INTRODUCTION

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This issue of Perspectives in Transfusion Medicine addresses improvements to the safety of blood transfusion resulting from application of modern-day technologies. Suzanne Butch discusses issues related to the selection of automated blood bank testing instruments. Factors to consider when selecting an instrument include: available test menus; on-board reagent storage capability; ability to connect to an automation line; turn-around and throughput times; time to first ABO/Rh result; stat processing; minimum sample volume and test tube size requirements; the amount of hands on time required to process samples; and, instrument–operator interface complexity. The benefits of automation include better compliance with regulatory bodies through standardization of testing procedures, increased safety resulting from positive sample identification and error reduction, and the ability to process more samples without increasing staff.

In an accompanying article, Hema Mistry reviews the recommendations of the United Kingdom independent, professionally led hemovigilance scheme, Serious Hazards of Transfusion (SHOT), and those promulgated by the UK Transfusion Laboratory Collaborative (UKTLC). Meeting these recommendations mandates use of automated sample processing equipment, and implementation of information technology systems that allow for easy access to patient data and place blood product release and traceability under electronic control. The UKTLC further recommends that transfusion service laboratories have walk-away automation, with bi-directional interfaces, in full-time operation. In the absence of automated testing (e.g., facilities processing <10 patient samples per week), double-blind entry of data is required.
AUTOMATION IN THE TRANSFUSION SERVICE

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Introduction

Although, automation in the transfusion service had lagged behind other laboratories, facilities considering adoption of automation or ready to replace existing automation platforms have more options to choose from than ever before. Early automated instruments were designed for batch processing in donor centers or large transfusion services. There were few automated instruments available. Laboratory managers considering adoption of automated testing or replacing existing instruments now have several platforms and manufacturers from which to choose. Instrumentation is now available that is affordable and works well in medium and smaller transfusion services. The decision to automate a laboratory, or replace existing automated testing, is complex involving both technical and financial decisions. This paper will review these considerations.

The Benefits of Automation

Few hospital transfusion services that have chosen to automate would consider going back to routine manual testing. The advantages of automation include standardization of the process, a more reliable turn-around-time, fewer opportunities for error and the ability to process more samples with less staff. Improvement in the safety of the pretransfusion testing is an important motivation for adopting automation.

It is true that in most facilities a staff member can process a single specimen in less elapsed time than an instrument can perform the same testing. However, most laboratories cannot afford to have an individual devoted to processing a single specimen. Multitasking is common and expected. The use of standardized processes through automation can provide a more expedient and reliable turn-around-time for all specimens both routine and urgent. Customers generally want to know how long before blood components will be available. A consistent processing time reduces the need for phone calls requesting an update on when products will be ready.

Defining Institutional Needs

Ideally, the selection process would begin with the transfusion service defining its needs for testing. An equally important next step is to identify any limiting factors such as space or financial constraints. It is not practical to do on-site assessment of all currently available instruments. Therefore, prioritizing the list into required and desired elements may help to reduce the number
of options to a manageable number. A device that works well at one institution may not be the best choice for another institution. Purchasing an instrument because it has a large test menu may not provide the desired throughput and turn-around-time if only type and screen testing will be processed.

**Methodology**

There are two major methods used in automation – gel column and microtiter plate technologies. Although there are differences in the sensitivity and specificity between the various automated methods, all are routinely used for pretransfusion testing. Other factors may be more critical to the decision making process than the method used in the instrument. The lack of reproducibility of weak reactions and false positive reactions are an unwanted consequence of automation. Each false positive reduces the staff’s confidence in the system, results in costly antibody identification tests, requires the use of additional patient sample and delays patient care. Early on, some methods had periodic false negative reactions leading to some manufacturers to adjust their reagents to be more sensitive. While individuals may have a preference of one method over another, there is not enough evidence to exclude a method from consideration on the basis of specificity and sensitivity.

**General Features of Automated Systems**

Fully automated systems would be expected to have security systems that track users, limit access to functions, store and archive data, monitor reagents levels and expiration, warn that quality control has not been done, detect clots in samples, use barcoded samples and reagents positive sample, can be interfaced to Laboratory Information Systems and allow some customization. Table 1 lists available test menu options. Table 2 lists features that vary by instrument. Because facility requirements differ, an instrument with a wide test menu may be more desirable to a facility that collects donor units than to a hospital transfusion service that may be limiting automated testing to ABO, Rh and Antibody Screening as a part of pretransfusion testing. However, there may be future opportunities to expand testing and a larger set of options may prove beneficial.

**Instrument Reliability**

The amount of time an instrument is down for routine maintenance for both daily, weekly, monthly or manufacturer recommended recalibration can be estimated. What is more difficult to assess is the amount of time the instrument will be down for operator preventable reasons. Failure to remove the tube cap or improperly loading tubes in the device or tube carrier may cause a malfunctioning probe. Other system malfunctions occur because of normal wear and tear on the instrument. It is not uncommon to have a higher number of unanticipated instrument downs during the first few months after installation especially when there are a large number of new users.

The amount of unanticipated down time is dependent on the ability of the user to make the repairs. If spare parts are available and the skill needed to make the repair is low, down time will be reduced. If a service engineer is needed to make the repair, the down time varies with the number of spare parts immediately available, the distance the service engineer must travel to the site, and the number of customers supported. Much time can be squandered waiting. Since facilities must have a backup plan for instrument downs, some facilities operate two instruments. Other facilities revert back to manual testing. This may mean receiving cell shipments that are never used unless the system becomes non-operational adding to the cost of running the instrument.

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interfaces

The ability to interface the instrument to the laboratory information system depends on a number of variables including the age of the transfusion service computer system, the need for middleware, and the ability to translate the symbols used by the instrument to those used in the transfusion service. One illustration of this problem is the symbol that is used to record a negative test. The instrument may use the symbol “-” and the laboratory information system may use the symbol “0”. It may not be possible to reprogram with laboratory information system to accept the “-” to mean negative if this has previously been used to mean something different. Middleware can make the transformation, but this adds complexity to the system. Further complicating the issue could be how the instrument tracks results unable to be interpreted by the instrument. If the instrument attaches a symbol to result to indicate it was modified or manually interpreted (e.g. 3+ would appear as 3+M), the number of results that must be validated in the laboratory information system increases almost exponentially.

Another important consideration is being able to track the instrument that was used to perform the testing for process control and maintaining the records required for good manufacturing practices.

physical location and utilities

The path of the workflow needs to be considered. In addition, some instruments require access to the back of the instrument. Placing the instrument on a wheeled table that is capable of handling the weight of the instrument may provide the flexibility necessary for proper workflow and maintenance. If renovation is necessary, these costs should be included in budgeting. Most instrument configurations will include an uninterruptable power supply to even out power fluctuations and allow appropriate shutdown in the case of a power outage.

Waste management is also a consideration. In some instruments, the frequency of used plate and card removal may be reduced by placing a discard hole in a bench top. Some instruments have liquid waste that collects in a container. Local fluid waste disposal regulations need to be reviewed before any liquid wastes are disposed down a drain.

the cost of automation

The cost of automation can be broken down into three areas: the original acquisition of the instrument, validation and training, ongoing operation and maintenance and personnel costs. Prior to automation, the capital outlay for transfusion service equipment was relatively modest when compared to the hematology or chemical pathology laboratories. The cost of a new instrument may range from $50,000 to $200,000 US dollars depending on the instrument’s size, throughput and features. In addition, there may be significant costs to renovate the laboratory to accommodate the instrument workflow. There are a number of ways that the capital costs for automation may be financed and will vary in facilities and countries. It may be necessary to plan to purchase automation at a time when other laboratory sections are not vying for scarce capital equipment dollars. Although the reagent costs for automation tend to be higher than the cost of manual testing, the operational costs may be reduced by unexpected factors such as reduced expenses for solid waste disposal or bulk purchases.

Early cost models often significantly underestimated the cost of ongoing operations. The most frequent issues are the cost of reagents used to perform routine instrument functions such as pipette washing and clot removal, dead space in the instrument lines that consume more reagents than estimated when specimens are tested one at a time, failing to recognize that there is a residual
volume in reagent bottles that the instrument cannot use, and overestimating the actual testing batch size resulting in increased testing of positive and negative antibody screening controls. Models have improved, but the processes used for non-automated functions related to testing, the pattern of specimen arrival, the number of “stat” specimens and laboratory staffing patterns all affect optional costs. The true cost of automated testing can only be determined once routine patterns of testing have been established and the staff is comfortable operating the instrument.

As with the implementation of any new test system, there are the costs associated with training personnel and validating the testing process which must be included when assessing the financial impact of automation. Undoubtedly, automation reduces the need for hands-on time for processing specimens. A saving in personnel cost is not often realized as staff are reassigned to addition duties but are not eliminated. When a facility has multiple instruments, a single individual is able to operate multiple instruments. Some of the costs of automation may be offset by the ability to process specimens from outside facilities such as physician offices.

Summary

Automation has great potential in transfusion services large and small. Selecting the best instrument for a laboratory requires consideration of a number of factors. While cost is a factor in selecting an instrument, other factors weigh heavily on the success of the installation and must be considered. The potential for adding immunohematology instrumentation to an automation line and autoverification of routine test results will further streamline transfusion service operations.

References:
Table 1: Instrument Variables to Consider in Selecting Transfusion Service Automation

<table>
<thead>
<tr>
<th>Testing menu</th>
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<tbody>
<tr>
<td>ABO</td>
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<tr>
<td>Rh</td>
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<tr>
<td>Antibody Screen</td>
</tr>
<tr>
<td>Type and Screen</td>
</tr>
<tr>
<td>Antibody Identification Panels</td>
</tr>
<tr>
<td>DAT</td>
</tr>
<tr>
<td>Antigen typing</td>
</tr>
<tr>
<td>ABO/Rh Donor unit confirmation</td>
</tr>
<tr>
<td>Serologic crossmatch</td>
</tr>
<tr>
<td>Immediate spin</td>
</tr>
<tr>
<td>Antiglobulin</td>
</tr>
<tr>
<td>Platelet antibodies</td>
</tr>
<tr>
<td>Syphilis</td>
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</tbody>
</table>

Table 2: System Features

| Ability to connect to an automation line |
| Ability to use various tube sizes       |
| Batching versus continuous flow         |
| Cord blood sample testing               |
| Cost per test                            |
| Ease of operation – operator/instrument interface complexity |
| Minimum volume                           |
| Minimum tube size                        |
| Number and frequency of testing controls|
| On board reagent storage time            |
| Physical instrument footprint            |
| Stat testing capabilities                |
| Symbols used                             |
| Time for first ABO/Rh result             |
| Turn-around time                         |
| Throughput time                          |
| Walk-away time (time the instrument can be left unattended) |
| Waste disposal                           |
AUTOMATION IN UK BLOOD TRANSFUSION LABORATORIES: STRATEGIES FOR ERROR REDUCTION

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Introduction
The laboratory plays an important part in the transfusion pathway. The United Kingdom (UK) blood transfusion laboratories are currently undergoing organisational changes to optimise provision of blood transfusion services in a climate where workload is becoming increasingly demanding. Automation improves accuracy by reducing the number of manual steps required compared with manual testing, therefore reducing the potential for human error. It also increases efficiency (as fewer staff are required to perform the test). In 2009, recommendations were made for the increased use of automation and Information Technology (IT) systems in the UK blood transfusion laboratories to minimise or reduce errors, especially those related to manual intervention.

The benefits associated with using automation and IT systems are considered below, with reference to recommendations and key learning points made by the UK independent, professionally-led, haemovigilance scheme, Serious Hazards of Transfusion (SHOT)34, and recommendations on the minimum standards for hospital transfusion laboratories published by the UK Transfusion Laboratory Collaborative (UKTLC)25.

Background
SHOT collects and analyses anonymised information on adverse events and reactions in blood transfusion from all healthcare organisations that participate in the transfusion of blood and blood components in the UK. SHOT identifies areas where laboratory and clinical practice need to be improved; highlights ‘learning points’ and makes appropriate recommendations for changes to improve patient safety.

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The UKTLC has representation from SHOT, the Institute of Biomedical Science, the Royal College of Pathologists, the British Blood Transfusion Society, and the National Blood Transfusion Committee in England. The published standards and recommendations are intended to promote effective and appropriate use of staff and technology in hospital transfusion laboratories.

**Challenges to UK hospital blood transfusion laboratories**

In addition to regulatory and professional demands, there are other challenges that UK hospital transfusion laboratories have to consider. These include increasing workload including a greater demand especially for out-of-hours work, and increased cross cover by staff from other pathology disciplines (e.g. biochemistry) who may have less transfusion training and a lower level of knowledge, plus lack of investment in educational resources and training as illustrated in a recent survey carried out by the UKTLC in 2013 (unpublished data). Adequate IT systems play a vital role in facilitating good transfusion practice and maintaining compliance by UK hospital blood transfusion laboratories. There are various UK regulations that seek to ensure the quality and safety of blood and blood products throughout the transfusion process, these include:

- The Blood Safety and Quality Regulations 2005 (BSQR) administered by the Medicines and Healthcare products Regulatory Agency (MHRA)
- Clinical Pathology Accreditation (CPA)
- Quality Management Systems - document control (QMS)
- Pharmaceutical legislation – greater knowledge of Good Manufacturing Practice and its importance in safety (GMP)

**Benefits of automation and IT systems**

- Process multiple samples at the same time
- Detect if sample is unsuitable e.g. clotted or insufficient volume
- Easier access to patient historical records
- Easier to maintain and archive electronic data
- Allow staff to perform other tasks while testing is being performed
- Audit trails (e.g. location and history of the blood component/sample and who has carried out the related testing and processing)
- Automatic upload of results to patient electronic records reduces the risk of transcription errors
- Can be interfaced to laboratory information managements systems (LIMS)
- Electronic patient records can be merged or reconciled therefore removing potential identity confusion.
- Users can manually generate alerts or warnings that appear on the computer screen like a ‘flag’ to warn the user of a specific requirement, e.g. requires irradiated cellular products.
- Alerts can also be generated based on pre-programmed algorithms e.g.: automatic checking of ABO group compatibility or requirements related to age and/or gender.
- Traceability of components can be achieved that allows documentary evidence on the journey of blood and blood components from donor to patient, including blood tracking for improved monitoring and audit of cold chain and restriction of unauthorised access to blood components

Overall, automation improves accuracy as fewer steps are involved in testing. It is less time consuming when compared with manual testing and is not subject to distractions or interruptions. Automation involves a standard amount of time to process samples, therefore enables staff to manage the workload more effectively. The use of automation can also allow harmonisation of standard

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operating procedures across the country/region. Nevertheless, there are drawbacks associated with automation and IT systems. These are listed below.

**Drawbacks of automation and IT systems**

- Robust back up systems are needed for downtime, i.e. period of time in which automated machinery or IT system is not functioning or inaccessible. If this requires blood transfusion staff to revert to manual testing, they may be less proficient due to lack of practice in manual techniques.
- Cannot always predict downtime of equipment, e.g. system malfunctions can occur due to wear and tear of the system.
- The initial cost of automation is expensive, and requires a large investment.
- Further expenses include:
  - The need to replace IT hardware and automation, as required. This is often in accordance with a formal replacement plan based on the expected depreciation of equipment.
  - The cost of service and maintenance contracts, to cover regular checks on IT and automated equipment.
- A variety of automated testing equipment is available and the features and benefits may vary from one product to another.
- Laboratories may need restructuring to accommodate the hardware. Software for interfacing equipment will also be necessary.

**Recommendations and key learning points**

Recommendations have been made by SHOT in response to the large number of ‘wrong blood’ errors originating in blood transfusion laboratories reported since SHOT’s inception in 1996. The aim is to prevent recurrence. The UKTLC\textsuperscript{2, 5}, following on from the work carried out by SHOT, has recommended that:

“UK blood transfusion laboratories should have full walk away automation which is in use 24 hours, 7 days a week, with bidirectional interfaces to the laboratory information system.

Where the workload does not warrant such technology, e.g. hospitals with a remote and rural location performing in the order of 10 group and screens per week, then the collaborative expects measures to be taken in order to mitigate procedural laboratory errors – for example double-blind entry of results\textsuperscript{2, 5}.”

SHOT recommends\textsuperscript{4} that “where manual testing cannot be avoided then checks of the critical steps by a second person should be employed.”

**The future of automation**

Improved technology has resulted in faster, more reliable, more flexible testing. Integrated analysis software, allows full traceability of processes. The UK blood transfusion laboratories are becoming increasingly automated and the IT environment in which systems operate is growing rapidly. Further expansion of bedside automation with barcoded patient identity bands would improve the safety of blood transfusion. Where these systems exist, transfusion can be under IT control from the point of taking the patient’s sample, through testing and compatibility processes and back to the component being transfused to the patient.

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The next possible advancement in automated testing might be large scale molecular genotyping. This can be performed by a high throughput multiplex assay, allowing genetic characterisation of extended blood group antigens. However, it is not suitable for ABO grouping, which is the most important aspect of pre-compatibility testing, because the genetic complexity ABO blood group system does not always allow the blood group phenotype to be determined from a person’s genotype.

**Conclusion**

Automation improves patient safety within blood transfusion laboratories; however laboratories may experience financial and practical constraints in implementing fully integrated IT systems. The recommendations made by the UKTLC\(^2\), SHOT\(^3\)-\(^4\) and the British Committee for Standards in Haematology\(^6\) in the use of automation and IT systems have been implemented in the UK to support transfusion safety and provide traceability outside the laboratory. The use of automation together with integrated IT systems adds additional levels of safety if the software is configured and used appropriately. However SHOT data over the last 6 years demonstrate that errors related to laboratory practice continue to contribute to adverse events. The introduction of integrated IT systems have been implemented specifically to reduce such errors, but errors especially in overriding or ignoring warning flags and/or logic rules are increasing year on year\(^8\). It is imperative that transfusion staff do not become over-reliant on automation and IT systems by believing that these circumvent human error. Laboratory staff must understand the working of these systems and be trained and competency assessed to react appropriately to alerts and warning flags.

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