RFID in Health Care

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Vein-to-Vein Implementation of HF RFID in Blood Collection through Transfusion

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RFID advantages over bar codes

“Health care has to look at medical errors not as a special case of medicine, but rather as a special case of error ….

And apply technologies and approaches used in other fields to reduce errors and improve patient outcomes.”
RFID vision

- RFID technology has the potential to advance both patient safety and operational efficiency
- Require consistent standards for RFID use throughout the entire blood supply chain
  - Which also need to be consistent with ISBT128 standards
- RFID technology must be integrated with
  - Existing ISBT128 bar code based procedures
  - Existing blood center and hospital IT systems
RFID advantages over bar codes

- Ability to read, write and update information on blood bag
- Ability to multiple tags in reader RF field all at once
- No line of sight required - Can read through closed container
- Can be used to locate and track products automatically
Building upon the ISBT RFID Guidelines

- **Principles of the 2010 RFID Guidelines** have been implemented by the Consortium
  - Guidelines build on ISBT128 bar code data structures
  - Based on the use of ISO 15693/ISO18000-3 mode 1 HF RFID
  - Members of the RFID consortium participated in their development
Guiding principles for RFID use

• RFID tag will not substitute for, replace, or contradict any required ISBT128 barcode labeling information

• RFID augments existing ISBT128 barcode-based blood center operations and hospital transfusion systems, not replace them
  
  • RFID augments bar codes AND bar codes back up the RFID tag
  
  • The barcode-based Blood Enterprise Computing System (BECS) remains the system of record - RFID is only used as a supplementary tracking application
RFID tag memory structure assumptions

- **Only ISBT128 compliant data structures are used in tag memory**
  - Designed for Code 128, but uses data carrier independent 7-bit ASCII
  - Additional ISBT128 data structures will be designed for new RFID features not supported in ISBT128 barcodes

- **Additional CRC-16 checksum data security is used on the tag**
  - Checksum is over all key tag data fields
  - Checksum detects either memory data integrity or memory corruption
  - If data integrity test ever fails, the tag will be “killed” and only barcode data on the bag will be used
Where RFID helps in the blood center

Identify and Prioritize “Pain Points”

Create RFID Enabled Processes

- Reconciling data with physical reality
  - Build RFID unit → RFID container relationships enabling better tracking and faster reconciliation

- Physically locating products
  - Use RFID to update “last seen” location of all products encountered during searches

- Track time out of temperature-controlled locations
  - Provide an alert if the time between “last seen” in a uncontrolled temperature locations is too long

- Rapid check-in and shipment verification
  - Use RFID’s ability to read multiple units in closed containers to dramatically reduce labor
Physically tagging blood products

- Existing preprinted ISBT128 Donation Number (DIN) bar code label sets will continue to be used for now.

- At Donation Site, apply 14x31 mm RFID tag under DIN label:
  - On just the RBC product bag for whole blood collection in a 3-bag set.
  - On all bags in apheresis collection set.
  - In the future, tags may be pre-applied and pre-encoded by the bag manufacturers.

- Manufactured blood products (ex: plasma) get a blank RFID tag applied and programmed during final product labeling.
ISO 18000-3 mode 1 memory allocation

- Use only first 1280 bits of 2048 bit tag – Allows use of all brands of ISO 18000-3 mode 1 tags
- Blocks allocated in 40 32-bit physical memory blocks, individually addressable and lockable
- Blocks 0-23 for blood center; 28-36 for transfusion service; 24-27 shared
- Blocks 14, 15 also identify this as the Transfusion Medicine RFID Consortium memory layout

<table>
<thead>
<tr>
<th>Block</th>
<th>Data Structures</th>
<th>Cum</th>
<th>ISBT Structure</th>
<th>Information Carried</th>
<th>Field Owner</th>
<th>Write Lock Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>b q q w w w w</td>
<td>64</td>
<td>017</td>
<td>Bag Mfr Info</td>
<td>Bag Mfr</td>
<td>Preloaded or read from bar code; locked</td>
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<tr>
<td>1</td>
<td>w w w w w j x</td>
<td>128</td>
<td>017/018</td>
<td>Bag Mfr Info; Bag Mfr Lot #</td>
<td>Bag Mfr</td>
<td>Preloaded or read from bar code; locked</td>
</tr>
<tr>
<td>2</td>
<td>x x x x x x</td>
<td>192</td>
<td>018</td>
<td>Bag Mfr Lot #</td>
<td>Bag Mfr</td>
<td>Preloaded or read from bar code; locked</td>
</tr>
<tr>
<td>3</td>
<td>&amp; a x x x c y j</td>
<td>256</td>
<td>local/007</td>
<td>Donor info; Collection Start Date &amp; Time</td>
<td>Blood Center</td>
<td>Written at collection; locked</td>
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<tr>
<td>4</td>
<td>y j j h h m m m</td>
<td>320</td>
<td>007</td>
<td>Collection Start Date and Time</td>
<td>Blood Center</td>
<td>Written at collection; locked</td>
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<tr>
<td>5</td>
<td>= a p p p y y</td>
<td>384</td>
<td>001</td>
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<tr>
<td>6</td>
<td>n n n n n n f f</td>
<td>448</td>
<td>001</td>
<td>Donation Number</td>
<td>Blood Center</td>
<td>Preloaded or read from bar code; locked</td>
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<tr>
<td>7</td>
<td>&amp; d x x &amp; c b b</td>
<td>512</td>
<td>local/local</td>
<td>Tag Generation; Key Data Checksum</td>
<td>Blood Center</td>
<td>Updated until ABO written, then locked</td>
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<tr>
<td>8</td>
<td>= % g g r e</td>
<td>576</td>
<td>002</td>
<td>ABO/Rh</td>
<td>Blood Center</td>
<td>Loaded in final labeling; locked</td>
</tr>
<tr>
<td>9</td>
<td>&lt; a o o o o t</td>
<td>640</td>
<td>003</td>
<td>Product Code</td>
<td>Blood Center</td>
<td>Updated during processing; never locked</td>
</tr>
<tr>
<td>10</td>
<td>d s &amp; &gt; c y y j</td>
<td>704</td>
<td>003/005</td>
<td>Product Code; Expiration Date &amp; Time</td>
<td>Blood Center</td>
<td>Updated during processing; never locked</td>
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<tr>
<td>11</td>
<td>j j h h m m m m</td>
<td>768</td>
<td>005</td>
<td>Expiration Date &amp; Time</td>
<td>Blood Center</td>
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<tr>
<td>12</td>
<td>&amp; b z x &amp; j c j</td>
<td>832</td>
<td>local/009</td>
<td>Process State; Process Time Stamp</td>
<td>Current Holder</td>
<td>Updated during processing; never locked</td>
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<tr>
<td>13</td>
<td>y j j j h h m m</td>
<td>896</td>
<td>9</td>
<td>Process Time Stamp</td>
<td>Current Holder</td>
<td>Updated during processing; never locked</td>
</tr>
<tr>
<td>14</td>
<td>&amp; &amp; a a 1 8 x x</td>
<td>960</td>
<td>025</td>
<td>Patient Identification Number</td>
<td>Transfusion Service</td>
<td>Written but never locked; may be cleared</td>
</tr>
<tr>
<td>15</td>
<td>x x x x x x</td>
<td>1024</td>
<td>025</td>
<td>Patient Identification Number</td>
<td>Transfusion Service</td>
<td>Written but never locked; may be cleared</td>
</tr>
<tr>
<td>16</td>
<td>&amp; &amp; # a a 1 8 x x</td>
<td>1088</td>
<td>025</td>
<td>Patient Identification Number</td>
<td>Transfusion Service</td>
<td>Written but never locked; may be cleared</td>
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<tr>
<td>17</td>
<td>x x x x x x</td>
<td>1152</td>
<td>024</td>
<td>Patient Date of Birth</td>
<td>Transfusion Service</td>
<td>Written but never locked; may be cleared</td>
</tr>
<tr>
<td>18</td>
<td>m m m m m m m m</td>
<td>1216</td>
<td>024/TBD</td>
<td>Patient Date of Birth; Reserved</td>
<td>Transfusion Service</td>
<td>Written but never locked; may be cleared</td>
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<tr>
<td>19</td>
<td>Reserved</td>
<td>1248</td>
<td>Reserved</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>20</td>
<td>Reserved</td>
<td>2048</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

$Used to carry collection stop time prior to processing
RFID tag data handling at the blood center

Data written to the user memory of the RFID tag during blood center processing

Blood Donation
Component Manufacturing:
Define Product
Component Remanufacturing:
Redefine Product
Final Labeling

ISBT 128 Donation ID
Procedure Type, Date and Times
Product ID, Expiration Date Expiration Time
Step Stamp
Time Stamp
ABO/Rh

Write Once & Lock
Write Once & Lock
Re-Writable
Re-Writable
Write Once & Lock

RFID in Health Care
RFID tag data handling at the hospital

Data written to the fixed user memory area of the RFID tag during transfusion services processes:

- **Issue and Release for Transfusion**
- **Return Product to Blood Bank (1)**
- **Product Modification**

Patient ID Number, Patient DOB, Product ID, Expiration Date, Expiration Time, Step Stamp, Time Stamp

Re-Writable, Re-Writable, Re-Writable, Re-Writable

(1) MUST clear Patient ID Number & DOB data blocks
RFID tag data handling at the blood center

**Donation Site**
1. Initialize New Blood Bag
2. Packing Containers
3. Load and release a Pick-up

**Blood Center**
1. Check-in Donations
2. Label Product
3. Check-in Inventory
4. Verify Shipment
5. Check-in Imports
6. Check-in Returns
Impact analysis conclusion – Blood centers

• It is technically feasible to implement 13.56 MHz (HF) RFID-enabled processes throughout the blood bank supply chain

• Assessed economic justification for RFID enablement
  – Quality gains (eliminating discards and “lost products”) by better reconciliation and “last seen” guidance
  – Efficiency gains with faster reconciling of donations and shipments
  – Less individual bag scanning greatly reduces labor
  – Cost of infrastructure and implementing new processes may be recovered by a blood center in 2-3 years
SAFETY OF HF RFID WITH BLOOD PRODUCTS
Mandate from FDA to consortium:

“You can do all the testing you want with RFID tags on blood bags, but you can’t transfuse a single unit of that blood until you prove that exposure to the RFID reader radiation hasn’t compromised the safety or efficacy of that blood product”

Dr. Jay Epstein, Director
Office of Blood Research & Review
FDA CBER
March 15, 2007
“Limit Test” concept for RF exposure safety

- Protocol jointly developed by FDA’s CBER & CDRH and the RFID Consortium

- Concept: Expose a small group of blood components to higher reader RF power levels and much longer times than would be seen in practice

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Real-Life</th>
<th>Limit Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF exposure time</td>
<td>Intermittent, total &lt;20 min over lifetime</td>
<td>Continuous over 23-25 hours with 1hr break</td>
</tr>
<tr>
<td>RF magnetic field strength</td>
<td>~1 Amp/meter</td>
<td>5 Amps/meter</td>
</tr>
</tbody>
</table>

- Assay blood product samples at 0h, 7h and 24h for morphological and biochemical changes as compared to an unexposed control sample
RF Limit Test
Apparatus at U Wisconsin-Madison RFID Lab

Tested Blood Product
2007 & 2010 Limit Test Results

- 2007 test results: Young RBCs and platelet products had no increased cellular/protein degradation after high levels of extended exposure to RF
  - Joule heating by the RF field had acceptable effects on the temperature rise of RBC and platelet products
    - Davis, Rodeina, J Gottschall, A Gutierrez, C Hohberger, D Veeramani and J Holcombe. Transfusion 2010;50:1596-1603
  - FDA also requested additional tests on plasma and aged RBCs (near 42 days). 2010 test results:
    - Aged RBC test results consistent with prior tests of young RBCs
    - Plasma temperature rise due to Joule heating was acceptable with no impact on coagulation factors
    - Results led to first US approval by FDA to deploy HF RFID
RFID IMPLEMENTATION
Tunnel and pad antenna readers

- TAGSYS tunnel readers used at check in and outbound shipment to read Coleman and shipping box coolers and platelet warmer boxes without opening
- TAGSYS pad reader antenna used during final labeling, tray reading and by hospital
Unitech PA600 mobile clinical assistant

Primary reader used at donation site and at transfusion sites

- 1D/2D Bar code scanner
- 13.56 MHz RFID reader
- Dual thumb triggers, 1 each side
- Li-ion rechargeable battery with charging cradle

Connectivity:
- 802.11g wireless LAN
- USB
- Bluetooth 2.0
Tracient Bluetooth-connected RFID reader

- Primary reader used with finished goods inventory, and finding things in freezers
- Bluetooth Class 2; USB
- Single button operation
- 3 color LED display, beeper
- Rechargeable Li-Ion battery
- Can use Unitech reader for it’s programming, display and communications relay to WLAN
Tag performance testing conditions

- Each tag was attached to a simulated blood bag
- Testing was also done in three different containers
  - Cooler ($\leq 17$ bags) – Packed with ice
  - Styrofoam box ($\leq 30$ bags) – Packed with ice, dry ice or warmer gel packs
  - Refrigerator tray ($\leq 12$)
Tag survivability tests

- Paper at 2011 AABB Annual Meeting
- **Centrifugation**
  - 2x (4200 RPM for 10 Min)
  - Key is not folding tag antenna when loading centrifuge cup
- **Blast Freezing to -30 °C**
  - Tags functioned even below -40 °C
  - Did not function at -80 °C; worked OK when warmed up
- **Cs$^{137}$ gamma irradiation**
  - 2x 25 Gy exposure
  - No apparent impact on function; no memory corruption seen
  - CRC-16 check digit on memory contents detects corruption
RFID middleware eases BECS integration

RFID Middleware

RFID Application (by S3Edge)
RFID Reader Device Drivers
Microsoft BizTalk RFID Platform
Web-services based interface

Any Blood Enterprise Computing System (BECS)

RFID in Health Care
Where we are today- blood center summary

- Completed FDA-required RF safety testing on blood products
- Selected 13.56 MHz ISO 18000-3 mode 1 tags (2k bit) and readers
- Conducted successful performance and survivability tests with selected tags and equipment. Tags on blood bags tested to survive:
  - Centrifugation
  - Blast freezing of plasma and dry ice contact
  - Gamma irradiation
- S3edge has developed RFID middleware based on Microsoft BizTalk RFID which interfaces with MediWare LifeTrak® BECS used at BCW and Carter
- Pilot installation and testing at BloodCenter of Wisconsin begins in 4Q11; full deployment expected 1Q12
HOSPITAL RFID SOLUTION
Transfusion Services RFID-enabled touch points

Hospital Blood Bank

- **Receive**
  - Shipments from Blood Center
  - Pending check-in
  - BECS Work Station
  - Label
  - Dispense
  - Issue and Pending Release
  - BECS Labeling Station

- **Return**
  - Returns to Blood Center
  - Pending return to blood center
  - RFID Work Station
  - Pad reader

- **Reclaim**
  - Pad reader
  - RFID Work Station
  - Disposal

- **Check-in Location**

- **Check-out Location**

- **Point of care match**
  - Patient
  - Storage movement
  - Begin Transfusion
  - End Transfusion

**RFID in Health Care**

**RFID Consortium**
Augmented 3-way matching

• Match patient ID, transfusion order #, and product unit IDs
  – Increase transfusion safety by reducing/eliminating errors
  – Automate issue and release of blood
  – Automate recording of chain of custody
First scan barcoded or RFID wrist band ID
Record patient ID; check hospital computer for valid transfusion order #
Scan unit to verify match to order and ID
Handheld can collect patient’s vital signs
Transfusion completion and close-out

- Scans the patient wrist band
- Enters the transfusion results
- Scans the blood bag to complete the transfusion – the transfusion status is updated to “Complete” in computer
- Scanner deletes all patient-related info from the RFID tag on bag
Key challenges

• No “universal” hospital transfusion process
  – Every hospital does it a little bit different
• Hospital IT integration
  – Many different software systems in use
• Integration with concurrent patient care processes
• Safety gains –
  – Difficult to track and confirm
  – Biovigilance system development and adoption
• Nursing training and compliance
Impact analysis conclusions – Hospitals

- **Economic justification for RFID enablement**
  - It is economically justifiable to invest in RFID infrastructure and implementing new processes as cost may be recovered by a large hospital in 2-3 years.

- **Patient Safety justification for RFID enablement**
  - Patient safety model analysis provides promise that mortality rates could be improved by use of RFID
  - Morbidity effects will be studied next
Patient safety ROI model: **Errors → Effects**

- **Transfusion processes errors**
- **Identification / location related errors**
- **Adverse Reactions**
- **Patient effects**
  - **Overall Mortality Index**
    - Before
    - After
    - Gain %
  - **Overall Morbidity Index**
    - Before
    - After
    - Gain %
Where we are today – Hospital solution

- Process review and reengineering performed with University of Iowa Health Center (UIHC)
- Solution functional specifications completed – in final validation
- Will perform first round of hospital application testing at UIHC in 3Q11
For further information and updates

www.transfusionmedicineRFID.org
THANK YOU