



Research Article

Investigation of the effect of autoverification on hematology laboratory workflow

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Abstract

Objectives: The aim of this study was to evaluate the effect of an autoverification process on test turnaround time (TAT), sample rejection rate, and the sample test repetition rate.

Methods: The study was carried out in the core laboratory of Istanbul Kanuni Sultan Suleyman Training and Research Hospital. Sysmex XN9000 series middleware (Sysmex Corp., Kobe, Japan) was used to perform the autoverification. The rate of test rejection, test repetition, and TAT of the 3 months preceding use of autoverification were compared with those of a 3-month period following initiation of use of the Sysmex hematology analyzer autoverification process.

Results: A total of 612,639 test results of complete blood count profiles performed between January 2019 and March 2019 were collected to determine the distribution intervals. The sample rejection and test repetition rates and the TAT were significantly reduced (21.18%, 49.62%, and 23.9%, respectively) after implementation of the new analyzer. Reflex testing rates, such as peripheral smear and reticulocyte count, were significantly increased.

Conclusion: Autoverification improved laboratory performance parameters. The hematology lab workflow benefited, and the system decreased the sample rejection and test repetition rate, which reduces extra costs like tubes wasted, time spent, and most importantly, an unproductive patient blood draw. Autoverification tools should be considered in healthcare management.

Keywords: Autoverification, hematology, test repetition rate, turnaround time

A computer-based laboratory result approval support system, or an autoverification process, is an application that applies user rules, minimizes errors, saves time in laboratory operations, and assists the laboratory specialist. It can be used in clinical chemistry, immunoassay, hematology, and urine analysis, and is now included in laboratory and diagnostic guides. Laboratory device manufacturers and laboratory information system (LIS) software companies have conducted pioneering work in this field. Machine-learning algorithms and complex statistical functions have been used to reform procedures to recognize common pre-analytical errors [1].

Autoverification permits the release of clinical laboratory results without manual human intervention [2]. There are many scientific studies on the use of approval support systems. A rules-based system based on the quality of laboratory in-

strumentation and quality of the results generated has been described to help decide if a laboratory should pursue the advantages of autoverification [3]. Basic rule sets for autoverification have not significantly changed for most laboratories and laboratory information systems for the past 20 years. The increasing use of new informatics tools and the general expansion of networks, client servers, and middleware have made new capabilities for autoverification universally available. The technological development of analyzers, control of the pre-analytic and analytic phase, and the precision of qualitative and quantitative hemogram data enable a laboratory specialist to be more and more efficient in detecting hematologic diseases [4]. The French-Speaking Cellular Haematology Group (GFHC) has proposed a standardization of professional practices with recommendations for quantitative and/or qual-

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itative criteria that should trigger the microscopic examination of a blood smear. These practical recommendations aim to provide added clinical value to the physician prescribing a hemogram [5]. High test-rejection rates and test repetitions affect lab workflow and result in time wasted and increased test turnaround time (TAT).

The aim of this study was to evaluate the effect of an autoverification process on the TAT and the rates of test rejection and repetition using a recently installed hematology analyzer.

Materials and Methods

The study was carried out in the core laboratory of İstanbul Kanuni Sultan Suleyman Training and Research Hospital. We used GFHC rules and Sysmex XN9000 series middleware (Sysmex Corp., Kobe, Japan) for the autoverification process. The middleware reports on 21 parameters in the pre-analytical and analytical phases, and then verifies the result or redirects the result to the specialist. After an initial 6-month study in 2018, outpatients were included in October 2018, and then all patient groups (inpatients and emergency department) were added on January 1, 2019. The rates of test rejection and test repetition as well as the TAT of the 3 months preceding hematology analyzer autoverification were compared with those of a 3-month period once all patients were included in the process. The duration of complete blood count (CBC) test analysis beginning with laboratory acceptance through result verification as well as test rejection and repetition rates were evaluated. Body fluid analysis and cell counts were excluded.

All of the study data were obtained from the laboratory automation system. Statistical analysis was performed using SPSS Statistics for Windows, Version 17.0 (SPSS Inc., Chicago, IL, USA). SPSS frequency analysis was used to compare data before and after autoverification and analyze efficiency. A hypothesis verification t-test was applied to determine if the change in test completion time decreased randomly or systematically and if the change before and after the implementation of autoveri-

fication was statistically significant. The variation in the data before and after autoverification was considered to be significant with a p value of <0.05 at a 95% confidence interval.

Results

A total of 612,639 test results of CBC profiles performed between January 2019 and March 2019 were collected to determine the distribution intervals. The data are summarized in Table 1. The autoverification report rates according to the applied rules are shown in Figure 1. The most common rules and rates are summarized in Figure 2. The TAT evaluation, test repetition rate, and sample rejection rate before and after the use of autoverification are summarized in Table 2.

During the autoverification period, productivity increased, the mean TAT decreased from 70 minutes to 19 minutes, 31 seconds, and the SD decreased from 59 minutes, 36 seconds to 16 minutes, 49 seconds ($p=0.001$). The hospital quality system targets a blood count TAT of 120 minutes. While our efficiency in compliance with performance criteria before the autoverification period was 87.90%, with autoverification, the efficiency increased to 92.90%, providing results an average of 1 hour, 40 minutes, 29 seconds before the targeted time. The performance of the laboratory increased ($p=0.011$). The test repetition rate and the sample rejection rate decreased, and the difference was considered significant with a value of $p=0.021$ and $p=0.022$, respectively (Table 2, Fig. 3). Reflex testing rates, such as peripheral smear and reticulocyte count, were significantly increased (Fig. 4).

Discussion

Operating systems and other technology can now provide autoverification through middleware inserted between the device operating systems and the LIS. The system approves verified results based on defined rules and sends results it cannot verify with a flag and a comment to the user. A CBC is the most common blood test performed in hospital laboratories, measuring

Table 1. Autoverification approvals and distribution of approval in a 3-month period

	Patients (n)	Autoverification approval	Expert approval	Autoverification rate (%)
Total patients	612.639	298.544	313.993	48.73
Department				
Emergency	248.469	96.303	152.151	38.76
Outpatient	280.373	176.873	103.434	63.08
Inpatient	83.797	25.368	58.408	30.27
Age				
Pediatric	181.300	53.853	127.447	29.70
Adult	431.237	244.691	186.546	56.74
Gender				
Female	379.431	196.220	183.211	51.71
Male	233.083	102.315	130.768	43.90

Table 2. Laboratory performance indicators for outpatients

Criteria	Before autoverification	After autoverification	p
TAT (min) mean±SD	70±59.36	19.31±16.49	0.001
TAT target capture rate (%)	87.90	92.90	0.011
Test repetition rate (%)	1.33	0.67	0.021
Sample rejection rate (%)	2.03	1.60	0.022

TAT: Test turnaround time

the type and number of red and white blood cells and platelets. This test is very important to help diagnose conditions such as anemia, leukemia, and infection. Accurate, fast, and reliable results are essential in laboratories and for clinicians because of the valuable contribution to a differential diagnosis. There are established rules for the approval of this simple but important test. Autoverification systems can make a great contribution, given the increasing laboratory workload. Autoverification decision rules can be designed to incorporate quality control, specific analytical error flags, critical values, limited range check, delta check, and logical check, as well as patient information. Once the Sysmex middleware (extended information process unit [IPU]) was installed in the hospital, we examined the number of approved CBC analysis samples. The autoverification system approved nearly half (48.7%) of the samples. We compared the important efficiency parameters of TAT, test repetition rate, and sample rejection rate before and after implementing the autoverification process and found that autoverification led to improvement in these parameters.

In recent years, many studies have analyzed the merits of autoverification. Krasowski et al. [2] studied selected biochemistry parameters and concluded that a high rate of successful autoverification is possible and allows laboratory specialists to focus on the small number of specimens and results that require manual review and investigation. In another study, researchers found that autoverification reduced the routine and urgent TAT duration of thyroid-stimulating hormone, prothrombin time, and CBC tests [6]. In another study conducted in Colombia, the authors reported that hemogram samples were approved by autoverification at a rate of 53.5%, which enabled laboratory experts to allocate more time to the pathological results [7]. Recently, a study examined the 4 most common coagulation assays as approved by autoverification protocols, and the authors confirmed that the automated validation system for coagulation tests can stop samples with abnormal values for manual verification, reliably assure medical safety, minimize manual work requirements, shorten TAT, and improve work efficiency [8]. In our study, a CBC test was selected for autoverification anal-

ysis because it provides basic analytical information and is vital for assessment of numerous diseases or physical conditions. Autoverification makes a significant contribution to improving hematology laboratory workflow efficiency by reducing test repetition rates and TAT.

The CBC is the most frequently ordered test panel for which autoverification algorithms are constructed [9]. Hematology tests

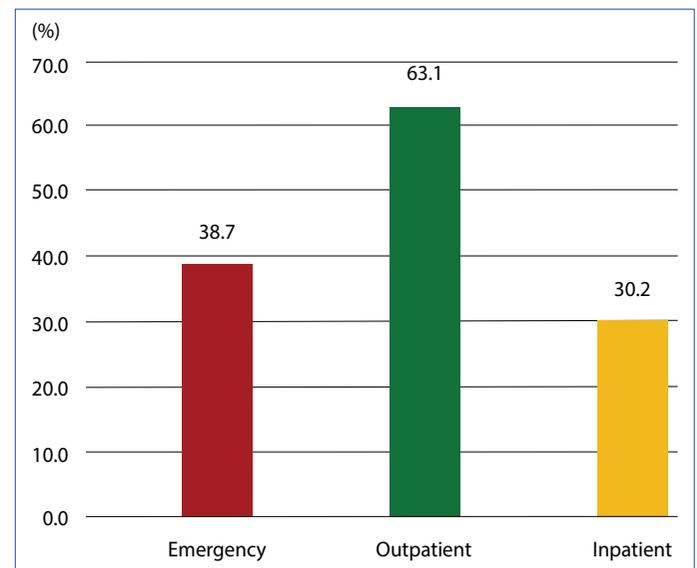


Figure 1. Autoverification approval rate of laboratory tests for emergency patients, inpatients, and outpatients.

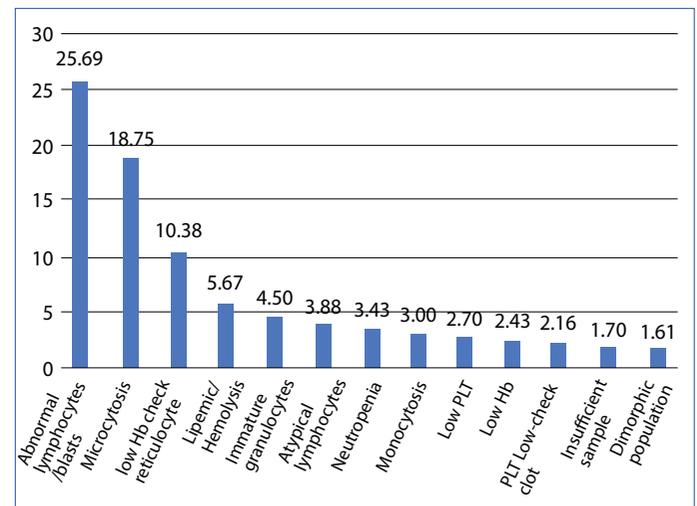


Figure 2. The ratio (%) of the most common rules used in automatic verification is given on the y-axis. This system most often recommends checking for abnormal lymphocytes and blasts. Reticulocyte analysis is recommended in the presence of microcytosis and low hemoglobin. Sample control for lipemic and hemolyzed blood is suggested. When immature granulocytes are above 2%, the system recommends assessment by peripheral smear. It also suggests a peripheral smear in the presence of neutropenia, monocytosis, low platelet count, low Hb, anisocytosis, and dimorphic erythrocytes.

Hb: Hemoglobin, PLT: Platelet.

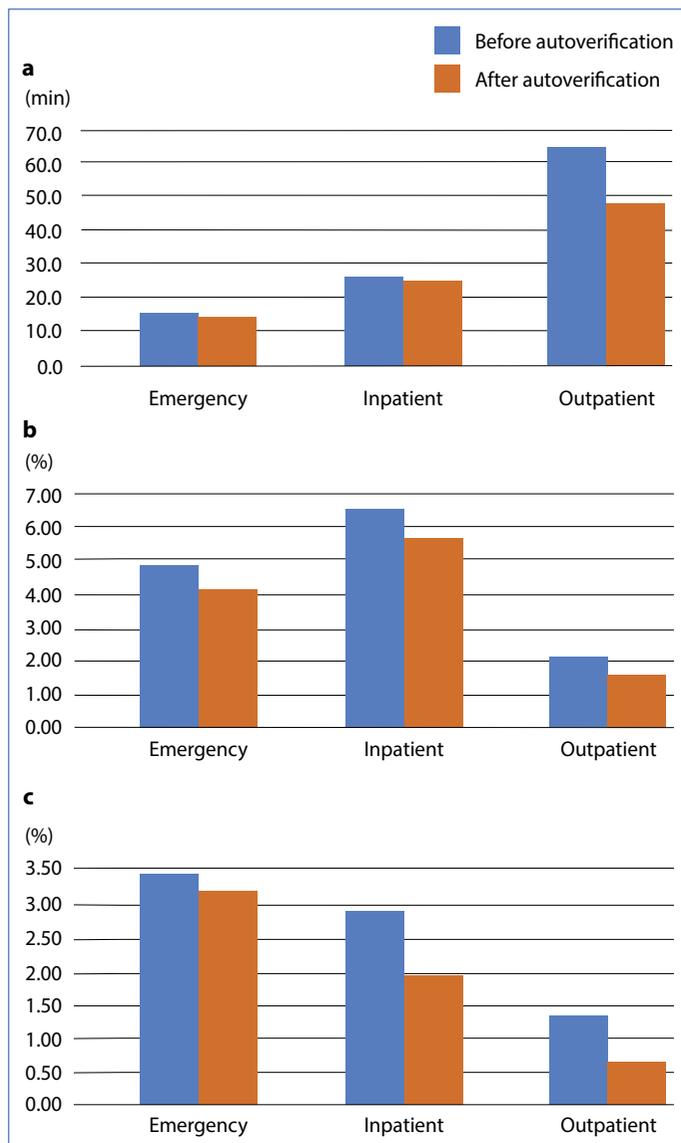


Figure 3. The change in (a) test turnaround time, (b) sample rejection rate, and (c) test repetition rate after autoverification.

have unique challenges due to sample quality issues, such as coagulation and hemolysis. The variety of tools and result flags require reflexive microscopic examination [10]. However, all of the literature studies have reported enhancement in TAT with autoverification, and 1 study indicated an error rate reduction of >90% [7]. Despite the convenience of using a standard rule set, there is still significant variability in the quantity and type of rules used and, as a result, there are important differences in autoverification, with pass rates ranging from about 50% to >90% [7, 11, 12]. The extended IPU in our study runs an inquiry on 21 parameters in the pre-analytical and analytical phases. An important factor that increases the number of samples to be examined manually is the number of pathological results that require a blood smear, and thus, the proportion of inpatients to outpatients is a significant factor [13]. We observed that laboratory performance particularly improved in outpatient cases.

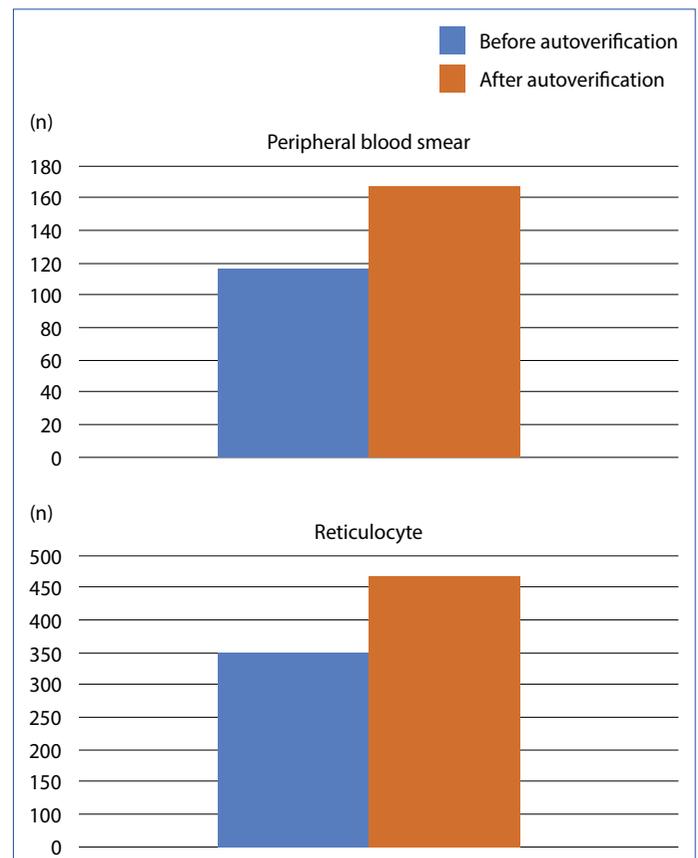


Figure 4. The change in the number of requests (n) that generates the reflex test before and after the use of automatic verification. The reflex test for a peripheral blood smear and reticulocyte was particularly important to the hematology clinic.

Other factors include the use of reference change value-based delta check thresholds, and result limit check thresholds [11]. High autoverification pass rates in hematology testing require careful attention to the utility of the criteria used in delta checks and result limit checks, as well as assessment of automating rules for a manual differential white blood cell count. Due to the lower index of individuality of numerous CBC parameters, methodologies using univariate and multivariate delta checks tend to be more useful than clinical chemistry parameters in detecting mislabeled samples [14, 15].

In our study, another important point in terms of clinical diagnosis was that the differential diagnosis was aided by autoverification as a result of increased reflex tests, such as blood smear and reticulocyte. Our hospital has a large hematology clinic and we received feedback that the physicians were very satisfied. It is very important to determine precise algorithms for reflex tests in the differential diagnosis of anemia or in the early diagnosis of malignant diseases related to white blood cells, such as lymphoma and leukemia [16, 17].

In this study, efficiency was evaluated using the TAT and test repetition rate. The definition of TAT differs, depending on the initial point in the cycle: test order, phlebotomy, or laboratory delivery [18]. It can also be classified according to the urgency

of the request (urgent or routine). Our laboratory is responsible for all stages of sample processing, i.e., monitoring the total TAT from phlebotomy to reporting. Therefore, TAT is one of the most significant quality indicators of our laboratory performance. The preliminary autoverification rules that were applied to some chemistry tests contained only results that were outside the reference ranges. In a study conducted by Shih et al. [19], autoverification rules with broad ranges were applied to avoid any unnecessary delay in the release of results. A wider autoverification cut-off was used with a distribution interval of patient data between 2% and 98%. Thus, individual variances in the verification of test results were eliminated and the TAT was reduced [19].

Laboratory test repetition is very common, which is costly and an important element of total test utilization, however, it is readily modifiable [20]. Clinicians may elect to repeat a laboratory test to ascertain validity or to follow a trend in results. The primary causes of variation in laboratory tests are analytical imprecision, within-subject biological variation, and between-subject variation [21]. The cost effect of multiple results from the same sample or from the same patient over time should be kept in mind. Laboratory information technology provides useful data for assessing potentially unnecessary repeat laboratory testing [22, 23]. However, due to the intense workload in the laboratory, these data often cannot be analyzed. Test repetition rates for a technical or expert approval vary depending on individual differences. Therefore, setting standards and preventing unnecessary test repetitions is important for cost-effectiveness and patient safety. Autoverification reduces unnecessary repetition by ensuring standardization [24]. In our study, we determined that the repetition rate decreased, especially for outpatients. TAT is reduced by providing lab specialists with additional time. Decisions on corrective action are also improved. Exchanging subjective criteria for systematic and qualified rules management for strategic procedures in laboratory medicine improves the quality of laboratory services [25].

Our study showed that autoverification was beneficial in terms of cost-effectiveness, time management, and patient-oriented work, and had a positive contribution to the hematology laboratory workflow.

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