Patient Safety, Error Reduction, and Quality Improvement: Successes and Lessons Learned from 10 Years of Lean, Process Redesign, and Hospital-wide Staff Engagement

Milenko J. Tanasijevic, M.D., M.B.A.
Vice Chair for Clinical Pathology, Quality and Safety
Department of Pathology, Brigham & Women’s Hospital
Associate professor of Pathology, Harvard Medical School
Brigham and Women’s Hospital

- 763-bed teaching affiliate of Harvard Medical School
- Founding member of Partners HealthCare.
- > 4.2 MM annual patient visits
- 46,000 inpatient stays
- The largest birthing center in Massachusetts
- 47 operating rooms, 150 ambulatory sites
- > $2.6 billion in operating revenues
- 16,000 employees
- Biomedical Research Institute
  - $670 million in research funding
  - Second largest NIH funded hospital in the U.S.
BWH Department of Pathology

<table>
<thead>
<tr>
<th>Service</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical Laboratories</td>
<td>&gt; 5.6 MM billed tests</td>
</tr>
<tr>
<td>Transfusion Service</td>
<td>48,300 blood products</td>
</tr>
<tr>
<td>Surgical Pathology</td>
<td>53,000 accessions + 24,500 consults</td>
</tr>
<tr>
<td>Cytopathology</td>
<td>35,000 accessions + 1,760 consults</td>
</tr>
<tr>
<td>Cytogenetics</td>
<td>7,800 accessions</td>
</tr>
<tr>
<td>Molecular Diagnostics</td>
<td>10,500 accessions</td>
</tr>
<tr>
<td>Autopsies</td>
<td>219 adults + 35 infants</td>
</tr>
</tbody>
</table>
Our Mission

The mission of Brigham and Women's Department of Pathology, as one of the world's premier Pathology Departments, is to provide the highest quality and most cost-effective care for our patients; to lead the field of Pathology discovery through innovative basic, translational and clinical research; and to provide exceptional training for the next generation of pathologists.

Ramzi Cotran, M.D.
1933-2000
Chairman of BWH Pathology
(1974-2000)
Strategic Goals

Core Laboratories

- Process Improvement
  - Clinical Decision Support
  - LEAN
  - Automation

Advanced Diagnostics

- Molecular Pathology
  - Center For Advanced Molecular Diagnostics
- Toxicology / LCMS
- Flow Cytometry
- Immunology

Resource Redeployment
Process Improvement Initiatives

- Central Processing
  - Communication Handoff
  - Supply Standardization
- Hematology Automation
  - Auto verification
- Phleb Rounding Assignments
  - EPIC / Sunquest

- Physician Order Entry-Based Clinical Decision Support
  - 2nd Gen Automation

- Positive Patient Identification
- Outpatient Phlebotomy
- Analytical \[\begin{array}{c}
\text{Chemistry Automation} \\
\text{Blood Draw Process}
\end{array}\]
- Displaying Order Instructions to RN
- Phlebotomy Staffing Model
A NASCAR pit stop taken by a U.S. soldier. The U.S. Army #01 car driven by Mark Martin in the pits at Daytona for the Daytona 500. From flickr (CC-BY-SA 2.0) but claimed originally from U.S. Army. http://flickr.com/photos/soldiersmediacenter/40609446
Talk Outline

I. Optimization of test ordering
   • Physician Order Entry-Driven Clinical Decision Support
   • Computerized alert-value paging system (prototype)

II. Phlebotomy

III. Order Communication System including Positive Patient Identification

IV. Pathology-wide Safety Reporting System
I. Physician Order Entry-Driven Clinical Decision Support

- Templates
- Order Sets

Moderate Cost & Complexity

- Alerts
- Reminders
- Protocols

High Cost & Complexity

Low Cost & Moderate Complexity

- Reports
- Dashboards

Low Cost & Complexity

- Infobuttons (clinical reference)

Credits: Roberto A. Rocha, MD, PhD
Clinical Decision Support Initiatives

- **Optimized Lab Utilization**
  - Lab charges display
  - Reminders for redundant labs
  - Appropriateness guidelines
  - Frequency reminders

- **Improved Patient Safety**
  - Computerized alert value identification and auto-paging
    - Test result trending
    - Drug-lab interactions
  - Appropriate timing of therapeutic drug levels
Guiding Principles

- **Speed** is everything
- Anticipate needs and deliver in **real time**
- Fit into the user’s **workflow**
- Little things can make a big difference – proper **defaults**
- Physicians **resist stopping** - never say never
- Provide **alternatives**
- Simple activities work best – not complex guidelines
- Avoid manual data entry - be sure you really need it
- Monitor **impact**, get feedback, and respond
- **Manage** and update content on the ongoing basis

Bates et al, JAMIA 2003
Redundant Test Reminders

Potential Redundant Lab

Redundant Order: PROFILE 20: NEXT AVAILABLE; on 12/02/94 at 7am;

Tests in Lab:

ACCORDING TO THE ANCILLARY UTILIZATION COMMITTEE, A PROFILE 20 IS GENERALLY NOT NEEDED MORE OFTEN THAN 1 TIME(s) EVERY 24 HRS. CONTACT DAVID BATES, x7063 IF YOU HAVE QUESTIONS.

[X] C Cancel order(s) Reason to Proceed:
[ ] A Clinical condition has changed
[ ] B Different site or testing conditions
[ ] D Previous specimen unsatisfactory
[ ] E Last Result requires confirmation
[ ] F Condition warrants more frequent testing
[ ] O Other

Type the letter of the reason. Type <C> to cancel the order. <Enter>: done.
## Level of Acceptance of Reminders

<table>
<thead>
<tr>
<th></th>
<th>Intervention (n = 437)</th>
<th>Control (n = 502)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Accepted reminder</td>
<td>300 (69%)</td>
<td>N/A</td>
</tr>
<tr>
<td>Test performed after reminder</td>
<td>117 (27%)</td>
<td>257 (51%)</td>
</tr>
</tbody>
</table>
### Reasons for Overrides of Redundant Tests

<table>
<thead>
<tr>
<th>Reason</th>
<th>Frequency</th>
<th>Test Done</th>
<th>Justified</th>
</tr>
</thead>
<tbody>
<tr>
<td>Condition warrants more frequent testing</td>
<td>43 (31%)</td>
<td>34 (79%)</td>
<td>21 (49%)</td>
</tr>
<tr>
<td>Clinical condition has changed</td>
<td>34 (25%)</td>
<td>20 (59%)</td>
<td>11 (32%)</td>
</tr>
<tr>
<td>Last result requires confirmation</td>
<td>18 (13%)</td>
<td>12 (67%)</td>
<td>10 (56%)</td>
</tr>
<tr>
<td>Previous specimen unsatisfactory</td>
<td>15 (11%)</td>
<td>7 (47%)</td>
<td>6 (40%)</td>
</tr>
<tr>
<td>Different site or testing conditions</td>
<td>11 (8%)</td>
<td>6 (55%)</td>
<td>5 (45%)</td>
</tr>
<tr>
<td>Other</td>
<td>16 (12%)</td>
<td>9 (56%)</td>
<td>3 (19%)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>137 (100%)</td>
<td>88 (64%)</td>
<td>56 (41%)</td>
</tr>
</tbody>
</table>
Potential Adverse Consequences of Canceled Tests

- Evaluated canceled tests followed by abnormal result within 3 days
- Only 8 (4%) of these tests provided new information
  - 3 UA w/ few RBCs or WBCs, previously negative
  - 3 Sputum Cx w/ new pathogen, all patients had stable CXR
  - Digoxin level dropped from 1.0 to 0.5 ng/mL
- Change of medical management in 2/8 cases
  - One patient given new Abx
  - One patient given an extra dose of digoxin
## Redundant Orders In EPIC

<table>
<thead>
<tr>
<th>Tests</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>CBC with autodiff</td>
<td>24 hours</td>
</tr>
<tr>
<td>Hypercoag Panel</td>
<td>30 days</td>
</tr>
<tr>
<td>Hemoglobin electrophoresis</td>
<td>30 days</td>
</tr>
<tr>
<td>Hgb A1C</td>
<td>30 days</td>
</tr>
<tr>
<td>Protein electrophoresis</td>
<td>7 days</td>
</tr>
<tr>
<td>Immunology (ANA, RF, CCP)</td>
<td>1 year</td>
</tr>
<tr>
<td>Vitamin D</td>
<td>7 days</td>
</tr>
<tr>
<td>Anemia (Ferritin, Folate, B12)</td>
<td>7 days</td>
</tr>
<tr>
<td>Thyroid (TSH, free T4, total T4)</td>
<td>7 days</td>
</tr>
<tr>
<td>*Phenobarbital</td>
<td>20 days</td>
</tr>
</tbody>
</table>
## Redundant Orders In EPIC

<table>
<thead>
<tr>
<th>Tests</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>*Antiepileptics</td>
<td>3 days</td>
</tr>
<tr>
<td>*C. Difficile</td>
<td>5 days</td>
</tr>
<tr>
<td>*Stool Culture</td>
<td>24 hours</td>
</tr>
<tr>
<td>O&amp;P</td>
<td>24 hours</td>
</tr>
<tr>
<td>*Urine culture</td>
<td>24 hours</td>
</tr>
<tr>
<td>*Sputum culture</td>
<td>24 hours</td>
</tr>
<tr>
<td>Viral loads</td>
<td>24 hours</td>
</tr>
<tr>
<td>Viral and Micro serologies</td>
<td>7 days</td>
</tr>
<tr>
<td>Beta glucan and GM</td>
<td>4 days</td>
</tr>
</tbody>
</table>
Duplicate Reminder in EPIC
“Daily” will not be allowed as frequency
Clinical Decision Support for Therapeutic Drug Monitoring

32% 68%

Levels Drawn Too Early
Correctly Timed Levels

Number of Vancomycin Levels

Time Since Last Dose (Hours)

Percent of Vancomycin Levels

Melanson / Tanasijevic: Am J Clin Path. 2013
Ib. Computerized Communication of Alert Laboratory Values

<table>
<thead>
<tr>
<th>Rule</th>
<th>Alerting Criterion</th>
<th>No.</th>
<th>(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Hematocrit has fallen 10% or more since last result and is now less than 26%†</td>
<td>38</td>
<td>(19.8)</td>
</tr>
<tr>
<td>2</td>
<td>Serum glucose is greater than or equal to 400 mg/dL</td>
<td>34</td>
<td>(17.7)</td>
</tr>
<tr>
<td>3</td>
<td>Hematocrit has fallen 6% or more since previous result, and has fallen faster than 0.4% per hour since last result, and is now less than 26% and the patient is not on the cardiac surgery service†</td>
<td>32</td>
<td>(16.7)</td>
</tr>
<tr>
<td>4</td>
<td>Serum potassium is greater than or equal to 6.0 mEq/L</td>
<td>32</td>
<td>(16.7)</td>
</tr>
<tr>
<td>5</td>
<td>Serum potassium has fallen 1.0 mEq/L or more over the last 24 hours and is now less than 3.2 mEq/L‡</td>
<td>29</td>
<td>(15.1)</td>
</tr>
<tr>
<td>6</td>
<td>Serum potassium less than 3.3 mEq/L and patient has an active order for digoxin‡</td>
<td>15</td>
<td>(7.8)</td>
</tr>
</tbody>
</table>

Kuperman G et al., J Am Med Inform Assoc. 1999
Design of the Alerting System

New data (e.g., laboratory results, medications)

- all new clinical data is evaluated by event monitor
- notifier called if alert detected

Event monitor

- automatic interface from HIS to page computer

Notification program

Coverage list database

- indicates which house officer is covering the alerting patient

Page computer

- physician sees ‘8888’ on digital pager

Physician

- physician logs onto computer to review alert and take action

Review alert, take action
Fail-Safe Notification Sequence

Step 1:
- Page computer
  - If alert not acknowledged by MD within 15 min

Step 2:
- Border of computer screen on patient’s floor turns red
  - If alert not acknowledged within 30 min

Step 3:
- Workstation in Telecommunications starts beeping

Person notified:
- Physician
- Nurse
- Phone operator

Review alert, take action

Phone operator reads alert and calls floor
“Alerts” Screen: Emphasizing an Abnormality
Clinical Action Sub-Screen

View: EtLookup
Patient: XXXXXXXXXX, XXXX 75F 00000000  Adm: 06/30/98 Room: 14A-202
Time: 03:46 PM Jul 2, 1998 Alert #1000315 14A phone: x7910
Alert: DANGEROUSLY LOW SERUM POTASSIUM

Reason: (BLOOD) K = 2.9 at 11:24 am, 07/02/98. VERIFIED.
Patient is currently on DIGOXIN.

Relevant medications and lab results:
Change DIGOXIN PO to 0.125 MG PO QD HOLD IF: ht < 55 (07/02)
LASIX 40 MG PO QD Starting ON 7/2/98 (07/02) (07/01)

Act: [ ]A D/C or EDIT relevant medications
[ ]B Order POTASSIUM CHLORIDE IV
[ ]C Order KCL IMMEDIATE REL. PO
[ ]D Order KCL SLOW REL. PO
[ ]E Order set: STAT EKG
[ ]F Order set: STAT K
[ ]G Exit to order entry

Poon, Eric Gon-Chee, M.D. Bp#30051 was paged on 03:48 PM Jul 2, 1998
Covering M.D.: Poon, Eric Gon-Chee, M.D. Bp#30051
<Page M.D.> <New data>
<Done> <Not my patient> <Comments> <Logic>
Alert Evaluation

Please check one or more.

- A. [X] I will take action as a result of this message
- B. [ ] I was already aware of this condition
- C. [ ] This information is interesting but I won’t do anything differently
- D. [ ] Alert is incorrect (data do not reflect patient’s true condition)
- E. [ ] None of the above (Please leave comment)

Press M for Comments

M. Comments

Ok  Contact Gil Kuperman, M.D. at x0549 or Bp#1783 for immediate concerns.

Please type the letter or letters that best describe alert. Enter A, B, C, D or E. Enter M to go to the comments box.
<table>
<thead>
<tr>
<th>Alert Type</th>
<th>Examples of Appropriate Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low or falling sodium</td>
<td>Isotonic or hypertonic solution intravenously, fluid restriction, demeclocycline</td>
</tr>
<tr>
<td>High sodium</td>
<td>Isotonic or hypotonic solution intravenously</td>
</tr>
<tr>
<td>Low or falling potassium, or low potassium with patient on digoxin</td>
<td>Potassium replacement (intravenous or oral)</td>
</tr>
<tr>
<td>High potassium</td>
<td>Discontinue potassium 50% dextrose with insulin</td>
</tr>
<tr>
<td></td>
<td>Furosemide</td>
</tr>
<tr>
<td></td>
<td>Bumetanide</td>
</tr>
<tr>
<td></td>
<td>Discontinue spironolactone or triamterene</td>
</tr>
<tr>
<td></td>
<td>Kayexalate (sodium polystyrene sulfonate)</td>
</tr>
<tr>
<td></td>
<td>Sodium bicarbonate</td>
</tr>
</tbody>
</table>
Impact of Auto-Alerting System

<table>
<thead>
<tr>
<th></th>
<th>Intervention (N = 94)</th>
<th>Control (N = 97)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Time Until Rx Ordered (hrs)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Median</td>
<td>1.0</td>
<td>1.6</td>
<td>0.003</td>
</tr>
<tr>
<td>Mean</td>
<td>4.1</td>
<td>4.6</td>
<td>0.003</td>
</tr>
<tr>
<td><strong>Time Until Condition resolved</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Median</td>
<td>8.4</td>
<td>8.9</td>
<td>0.11</td>
</tr>
<tr>
<td>Mean</td>
<td>14.4</td>
<td>20.2</td>
<td>0.11</td>
</tr>
<tr>
<td>Knowledge Asset</td>
<td>Type</td>
<td>Epic Capability</td>
<td>Content Gap</td>
</tr>
<tr>
<td>-----------------------------------------------------</td>
<td>-----------------------</td>
<td>-----------------</td>
<td>-------------</td>
</tr>
<tr>
<td>KnowledgeLink - Infobutton manager: ~650 rules</td>
<td>Reference: local</td>
<td>P</td>
<td>TBD</td>
</tr>
<tr>
<td>Partners Handbook - POC web portal</td>
<td>Reference: local</td>
<td>x</td>
<td>TBD</td>
</tr>
<tr>
<td>Knowledge Management Portal</td>
<td>Reference: local</td>
<td>x</td>
<td>TBD</td>
</tr>
<tr>
<td>Clinical Reminders - disease management and preventive care: ~340 rules; outpatient</td>
<td>Rule: local</td>
<td>✓</td>
<td>TBD</td>
</tr>
<tr>
<td>Drug-Pregnancy Alerts: ~687 rules; outpatient</td>
<td>Rule: custom</td>
<td>✓</td>
<td>TBD</td>
</tr>
<tr>
<td>Drug-Laboratory Alerts: ~440 rules; outpatient</td>
<td>Rule: custom</td>
<td>✓</td>
<td>TBD</td>
</tr>
<tr>
<td>Drug-Disease Alerts: ~509 rules; outpatient</td>
<td>Rule: custom</td>
<td>✓</td>
<td>TBD</td>
</tr>
<tr>
<td>Drug-Utilization Alerts: ~12 rules; outpatient</td>
<td>Rule: local</td>
<td>✓</td>
<td>TBD</td>
</tr>
<tr>
<td>Health Monitoring: ~70 rules; outpatient</td>
<td>Rule: local</td>
<td>✓</td>
<td>TBD</td>
</tr>
<tr>
<td>Critical Laboratory Alerts: ~70 rules + 175 (new); results review</td>
<td>Rule: local</td>
<td>✓</td>
<td>TBD</td>
</tr>
<tr>
<td>Problem List Dictionary: ~4,000 concepts from SNOMED CT with ICD mappings; in/outpatient</td>
<td>Dictionary: custom</td>
<td>✓</td>
<td>TBD</td>
</tr>
<tr>
<td>Problem List Classification Subsets: ~501 problem classes using SNOMED/ICD/CPT; in/outpatient</td>
<td>Dictionary: local</td>
<td>✓</td>
<td>TBD</td>
</tr>
<tr>
<td>Immunization Schedule Reminders: ~370 rules; outpatient</td>
<td>Rule: local</td>
<td>✓</td>
<td>TBD</td>
</tr>
<tr>
<td>Maple - Problem-list reminders: ~70 rules; outpatient</td>
<td>Rule: local</td>
<td>✓</td>
<td>TBD</td>
</tr>
<tr>
<td>Documentation Flowsheets: ~5 templates + 400 concepts; outpatient</td>
<td>Template: local</td>
<td>✓</td>
<td>TBD</td>
</tr>
<tr>
<td>Master Drug Dictionary (MDD): ~8,600 customized medication concepts; 3,500+ non-commercially available medications; in/outpatient</td>
<td>Dictionary: local</td>
<td>✓</td>
<td>TBD</td>
</tr>
<tr>
<td>MMIDL - Medication Concept Mappings: 15,700 mappings to First Databank and RxNorm</td>
<td>Dictionary: local</td>
<td>P</td>
<td>TBD</td>
</tr>
<tr>
<td>Outpatient neonatal dosing dictionary: 60 orderable medication concepts; outpatient</td>
<td>Dictionary: local</td>
<td>✓</td>
<td>TBD</td>
</tr>
<tr>
<td>Drug-Drug Interaction Knowledge Base (DDI): ~10,000 rules; in/outpatient</td>
<td>Rule: local</td>
<td>✓</td>
<td>TBD</td>
</tr>
<tr>
<td>Duplicate Therapy Alerts: 23 duplicate therapy categories; in/outpatient</td>
<td>Rule: custom</td>
<td>✓</td>
<td>TBD</td>
</tr>
<tr>
<td>Nephros - Drug Dosing in Renal Insufficiency: 400 dosing rules; in/outpatient</td>
<td>Rule: local</td>
<td>P</td>
<td>TBD</td>
</tr>
</tbody>
</table>

Roberto A. Rocha, MD, PhD
1. Patient Arrives
   • Patient hands in their laboratory requisition form.
   • Patient enters name and arrival time into log book.
   • Patient waits to be called.

2. Accession
   (3 minutes, 90th percentile)
   • Phlebotomist enters providers’ orders into the laboratory information system (LIS) and prints specimen labels.
   • Phlebotomist attaches the printed specimen labels onto requisition form and places in “ready basket”.

3. Patient Draw
   (7 minutes, 90th percentile)
   • Phlebotomist calls in patient based on arrival time.
   • Phlebotomist draws blood according to venipuncture procedure.

4. Patient Leaves
   • Phlebotomist sends specimen to appropriate laboratory for testing.

Primary End-Point: Patient Wait Time
Goal: 90% of patients waiting less than 10 minutes

Service Time
(10 minutes, 90th percentile)
Phlebotomist Circle of Work
(Blood Draw ~6 minutes)

- VA/Draw: 51%
- NVA(E) / VE: Prep for Draw & Label Package: 24%
- Wait: 10%
- Inspection: Spec Verification: 8%
- Travel: Calling Next Patient & Placing Bag in Bin: 0%
- Restick: 2%
- Processing: Copy of Standing Orders & Sealing Urine: 5%
Improvement Opportunities

• **Patient Wait Time**
  • Decrease
    • Optimize / reorder steps of the patients visit
    • Improve patient’s identification upon arrival
  • Manage Expectations
    • Clearly identify patient’s order in line
    • Explicit instructions for patients arriving prior to the 8 AM opening

• **Increase Available Phlebotomy Draw Time**
  • Eliminate duplicative work
    • Before sending specimens via pneumatic tube
    • Duplicate labeling
  • Optimize staffing levels according to volume
Optimization of Staffing

Number of Phlebotomists

Number of Draws

Time of Day

Mijailovic et al. Arch Pathol Lab Med 2014
Optimization of Staffing

Mijailovic et al. Arch Pathol Lab Med 2014
Patient Satisfaction

Excellent and Very Good Responses (%)

<table>
<thead>
<tr>
<th></th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>88%</td>
<td>93%</td>
<td>93%</td>
<td>91%</td>
<td>93%</td>
</tr>
<tr>
<td></td>
<td>62%</td>
<td>69%</td>
<td>72%</td>
<td>77%</td>
<td>56%</td>
</tr>
<tr>
<td></td>
<td>85%</td>
<td>82%</td>
<td>85%</td>
<td>85%</td>
<td>88%</td>
</tr>
<tr>
<td></td>
<td>85%</td>
<td>88%</td>
<td>92%</td>
<td>88%</td>
<td>80%</td>
</tr>
<tr>
<td></td>
<td>93%</td>
<td>90%</td>
<td>85%</td>
<td>90%</td>
<td>90%</td>
</tr>
</tbody>
</table>
IIb. Inpatient Phlebotomy

- **Centralized phlebotomy services**
  - 375,000 venipunctures per year
  - 50% of inpatient draws (non-central line draws)

- Until 2015, order entry *without electronic order communication* with LIS
  - Paper requisitions
  - Specimens relabeled in the lab
  - Stand-alone Positive Patient Identification System (Lattice)
**Variation in Blood Draw Process**

1. **Arrive on unit**
   - 1 min
   - **Requisition Review**
     - 1. Pull requisition
     - 2. Highlight tests ordered
     - 3. Initials and write ID#
     - 4. Fold and place in specimen bag

2. **Tube Preparation**
   - 1 min
   - **Select tubes for draw**
   - 2. Obtain gauze & alcohol pads
   - 3. Select patient name on Lattice
   - 4. Put on gloves

3. **Blood Draw of Patient**
   - 3 min
   - 1. Enter patient room
   - 2. Introduce him/herself to patient
   - 3. Ask for patient name and DOB
   - 4. Scan patient bracelet
   - 5. Ask for arm preference
   - 6. Draw blood
   - 7. Dispose of needles
   - 8. Step away from patient (may exit room)

4. **Specimen Prep for Sending to Lab Control**
   - 2 min
   - 1. Select tests on Lattice
   - 2. Scan own ID
   - 3. Print labels
   - 4. Label tubes
   - 5. Verify labels match MRN
   - 6. Place tubes in bag and seal
   - 7. Dispose of gloves

5. **Sign off on completed patients**
   - 1 min
   - 1. Write time on pod sheet
   - 2. Highlight completed pts
   - 3. Return pod sheet to UC desk

6. **Leave unit**

---

*Steps in blue indicate observed variation (what, where, when) in process*

Average is 7 minutes per patient, but can vary greatly (2-15 min)
Inpatient Phlebotomy: Challenges

Time of First Patient Draw Completed for Day Shift (June 2009)

- Frequency
- Cumulative %
Frequency Histogram for Draws per Hour for 8-9 AM
(Dec 09 - Jan 10)
Process Improvement Goals

- 80% of phlebotomists have first patient drawn within 30 minutes after start of shift
- 90% of phlebotomists complete 8 AM rounds by 9:30 AM
- 5-7 patient draws per hour during 8 AM rounds
- Less than 4 collection errors per thousand draws each month (mislabeled, unlabeled, wrong specimen, and no specimen)
Summary of Kaizen Events

1. Gather & organize supplies and equipment
2. Travel to assigned unit
3. Check phleb book for patients
4. Draw patients blood 1 at a time
5. Send specimen to lab via pneumatic tube
6. Proceed to next unit assigned by team leader
7. Return equipment and supplies


**Kaizen #1**
Supply Replenishment & Cart Standardization (Aug 2009)

**Workout Rounding Schedules and Assignments**
(Mar 2010)

**Kaizen #3**
Blood Draw Process (Feb 2010)

**Kaizen #2**
Communication & Workload Management (Oct 2009)

**Kaizen #1**
Handoff & Change of Shift Activities (Aug 2009)

Supply Standardization and Communication

- Communication Strategy within Shift
  - Communication Board
  - Team Leader priorities
  - Missed draw communication and handoff
  - Draws for patients who are not in room
- Use of Direct Connect phones to more easily contact phlebotomists
- Optimize rounding schedules in collaboration with nursing
New Blood Draw Process

- Eliminated unnecessary steps
  - Initializing the requisition
  - Highlighting phlebotomy log sheet
- Set rules for the use of cart and the order for patient draws
  - Cart to be placed in or near the patient room and locked
  - Order draws based on room #
- Rearranged steps and set proper order and location
  - Labeling tubes at the bedside
  - Highlighted 4 key safety checks
  - Developed memory aids for frequently missed steps
  - Use of pictures and catch phrases
Earlier Collection Times

- Performance with new staffing model
- Performance before reallocation
% Phlebotomist First Draw by 5:30 AM for 5:00 AM Rounds

Process Improvement

Kaizen #2

Kaizen #3

Workout and New Staffing Model

* Kaizen #1 Aug 2009

Month and year

% Phlebotomists Completing 8:00 AM Rounds by 9:30 AM

Month and Year

Process Improvement

Post-Process Improvement

Workout and New Staffing Model

* Kaizen #1 Aug 2009

Kaizen #2

Kaizen #3

Decreased Number of Safety Reports
III. Order Communication System

- Sunquest LIS (Nov 2014)
- Epic HIS (May 2015)
- Order communication between Epic and Sunquest
  - Limit the number of paper requisitions
  - Reduce specimen re-labeling
- Fully integrated Positive Patient Identification (PPID) system (Sunquest Collection Manager)
  - Sunquest labels generated at the bedside
  - Collection and processing instructions shown
  - Use of Collection Manager by nursing, ED, outpatient phlebotomy and procedural areas
Sunquest Collection Manager

Use scroll bar and +/- icons to navigate screen

Verify that correct patient is displayed

Tap Confirmed button to continue

Courtesy Stacy Melanson MD PhD
Collection Screen

Patient information

Ordered tests

Tube types Listed in correct Order of draw

Courtesy Stacy Melanson MD PhD
Print Labels – Label Specimens

You must click on 
**Labels** first and 
Label all specimens

When specimens 
Are labeled – click  
**Done**

Courtesy Stacy Melanson MD PhD
Reduction of Pre-analytical Errors Pre- vs. Post-Epic in Inpatient Nursing and ED

% Reduction in Errors

Series 1
Series 2

1: 66, 70
2: 60, 79
3: 86, 92
4: 27, 47
IV. Safety Event Reporting System

Types of Safety Events:

- **Pre-analytical**
  - Incorrect selection of tests by the ordering clinician
  - Specimen collection
    - Patient misidentification
    - Wrong number, type of specimen
    - Mislabelled / unlabeled specimen tubes
  - Transportation / lost specimens
  - Log-in errors
  - Processing and routing errors
    - Specimen sent to the wrong lab
    - Delays in sending out to reference laboratories

- **Intra-analytical**
  - Technical (QC, instrument failure)
  - Suboptimal quality or quantity of specimen
  - Specimen mix ups before or during analysis
  - Product recalls (reagent, instrument)

- **Post-analytical**
  - Incorrect interpretation or results
  - Result entry errors
  - Delayed reporting or results
  - Reporting of wrong results

Delays caused by HIS/LIS or Instrument downtime
Categories of Severity

• “No harm”
  • Low potential for patient harm
  • Identified before reporting of results to the ordering clinicians

• “Non-lab event”
  • Pre-analytical errors caused by clinical / nursing staff
    • Test incorrectly ordered by the provider
    • Mis-timing of specimen collection
    • Incorrect understanding about scheduled phlebotomy rounds

• “Near harm / near miss”
  • Potential to cause harm or injury
  • Identified before major harm occurred

• “Harm”
  • Direct patient impact resulting in serious injury or death
### Medical Directors Review

**Event List: Require Action Job Aid # 01-17**

<table>
<thead>
<tr>
<th>Event Description</th>
<th>Enter Safety Report</th>
<th>Event Requires Medical Director Review (refer to Workflow #02-17)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lost Specimen (includes specimens sent for testing intended for multiple locations eg. Micro and AP)</td>
<td>Yes</td>
<td>All events</td>
</tr>
<tr>
<td>Receipt of Mislabeled or Unlabeled Specimen (includes specimen/req mismatch, NO D/T/I)</td>
<td></td>
<td>For AP, CAMD, Cytology only mislabeled and unlabeled specimens which impact clinical care or have the potential to impact clinical care.</td>
</tr>
<tr>
<td>Specimen Mislabeled in laboratory (excludes pathology mislabeled slides and blocks)</td>
<td></td>
<td>For AP, CAMD, Cytology only events which impact clinical care or have the potential to impact clinical care. *Note: Mislabeled slides and blocks are tracked in PowerPath only, entry of a safety report is not required.</td>
</tr>
<tr>
<td>System testing/Process failure which impacted tissue quality, test results or diagnosis (eg. instrument problem that impacted a number of tests/test results,diagnosis)</td>
<td>Yes</td>
<td>All events</td>
</tr>
<tr>
<td>Finalized report with misidentified (incorrect) patient</td>
<td>Yes</td>
<td>All events</td>
</tr>
<tr>
<td>Finalized report with incorrect test results or major diagnostic error</td>
<td>Yes</td>
<td>All events</td>
</tr>
<tr>
<td>Delay Reporting Results</td>
<td></td>
<td>For AP, CAMD, Cytology, BB only delay reporting results which impact clinical care.</td>
</tr>
<tr>
<td>Failure to report Critical Value or Result</td>
<td>Yes</td>
<td>For CP only delay reporting results for category 3 and 4 safety reports.</td>
</tr>
<tr>
<td>Injury to patient or donor</td>
<td>Yes</td>
<td>All events</td>
</tr>
<tr>
<td>Adverse patient or donor outcome</td>
<td>Yes</td>
<td>All events</td>
</tr>
<tr>
<td>Safety report classified by reporter as 3 or 4</td>
<td>NA</td>
<td>All events</td>
</tr>
</tbody>
</table>

**Blood Bank only**

<table>
<thead>
<tr>
<th>Event Description</th>
<th>Enter Safety Report</th>
<th>Event Requires Medical Director Review (refer to Workflow #02-17)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incorrect blood product issued</td>
<td>Yes</td>
<td>Requires Medical Director review when patient care is impacted</td>
</tr>
<tr>
<td>Wrong blood in tube (blood sample does not match historical ABO type)</td>
<td>Yes</td>
<td>Requires Medical Director review when patient care is impacted</td>
</tr>
<tr>
<td>Product Wastage</td>
<td>NA</td>
<td></td>
</tr>
<tr>
<td>Product transfused without transfusion order or consent</td>
<td>NA</td>
<td></td>
</tr>
<tr>
<td>Emergency release without patient name or MRN</td>
<td>NA</td>
<td></td>
</tr>
<tr>
<td>Products issued/transfused not meeting patient special requirements (eg. irradiated, washed, etc)</td>
<td>Yes</td>
<td>NA</td>
</tr>
<tr>
<td>Delay receiving ordered blood products</td>
<td>Yes</td>
<td></td>
</tr>
</tbody>
</table>
Weekly team huddles

Follow-up to External Reported Events
Guide for Technical Directors and Pathology Managers
Workflow #02-17

Technical Director/Pathology Manager receives email notification of Hospital Safety Report

Technical Director/Pathology Manager reviews report and collects details of what happened

Using definitions in SOP # QSA1.4, Technical Director/Pathology Manager assigns a preliminary event type of No Harm, Near Harm/Near Miss, Harm or No Latent event.

AP, CAMD, Cytology: review all reports with Laboratory Director, Pathologist and Director of Ops.
BB and CP refer to Event List: Requires Action
Job Aid #01-17 for those events that require review with Medical Director and Director of Ops.
Suspected Harm, Harm and Harm events must be reviewed with the Medical Director, Director of Ops and Laboratory Director prior to initiating notification process.

Complete investigation and document on Department Form

Review completed investigation with Pathologist or Medical Director, Director of Ops, Dept Compliance Officer and Laboratory Director

Did event cause harm?

Yes

Near Harm/Near Miss Event
For near harm/near miss events notify via Email:
QA Vice Chair
QA Director
QA Compliance Officer
BB, TTL Compliance Officer (as appropriate)
Note: For DFCI patients, BWH QA Director and BWH Risk Management will assess notification requirements

No

Did event cause harm or near harm?

Yes

Complete Investigation

Enter follow-up into safety reporting system.
Do not close report.
Note: reports closed by Risk Management.

No

Complete Investigation

Is RCA or Risk Debrief needed?
QA Director & Risk Management will assess

Yes

QA Director determines who will perform RCA/Risk Debrief
RCA/Risk Debrief Performed

No

Is investigation complete and closed?

Yes

Prepare and Enter hospital safety report response, enter factual summary. State action items are being implemented.

Complete Action Items

Send evidence of completed actions to QA Compliance Officer

QA Compliance Officer creates electronic investigation file

Events that cause patient harm or near harm are tracked and trended and shared via dashboard by Director of QA

Weekly team huddles
Staff Training

‘Healthstream’ training modules
In-person (1.5 hr, case scenarios)

Trainees:
Pathologists
Directors of Operations
Technical Directors
Managers
Compliance Officers
Compliance Sr. Techs
Supervisors

Content:
1. Roles and Responsibilities
2. Event notification and discovery
3. When and How to enter a report
4. Event Types
   • No Harm
   • Near Harm/Near Miss and Harm
   • Not Lab Event
5. Investigation
6. Leadership notification
7. QA Review
8. How to enter follow-up in Hospital Safety Reporting System
9. Quiz

Courtesy of Denise M. Fountain MS, MT(ASCP)SBB CQA(ASQ)
Director of Quality Assurance and Regulatory Compliance
# Training Scenarios

<table>
<thead>
<tr>
<th>Event Description</th>
<th>Event Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Unit collect - 4 blood specimen tubes collected and placed in one specimen bag. Upon receipt in Lab Control only the gray top tube was labeled with a Sunquest label, all other tubes were unlabeled.</td>
<td></td>
</tr>
<tr>
<td>2 The molecular chimerism report for patient A was manually filed in Epic into patient B’s record.</td>
<td></td>
</tr>
<tr>
<td>3 Two microcontainers received at same time on Twin A and Twin B. Upon receipt in Lab Control Twin B microcontainer tube was relabeled with Twin A label. Samples given to Chemistry for testing and since both labeled with Twin A identifiers pooled together for testing. Results reported on Twin A.</td>
<td></td>
</tr>
<tr>
<td>4 Urine HCG was resulted as positive in Sunquest/Epic. Serum HCG ordered and resulted as negative. Provider called to request verification of urine HCG. Investigation showed that urine HCG had been resulted and recorded on the urine HCG testing form as negative but transcribed in Sunquest as positive.</td>
<td></td>
</tr>
<tr>
<td>5 Department of Pathology received consult slide material on 6/21/17 and subsequently lost the patient slides between the point of department receipt and transport to the MRB laboratory for consultation.</td>
<td></td>
</tr>
</tbody>
</table>
Safety Event Trending

Safety Events by Fiscal Year

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Delays</td>
<td>131</td>
<td>1</td>
<td>45</td>
<td>19</td>
<td>20</td>
<td>24</td>
<td>19</td>
</tr>
<tr>
<td>Mislabeled</td>
<td>91</td>
<td>2</td>
<td>14</td>
<td>13</td>
<td>20</td>
<td>26</td>
<td>19</td>
</tr>
<tr>
<td>Unlabeled</td>
<td>100</td>
<td>3</td>
<td>21</td>
<td>17</td>
<td>18</td>
<td>25</td>
<td>16</td>
</tr>
<tr>
<td>Other</td>
<td>163</td>
<td>1</td>
<td>29</td>
<td>20</td>
<td>23</td>
<td>43</td>
<td>47</td>
</tr>
</tbody>
</table>
Process Improvement
Key Factors for Success

• Project definition
  • Sharply defined problem(s)
  • Realistic goals (ambitious but achievable)
  • Clear articulation of boundaries

• Process improvement events
  • Direct engagement of front-line staff
  • Detailed value stream map
  • Simple, well-defined interventions
  • Real-time testing
  • Real-life environment
  • Rapid iteration

• Post-intervention period
  • Dashboards for key metrics
  • Application to related processes and activities
  • Culture of continuous process improvement

Communication
Strategic Goals

Core Laboratories

• Clinical Decision Support
• LEAN
• Lab Automation

Advanced Diagnostics

• Molecular Pathology
• Center For Advanced Molecular Diagnostics
• Molecular Virology
• Tissue Typing
• LCMS
• Flow Cytometry

Resource Redeployment
Quality Team
Stacy Melanson
Denise Fountain
Pam Wakefield
Ellen Goonan
Bill Lane
Athena Petrides
Cathleen Quade
Fred Schoen
Ed Cibas
Jason Hornick
Rick Kaufman

Research Assistants
Aileen Morrison
Rachel Le
Alex Mijailovic
Ida Bixho
Michael Kantartjis
Jamie Ransohoff
A NASCAR pit stop taken by a U.S. soldier. The U.S. Army #01 car driven by Mark Martin in the pits at Daytona for the Daytona 500. From flickr (CC-BY-SA 2.0) but claimed originally from U.S. Army http://flickr.com/photos/soldiersmediacenter/40609446