 20% of the laboratories reported at least 1 incident in the prior calendar year where clinicians felt that a reporting delay adversely affected patient care. This Q-Probes study did not assess the manner and seriousness of the impact of reporting delays on clinical care; however, reported adverse events secondary to delayed laboratory service should be investigated and the root cause(s) determined.

Laboratory and hospital accrediting organizations require clinical laboratories to have mechanisms in place to communicate critical values in a timely and accurate manner to ordering providers. It has been a common practice for laboratories to repeat critical values to verify their accuracy before reporting the test results to the clinicians.[1–4] We did not assess why laboratories repeat critical values in this Q-Probes study. However, based on the fact that most laboratories repeat the analysis a third time when the initial 2 results disagree (presumably in an attempt to determine

Table 4. Laboratory Practices Relating to Critical Values

	Chemistry Laboratory Section		Hematology Laboratory Section	
	No. of Institutions	Percentage	No. of Institutions	Percentage
Are critical values repeated?				
Always	48	60.8	41	52.6
Sometimes	31	39.2	37	47.4
If critical values repeat "sometimes," which circumstances exclude repeat analysis?[a]	[b]		[c]	
Prior critical result already reported	25	80.6	32	86.5
Not a delta check result for patient	9	29.0	13	35.1
Due to patient type, clinical service or ward location	8	25.8	10	27.0
Only critical results from a subset of tests offered by the laboratory are subject to repeat analysis	3	9.7	1	2.7
Other	7	22.6	6	16.2
Laboratory has at least 1 backup analyzer				
Yes	72	91.1	73	93.6
No	7	8.9	5	6.4
Critical values routinely repeat on:				
Same analyzer that produced initial result	57	79.2	48	68.6
Different analyzer	15	20.8	22	31.4
System allows automatic repeat of critical values without tech intervention				
Yes	47	72.3	4	6.8
No	18	27.7	55	93.2
If initial analysis was performed on an aliquot, is repeat analysis performed on the primary sample?				
Always	27	37.0	35	52.2
Sometimes	35	47.9	16	23.9
Never	11	15.1	16	23.9

Abbreviation: tech, technician or technologist.

[a] Multiple responses allowed.
[b] N = 31.
[c] N = 37.

Table 5. Frequency That the Repeat Result Is Still Critical and Significantly Different, for Each Test Type

	Frequency	Percentage
Glucose		
Repeat still a critical value		
Yes	2517	99.5
No	13	0.5
Repeat significantly different		
Yes	8	0.3
No	2515	99.7
Potassium		
Repeat still a critical value		
Yes	2651	99.0
No	28	1.0
Repeat significantly different		
Yes	5	0.2
No	2667	99.8
WBC count		
Repeat still a critical value		
Yes	2213	99.3
No	16	0.7
Repeat significantly different		
Yes	4	0.2
No	2220	99.8
Platelet count		
Repeat still a critical value		
Yes	2153	98.1
No	41	1.9
Repeat significantly different		
Yes	37	1.7
No	2143	98.3

Abbreviation: WBC, white blood cell.

which of the initial results is accurate), it is reasonable to conclude that laboratories are trying to exclude the possibility that the measurement system has produced an unexpected, aberrant result. In the absence of evidence for a problem with a specific sample or assay, our data suggest that this is an unproductive exercise, and comes at the price of delayed result reporting and greater reagent and labor costs. Therefore, given the sophistication of many of the chemistry and hematology instruments currently in use, routine, repeat analysis is an unnecessary step that delays prompt clinical decision making and therapeutic intervention without adding value to the quality of the test result. Since neither the rate of repeat analysis nor the reproducibility of results varied significantly by analyzer or assay, the data presented in this Q-Probes study should be applicable to a variety of laboratories.

Table 6. Distribution of Participants' Median Times for Repeat Analysis

	All Institutions' Percentiles					
Median Time to Repeat Test, min	N	10th	25th	50th (Median)	75th	90th
Glucose	75	0.0	0.0	7.5	14.0	20.0
Potassium	73	0.0	0.0	6.0	13.5	20.0
WBC count	67	3.0	5.0	7.5	10.0	17.0
Platelet count	66	3.5	5.0	8.0	10.5	21.0

Abbreviation: WBC, white blood cell.

In summary, repeat analysis of samples with critical potassium, glucose, white blood cell, or platelet results rarely produced clinically discrepant results. Laboratories should assess the reproducibility of assays/measurements on their instrumentation and the clinical risk of nonreproducible results in their patient populations, and weigh those risks against the impact of delayed reporting of critical results to clinicians to determine whether routine repeat analyses of chemistry and hematology critical results are justified.

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