Automated Alert Management at CHRISTUS Health

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Agenda

• Introduction to CHRISTUS
• Why RASMAS?
• Overview of RASMAS
• CHRISTUS RASMAS Implementation
• Alert Management Business Process Improvement
• RASMAS Performance Metrics and CHRISTUS Results
• Benefits of Automated Alert Management
CHRISTUS Health System
A faith-based, not-for-profit health system comprised of more than 40 hospitals, inpatient and long-term care facilities, and dozens of clinics and other healthcare services.

St. John Hospital
With 135 acute-care beds, more than 400 physicians on the medical staff and almost 700 associates, CHRISTUS St. John Hospital provides a broad spectrum of adult, pediatric, medical, surgical and obstetrical care, as well as numerous ambulatory services.
Why RASMAS?

- Pre-automation alert management problems
  - Recalls were patchwork process; no way to assure that tasks were done; no mechanism for sharing notices between facilities

- Responsibility for finding a solution
  - Corporate quality committee

- Approach to finding a solution
  - Evaluation of alternative technical solutions; parallel evaluation by product domains of completeness and compliance with established protocols

- Important factors in selecting RASMAS
  - Alerts for all product types; web-based solution; available audit trail; profile-based alert distribution; ease of use; litigation protection

Note: Information based on interviews with corporate management.
RASMAS Business Process Met CHRISTUS Needs

Business Process Objectives
- Reduce hospital at-risk days (improved patient safety, reduced liability)
- Provide enterprise-wide solution
- Minimize staff effort
- Useable in all hospital settings
- Cost justifiable

Business Process Fundamentals
- Comprehensive process which supports all product types
- Efficient alert processing and closure
- Accountability at all times
- Support for management oversight
- Historical information for process improvement
What is RASMAS?
Risk and Safety Management Alert System

Web-Based
• No IT Involvement
• Minimized Mitretek on-site involvement

Comprehensive
• Alert Scope
• Process Scope

Scalable to Any Size Organization

Structured Workflow Process
• Clear Accountability
• Efficient Internal Communications
• Automatic Delay Detection and Notification

Management Tools
• Real-time Status Reporting
• Delay Notice Generation
• Audit and Process Improvement Reports
### Domains, Alert Types, and Sources

#### Product Domains
- Biologics
- Biomedical Devices
- Blood Products
- Children’s Consumer Products
- Engineering & Facilities
- Food
- Information Systems
- Laboratory Products
- Medical Supplies
- OR Products
- Other Products
- Pharmaceuticals
- Radiology Products
- Tissue

#### Alert Types
- Recall Notices
- Field Corrections
- Bulletins
- Public Health Notifications
- Subscriber Provided Safety Alerts

#### Sources (selected)

**United States**
- FDA
- FDA MedWatch & Patient Safety News
- FDA Center for Biologics Evaluation and Research (CBER)
- FDA Center for Drug Evaluation and Research (CDER)
- FDA Center for Devices and Radiological Health (CDRH)
- United States Army Medical Materiel Agency (USAMMA)
- American Society of Health-System Pharmacists (ASHP)
- Consumer Product Safety Commission
- USDA Food Safety and Inspection Service (FSIS)
- Consumer Reports
- Subscriber Hospital Submissions

**International**
- Health Canada
- The Canadian Food Inspection Agency (CFIA)
- Safety Alert Broadcast System (SABS)
- Program for Monitoring Emerging Diseases (Pro Med)
- Food Safety Authority of Ireland (FSAI)
- Irish Medicines Board
- Reuter’s Health
- Medicines & Healthcare products Regulatory Agency (MHRA)
- European Medicines Agency (EMEA)
Alert Acquisition Process
Alert Management Process
# Average Number of Alerts Per Week

<table>
<thead>
<tr>
<th>Product Domain</th>
<th>Volume</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmaceutical Products</td>
<td>8.8</td>
</tr>
<tr>
<td>Food</td>
<td>8.1</td>
</tr>
<tr>
<td>Medical Supplies</td>
<td>4.2</td>
</tr>
<tr>
<td>Biomedical Devices</td>
<td>3.7</td>
</tr>
<tr>
<td>Laboratory Products</td>
<td>3.5</td>
</tr>
<tr>
<td>Children’s Consumer Products</td>
<td>2.2</td>
</tr>
<tr>
<td>Engineering and Facilities</td>
<td>1.9</td>
</tr>
<tr>
<td>OR Products</td>
<td>1.7</td>
</tr>
<tr>
<td>Radiology Products</td>
<td>1.3</td>
</tr>
<tr>
<td>Tissue</td>
<td>0.5</td>
</tr>
<tr>
<td>Blood Products</td>
<td>0.3</td>
</tr>
<tr>
<td>Information Systems</td>
<td>0.2</td>
</tr>
<tr>
<td>Other Products</td>
<td>0.3</td>
</tr>
<tr>
<td>Biologics</td>
<td>0.0</td>
</tr>
<tr>
<td>Total</td>
<td>36.5</td>
</tr>
</tbody>
</table>
CHRISTUS RASMAS Implementation

- Scope: 11 regions and 21 facilities
- Initial implementation: April 2005
- Defined users: approximately 500
- Facility Sizes: 40 – 600 beds
- Responsibility for implementation
  - Corporate risk management in partnership with materials management
- Management Approach
  - Common corporate policy standard based on RASMAS use
  - Regional autonomy in defining users and administering program
Alert Management Business Process Improvement

**Manual Environment**
- **Organization**
  - Department-based organizations
  - Inconsistent and loosely defined roles
- **Infrastructure**
  - Manual or partially automated
  - Minimal reporting
- **Process**
  - Inconsistent
  - Minimal accountability
  - Loose management oversight

**RASMAS Implementation**

**Automated Environment**
- **Organization**
  - Enterprise-wide virtual organization
  - Organization-wide and clearly defined roles and privileges
- **Infrastructure**
  - Fully automated
  - Complete audit & reporting
- **Process**
  - Standardized
  - Full accountability
  - Tight management oversight

**Improved Performance**
- Increased scope
- Improved timeliness
- Improved diligence
- Reduced risk

**Results**
Alert Management Business Process Improvement

RASMAS Implementation

Change Organization
- Identify management
- Assemble cross-functional team
- Train team

Change Infrastructure
- Develop implementation plan
- Introduce new technology
- Manage implementation

Change Process
- Define new process
- Monitor and enhance process

Challenge: Coordinators managing responders in other departments

Challenge: Staff comfort with new technology

Challenge: Staff resistance to change

Manual Environment ➔ Automated Environment
RASMAS Performance Metrics

• **Scope**
  – Number of domains defined
  – Number of alerts released

• **Timeliness**
  – Average days to close alerts
  – Number of open alerts
  – Percent of alerts closed
  – Percent of alerts with delay notices

• **Diligence**
  – Closing actions summary

• **Risk**
  – Avoided at-risk days
Operational Review

- Period: Apr. 1 – Dec. 13, 2005
- Scope: 11 regions and 21 facilities
- Total volume: 21,549 alerts
RASMAS Performance Metric: Timeliness
Average Days to Close Alerts – Initial Period

- Month 1: 13 days
- Month 2: 12 days
- Month 3: 11 days
- Month 4: 10 days
- Month 5: 9 days
- Month 6: 8 days
- Month 7: 7 days
- Month 8: 6 days

Hospitals: 21, 21, 21, 21, 21, 18, 11, 9
RASMAS Performance Metric: Diligence
Closing Actions Summary

<table>
<thead>
<tr>
<th>Action Group</th>
<th>Closing Action</th>
<th>Number</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Accept Action Taken</td>
<td></td>
<td>1047</td>
<td>5.2%</td>
</tr>
<tr>
<td>Changed procedure</td>
<td></td>
<td>17</td>
<td>0.1%</td>
</tr>
<tr>
<td>Performed corrective maintenance</td>
<td></td>
<td>95</td>
<td>0.5%</td>
</tr>
<tr>
<td>Product destroyed</td>
<td></td>
<td>17</td>
<td>0.1%</td>
</tr>
<tr>
<td>Product quarantined</td>
<td></td>
<td>12</td>
<td>0.1%</td>
</tr>
<tr>
<td>Product removed from inventory</td>
<td></td>
<td>151</td>
<td>0.7%</td>
</tr>
<tr>
<td>Remedial Action Taken</td>
<td></td>
<td>1,339</td>
<td>6.6%</td>
</tr>
<tr>
<td>Closed by Risk Manager</td>
<td></td>
<td>89</td>
<td>0.4%</td>
</tr>
<tr>
<td>Information forwarded to users</td>
<td></td>
<td>483</td>
<td>2.4%</td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td>424</td>
<td>2.1%</td>
</tr>
<tr>
<td>Other Action Taken</td>
<td></td>
<td>996</td>
<td>4.9%</td>
</tr>
<tr>
<td>No action required</td>
<td></td>
<td>2106</td>
<td>10.4%</td>
</tr>
<tr>
<td>No product found</td>
<td></td>
<td>5227</td>
<td>25.7%</td>
</tr>
<tr>
<td>Not in Geographic Region</td>
<td></td>
<td>1341</td>
<td>6.6%</td>
</tr>
<tr>
<td>Product in stock, no lot/serial numbers</td>
<td></td>
<td>186</td>
<td>0.9%</td>
</tr>
<tr>
<td>Product never purchased</td>
<td></td>
<td>6540</td>
<td>32.2%</td>
</tr>
<tr>
<td>Product not in inventory</td>
<td></td>
<td>2594</td>
<td>12.8%</td>
</tr>
<tr>
<td>No Action Taken</td>
<td></td>
<td>17,994</td>
<td>88.5%</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>20,329</td>
<td>100.0%</td>
</tr>
</tbody>
</table>

Estimated total action taken
= 100% Remedial Action + 50% Other Action
= 6.6% + 2.4%
= 9.0%

Result: Estimated 9.0% of alerts (1,837) required action
### RASMAS Performance Metric: Risk
Avoided At-Risk Days

<table>
<thead>
<tr>
<th>Label</th>
<th>Description</th>
<th>Value</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Average number RASMAS recall alerts per week</td>
<td>38</td>
<td>RASMAS</td>
</tr>
<tr>
<td>B</td>
<td>Percent of alerts CHRISTUS performed action on</td>
<td>9.0%</td>
<td>Slide 17</td>
</tr>
<tr>
<td>C</td>
<td>Average number recall alerts per week requiring action</td>
<td>3.4</td>
<td>A * B</td>
</tr>
<tr>
<td>D</td>
<td>Estimated CHRISTUS manual at-risk days</td>
<td>20</td>
<td>Survey</td>
</tr>
<tr>
<td>E</td>
<td>Current CHRISTUS RASMAS at-risk days</td>
<td>2.7</td>
<td>Slide 16</td>
</tr>
<tr>
<td>F</td>
<td>Avoided at-risk days (for each recalled product)</td>
<td>17.3</td>
<td>D - E</td>
</tr>
<tr>
<td>G</td>
<td>Total avoided at-risk days for 3.4 alerts in 1 week at 1 facility</td>
<td>59</td>
<td>C * F</td>
</tr>
<tr>
<td>H</td>
<td>Total avoided at-risk days for 3.4 alerts in 1 week at 21 facilities</td>
<td>1,248</td>
<td>21 * G</td>
</tr>
</tbody>
</table>

Note: Each day that a recalled product remains in a hospital may be considered an “at-risk” day.
General Benefits of Automated Alert Management

• Alert Structure
  – Proven standards for structure and content of alerts

• Alert Distribution
  – Standard automated mechanisms for notifying hospitals of recalls; alerts usually released within 4 hours of arrival
  – Duplicates from multiple sources eliminated

• Alert Processing
  – Enterprise-wide solution provides uniformity in processing alerts across departments
  – Strict accountability for alert ownership and resolution

• Management Oversight
  – Robust mechanisms to monitor and report status
  – Rapid and full support for regulatory audits

• Risk
  – Support for rapid assessment of risk
  – Reduced exposure to defective products
Conclusion

The implementation of RASMAS, an automated alert management system, has required organizational change and process change, and has resulted in significant performance improvement at CHRISTUS healthcare facilities.