

Integration or Disintegration of Transfusion Service Information



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DEPARTMENT OF PATHOLOGY

Objectives

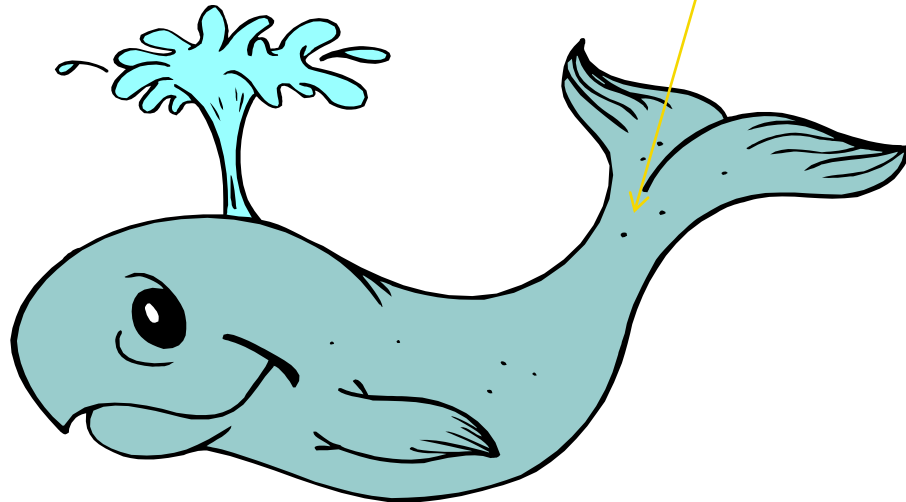
- 🔴 Define the current state
- 🔴 Identify deficiencies in software
- 🔴 Suggest changes that will improve transfusion documentation

Disclaimer

- 🔴 I am not describing any specific systems
- 🔴 I am speaking in general terms
- 🔴 Software is constantly changing
- 🔴 I speak from my personal experiences and from those of my colleagues at other institutions
- 🔴 Only the vendor can describe the current and potential functionality and capabilities of their system(s)

Transfusion Services

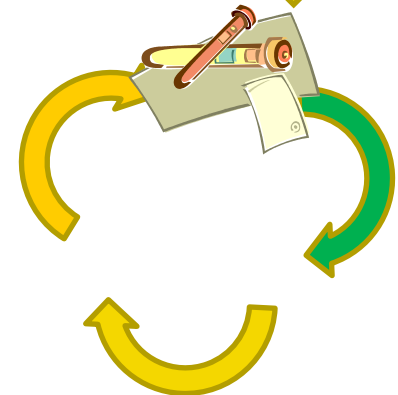
- Are costly
- Don't make money
- Lack significant consultation fees
- Highly regulated



System Wish List

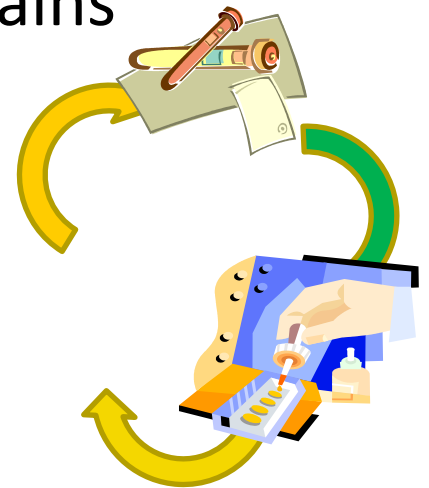


- 🔴 Tracking from patient specimen collection through the system and unit back to patient
 - Patient correctly identified at any time they interaction with the healthcare system
 - Patient identification system used
 - Barcoded specimen label created at the bedside
 - Label placed on tube at the bedside
 - Phlebotomist ID traceable



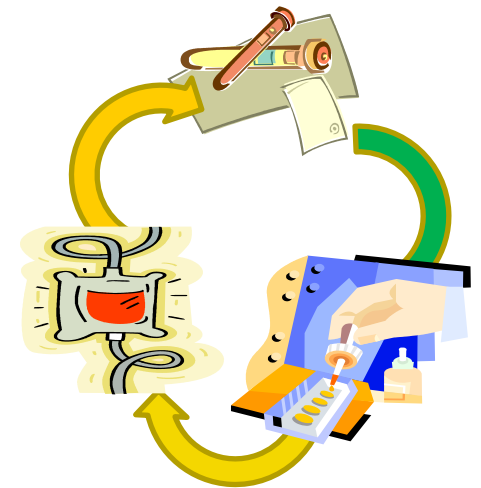
Wish List -2

- Barcoded label used throughout processing
 - Receipt in lab
 - Automated testing
 - Manual testing
- Software designed to prevent data entry errors
- Transfusion record form/ID tag contains barcoded information
- Unit labeling verified at dispense



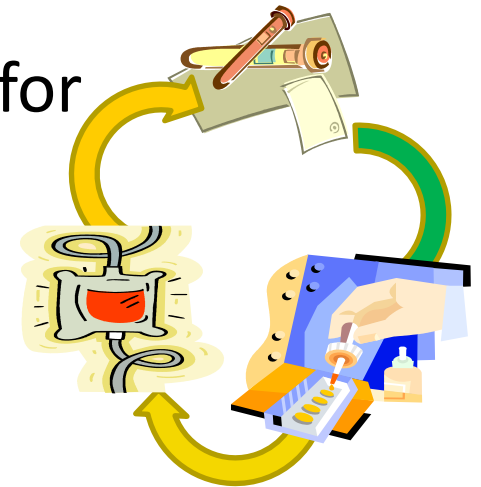
Wish List -3

- Patient/Unit/Compatibility verified at the bedside
- Transfusion Service software talks to software doing the verification process
 - Double verification
 - Patient ID
 - Unit/product
 - Transfusion record form contains barcoded information



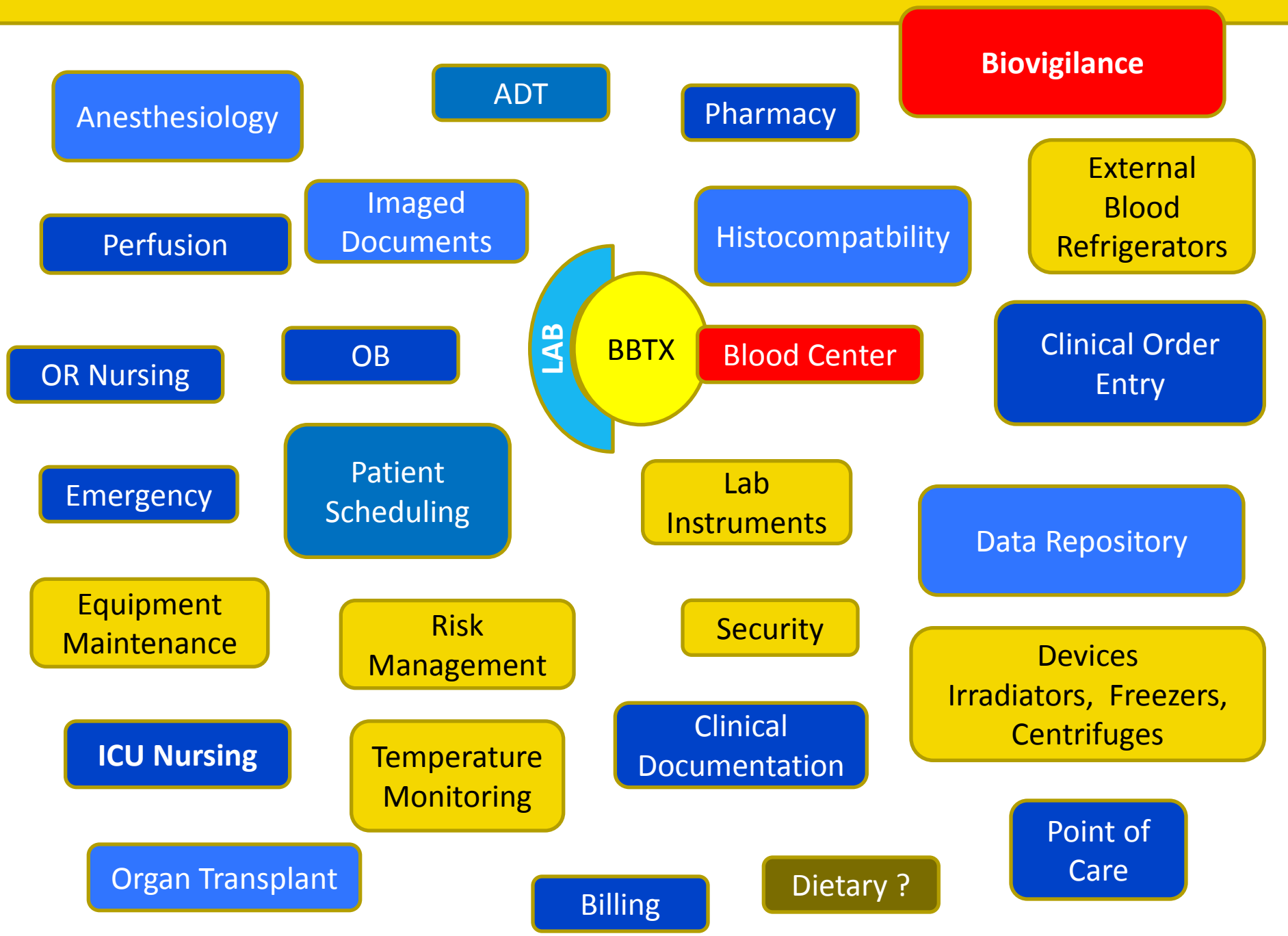
Wish List -4

- Vital signs and transfusion documentation in the electronic patient medical record
- Transfusion information sent back to the transfusion service information system
- Transfusion service information system records the date/time and final disposition of the unit
- Data can be collected and analyzed for utilization review, biovigilance, regulatory reporting



Customers

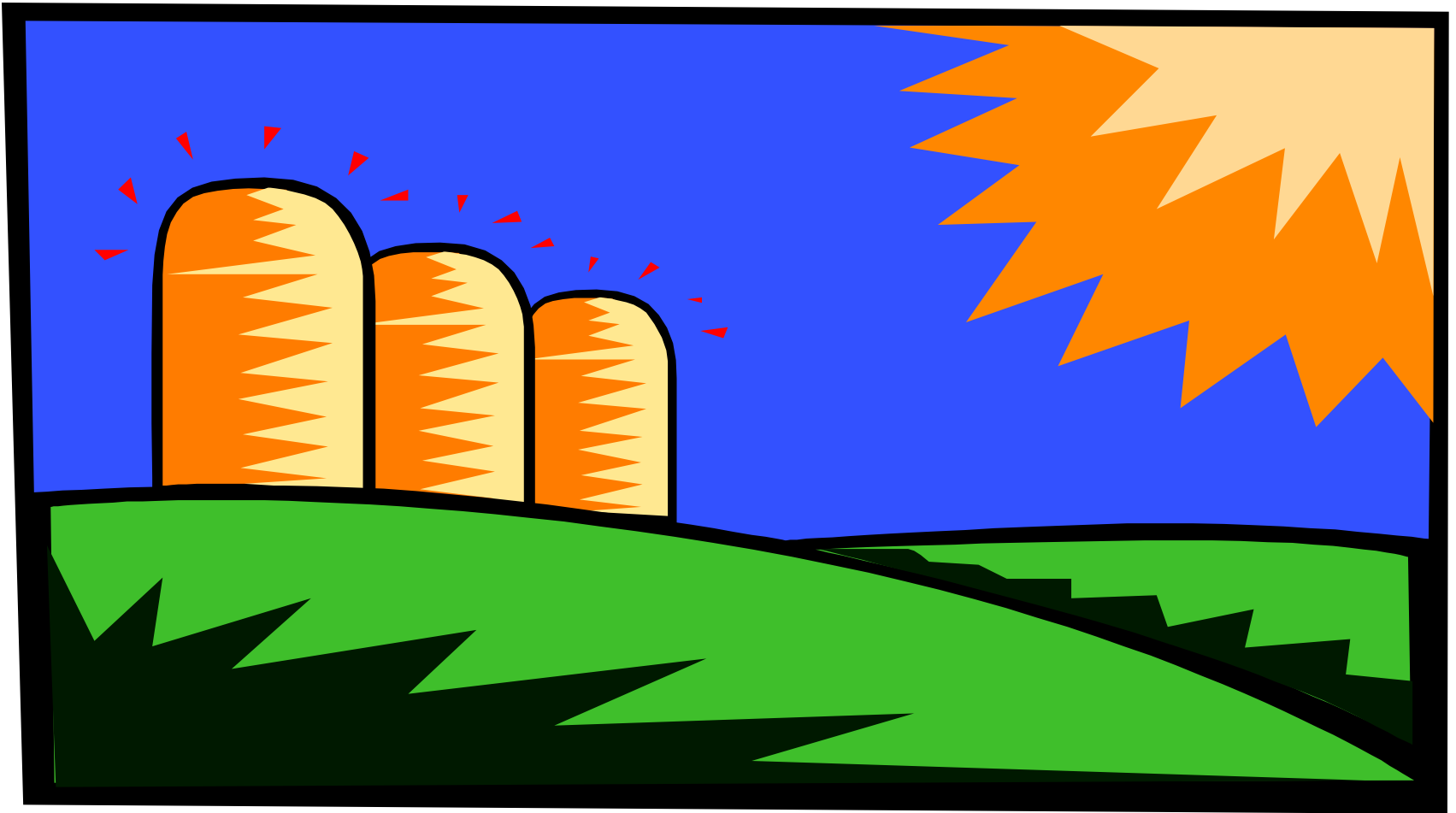
- 🔴 Patients
- 🔴 Physicians
- 🔴 Nurses
- 🔴 Clerks
- 🔴 Transfusion service staff
- 🔴 Billing
- 🔴 Quality management
- 🔴 Regulatory agencies



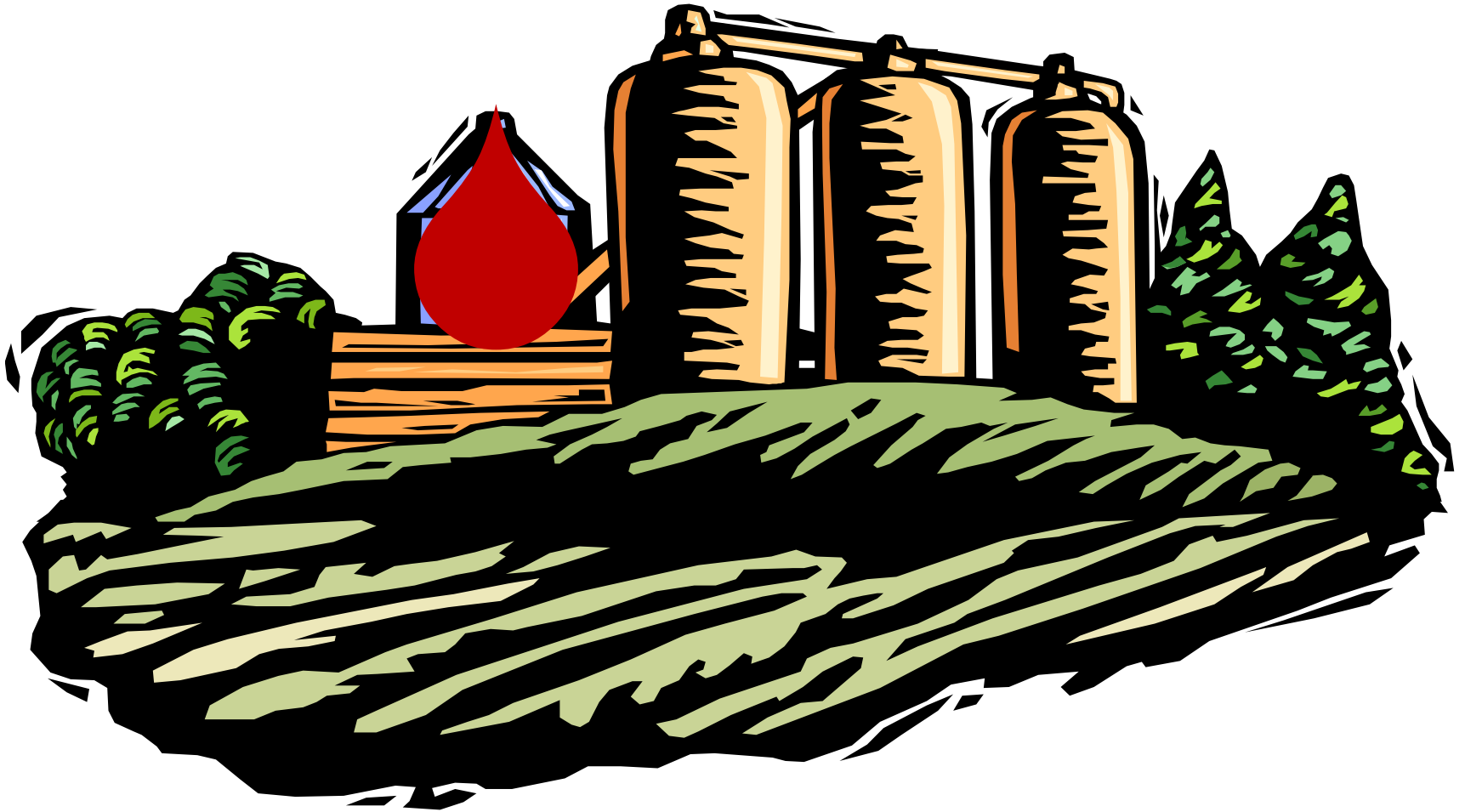
Needs

- 🔴 Genetic testing
 - Sickle/thal
 - Hard to crossmatch
- 🔴 Imaging
- 🔴 Type fonts a person over 40 can easily read
 - Fatter fonts
 - Good use of white space
 - Popups to avoid scrolling

Silos



Connected Silos



Looks Connected

BUTCHS (Butch, Suzanne)

[NEWS](#) | [Help](#) | [Support](#) | [My CareWeb](#) | [References](#) | [Logout](#)

- Inbox (---)
- Schedule
- Inpatient Tools
- Caregiver Search
- Patient Search
- Patient Lists
- SELECT PATIENT LIST
- TEST, ABNORMAL TTT
92011057 - Age: 49 Years
- PSL/SocHx/FamHx
- Inpatient Care Team
- Demographics
- Appointments/Visits
- Documents
- Lab
- Rad/Nuc
- Other Results
- Infusion Center
- Immunizations
- Inpt. Med. Profile
- ED Inpt. Periop
- Continuity
- Forms

Reg#: 92011057
Name: TEST, ABNORMAL TTT
DOB: 01/01/1962
Sex: F
Age: 49 Years
User Name: BUTCHS

Demographics (from most recent visit)

Patient Information:

Address:

City:

State: Zip:

County:

Country:

SS#: [View Full SSN](#)

Risk Code:

Isolation Type:

Race:

Language for Health Care:

Religion:

Marital Status:

Maiden Name:

Mother's Name:

Father's Name:

Tel# - Primary:
Work:

Next of Kin: ()

Tel# (Home):

Tel# (Work):

Address:

City:

State: Zip:

Country:

Emergency Contact: ()

Tel# (Home):

Tel# (Work):

Visit Information:

No Data Found

Visit Caregiver Information [PCP / Referring Summary](#) | [Visits](#)

Visit Role	Doctor#	Name	Tel.	Visit#
No Data Found				

Visit Insurance Information

Company	Start	Expire	COB	Insured Name
No Data Found				

Inpatient Information: Not currently an inpatient in UMH

Multiple Systems One “Dashboard”

🔴 Not all here

– OB

– Intraoperative Nursing Notes

The screenshot shows a vertical medical dashboard interface. At the top, it identifies the user as 'BUTCHS (Butch, Suzan)'. Below this is a list of yellow buttons for navigation: 'Inbox (--/--)', 'Schedule', 'Inpatient Tools', 'Caregiver Search', 'Patient Search', and 'Patient Lists'. There are two dropdown menus, one labeled 'SELECT PATIENT LIST'. Below these is a section for a specific patient: 'TEST, ABNORMAL TTT' with ID '92011057- Age: 49 Years'. This section contains a list of blue buttons for patient-specific actions: 'PSL/SocHx/FamHx', 'Inpatient Care Team', 'Demographics', 'Appointments/Visits', 'Documents', 'Lab', 'Rad/Nuc', 'Other Results', 'Infusion Center', 'Immunizations', 'Inpt. Med. Profile', 'ED', 'Inpt.', 'Periop', 'Continuity', and 'Forms'.

Attempts at Connections

- 🔴 Instrument interfaces
 - Older standards based on ASTM or European coding systems
- 🔴 HL-7
 - Expanding to include donor center data
- 🔴 LOINC
- 🔴 Codabar, ISBT 128

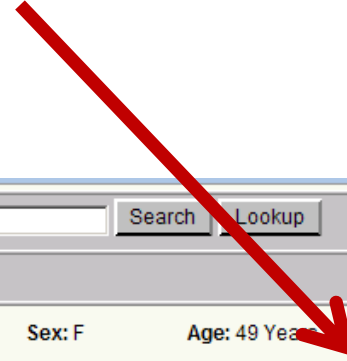
TX2 PRBC ASAP

- 🔴 Multiple clicks after identifying the correct patient
- 🔴 Order specimen collection
- 🔴 Order for products dumps in the blood bank – does not write an order in the LIS
- 🔴 Does not order a crossmatch
- 🔴 Send blood request from nurse

Question

- How do I find out how much blood was transfused to my patient?
- Answer:
 - Count the paper records in the medical chart
 - Wait for the paper records to be scanned
 - Look in the Emergency Department computer system
 - Look in the nursing notes for the inpatient visit
 - Look in the records of five different databases
 - Call the Blood Bank
 - Presumed transfused

Attempt to Give Information



Search:

Shown from(mm/dd/yyyy):

Reg#: 92011057 Name: TEST, ABNORMAL TTT DOB: 01/01/1962 Sex: F Age: 49 Years User Name: BUTCHS

Blood Components Issued | [Pathology Handbook](#)

ACCN Number	Order Test Code	Order Test Name	Last Updated	Print
ACCN: 11-083-03389 Collected:03/24/2011 09:01	BBC	BLOOD BANK COMMENTS	Updated:03/24/2011 09:04	<input type="checkbox"/>
BLOOD BANK COMMENTS Source: Recommend using washed Red Blood Cells to prevent future reactions to plasma proteins.				
ACCN: 11-083-03389 Collected:03/24/2011 09:01	COMP CONS	COMPONENT CONSULTATION	Ordered:03/24/2011 09:01	<input type="checkbox"/>

Reg#: 92011057 Name: TEST, ABNORMAL TTT DOB: 01/01/1962 Sex: F Age: 49 Years User Name: BUTCHS

IMPORTANT:

Patient may not have received units; units may be in a cooler or refrigerator

If you have any questions regarding the data on this page, please call the Blood Bank at 6-6888.

Summary of Units Issued and Not Returned in the last 24 hours:

Unit Type	Units Issued
No Data Found	

List of Units Issued and Not Returned in the last 24 hours: [Product Abbreviations](#)

Unit Number	Product	Category	Volume (mL)	Date/Time of Status
No Data Found				

Summary of Components Issued and Not Returned since 09/23/2011:

Unit Type	Units Issued
No Data Found	

Close

Question

From Pathology Resident

- A call has come in from the donor center concerning an apheresis platelet from a double collection
- A patient at another facility has what could be a reaction from a the transfusion of a bacterially contaminated unit
- Was the unit transfused?
- To whom?
- When?

Question

- 🔴 From the Medical Records: Hard to tell
 - We know when it left the blood bank and to whom it was assigned
 - When was the unit transfused?
 - When the transfusion was entered into the patient record – Maybe
 - Two people signed the paper transfusion record form but no date/time
 - Dated and timed on-line Anesthesia record says “1 unit of platelets” but no specific unit number

What Really Happened

- 🔴 It's actually not transfused
- 🔴 It was found the following morning without its accompanying transfusion record form improperly stored in the ICU blood refrigerator
- 🔴 Massive transfusion: documentation takes place after the fact on forms removed from the units in a batch

Question

- 🔴 The head of the transplant department wants to know how many units were transfused and the age of the units at the time of transfusion.
- 🔴 Can you send this information to merge with their data base?

Answer: No

- 🔴 Date of collection is not in the database for units received from the blood supplier
- 🔴 Future:
 - File sent from blood supplier to hospital with all needed information
 - Receiving system has a place to put the data
 - Only barcode to read is the unit number not all of the barcodes on the unit to receive the unit or
 - Scan box with RFID reader

Question

Asked by Chief Medical Officer of the Institution

- 🔴 Can the new Pharmacy medications administration system be used for transfusion documentation?
- 🔴 Answer: No
 - The NDC number on the drug is unlike the barcode on the blood components
 - Different software needs for data capture
 - The dreaded 510k process – specifically avoided blood component application

Question

- Can the person who collected the specimen be **reliably** determined?
- Answer: Not really
 - The system records a name of a person printing a label
 - This may or may not be the person who actually collected the unit
 - Where the label prints is critical
 - The further away from the patient the label prints the more likely the label is inaccurate

Impediments

- 🔴 Lack of contemporaneous record keeping
- 🔴 Actual transfusion date and time is not in the database
- 🔴 Barcode technology – Codabar still used & ISBT 128 not readable by all software
- 🔴 Collection date is not in the database
- 🔴 Information is dynamic and not static
- 🔴 Imaged documents are not searchable

Regulations

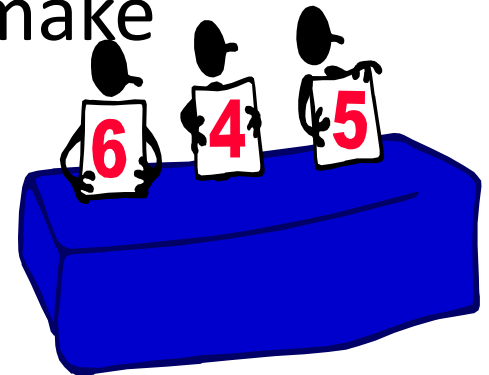
- 🔴 Premarket Notification (PMN) - also called 510(k) Medical Device Submissions
- 🔴 Section 510(k) of the Food, Drug and Cosmetic Act requires device manufacturers who must register, to notify FDA of their intent to market a medical device at least 90 days in advance.

Premarket Notification If

- 🔴 Intend to introduce a device into commercial distribution for the first time or
- 🔴 Reintroduce a device that will be significantly changed or modified to the extent that its safety or effectiveness could be affected
- 🔴 Change or modification could relate to the design, material, chemical composition, energy source, manufacturing process, or intended use

SEC. 513. [21 USC §360c]

- 🔥 Under section FDA must classify devices into one of three regulatory classes
- 🔥 Class I- general controls are sufficient
- 🔥 Class II- special controls
- 🔥 Class III- premarket approval
- 🔥 Classification panel convened to make determinations



Class III

- If
 - there is insufficient information
 - the device is a life-sustaining or life-supporting device or
 - is for a use which is of substantial importance in preventing impairment of human health, or
 - presents a potential unreasonable risk of illness or injury

Equivalent Device

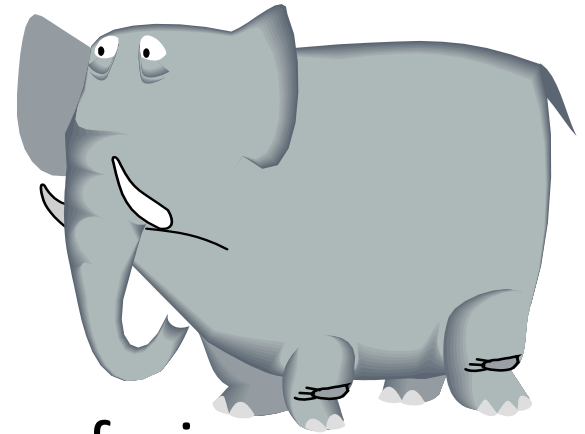
- 🔴 “New” devices (not in commercial distribution prior to May 28, 1976)
- 🔴 Equivalent to a device already placed into one of the three classification categories
- 🔴 CDRH Substantially Equivalent 510(k)s are available ~ the 5th of each month



Equivalent to ?



What class is it?



- Does it need a 510k?
 - Is it integrated with the blood transfusion laboratory software?
 - Does it perform a control function?
 - Does it report back to the blood transfusion laboratory software?

Does it Have a 510 (k)?

Source: CAP Today July 2011 Issue

Vendor	Was 510K obtained?
Cerner Bridge	Yes
Cerner Millennium	Yes
Endur ID	-
Iatric Systems	Unnecessary
Korchek Technologies	Yes
Lattice	Unnecessary
McKesson – Horizon	Unnecessary
SCC Soft Computer – SoftID	Unnecessary
SCC Soft Computer – SoftID-Tx	Yes
Siemens Healthcare Patient Identification Check	Yes
Sunquest Collection Manager /Transfusion Manager	Yes

Institute of Medicine

- 🔴 The 510k
 - “The underlying assumption is that if a new device is equivalent to a previous similar device, it will be at least as safe and effective as that device”
- 🔴 Recommendation to eliminate the [510\(k\)](#) clearance process for medical devices
- 🔴 Establish and implement [post-market surveillance systems](#)

510k Process Drawbacks

- 🔴 Separation of blood bank software
- 🔴 Lack of vendors
- 🔴 Reluctance/slowdown of process to make modifications
- 🔴 Multiple interfaces to other systems
- 🔴 In summary: the 510k process fails to provide the intended protection and inhibits advancement

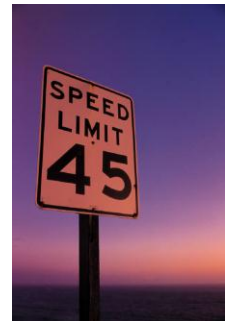
Lack of Standardization

- 🔴 Transfusion service operations are quite variable
- 🔴 Software may not accept data in the manner it is provided
- 🔴 Limited error prevention



Lack of Standardization

- 🔴 How do I know this is the same patient?
- 🔴 Interfaces between Transfusion Service software and devices may be limited or not available
 - Humans make decisions on what to include in the interface
 - Work-arounds – screen scrapes to transfer data



Lack of Process Controls

- 🔴 Identification of the person performing each significant step in the process
- 🔴 Inventory and Lot number control lacking
- 🔴 Temperatures & humidity
- 🔴 Equipment used
- 🔴 Reagents used

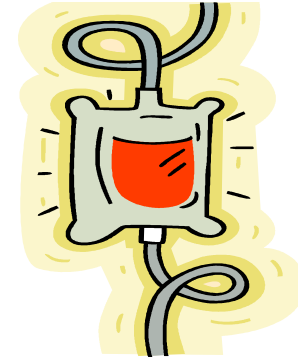
21 CFR 606.121(c)(13)

Container Labeling

- 🔴 Machine readable
 - Unique facility identifier
 - Lot number relating to the donor
 - Product Code
 - ABO and Rh of the donor
 - Must be unique to the blood or blood component
- 🔴 Approved symbology (Codabar, *ISBT-128*)

What's on the Unit?

- Blood Bag Label
 - Codabar
 - *ISBT-128*
- Patient Identification Label or Tag
 - Recipient's two identifiers
 - Donation identification number or pool number
 - Interpretation of compatibility tests, if performed



Codabar

🔴 Red Cross Unit Numbers

– **NNAANNNNN**

- **N** = Number
- **A** = Alpha

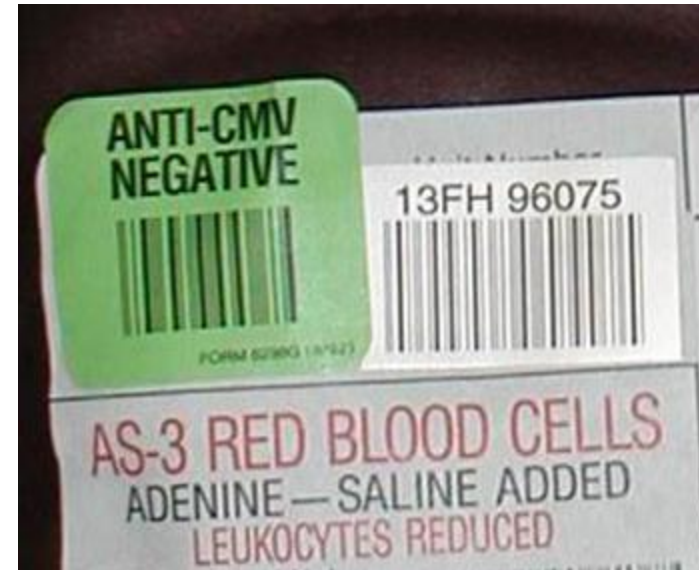
🔴 Eye Readable

- Prefix + Alphas converted from numbers + 5 digits
- Donation site ID barcode is in the bottom right

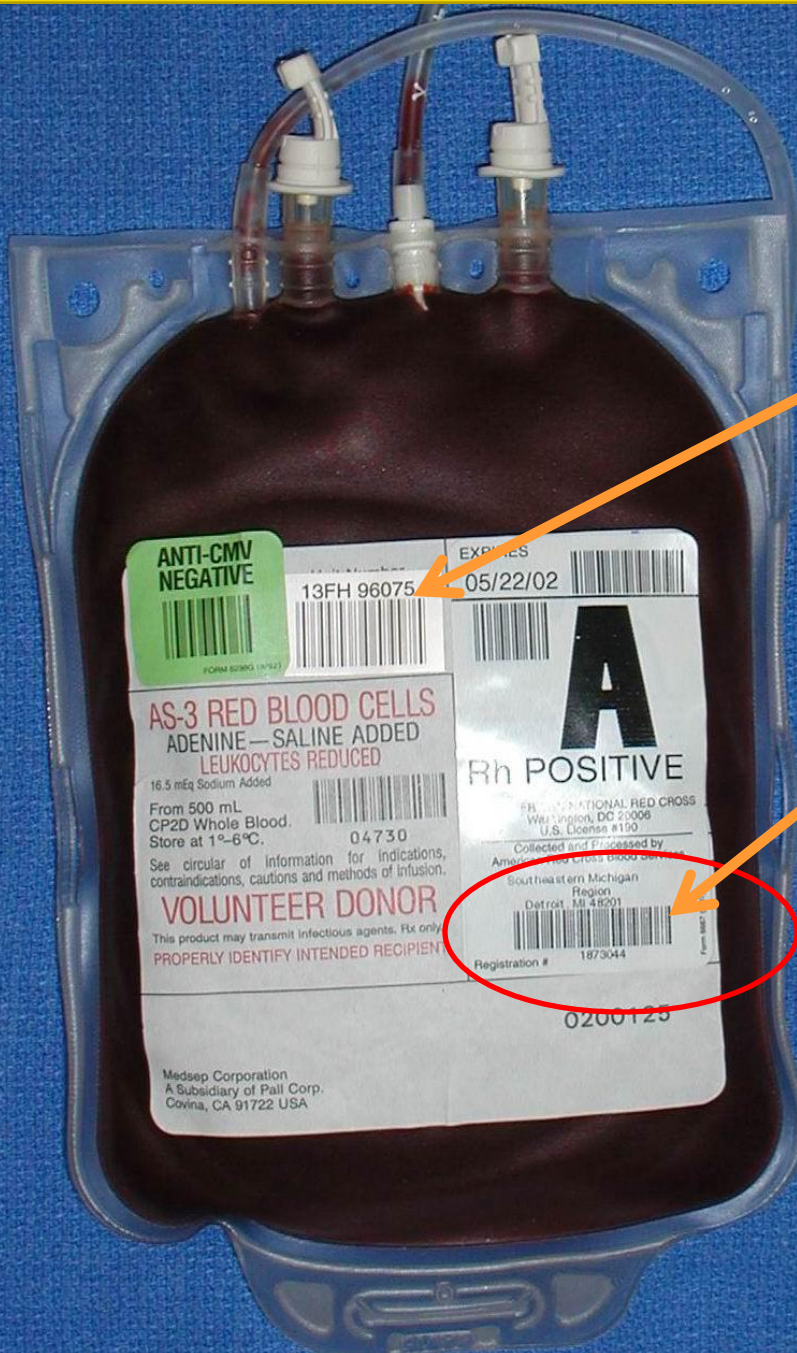
🔴 In the unit number barcode

– **Start Code** + Numbers + **Stop Code**
A2496075D

Where the number 24 is converted to FH



Unit Number
A2496075D
FH96075



Supplier Prefix


21 CFR 606.140 (c)

Laboratory Controls

- Adequate identification and handling of all test samples so that they are accurately related to the specific unit of product being tested, or to its donor, or to the specific recipient, where applicable.



How Is A Patient Identified?

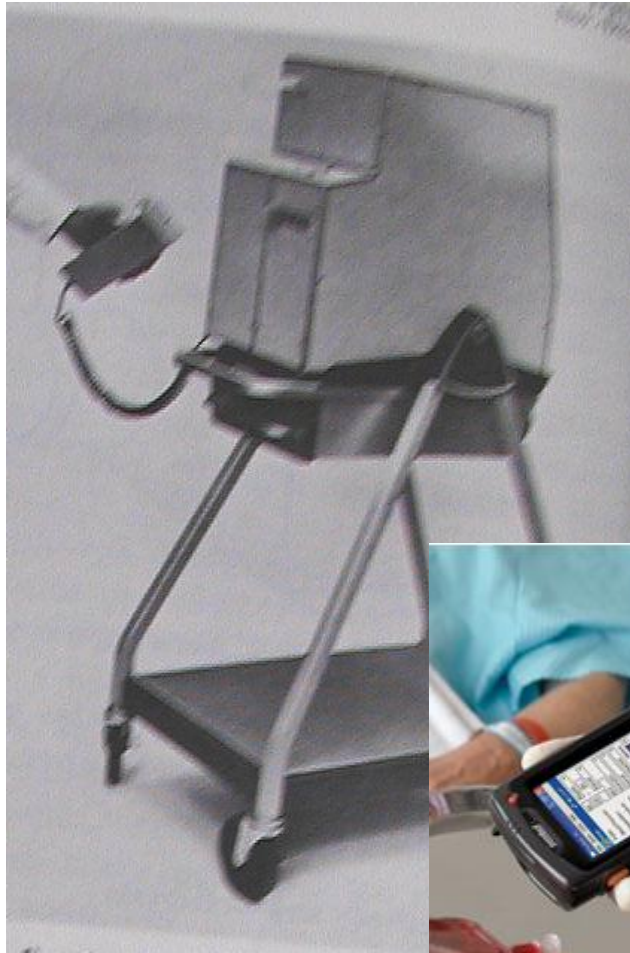
- Name
- Birthdate
- Medical Record Number
- Encounter/visit/billing number
- Case number – OR software
-  **Bed number**

Medical Record Number

- ❖ Lacking a Social Security Number or national patient identifying number facilities must assign their own identifying number.
- ❖ Must do a history check for antibodies and serious reactions before transfusion
- ❖ A name searches set up the potential for errors



Newest Technology?



UNIVERSITY MEDICAL CENTER

LIBERTYVILLE, IL

Developed by Healthcare-ID, Inc. (708) 367-2223

CUMMINGS, LINDA J 10/13/57 F

DR. WM. FLEMMING 02/25/95



A12345

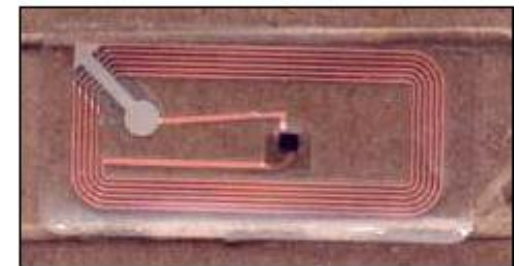
What's on the Wristband?

- Eye readable
 - Patient Full Name
 - Patient birthday
 - Patient “visit or billing” number
 - Patient permanent medical record number
- Barcode readable
 - Patient medical record number?
 - Patient “visit or billing” number?
 - Both (2-D)
 - All patient information (2-D)



Barcodes

- 🔴 Have data identifiers (location identifiers)
 - Wristband
 - Specimen tube
 - Paper record label
 - Transfusion record form
 - Blood Unit
 - Employee ID
 - Others



The Joint Commission (TJC)

- 🔴 Folks outside the laboratory care about TJC
- 🔴 National Patient Safety Goals
- 🔴 Label at the bedside
- 🔴 NPSG.01.01.01.02
 - Label containers used for blood and other specimens in the presence of the patient. (See also NPSG.01.03.01, EP 1)

TJC - Use Two Identifiers

- 🔴 NPSG.01.01.01.01
 - Use at least two patient identifiers when administering medications, blood, or blood components; when collecting blood samples and other specimens for clinical testing; and when providing treatments or procedures.
 - The patient's room number or physical location is not used as an identifier. (See also MM.05.01.09, EPs 8 and 11; NPSG.01.03.01, EP 1)

TJC National Patient Safety Goal

- NPSG.01.03.01.01
 - Before initiating a blood or blood component transfusion:
 - Match the blood or blood component to the order.
 - Match the patient to the blood or blood component.
 - Use a two-person verification process or a one-person verification process accompanied by automated identification technology, such as bar coding.
- (See also NPSG.01.01.01, EPs 1 and 2)

CLSI Tube Label

🔴 Specimen/accession number

🔴 Human Readable Options

- Ordering physician (authorized prescriber)
- Test order name or number
- Collection priority: routine, stat
- Source of specimen (eg, nasal swab)
- Site of specimen (eg, left side of chest, leg wound)
- Space for instructions, or information (eg, keep at 4 °C)
- Temperature class
- Collection order of tubes
- Container size (eg, 5-mL)
- Container type (eg, lavender-top tube)
- Collection class: laboratory section (eg, hematology, immunology, where and to whom it is to be sent)

TRM.30575

Misidentification Risk



- The facility has a plan to implement a system to reduce the risk of mistransfusion for non-emergent red cell transfusions.
- *Note: The laboratory is expected to participate in the development of a plan to reduce these risks through implementation of a risk-reduction system.*
- *Among options that might be considered are:*
- *(1) Documenting the ABO group of the intended recipient on a second sample collected at a separate phlebotomy (including documentation in the institution's historical record);*

TRM.30575

Misidentification Risk



- *(2) Utilizing a mechanical barrier system or an electronic Identification verification system that ensures that the patient from whom the pretransfusion specimen was collected is the same patient who is about to be transfused.*
- *Other approaches capable of reducing the risk of mistransfusion may be used. The laboratory should participate in monitoring the effectiveness of the system that it implements.*
- *The laboratory should also consider improvements in procedures and/or educational efforts as part of its program to reduce the risk of mistransfusion.*

At the Patient Side

- 🔴 Universal Barcode (RFID) reader
- 🔴 Label Printer
- 🔴 Computer/hand held
 - With applications that can
 - Parse data into the correct fields
 - Provide useful warnings
 - Can be read by a person over 40



AABB


- Transfusionist must verify matching the blood unit and intended recipient
 - Two patient identifiers
 - ABO group & Rh of patient
 - Donation identification number, ABO group and Rh of donor
 - Interpretation of crossmatch tests
 - **Special transfusion requirements**
 - **Data may not be in the clinical database**
 - Expiration date/time of the unit

Electronic Crossmatch

- 🔴 1992
- 🔴 Use still less than hoped
- 🔴 Regulatory ineptness
- 🔴 Poorly written software



HIPPA

- Called other hospitals to obtain information about previous transfusions and problems
- Patient release of information form
- Call back through hospital switchboard
-  National registry of antibodies

Problem Summary

- 🔴 Data needed to assess blood transfusion effectiveness is scattered in multiple unlinked computer systems
- 🔴 The 510k process for premarket approval of Blood Bank and Transfusion Service software inhibits development and data integration
- 🔴 Current Transfusion Service software fails to assist the user in many functions

Recommendations

🔥 Federal Level

- Ditch the 510k system
- Foster software development

🔥 Transfusion Services

- Challenge vendors to
 - Allow easy data transfer
 - Improve their product to prevent errors
- Continue to emphasize safety over efficiency as a value

Vendors



- 🔴 Design to prevent errors
- 🔴 Making using the system easier than working around it
- 🔴 Design to capture cGMP steps
 - Accept information from devices
 - Adopt current data transfer standards
- 🔴 Design blood bank instruments to work on an automation line
- 🔴 Quit using the 510k process as an excuse for developing useable integrated software