DOKUZ EYLÜL UNIVERSITY
GRADUATE SCHOOL OF NATURAL AND APPLIED SCIENCES

BLOOD BANK MANAGEMENT SYSTEM APPLICATION SOFTWARE

by
Murat ORAL

July, 2005
İZMİR

BLOOD BANK MANAGEMENT SYSTEM APPLICATION SOFTWARE

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M.SC THESIS EXAMINATION RESULT FORM

We certify that we have read this thesis and **"BLOOD BANK MANAGEMENT SYSTEM APPLICATION SOFTWARE"** completed by **MURAT ORAL** under supervision of **PROF. DR. R.ALP KUT** and that in our opinion it is fully adequate, in scope and in quality, as a thesis for the degree of Master of Science.

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Murat ORAL

BLOOD BANK MANAGEMENT SYSTEM APPLICATION SOFTWARE

ABSTRACT

Blood bank is a unit for carrying out all of the operations for producing blood components, determining usefulness of these components, preparing blood products, storing and distribution of blood components.

The aims of developing blood bank management application software are providing efficiency between the elements of process-role-source triangle by optimizing internal processes, decreasing the workload of blood bank staff, minimizing source of erroneous by integrating automated laboratory instruments and developing decision-making mechanisms, implementing widen able application by using national and international standards, under-controlling incomes of blood bank.

Main target of the application that developed as the result of this thesis is collecting and interpreting the blood bank data, which can directly affect the life of a human, in reliable and stable manner. In this thesis, following topics will be mentioned; labeling guide with ISBT 128 standard for blood bags, the method that could be followed for computerization of blood banking and the result software Dokuz Eylul University Blood Bank Management System Application Software.

Keywords: blood bank software, ISBT 128, HL7, specimen labeling, crossmatch

KAN BANKASI YÖNETİM SİSTEMİ UYGULAMA YAZILIMI

ÖZ

Kan bankası hastalara gerekli olan kan bileşenlerini temin etmek, bu bileşenlerin kullanılabilirliğini belirlemek, kan ürünleri hazırlamak, depolamak ve dağıtmak amacıyla kurulmuş birimdir.

Kan bankası bilgi yönetim yazılımıyla birimin iç süreçlerinin optimize edilerek süreç-rol-kaynak üçgeninde verimliliğin sağlanması, çalışan personelin iş yükünün azaltılması, laboratuar cihazları, karar destek sistemleri yardımıyla kişisel hata oranlarının en aza indirilmesi, ulusal ve uluslararası standartların kulanılmasıyla veri dağıtımının mümkün kılınabilmesi, birim gelirlerinin kontrol altına alabilmesi amaçlanmaktadır.

Bu tez sonucunda geliştirilen yazılımın temel hedefi insan hayatını doğrudan etkileyebilecek kan merkezi verilerinin güvenilir ve tutarlı bir şekilde kayıt altına almak ve bu verilerden ihtiyaçlar doğrultusunda çıkarımlar yapabilmektir. Tezin içeriğinde uluslararası ürün etiketleme standartı ISBT 128 kullanımı, kan bankasının bilgisayarlaştırılması için izlenebilecek yöntem önerisi ve bu yöntem ile geliştirilen Dokuz Eylül Üniversitesi Kan Bankası Yönetim Sistemi Uygulama Yazılımını irdeleyeceğiz.

Anahtar Sözcükler: kan bankası yazılımı, ISBT 128, HL7, numune etiketleme, crossmatch

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CHAPTER ONE
INTRODUCTION

"Blood centers are ripe for automation, in that a lot of what's being done in many centers is very manual. There are a lot of touch points for the operator, a lot of places where the operator is intervening, and that means more chance for error."

Today all donor centers are interested in automated types and screens. Automation systems for blood banks and transfusion services have two significant benefits, reducing erroneous of manual processes and optimizing efficiencies. Previous step of developing fully automated systems is implementing an information system according to blood bank processing steps. The use of computers provides safe provision of both blood components and also provides successful results for immunohematologic investigations. DEU Blood Bank Application Software is one of the result information system projects.

DEU Blood Bank Application Software is developed by the help of project management issues. All project phases are well defined immediately after hospital's management informs about requirement of "blood banking application software". Suggested project phases for most of the information systems are as follows (American Association of Blood Banks, 2005).

- Concept Phase
- Definition Phase
- Requirements Phase
- Design Phase
- Implementation of Design Phase
- Validation Phase
- Assessment Phase

Concept phase is generally about strategic planning, market research, assessing customer needs and feasibility studies. Luckily, the chief of laboratory technicians, physician who is responsible for blood bank and management units about blood bank of DEU Hospital all know conceptually what they need.

The output analysis of concept phase can be thought as inputs of definition phase. Definition phase is mostly about team definition and developing project plan like resources, budget and timeline. Lack of project members causes making risk assessment (quality, research and development, finance, management etc.) hard in this project. But all high-level requirements, the program plan and risk assessment reported before specifying requirements phase.

Although project related staff knows conceptually what they need, their poor IT knowledge results with unsuccessful Blood Bank Application Software v.1.0. Number of team members and timeline were not feasible. Also they could not translate their work flow as applicable flow for developing application software. After these management failures, there were four software engineers all work as analyst, designer, developer and maintainer. Hospital management and other team members were chosen me as team leader. These are all the reasons of success with developing Blood Bank Application Software v.2.0.

According to reports of definition phase, detailed system requirement specifications are developed, and approved in requirements phase. The master test plan and traceability requirements are reported. As the result of this phase, we all know that the required blood bank application software might have following features:

- Software might operate according to defined work flow,
- All probable erroneous sources must be minimized,
- Security issue could be achieved by role-workflow-resource cycle,
- System must processed with barcoded labels,
- International labeling standards might be used,

- Laboratory instruments must be integrated to application for preventing medical erroneous,
- Billing and financial controls require integration with Hospital Information System,
- System should also provide dynamic development features for future releases,
- Querying and reporting facilities should be enough for all hospital staff (personnel of blood bank, wards, and management units),
- Web interface should be provided for national healthcare integrations.

These requirements cause new job for project members, designing and developing prototypes which are capturing all requirements along to flow diagrams. Design phase can be thought as the last step before implementing the application software. Intended features are investigated and analyzed later then all details are documented with affecting time and resource planning. After modeling database, DEU blood bank application software is considered in implementation plan shown in table 1.1.

Table 1.1 Implementation plan and technology requirements

Implementation Step	**Programming Requirements**
Data Storage	ORACLE Database
Definition forms	Oracle Forms, Java Applet
Forms of donation work flow	Oracle Forms, Java Applet
Forms of laboratory work flow	Oracle Forms, Java Applet
Forms of delivery work flow	Oracle Forms, Java Applet
Query forms based on processing data	Oracle Forms, Java Applet
Reports	Oracle Reports, PDF
Integration tool for HIS communication	Java, Ftp, over HL7 mes. protocol
Integration tool for automated devices	Delphi, RS 232, over ASTM standard
Labeling	ZPL, PL/SQL
Web pages for ward or financial office queries	Web programming, PHP

Implementation and verification of design phase can be considered as actual coding of software application. Required manuals such as user guides and troubleshooting guides, training plan, maintenance plan, data verification methods all might be prepared. DEU Blood Bank Application Software is coded according to these suggestions. Each screen designed with help buttons. The capabilities of form, how to use images, unexpected messages are described for end users for guidance purpose. Application software v.2.0 couldn't provide billing and intranet requirements. Update requirements, risk assessment plan and all working pages are technically documented.

Until validation phase, the application software v.2.0 is used as secondary entry point. Both application software and previous manual on-paper method are operating together. Validation phase is mostly about classifying success of software and reliability issues of project. Testing and validation process took six months with approximately 6000 donors, 15000 blood specimens and 9000 blood component deliveries.

Billing and intranet features are added to application software before the assessment phase. End users' feedback is collected by the help of questionnaire. This questionnaire has questions like "Is the software decreases or increases your workload?" or "which page is the hardest for your entries?" Also assessment documentation is prepared according to problems that programmers, trainers and analysts met with. These entire assessment plans are important for feature releases of DEU Blood Bank Application Software.

In the rest of the document, features of world wide projects, labeling standards, computerization steps of blood banking, restrictions of medical application software and a success story of DEU Blood bank application software will be described according to my project experiences.

CHAPTER TWO
REVIEW OF RELATED PROJECTS

College of American Pathologists have been publishing CAP Today magazine since 2000. From 2001 October up to now, Blood Bank Information Systems are reviewed by Suzanne H. Butch 2003 October Blood Bank Information Systems Review (Butch, 2003) made between 10 companies with 18 different projects.(Table2.1) System review criteria about required features, which should provided by automated blood bank application software is listed in Table 2.2

Table 2. 1 2003 October BBIS Review

	Company	BBIS Project
1	Blood Bank Computer Systems Inc. Craig Smith csmith@bbcsinc.com 253-333-0046 www.bbcsinc.com	Blood Bank Control System
2	Cerner Corp. Angela Betts abetts@cerner.com 816-201-2771 www.cerner.com	PathNet Blood Bank Donor PathNet Blood Bank Transfusion
3	Information Data Management Inc. Susan L. McBride slm@idm.com 800-249-4276/847-825-2300 www.idm.com	IDM Select Series for Blood Centers PCMS: Plasma Center Management System
4	Mak-System Corp. Stephane Sajot s.sajot@mak-system.net 847-803-4863 www.mak-system.com	Progesa
5	Meditech Inc. Paul Berthiaume pberthiaume@meditech.com 781-821-3000 www.meditech.com	Meditech Blood Bank (client/server) Meditech Blood Bank (Magic)

6	Mediware Information Systems Inc. Joe Tehan joe.tehan@mediware.com 972-536-2909 www.mediware.com	Hemocare Hemocare LifeLine (HCLL) LifeLine Blood Bank Data Management System LifeTrak
7	Misys Healthcare Ken Kark ken.kark@misyshealthcare.com 520-570-2000 www.misyshealthcare.com	Misys Blood Bank–Donor Misys Blood Bank–Transfusion
8	Psyche Systems Corp. Patricia Salem pattys@psychesystems.com 800-345-1514 www.psychesystems.com	LabWeb–SBB
9	SCC Soft Computer Ellie Vahman ellie@softcomputer.com 727-789-0100 www.softcomputer.com	SoftBank II
10	Wyndgate Technologies Patti Larson patti@wyndgate.com 800-WYNDGATE www.wyndgate.com	SafeTrace SafeTrace Tx

Table 2. 2 October BBIS Criteria of Review between 18 Projects

	Feature	**Total Availability (Projects)**
1	Donor recruitment	13 of 18
2	Mobile scheduling	7 of 18
3	Laptop-based mobile donor registration module	6 of 18
4	Bar-coded donation or donor tracking	18 of 18
5	Type and screen test results	11 of 18
6	Antigen-Antibody typing	18 of 18
7	Cross-Match screening	18 of 18
8	Electronic Cross-Match decision-making	4 of 18
9	Interface with blood grouping machines	6 of 18

10	Interface with serological test machines	-
11	Interface with blood irradiator/centrifuges	0 of 18
12	Printing bar coded donor unit labels	18 of 18
13	Full support of ISBT 128 unit labeling	10 of 18
14	Autologous and directed unit tracking	18 of 18
15	Source/recovered plasma management	11 of 18
16	Track all steps in production of product	18 of 18
17	Stock and Unit Inventory	18 of 18
18	Reporting facility	18 of 18
19	Accounts receivable	9 of 18
20	Management reports	18 of 18
21	Availability of HIS interfaces	13 of 18
22	Availability of LIS interfaces	12 of 18
23	System provides standard ASTM/HL7 interface	13 of 18
24	Tools to help clients validate their systems	18 of 18
25	Complete blood bank ASP solution?	9 of 18
26	User acts, groups and user dependent abilities	18 of 18
27	Customizable user screens	18 of 18
28	Customizable report writer	18 of 18

Blood Bank Project development platform and other technology dependent choices are varied and successfully used by vendors (Check, 2002), so that, quality assurance and functionality features such as checking ABO group incompatibility, capturing all steps in processing blood component to prevent errors of blood bank technician, electronic cross-match, ISBT 128 capabilities, instrument interfaces are much more significant for choosing ideal project.

Some countries were developed their blood related technologies and projects according to their national blood banking strategies. So that, according to selected strategies, countries does not have to use specific standards such as HL7, ISBT 128 or ABC Code Bar but all individual blood bank projects must use global or national appropriate standards and classification schemas, which are defined by ministry of

health. This is the best way for integration between blood related organizations or hospitals and reliability issue of blood banks.

ISBT 128 labeling schema is widely used in American and European blood banks for blood product labeling (Butch, Friedman, Holmberg, Howard, Lupo, & Steane, 1999). In Turkey, four hospitals register their blood banks to ICCBBA, and three of them, which are DEU Hospital Blood Bank, AU Ibni Sina Hospital Blood Bank and Florence Nightingale Hospital, using ISBT 128 unit labeling actively (Gazi University Hospital's IT department is still developing their blood bank project). Also in America, "Bar Code Label Requirement for Human Drug Products and Biological Products" is published by Department of Health and Human Services, Food and Drug Administration for other labeling requirements in medical wards (FDA 21 CFR, 2004).

Getting patient information, traceability of transfusion, ordering blood related patient requirements from hospital wards; online billing features require closely integration between blood bank management system and hospital information system. So that, blood bank management systems which are shipping with hospital management systems may be preferred rather than third party projects. HL7 provides standards for the exchange, management and integration of data that support clinical patient care and the management, delivery and evaluation of healthcare services. Specifically, to create flexible, cost effective approaches, standards, guidelines, methodologies, and related services for interoperability between healthcare information systems. Integration between Blood Bank Application Software and Laboratory Information System (LIS) or Hospital Information System (HIS) should be achieved by using HL7 standard.

In North American and European countries there are many paid donors available (Butch., 1999). Self scheduling donation over web feature was developed especially for these donors. Mobile scheduling is imported for donor tracing, if system has ability to provide donor identification uniqueness, and also important for donor satisfaction. Also, like Kızılay in Turkey, whole blood may be collected out of blood

bank central office, so that, mobile registration module is another strict requirement for out-office donations.

Wireless technologies and web-based Blood Bank Application Software development together may be another alternative method for mobile scheduling and mobile recruitment. Web-based solution also provides client-side machine maintenance, increase system availability, enables co-ordination between different blood bank applications.

Expected information systems should achieve documenting and retrieving all the necessary information about patients and blood units quickly and accurately and in a manner that facilitates use of the information.

CHAPTER THREE
LABEL SYSTEMS

Blood Labeling is a process that includes patient identified specimen collecting, donation or donor tracing, blood product or component defining, specimen testing and all other blood related operations like safely transfusing component. AABB Standards (Butch., 1999) and FDA regulations (FDA 21 CFR, 2004) must be used for labeling of blood components, products, blood bank specimens in American health-care laboratories and blood banks. These standards defining label requirements in detail many other countries referenced these labeling schemes.

3.1. Labeling and Documentation in Transfusion Cycle

Blood transfusion is one of the most important parts of medical care. Defining and tracing blood transfusion may be applicable using and successfully administrating unit or specimen label scheme.

Blood transfusion life cycle begins with collecting and labeling patient specimen, then preparing matched products and ends with component transfusion. Errors in blood transfusion practice are mostly originated by on arrival of the specimen with patient identification details. Lack of bed side labeling and pre-transfusion checking are causing with human errors and patient safety problems. There are many pre-transfusion recommendations available for health-care givers, moreover, usage of tags fixed to blood bag (Whitehead, Kenny-Siddique, Scott, Parker, Hardy.& Wallis, 2003), and special reservation label fixed to blood bag are widely used and advised methods. Most of recommendations are about labeling methods for providing patient safety. With computer systems, it has become standard practice to transcribe the details of request into electronic records and print out both compatibility labels and the compatibility forms depended on this stored electronic records.

Many healthcare associations recommend using barcoded wrist bands with patient protocol number as primary patient identification method (Turner, Casbard & Murphy, 2003). Nurses should label patient specimen tubes with both eye and system check using printed protocol number on wrist band or patient information form. Specimen label should include barcoded tube identification number, patient identification number (especially protocol number), patient name, ward name, nurse name and date of specimen collect. (Figure 3.1) After appropriately labeled patient specimen and prepared request form which includes any special blood related requirements, order is entered and form and blood sample transferred to blood bank information system.

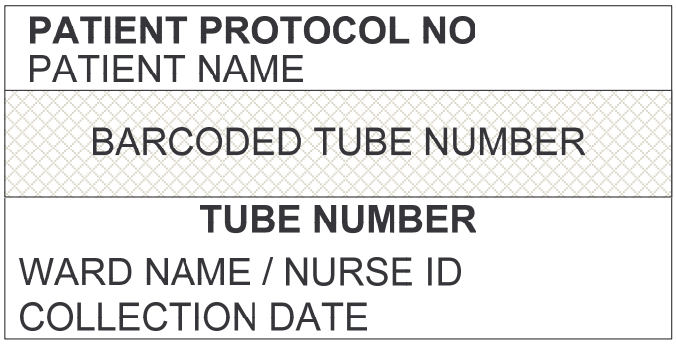

Figure 3. 1 Specimen label template includes two distinct identifiers protocol and tube number.

In blood bank laboratory, for all patients' specimens ABO RhD group and subgroup tests should screened, then a result form is printed out and sent to the request source. Preparing units with or without crossmatch is differing based on product type; therefore, product reservation labels may have different templates (Figure 3.2). After required tests are carried out, reservation labels are printed out and fixed to related units with a carefully check as to whether the label has been fixed to the correct unit. Besides, a form should printed out for detailing the units prepared, signing delivered units with laboratory technician name, who send product to ward.

Not only checking the compatibility of blood product label details and related form information, but also checking patient identifier details and related form details should be administrated by nurse or doctor in the transfusion or requested ward. It

has been noted that a common cause of error is to carry out this check away from the patients' bedside, typically at the ward nursing station. Before transfusion in the clinical area, doctor or nurse must check whether both the donation number and product code on the reservation label are same with product's label or not, and then healthcare member must check patient name and protocol number on the reservation label and wrist band.

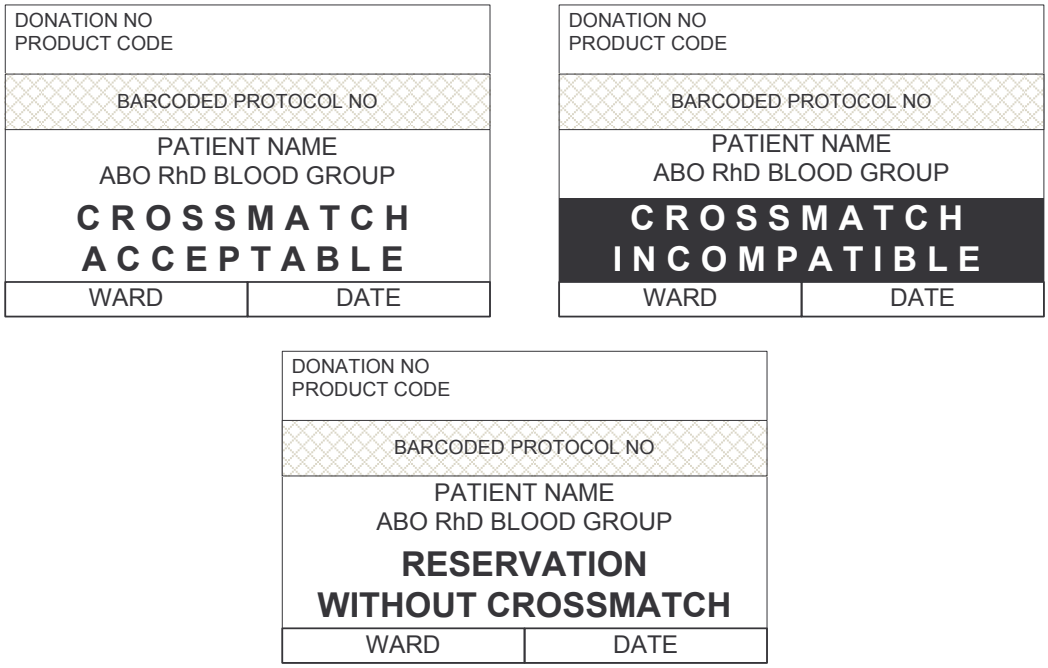

Figure 3. 2 Blood product reservation label templates

The complete flow chart of labeling and documentation life cycle is shown in Figure 3.3.

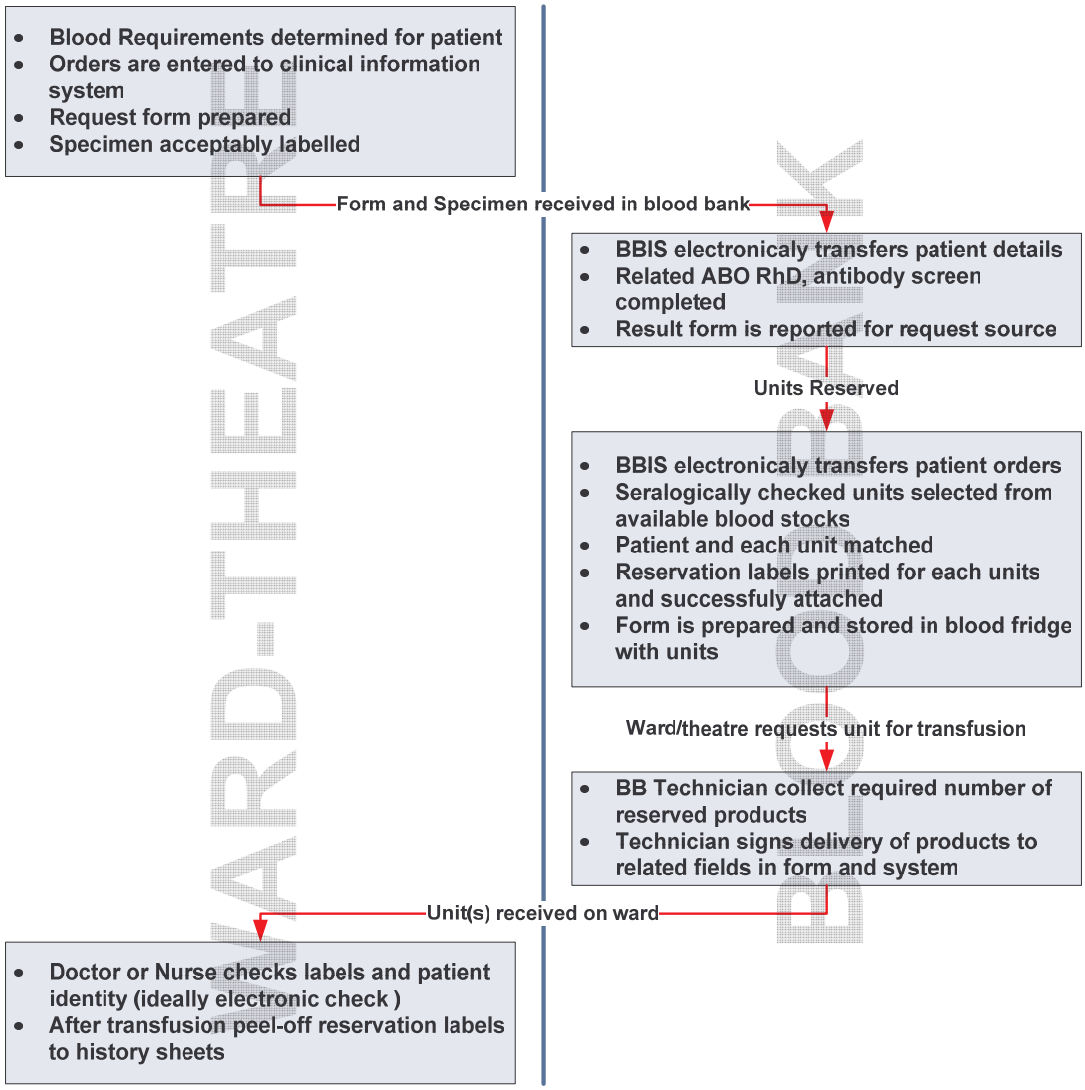

Figure 3. 3 Flow diagram for documentation and reservation of transfusion

3.2. Labeling in Blood Bank Laboratory

Although, after technological developments, preparing blood components while phlebotomy step is available for blood banking, we can still consider that raw material of donation is whole blood. First of all, blood bags may be labeled with tube labels which are prepared for identifying donor specimen and also identifying this donation. Usage of single or multiple blood bags may vary according to intended preparation of blood components. For aphaeresis product preparation different donation sets and bags are used. Nurses should type obtained to BBIS before finalizing donation. So that, laboratory healthcare technician may search and screen products typing donor specimen tube label. Specimen label should include barcoded

donation number, donor identification number, donor name and date of specimen collect (Figure 3.4).

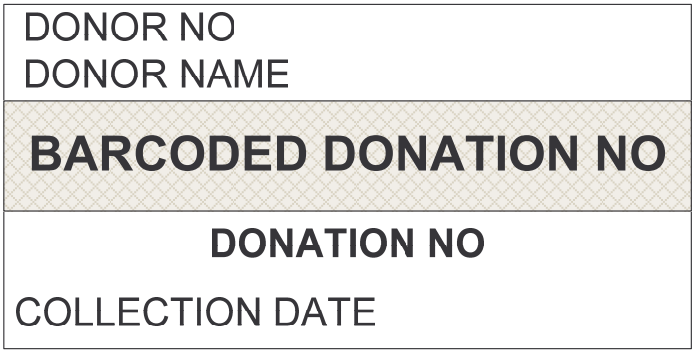

Figure 3. 4 Barcoded donation label

All donation based products quarantine in relevant fridge to prevent errors about nonconforming blood and blood components, until further investigation (especially serological tests and ABO RhD group typing) has occurred. According to any relevant labeling standard, all aspects of labeling (both format and information requirements) must be strictly controlled. AABB (American Association of Blood Banks) recommends requirements of blood product final labeling as table 3.1 (Tyler, 1999). An international effort, with recommendations of FDA and AABB, has established a new labeling guideline, ISBT128.

Table 3. 1 AABB label requirements

Label Requirements : The following information is required in clear readable letters on a label firmly attached to the container of all blood and component units:
• The proper name of the component, in a prominent position. • A unique numeric or alphanumeric identification that relates the original unit to the donor and each component to the original unit. • The amount of blood collected and the kind and quantity of anticoagulant (not required for cryoprecipitate or for frozen, deglycerolized, rejuvenated, or washed red cells). • For all blood and blood components, except for a single unit of Cryoprecipitated AHF, all pooled components, and components prepared by apheresis, the volume of the component must appear on the container.

- The expiration dates, including the date and year; if the shelf life is 72 hours or less, the hour of expiration must be stated.
- Recommended storage temperature.
- ABO group and Rh Type (Rh type not required for cryoprecipitate).
- Interpretation of unexpected red cell antibody tests when positive (not required for cryoprecipitate or frozen, deglycerolized, rejuvenated, or washed RBCs).
- Results of unusual tests or procedures performed when necessary for safe and effective use. Routine tests done to ensure the safety of the unit need not be on the label if they are listed in the Circular of Information.
- Reference to the Circular of Information, which must be available for distribution and contains information about dosage, directions for use, route of administration, and contraindications.
- Essential instructions or precautions for use, including the warning that the component may transmit infectious agents, and the two statements: "Caution: Federal law prohibits dispensing without a prescription" and "Properly Identify Intended Recipient."
- The appropriate donor classification statement, "autologous donor," "paid donor" or "volunteer donor" in type no less prominent than that used for the proper name of the component.
- Any additives, sedimenting agents, or cryoprotective agents that might still be present in the component.
- For licensed components, the name, address, and FDA license number of the facility that collected the blood and/or prepared the component. For components, the label must include the name and location of all facilities performing any part of component preparation, but there should not be more than two alphanumeric identifiers on the unit.

3.3. ISBT 128 – Product Labeling Standard

A world of increasing product dependent information complexity causes with International Society of Blood Transfusion 128 labeling standard, which has developed by ISBT working group (Butch, 1999). The ISBT working group was joined by the American Association of Blood Banks (AABB), the American Red Cross (ARC), the Department of Defense (DoD), and the Health Industry Manufacturers Association in the development of the symbology which was adopted as an international standard. This standard will be implemented world wide by January 2002 (American Association of Blood Banks, 2005). The International Council for Commonality in Blood Banking Automation (ICCBBA) was established and given the responsibility for implementation and management of the new standard. The ICCBBA will establish the site registration database, assign facility identification numbers, and maintain the product code database. The ICCBBA facility identification number, used as part of each donation identification number, will be different from your FDA registration number.

The ISBT 128 barcode allows for more information to be coded into a small space and includes an internal check digit to prevent barcode misreads. Each barcode contains two data identification digits embedded in the barcode that identify the barcode as a blood product and than identifies the specific category (ex. ABO/RH, Product Code) followed by the specific unit information which is reproduced in an eye readable format just below the barcode. Every facility will be receiving a labeling guideline with specific requirements for barcode and printed text formats.

3.3.1. ISBT128 Label Template

The ISBT128 standard specifies the placement of the following bar codes (see Figure 3.5):

- Barcode 1 : Donation Identification Number
- Barcode 2 : ABO/Rh Blood Groups

- Barcode 3 : Product Code
- Barcode 4 : Expiration Date (and Time)
- Barcode 5 : Container Manufacturer's ID and Container Description
- Barcode 6 : Container Manufacturer's Lot Number
- Bar code 7 : Special Testing (optional)

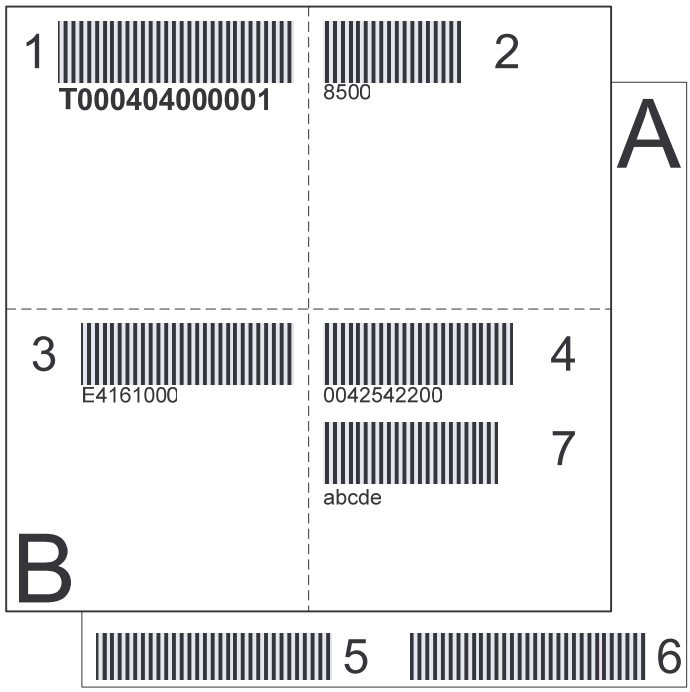

Figure 3. 5 ISBT128 label is prepared by combination of two distinct labels that both blood bag manufacturers' product label and blood product face label.

Manufacturers' product label should at least two barcodes at the bottom of label (see Figure 3.5, label A). Manufacturer's identification code (see Figure3.5, barcode no 5) contains bag information such as catalog or part number. This number can be related to a description such as CPD, quadruple blood-pack. Lot number allows product tracing and expiration date of pack (see Figure3.5, barcode no 6).

Blood product face label is split into four quadrants with each quadrant being divided in thirds to identify the required placement of barcodes and text.

3.3.1.1. Upper Left Quadrant:

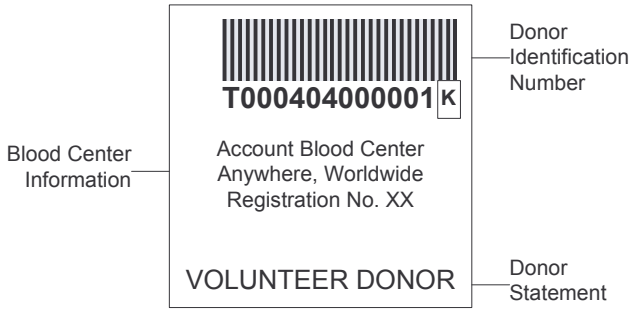

Figure 3. 6 Donation identifier

3.3.1.1.1 Donation Identification Number. Donation identification numbers will be used as we now use the facility identification and unit number to identify a unit. Only components manufactured from a specific whole blood or aphaeresis phlebotomy will share a donation identification number. Using the donation identification number in conjunction with the product code, you can identify any product anywhere in the world. It has the format 'a pppp yy nnnnnn' and is made up of the following components:

- Facility ID (apppp): The first five characters are the world wide facility identification
    - Country Code (a): The lead "alpha character" of the facility identification number designates the country code. The country code for the Turkey is 'T'. All facilities registered in the Turkey begin with a 'T'.
    - Collection Facility ID (pppp): These four digits are specific for each collection facility (ex. 0004 = DEU Hospital Blood Bank). They are assigned to each facility when they register with International Council for Commonality in Blood Banking Automation (ICCBBA).
- Collection Year (yy): The middle two numbers are the year of collection (ex. 98=1998, 00=2000).

- Serial Number (nnnnnn): The last six numbers are the specific serial number associated with the donation. These numbers will be started over again each year.
- Check Digit: To the right of the donation identification number on the label is a box with data characters in it. This is the manual entry check digit. It is calculated using an algorithm based on the 13 characters in the donor identification number. It is used to ensure the accuracy of manual data entry but is not used when the barcode is scanned.

3.3.1.1.2 Blood Center Information. The blood center registration and license number can be placed in this section or in the lower 1/3 of the lower right quadrant.

3.3.1.1.3 Donor Statement. Most commonly, this statement is, "Volunteer Donor". If anything other than "Volunteer Donor" is entered here, the intended recipient section of the ABO/Rh label (upper right quadrant) must match the donor statement.

3.3.1.2. Upper Right Quadrant:

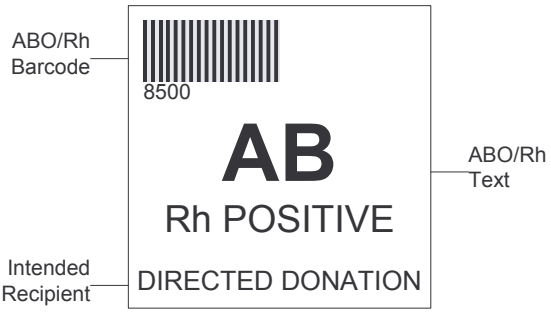

Figure 3. 7 ABO / RhD blood group identifier

The entire upper right quadrant is considered the ABO/Rh blood group label. This quadrant not only will be used on every product to identify the ABO/Rh type but also will be used to indicate an intended recipient if the product is other than a routine allogeneic donation.

3.3.1.2.1 ABO/Rh Barcode. The data structure of the ABO/Rh barcode is made up of four characters - 'ggre'.

- ABO/Rh Group & Donation Type (gg): ABO RhD Blood Group barcoding table is generated from older standard ABC Codabar. There are 16 different Codabar values available for blood grouping. According to donation type, each original Codabar value defines 7 different barcode. For example, based on ABC Codabar, AB Rh Positive value is 84, 83 defines volunteer directed collection and 85 defines Autologous collection A table listing the ABO/Rh group and donation type values is available for registered ISBT128 users.
- Phenotype information (r): Default it is always '0'.
- Reserve Character (e): This character has been reserved for future use. Currently it is always '0'.

For example, if BBIS reads the barcode as 8500 the table tells it that unit is an AB Rh positive, autologous collection, eligible for crossover. If the barcode value is 8200, the product is for directed recipient use only, biohazardous. An entry of 8300 designates the unit as both volunteer directed collection and eligible for crossover.

3.3.1.2.2 ABO/Rh Text. This section provides the ABO/Rh type in text format.

3.3.1.2.3 Intended Recipient. This section provides information intended recipient, (allogeneic, autologous, directed etc.) in text format. If anything other than "Volunteer Donor" was entered in the donor statement (upper left quadrant) the intended recipient section of the ABO/Rh label must match the donor statement.

3.3.1.3. Lower Left Quadrant:

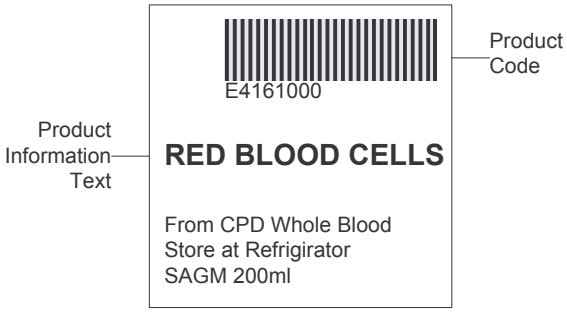

Figure 3. 8 Blood component identifier

3.3.1.3.1 Product Code. The product barcode consists of 8 data characters with the alphanumeric value appearing in the format 'annnn t ds'. This code describes the product number, donation type, and information about product divisions.

- Product Number (annnn): The first five data characters designate a specific product. These numbers have been assigned by ICCBBA to identify a single product including all the characteristics of that product. Every possible product has a different code (about 38,000 at this point). When the code number is matched against a look-up table the component class, any modifiers and special attributes are identified. The component class is the name of the cellular (Red Blood Cells etc.) or non-cellular (Fresh Frozen Plasma etc.) product. This information will correspond to the printed product text. Since product codes indicate a specific combination of component class, modifiers and attributes, anytime a product is modified or altered, the associated product barcode changes and a new product code label must be printed and the unit relabeled. Below are some examples of product numbers and the products they represent :

    - E4161 = RED BLOOD CELLS, SAGM, XX, refg
    - E0002 = WHOLE BLOOD, ACD-A, 450mL, refg, for mnf
    - E3429 = Apheresis PLATELETS, NaCitrate, XX, 20-24C, Plasma reduced

- Donation Type (t): The sixth data character indicates the donation type. There are currently 12 donation codes which cover allogeneic, autologous, directed, therapeutic and several donations not intended for transfusion. When creating labels, the donation type indicated in the product code should match that used when creating the ABO/Rh label. Some common donation type codes include:

    - V = routine allogeneic donation
    - 1 = autologous use only
    - 2 = directed donation for designated recipient only
    - X = autologous biohazardous
    - T = therapeutic collections

- Product Divisions (ds): The seventh and eighth data characters indicate splits of the original products. Since split units will carry the same donation identification number, these product codes will be used to uniquely identify and track each of the split products. If undivided, the code will be "00". The seventh character will designate the first level divisions and the eighth character will designate second level divisions. For example, if a volunteer red cell unit is split in two, the subdivisions' product codes would be 'annnn0A0' and 'annnn0B0'". If unit 'annnn0A0'" were further split into two units, the subdivisions' product codes would be 'annnn0Aa' and 'annnn0Ab'.

3.3.1.3.2 Product Information Text. The component class (name), anti-coagulant, source product, and storage temperature are printed in this section. Any modification of the product (washed, thawed, deglycerolized etc.) is printed above the component and any special attributes (irradiated, leuko-reduced etc.) are printed below the component.

3.3.1.4. Lower Right Quadrant:

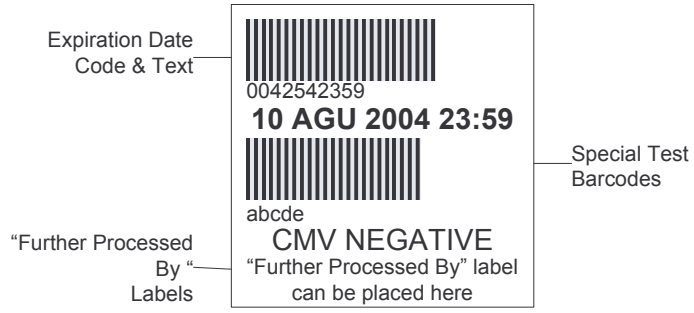

Figure 3. 9 Expiration date

3.3.1.4.1 Expiration Date Code & Text. The barcode consists of 10 data characters in the format 'cyyjjjhhmm' as below:

- Century (c): This number designates the century (ex. 9 for 1996-1999; 0 for 2000).
- Year (yy): These digits designate the year (04 for 2004).
- Julian Date (jjj): This is the Julian date for that year (254 is 10 Agu, 022 is 22 Jan).
- Hour (hh): The hour is specified in military time (00-23).
- Minutes (mm): The collection minute is specified here (00-59).

The barcode value will be converted and printed as a text expiration date in the standard format 'DD MMM YYYY' (ex. 10 AGU 2004). If a product has routine midnight expiration, the barcode value will be 'cyyjjj2359' and no expiration time will be printed in the text. If the expiration time is other than midnight, as for pooled products, the time will be included in the barcode value (cyyjjj1430) and will also be printed in the text in the format 'DD MMM YYYY HH:MM' (ex. 10 AGU 2004 14:30)

3.3.1.4.2 Special Test Barcodes. This section will be used to designate any special testing.

3.3.1.4.3 "Further Processed By" Labels. This section can be used to place "further processed by" labels when products are modified (thawed, pooled, frozen) at a facility other than the original collection facility.

3.3.2. ISBT128 Features

The most significant ability of ISBT128 is this labeling system allows every blood product to be specifically identified and tracked anywhere in the world. A unique donation number is given to each product. Donation number includes an assigned collection facility code. Uniform product codes provide same labeling scheme for every product, so that an aphaeresis platelet, irradiated, and leuko-reduced will be labeled the same way every time. Blood product labels will look the same and all barcodes will scan the same. This minimizes the need for site specific software and limits the high cost associated with future software development. If BBIS data model has ability to set relation between ISBT requirements and itself, scanning of two barcodes (donation identification number and product description code) can be enough for identifying blood product rather than five barcoded sections.

CHAPTER FOUR
COMPUTERIZED STEPS OF BLOOD BANKING

In the UK each year it is estimated that over 800 000 adverse events occur in hospitals (Department of Health, 2000) in the USA same erroneous ends with deaths between 44000 and 98000 (Kohn, Corrigan & Donaldson, 2000). It is also reported that many adverse events involve patient misidentification. Errors related to blood administration and blood transfusion may produce catastrophic consequences, and preventing patient identification is the most critical step to achieve.

4.1. Unique Patient and Donor Identifiers

For patient identification there are several numbering systems available but at least two distinct numbering schemas must be used for such identification. In Turkey TC Identity Number must be used for national approach. Second identifier should be the protocol number of hospital. Blood bank computing systems independently achieve donor and patient admission and requirement of identification, or ideally they should be integrated with hospital's patient administration system if there is available (Ashford, Gozzard, Jones, Revill & Wallis, 2000). Minimum record requirements for patient admission are

- Patient name
- Patient surname
- Patient sex
- Patient date of birth
- TC Identity Number (for national identification in Turkey)
- Hospital Protocol Number
- Patient address (optional)
- Patient's mother name (optional)
- Patient's father name (optional)

Donor admission system may differ according to healthcare provider's requirements. One approach for donor registration is donor's records must be exactly independent from patient records. This approach results with two independent medical flows for same person as a blood donor and as an hospital patient. So that, blood bank blood findings (e.g. ABO Rh blood group test result) could not used for a donor when the person comes to same hospital as a patient.

Another approach for admission is generating two different unique identifiers as donor registration number and as patient registration number. Medical requirements achieved using identifier matching tables, which could help synchronizing these two different unique numbers.

DEU hospital information system generates unique identifiers for patients; Blood bank administration preferred using these patient identifiers also for donor identification. This approach should be the best way for the uniqueness. By using patient unique identifier, there is no more need any electronically data synchronization between person's records which based on admission as patient and person's blood finding records as donor, which are tested by blood bank system. The confusion that developers may meet is issued with expenses. Volunteer donors might be considered as supplier and they must protect from expenses but patients might be considered as customer for healthcare giver and expenses of care might be received from patient itself or its guarantor. Donor takes healthcare but hospital management wants to charge expenses from the patient whom the blood will be transfused.

4.2. Electronic Requesting Procedures

Ward or service based requests should be electronically transferred to blood bank information system, if and only if there is an hospital wide information system with patient administration ability is available. Such an integration immediately results with preventing transcription errors and increasing speed of entry of the request into the blood bank information system. There should be full patient admission system available within hospital information system. From the doctor's point of view patient uniqueness, from the hospital management's point of view charging expenses should

be properly achieved by these patient admission system. Required patient information for electronic requesting is listed in Table 4.1.

Table 4. 1 Required information for electronic request from blood bank information system

Immunohematologic Test Request	**Component Request**
Patient Protocol Number	
Patient Name	
Patient Surname	
Patient Sex	
Patient Date of Birth	
Unique Request Number	
Ward / Clinic Name	
Request Date and Time	
Requesting Doctor	
Requested Investigation (Crossmatch, Blood Group Typing etc.)	Type of component (including special requirements)
	Number of Units

In some cases patient's blood related information (ABO Rh Blood Group, presence of known antibodies), transfusion history, and pregnancy information known by ward doctors, so that these critical knowledge should also be passed to blood bank information system as an additional information field.

The request may be transferred to blood bank information system more than one time. Blood bank system should either prevent duplication before inserting them to database or if erroneous requests recorded at least warn laboratory technician for these duplicate entities, because duplication errors result with wasting both time of technicians and medical sources of hospital.

Paper request forms also could be used with electronic requisition. These forms guarantee the transferred orders are blood related request, and should also increase reliability of transferring procedure.

Another significant requirement for system integration is well defined system interface with security and communication protocol issue. Health Level Seven (HL7) is one of several American National Standards Institute (ANSI) -accredited Standards Developing Organizations (SDOs) operating in the healthcare arena (HL7, n.d.). HL7 defined most standards for a particular healthcare domain such as pharmacy, medical devices, imaging or insurance (claims processing) transactions. In the first quarter of 2005, Turkish ministry of health joined to HL7 committee. With protocols that specified by HL7, interoperability between healthcare information systems became more effective and reliable.

4.3. HL7 Messaging Between Blood Bank Information System and Hospital Information System

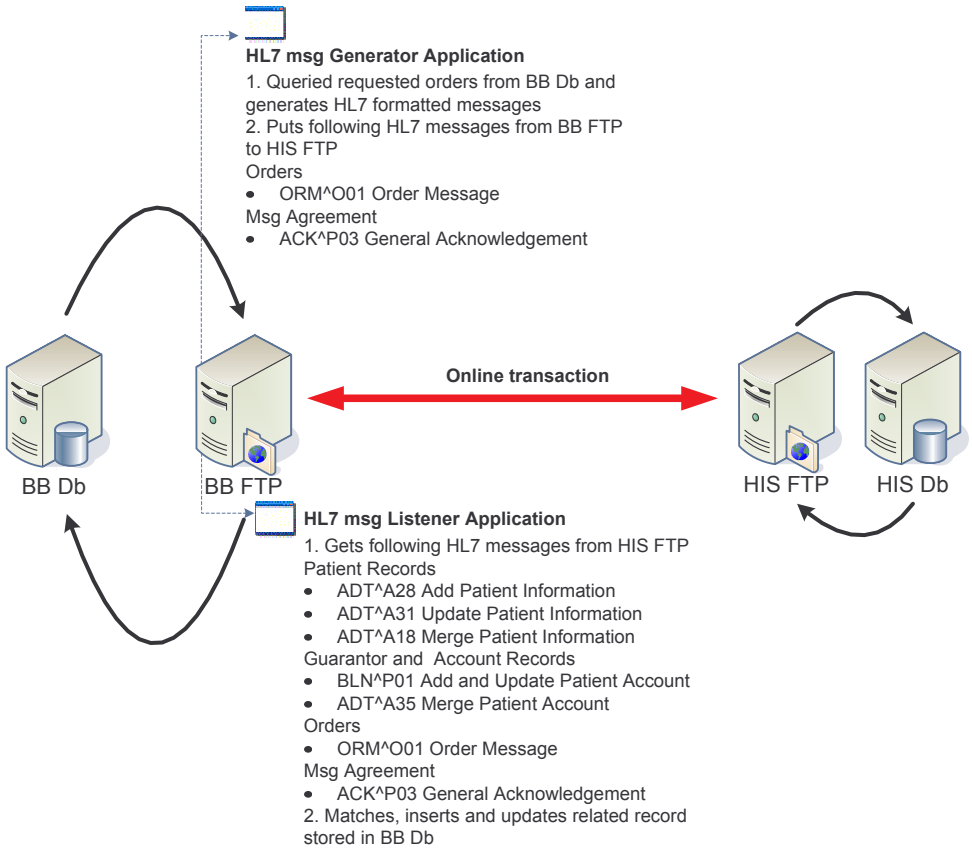

Figure 4. 1 HL7 message flow between HIS and BBIS

4.3.1. Sample Structure for HL7 Messaging:

Add Person Information (ADT^28) and Update Person Information (ADT^31) with HL7 v 2.3 (HL7 Version 2.3, (n.d.)).

Table 4. 2 Required ADT schema for blood banking

ADT Message

Message Header (MSH)

Field#	Field Name	Sample Data
1	Field Separator Encoding	^~\&
2	Sending Application	HIS
3	Sending Facility	HIS
4	Receiving Application	BBIS
5	Receiving Facility	BBIS
6	Date/Time of Message	TIMESTAMP
7	Security	
8	Message Type	ADT^A28 or ADT^A31
9	Message Control ID	UNIQUE MSG ID
10	Processing ID	P
11	Version ID	2.2
12	Sequence ID	
13	Continuation Pointer	
14	Accept ACK Type	AL
15	Application ACK Type	NE
16	Country Code	

Event Type (EVN)

Field#	Field Name	Sample Data
1	Event Type Code	A28 or A31
2	Date/Time of Event	TIMESTAMP
3	Date/Time of Planned Event	
4	Event Reason Code	
5	Operator ID	

Patient Identification (PID)

Field#	Field Name	Sample Data
1	Set ID - Patient ID	
2	Patient ID (External ID)	
3	Patient ID (Internal ID)	Patient's Protocol#
4	Alternate Patient ID	
5	Patient Name	SURNAME and NAME
6	Mothers Maiden Name	
7	Date of Birth	DATE
8	Sex	(M)ale/(F)emale/(U)nknown
9	Patient Alias	
10	Race (Age)	
11	Patient Address	**Partitions** Street Address Other Designation City State Postal Code Country Address Type Other Geog.Designation
12	Country Code	90
13	Phone Number - Home	XXX XXX XX XX
14	Phone Number - Business	XXX XXX XX XX
15	Language – Patient	
16	Martial Status	
17	Religion	
18	Patient Account Number	
19	SSN Number - Patient	TC IDENTITY#
20	Driver's Lic Num - Patient	
21	Mothers Identifier	

22	Ethnic Group	
23	Birth Place	
24	Multiple Birth Indicator	
25	Birth Order	
26	Citizenship	
27	Veterans Military Status	

Next of Kin / Associated Parties [{ NK1 }]

Field#	Field Name	Sample Data
1	Set ID - Next of Kin	1 or 2
2	Name	Father or Mother Name
3	Relationship	Father or Mother
4	Address	
5	Phone Number	
6	Business Phone Number	
7	Contact Role	
8	Start Date	
9	End Date	
10	Next of Kin Job Title	
11	Next of Kin Job Code/class	
12	Next of Kin Employee Number	
13	Organization Name	

4.3.2. Sample ADT^A28 Message

MSH|^~\&|HIS|HIS|BBIS|BBIS|20050404160620||ADT^A28|2589|P|2.2|||AL|NE
EVN|A28|20050404160620
PID|||1078584||SAMPLE^PATIENT||19960229|U||
|## XX St.#^^ city^postalcode^country|35|XX|XX
NK1|1|FATHER NAME|FATHER
NK1|2|MOTHER NAME|MOTHER

4.4. Computerization Steps of Blood Banking

Many of the system analysts agree that data entry point is the most significant point for systems usability and reliability. No doubt, best way to force users about entry of reliable data is organizing input, process and output screens according to their workflow. Workflow is the tasks of procedural steps for organizations or people involves required input and output information and also tools needed for each step in a business process. Workflow management focuses on processes rather than documents. Blood bank information system has three primer flows that define three phases of blood bank computerization.

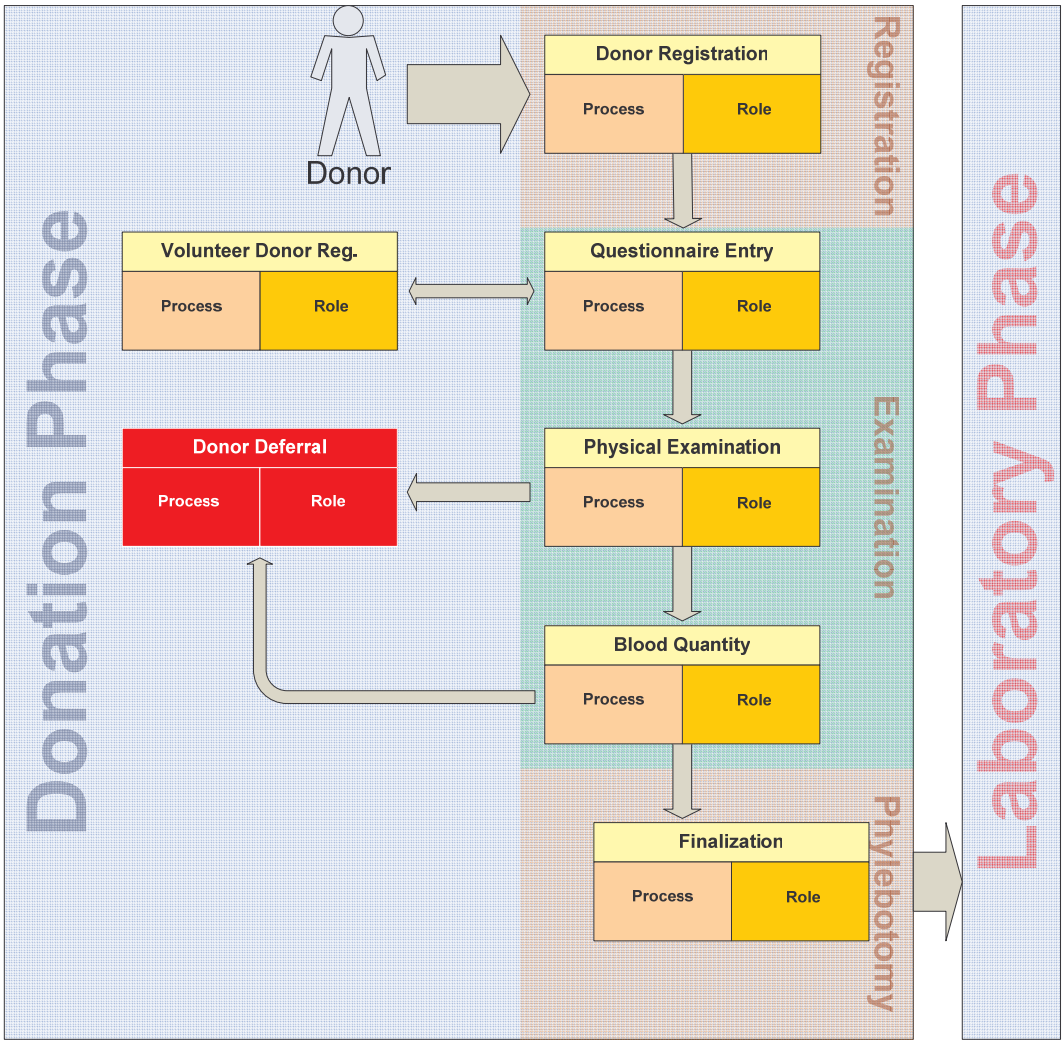

Figure 4. 2 Work flow of donation phase

4.4.1. Donation Phase:

Donor registration is the first step of donation phase. Donor's first and last name, address and phone number, social security number (TC Identity Number in Turkey) as primer identifier and generation of secondary identifier for blood donor (especially hospital related unique number) are the minimum requirements for donor registration. Combining donor registration and patient registration together prevents collecting mismatched demographic information because donor related fields and also many additional information (guarantor of patient, occupation, forename of patient's mother and father etc.) are recorded while patient admission.

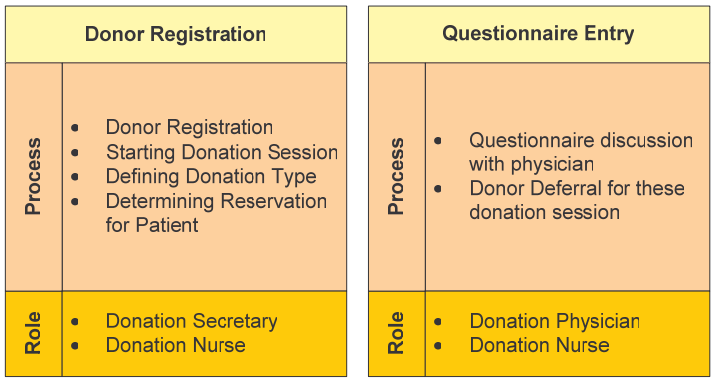

Figure 4. 3 User roles and available processes of registration and questionnaire steps

Each donation could be considered as an appointment for donor. Acceptability of donor and detecting inflected donors should be searched from previous appointments, and donor could be warned about problem by secretary before his/her entry of donation room.

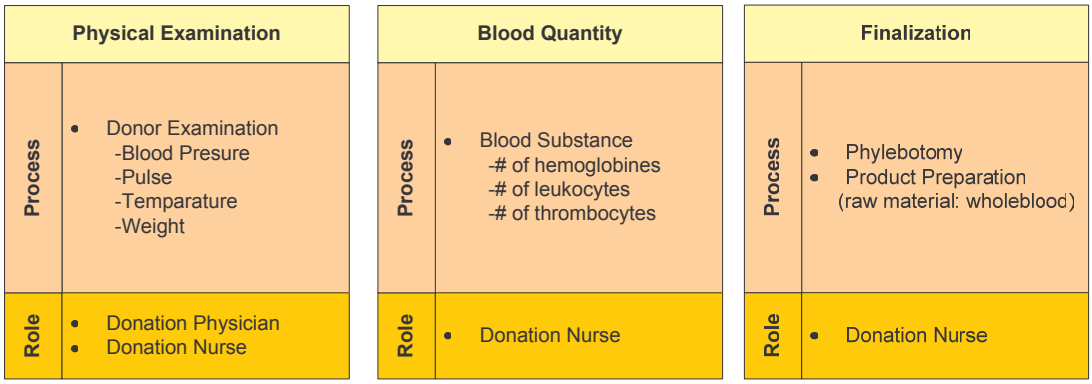

Figure 4. 4 User roles and available processes of examination, blood counting and finalization steps

Second step of donation phase is examination. Date of donation, date of last donation, record of pre-donation questionnaire, identification of interviewer, record of physical examination (blood pressure, pulse, temperature, weight, number of hemoglobin, leukocyte and thrombocytes), identity of examiner doctor and record of whether donor is accepted or not should be recorded before phlebotomy step.

Identification of the phlebotomist, record of donor reaction, time released, notation if the donor refuses treatment or advice should recorded to donor's that donation appointment in phlebotomy step. Successful phlebotomy step results with a blood product. The line between pre-donation and post-donation is venepuncture, so that, unique donation identification number (Figure 3.4) generated during venepuncture. Product related information like name of the manufacturer and lot number of the container, anticoagulant name, gathered product type also recorded this finalization step. Computer generated label includes bar-coded donation number printed pasted on to product container and donor specimen tube by donation room nurses.

Donor could be deferred for a later time or rejected permanently at any step of donation phase. This critical situation should be recorded with notification note, deferring date and identity of blood bank staff. On the other hand, there should be at least 4 weeks donation interval for whole blood collections (Table 4.3). Computer system should prevent conflicts with its decision support benefits.

Table 4. 3 Time intervals between previous and next donations

Time Interval	**Donated Blood or Component**
8 weeks	double RBC
4 weeks	RBC or Whole Blood
2 weeks	TDP
72 hours	PLT

Obtained blood product differs by means of donation type (volunteer whole blood donor, aphaeresis, autologous etc.). These products also called special collections.

Required information that might record (Tyler, 1999) for special collections is listed above.

4.4.1.1. Autologous donations:

- Written consent of the patient's physician, the blood bank physician, and the patient (or, if indicated, the patient's parent or guardian)
- Physician examination of the donor and certification of good health if the donation interval is less than 8 weeks. (The doctor's written order requesting autologous collections is an acceptable alternative.)
- Permission from the receiving transfusion service and a written statement from the attending physician indicating it is acceptable to ship units: confirmed positive for hepatitis B surface antigen, confirmed positive for antibodies to human immunodeficiency virus, type 1 (anti-HIV-1) an/or anti-HIV-2 (or repeatedly reactive and confirmation is not yet available), repeatedly reactive for HIV-1 antigen. However, a US Supreme Court decision makes it illegal to offer autologous blood services without offering those services to individuals protected under the Americans with Disabilities Act.
- Documentation that the attending physician has been notified if the units are positive for antibodies to hepatitis C Virus, repeat reactive for antibodies to hepatitis B core antigen, or confirmed positive for syphilis
- Documentation of destruction of blood not released.

4.4.1.2. Aphaeresis (Cytapheresis and plasmapheresis):

The following record-keeping requirements are in addition to those that apply to Whole Blood donation.

- The name of the manufacturer and the lot numbers and volumes of all solutions, software, and drugs used.

- The result of laboratory tests that qualify the donor, time the procedure begins and ends, the volume of each component harvested the estimated blood cell loss, and any adverse events.
- Description of the procedure and informed consent.
- For aphaeresis donors who are given medications or are immunized, there must be a separate informed consent as well as complete information on the drug or antigen source; the schedule, dosage, and route of administration; adverse events; and response (e.g. antibody titer) to the stimulating agent as measured by laboratory tests.
- All initial and periodic physical examinations by a physician, including medical history interviews.
- The physician's acceptance or rejection of the donor, based on the accumulated laboratory data.

4.4.1.3. Therapeutic apheresis/Hematopoietic progenitor cells:

- Physician's order
- Patient identification
- Diagnosis
- Type of procedure performed
- Method used
- Extracorporeal blood volume
- Nature and volume of component removed
- Nature and volume of replacement fluids
- Any occurrence of adverse events
- Medication administered
- Informed consent

4.4.1.4. Therapeutic Phlebotomy:

- A record that the patient's physician has ordered phlebotomy
- Volume of blood drawn

- Final disposition of unit
- If transfusion components are prepared, the records of these procedures must include all information required for blood donors as well as the name of the disease

4.4.2. Laboratory Phase:

As mentioned at the beginning of this chapter the medical erroneous cycle of transfusion practices starts with identification errors of patients. Laboratory phase is another possible error source for transfusion practices, so that all steps of laboratory phase should be defined according to exact workflow diagrams as black boxes. Pre and post requirements might be exactly defined like inputs and outputs. Workflow approach may be considered as warning system for user about possible mistakes. In any undesirable situation, system must terminate itself to prevent data entry for possible erroneous record. Laboratory phase of blood bank computing is responsible for preparation, labeling and stocking of components and also immunohematologic processing of both donor and patient specimens. There are two processing flows (specimen processing workflow and component processing workflow) available in laboratory phase. Before component processing workflow some immunohematologic tests must be applied to donor specimen in specimen processing workflow as prerequisite.

It is desirable to have an on-line connection with the analyzers that enter the results of the tests and can automatically rule out some of the donations according to pre-determined criteria. The printouts of the results then must be re-checked against the primary documentation. The performing personnel and the identification of the equipment used are entered into the record.

4.4.2.1. Patient and Donor Specimen Processing:

Computer system should allow laboratory technicians and automated systems typing of any blood related investigation only once in that session. All corrections or

editing features should be active for supervisory with appropriate audit trail. AABB defines minimum record requirements for donor and patient specimens processing, so that before analyzing blood bank laboratory computerization, pre-requisitions should be defined as follow:

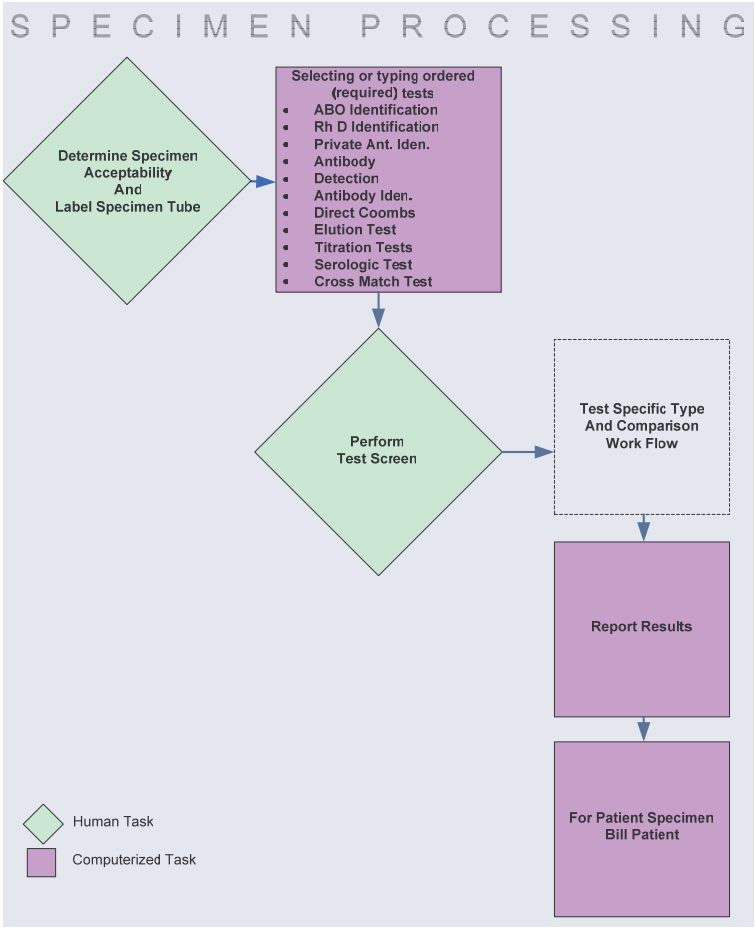

Figure 4. 5 Work flow diagram of specimen processing

4.4.2.2. Record requirements of Laboratory tests on Patient Specimens:

- At least two unique identifiers should be labeled on specimen tube such as patient name surname and patients hospital protocol number.
- It's desirable to print collection date of specimen on to label.
- Identification of phlebotomist's should be recorded.
- Special behaviors of patient for example pregnancy of patient should be recorded.

- Date and time of testing, type of performed test, verified test result, and final interpretation should be traceable from blood bank computer system.
- Identity of person(s) entering and validating results and technique used for test also should be recorded.
- Also critical findings like weak D, unexpected antibodies, difficulty in blood grouping or serious adverse effects of transfusion should be recorded to blood bank computer system.

4.4.2.3. Record requirements of Laboratory tests on Donor Specimens:

- Donor unit number, donation number and donor specimen tube number should all have same unique number or closely related and traceable identifiers. This could be achieve by using donation number as unique identifier for all.
- Results of ABO and Rh testing, weak D indication, antibodies, negative and positive controls that run with donor specimens, serologic tests should be added to donor's donation history.
- All other record requirements of patient specimen also could be applied on to donor specimen records.

4.4.2.4. Laboratory Tests:

4.4.2.4.1 ABO Blood Group System Identification. The ABO Blood Group System was the first to be identified and is the most significant for transfusion practice. Accurate testing of donor and patient (recipient) blood for ABO compatibility is essential for the prevention of hemolytic transfusion reactions.

The computer system should enable user to typing and screening of primer and mostly know ABO blood group types A, B, AB and O (Table 4.4).

Table 4. 4 Primer ABO blood groups

Routine ABO Typing					
Reaction of Cells Tested With		**Reaction of Serum tested against**			**Interpretation**
Anti A	Anti B	A1 Cells	B Cells	O Cells	ABO Group
0	0	+	+	0	0
+	0	0	+	0	A
0	+	+	0	0	B
+	+	0	0	0	AB

Also computer system should enable user to choose red blood cell phenotype if these detailed investigation is applicable in laboratory (Table 4.5). Investigating anti-A, anti-B, anti-AB, lectin-H, and lectin-A1 also called with forward grouping, A1-cell, A2-cell, B-cell and 0-cell also called with reverse grouping. If there is no automated system available for blood group detection, these two grouping should be investigated and entered to BBIS by different laboratory technicians.

Table 4. 5 Phenotype determination list

Some Red Blood Cell Phenotypes									
RBC Phenotype	Reactions of Cells with Known Antiserum to					Reaction of Serum Against Reagent Red Blood Cells			
	A	**B**	**A,B**	**H**	**A1**	**A1**	**A2**	**B**	**0**
A1	4+	0	4+	0	4+	0	0	4+	0
Aint	4+	0	4+	3+	2+	0	0	4+	0
A2	4+	0	4+	2+	0		0	4+	0
A3	2+mf	0	2+mf	3+	0		0	4+	0
Am	0/±	0	0/±	4+	0	0	0	4+	0
Ax	0/±	0	1+/2	4+	0	2+/0	1+/0	4+	0

Although automated systems are more reliable than manual entries, there should be a warning mechanism available for differences between patient's old and new blood groups and critical foundations during automated ABO blood group

investigation. Manual entries should be verified by a second technician's entry of the confirmation page.

4.4.2.4.2 Rh D System Identification. The Rh blood group system is extremely complex, and certain aspects of its genetics, nomenclature and antigenic interactions are not fully understood. After the A and B antigens of the ABO system, the D antigen of the Rh system has the most significant implications for transfusion practice. The D antigen is more immunogenic than virtually all other red cell antigens. The Rh system also contains other clinically significant antigens (C, c, E and e) and some less significant antigens.

In common terms, absence of red cell antigen D is called as Rh negative or Rh positive. All antigen related findings investigated by applying antibody of that antigen and calculating reaction degree. Rh Subgroup is investigated by calculating reactions of specimen when Anti-D, Anti-C, Anti-c, Anti-E and Anti-e antibodies applied on to specimen. Probable solution table is shown at Table 4.6.

Table 4. 6 List of some subgroups

Determination of Rh Phenotypes and Subgroups						
Anti-D	Anti-C	Anti-E	Anti-c	Anti-e	Rh Subgroup	Probable Phenotype
+	+	0	+	+	CcDee	R1r
+	+	0	0	+	CCDee	R1R1
+	+	+	+	+	CcDEe	R1R2
+	0	0	+	+	ccDee	R0R0/R0r
0	0	0	+	+	ccee	rr
0	+	0	+	+	Ccee	r'r
0	0	+	+	+	ccEe	r''r
0	+	+	+	+	CcEe	r'r''

4.4.2.4.3 Weak expression of D. Red cells that carry weak forms of D are classified as D-positive and may be described as "weak D". AABB Standards for Blood Banks and Transfusion Services requires donor blood specimens to be tested

for weak expression of D and to be labeled as D-positive if the test is positive. If D-positive blood is given to recipients of the weak D phenotype, it is important to safeguard against careless or incorrect interpretation of tests. Although, D antigen value is evaluated in positive manner, appropriate blood group investigation for weak D recipient's specimen is D-negative; in contrast, blood group of component that donated from weak D donor may be labeled as D-positive blood. So that, weak-D investigation should be recorded to blood bank information system.

4.4.2.4.4 Other Blood Group Systems (Private Antigens Identification). In addition to ABO and Rh systems, there are more than 200 antigens are located on red cells, other blood cells and in body fluids. ABO and Rh system antigens present in almost all persons and in general they known as high-incidence or public antigens. Other antigens are generally known as private antigens and they present in very low incidence. Several different methods (e.g. tube method, gel method) are applying for blood tests, like antigen, antibody determination or cross-matching. In Table 4.7, the most known private antigens that investigated by gel centrifugation are listed.

Table 4. 7 Other blood group systems

ISBT Number	**Blood Group**	**Phenotypes**
001	ABO	A1,A2,B,0,H
002	MNS	M,N,S,s,U
003	P	P1,P2,$P1^k$,$P2^k$,p
004	Rh	D,C,c,E,e,Cw
005	Lutheran	Lu^a,Lu^b
006	Kell	K,k,Kp^a,Kp^b,Js^a,Js^b
007	Lewis	Le^a,Le^b
008	Duffy	Fy^a,Fy^b
009	Kidd	Jk^a,Jk^b

Similar type and screen procedure that applied to Rh System entry may be applied to other blood group systems. Positive (+4 to +1) or negative (0) evaluation of each phenotype of blood group system is enough for determining patient related antigens.

BBIS should also enable user to enter individually phenotype values rather than whole blood system investigation. Table yy shows the probability of antibody creation for clinically significant antigens.

Table 4. 8 Antibody creation probability for negative antigen recipient after transfusing positive RBC

Blood Group Antigen	**Probability of antibody creation**
D	70.0
C	0.22
C	4.1
E	3.38
E	1.12
K	10.0
K	3.0
Jka	0.14
Jkb	0.06
Fya	0.46
S	0.08
S	0.06

4.4.2.4.5 Antibody Detection and Identification (Indirect Coombs). The antibodies that occur against blood group antigens could be determined by reverse grouping, cross match test that applied before transfusion practice or antibody identification techniques (gel test column technique vs.). Antigens could either locate on red blood cell surface or be freely locate in serum. The antibodies that occur against the first type of antigens called alloantibody, and second type antibodies called autoantibody. Anti-A and Anti-B are natural alloantibody. Transfusion or pregnancy may be reasoned with unexpected alloantibody. Indirect coombs test is applicable for unexpected alloantibody which is freely placed inside serum.

Both antibody detection and identification techniques are similar. The methods that are using for antibody detection are applied more focused and based upon the reactivity patterns for antibody identification. In general serum is widely used for

screening and identification of antibody. FDA (Food and Drug Administration) determined following antigens D, C, E, c, e, M, N, S, s, P1, Le^a, Le^b, K, k, Fy^a, Fy^b, Jk^a, and Jk^b for most clinically relevant antibodies. Table 4.9 could be used for antibody detection

Table 4. 9 Antibody detection cells

Auto-Control Cell	**Test Cell**	**Antibody**
Positive	Negative	Autoantibody
Negative	Positive	Alloantibody
Positive	Positive	Autoantibody / Autoantibody+Alloantibody

After recording existence of antibody, truly identifying antibody according to LISS, enzyme and cold agglutinin values must also record to patient's medical history. Positive values are changing from "+4" to "+1" and negative value is defined as "0" value. Multiple antibody and mixed field findings should also be recorded to patient's blood related medical history.

4.4.2.4.6 Direct Coombs Test. Direct coombs test is applicable for antibodies, which were covered the surface of red blood cells. Patient should either positive or negative signed for DC test. Also mixed field is another indicator for DC test. Project also enables user for detailed description of DC test with Ig G, Ig A, Ig M, C3c and C3d values between negative to positive 4 and also mf (mixed field).

4.4.2.4.7 Elution Test. For direct coombs positive indicated patient's specimen, elution test is applied to freeing antibody molecules from sensitized red cells. After elution test, these antibody values should recorded to BBIS according to enzyme, LISS and 4ºC (also called cold agglutinin) environment.

4.4.2.4.8 Anti-A Anti-B and Rh Subgroup Titration Test. Laboratory technician should be enabled to indicate and enter titration values of a specimen according to research cell, positive and negative founds inside 1, 2, 4 …256, 512 scope.

4.4.2.4.9 Infection Tests. The most significant safety point of transfusion is closely related with non-inflected component usage. All donor specimens might be stored in a quarantine refrigerator before applying serological test. Turkish ministry of health forces blood related healthcare givers and also blood banks to apply serologic tests for four mostly seen infectious types that named hepatitis B surface antigen (HBsAg), antibody to hepatitis C virus (anti-HCV), antibody to human immunodeficiency virus (anti-HIV) and VDRL/RPR. Table 4.10 guides automated serological test machine evaluation values.

Table 4. 10 Infection test resulting criteria

Test Name	Critical Value	Highest Value	Middle Value	Lowest Value
HBsAg	106	1	0.8	0
Anti-HCV	841	1	0,8	0
Anti-HIV	817	1	0,9	0
VDRL/RPRO	0	1	0,99	0

Patient specimen value is divided to critical value. If result is higher than highest value patient indicated positive for this test. Grey zone indication is used for results between middle value and highest value. Negative indicates results between middle value and lowest value.

4.4.2.4.10 Cross-Match Test. Cross-match negative components reserve to owner of blood specimen until specified date. This date could be calculated by the help of use date which is informed by component order message. Cross – Match negative (or CM Appropriate) label should stick on to product container bag. All reserved products become reserved blood products stock from free stock.

Some times wrong or urgent transfusion results with antibody creation inside patient blood. Cross match test continuously gives positive result, so that, Cross – Match positive (or CM inappropriate) label could be used for reserved product for these patients.

4.4.2.5. Blood or Component Processing

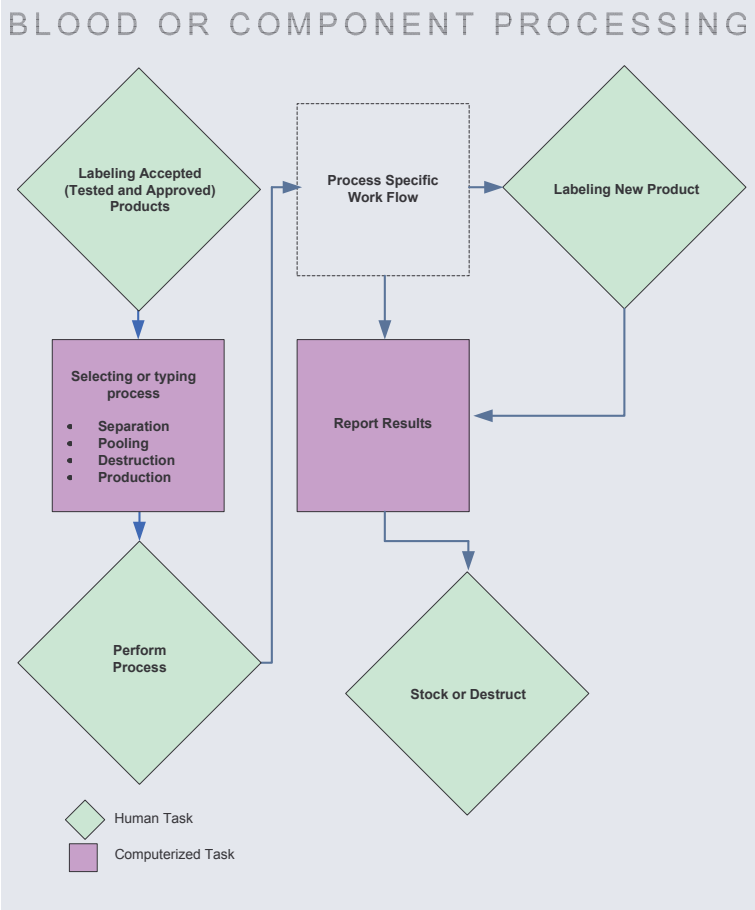

Figure 4. 6 Work flow diagram of blood or component processing

4.4.2.5.1 Preparation of Component. Record requirements for component preparation are listed below:

- Unique donation number or donor number
- Method which is used for preparation (either manual or automated)
- Date and, if appropriate, time drawn
- Name of anticoagulant
- Name of component
- Date and time each component was prepared.
- The time each step was taken preparation step must be documented (separation, freezing, thawing)
- Expiration date of component

- Volume of component
- When recovered plasma is pooled for further manufacture, records must indicate the donor unit number and the identification of the collecting facility for each unit in pool
- Pooled component labels must have

    - Name of the pooled component
    - Final volume of the pooled component
    - Name of the facility preparing the pooled component
    - Unique numeric or alphanumeric identification
    - Number of units in the pool
    - ABO and Rh type of units in the pool

4.4.2.5.2 Disposition of Blood and Components. Record requirements for disposition of blood and components listed below:

- Documentation and confirmation that all components from a unit have been quarantined, as indicating; documentation of appropriate release from quarantine
- When destruction is necessary, the identification of each of the components destroyed, the reason for destruction, date and method of destruction

4.4.2.5.3 Blood and Components Received from Other Facilities. Record requirements for blood and components received from other facilities are listed below:

- Name and address of shipping facility. It is not necessary to record the address with each unit if this information is readily available.
- Name of component
- Donor unit number assigned by collecting facility
- Accession or inventory number, if any, assigned by receiving facility
- ABO and Rh type

- Component expiration date and time, if indicated
- Date component was received
- For blood that is received already cross matched, the name and identification number of the intended recipient and interpretation of results of compatibility tests
- Results and interpretation of tests done by the receiving facility

4.4.3. Delivery Phase:

It is so hard to control blood product's trip without computerized system from ward or service ordering to transfusion practice (Napier, Chapman, Forman, Kelsey, Knowles, Murphy & Wood, 1996). Interoperability between different computer systems is required for reliable tracing and successful transfusion. Clinical orders, specimen collecting, transfusion practices could be traceable by the help of clinical information system. Moreover, billing blood product might be related with financial information system and blood bank information system required for all blood related investigations and preparations.

4.4.3.1. Ordering Component:

The blood requirement of patients is determined by the service doctors. Either doctor or service secretary may order component by typing requirement from CIS terminal (Figure 4.7). CIS generates HL7 messages using ORM^O01 common order template. Table m shows minimum required data fields, which are carried by ORM message.

Healthcare staff of service must also correctly collect patient specimen into the tube. Tubes should be either labeled with patient's hospital protocol number or order specific unique number.

After parsing or decoding message text by HL7 Listener tool, service order is recorded to BBIS's database according to gathered protocol and episode number with

"WAITING SPECIMEN" flag. Date and time of order, service's and doctor's id, patients declared ABO/Rh blood group, type of order, required quantity and type of blood product information also may be recorded to database with patient identifiers. When patient specimen is brought to Blood Bank laboratory, "WAITING SPECIMEN" flag changes into "WAITING PRODUCT PREPARATION" flag.

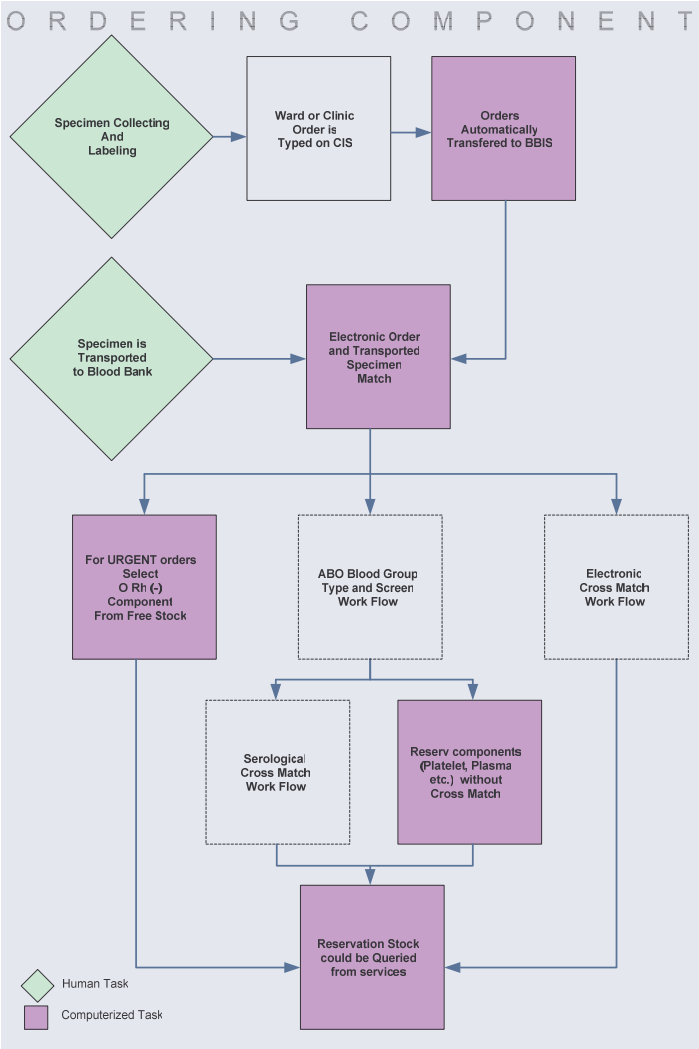

Figure 4. 7 Component order flow

Product preparation was described at Laboratory phase section in detailed. Firstly, when patient blood specimen is transported to blood bank laboratory, ABO/Rh Blood group determination test should be applied. Test results should be typed to BBIS. Laboratory technician should choose required blood product with same ABO/Rh group from the free blood product stock. BBIS should guide technician about

location of probable appropriate products. In general, cross-match test should be applied and results typed to BBIS before reservation of Whole Blood or Red Blood Cell. Electronic cross-match is another solution for these products' reservation. BBIS should prevent user for making mistake about unsuitable blood, because system should warn about ABO Group mismatches, Rh Group mismatches, antibody related mismatches and donor mismatches (relationship between patient and donor). Appropriate products labeled with reservation labels and reserved three days for patient, and stored inside reservation stock till delivery phase. After three days product is automatically (also manually at any time) returned to free stock by BBIS. System should also monitor these stock movements for laboratory technicians. BBIS should also enable service doctors to monitor and query patients' blood related test results and blood product preparations simultaneously with laboratory processes.

Services defined maximal surgical codes according to maximal initial requirements of blood products. So that, if the blood is ordered for medical operation and there is no special exception noted for patient, BBIS automatically decreases the number of blood requirements by using maximal surgical code table. This feature is important because:

- It prevents extra Cross-Match tests and saves laboratory technician's time.
- Extra product reservation may cause lack of appropriate blood product for urgent circumstances.
- It prevents storing blood products in improper store conditions outside of blood bank. Delivery of extra products generally means damage or waste of them.

4.4.3.2. Delivery of Component:

Delivery flow, which is about providing ordered products, could be considered as the part of order flow, which is about defining required products (Figure 4.8). So that, an observation screen, which displays unprovided orders should be useful for

BBIS laboratory staff. After reserving products, patient's hospital protocol number could be enough for monitoring patient's blood product stock. In general, product number, donation number, product code, name of product, blood group of patient and product, expiration date and maximum date of reservation should be enough for screening prepared stock for laboratory staff. Number and type of blood products, and maximum reservation date information should be also queried by services or wards.

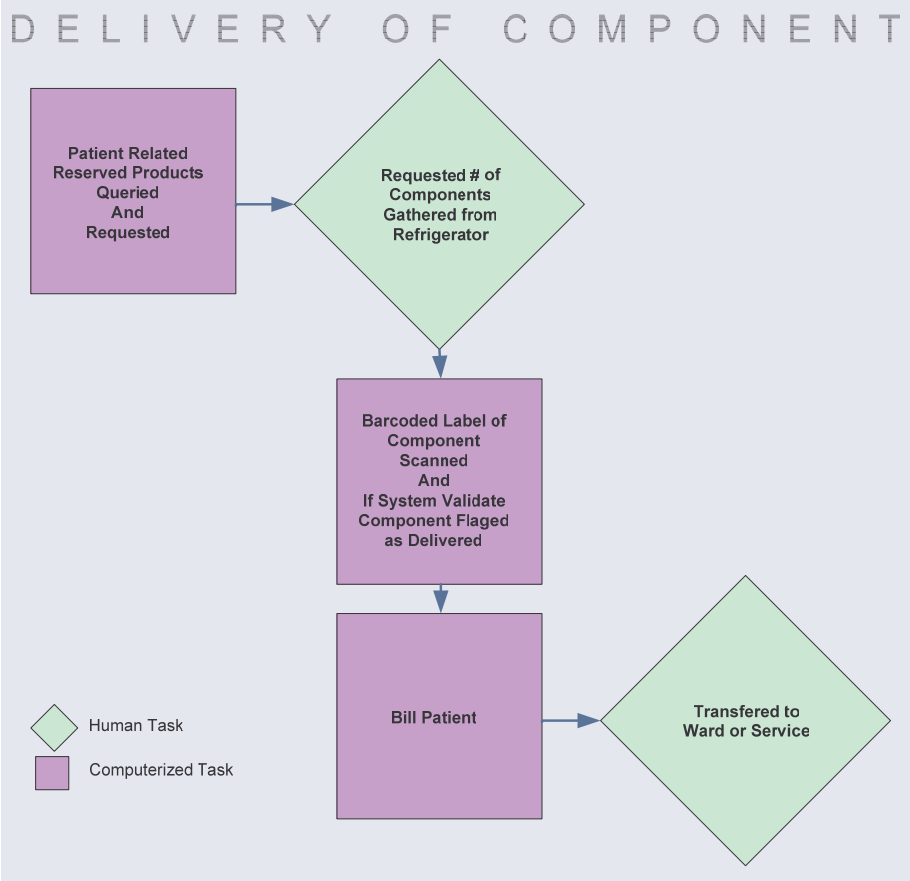

Figure 4. 8 Work flow of delivery phase

Service or ward of patient queries this information, and specific number or all of the products could requested from blood bank laboratory at any time. When requisition arrives to BBIS, laboratory staff types following fields into delivery screen (Table 4.11).

Table 4. 11 Required fields about delivery screen

Staff Id	Date and time of delivery
Owner of Requisition Id	Donation Number of Product
Transporting Staff Id	Product Code
	Product Number

Bar-coded product bag labels also should be used for secondary check screen before ending delivery step. If system gathers unacceptable product information after secondary check, this situation must be messaged to user and system should prevent this product's delivery.

AABB offers minimum record requirements (Tyler, 1999) for shipping of blood or component as follow:

- When units are shipped, the shipping facility must record the following information:

    - Name and address of receiving facility
    - Date and time of shipment
    - A list of each donor unit number, blood group and expiration date
    - Name of each component
    - Results of final inspection of whole Blood and components
    - Name of person filling order
    - Periodic tests documenting that shipping containers maintain an acceptable storage temperature range

CHAPTER FIVE
DEU BLOOD BANK APPLICATION SOFTWARE

DEU Blood Bank Application Software is developed as web application that works on java applet. Web based application minimizes client side maintenance requirements. Internet connection, member of restricted IP group and an internet browser is enough for a system's operability. Application server provides requested forms at any time. The advantage of web application is serving application from one-site increases reliability, functionality, usability, maintainability and quality of application. Oracle application and database server requires powerful machines for efficiently operate. This requirement causes extra hardware cost.

Power Designer case tool is used for modeling database. This tool reduces the amount of effort required to produce application. Also product quality, reliability and development are all improved. All analysis firstly described as conceptual data model with ERD (Entity Relationship Diagram). After testing consistency of model, physical data model generated for ORACLE database. Physical data model provides final check for all tables, relations, constraints and fields before generating SQL script. After running script on server, whole structure is created on database server.

OLB objects helps developer to produce structural modeling with Oracle forms. User interface, handling common warning or error messages, information messages about success of process, requirements of form initialization and finalization (global variables, connection statements etc.), bar-code label templates all function data and behaviors that have reusable potential defined one time inside these OLB objects. Stored procedures are also significantly useful for collecting data from complex relationships of the database.

The structure and capabilities of DEU Blood Bank guides project requirements analysis. Data flow diagrams and external events for blood bank computerization are

described in previous chapter. As solution, modeling database with three phases (donation, laboratory and delivery phases) might be enough for implementing blood bank requirements. Also addition of these three phases user groups, billing procedures and audit logs are modeled for developing application software in full manner.

5.1. Implementation of Donation Phase:

5.1.1. The Conceptual Data Model:

Both donor and patient concepts are trying to define a person. Also any donor's blood history is useful information for future blood requests for a donor who will become patient. Demographic information requirements are very similar for donors and patients. All these meaningful similarities show that only the patient table (HASTA) can be enough for patient identification. There are two unique identifiers (protocol number and national identity card number) available in patient table.

Donation can be though as appointment of donor at blood bank (Figure 5.1). The reason of donation selected from table (DONASYON NEDENI) and donation session starts for donor. The appointment table (RANDEVU) is holds current donation sessions data.

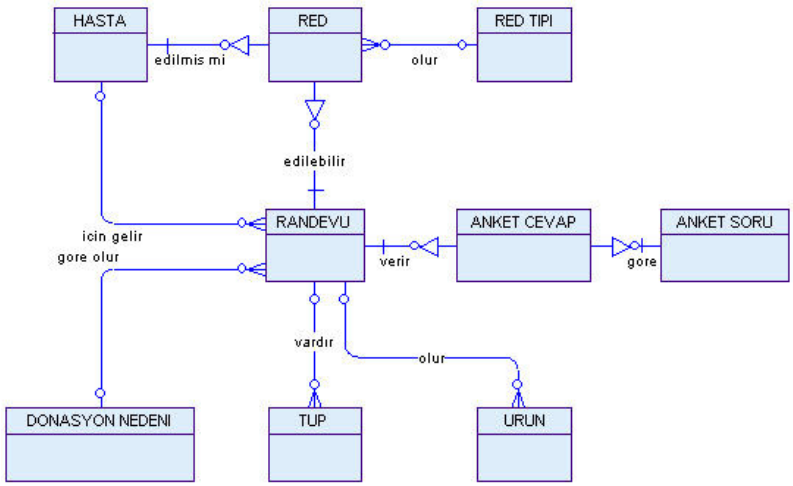

Figure 5. 1 Donation diagram

The pre-donation questionnaire data are holding tables questionnaire answer (ANKET CEVAP) and question (ANKET SORU) tables. At any donation step, donor can be rejected. Rejection table (RED) gets the reason of rejection from rejection types table (RED TIPI). Successful donations finalize with a whole blood or any blood component. The relation between appointment table and product table (URUN) shows this result. The product is firstly flagged as quarantine. The blood bag must be labeled some identifiers until required tests are applied to donation sample. The tube table (TUP) holds the identifier of both donation bag and donation sample tube. All success stories about donation session are held in appointment table. Blood product, which is obtained from donation, is automatically added to quarantine stock. Immunohematologic investigations like ABO/RhD Blood Group determination, serologic tests and subgroup determination are automatically drop to laboratory investigation list.

5.1.2. User Roles:

There are three types of user's available for donation phase. These are donor registration secretary, phlebotomy nurse and doctor. Each role can only reach the allowed part of input forms. Figure 5.2 shows all available menu items about donation processes.

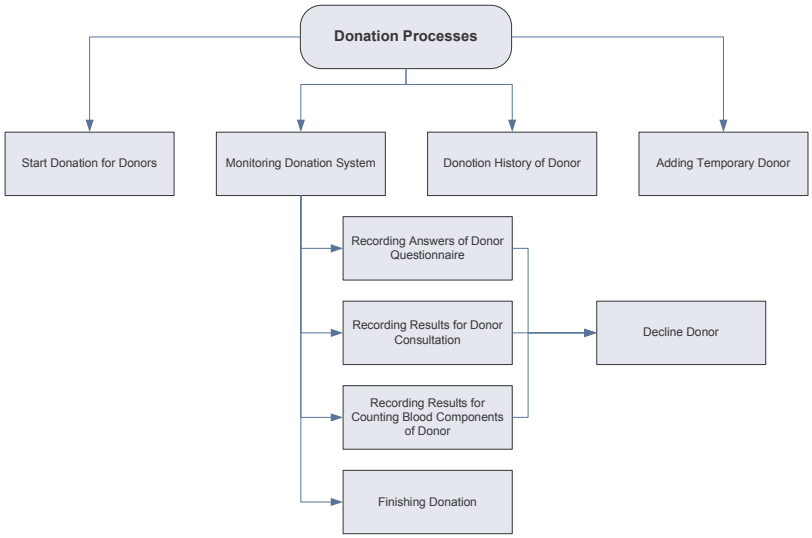

Figure 5. 2 Available processes of DEU Blood Bank Application Software for donation

5.1.2.1. Donor Registration Secretary:

The donor firstly meets with donor registration secretary. Demographic information typed and added to system. System generates unique protocol number for this donor. If any registration information available for same person or if there is any similarities between person's information and previous records (name, surname, date of birth mother name etc.), system warns user about duplicate entry. Another job for secretary is starting donation session. Meeting time of donor, reason of donation (Therapeutic phlebotomy, volunteer donor, specific patient, autologous donation), for the reason of specific patient protocol number and name of patient are the required fields that can be recorded in start of donation.

The menu elements available for registration secretary are

- Donor Registration
- Start Donation for Donors (Figure 5.3)

Figure 5. 3 Donation session start by the entry screen

- Adding Temporary Donor

5.1.2.2. Phlebotomy Nurse:

Nurses of blood bank concern with most of the steps of donation session. All functionality of secretary also met with nurses. In addition to these jobs, counting blood components (# of hemoglobin, thrombocyte and leukocyte) and finishing donation session are made by nurses. There is a monitoring system available for nurses and doctor to follow state of donors. Available states are waiting for

questionnaire answers, waiting for examination, waiting for blood counting, and waiting for finalizing donation. Collected blood name is selected from determining type of product screen (Figure 5.7). This screen is related with ISBT 128 product code table. Firstly class of blood is selected, then according to entered anti coagulant, stored condition and volume information, system suggests probable products from ISBT 128 product code table. Donor may be decline in any steps of donation session. Type of decline (permanent or temporary), if temporary decline end time of decline information are asked for recording.

Allowed menu elements for nurses are

- Donor Registration
- Start Donation for Donors
- Adding Temporary Donor
- Monitoring Donation System (Figure 5.4)

Figure 5. 4 All available statements are listed on donation queue monitoring screen

- Recording Results for Counting Blood Components of Donor (Figure 5.5)

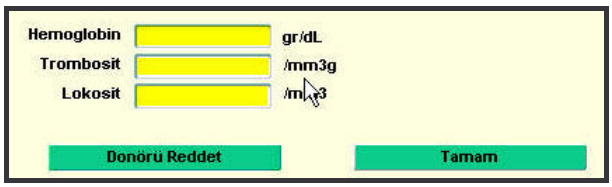

Figure 5. 5 Blood counting values entered from the screen above.

- Decline Donor
- Finishing Donation (Figure 5.6)

Figure 5. 6 General finalizing information is filled on screen

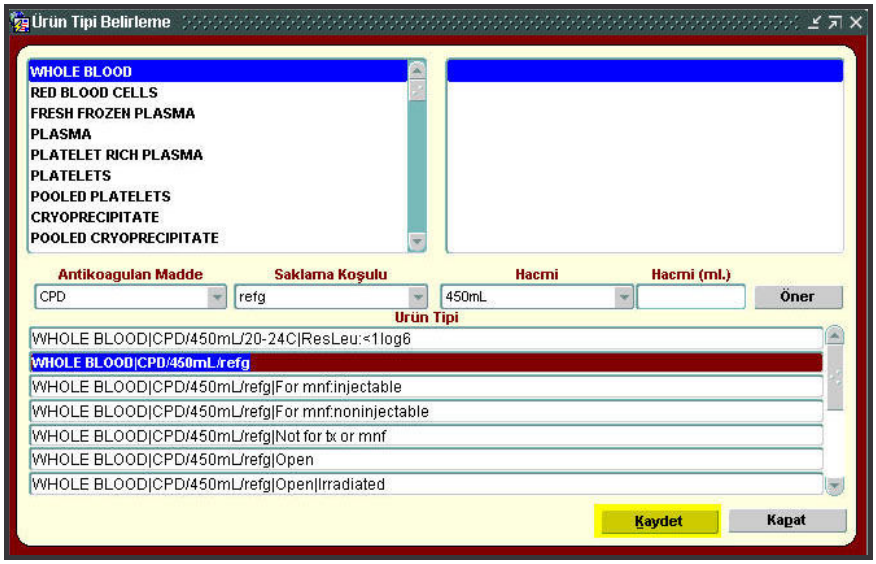

Figure 5. 7 Collected blood component selected from ISBT product types screen

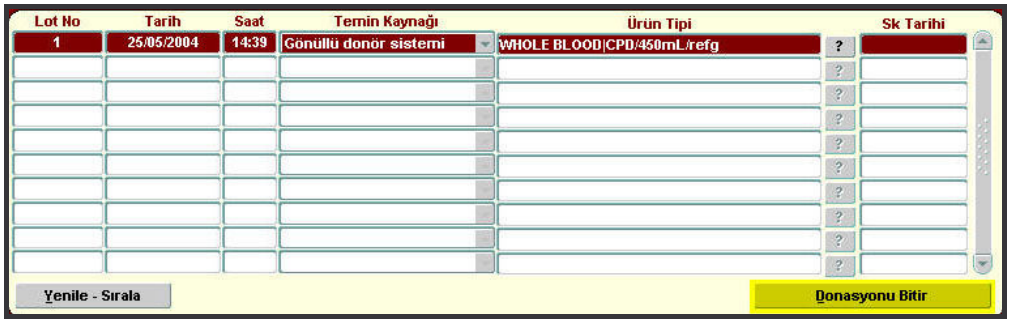

Figure 5. 8 Donation session is closed

5.1.2.3. Medical Doctor:

They firstly ask each donor about answers of a pre-donation questionnaire. If medical doctors decide any suspicious answer or behavior of donor, they may decline donation session. After recording questionnaire form, donor examination is made.

Following menu items are available for medical doctors' entry:

- Monitoring Donation System
- Recording Answers of Donor Questionnaire (Figure 5.9)

Figure 5. 9 Form of electronic questionnaire

- Recording Results for Donor Consultation (Figure 5.10)

Figure 5. 10 Examination results typed into screen shown above

- Donation History of Donor
- Decline Donor

5.2. Implementation of Laboratory Phase:

5.2.1. The Conceptual Data Model:

There are two sub-phases available inside laboratory phase. One of them is about immunohematologic investigations. Not only donors' blood specimens but also patients' specimens are tested in blood bank laboratory. All investigation types have different tables and also require different type of information to be recorded. The table process pool (ISLEM HAVUZU) holds the type of investigations (cross-match, direct coombs, indirect coombs, ABO reverse and forward grouping, titration, serological tests, subgroup determination etc.) that can be examined inside DEU blood bank.

Operation starts with selection of

- Specimen from table tube (TUP)
- Investigation from table process pool (ISLEM HAVUZU)
- Laboratory technician from table personnel (PERSONEL)

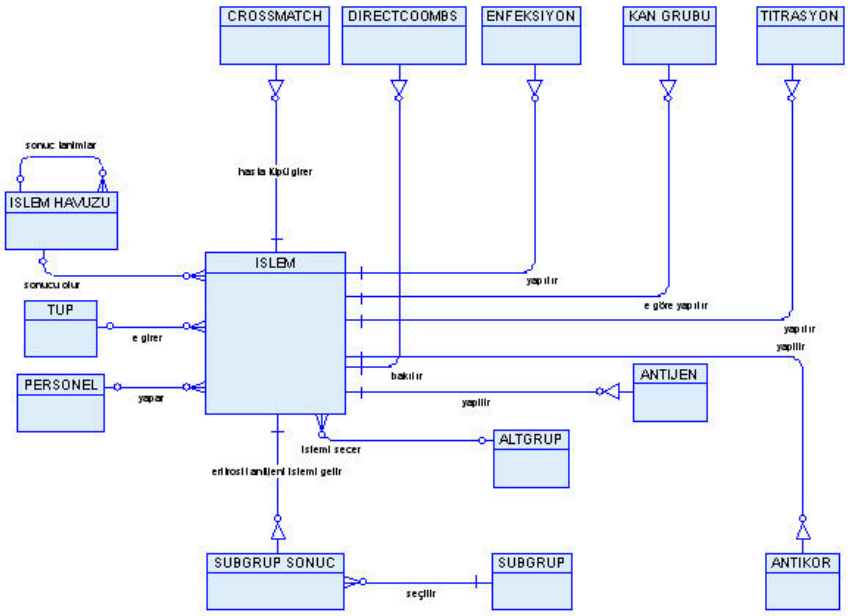

Figure 5. 11 Diagram of immunohematologic investigations

All detailed and test specific values of investigations data are hold inside tables, which are named with test name. The table process (ISLEM) only aware of who is the responsible of test, date and time of resulting, state of test (waiting, started, finished in success) information.

Blood component related processes can be though as other part of laboratory phase (Figure 5.12). There is another table, product process pool (URUN ISLEM HAVUZU) stores product separation, pooled product preparation, product finalization and destruction processes. Any laboratory technician from table personnel (PERSONEL) may be select process to a specific blood component from table product (URUN) and may apply process and store all these information inside product process table (ISLEM URUN). Pooled product preparation process is a bit different from other operations. All other processes are applied on one product and generally result with many other products. Pooling operation results with one product, although many of them are entered to process. So that multi donor table (MULTI DONOR) holds used blood products' information.

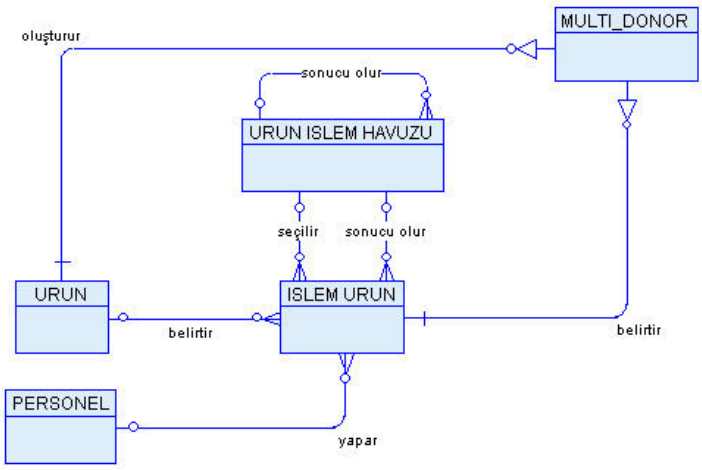

Figure 5. 12 Diagram of component related processes

Implementation of ISBT 128 product coding requires special modeling for product definition (Figure 5.13). Blood product table (URUN) has two identification number as primary key. One of them is donation identification number from donation appointment table (RANDEVU).

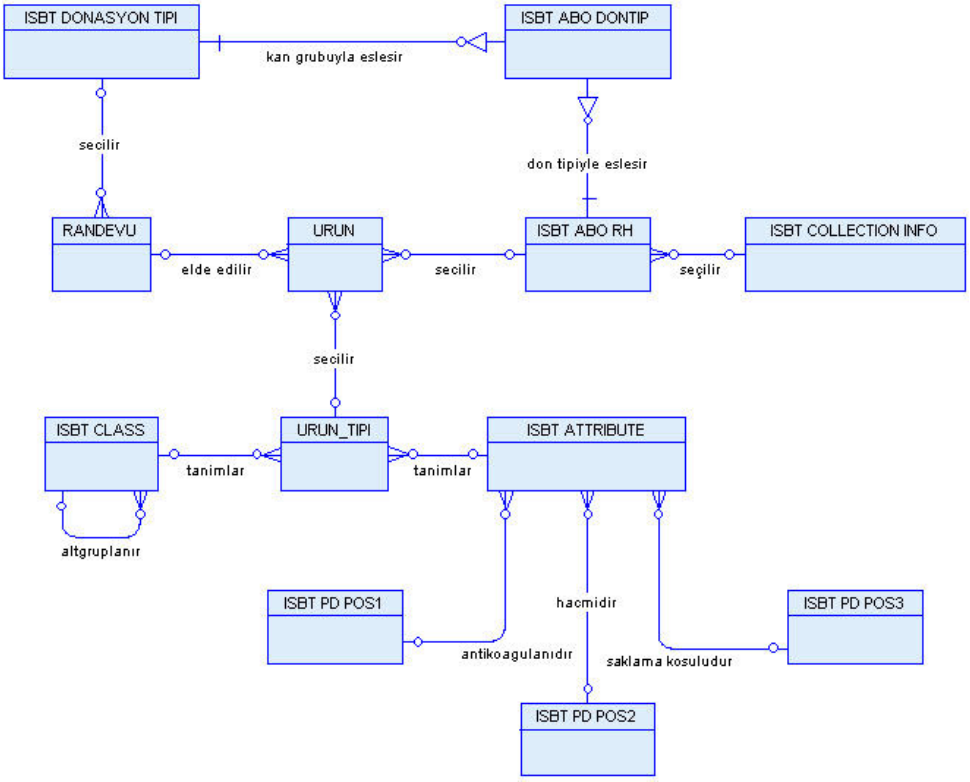

Figure 5. 13 Model of ISBT related product type determination

DEU hospital registered T004 as facility number. Facility number, last two digits of collection year (05 for 2005) and six digits of incremental serial number set enough for determining donation. T00405000001 identifies the blood product, which is the first donation of DEU Blood Bank in 2005. Second identifier is product code that determines according to tables ISBT CLASS and ISBT ATTRIBUTE. ISBT attribute changes according to anti coagulant name, storing conditions and volume information. E0001 product number defines whole blood with CPD, 450 ml and stored at refrigerator. Donation type V means routine allogeneic donation and product divisions typed with number 00. E0001V00 identifies the product specification. More detailed information about ISBT 128 is explained in chapter 2. According to donation type (stored in ISBT DONASYON TIPI table) the ABO/RhD blood group code specification may differs. ISBT donation type table (ISBT DONASYON TIPI), ISBT ABO RH table and ISBT COLLECTION INFO tables are used for implementing Blood group of product.

5.2.2. User Roles:

DEU blood bank laboratory is not only interested in donor specimens and product preparation but also makes immunohematologic tests to patient specimens. So that, another name of DEU blood bank is immunohematology laboratory. The roles defined for blood bank laboratory are laboratory technician and blood bank secretary.

5.2.2.1. Blood Bank Secretary:

After blood specimen is collected from any service, service or ward secretary entered required blood investigations to hospital information system. All these orders automatically transferred to blood bank information system by using HL7 messaging. Blood bank secretary is the final step of electronic requesting procedure. Secretary accepts patient blood specimen with printed request form. She compares request form with electronically transferred orders and passed specimen to laboratory.

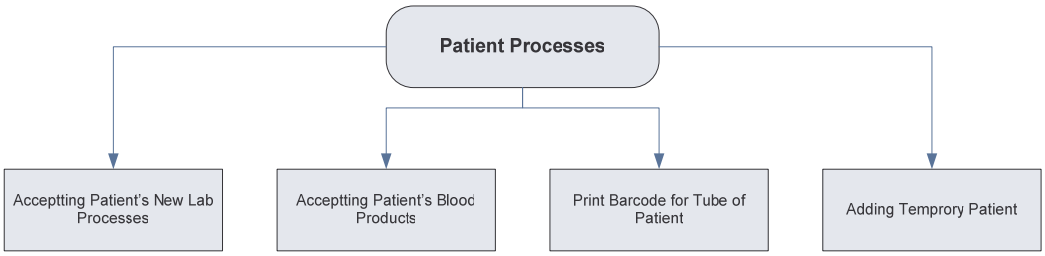

Figure 5. 14 Available patient specimen processes

Till preparation of this thesis, in DEU hospital patient specimen tubes unfortunately can not label at the bedside. So that, labeling patient specimen is another job of this role. Out source products, which aren't collected in house donations, are also received by blood bank secretary.

The menu elements available for this role are

- Accepting Patient's New Laboratory Processes (Figure 5.15)

Figure 5. 15 New investigation selections

- Accepting Patient's Outsource Blood Products
- Printing Label for Patient Specimen Tube

5.2.2.2. Laboratory Technician:

Blood bank application automatically opens ABO/RhD blood group determination, Rh Subgroup determination and serological test processes after each success donations. Firstly samples are flagged as waiting in laboratory processes monitoring page. Laboratory technician is only aware of barcoded tube label. Technician uses barcode scanners on monitoring page and requested investigations for that sample is listed on screen (Figure 5.16).

Figure 5. 16 The investigation list for monitoring laboratory processes

Like donor's blood specimen, patient's specimens are also listed on this monitoring screen. User can pass to investigation entry forms after double clicking

the name of investigation which is displayed on processes list. If it's required, technician can add new investigations to sample of patient or donor. These added requirements are also screened on monitoring page.

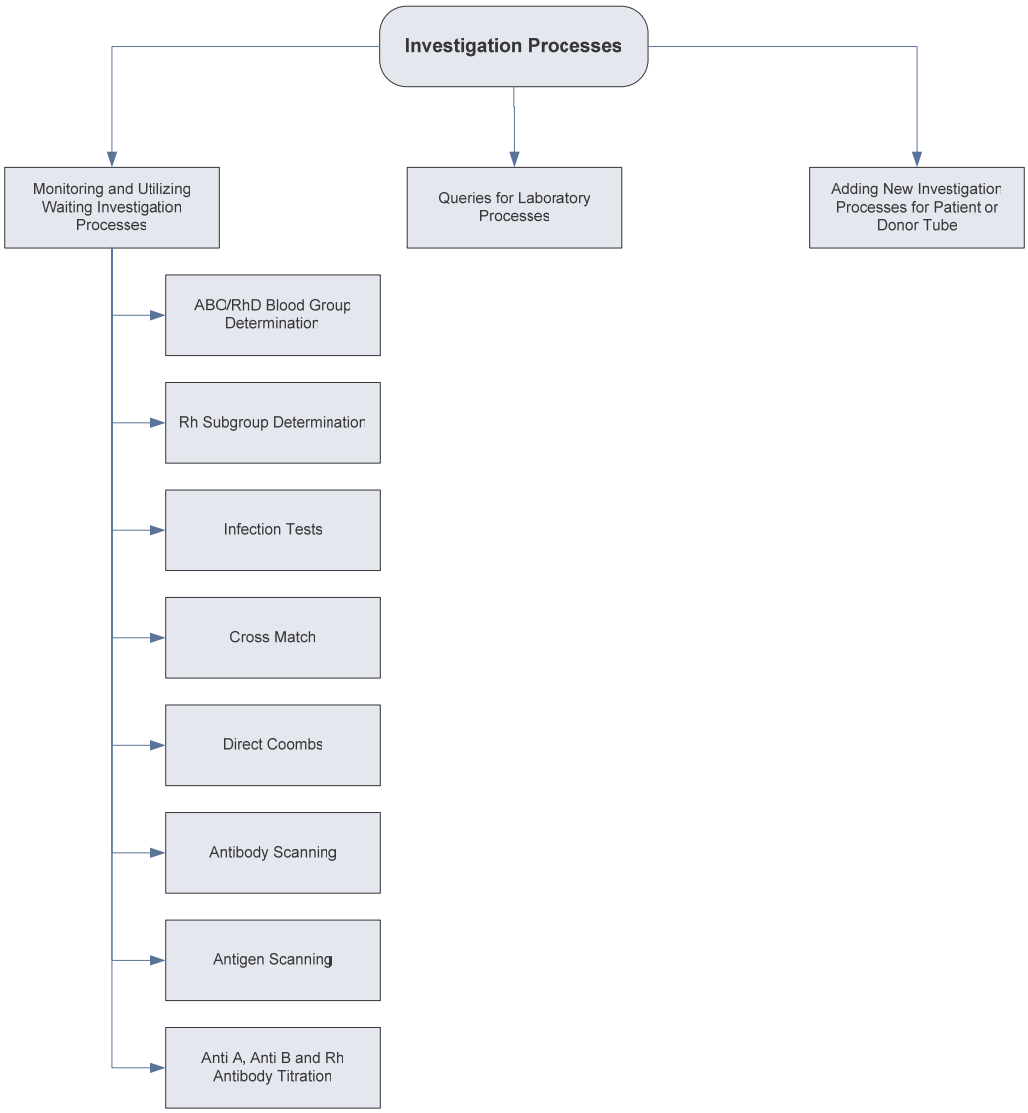

Figure 5. 17 System provides the investigation menu items listed above

If user starts to enter required information to any investigation page, that page is locked to other users until user finishes the entry. This feature prevents duplicated entries and controls the sequence of jobs. The system is able to store and recall all the immunohematologic history of all specimens received in the blood bank.

If manual step is required for ABO / RhD blood grouping, system is hiding previous results from user. Forward and reverse grouping might be typed by two different users. System has important decision support ability for blood group and phenotype determination. According to forward and reverse grouping values, system is able to suggest possible phenotypes and blood groups to laboratory technician.

Similar decision support ability is available for Rh Subgroup determination. Technician enters C, c, D (also coming from ABO / RhD blood grouping), E, e values and system automatically assigns proper subgroup value as result. Rh Subgroup determination is finished after the entry of Cw and K values. (Figure 5.18)

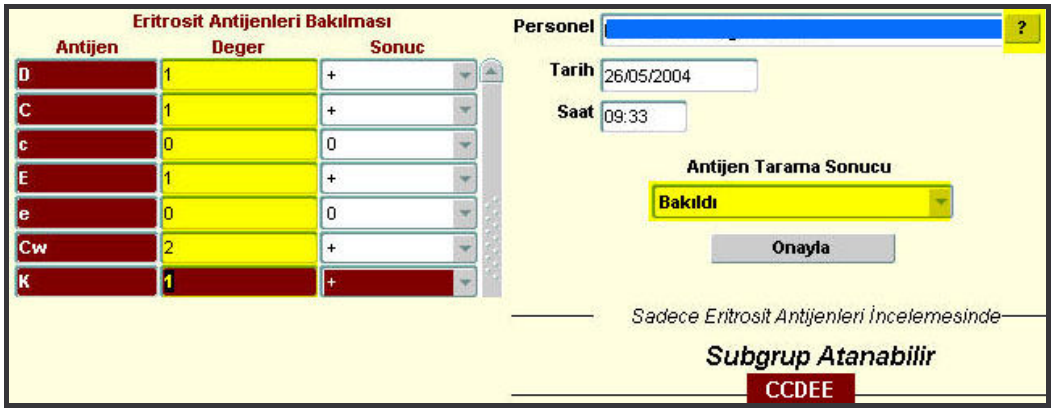

Figure 5. 18 Rh subgroup determination screen

Clinically significant and insignificant antibodies were defined to blood bank information system. If the result of antibody detection is positive, laboratory technician can type the antibody screen in significance manner.

Infection tests are made by automated laboratory instrument, Abbott AxSYM® System. Laboratory technicians use Heracles communication tool for sending test order to machine and gathering the results of HBsAg, HCV3 and HIV tests from AxSYM system. There is one more test VDRL test must be applied to donor sample. This test and all other integrated test results are displayed on infection typing page of Blood Bank Information System. Laboratory technicians are not allowed to modify AxSYM results; they only enter the value of VDRL result. Donor is declined if there is any suspicious (gray zone) or positive result.

Crossmatch test is applied on patient specimen with selected donation product specimens. Blood Bank application software compares ABO / RhD Blood groups of both specimens. Laboratory technician is warned if there is an unexpected match. Result values of AHG and enzyme environment tests entered and if proper blood product is determined, this product is reserved on patient for future 72 hours usage. After 72 hours, system automatically transfers products from reserved stock to free stock. Product reservation with or without cross-match procedures are also available for laboratory technicians.

Another monitoring page is available for controlling product related processes. Product pooling, separation, and destruction processes are displayed on monitoring screen. Both free processes and processes that have owner are listed in this screen. Laboratory technicians are able to record and store details of unit movements including transfer between unreserved and reserved stock, issues to wards and services and transfers to other hospitals into blood bank application software.

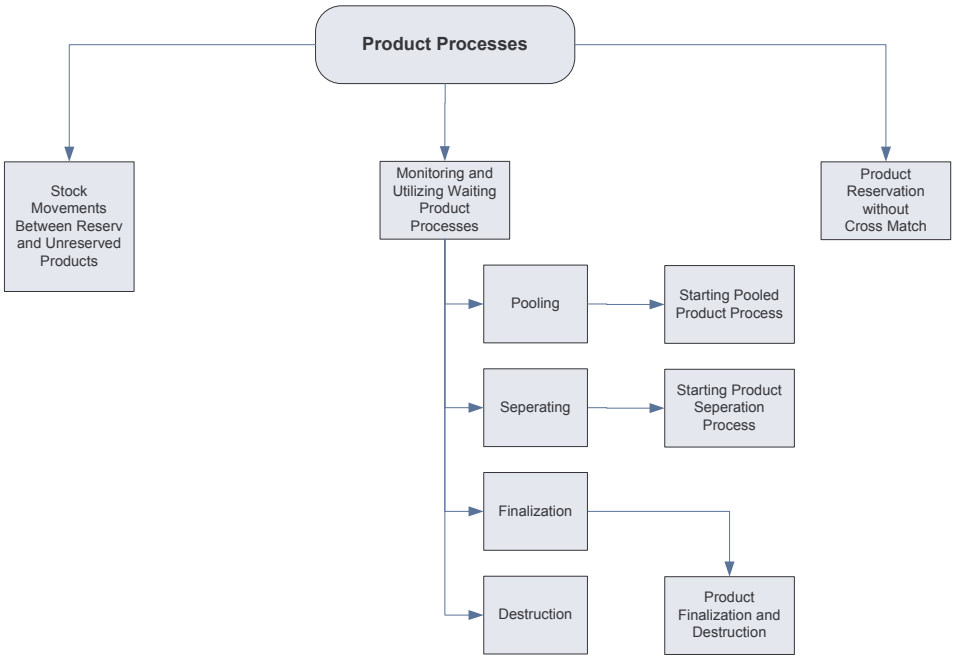

Figure 5. 19 System provides the product process menu items listed above

Pooling process is made by laboratory technicians and applied in following manner. Firstly appropriate platelets selected from free platelet stock, later on these products combined together. Blood Bank Information System provides the history of

pooled components from donation phase to separation process. All previous information like anti coagulant, volume, expiration date, ABO / RhD blood group of processed components are revised by both information system and technicians. Final product is named as pooled component and has medical history of multiple donations and donors.

Whole blood separation process is especially made after donation process approximately one hour later. In DEU Hospital Blood Bank, whole blood is separated into three components, which are red blood cells, platelets and plasma; besides, that's the reason of usage ternary blood bags for gathering whole blood. Unique donation identifier, ABO/RhD group, component type code and expiry date are captured for each individual unit.

Component finalization is the previous step before deciding if the component can be used for another product preparation like cryoprecipitate or can be safely destructed. System prevents any patient related operation or reservation after a component flagged as finalized or destructed. System requires storing the identity of technician and date time of process is recorded with the finalization or destruction reason.

The menu elements available for laboratory technician role are all blood bank secretary roles and:

- Investigation Processes
    - Monitoring Investigation Processes
        - ABO / RhD Assignment
        - Rh Subgroup Determination
        - Infection Tests (Figure 5.20)

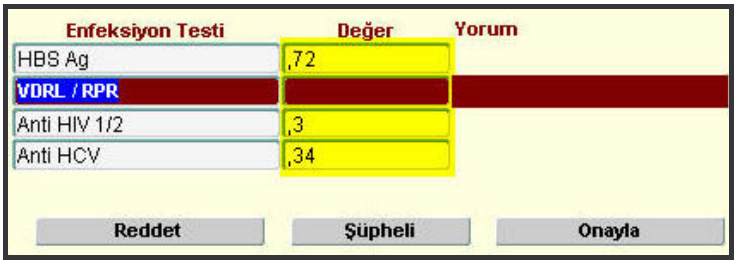

Figure 5. 20 Controlling final values of infection tests

- Crossmatch (Figure 5.21)

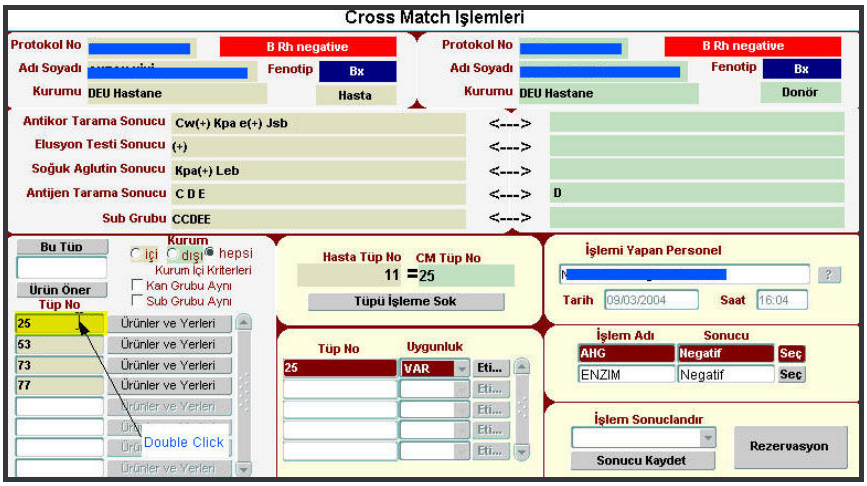

Figure 5. 21 Crossmatch screen

- Direct Coombs test
- Antibody Detection and Determination
- Other Blood Groups Determination
- Anti A, Anti B and Rh Antibody Titration

- Product Processes

  - Monitoring Product Processes

    - Pooling Process
    - Separation (Figure 5.22)

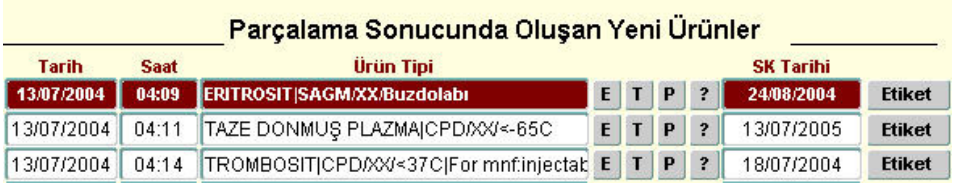

Figure 5. 22 New products after separation process

- Finalization
- Destruction

- Stock Movements Between Reserved and Unreserved Products
- Product Reservation without Crossmatch

- Queries for Laboratory Processes

5.2.3. Heracles Tool:

DEU Blood Bank laboratory is only interested in donor samples to apply infection tests. Donation phase finalizes with collected blood products and labeled sample tube. Blood Bank Information System automatically stores all these products as quarantine, and sends the infection test order to work list of Heracles application (Figure 5.23).

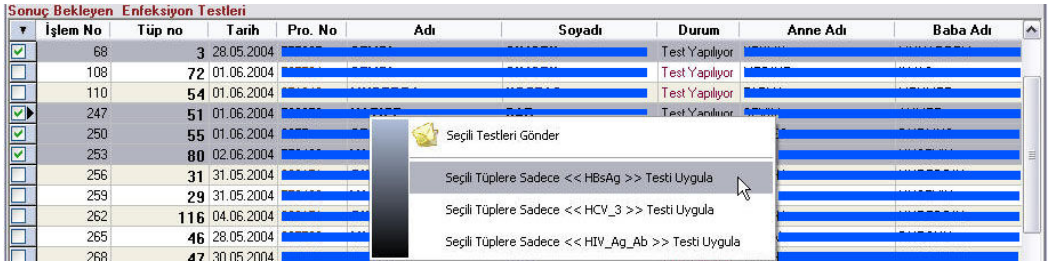

Figure 5. 23 Waiting specimens list of Heracles tool

Laboratory technician physically locate tubes into AxSYM device, and upload listed infection tests to automated system. AxSYM system runs requested tests and sends results to host machine. Heracles automatically collects coming result messages and inserts related data to the database of blood bank.

Interfacing the AxSYM System to Blood Bank Information System computer is made across the serial RS-232 communication port. ASTM E1381-91 standard is used in Physical Layer and Data Link Layer low level communications. The data link layer three communications phases, which are establishment phase, transfer phase and termination phase. Message characters enquiry (<ENQ>), start of text transmission (<STX>), acknowledge (<ACK>), end of transmission (<EOT>), carriage return (<CR>), line feed (<LF>) in Table 1 represents low level communication parameters. ASTM E1394-91 communication protocol is used for Application and Presentation Layer communication capabilities of AxSYM System. In table 1, header (H) identifies the message header, patient information (P) contains information about patient and test order (O) contains information defining tests performed or requested.

Table 5. 1 Sample messaging structure required for query response

<ENQ><ACK>
<STX>H|\&|||||||||P|1<CR><LF><ACK>
<STX>P|1|TUBE_NO|TUBE_NO|PROTOCOL_NO| SURNAME^NAME<CR><LF><ACK>
<STX>O|1|||^^^ASSAY_NUMBER|||||||A(Sample)|||||||||O <CR><LF><ACK><EOT>

5.3. Implementation of Delivery Phase:

5.3.1. The Conceptual Data Model:

The final modeling phase of Blood Bank Application Software is Delivery. In DEU hospital all medical data flow of patient is recorded by means of patient's unique identifier that is named protocol number. There is one more unique identifier is using for controlling medical expenses and billing requirements. So that, the primary key of patient (HASTA) table is protocol number and the primary indexing key of patient expenses card (HASTA KARTI) table is both protocol and episode number.

Ward secretaries orders patient products according to protocol and episode number identifiers. Orders are automatically transferred to order (TALEP) table by HL7 order messages. Type (from table product type – URUN TIPI) and number of required products are detailed inside products of order (TALEP URUN) table.

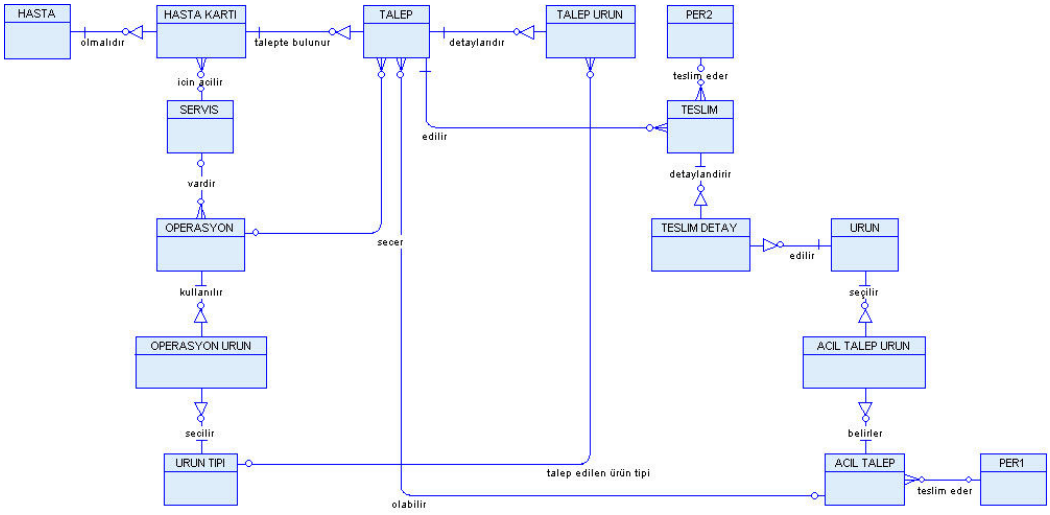

Figure 5. 24 The model of delivery of blood product

There is a working group constituted by DEU Hospital management that is interested in maximum blood product necessities of surgical operations. If order type is surgical operation, requested number and type of product is compared with maximal necessities by computer system. User can be informed about overloaded product orders; in this way, inconsistent orders are reviewed before delivery procedure.

Ordered components are selected from free stock, and appropriate ones are reserved to patient with or without crossmatch test. Urgent orders are considered in different manner in urgent order (ACIL TALEP) table. Free stock is directly used for urgent delivery without any reservation procedure. The delivery (TESLIM) table is detailed with delivered components (TESLIM DETAY) table. System automatically sends the billing messages to Hospital Information System at the same time of delivery.

5.3.2. User Roles:

Blood bank secretary and laboratory technician are the users of delivery phase. Because of the electronic order procedure, blood bank information system requires one more user type as ward secretary from Hospital Information System.

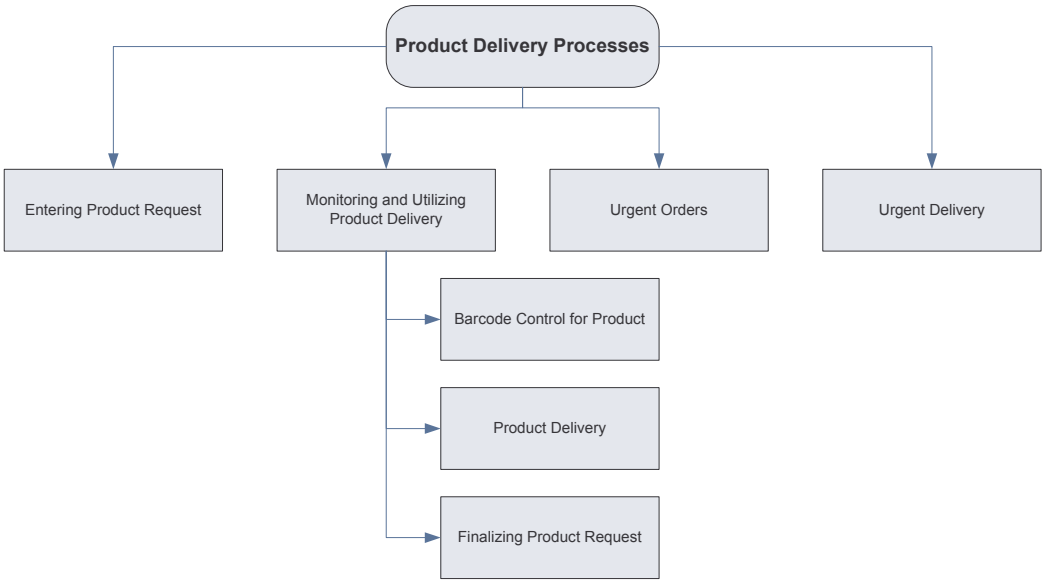

Figure 5. 25 User menu items for product delivery processes

5.3.2.1. Ward secretary:

Ward secretaries aren't active system users but ordering blood component is made by them. Hospital information system sends the order messages with the name of these users. In the HL7 order messages, the source of demand is recorded with the name of ward and secretary.

5.3.2.2. Blood Bank Secretary:

Order step starts after the patient blood specimen reaches to blood bank secretary. She checks the orders of patient and confirms requisition which is electronically transferred to blood bank information system. Laboratory technicians are informed about request meanwhile the crossmatch and order entry of secretary.

Delivery session closes with delivery of ordered components. Secretary enters the delivery information in the following manner. Number and type of blood components, blood bank personnel that is delivering products, personnel identifier that is transporting components, date and time of delivery. System also has an input form about transfusion success but in general no more information returns after delivery procedure.

The delivery phase menu elements available for blood bank secretary role are:

- Entering Product Orders
- Urgent Orders
- Monitoring Product Delivery
    - Barcode Control for Product
    - Product Delivery (Figure 5.26)

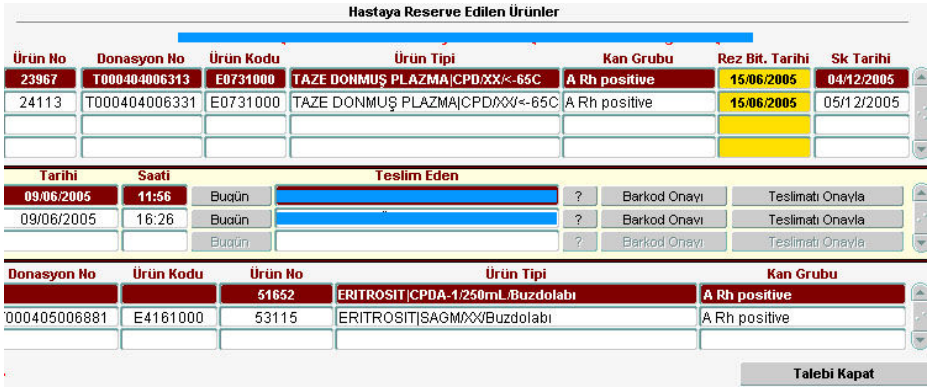

Figure 5. 26 Blood component delivery screen

    - Finalizing Product Request

- Urgent Orders Delivery

5.3.2.3. Laboratory Technicians:

Laboratory technicians are mostly interested in preparation of requested blood components to the patient. Reservation of blood component can be made in two different ways. In general, Red Blood Cell (RBC) and Whole Blood (WB) are reserved to patient after crossmatch tests applied. Blood component's bag is labeled with crossmatch acceptable or crossmatch incompatible labels. Other blood components reserved without crossmatch and labeled reservation without crossmatch label. Laboratory technicians are also has the role and menu elements of blood bank secretary.

5.4. Implementation of Custom Queries, Reports and Administrative Elements:

DEU Blood Bank Information System has many query screens, it allows the review of all testing performed in the laboratory, donation history or delivered products of the past days or weekend to be documented online rather than printing. But users and hospital management still prefers print out reports rather than reducing the paper used.

Service or ward physicians and secretaries can on-line query the specific blood samples investigations from intranet. How many blood components prepared, how many products are available for patients' usage all can be queried by using intranet web pages. Requirements of Turkish Minister of Health are provided and reported by using custom statistical queries; stock movements, summary of monthly laboratory and product processes are listed every month.

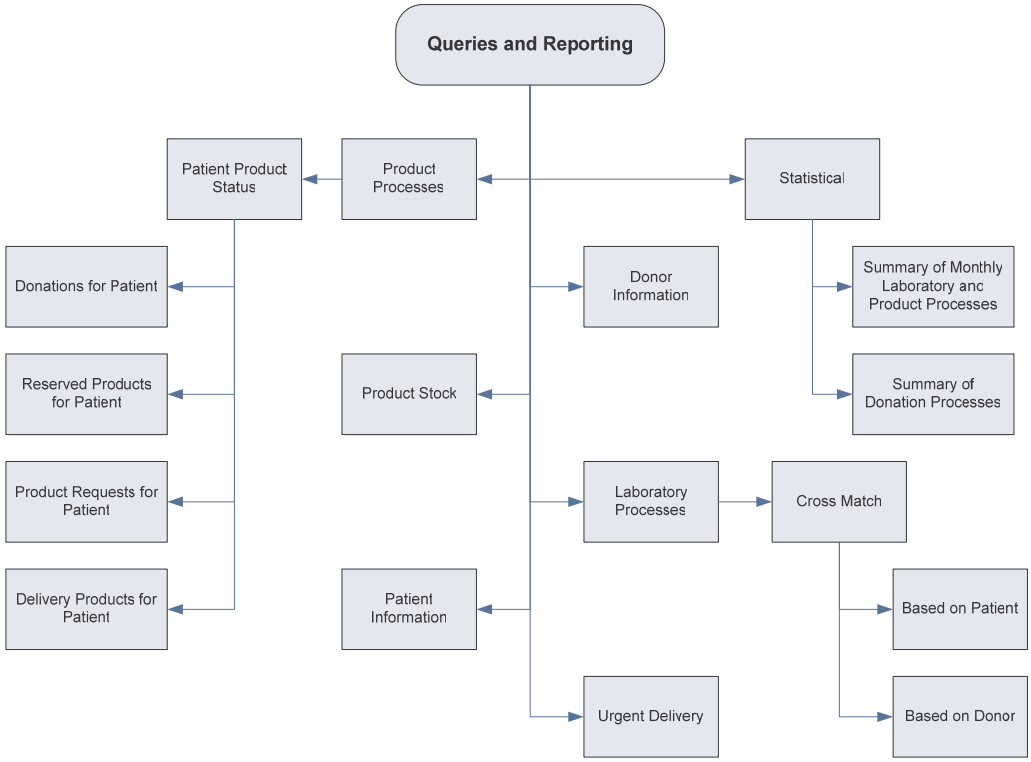

Figure 5. 27 Available menu items about querying and reporting

Free, reserved or quarantine component stock, wasted components, performance of system users, and error rate of staff, medical history of donations and donors, day time work load management, urgent or routine delivery procedures, audit trails all can be traceable at any time from Blood Bank Information System.

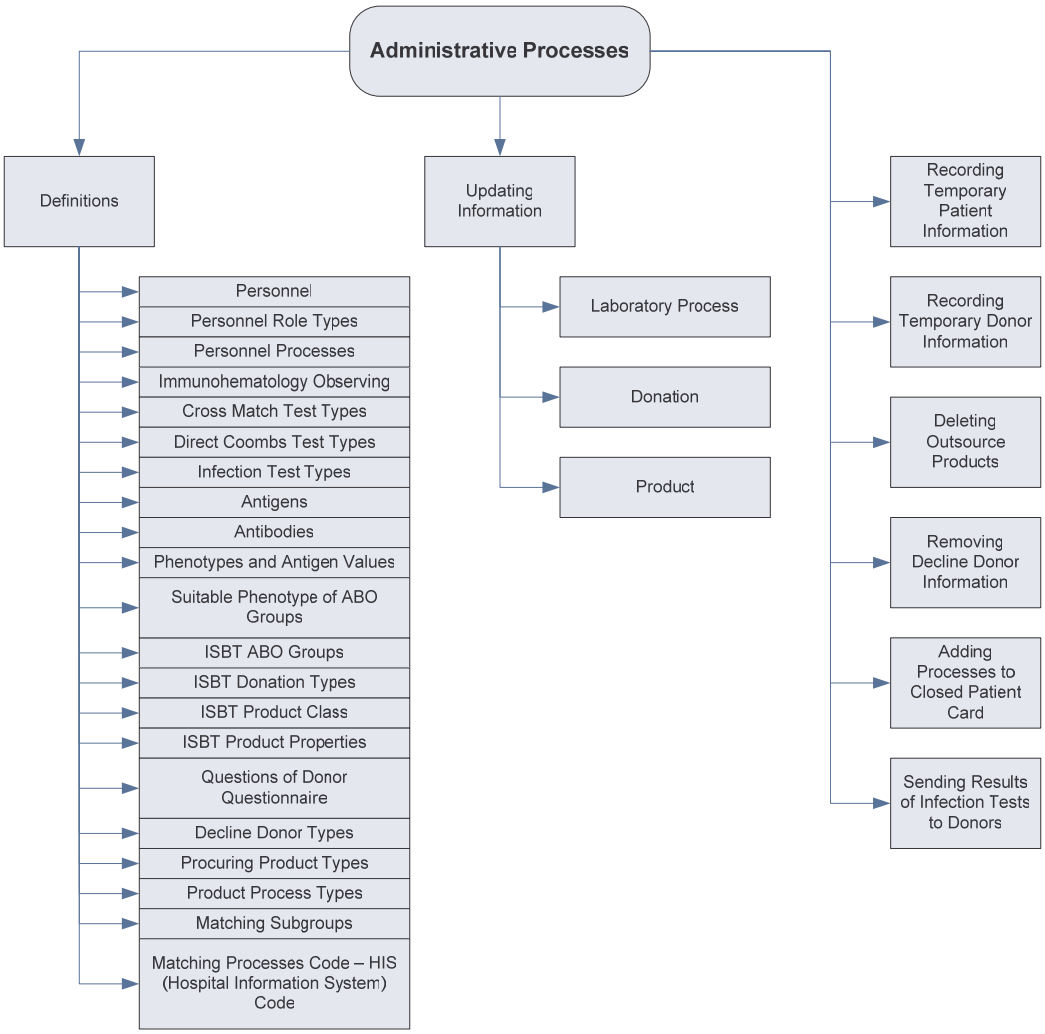

Figure 5. 28 Administrative roles

The role, system administrator is defined for correction or modification requirements. These users are well-informed about modeling of system. System holds both previous and updated values of corrected fields. Also date time of correction, who is responsible from this modification all these information is stored inside log tables. System administrators also define new categories or fields for any investigation.

CHAPTER SIX
CONCLUSION

All transfusion services and blood related associations agree about the importance of computerization. But the meaning of computerization is varied not only among the countries but also within the same country or region. Till now, the most authorized organization of Turkish republic the ministry of health still didn't define the minimum requirements of such application software. Unfortunately, each blood center is using different, indiscriminate, un-standardized system. Especially home-made systems are providing the local requirements but they are so close for national or globally widening. That means it seems very difficult to integrate such systems to national or regional system without major costs.

DEU Blood Bank Application Software is developed under the guidance of international publications such as AABB, FDA and previous success stories of software companies. ISBT 128 labeling standard makes our blood bank globally registered. Using the error-checking features of ISBT 128 is providing to detect data-entry and labeling errors. ASTM E-1381 95 and ASTM E-1394 91 standards establish format for the message that must be sent from the host to the instrument and vice versa. The reliability of messaging between Blood bank information system and instrument is provided by check sum calculation. HL7 is another protocol that establishes message format for integrating hospital information system, laboratory information system and blood bank information system together.

DEU Blood Bank Management System Application Software provides reliable, stable, integrated and user friendly electronic data processing system.

Security issue is important for developing reliable system. The first layer of security issue is about authorization. User groups are defined and authorized according to roles of users. For instance; doctors are not interested in secretary forms, or system does not allow nurses to displaying laboratory related pages.

Secondary security issue is about levels of security for all tasks – view; view and enter; view, enter, modify and delete. Application software also provides audit trail for every modification or deletion routines. Original value, new value, originator identification, modifier identification and date and time of change are logged in audit trail routine. As a consequence, reliability and data integrity features of DEU Blood Bank Application Software are achieved by strong and two layered security issue.

Application software also provides many searching abilities for tracing of any blood component or specimen from donor to patient and vice versa. Patient related data tracing is starting with electronic ordering from wards. Blood bank staff searches and reports all processes related with either donor or patient specimen and blood components. Authorized ward staff also traces the state and the result of orders, reserved components etc. Complete transfusion cycle must be started with specimen collecting with unique identified labels, later on, ended with blood transfusion procedure at patient bed side or in operation theatre. Hand held machines may be used for pre-transfusion confirmation, hospital widened tube labeling may be installed for controlling full transfusion cycle. Meanwhile, I'm preparing thesis documentation; we are still trying to expand DEU Blood Bank Management Application Software to control full transfusion cycle.

In the future, additional modules can expand the features and capabilities of DEU Blood Bank Management System Application Software. For instance, today, aphaeresis unit and irradiation unit are controled with individual applications. After implementing aphaeresis and irradiation modules, units could be operated more systematically than manual effort. Integration requirements are also growing up with the coming of new devices. Optical separator machine, automated investigation devices will need to be integrated to our system.

Today it is not an only argument, it is also assert that DEU blood bank application software can be globally widen as a result of successfully implemented standards with all other computerized blood banking features.

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