
# Blood Bank LIS

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# Disclosures

Absolutely none

# Objectives

Discuss the regulatory aspects of the BB

Review unique aspects of the BB LIS

Explore the role of informatics to improve transfusion practice

# The Blood bank, does it matter?

- Transfusions are Commonly used
- Risky business
- Limited resource dependent on the goodwill of the public
- Expensive!
  - $ often in the millions even for a medium sized hospital.
  - Mean price of purchasing (n=213, 2011)
    - apheresis platelet ~$500-$600.
    - pRBC ~$200

# Similar to the rest of the lab

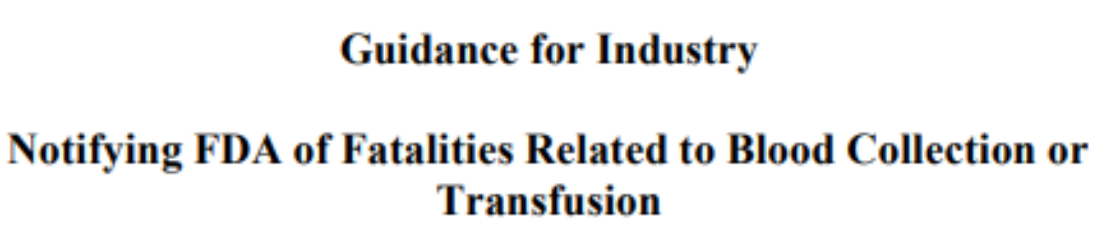
- We also struggle with many of the same issues as rest of the Clinical lab
- The never ending race for improved efficiency.
  - Cost constraints, higher workloads, shortage of qualified lab technologists.  All while improving turnaround times without compromising on quality and patient safety
- Increasing use of automation to handle the higher volumes.


# …But just a little bit different too

- CLIA and CAP are on our minds
- Another accreditation body: AABB, FACT
- Even PT- unlike the rest of the lab, we have to get 100%!
- But we have additional regulations: FDA



# FDA through CBER


Guidance for Industry

Notifying FDA of Fatalities Related to Blood Collection or Transfusion

- FDA regulates and ensures the safety of the blood supply by creating and enforcing standards for blood collection and transfusion.
- Center for Biologics Evaluation and Research (CBER) is the Center within FDA that regulates biological products for human use under applicable federal laws.
- MUST BE AWARE OF YOUR REPORTING REQUIREMENTS! Build this into your SOPs
- By law, Transfusion Related Fatalities and Donation Related Deaths have to be reported to CBER as soon as possible (initial notification)
- Must submit a report of investigation within 7 days after the fatality
- Biological product deviation must be filled out if safety, purity or potency is affected

# What products does CBER regulate?

- BLOOD: Blood and blood components used for transfusion, such as red blood cells, plasma, and platelets. Derivatives such as clotting factors and immunoglobulins.
- DEVICES: Medical devices and tests used to safeguard blood, blood components, and cellular products from HIV, hepatitis, syphilis, and other infectious agents. Reagents used to type blood, automated T&S instruments, automated cell separators, transfer sets, and blood storage refrigerators and freezers.
- Machines and related software used to collect blood and blood components.
  - The blood bank LIS is considered a medical device and must be 510(k) cleared

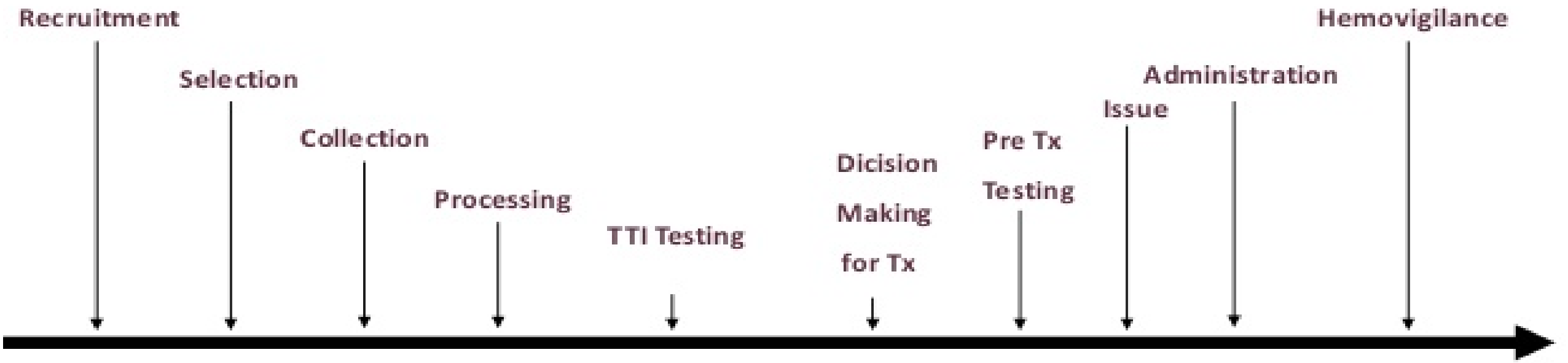
# What is ISBT 128?

- Since 2006, the FDA requires blood products to bear a machine-readable bar code. Both Codabar and ISBT 128
  - THE FDA requirements for labeling of blood components detailed in the Guidelines for Uniform Labeling of Blood and Blood components
- International barcode labeling standard for products of human origin
- allowing for better traceability of components (even across international lines), has built-in self checks for barcode read errors, and has a lower rate of misreads.
- AABB standard require the accredited facilities use of ISBT 128.
- FACT is moving in that direction

# Uses for BB- LIS

- Donor center: manufacturing process for determining donor eligibility and release of the blood component as suitable for transfusion
- Transfusion services: electronic crossmatch, compatibility testing and issuing a compatible unit
- Use to establish positive patient identification
- Use to perform other functions associated with transfusions, such as recording patient VS, tracking transfusion reactions, tracking blood products, inventory management, and recording QC

# Blood is not just a product! Transfusion therapy is a set of processes




LIS –ensure safe blood supply

LIS –ensure safe transfusion practice

## Blood Transfusion Safety

# A new blood bank LIS? Theres a guide for that!

- 2011 FDA guidance on validation:
  - Process Validation- defined as the collection and evaluation of data which establishes scientific evidence that a process is capable of consistently delivering a quality product.
- Establish user requirements- What do I need from the system
- Ensure the system performs correctly and consistently
- Continue to monitor performance


Free Access

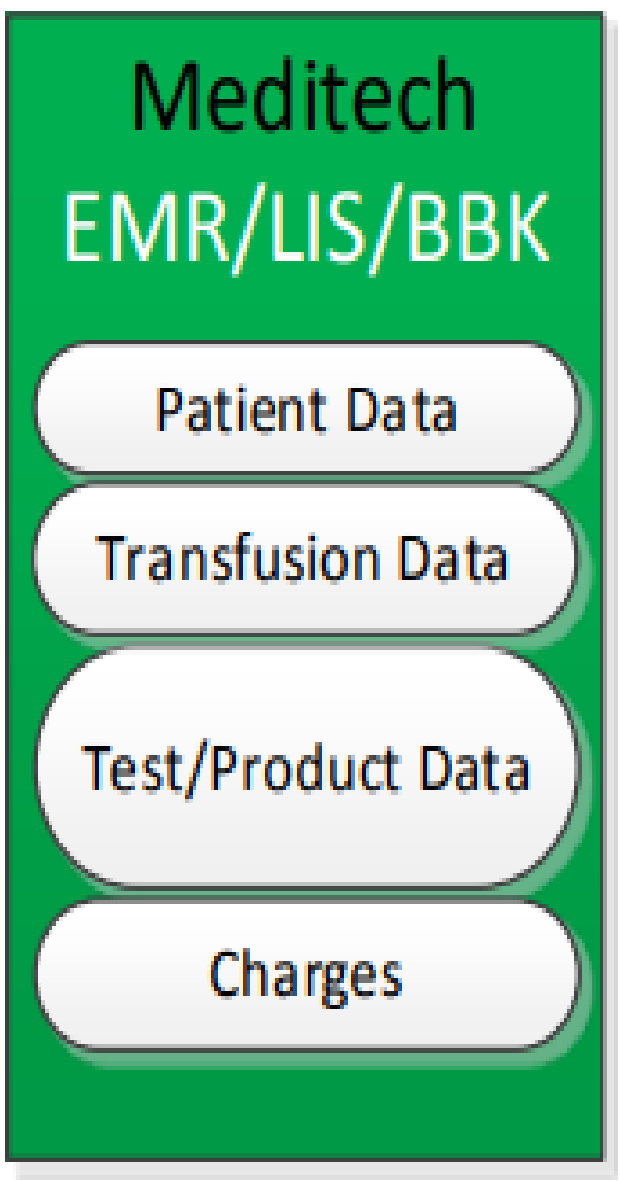
ISBT Guidelines for Validation of Automated Systems in Blood Establishments

# Considerations

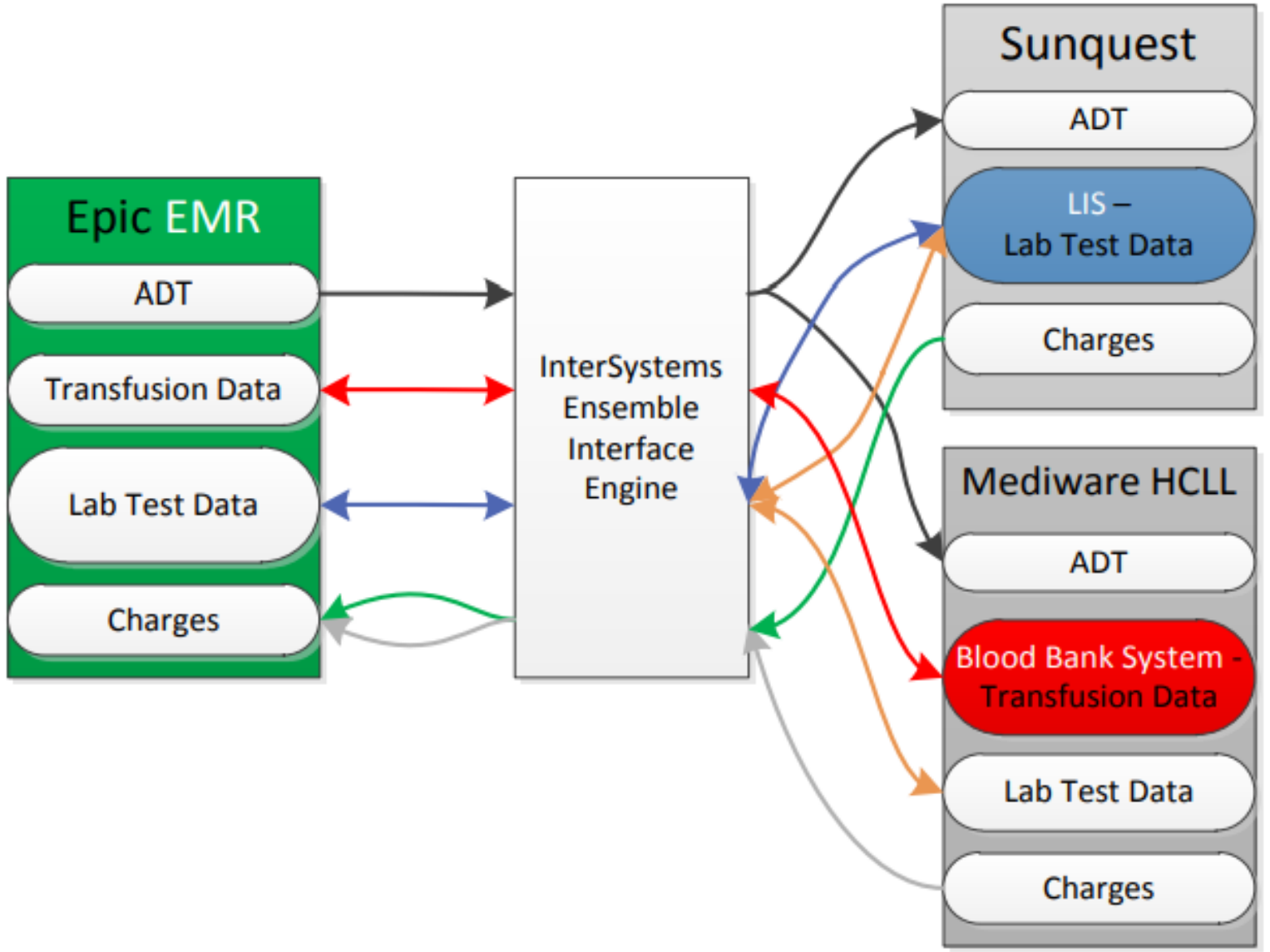
- Your needs today maybe different from your needs tomorrow- can the LIS accommodate
- How easy is it to interface this BBLIS with the instrument you are using/planning to use?
- How easy is it to interface this BBLIS with your Clinical lab LIS?
- Does the LIS have built in QC that is suitable for your own needs or will you have to continue your paper workflows?
- Data migration-AABB standards require certain BB testing results to be kept indefinitely- MAKE SURE You migrate this to your new LIS
  - Otherwise, you have to maintain the old system and your tech's have to search the old system for any data on that patient before they can issue any products for that patent

# Clinical situations and how they interact with your BBLIS:

- Clearly understand what your needs are from the system
- What is your patient population? Name change for unknown pt, must perform historical check
- Do you have a NICU- different type and crossmatch rules, different blood products
- Are you a pediatric hospital- how easy is it to base rules on age?
- Are you a busy trauma center- “unknown pt”-ffp?  Name change reports
- Do you have a Labor and delivery?- cord blood sample T&S-keeping mom and baby samples straight
- Intrauterine transfusions- the most special population you can think of! How does your BBLIS function to protect them?
- Sickle cell patients- special blood product requirements
- One BB providing transfusion testing for multiple satellite hospitals? Or one large hospita serving multiple special patient populations?

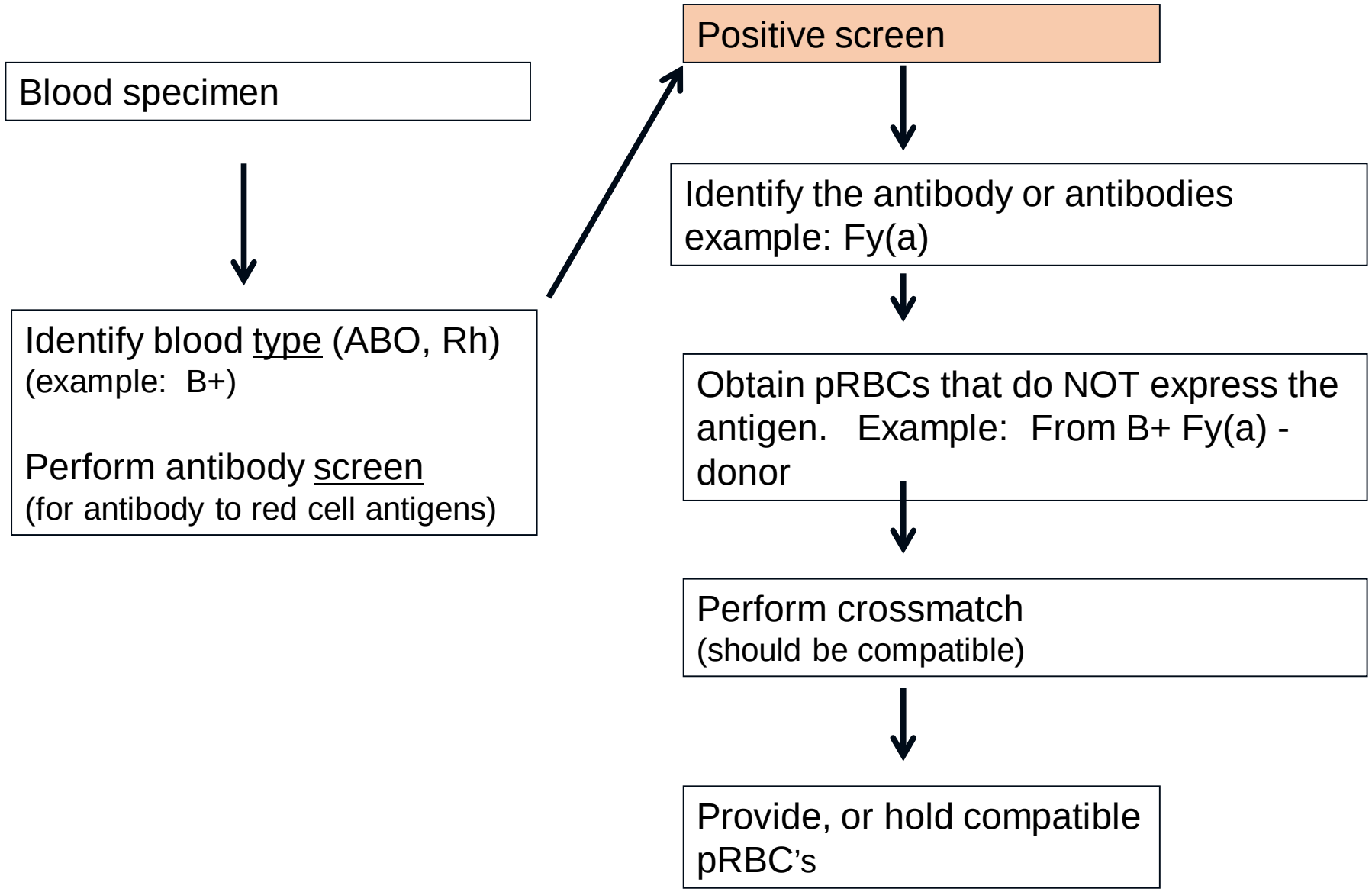



**OR**




http://www.healthnetconsulting.com/sites/default/files/HealthNET%20White%20Paper%20-%20Complex%20Landscape%20of%20Blood%20Bank%20Implementation_0.pdf

# How the BB provides compatible RBCs



# CPOE with CDS

- Select appropriate indication for transfusion
- Provide relevant laboratory data, (display hb, hct, reticulocyte count, plt count, fibrinogen, PT/INR, patient vitals)
- Limit to single unit pRBC or PLT orders for non-bleeding patients
- Ask relevant information (does the patient have sickle cell disease)
  - Special type of blood is issued to SCD patients, but your tehs can only provide that if they are made aware that the patient has that)
- Fire Alerts and track alert ignored rates
  - If order fails to meet preset criteria, fire an alert
  - Select why they decided to proceed anyway, or cancel the order that is out of institutional guidelines
  - Provide link to full institutional guidelines  evidence based articles Build order sets for special populations: intrauterine transfusion, neonatal transfusions
- Build order sets for red cell exchange (acute or chronic), TPE

# TOTAL BLOOD MANAGEMENT ALERT

The most recent haemoglobin level available for this patient is greater than 8g/dl, outside the OUH guidelines for administration of red blood cells based on evidence-based treatment for anaemia. Specific clinical conditions such as an acute ischemic event or acute on-going blood loss may justify a variation from the guideline. In the absence of these conditions, the risks of transfusion may exceed the benefits at this haemoglobin level. Please choose the appropriate action below to resolve this alert.

Alert Action

- Cancel Blood Transfusion Order
- Proceed with Blood Transfusion Order

OK

BestPractice Advisory

**This patient has a last measured hemoglobin result 7 g/dL or greater, or has no measured hemoglobin within the past 24 hours. In hemodynamically stable non-bleeding patients a hemoglobin threshold of 7 g/dL (or 8 g/dL with cardiovascular disease) decreases transfusion requirements and reduces adverse outcomes. ****Single unit transfusions are usually preferable. Please enter the indication for transfusion.****

Citations:

1. Hebert PC, et al. N Eng J Med 1999;340:409-17
2. Carson JL, et al. N Eng J Med 2011;365:2453-62

**Please choose an appropriate indication to proceed with transfusion.**
**OR**
**Check the box below to DISCONTINUE order.**

Last HGB=12.3 g/dL on 12/26/2016

Acknowledge reason:

Hemoglobin less than 8 g/dL with car... | Cardiac or cerebral ischemia | Active bleeding
Hemodynamically unstable | Symptomatic anemia (e.g. tachycardia,...
Specialized indication (e.g. cyanotic he... | Other (specify in comments)

Suggested for removal: Transfuse Leukoreduced RBC STAT, Transfuse 1 unit, Starting Today at 1202

# Creating a closed loop transfusion process- collection to transfusion

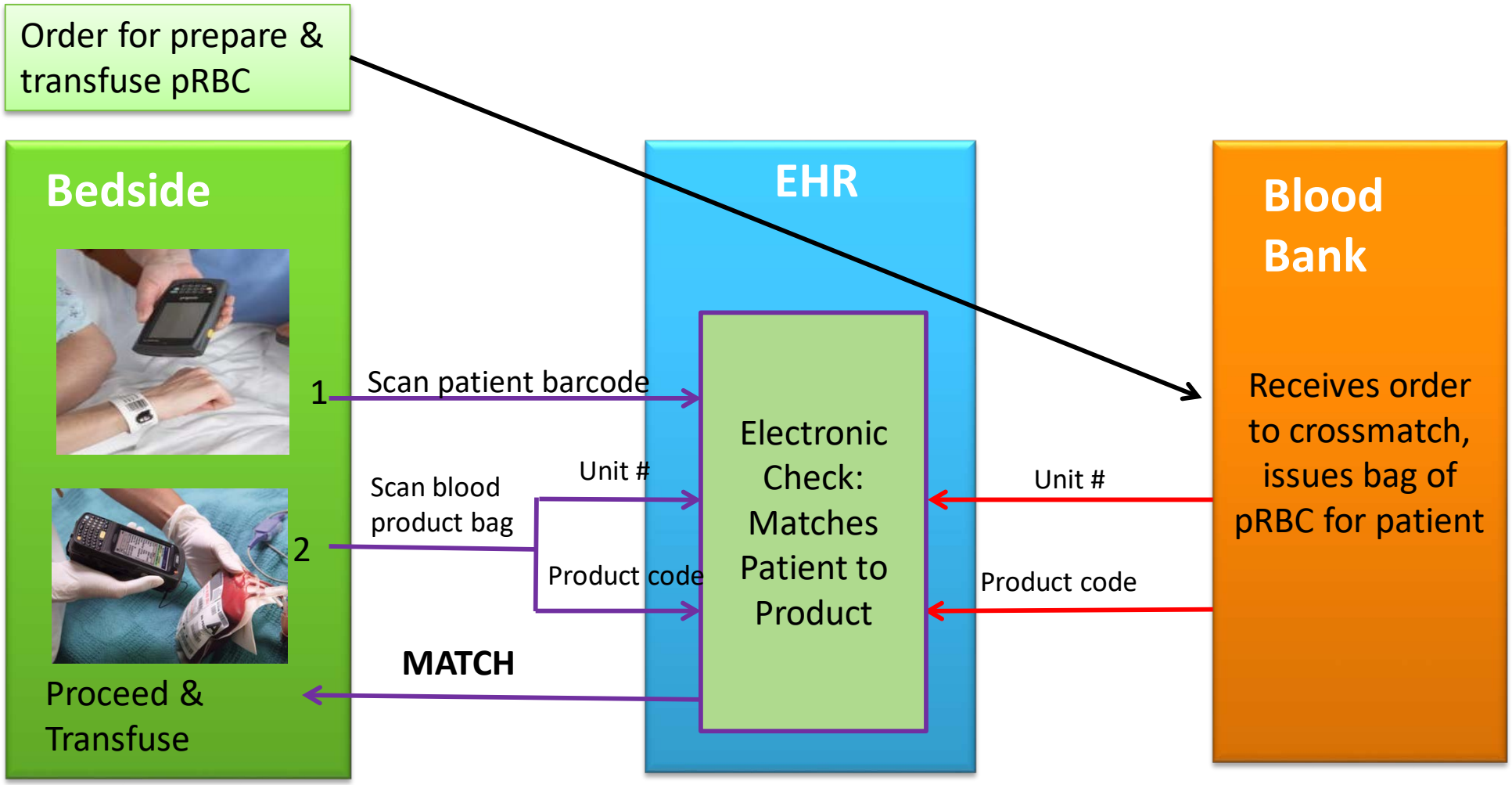
- From ensuring correct blood in tube to ensuring correct patient identification at bedside for blood administration.
- Often implemented to meet compliance with HIMSS level 6 and 7 certification
- HIMSS Stage 6 –Technology is used to verify blood products administration, Technology is used at point of care for specimen collection
- HIMSS Stage 7- Blood products & human milk included in closed loop med admin process

# PPID/ Transfusion Verification Systems

- Purpose: improve patient safety by electronically ensuring correct pairing of patient to a specific blood product
- Avoids possible ABO-incompatible transfusion
- Improve efficiency (second nurse verification not required per AABB)
- Uniquely Verify the patient:
- Uniquely Verify the product: based **unit number** and **product code**
- Ensure product was allocated by BB-LIS to the patient prior to transfusion
- **Alert** the user if the product is **not** allocated to the patient

** Slide taken from PPID Presentation at PI2017

# PPID- BA Workflow Diagram




Allows documentation: match, vitals, completion, transfusion reactions

# Bad things happen when proper transfusion procedures are not followed!

## Filipina nurse who killed a pensioner when she mixed up his name with another patient and gave him the wrong blood during a transfusion is facing jail

- Lea Ledesma was working at London Heart Hospital as a nurse
- She injected Ali Huseyin, 76, with blood meant for Irfan Hussain
- Her blunder caused Mr Huseyin to have a heart attack and die
- She was today found guilty of manslaughter and cried at verdict

By ANTHONY JOSEPH FOR MAILONLINE
**PUBLISHED:** 16:53 EDT, 14 December 2016 | **UPDATED:** 02:42 EDT, 15 December 2016

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A Filipina nurse who killed a pensioner when she mixed up his name with another patient and gave him the wrong blood transfusion is facing a jail sentence.

# Conclusions

- Be aware of the regulations unique to the BB
- Make it easy to do the right thing.
- Know the critical control points of your vein to vein transfusion workflow
- Build, implement, validate safeguards especially at those critical points, ongoing monitoring
- Exciting things ahead: supporting pre-hospital transfusions, pathogen reduced products, reporting to national hemovigilance program, building templates for apheresis procedures and red cell exchanges, templates for transfusion reactions

- Basically, it is my hope that you will be very involved in your blood banks and will use informatics to gain operational efficiency and improve transfusion safety in your institutes!!
- Why? b/c you recognize the potential to leverage LISs/EMRs to enhance transfusion processes and practices that lead to improve patient outcomes

**WHY GIVE TWO WHEN ONE WILL DO?**

Help reduce unnecessary red blood cell transfusions in our hospitals! Choose SINGLE UNIT TRANSFUSIONS!


stop being so negative
B-
A+