New Technology for Patient Transfusion Safety

Walter (Sunny) Dzik, MD
Blood Transfusion Service
Massachusetts General Hospital;
Harvard Medical School
Boston, USA

Errors in Medicine compared with Other Industries

Source: Institute of Medicine Report: “To err is human”
Mrs Johnston

- Mrs Johnston, a 48 yo woman is now 3 days post-op following resection of a right para-renal mass (benign).
- Immediately post-op, she had received 1 unit group A RBCs for Hct = 24, and towards the end of the unit:
  - a single short rigor
  - temperature 99 → 101 F
  - urine was already red from renal surgery
  - blood culture was sent (eventually was no growth)
  - CBC showed WBC = 12,000 with 60% polys
  - blood bank investigation was done: the empty bag and a freshly drawn sample were sent to lab

Mrs Johnston (con’t)

- Blood bank reported back: “wrong blood transfusion”
- Name / MRN on empty blood bag = Mary Johnson, MRN 2395783
- Post-transfusion reaction specimen = Mary Johnston, MRN 2395837

-------------------
- No pre-op specimen on a Mary Johnston
- Post-transfusion specimen was group O+; Unit of RBCs = A+
- Direct Coombs’ test was positive; plasma visibly hemolyzed
-------------------
- Mary Johnson does exist. An ER sample drawn 3 days ago and sent to the lab was Group A+. However, a follow-up sample sent yesterday from the Medical Service on Johnson was Group O+.
- People in the hospital are asking: “what happened”? 
Safe Transfusion: Processes not just products

Product

Recruit
Screen donor
Collect & Prepare
Inf Dis tests

No pre-transfusion sample in lab

Blood Bank

Ward sample
ER sample

O pos
A pos
A +

Post-reaction sample
O pos

Time

Mary Johnson, MRN 2395783
Mary Johnston, MRN 2395837

No pre-transfusion sample in lab
Safe Transfusion: Processes not just products

**Process**
- Recruit
- Screen donor
- Collect & Prepare
- Pre-tx testing
- Inf Dis tests
- Medical Reason for Tx
- Release from lab
- Deliver
- Administer (bedside)

**Product**

**Erroneous administration of RBCs: NY state 1990-1999**

<table>
<thead>
<tr>
<th>Reported events</th>
<th># cases</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABO-incompatible</td>
<td>237</td>
<td>1 in 38,000</td>
</tr>
<tr>
<td>ABO compatible</td>
<td>221</td>
<td>1 in 41,000</td>
</tr>
<tr>
<td>Total</td>
<td>462</td>
<td>1 in 19,000</td>
</tr>
<tr>
<td>Total adjusted for “silent errors”</td>
<td>659</td>
<td>1 in 14,000</td>
</tr>
</tbody>
</table>

Linden et al. Transfusion 1990; 40: 1209
Serious Hazards of Transfusion- UK

- Incorrect blood transfused
- Acute hemolysis
- Delayed hemolysis
- Post-tx Purpura
- TRALI
- GVHD
- Infection

Based on 2,630 reported adverse transfusion events.

Major Morbidity or Death

- Hemolysis, incorrect blood transfused
- Transfusion Acute Lung Injury
- Infection
- Graft vs Host Disease

Based on 2,630 reported adverse transfusion events.

* Data from Stainsby et al. Transfusion Med Reviews 2006; 20: 273
ABO incompatible transfusions: causes

- Patient I.D. not verified at bedside (32%)
- Laboratory clerical error (11%)
- Laboratory technical error (12%)
- Failure to ask stated name and match to wristband (5%)
- Failure to match wristband ID with blood bag label (38%)
- Failure to match wristband data with request form (5%)
- Failure to check results of compatibility testing and expiration (5%)
- Failure to do ALL 4 correctly (38%)

Bedside check: poorly done…

<table>
<thead>
<tr>
<th></th>
<th>1994</th>
<th>2000</th>
</tr>
</thead>
<tbody>
<tr>
<td>n=12,448</td>
<td></td>
<td>n=4046</td>
</tr>
<tr>
<td>Failure to ask stated name and match to wristband</td>
<td>32 %</td>
<td></td>
</tr>
<tr>
<td>Failure to match wristband ID with blood bag label</td>
<td>11 %</td>
<td></td>
</tr>
<tr>
<td>Failure to match wristband data with request form</td>
<td>12 %</td>
<td></td>
</tr>
<tr>
<td>Failure to check results of compatibility testing and expiration</td>
<td>5 %</td>
<td></td>
</tr>
<tr>
<td>Failure to do ALL 4 correctly</td>
<td>38 %</td>
<td></td>
</tr>
</tbody>
</table>

Novis et al. Arch Path Lab Med 2003; 127: 541
Bedside check: poorly done and getting worse!

<table>
<thead>
<tr>
<th></th>
<th>1994</th>
<th>2000</th>
</tr>
</thead>
<tbody>
<tr>
<td>Failure to ask stated name and match to wristband</td>
<td>32 %</td>
<td>57 %</td>
</tr>
<tr>
<td>Failure to match wristband ID with blood bag label</td>
<td>11 %</td>
<td>24 %</td>
</tr>
<tr>
<td>Failure to match wristband data with request form</td>
<td>12 %</td>
<td>46 %</td>
</tr>
<tr>
<td>Failure to check results of compatibility testing and expiration</td>
<td>5 %</td>
<td>27 %</td>
</tr>
<tr>
<td>Failure to do ALL 4 correctly</td>
<td>38 %</td>
<td>75 %</td>
</tr>
</tbody>
</table>

Novis et al. Arch Path Lab Med 2003; 127: 541

Preventing Transfusion Errors

New technology
Trained professionals
Professional standards
1. Patient’s name may or may not be legible

2. Bag number handwritten

3. Blood types hard to read
A simple intervention…

BEST Research Collaborative

- USA (3 sites)
- Sweden
- Canada (3 sites)
- Norway (2 sites)
- Australia (Sydney)
- Brazil (Sao Paulo)
- England

…but will it work or will the effect wear off?
Observe Observe

Labels applied

2 weeks 6 weeks

Study Design…

Test Ward

Observe

Control Ward

Observe

…Results: ??

Test Ward

Observe

Control Ward

…Results: No value !!
What has MGH done with patient ID?

Wristband (multiple platforms)...

Patient information

1D Code 128 bar code

2D Datamatrix bar code

Radiofrequency tag embedded in wristband

123 45 67
SMITH, JOHN
PH20 1 1/26/1945
M 058Y MED

7/21/03

Avoid Giving Blood to Wrong Patient

Mary Johnston
2395837

RBC A Pos

Johnson, Mary
# 2395783
Former method:
Bedside check at
Oxford, UK

Current method:
bar code

Passive RFID

No signal

Reader

Reader antenna

Slide courtesy of Mike Murphy, MD
(NBS, Oxford, UK)
Radio-Frequency ID Applications…

- **Active:**
  - Cell phones
  - Car clickers
  - Toll booth (drive through)
  - “Asset tracking”

- **Passive**
  - “Security cards”
  - ID badges
  - Electronic-article-surveillance (clothing store)
  - Subway pass
  - Patient “ID”

- **Antenna**
- **Data chip**

- **Low**
  - 0.33-120 mHz

- **High**
  - 13.56 mHz
    - credit cards

- **Very High**
  - ~900 mHz
    - Cell phone

- **Microwave**
  - 2,450 mHz
RFID: Potential Applications in Transfusion

- Blood provider
  - Inventory management
  - GMP
  - Labeling: Bar code (20 characters) versus Chip (20,000 chars)
- Hospital blood bank
  - Registering into lab system many units of blood
  - Inventory management; sample management
  - Temperature sensors
  - Issue many units of blood
- Bedside
  - Bedside clerical check
  - Documentation: writing to the digital medical record

The Boston Globe

System targets blood-type mix-ups
By Scott Allen, Globe Staff | February 24, 2005
START: Safer Transfusion with Advanced Radio-frequency Technology

Why focus on the O.R. and ICU?

- Operating room
  - Large volume of blood under urgent conditions
  - Patient is asleep
  - Health care team do not “know” patient
  - Distraction is common

- Intensive care unit
  - Patient is often unconscious
  - Many I.V. meds are given

Focus on ICU & OR…. Drugs and Blood

**Medication errors:** Rothschild Crit Care Med 2005; 33: 1694.
- 391 patients observed (1500 patient days)
  - 20% had adverse events
  - Serious errors (n=223) occurred at a rate of 1 every 8 hours in a 30 bed ICU.
  - 11% of serious errors were life-threatening or fatal.
- Most common life-threatening errors were medication errors & these were ‘slip’ errors, not cognitive errors.

**Transfusion errors:** Sazama Transfusion 1990; 30: 583.
- Most common site for wrong-patient transfusion is the Operating theatre.
Design Principles…
Making a RFID device for bedside hospital safety

• *Continuous* reading of the wrist band.
• Assumes the patient is stationery and the healthcare worker is moving!
• Assumes bedside computer.
• Simple to use.
• Generic.
• Suitable for both blood and I.V. medications

Description of the system:

![H.I.S.]

2. RFID label on the product: ID of the intended recipient.
The “smart” OR table….
1. knows when the patient has arrived;
2. knows WHO the patient is;
3. knows when the patient leaves.

RFID ‘bag reader’ built into computer

Low energy RFID readers built into table padding

Patient ID sent from wristband readers to OR computer.

The RFID bedside check…

….wave bag in front of computer.
Results of first pilot implementation:

* 13.56 Mhz RF is well suited to blood bank applications.
* RF tags are unaffected by prolonged storage, water bath, gamma irradiation, MRI exposure, and –80 C.
* In a pilot study among 20 major Ortho surgery patients, 233 Units were scanned under real-time OR conditions. (Multiple units were deliberately scanned for testing. Compatible “test units” with deliberate data mis-matches were also scanned.)
* The software correctly reported “Match” or “NO Match” results for all scanned units.
* Bedside check required < 0.5 seconds.
* In 2 patients (10%), the wristband signal was not detected by RF readers built into the table arm boards.

Device for testing in 2008
RFID at the bedside: Bridging Existing Information Systems

- No software interface is required between large existing systems
- Solution is add on – no change to existing systems
- Solution is generic-- does not depend on any individual vendor I.T. system
Ms Johnston (concluded)…

- Apart from fever, Ms Johnston had no other symptoms.
- Her urine output rapidly declined.
- By day #2 she had complete kidney shut-down.
- The error was explained to the patient and her family.
- No further transfusions were needed.
- On day #10, she was begun on hemodialysis.
- She remains on chronic hemodialysis, unable to work.
- She hopes to get a kidney transplant.
8 opinions..

- Patient safety should be more important than any other driver— at the bedside
- Both blood and drugs ( $$ & user acceptance)
- ID = passive; Location = active
- Do not have “treat” all patients (go where the problems are)
- Continuous monitoring of patients— avoid the wand if you can
- People stationery = barcode; people moving=RFID
- Not just identification → retrieve information
- A bridge between existing IT systems

Final word…

“Health care has to look at medical errors not as a special case of medicine, but rather as a special case of error …and to apply technologies and approaches used in other fields to reduce errors and improve patient outcomes.”

Institute of Medicine Report: To err is human, 2000