Bringing the Blood Bank to the Bedside:

Multi-Institutional Evaluation of Gaps in Positive Patient ID Systems for Blood Administration

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- None of the authors have any relevant financial or other disclosures to report

Introduction

- Positive patient identification for blood administration (PPID-BA) systems improve safety
  - Prevent wrong blood products from being transfused
- However…if technology/implementation is poor…
  - may fail to improve or worsen safety
  - can jeopardize compliance with regulations and accreditation standards
- Guidance is needed for software developers and implementers

It all started with the API Listserv…

From: Association for Pathology Informatics [mailto:API@LISTS.UCDENVER.EDU] **On Behalf Of** Carter, Alexis
Sent: Thursday, October 06, 2016 2:45 PM
To: API@LISTS.UCDENVER.EDU
Subject: barcoded blood product matching

For those of you who are doing positive patient ID for transfusion verification (in this case, defined as scanning a patient ID and then scanning a blood product unit number and product code with software that will alert you when there is or is not a match prior to transfusing the product):

- Do you require your providers to use the system for Massive transfusion protocols and/or emergency released units?
- Do you require your providers to use the system for rapid infusions of larger numbers of products which are not part of an official massive transfusion protocol and which are not emergency released? For example, transfusing 40 products over a 24 hour period into a single patient in the ICU?

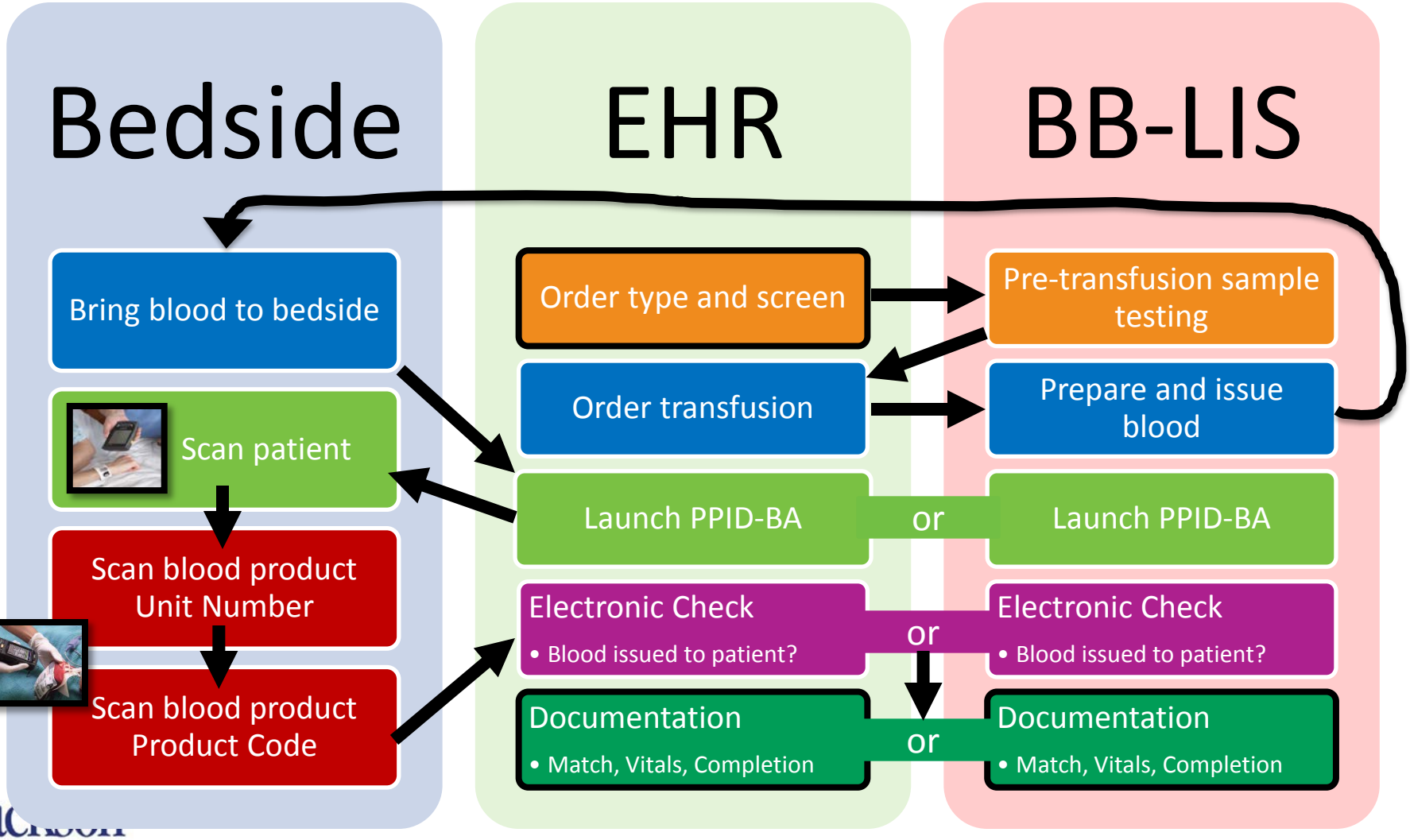
Sincerely,
Alexis

Alexis B. Carter, MD, FCAP, FASCP

From Listserv to Multi-Institutional Effort

- All the authors participated in an implementation of PPID-BA
- All systems implemented were 510(k) cleared by FDA
- Little guidance available in literature
- All authors shared the following experiences
  - Technology design problems
    - Usability, interoperability and compliance
  - Implementation and post-implementation gotchas
  - Felt like re-creating the wheel

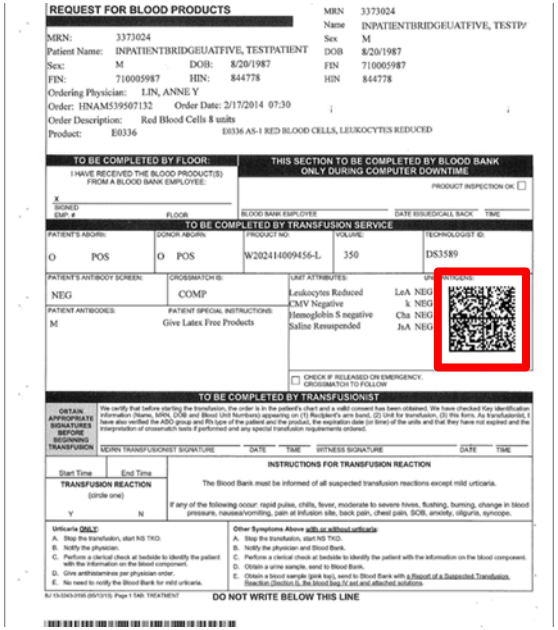
PPID-BA Workflow Example



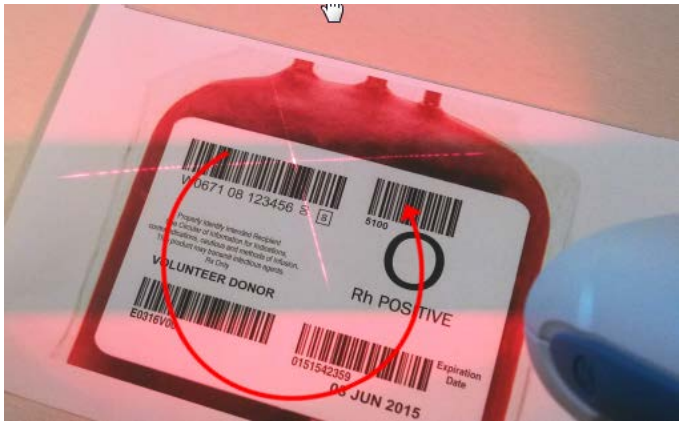
PPID-BA Process at Bedside

1: Wristband

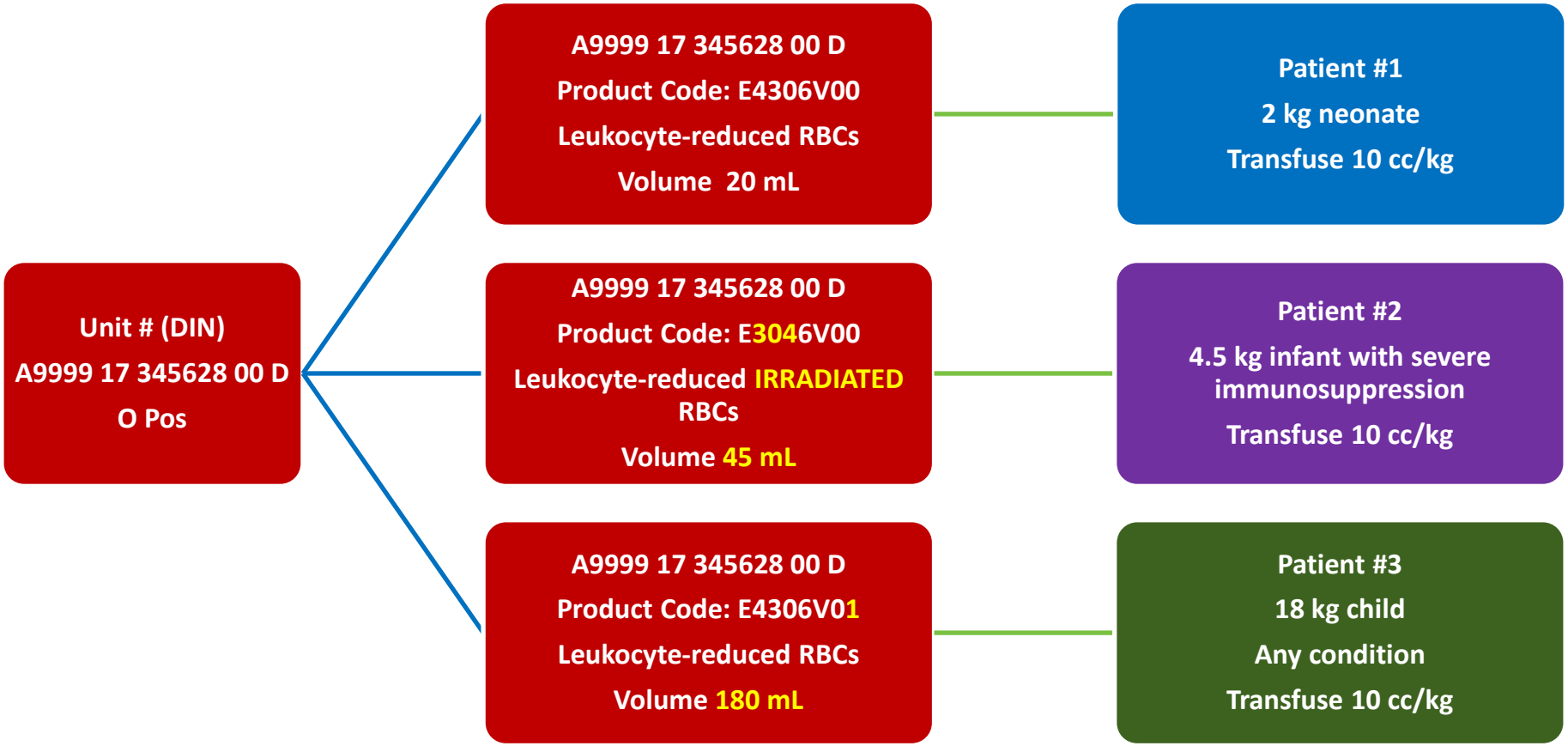
2: Blood Product Request Form – MRN Barcode



3: Blood Product

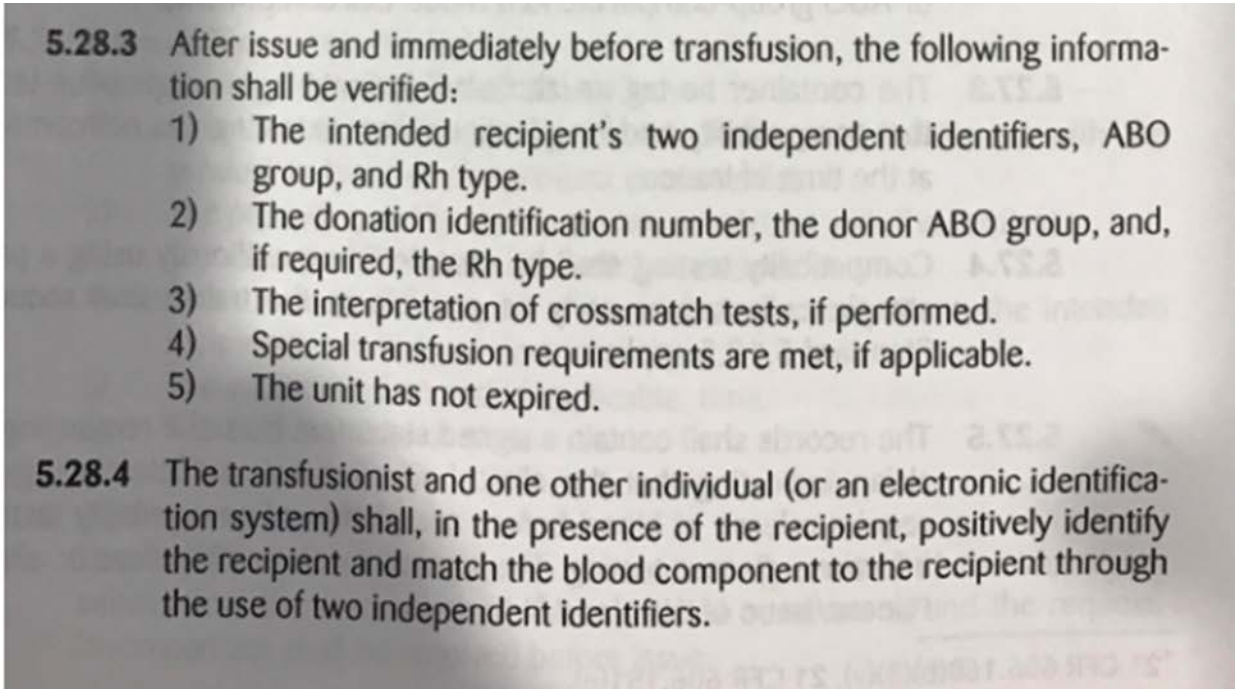


Background on PPID-BA



Background on PPID-BA

AABB:



5.28.3 After issue and immediately before transfusion, the following information shall be verified:

1) The intended recipient's two independent identifiers, ABO group, and Rh type.
2) The donation identification number, the donor ABO group, and, if required, the Rh type.
3) The interpretation of crossmatch tests, if performed.
4) Special transfusion requirements are met, if applicable.
5) The unit has not expired.

5.28.4 The transfusionist and one other individual (or an electronic identification system) shall, in the presence of the recipient, positively identify the recipient and match the blood component to the recipient through the use of two independent identifiers.

AABB Standards for Blood Banks and Transfusion Services, 18th ed. 2016

CAP:

***REVISED** 07/28/2015*

TRM.41300 Bedside Identification **Phase II**

The recipient is always identified conclusively at the bedside with two patient identifiers by either two persons (*e.g.* by checking the wristband for name and hospital number), or by using bedside patient identification technology instead of a second person; and this information is matched to the unit of blood (or components) before transfusion.

CAP Transfusion Medicine Checklist, 8/17/2016

Before we get started…

- If systems are properly implemented
  - Prevents blood allocated to patient A from being transfused to patient B
- Gotchas
  - Systems were designed for nice, calm transfusions
  - Three of us will tell a story – none are our own stories

Ron

- PPID-BA monitored for compliance
- Expected to use PPID-BA for > 95% of transfusions meeting criteria
  - Criteria complex → confusion
- System problem at scan time
  - barcode scanner didn't work, single-sign-on problem, other error
  - Nursing used 2-person manual check then started transfusion
  - To meet compliance, nursing tried barcode matching again AFTER the unit was transfusing

Kinjal

- Biggest hurdle: End-user buy in
- Hospital leadership wants PPID
- Four imp functions of PPID module
  - 1) PPID 2) Document Start & Stop times 3) Capture what unit #s transfused 4) VS monitoring
- Concerns raised by clinician champions:
  - Trauma Bay- Impractical to document VS during resuscitation/code, current documentation is entirely post-code on paper- PPID module did not allow modifying the start time to have occurred in the past
  - OR- Anesthesia solution already documents Start and stop times, volume transfused and VS. Module just to document unit #?
  - Routine/Inpatient/ED: Hospital chose not to eliminate second signature, just replicating current paper
- Low adoption and compliance rates

Alexis

- Problem #1: Overutilization of rapid infusion mode
  - Standard PPID-BA: Scan patient → 1 product → Match → REPEAT
  - Rapid infusion mode:
    - A: Scan patient once then all products WITH electronic matching OR
    - B: Same process with NO matching (documentation only)
    - Mode A does not require 2 person check; Mode B does (per AABB)
- Problem #2: Both modes for this PPID-BA system were strictly EHR-based: Product scan flag product as "used" in EHR but **not** BB-LIS
  - Unused products returned to blood bank and reissued to different patient if not expired
  - EHR alert: "product given to another patient" (because EHR was not updated when product put back into inventory)

Guidelines

- Implementation is hard if no guidelines…
- Guidelines are needed
  - Buy-in, system selection, implementation, monitoring
- Authors met multiple times to describe various issues with their experiences
- Results of discussion generated
  - System-agnostic guidelines
  - Categorized into groups
  - Sequenced according to workflow

Outline

- Design
- Implementation
- Validation
- Training
- Post-Go-Live Monitoring/Support

- Time permits covering guidelines at high level only
  - Stay tuned for paper

Outline

- **Design**
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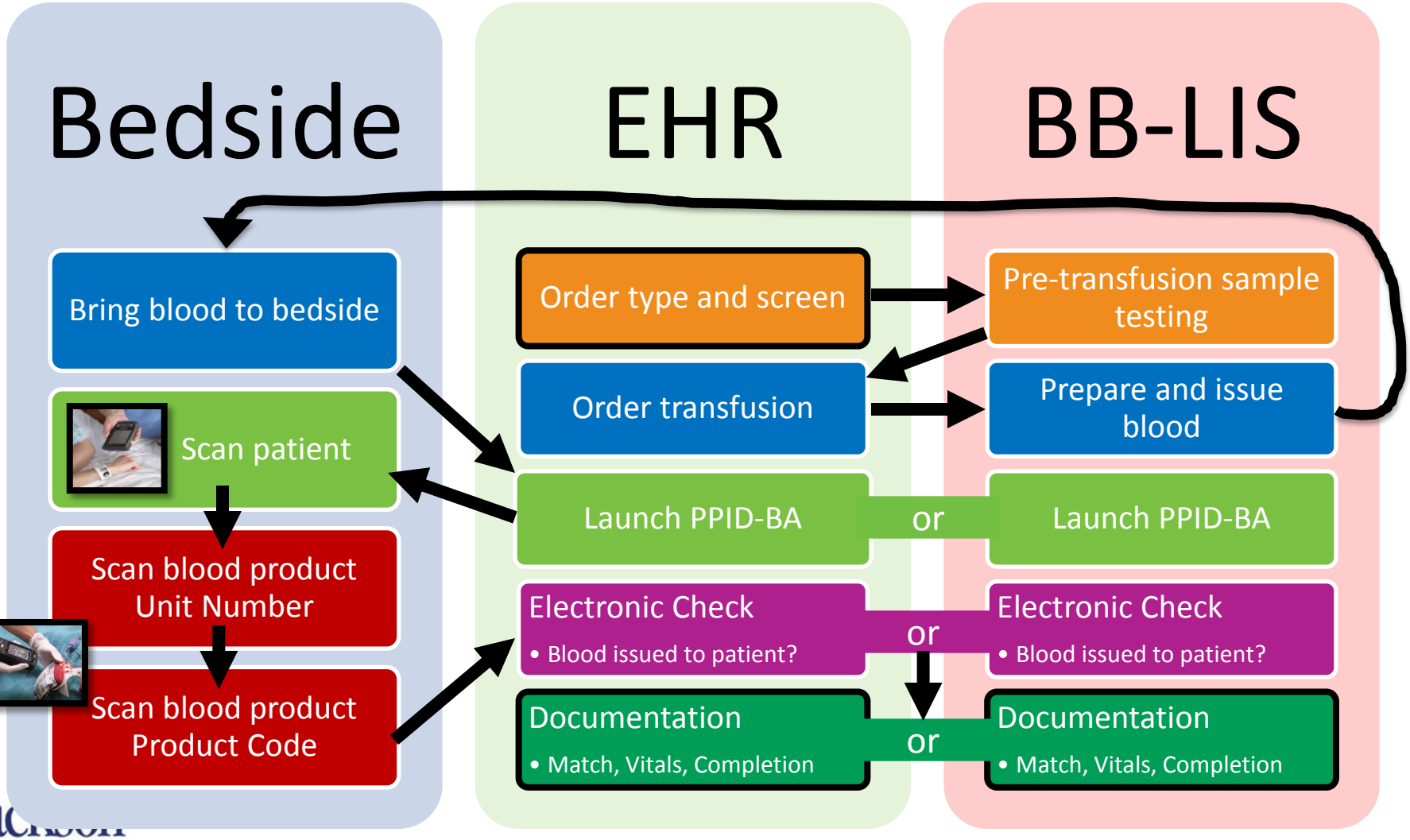
Design

- Largest category by far
- Includes things to determine BEFORE system selection or purchase

Why	Why do you want to implement? Safety, marketing, workflow, compliance. Helps with buy-in.
Who	Who can use the system? Access, authentication, authorization.
What	What system to purchase? Cost, components needed, workflow.
Where	Where will it be used? OR, ED, Floors, Inpt/Outpt, etc. Where will the electronic checking reside? EHR vs. BB-LIS?
When	When will it be used? Calm vs. ED, OR, Emergencies, Bedside Surgery.
How	How will the system work? → largest subcategory…see next slide

PPID-BA Workflow Example



Design - How

- Suggest FMEA with all operations stakeholders

Pre-transfusion specimen collection	Security of process (PPID), tracking of specimen through testing to product allocation, collection encounter vs. transfusion encounter
Patient armbands	Barcode-encoded content (encounter-dependent?), manual entry permissible?, access to armband (OR)
Blood product barcodes	ISBT 128 compliance in each data field, ISBT 128 barcodes scanned (symbology and type)
Matching process	EHR vs. BB-LIS, partial vs. full match, standard vs. rapid infusion module mechanism, blood product status vs. availability to PPID, alert messages decipherability
Transfusion documentation	Location of documentation for match, vitals, transfusion completion; degree of transparency between EHR and BB-LIS
Post-transfusion auditing	Audit mechanism, EHR vs. LIS data or both, responsibility for audit, communication of results
Downtime preparation	Process during EHR downtime vs. BB-LIS downtime vs. both

Outline

- Design
- **Implementation**
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- Training
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Implementation

- Get buy-in before you start
- Use the FMEA to design workflows (human and IT)
- Set expectations
- Have a goal for what you are trying to achieve
  - Outcome measures (reduction in near misses; wrong transfusions)
- Get your compliance reports constructed EARLY
  - Take longer than you think (custom code)

Outline

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Validation

- Validation plan: Design to capture every problem
- Realize you will only catch 80-90% of problems
- Do not assume that barcodes are 100% accurate
- Blood bank validation has different FDA requirements
  - Best practice to validate during a no-change window then go live

Outline

- Design
- Implementation
- Validation
- **Training**
- Post-Go-Live Monitoring/Support

Training

- No small feat → 1000s of nurses
- Train within 4-6 weeks of go-live
- Emphasize process AND compliance/criteria
- Create multiple training modes and choose which to require vs. just offer
  - Unlike meds, used blood products are taken out of availability → Computer-based training is KEY
  - Tip sheets, videos, procedures, reminders, in-person
  - Transparency and obviousness of workflow
    - Manual forms may need new instructions
  - Nursing supervisor sign-off

Outline

- Design
- Implementation
- Validation
- Training
- **Post-Go-Live Monitoring/Support**

Post Go-Live Monitoring

- Super-users should follow the blood as it is issued
- Monitor compliance frequently (by shift, weekly)
  - Make it TRANSPARENT
- Be available for questions (lots of them)
- Command center 24/7 for at least 3 days
- At least 7 days of on site 24/7 support
  - Need to get weekend staff as well as weekday

Post Go-Live Monitoring (cont.)

- Vigilance required
  - Nurses doing duplicate electronic and manual workflows
  - Using system after rather than before transfusion
  - Completing transfusions (FDA requirement)
  - Workarounds = System not working
    - Workflow may need clarification or focal re-design
- Be prepared to redefine your scope
  - ECMO cannulations
  - NICU bedside surgeries
  - Apheresis procedures – emergent vs. not

EMORY

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School of Medicine

Gotcha Resolutions

Jackson
MEMORIAL HOSPITAL
Jackson Health System

Alexis

- Better defined when and where rapid infusion should be used (>=5 units in 4 hours)
- Removal of second signature used as **incentive** to use standard PPID (with electronic match) instead of rapid infusion (no electronic match)
- Partnered with ICU nurse managers to educate nurses on appropriate use of rapid infusion
- Interventions reduced inappropriate use of rapid infusion significantly

Kinjal

- Achieved increased adoption & compliance :
- Explore current workflow to identify areas of improvement
- Emphasize or deemphasize functionality based on end-user group/needs
  - Consider turning off “VS monitoring requirement” inside PPID, great acceptance b/c now they don’t manually document each unit # and start & stop time of each unit
  - Routine inpatient transfusions: Emphasized patient safety aspect of electronic PPID, appealed to professional pride

Ron

- Reminded nursing of purpose of monitoring compliance
- Non-threatening, non-punitive
- Intended to find reasons why system could not be used at the time checking done

Lessons Learned

- Make sure you understand how and when the PPID-BA system is performing actual matching vs. simple documentation.
- Obtain buy-in from all departments, particularly those likely to administer blood rapidly or emergently (ED, surgery, ICU).
- Monitor compliance AND meet with transfusionists regularly to investigate (in a non-judgmental environment) for workarounds and other threats.

Conclusions

- PPID-BA is a double-edged sword:
  - Used properly, it may increase transfusion safety.
  - Poor implementation, unintended consequences, and unexpected failures may also incentivize workarounds that put transfusion recipients at greater risk of harm.
- Guidelines for PPID-BA implementation and post-implementation are needed to ensure consistency, compliance, and ultimately safety.

Acknowledgements

- Joseph Zeitouni, MD
  - Bringing up an LIS this week!

Questions