Autoverification Improved Process Efficiency, Reduced Staff Workload, and Enhanced Staff Satisfaction Using a Critical Path for Result Validation

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ABSTRACT

Objective: Continuous process improvements enhance accuracy and productivity in a clinical laboratory setting. This study aimed to investigate the accuracy and efficiency of a new autoverification (AV) system designed to improve the consistency and uniformity of reported laboratory test results.

Methods: Limit checks, delta checks, and consistency checks were established, and then retrospective data from 500 requested tests were used to evaluate the accuracy of AV rules compared to manual verification, which was performed by five experienced medical technologists. Efficiency was evaluated by comparing turnaround time (TAT), error rates, workload, and staff satisfaction between before and after AV implementation.

Results: AV had 100% sensitivity, 77.6% specificity, and a 22% false-positive rate. The AV passing rate was 95%, 85%, 42%, and 39% for chemistry, coagulation, microscopy, and hematology, respectively. The overall passing rate was 65%. After implementation, the mean overall TAT decreased from 54.2±26.6 to 52.4±24.2 min (p<0.001). However, TAT during peak hours increased (p<0.05). Incident reports decreased 8-fold (p<0.05), net workload decreased by 0.76 full-time equivalent, and overall staff satisfaction increased (p<0.001).

Conclusion: Our laboratory's new AV system demonstrated an overall passing rate of 65% with decreases in TAT, incident reports, and workload, and an increase in staff satisfaction.

Keywords: Autoverification; critical path; delta check; full-time equivalent; laboratory information system; turnaround time (Siriraj Med J 2020; 72: 296-306)

INTRODUCTION

Autoverification (AV) uses predetermined rules to direct the release of laboratory results, and verifies results by computer without staff review.[1,2] Previous studies reported that AV improved turnaround time (TAT)[3-7], reduced manpower requirements[4,5], decreased error rates[7], and enhanced physician satisfaction.[3] AV algorithms usually include instrument status flag, quality control (QC) checks, interference indices (hemolysis, icterus, lipemia), critical values, limit checks, delta checks, and consistency checks to filter unusual data.[8-10]

According to Clinical and Laboratory Standards Institute (CLSI) guideline[1], the criteria included in AV algorithms can be simple or complex comprising multiple data elements and multiple-step defined Boolean logic to validate clinical laboratory results. Computer-based actions could include immediate verification of a result, repeat analysis, reflexive testing, addition of comments,

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or manual steps, including manual review of the results.[1] Previous studies described the use of AV in some sections or specific test groups of laboratories, including clinical chemistry[2,7,8,11-13], arterial blood gas[14], thyroid function[4,6], sex hormones[4], hepatitis B serological markers[15], urinalysis[7,16], hematology[17-20], and coagulation.[18, 21-24]

Our laboratory experiences a 3-9% annual increase in testing volume each year; however, the number of personnel that perform manual result verification has not increased. In response and in order to improve operational efficiency, we designed and implemented the AV system profiled in this report to improve TAT, improve the consistency of result verification, and to reduce the workload of staff in our laboratory. Here, we present a detailed description of the implementation of AV in clinical chemistry, microscopy, hematology, and coagulation. This study is the first to describe the implementation of an AV system that simultaneously incorporates multiple disciplines using a critical path concept.[25,26] This study aimed to investigate the accuracy of the AV rules, and the efficiency of a new AV system designed to improve the consistency and uniformity of reported laboratory test results. We evaluated the AV passing rate, and determined the impact of the AV system on laboratory personnel. We also compared TAT, requisition sheets per hour, laboratory staff survey, and error rates between before and after the implementation of the AV system.

MATERIALS AND METHODS

Setting and ethics

This study was conducted at the central laboratory of Siriraj Hospital, which is a 2,300-bed national tertiary referral center located in Bangkok, Thailand. This laboratory provides clinical chemistry, microscopy, hematology, and coagulation testing for both outpatient and inpatient services. Our laboratory performs approximately 6 million tests per year using a cobas 8000 (Roche Diagnostics, Mannheim, Germany) for clinical chemistry, a UX-2000 (Sysmex Corporation, Kobe, Japan) for urinalysis, an XN-3000 (Sysmex Corporation) for hematology, and the CA-1500 & CS-2100i systems (Sysmex Corporation) for coagulation analysis. The HCLAB system (Sysmex Corporation) is the laboratory information system (LIS) used in our laboratory. The protocol for this study was approved by the Siriraj Institutional Review Board of the Faculty of Medicine Siriraj Hospital, Mahidol University (Si 331/2015 EC2).

Study design

Fig 1 shows the study protocol for the design and implementation of our AV system. First, we defined the scope of the AV system, including selection of team members, tests, and tools. The tool used in this study was our laboratory information system (LIS). We then collected the information needed to set the AV rules, after which the rules were decided by consensus among the study team members. Next, we collected efficiency data before implementation of AV, and set up rules in the computer system. The accuracy of the AV rules was assessed before implementation into clinical service. After implementation, we collected efficiency data, surveyed laboratory staff, and calculated AV passing rate and full-time equivalent reduction (FTE).

Test selection

We selected tests that are performed on automated analytical systems and that are released automatically via the LIS, including 86 parameters in clinical chemistry (71 plasma/serum/blood parameters, and 15 urine parameters, 1 test in microscopy (urinalysis), 2 tests in hematology (complete blood count [CBC], and automated hematocrit [Hct]), and 5 tests in coagulation (Table 1).

Development of the autoverification algorithm

Fig 2 shows the multicomponent critical path for autoverification. The algorithm for the clinical chemistry and coagulation tests was developed according to the CLSI AUTO10-A guideline.[1] For clinical chemistry, the cobas® 8000 Data Manager was used to check instrument status flags, quality control (QC) results, and interference indices. If there were instrument flags or tests that failed QC, the test results would not be released. If interference indices exceeded the threshold for respective tests, the results would be released with comments to the LIS. For coagulation, the results would be released directly to the LIS.

After entering the AV system, the order of verification was limit checks, delta checks, and consistency checks. If the analytes had critical values, the critical values were used as their limit checks. If the results failed the limit checks, the delta checks were used. Delta checks compared the current data with previous data from the same patient to determine the differences. If the differences were within the range of delta check acceptability, consistency checks were followed. If the test results passed all of the above checks, they were reported by the AV system. If the test results failed any of the above checks, they were reported by manual verification (MV).

Criteria for hematology (complete blood count) and microscopy (urinalysis) tests derived from our previous studies were set in middleware before entering the LIS.[27,28]

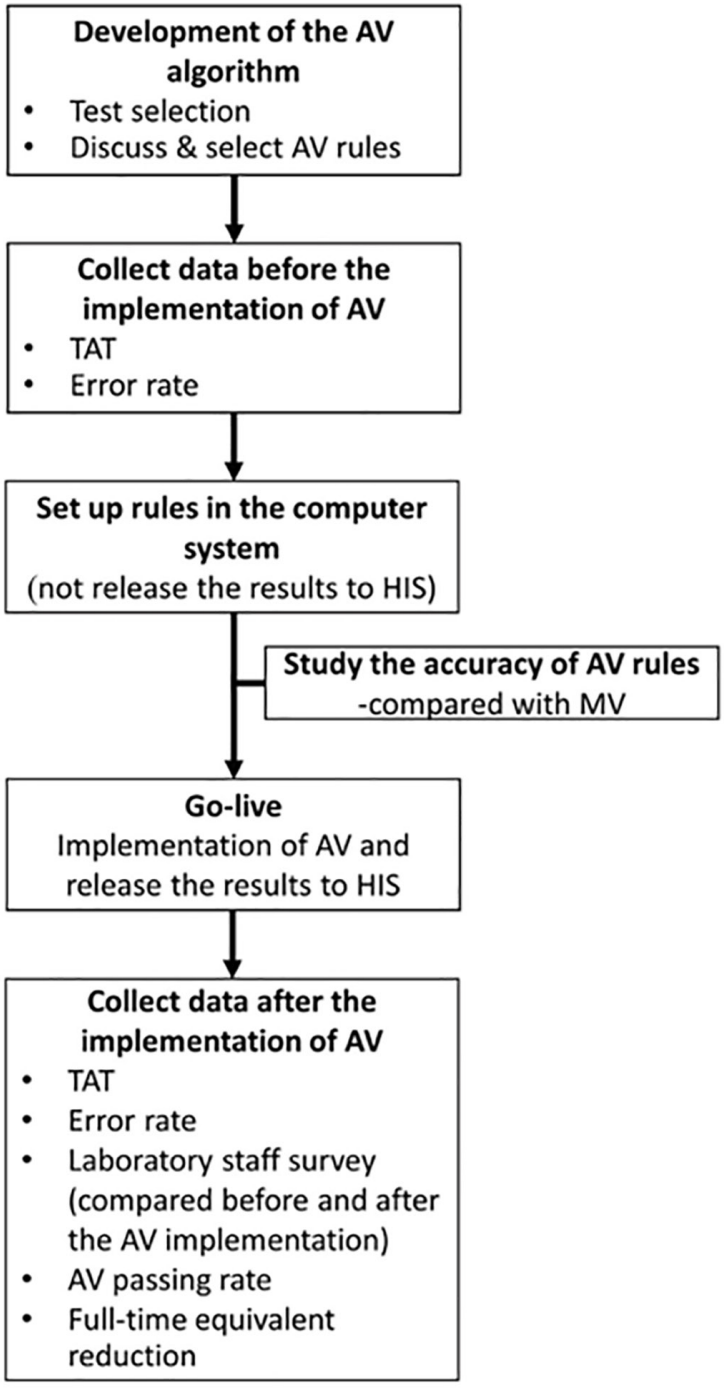

Fig 1. Flow diagram describing the study protocol for the design and implementation of the autoverification system (AV).
Abbreviations: AV, autoverification; HIS, hospital information system; MV, manual verification; TAT, turnaround time

Development of AV rules

Hematology tests

For complete blood count analysis, the first time test results were held in the presence of hemoglobin <7 or >19 g/dL, mean corpuscular volume <70 or >110 fL, red cell distribution width >22%, white blood cell (WBC) <1,500 or >30,000/µL, platelet <100,000/µL or >600,000/µL, no differential of WBC, absolute neutrophil counts <500/µL or >25,000/µL, absolute lymphocyte counts >7,000/µL, absolute monocyte counts >3,000/µL, absolute eosinophil counts >2,000/µL, absolute basophil counts >500/µL, absolute reticulocyte count >250/µL, or suspect flags.[27] In repeated samples, criteria included WBC <1,500 or >30,000/µL and delta WBC ≥10,000/µL within 3 days, platelet <100,000/µL and delta platelet >20,000/µL, and the presence of suspect flags. All automated hematocrit results were released by autoverification.

TABLE 1. List of tests in the autoverification system for clinical chemistry and coagulation.

Plasma/serum/blood in clinical chemistry		
25-hydroxyvitamin D	Follicle stimulating hormone	Placental growth factor
Alanine aminotransferase*	Free calcium	Potassium*
Albumin*	Free thyroxine	Potential of hydrogen (pH)
Alkaline phosphatase*	Free triiodothyronine	Prealbumin
Alpha-1 antitrypsin	Gamma-glutamyltransferase	Procalcitonin
Ammonia	Glucose*	Progesterone
Amylase	Haptoglobin	Prolactin
Anion gap	Hemoglobin A1c*	Sodium*
Aspartate aminotransferase*	High-density lipoprotein cholesterol*	Soluble fms-like tyrosine kinase-1
Beta-crosslaps	High-sensitivity C-reactive protein	Testosterone
Bicarbonate*	Insulin	Thyroid stimulating hormone
Carboxyhemoglobin	Lactate	Thyroxine
Ceruloplasmin	Lactate dehydrogenase	Total bilirubin*
Chloride*	Lipase	Total calcium
Cholesterol*	Low-density lipoprotein cholesterol*	Total procollagen type 1 amino-
terminal propeptide		
Cortisol	Luteinizing hormone	Total protein*
C-reactive protein	Magnesium	Transferrin
Creatine kinase	Methemoglobin	Triglyceride*
Creatine kinase-MB (mass)	N-mid osteocalcin	Triiodothyronine
Creatinine*	N-terminal pro-brain natriuretic peptide	Troponin-T (high-sensitivity)
Direct bilirubin*	Parathyroid hormone	Urea nitrogen*
Estradiol	Partial pressure of CO2 (pCO2)	Uric acid*
Ferritin Partial pressure of O2 (pO2)	Vitamin B12	
Folate Phosphorus		
Urine in clinical chemistry		
Albumin	Creatinine	Protein
Albumin/creatinine	Glucose	Protein/creatinine
Amylase	Magnesium	Sodium
Calcium	Phosphorus	Urea nitrogen
Chloride	Potassium	Uric
Coagulation tests		
Activated partial thromboplastin time*	Fibrinogen*	Prothrombin time*
D-dimer	International normalized ratio*	

*candidate tests incorporated during the trial of the autoverification system

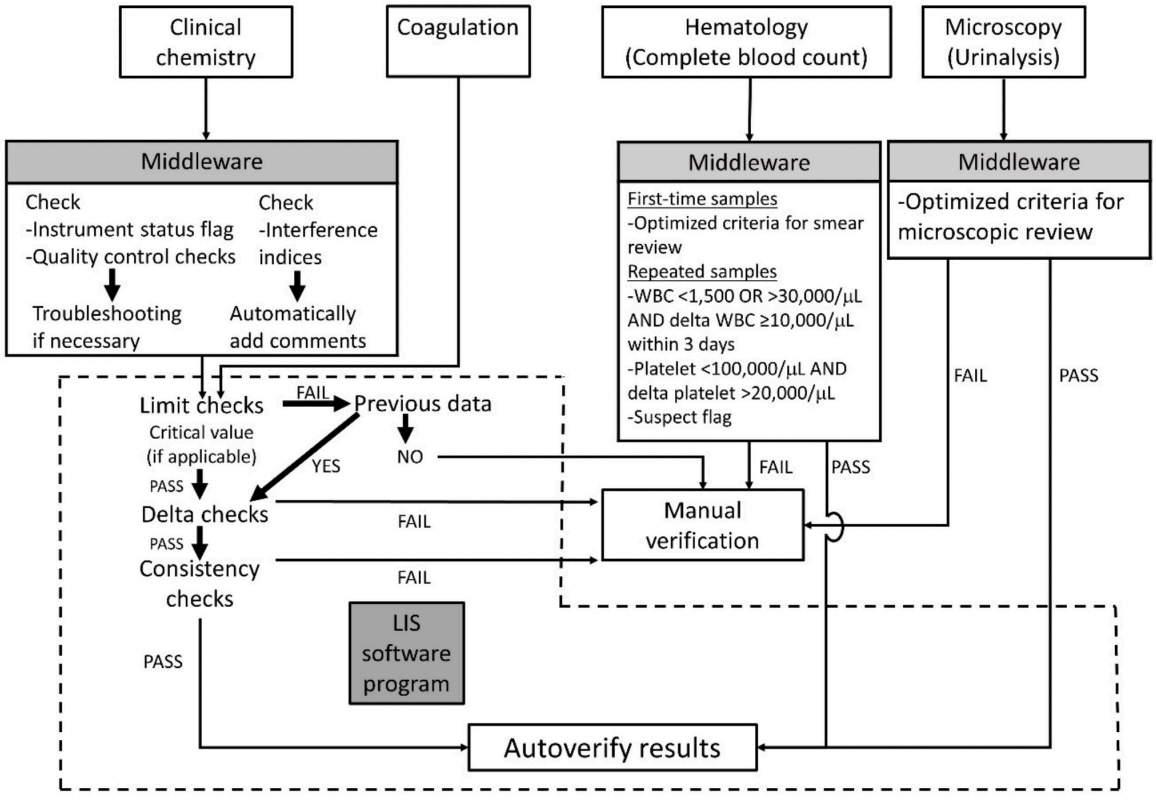

Fig 2. Flow diagram describing the critical path for autoverification (AV). Clinical chemistry tests were checked by middleware before entering the AV system established in the laboratory information system (LIS). Coagulation tests entered the AV system directly. AV rules were set in middleware for hematology and microscopy tests. For optimized criteria for smear review in first-time samples and microscopic review, please refer to the manuscript text.

Microscopy tests

For urinalysis, the results were held in the presence of red blood cells (RBC) >28.1/μL with negative blood tests from chemical strip, RBC 17-59/μL with positive blood tests, RBC >300/μL regardless the blood test results, WBC 50-120/μL, epithelial cells 56-120/μL, small round cells >10/μL, hyaline casts >3/μL, pathological casts >1.5/μL, crystals >10/μL, yeast like cells, sperms >3/μL, or flags.

Clinical chemistry and coagulation tests

The AV rules used in clinical chemistry and coagulation tests included limit checks, delta checks, and consistency checks. All D-dimer results were released by autoverification. The methods for developing the AV rules were, as follows:

1. Limit checks

Limit checks were developed using different methods, as follows:

1.1 Critical values

Critical values are potentially life-threatening laboratory results that require immediate medical attention. The critical values were derived from the literature[29,30] and discussed with clinicians. The analytes for which critical values were used as a limit check were free calcium, glucose, pCO_2, pO_2, potassium, pH, sodium, and troponin-T (high-sensitivity).

1.2 Other sources

We used different sources to employ limit checks. Limit checks were derived from a distribution interval of patient data between the 2.5th and 97.5th percentiles (modified from a previous study)[12], a near-midpoint between the median reference range value and the analyzer's linear analytical measurement limits[7], and the analytical measurement limits.

2. Delta checks

Delta check can be used to identify cases of patient specimen misidentification, specimen integrity issues, and analytical issues.[31] Our laboratory used this formula to calculate delta check:

Delta check (%) = [(current result-previous result)/previous result] *100

The acceptability limit of delta checks in this study was obtained from:

2.1 Reference change value (RCV)

RCV denotes the amount of change that would

indicate a significant difference between two sequential results. The simplified formula for RCV calculation includes variations associated with analytical variation and intra-individual biological variation, as follows:

Reference change value (RCV) = $2^{1/2}$*Z*(CV_A^2+CV_I^2)$^{1/2}$

(Z = Z score, CV_A = analytical variation, CV_I = intra-individual biological variation). In this study, a bidirectional Z-score was used (1.96 for a 95% probability), CV_A was derived from analytical variation during a 1-month period in our laboratory, and CV_I was obtained from the literature.[32]

2.2 Other sources

We applied delta checks from previous autoverification study[2], textbook[30], and delta check rules from another institute (Swedish Covenant Hospital, courtesy of Susan Dawson). The duration of delta checks was 120 days.

3. Consistency checks

The consistency checks were, as follows: (a) If triglyceride was above 800 mg/dL (9 mmol/L) and sodium was simultaneously requested, results would be held. Sodium would be analyzed by direct ISE method instead of indirect ISE method; (b) Direct bilirubin was more than total bilirubin; (c) Albumin was more than total protein; (d) T3 or FT3 or T4 or FT4 was more than the upper limit check for each test, but TSH was not less than the lower limit of the reference interval; and, (e) T3 or FT3 or T4 or FT4 was less than the lower limit check for each test, but TSH was not more than the upper limit of the reference interval.

Implementation

Initially, limit checks, delta checks, and consistency checks were applied to 24 candidate tests to test the system and detect errors in AV settings (Table 1). We then applied them to clinical chemistry and coagulation tests without releasing the results to physicians. Results that passed all AV rules would be labelled as auto-released, and then they were subjected to MV before delivery to clinicians. Results were checked retrospectively to detect discrepancies and errors using simulation program. When no errors occurred, we started to release the results to clinicians without MV.

Accuracy of the AV rules

Before implementing AV into clinical service, we validated the accuracy of AV rules and algorithms by comparing 500 patient reports between AV using simulation and MV by 5 experienced medical technologists (MT). If the verification results were not in agreement with at least 4 of the 5 MT, the decision would be made by consensus among 4 clinical pathologists. If AV rules were triggered and the results were held by MV, the report was graded as true-positive [TP]. If the report was released by both AV rules and MV, it was graded as true-negative [TN]. False-positive [FP] was defined as a report unvalidated by AV, but that was released by MV, and false-negative [FN] was graded as a report validated by AV, but that was held by MV.[33] Accuracy was defined as [TP + TN]*100/[all results].

Efficiency of the AV system

AV passing rates were obtained from each discipline and per requisition sheet using data from 24 h of 5 working days. Laboratory turnaround time (TAT) was defined as the time from specimen receipt to result reporting. We obtained laboratory TAT per hour for 20 days before and 20 days after implementation of the AV system. Error rates were gathered from non-conformities (NC), occurrence reports, and customer complaints during 1 month of each period.

A decrease in full-time equivalent (FTE) was calculated using the following formula: Decrease in FTE = (productive minutes/total work minutes) * the overall AV passing proportion per requisition sheet.

Productive minutes = MV time per day (minutes)* number of requisition sheets per day * 365 days.

MV time was obtained from the average time for MV in triplicate among 13 experienced MT. The total work minutes in our laboratory was calculated to be 96,600 minutes per year.

The questionnaire that we used in this study to determine laboratory staff satisfaction comprised 5 questions that were scored 1 to 10, as follows: (a) How would you describe your workload? (b) How much confidence do you have when reporting laboratory test results? (c) How many incident reports do you think the laboratory receives, either verbal communication or written document? (d) Describe your level of satisfaction with the speed with which laboratory results are reported. (e) What is your overall level of satisfaction with the laboratory reporting system?

Statistical analysis

AV passing rates from each discipline were compared using Pearson's chi-square test. Unpaired t-test was used to compare mean laboratory TAT each hour from 20 days before and 20 days after the implementation of AV. Mann-Whitney U test was used to compare the total number of requisition sheets per hour from 20 days before and 20 days after the implementation of the AV system, and TAT for only AV results versus manually

verified results after the implementation of AV. Error rates were compared using Fisher's exact test. Data from the survey of laboratory staff were compared using paired *t*-test. Statistical analyses were performed using PASW Statistics version 18.0 (SPSS, Inc., Chicago, IL, USA). A *p*-value of <0.05 was considered statistically significant.

RESULTS

Accuracy of autoverification rules

Using the data from a collection of 500 retrospective laboratory test requests, the TP rate was 76.4% (382/500), the TN rate was 1.6% (8/500), the FP rate was 22% (110/500), and the FN rate was 0% (0/500). The accuracy of AV rules was 78% (390/500), the diagnostic sensitivity was 100% (8/8), and the specificity was 77.6% (382/492).

Efficiency of the AV system

1. AV passing rate

To study the AV passing rate, 123,957 test results derived from 13,342 requisition sheets were collected from 5 working days. The highest AV passing rate was found in clinical chemistry at 95% (95% confidence interval [CI]: 94.9-95.1%), whereas the lowest AV passing rate was found in hematology at 39% (95% CI: 37.8-40.0, $p<0.001$). The AV passing rates in microscopy and coagulation were 42% (95% CI: 40.3-43.7) and 85% (95% CI: 83.7-86.2), respectively. The overall AV passing proportion per requisition sheet was 65% (95% CI: 64.2-65.8) (Fig 3).

2. Turnaround time (TAT)

Mean ± standard deviation (SD) laboratory TAT was reduced by 1.8 minutes (54.2±26.6 *vs.* 52.4±24.2 minutes, $p<0.001$) between 20 days before (n=63,813) and 20 days after (n=68,947) implementation of the AV system. The mean TAT after implementation of AV was significantly lower than the mean TAT before AV implementation at the 1st ($p=0.03$), 4th ($p=0.002$), 6th ($p<0.001$), 10th ($p=0.001$), 11th-21st ($p<0.001$), and 24th ($p=0.004$) hours. In contrast, the mean TAT before implementation was significantly lower than the mean TAT after implementation of AV at the 8th (59.4 *vs.* 61.9 minutes, $p<0.001$) and 9th (58.9 *vs.* 60.0 minutes, $p=0.004$) hours (Fig 4). The total number of requisition sheets per hour from 20 days was not different between before and after implementation of the AV process (n=24 hours, median = 2,014 *vs.* 2,151 sheets, $p=0.789$).

3. Error rates

Before implementation of the AV system, errors were found in 7 test results of 848,377 tests per month (0.0008%). After the implementation of AV, errors were detected in 1 of 870,511 tests per month (0.0001%) ($p=0.037$).

4. Impact of AV on laboratory staff

The average time for MV in triplicate by 13 MT was 6.98 seconds per 1 requisition sheet. The average number of requisition sheets per day (n=5 days, the same period we used to determine the AV passing rate) was 2,669 sheets/day. Therefore, the mean total time for MV was 310 minutes per day. The productive time (minutes) = 310 mins * 365 days. After the implementation of AV, the AV passing rate was 65%, which translates to a reduction of 0.76 FTE medical technician personnel needed for result verification.

5. Laboratory staff survey

From the perspective of laboratory staff (n=43), mean±SD score for workload was reduced from 83±18% to 52±21% ($p<0.001$). The confidence to report laboratory results was not different between before and after AV implementation ($p=0.234$). From a staff point of view, incident reports decreased about 9% ($p=0.045$), and the speed of the reporting of results improved by 31% ($p<0.001$). Overall staff satisfaction increased from 65±17% to 89±11% after the implementation of AV ($p<0.001$) (Fig 5).

DISCUSSION

The accuracy of AV rules and algorithms was 78% when compared to MV. The FP rate was 22%, and the FN rate was 0%. The sensitivity and specificity were 100% and 77.6%, respectively. Fuentes-Arderiu, *et al.* compared the Validation Assistée aux Laboratoires d'Analyses Biologiques (VALAB) Expert System to MV by nine clinical biochemists among 500 clinical laboratory reports. They found the diagnostic sensitivity of the VALAB Expert System to be 100%, and the diagnostic specificity was 95.7%.[11] Our study had lower specificity because we used thresholds of limit checks at 2.5th and 97.5th percentile of cumulative patient data so about 5% of results would be held by AV. We plan to decrease false-positive alerts through adjusting thresholds, and by modifying non-specific rules.

Our overall passing rate, which included several disciplines in the critical path, was 65%. For clinical chemistry, the AV passing rate was 95% compared to 84.8% in the study by Fuentes-Arderiu, *et al.*[11] Krasowski, *et al.* reported an increase in the passing rate for clinical chemistry from 40% in 2000 using the rudimentary rules set in the LIS to 99% in 2010 after the implementation of sophisticated rules in middleware[2]. For microscopy, the AV passing rate in this study was 42%, which is nearly the same as the 43% rate reported by Torke, *et al.*[7], and the

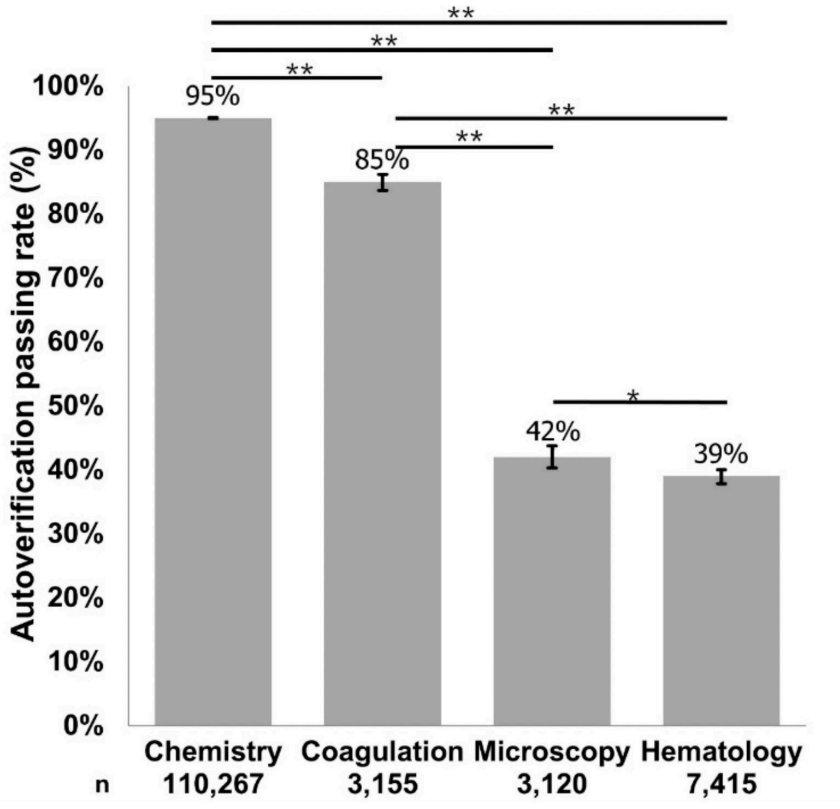

Fig 3. Autoverification (AV) passing rates (95% confidence interval). AV passing rates for chemistry, coagulation, microscopy, and hematology obtained from 5 working days (*p<0.05, **p<0.001).

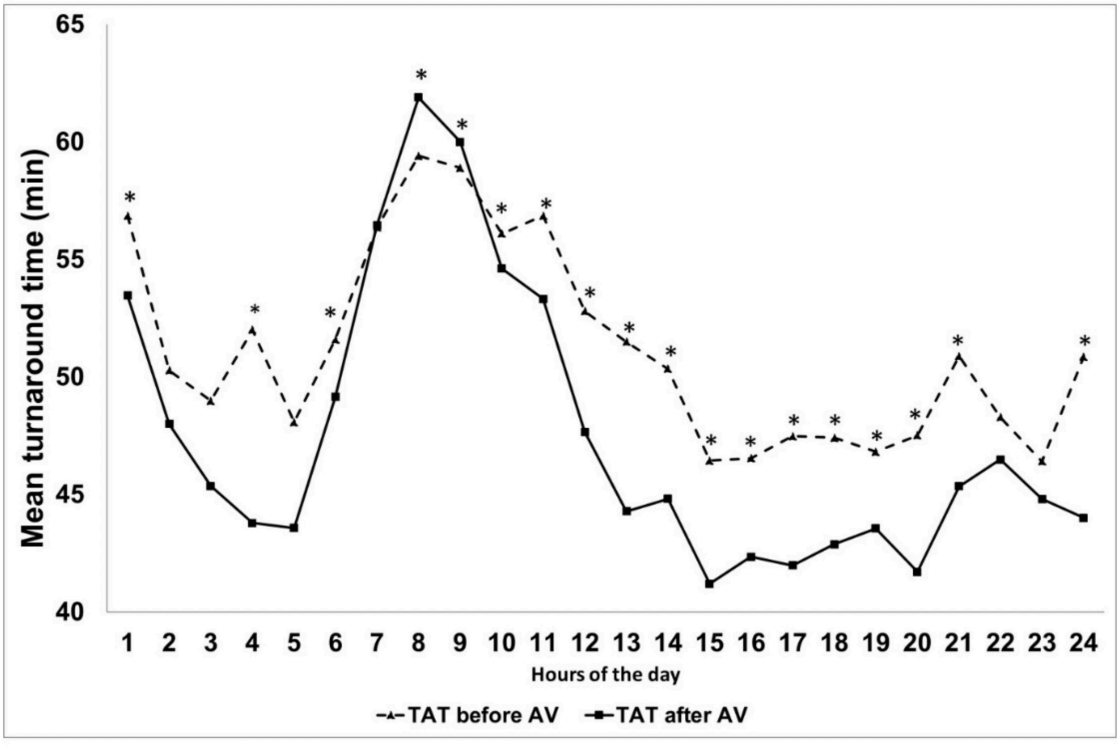

Fig 4. Turnaround time (TAT) before and after the implementation of autoverification (AV). Mean hourly TAT compared between 63,813 requisition sheets obtained during 20 days before and 68,947 requisition sheets obtained during 20 days after the implementation of AV (*p<0.05).

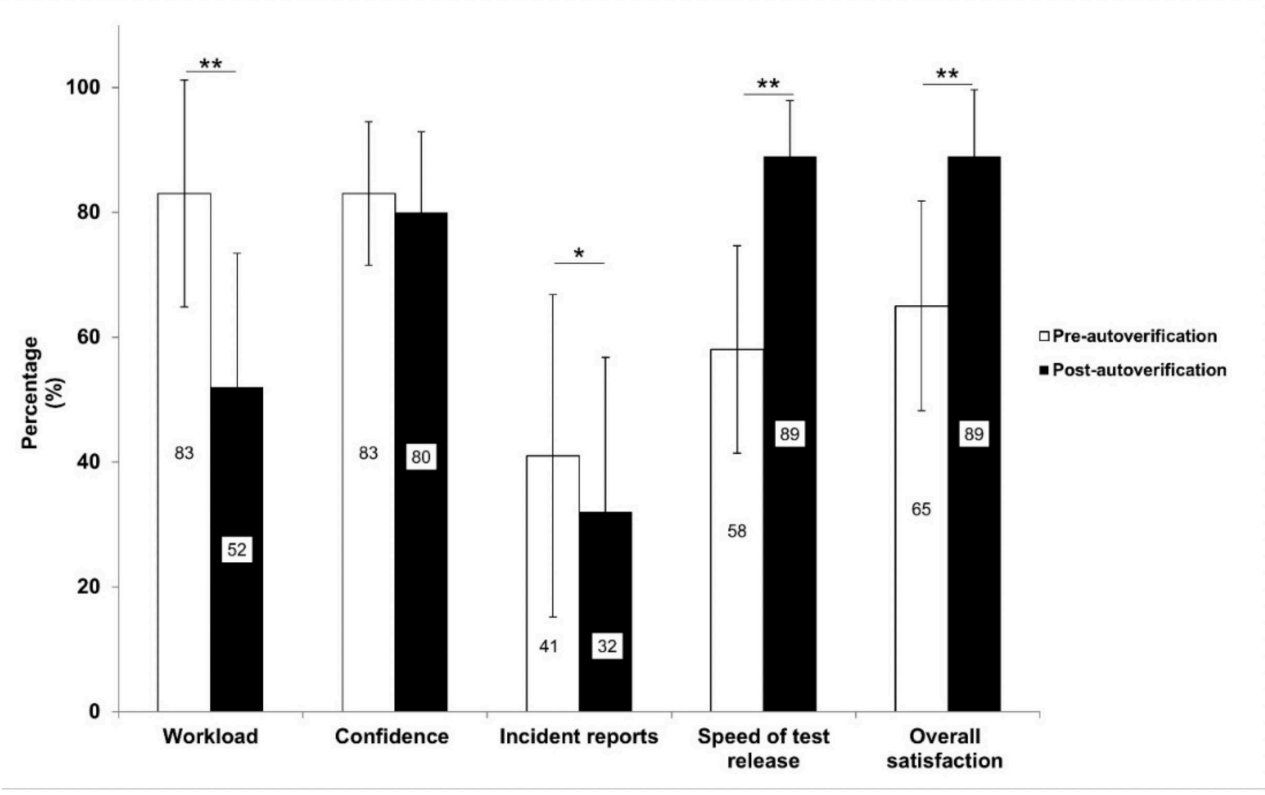

Fig 5. Laboratory staff survey. Mean ± standard deviation percentage of survey items (n=43) compared between before and after the implementation of the autoverification system (*p<0.05, **p<0.001).

47.6% rate reported by Palmieri, *et al.*[16] For hematology, the passing rate in this study was 39%. Martinez-Niteo, *et al.*[17] found a passing rate of 53.4% in pilot study, with a subsequent increase to 60% 18 months later – both of which were very high compared to our result. For coagulation, our passing rate was 85%, which is similar to the 82% result reported by Zhao, *et al.*[21]

Our study found that the overall TAT decreased from 54.2 to 52.4 minutes (3.3%) after the implementation of AV. However, the TAT during the peak hours (8th and 9th hours) was significantly increased. A possible explanation for this increase may be insufficient capacity of the computer server to manage the increased number of processing requests during the peak period. A previous study from a large, urban, tertiary acute care public hospital and trauma center showed that the TAT, calculated from time of specimen received to result released, was reduced by 22% (142 min *vs*. 112 min) after the implementation of AV.[7] However, the baseline TAT in our laboratory was about half of the baseline TAT in that study; therefore, the percent reduction might not be comparable.

The error rate in our study decreased from 0.0008% to 0.0001%. Previous study from John H. Stroger, Jr. Hospital of Cook County (JHSHCC) showed that error rates decreased from 0.06% to 0.009%.[7] We found that after implementation of AV, the number of laboratory staff needed for MV was reduced by 0.76 FTE. The study from JHSHCC found a much more dramatic reduction from 14 FTEs to 8.5 FTEs (a reduction of 40%) after implementation of AV.[7] Our laboratory had a lower reduction of FTE because criteria for manual review of complete blood count and urinalysis were already in place before the implementation of AV in all disciplines. After implementation of the AV system in our central laboratory, laboratory staff found the amount of workload and defects to be decreased, and the speed of test result reporting and overall satisfaction to be increased.

Although the AV system implemented at our center has many advantages, it also has some limitations. The software that our laboratory used to design our system was not specifically designed to build the rules and algorithms for the AV system. Software used to build AV rules and algorithms according to CLSI guideline should have the ability to use multiple data, to make changes to algorithms, and to provide an easy to use and flexible user interface that provides laboratory defined information in real time.[1] In some contrast, we were limited in our ability to set rules due to the functional limitations of our software. Moreover, large volume traffic during peak hours caused processing delays, which resulted in delays

in the reporting of results. Lastly, our software does not currently have a feature that facilitates comparison of result verification time between AV and MV.

CONCLUSION

Our new AV system demonstrated high sensitivity for error detection. The overall AV passing proportion per requisition sheet was 65%. This passing rate is similar to previous studies in clinical chemistry, microscopy, and coagulation tests. TAT time improved after implementation of the AV system, except during peak hours (8th and 9th hours), and this was likely due to a high traffic-related CPU slowdown. Overall staff satisfaction increased, and incident reports and workload decreased after the implementation of AV.

AV has many advantages relative to the reporting of test results; however, MV is still necessary to verify results after they fail AV. The improved efficiency of AV allows staff to spend more time on result verification. We will continue to evaluate rules to decrease false-positive alerts by modifying non-specific rules, and by addressing rules that triggered alerts that had no further action. If implemented broadly, this approach could enhance laboratory understanding and performance via successive critical path improvements.

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Authors' contributions

All authors contributed sufficiently to this study to be included as an author. All authors have read and approved the final version of this manuscript, and all authors are in agreement with the decision to submit this manuscript for journal publication.

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Conflict of interest declaration

All authors declare no personal or professional conflicts of interest, and no financial support from the companies that produce and/or distribute the drugs, devices, or materials described in this report.

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