J Pathol Inform

Editor-in-Chief:
Anil V. Parwani , Pittsburgh, PA, USA
Liron Pantanowitz, Pittsburgh, PA, USA

OPEN ACCESS
HTML format

For entire Editorial Board visit : www.jpathinformatics.org/editorialboard.asp

Review Article

Contemporary issues in transfusion medicine informatics

Gaurav Sharma, Anil V. Parwani, Jay S. Raval[1], Darrell J. Triulzi[1], Richard J. Benjamin[2], Liron Pantanowitz

Division of Pathology Informatics and [1]Transfusion Medicine, Department of Pathology, University of Pittsburgh Medical Center, Pittsburgh, Pennsylvania, [2]National Headquarters, American Red Cross, Washington D.C.

E-mail: *Liron Pantanowitz - pantanowitzl@upmc.edu
*Corresponding author

Received: 27 October 10 Accepted: 01 December 10 Published: 07 January 2011
DOI: 10.4103/2153-3539.74961 *J Pathol Inform* 2011, 2:3
This article is available from: http://www.jpathinformatics.org/content/1/2/3

This article may be cited as:
Sharma G, Parwani AV, Raval JS, Triulzi DJ, Benjamin RJ, Pantanowitz L. Contemporary issues in transfusion medicine informatics. J Pathol Inform 2011;2:3
Available FREE in open access from: http://www.jpathinformatics.org/text.asp? 2011/1/2/3/74961

Abstract

The Transfusion Medicine Service (TMS) covers diverse clinical and laboratory-based services that must be delivered with accuracy, efficiency and reliability. TMS oversight is shared by multiple regulatory agencies that cover product manufacturing and validation standards geared toward patient safety. These demands present significant informatics challenges. Over the past few decades, TMS information systems have improved to better handle blood product manufacturing, inventory, delivery, tracking and documentation. Audit trails and access to electronic databases have greatly facilitated product traceability and biovigilance efforts. Modern blood bank computing has enabled novel applications such as the electronic crossmatch, kiosk-based blood product delivery systems, and self-administered computerized blood donor interview and eligibility determination. With increasing use of barcoding technology, there has been a marked improvement in patient and specimen identification. Moreover, the emergence of national and international labeling standards such as ISBT 128 have facilitated the availability, movement and tracking of blood products across national and international boundaries. TMS has only recently begun to leverage the electronic medical record to address quality issues in transfusion practice and promote standardized documentation within institutions. With improved technology, future growth is expected in blood bank automation and product labeling with applications such as radio frequency identification devices. This article reviews several of these key informatics issues relevant to the contemporary practice of TMS.

Key words: Blood bank, barcode, computer, donor, electronic crossmatch, FDA, informatics, transfusion medicine, virtual

INTRODUCTION

In a hospital-based setting, the Transfusion Medicine Service (TMS) may be called upon to provide multiple services, each vital to patient care. These services include a donor collection, blood component preparation and storage, testing of patient samples (e.g. blood type, antibody screen, crossmatch), issue of blood products, apheresis medicine services (e.g. plasmapheresis), and possibly reference test work. The stakes are high, because blood bank systems need to be operational 24 h a day and even seemingly minor clerical errors can result in serious (possibly fatal) patient harm. These demands present significant informatics challenges.[1] Accordingly, fairly sophisticated blood bank computer systems have been developed since the early 1980s to meet these challenges.[2] Computing options range from stand alone computer systems, to a general laboratory information system (LIS)

with modules designed specifically for transfusion services (blood bank) and blood donation (blood donor), to complete blood bank application service provider (ASP) solutions. In the United States (USA), there are around 18 different vendors that supply and support such information systems.[3-5] These vendors range from small "niche" companies dealing specifically with blood bank applications to large corporations that offer transfusion medicine modules as packages of larger health information management systems. Overall, these varying TMS information systems have enabled better utilization of laboratory resources, enhanced workflow management with automation, and improved patient safety. This article provides a review of several key informatics issues relevant to the contemporary practice of TMS.

Regulatory Oversight

Blood banks operate within a very highly regulated environment as they must satisfy requirements from several regulatory agencies. In the USA, the Food and Drug Administration (FDA) regulates the collection, manufacture and distribution of blood in the USA through law, industry guidance and regular inspections of licensed and registered facilities. In addition, the Joint Commission, the AABB (formerly known as the American Association of Blood Banks), and the College of American Pathologists (CAP) impose accreditation standards on blood use, a requirement for hospital-based TMS facilities not under FDA scrutiny. The FDA is charged with ensuring the overall safety and efficacy of blood products and requires licensing or registration of blood establishments that collect or manufacture blood products. These regulations impact virtually every aspect of operations, including the role that informatics plays in TMS. Outside the USA, the oversight model is highly variable and ranges from national regulatory bodies with TMS-specific regulations, rigid quality assurance procedures, to minimal regulation of all or some parts of the blood product cycle.[6]

Food and Drug Administration

In the USA, the FDA considers computerized systems to include hardware, software, peripheral devices, "personnel," and standard operating procedures.[7] It considers the blood bank LIS to be a "medical device" integral to the manufacture of blood products as drugs, and similar to the computer systems blood centers employ to control the collection, manufacture and distribution. Therefore, blood banks are responsible for assuring that their LIS repeatedly and reliably performs as intended (i.e. ensure that it is a properly validated "device"). This also means that FDA 510(k) clearance (or pre-market notification) is required by blood bank LIS vendors, just as a medical device would, which includes major upgrades of their systems. Unlike other medical devices that are regulated by the FDA Center for Devices and Radiological Health (CDRH), the Center for Biologics Evaluation and Research (CBER) regulates "blood establishments computer software" (BECS) and maintains a list of all blood products it has cleared. CBER is the center within the FDA that regulates biological products for human use under applicable federal laws, including the Public Health Service Act and the Federal Food, Drug and Cosmetic Act.

The FDA recommends that electronic data systems used in blood centers exhibit the capacity to trace the history of (1) every donation forward from entry all the way through to final disposition of each component, including all reagents, supplies, devices, and staff involved, and to track (2) from each transfusion, infusion, or sale of a blood product backward to the original donor.[8] Such data, for example, would be important in the event of a product recall. Although software products other than the LIS used in the blood bank are not currently regulated as medical devices, the recommendation is that they too should be validated for their intended use.[9] As mentioned, documentation is a key component of blood bank computerized systems. In fact, failure to document computer training by blood bank staff and validation of change procedures are common deficiencies cited by the FDA.

Current Good Manufacturing Practice

Blood products are regulated by rules that pertain to the good manufacturing practice (GMP) of biological products. GMP requirements are specified in Title 21 of the Code of Federal Regulations (CFR).[10] Several countries have legislated that medical device companies need to follow GMP procedures, and have created their own guidelines that correspond to their legislation. Table 1 shows most of the elements of GMP.[9] GMP is enforced in the USA by the FDA, under Section 501(B) of the 1938 Food, Drug, and Cosmetic Act (21USC351). The FDA regulations use the phrase "current good manufacturing practices" (cGMP) to describe these guidelines.

HIPAA and Patient Privacy

The Health Insurance Portability and Accountability Act (HIPAA) in the USA, which was passed in 1996, helps

Table 1: Elements of the current Good Manufacturing Process (cGMP)

Standard operating procedures
Record keeping (paper-based and electronic)
Personnel management (e.g. training, competency testing)
Calibration (e.g. instruments, equipment)
Validation (including revalidation requirements)
Labeling (e.g. lots, units)
Error management (e.g. reporting adverse reactions)
Quality control and auditing
Facilities (e.g. workflow design) and equipment
Process and production change control

ensure that privacy is maintained with regard to patients' medical records. It also created a set of standards to which all electronic medical records must adhere. HIPAA applies only to certain covered entities (e.g. health-care providers) that conduct specified transactions dealing with personal health information (PHI). During the regulatory process the United States Department of Health and Human Services (DHHS) implemented a "procurement exclusion" that applies directly to blood/tissue collection. Thus, because procurement is not intended for health care of the donor, HIPAA in this instance is inapplicable.[11] Therefore, if an organization is in the business of blood collection only, it is not considered to be a health care provider and the HIPAA privacy rule does not apply. However, blood/tissue collection centers that also perform patient-related support services (e.g. diagnostic testing or provide transfusions) are covered entities, and thus must comply with HIPAA.

Laboratory Information Systems

The LIS is central to many blood bank and donor operations. Some systems may be part of integrated systems while others may represent a standalone LIS. LIS functions include workflow management, specimen and product tracking, data entry and reporting, assistance with regulatory compliance, code capture, inventory control, billing, and interfacing with other systems such as the hospital information system, and electronic medical record.[12] The LIS supports workflow throughout the pre-analytic (e.g. specimen accessioning), analytic (e.g. test performance and reporting), and post-analytic (e.g. report transmission) testing process. Components of the LIS include hardware (e.g. servers, computer workstations), peripheral devices (e.g. instruments, printers), a network, interfaces (e.g. links to other information systems), database(s), and software (e.g. application, database management system).

Transfusion Medicine Functionality

The LIS serves as an electronic database, providing a mechanism to archive patient and donor records. A small number of regions are served by a centralized transfusion service (CTS) providing integrated laboratory support across multiple hospitals and even multiple health care systems. In such settings, access to a centralized patient database from anywhere in the health system has been shown to reduce blood typing errors and prevent mis-transfusions.[13] Successful integration requires unique information technology capabilities such as tracking patients that may go from one hospital to another, monitoring blood inventories in multiple locations, and tracking samples that may be in multiple locations. CTS systems combine samples from multiple hospitals and thus typically use automated testing platforms extensively. Interfaces to automated equipment is thus a necessity for CTS systems. Software with these capabilities is available commercially. The blood bank LIS also facilitates patient testing (e.g. blood type and screen, component preparation, pre-transfusion compatibility testing).

The LIS permits users to input data about blood products and associated testing or modification (e.g. irradiation) of the product, to manage multiple aliquots of blood units, and offers a mechanism to track products (i.e. vein-to-vein tracking). In addition, the LIS provides a mechanism to report results (e.g. antibody findings) and perform documentation (e.g. record the issue of emergency-released products). The blood bank LIS also permits inventory management of the various blood products. It should allow blood product inventory reports to be created which may include data about product type, availability and expiry date. The LIS may also allow users to be flagged when specific patient transfusion requirements (e.g. the need for washed or irradiated units) are not met. Several blood bank LISs also provide bi-directional interfaces with instruments and automated equipment (e.g. blood irradiators). The trend in TMS is to move from tube testing to gel. Thus, automated platforms for gel testing are becoming increasingly common. Interfacing may be a problem if home grown software is employed, as most major manufacturers will create interfaces for common systems. They may also offer a handheld phlebotomy module and web-based interface. Current blood bank LISs are, however, limited in their capacity to generate text-based synoptic reports (e.g. apheresis medicine consult notes). As a result, some institutions have relied on their Anatomical Pathology LIS instead for this reporting function.[14] Table 2 summarizes some of the key functions of a LIS in TMS.

Record Retention

TMS must maintain and archive several types of records, as required by accrediting agencies and sometimes for indefinite periods. These include donor records, patient records, quality control records, and for some centers tissue and cellular product records. Such records are required to be readily available to support daily clinical practice, and may be required to support quality management, inspection, regulatory and compliance needs. Even during a computer downtime certain patient

Table 2: Key functions of the TMS-LIS

Workflow management
Inventory of blood products
Record of procedures (donor and recipients)
Record of product modifications (e.g. irradiation)
Record of results (donor and recipient)
Record of patient procedures (e.g. transfusion and apheresis)
Interface with other systems and instruments
Reporting and transmission of results
Electronic crossmatch
Code capture
Billing for services
Documentation and regulatory compliance

data (e.g. blood type) must be made available. Donor data, on the other hand, is not considered to be as critical. In the USA, record retention periods range from 5 years (e.g. quality control records), to 10 years (e.g. patient transfusion and apheresis records), to those records that may need to be kept indefinitely (e.g. deferred donors and transfusion reactions).

In general, the blood bank LIS in a hospital setting is considered to be a critical (i.e. indispensable) system, and as such requires regular backup and an executable recovery plan in case of a disaster. Longevity of databases is a key feature of any blood bank LIS. Not only is access to long term patient records mandatory (e.g. blood type and antibody history), but as noted above, accessible donor records may need to be retained indefinitely (e.g. permanent deferral data). Periodic audits of stored data are recommended to assure that timely retrieval and accurate information reporting are available. It is equally important that blood bank systems exert strict control over database changes.[15] Data storage is also important for hemovigilance programs.

Electronic Crossmatch

Electronic or computer crossmatch (sometimes referred to as EXM, e-crossmatch or termed electronic issue) is an electronic method used to confirm that a blood unit is suitable for transfusion to the intended recipient by using validated software logic to determine compatibility. First introduced at the University of Michigan in 1992, it provided an alternative to immediate spin crossmatch for ABO compatibility between the donor and the recipient, and was found to be more rapid and generally safer than serologic techniques, in eligible patients.[16-20] Requirements that are essential for the safety of an EXM are shown in Table 3 and illustrated in Figure 1. To date, the AABB and British Committee for Standardization in Hematology (BCSH) have published specific guidelines regarding EXM, and it is being increasingly accepted around the world.[20] Overall, the advantages of EXM include reduction in laboratory workload, unit expiration, transfusion requests, sample volume requirements and

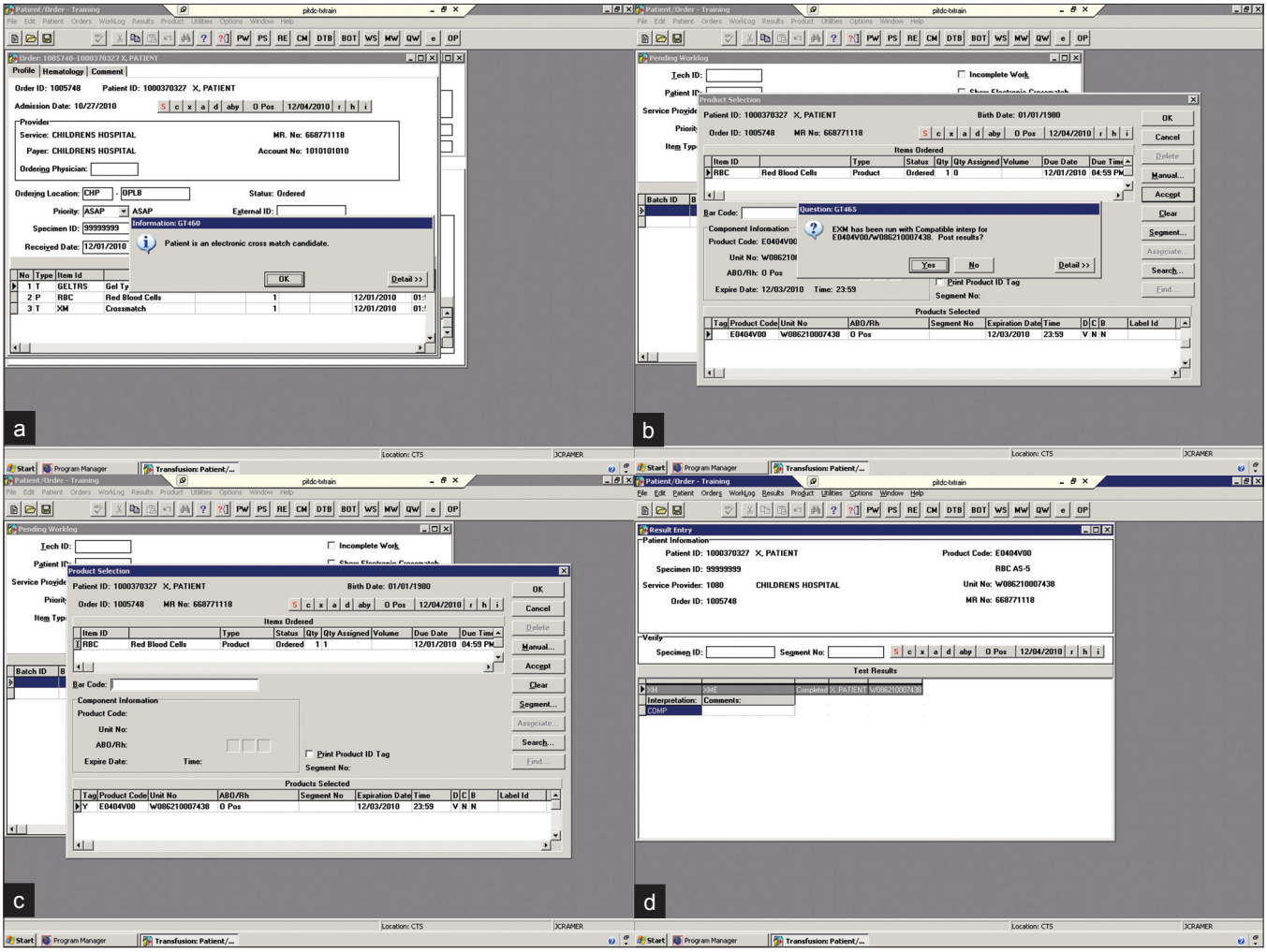

Figure 1: Screenshots demonstrating electronic crossmatch (EXM) in a blood bank (test) information system. (a) An order placed in the system alerts the blood bank that this particular patient is eligible for an electronic crossmatch; (b) Blood is assigned from a pending work-log and an EXM is run; (c) A compatible product is selected and; (d) Recorded in the computer system

cost saving. Disadvantages include the requirement to have two separate and identical ABO/Rh type results in the TMS record before being able to use electronic release, the potential for failure to detect antibodies directed to low-frequency antigens since these may not be represented on the screening cells used in the type and screen assessments, the necessity of computer downtime documentation alternatives, and increased financial investment in technology.

Virtual Blood Banks

While most blood within hospitals is housed within the blood bank, at some sites blood products may also be stored throughout the hospital (e.g. in operating rooms or the emergency department) to be made available in emergent situations. Such remote refrigerators have been shown to facilitate "virtual blood banking" with "self-service" ordering and electronic remote blood issue (ERBI).[21,22] ERBI has been shown to help reduce the time it takes to make blood available for surgical patients, decreases the workload of both blood bank and clinical staff, and improves the efficiency (e.g. lower wasted units) of hospital transfusions. In medical centers with virtual blood banks, computer systems are required to provide remote monitoring of all inventory and blood-storage refrigerator temperatures.

Barcode Technology

Many blood centers have label printers that can provide on-demand custom labels for blood components. Although printer technology has greatly improved, it is important that these printers be validated and frequently checked, making sure that their labels are readable. For example, the difference between the blood antibodies anti-K (with a capital) and anti-k (without a capital) is important. The FDA requires blood products to have machine-readable labels on them that include a unique facility identifier, unit/lot number, product code, and ABO/Rh type.[9]

Barcode Standards

Most blood bank LISs have the ability to print and read barcode labels. In the world of transfusion medicine, the two major barcode symbologies are Codabar and ISBT 128.[23] Codabar is a soon to be obsolete linear barcode symbology designed to be accurately read even when printed on dot-matrix printers. With Codabar there are only a limited number of available barcodes. ISBT 128 is a newer internationally standardized bar coding system used for identification, labeling and processing of not only human blood, but also tissue and cellular therapy products. ISBT stands for the International Society of Blood Transfusion and 128 is the barcode symbology used. This system offers many more specific codes. Table 4 shows the data structures provided by ISBT 128.ISBT 128, first published in 1994, was intended to replace the Codabar system.[24,25] The ISBT 128 system increases the level of standardization in transfusion medicine. ISBT 128 certainly simplifies the transfer of donor unit testing information between facilities. The Council for Commonality in Blood Banking Automation, Inc. (ICCBBA) is the non-profit company that manages ISBT 128. Since 2006, the FDA requires blood products to bear a machine-readable bar code. Both Codabar and ISBT 128 meet that requirement. Although Codabar is being widely replaced by ISBT 128, blood banks still need to be prepared to handle blood units that may contain older barcodes. For example, frozen products that have a very long shelf life may still have old labels on them. If the LIS cannot handle both types of bar codes, such products may have to be re-labeled. With ISBT 128, each blood product is given a unique donation identification number that includes an assigned collection facility code. This allows every product to be identified and tracked anywhere in the world. Figure 2 illustrates the Unique Donation Identification barcode format. The ISBT 128 barcode allows for more information to be coded into a small space. It also includes an internal check digit to prevent barcode misreads. ISBT 128 also provides a standard labeling format that ensures a consistent layout of product labels with these barcodes [Figure 3].

Table 3: Essential requirements for the electronic crossmatch of blood

The computer contains logic to prevent assignment and release of ABO incompatible blood
Donor data is contained in the system
The recipient has no history of clinically significant antibodies
The recipient's ABO/Rh blood type has been determined twice (once from a current sample) and they are in agreement
The system has been validated on-site
There are mechanisms to verify the correct entry of data prior to release of blood

Table 4: Data structures provided by ISBT 128

Donation identifier (includes the collection facility, year, and donation sequence)
Product code
ABO and Rh(D) blood groups
Product description
Type of donation (volunteer, directed, autologous, etc)
Expiration date and time
Collection date and time
Red cell phenotyping information
HLA typing information
CMV and other test results
Collection container catalog and lot number
Patient date of birth and identification number

Patient Identification Technologies

The goal in Transfusion Medicine is to get the right blood to the right patient. The bedside verification when collecting a blood sample or prior to giving a transfusion is a critical step. While most studies have demonstrated

Figure 2: Format of unique donation identification barcode using ISBT 128. It has three elements: (1) the collection facility identified by the first five characters (W0000); (2) then the collection year (2011); (3) followed by a donation number assigned by the collection facility (123456). The last digit within a box is a checksum character. (Reproduced with permission from ISBT 128 An Introduction © ICCBBA Inc. http://iccbba.org/uploads/a2/6e/a26e9302a6b32cae265322947c0ef239/ISBT128introbooklet.pdf)

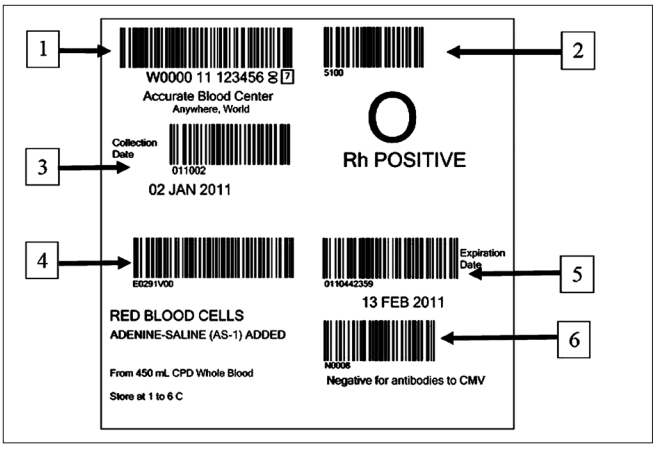

Figure 3: Standard labeling format of the ISBT 128 barcode. (1) Donation Identification Number; (2) ABO/Rh groups; (3) Collection date; (4) Product code; (5) Expiration date and time; (6) Special testing (optional). (Reproduced with permission from ISBT 128 An Introduction © ICCBBA Inc. http://iccbba.org/uploads/a2/6e/a26e9302a6b32cae265322947c0ef239/ISBT128introbooklet.pdf)

incremental improvements in patient safety with bedside verification of patient wristband and/or blood unit barcodes, a defect rate of around 2-3% has still been demonstrated in large institutions. Failure points include non-compliance by the operator, device malfunctions and wristband print errors.[26] Barcoded blood products can be used not only to track and trace units, but when used at the patient bedside they have been shown to also help prevent misidentification errors arising prior to transfusion.[27] However, inherent limitations of using a barcode-based technology include soiling of barcodes and occasionally having the need for a nurse to put down the selected blood unit so as to line up the wristband with a barcode scanner. The latter can be perceived as an extra and often "clumsy" step, with the possibility of a bag mix-up even after the barcode reading has been approved. Barcode readers themselves may also present problems as some devices may potentially be incapable of reading blood bank barcodes, but can be used without problems for other non-blood bank areas like the pharmacy. Finally, it is worth noting that donor identification cards also carry barcodes and are in use in several countries.

Radio Frequency Identification Devices

Radio frequency identification devices (RFID) have theoretical advantages over using barcode identification since these tags do not depend on "line of sight" identification, eliminating the need to use both hands to line up identification tags. The generation of a radio signal by a RFID tag is independent of surface soiling. RFID tags can be active (battery powered that continuously transmit a radio signal) or passive (powered from a radio signal received from a reader). Active RFID tags are expensive, but easily registered and better suited for asset tracking items that are stored/used for short period of times owing to their limited battery life. While passive RFID tags are cheaper and last for a very long time, their detection is very much dependent on the range of the RFID receivers. In Transfusion Medicine, RFID has been shown to have the potential to support rapid and easy access to process data generated in the blood supply chain, including collection, manufacturing, testing, release labeling, inventory, and distribution.[28-30] This could, in turn, facilitate and improve compliance with cGMP. User trials of RFID for autologous blood transfusions and allogenic blood transfusions have shown improved patient safety by reducing the number of steps that require handling of wristband barcodes. Nevertheless, integration of RFID technology with a hospital's information technology infrastructure is perceived to be a crucial factor in the implementation of this technology. RFID technology can also be used to perform real-time tracking of products.[31] This latter capability will be particularly useful in the event of a recall that affects a batch of products.[32]

Donor Centers

The informatics needs required to support a blood donor facility are somewhat unique. These donor systems or modules may need to support donor recruitment, mobile collection unit scheduling, donor management, deferral, blood testing, reporting of transmissible diseases to the Department of Public Health, manufacturing and labeling of blood products, and the distribution of blood while ensuring trackability and traceability at each step. Overlying these requirements is the need for business management tools to ensure the efficient and timely management of resources to minimize costs and undue delays. The core functions of donor management, testing, manufacturing and labeling are regulated functions, while donor recruitment software and business functions are not, leading some centers to maintain separate client relations management (CRM) software and a non-regulated

data warehouse function to allow the development of business tools. Some CRM platforms can even use text messaging to reach potential donors via mobile phones.[4] Other unique features of the regulated computer systems may include a self-administered computerized donor interview and eligibility determination, based upon calculations for donor eligibility performed at the time of donor registration. Studies have shown that automated computer-assisted interviewing increases the elicitation of behaviors associated with the risk of transfusion-transmissible infection in donors, improves donor and staff satisfaction, as well as reduces errors and omissions that frequently accompany traditional interviewing methods.[33] For mobile blood donor facilities out on the road, technical support may be challenging with respect to hardware needs (e.g. laptops) and telecommunication requirements (e.g. secured wireless network to donor records).

Electronic Medical Record

The electronic medical record (EMR) is increasingly being employed in medical institutions. Some of the benefits of an EMR include portability of information, enhanced patient safety (e.g. reduced medication errors), and promotion of standardized (protocol-based) patient care. The EMR has also been utilized to address issues related to quality transfusion practice within institutions.[34-36] At the time of computerized physician order entry (CPOE), for example, criteria for blood usage can be displayed and/or transfusion requests can be reviewed and flagged if they are considered to be inappropriate. The generation of such data could be measured and accordingly used to continuously improve institutional transfusion practice. In a recently published study, it was shown that with investment in adequate user training and clinician-pathologist dialogue, a consistency in ordering patterns was achieved with greater ease of monitoring.[37] The EMR has also begun to be utilized for the documentation of patient care related clinical services (e.g. Apheresis Medicine Services) that are managed by TMS.[38] This is particularly useful in institutions that are moving toward a paper-free environment. If utilized effectively, the EMR can enhance communication between the TMS and clinical teams, as well as promote standardized documentation of patient care within and across service lines.

National Blood Banking

The integration of multiple blood centers into national or regional systems under a single FDA license, such as the American Red Cross Biomedical Services (ARC) or Blood Systems Incorporated (BSI), engenders unique issues in terms of scale. There is no national donor deferral system in the USA and donors deferred by one blood center may readily give blood at a different center. For national or regional systems, the FDA requires a single donor deferral database that can be accessed anywhere in the system to determine donor eligibility, as a core function to prevent the collection of unsafe blood. The Red Cross has ~10,000 employees collecting 20,000 blood products each day in ~40 states, with multiple, sometimes simultaneous, access to single records required by different steps in the collection, manufacturing and testing process. With organizational functionality the collection, testing, manufacturing and distribution steps often occur in geographically disparate sites, with products, test samples and data moving across state lines and often across the continent. Until recently, performing these functions as part of a regulated drug manufacturing process under a single integrated computer system was not possible. However, web-based software systems are now available to meet this need.

Conversion of a national or regional blood system, however, from one computer system to another, creates another set of unique headaches. As software and standard operating procedures in blood centers are intimately entwined, the implementation of 510(k) approved computer software triggers a premarket approval (PMA) review process by the FDA, that may (and often does) take 12 months to complete. This occurs after all procedures are complete and the blood center is ready to implement change. Once approved, implementation at each site requires complex validation. To ensure that the blood system is able to remain functional, computer software conversions take many years to plan and are usually implemented in a rolling fashion across the system, which itself may take many months. Conversion of these systems therefore is not undertaken lightly.

The advantages of national and regional systems, once implemented, cannot be overly stressed. Blood donors are mobile, and large systems allow recruitment to track donors as they move. Data warehousing functions provide non-regulated information for business development and research applications. Hemovigilance programs allow tracking of rare adverse events and implementation of corrective actions whose impact can only be assessed over large systems. Examples include the use of male plasma to prevent transfusion-related acute lung injury (TRALI) and bacterial screening of platelet products to prevent sepsis. From a business view point, national or regional systems allow matching to hospitals that are increasingly consolidated into their own systems that cross regional boundaries.

A major deficiency in the current information systems design is the lack of communication between the end users (hospitals) and the blood centers. Problems with LIS interfaces between hospitals and donor centers as well as security firewalls are potential hindrances in this endeavor. Currently, the centers responsible for collecting blood have little direct connection to the end user

making it difficult to match blood supply and demand on a day-to-day basis. This may be one reason that blood shortages remain an issue in the USA. It is hoped that the development of more national systems that can integrate information from large hospital systems will help to fill this deficiency.

Surgical Tissue Banking

Informatics issues related to surgical tissue banking are briefly noted here, as a detailed discussion of this topic is outside the scope of this review. Several blood banks are involved in the oversight of human allogeneic and autologous tissue in healthcare facilities.[39-41] Oversight of tissue banking for transplantation may stem from state laws, federal regulations, and voluntary accrediting organizations. Tissue standards provided by the Joint Commission in the USA for hospitals include assigning oversight responsibilities, standardized procedures for storage and issuance, record keeping to ensure traceability, and investigation of adverse events.[40] At present one of the major informatics demands for tissue services is traceability.[42-43] Recent investigations have demonstrated the transmission of serious pathogens (e.g. human immunodeficiency virus, rabies, hepatitis C virus) through tissue transplantation. However, investigation of such events were shown to be impaired because some of the recipients of these contaminated tissue allografts could not be identified.[40] Hence, common identification numbers (e.g. using ISBT 128) that permit linkage of organs and diverse tissues derived from a single donor are needed. Like blood and blood products, each tissue has unique identification numbers along with dates (receipt and expiration), vendor, etc. Tissue usage and compliance with standards can be accomplished using an existing blood bank LIS or specific software packages. Several tissue tracking systems available are web based and offered as a subscription service. These information systems should allow tissue/blood banks to manage and track the receipt, transfer, issuance, validation, implantation, and disposal of human tissue products. Clearly, as the use of tissue grafts continues to increase, more attention to the informatics needs to support this practice is needed.

CONCLUSION

Due to its diverse and critical applications in healthcare, TMS continues to be a closely regulated specialty with multiple oversight agencies and applicable regulations. Information systems in TMS have gradually evolved from simple isolated databases to fully integrated workflow applications that interface with other healthcare information systems, enable electronic audit trails and data mining, as well as incorporate rules based decision making such as electronic cross matching. Barcoding has improved not only compliance with cGMP, but in the field of TMS patient safety has been enhanced by utilizing positive identification technologies for patients, their specimens, and blood products. Newer barcoding protocols like ISBT 128 have started to replace the Codabar standard. These new standards are able to handle further data that can be used to efficiently manage inventory as well as perform tracking, product identification and audit trail functions. Integration with of the LIS with devices and other information systems has enabled automation, workload reduction and judicious use of available units. With automation and standardization, on the spot vending of blood products by interconnected kiosks have been shown to reduce turnaround time where blood is needed quickly (e.g. emergency and operating rooms). In the future, with improved standards and interoperability of information systems community hospitals will hopefully become better connected to each other and their blood suppliers on a national and perhaps even international level. This would be a boon for sourcing and supplying units of rare blood units. The same principles of information and product management can be extended to blood products and tissue banking.

REFERENCES

1. Kern DA, Bennett ST. Informatics applications in blood banking. Clin Lab Med 1996;16:947-60.
2. Clark IR, Parekh J, Peters M, Frew I, Ibbotson RN. Hospital blood bank laboratory data processing system. J Clin Pathol 1984;37:1157-66.
3. Wagner K. Blood bank information systems. System review series. CAP Today 2007;October 9-37.
4. Ford A. Companies fashion features to beef up blood bank systems. CAP Today 2008;September 2-4.
5. Stone E. Blood bank information systems. System review series. CAP Today 2010;September, 79-92.
6. Mascaretti L, James V, Barbara J, Cárdenas JM, Blagoevska M, Haracić M, *et al*. Comparative analysis of national regulations concerning blood bank safety across Europe. Transfus Med 2004;14:105-12.
7. Motschman TL, Jett BW, Wilkinson SL. Quality systems: Theory and practice. In: Roback JD, Combs MR, Grossman BJ, *Hilyer CD*, editors. Technical manual. 1th ed. Bethesda, Maryland: AABB; 2008. p. 1-31.
8. Food and Drug Administration (FDA). Center for Biologics Evaluation and Research (CBER). Memorandum: Computerization in Blood Establishments. April 6, 1988.
9. http://www.fda.gov/downloads/BiologicsBloodVaccines/Guidance Compliance RegulatoryInformation/OtherRecommendationsforManufacturers/MemorandumtoBloodEstablishments/UCM063007.pdf
10. Hoppe PA, Kochman SA. Current good manufacturing practice. In: Simon TL, Snyder EL, Solheim BG, *et al*. Rossi's principles of transfusion medicine. 4th ed. West Sussex, UK: Wiley-Blackwell; 2009. p. 1010-31.
11. Code of federal regulations. Food and drug administration 21 CFR (revised as of April 1, 2008) and 42 CFR (revised as of October 1, 2007). United Status: AABB; 2008.
12. Mansfield EM, Berg TK, Leifheit KA, Sweeney JP, Rigney PR. Current legal issues in transfusion medicine. In: Simon TL, Snyder EL, Solheim BG, *Stowell CO, Strauss RG and Petrides M*..Rossi's principles of transfusion medicine. 4th ed. West Sussex, UK: Wiley-Blackwell; 2009. p. 993-1009.
13. Pantanowitz L, Henricks W, Beckwith B. Medical laboratory informatics. Clin Lab Med 2007;27:823-43.
14. MacIvor D, Triulzi DJ, Yazer MH. Enhanced detection of blood bank sample collection errors with a centralized patient database. Transfusion 2009;49:40-3.
15. Nord AT, Britton RM, Gregurek SF, Skipworth E, McCarthy LJ, Smith DS.

Synoptic apheresis reports. J Clin Apheresis 2010;25:19.
16. Ashford P, Gozzard D, Jones J, Revill J, Wallis J, Bruce M, *et al*. Guidelines for blood bank computing. Transfus Med 2000;10:307-14.
17. Butch SH, Judd WJ, Steiner EA, Stoe M, Oberman HA. Electronic verification of donor-recipient compatibility: The computer crossmatch. Transfusion 1994;34:105-9.
18. Judd WJ. Requirements for the electronic crossmatch. Vox Sang 1998;74:409-17.
19. Chapman JF, Milkins C, Voak D. The computer crossmatch: A safe alternative to the serological crossmatch. Transfus Med 2000;10:251-6.
20. Butch SH. Computerization in the transfusion service. Vox Sang 2002;83:105-10.
21. Arslan O. Electornic Crossmatching. Transfusion Med Rev 2006;20:75-9.
22. Wong KF, Kwan AM. Virtual blood banking: A 7-year experience. Am J Clin Pathol 2005;124:124-8.
23. Staves J, Davies A, Kay J, Pearson O, Johnson T, Murphy MF. Electronic remote blood issue: A combination of remote blood issue with a system for end-to-end electronic control of transfusion to provide a "total solution" for a safe and timely hospital blood transfusion service. Transfusion 2008;48:415-24.
24. Li BN, Chao S, Dong MC. Barcode technology in blood bank information systems: Upgrade and its impact. J Med Syst 2006;30:449-57.
25. Butch S, Distler P, Georgsen J, Grabowski S, Muon M, Slaper-Cortenbach I. ISBT 128 An introduction. 3rd ed. 2006. Available from: http://iccbba.org/ISBT128introbooklet.pdf [Last accessed on 2010 Apr].
26. Ashford P, Distler P, Gee A, Lankester A, Larsson S, Feller I, *et al*. ISBT 128 implementation plan for cellular therapy products. Transfusion 2007;47:1312-8.
27. Ohsaka A, Kobayashi M, Abe K. Causes of failure of a barcode-based pretransfusion check at the bedside: Experience in a university hospital. Transfusion Med 2008;18:216-22.
28. Murphy MF, Kay JD. Barcode identification for transfusion safety. Curr Opin Hematol 2004;11:334-8.
29. Jiang M, Xing B, Sun Z, Fu P, Chen H, Chen M, *et al*. A Dynamic Blood Information Management System Based on RFID. Conf Proc IEEE Eng Med Biol Soc 2005;1:546-9.
30. Briggs L, Davis R, Gutierrez A, Kopetsky M, Young K, Veeramani R. RFID in the blood supply chain - increasing productivity, quality and patient safety. J Healthc Inf Manag 2009;23:54-63.
31. Knels R, Ashford P, Bidet F, Böcker W, Briggs L, Bruce P, *et al*. Guidelines for the use of RFID technology in transfusion medicine. Vox Sang 2010;98:1-24.
32. Davis R, Geiger B, Gutierrez A, Heaser J, Veeramani D. Tracking blood products in blood centres using radio frequency identification: A comprehensive assessment. Vox Sang 2009;97:50-60.
33. Dalton J, Ippolito C, Poncet I, Rossini S. Using RFID Technologies to reduce blood transfusion errors. White paper. Available from: http://www.cisco.com/web/IT/local_offices/case_history/rfid_in_blood_transfusions_final.pdf [Last accessed on 2010 Oct 27].
34. Katz LM, Cumming PD, Wallace EL. Computer-based blood donor screening: A status report. Transfus Med Rev 2007;21:13-25.
35. Lepage EF, Gardner RM, Laub RM, Golubjatnikov OK. Improving blood transfusion practice: Role of a computerized hospital information system. Transfusion 1992;32:253-9.
36. Dzik S. Use of a computer-assisted system for blood utilization review. Transfusion 2007;47:142S-4S.
37. Scheurer DB, Roy CL, McGurk S, Kachalia A. Effectiveness of computerized physician order entry with decision support to reduce inappropriate blood transfusions. J Clin Outcomes Management 2010;17:17-26.
38. Choi YJ, Krause L. The benefit of computer physician order entry in blood management. Arch Pathol Lab Med 2010;134:1396.
39. Levy R, Pantanowitz L, Cloutier D, Provencher J, McGirr J, Stebbins J, *et al*. Development of electronic medical record charting for hospital-based transfusion and apheresis medicine services: Early adoption perspectives. J Pathol Inform 2010;1:8.
40. Warwick RM, Eastlune T, Fehily D. Role of the blood transfusion service in tissue banking. Vox Sang 1996;71:71-7.
41. Kuehnert MJ, Yorita KL, Holman RC, Strong DM; AABB Tissue Task Force. Human tissue oversight in hospitals: An AABB survey. Transfusion 2007;47:194-200.
42. Eisenbrey AB, Frizzo W. Tissue banking regulations and oversight. Clin Lab Med 2005;25:487-98.
43. Brubaker SA, Wilson D. Coding and traceability: Cells and tissues in North America. Cell Tissue Bank 2010;11:379-89.