Automation and Data Processing with the Immucor Galileo® System in a University Blood Bank

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Summary
Background: The implementation of automated techniques improves the workflow and quality of immunohematological results. The workflows of our university blood bank were reviewed during the implementation of an automated immunohematological testing system.
Methods: Work impact of blood grouping and subgrouping, cross-matching and antibody search using the Immucor Galileo system was compared to the previous used standard manual and semi-automated methods.
Results: The redesign of our workflow did not achieve a significant reduction of the specimen's working process time, the operator's time however was reduced by 23%. Corresponding results were achieved for blood grouping, Rhesus typing, antibody screen and for autocontrol when changing from two semi-automated to the Galileo system. Because of the higher sensitivity of the Immucor antibody detection system, the rate of the initial positive antibody screens rose from 4 to 6% **Conclusion:** The Immucor Galileo system automates routine blood bank testing with high reliability, specificity and higher sensitivity compared to our previous used standard manual and semi-automated methods.

Zusammenfassung
Hintergrund: Die Einführung automatisierter Techniken verbessert den Arbeitsablauf und die Qualität bei immunhämatologischen Untersuchungen. Die Arbeitsprozesse in unserer Blutbank wurden während der Einführung eines neuen immunhämatologischen Testsystems untersucht. **Methoden:** Die Arbeitsbelastung bei der Bestimmung von Blutgruppen und Blutuntergruppen, der serologischen Verträglichkeitsprobe und der Antikörpersuche mit dem Immucor-Galileo-System im Vergleich zu den bisher benutzen manuellen und teilautomatisierten Standardmethoden wurde untersucht. **Ergebnisse:** Die Neuorganisation unserer Arbeitsprozesse führte zwar nicht zur Verkürzung der eigentlichen Prozesszeit der Probe, jedoch zu einer signifikanten Verkürzung der Zeitbelastung der medizinisch-technischen Laborassistenten in Höhe von 23%. Die Ergebnisse bei allen immunhämatologischen Untersuchungen waren nach dem Wechsel von den bisherigen zwei teilautomatisierten Methoden zum Galileo-System vergleichbar. Die Rate der initial positiven Antikörpersuchen stieg aufgrund der höheren Sensitivität des Immucor-Systems von 4 auf 6%. **Schlussfolgerung:** Das Immucor-Galileo-System bietet bei der Automation immunhämatologischer Routinetests (erweiterte Blutgruppenbestimmung, Antikörpersuche und Kreuzprobe) eine hohe Reliabilität, Spezifität und eine höhere Sensitivität verglichen mit unseren bisherigen Standardmethoden.

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Introduction

The adoption of good manufacturing practice (GMP) and good laboratory practice (GLP) requires an overall standardization of laboratory testing methods used [1]. The implementation of automated techniques improves standardization of methods and the quality of achieved results. Human errors in manual processing are significant causes of fatal transfusion complications [2–6]. We redesigned all immunohematological routine testing processes at the blood bank of the Clinic of the University of Munich in two branch sites according to GMP and GLP by introduction of a new automated immunohematological testing system.

The Clinic of the University of Munich is a large level IV university based hospital. Our blood bank provides transfusions for inpatients and outpatients from the hospital itself and from area clinics and hospitals. The transfusion service (TS) performs approximately 70,000 cross-matches for nearly 45,000 red blood cell units per year. Thereby nearly 35,000 blood grouping and subgrouping orders for red cell antigens (ABH, A1, A2, D, C, c, E, e, Cw and K1) and about 40,000 antibody screens are done.

The Immucor Galileo system (Immucor Medizinische Diagnostik GmbH, Rödermark, Germany) was developed to automate a high throughput repertory of immunohematology testing using the Immucor Capture® solid phase technology.

Our report embraces the implementation of automation and data processing in both branch sites of the blood bank of the Department of Transfusion Medicine and Hemostaseology of the Clinic of the University of Munich using the Immucor Galileo system and compares the workflow and the results of routine blood bank testing by this system in an 1-year period with those of the semi-automated methods used previously.

Assessment Goals and Scope

In view of the high and still growing order volume of routine immunohematological tests in a relation of nearly 3 to 1 in both branch sites of our blood bank, our institution was in interested in exploring an automated solution for both high and low throughput work more for a normal operation mode than for working off emergency specimens, which remains the sphere of immediate manual tube ABH and Rhesus (Rh) typing and cross-matching. Our evaluation centered on blood grouping, subgrouping, antibody screen and cross-matching in the areas of:

– pre-analytical and analytical workflow,
– material flow analysis (patients and blood donors specimens),
– operator hands-on time,
– daily work process,
– economy of space and costs.

Materials and Methods

Specimen and Request Form

Because of the service oriented alignment of our TS, samples and request forms are incoming with two daily peaks at 11:00 am and 04:00 pm. Blood grouping, Rh typing, antibody search and cross-matching for this report were performed from the routine samples comparing the periods from January 2005 to December 2005 for our previously used set of standard manual and semi-automated methods, and February 2006 to January 2007 for the Immucor Galileo system. In January 2006 we monitored and redesigned the workflows in our institution.

Monitoring and Redesign of our Workflow

To evaluate the workflow in our institution, the activities of the operators were observed by an independent bystander. The workflow was documented by flow charts (Visio® 2003, Microsoft Deutschland GmbH, Unterschleißheim, Germany) and redesigned in order to fulfil the requirements for an optimal operating grade for the Galileo system and a high utilization of automated methods. The abbreviated workflows are shown in figure 1 and 2. Our previous workflow was characterized by a double passing through in semi-automated system in order to achieve the complete standard immunohematological results for each probe before cross-matching. The redesigned workflow shows a single track solution

Previous Testing Systems

Blood grouping and subgrouping were done with the Immunoscan® plus system (Ingen, Rungis, France). Main problems with this testing constellation turned up with fulfilling the in vitro diagnostic directive of the EC (98/79/EC). All testing sera with all new lots used have to be subjected to a new inhouse validation after the dilution to the final working concentration for this device in our first branch institute. Our second branch institute worked standard tube tests.

Antibody search was done with an semi-automated testing system: Tecan probe dispenser (Tecan Deutschland, Crailsheim, Germany) combined with DiaMed test boxes (DiaMed Deutschland, Ottobrunn, Germany) and semi-automated reading in a centrifuge. Here the problem was that this particular testing configuration was not supported and maintained by DiaMed anymore.

Immucor Galileo System

The Immucor Galileo system is a robotic instrument programmed to move all of the necessary microplates, liquid reagents and blood samples to the intended areas of processing for the given immunohematological assays in the correct sequence (e.g. incubator bays, microplate washing station, centrifuge, CCD camera reader). The software calculates a reaction value for each well from the captured images. Result interpretation is then assigned to the wells based on pre-defined criteria associated with the calculation reaction value. The determination of results is based on microplates and Immucor Capture solid phase technology. The device has multitasking flexibilities with the ability to access samples and reagents without interruption, perform multiple tests on each sample, and view results while running. A high throughput is ensured by two pipetting arms that operate independently and simultaneously. The software and hardware are optimized to an intuitive handling. The system may be used as an independent system as well as connected to the customer laboratory information system (LIS) in terms of a bidirectional link with sample data passing from the LIS to the Galileo and test results passing from the Galileo to the LIS vice versa.
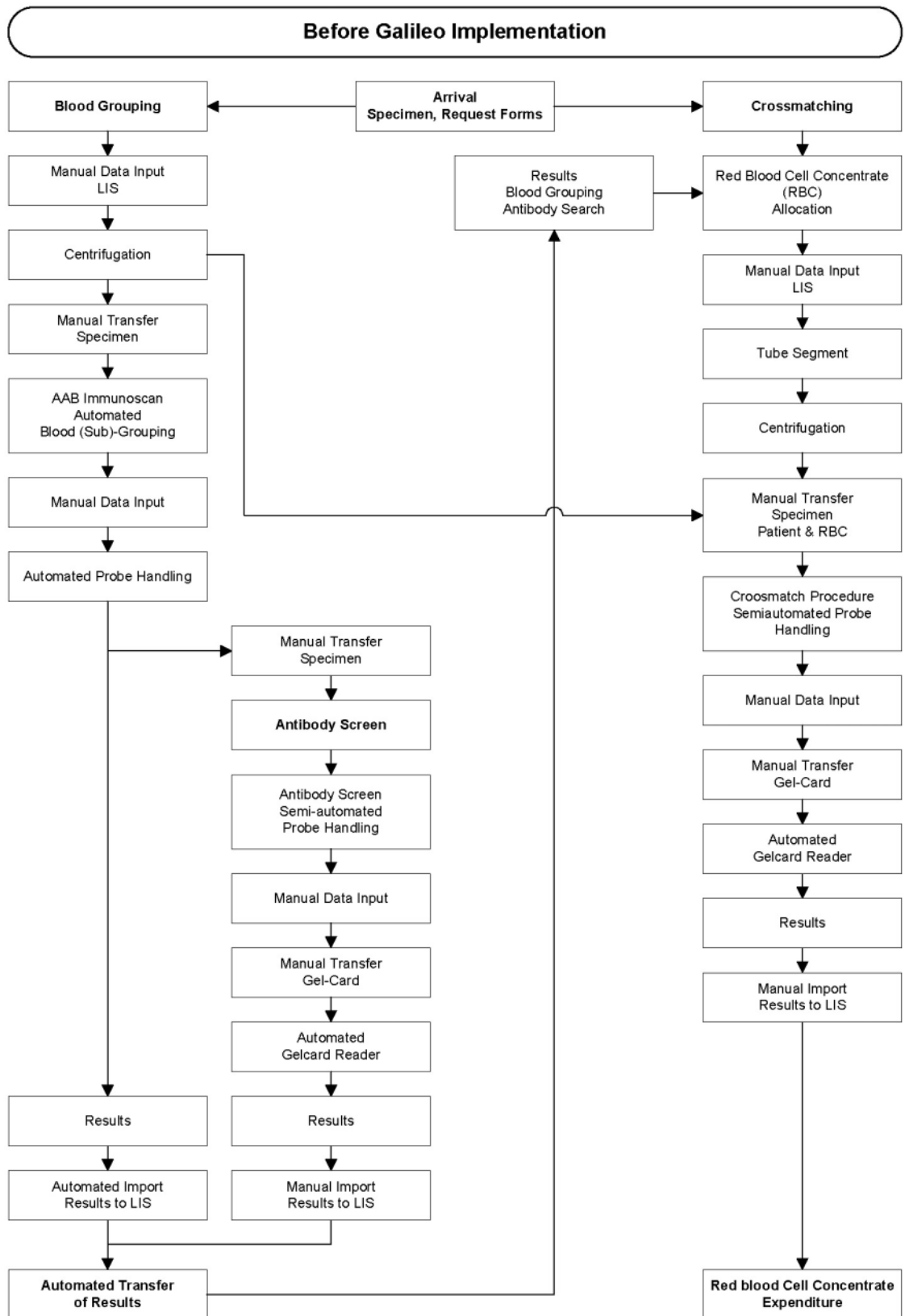
Before Galileo Implementation

Fig. 1. Abbreviated process workflow before the implementation of the Immucor Galileo system.

Results

In the validation phase of implementation, the analyzer produced consistent results in routine samples in comparison with our previous used manual and semi-automated methods. 1,500 specimens of patients and blood donors of our institution were analyzed. Parallel blood grouping and subgrouping for red cell antigens (ABH, A1, A2, D, C, c, E, e, Cw and K1) did not re-

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After Galileo Implementation

| Blood Grouping Antibody Screen | ← | Arrival Specimen, Request Forms | → | Crossmatching |

Left column flow:
- Blood Grouping Antibody Screen
- Manual Data Input LIS
- Centrifugation
- Manual Transfer Specimen
- Immucor Galileo Automated Blood (Sub)-Grouping
- Automated Data Transfer LIS to Galileo
- Automated Probe Handling
- Results
- Automated Import Results to LIS
- **Automated Transfer of Results**

Center:
- Results Blood Grouping Antibody Search

Right column flow:
- Crossmatching
- Red Blood Cell Concentrate (RBC) Allocation
- Manual Data Input LIS
- Tube Segment
- Centrifugation
- Manual Transfer Specimen Patient & RBC
- Crossmatch Procedure Immucor Galileo Automated Probe Handling
- Automated Data Transfer LIS to Galileo
- Results
- Automated Import Results to LIS
- **Red blood Cell Concentrate Expenditure**

Fig. 2. Abbreviated process workflow after the implementation of the Immucor Galileo system.

veal any discrepancies. Discrepancies were observed in antibody screening comparing the last 30,000 consecutive antibody screenings done with the previously used methods and the first 30,000 screenings of the Galileo system. The Galileo system revealed significantly more probes with initially positive antibody search than our previous methods: 6 (1,789/30,000) versus 4% (1,193/30,000), $p < 0.01$ chi-square test (Sigma-Stat 3.5, Systat software GmbH, Erkrath, Germany). In the Galileo cohort two clinically highly significant antibodies against public antigens Anti-Vel and Anti-AnWj reacted only in the Galileo system. The increase in the Galileo system of low-reactive antibodies such as Anti-Jka (n = 7), Anti-Jkb (n = 5), Anti-Fya (n = 3), and Anti-Fyb (n = 4) not detected by a consecutive testing in our previously used methods was remarkable.

The workflow of the average day specimen load (70–95) was manageable with an average labor utilization of 10.20 man hours with the Galileo system. Thus, the demand dropped by 23% (13.25 versus 10.20 h). However, the turnaround time in our TS was not shortened.

The error rate was equal; all investigated blood samples that are performed in the two observation periods of 18 months, were correctly identified.

With the new installation of the Galileo system we also reduced the space needed for the routine immunohematological testing (2.3 m²).

The overall laboratory costs for the routine immunohematological testing in 2006 dropped by 3.7% in comparison to the calculated costs with our previous tests.

Discussion

In this study we report our experiences with the implementation of a new integrated automated system, Immucor Galileo. We reviewed and redesigned our work processes in order to improve our labor utilization as well as the economy of space and costs.

The demand for automation is evident across all laboratory fields in transfusion medicine. Most of approaches have been made in the great blood donation services to optimize standard blood grouping, serological testing for blood borne infectious diseases and molecular tests, e.g. for HCV and HIV RNA [7–11]. These automated methods have led to a remarkable improvement in blood safety and to a considerable decrease of the risk of viral transmission [12]. The application of automation is now growing in hospitals and transfusion services, because human errors can lead to life threatening consequences for the patients [7, 8, 13, 14].

In our report we compared the automatic Immucor Galileo system with the established DiaMed typing system (gel centrifugation test) using standard manual testing and our in-house solution with a semi-automated system configuration in terms of the detection of human blood typing, antibody screening and cross-match testing. It is generally accepted that gel technology is a highly sensitive method [15, 16]. Our results indicate that the Immucor Galileo system performs routine blood bank tests with the same accuracy like standard manual and semi-automated methods. The discrepancies in the antibody screening are based on the higher sensitivity of the Immucor Capture solid phase technology. This benefit is accompanied on other hand by a higher expenditure of time and effort for antibody identification or the verification of false-positive reactions in the initial antibody search [17–19].

The advantage of all systems like the Immucor Galileo is the system and process stability and the concordance with the given standard operating procedures according to the demands of GLP and the data security with automated reading, positive sample and reagent identification, positive cassette identification, reaction grading and interpretation of results. A still lasting disadvantage of all systems is emergency analysis. Although interposition of emergency probes is possible with several automated systems, automated blood typing systems are not capable to match the speed of an experienced blood bank technologist performing a manual tube testing, abbreviated antibody screening and cross-match analysis. The field will remain the sphere of manual methods, until new technologies such as the lateral flow technique for rapid multi-parameter blood grouping [20] are widely introduced. Therefore, 10–15% of our samples are still tested manually.

Because we did no comparative studies with the competitors in highly automated immunohematological testing system in the market, e.g. the Ortho AutoVue® Innova System (Ortho-Clinical Diagnostics GmbH, Neckargemünd, Germany) or the Biotest Tango® optimo (Transfusion Biotest AG, Dreieich, Germany), our results reflect only the improvements when changing from manual and semi-automated methods to a fully automated system. Further investigations are necessary to compare fully automated test systems in terms of quality, speed and costs in routine immunohematology testing.

The Immucor Galileo system has now been effectively implemented in our transfusion medicine institute for more than 18 months and still achieves the expectations in the everyday routine work.

Conclusion

The Immucor Galileo system automates routine blood bank testing including blood grouping and subgrouping (ABH, A1, A2, D, C, c, E, e, Cw and K1), antibody search and cross-matching with high reliability, specificity, and a higher sensitivity compared to our previously used methods. The system improves GLP and quality in our institution in terms of consistency and integrity of techniques and results by high standardized procedures in pipetting, incubation, centrifugation, reading and interpretation of results by automatic readers. The total automation process reduces the employment of staff facing a constant testing capacity of our laboratory. Comparative studies among different fully automated systems and further developments in the automation of emergency immunohematology testing will have to be done.

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