Utilizing Quality Management System (QMS) Audits to Improve Process Reliability and Efficiency

April 30, 2016
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Objectives

1. Describe standardized approach used to train QMS auditor, conduct and report on QMS audits
2. Demonstrate how processes have been improved as a result of the QMS audit process through the use of interactive, real-life examples
3. Explain the relationship between QMS audits and meaningful outcomes
4. Describe how to incorporate key processes and audit results into key performance indicators
5. Use this methodology to scale innovation across the enterprise
About Advocate Health Care

- Based in Downers Grove, Illinois
- Largest fully integrated health care delivery system in the state of Illinois.
- Recognized as one of the top health care systems in the country, based on clinical performance.
- Advocate operates more than 250 sites of care, including 12 hospitals that encompass 11 acute care hospitals and the state’s largest integrated children’s network.
Strategic Question

- How will the ISO 9001 Quality Management System provide value to Advocate and help it achieve its 2020 goal of zero serious safety events and top decile performance in health outcomes?
ISO 9001 QMS Fundamentals

• **Consistency** of product or service
• Enhanced **Customer** Satisfaction
• **Continual** Improvement
• Performance and process based approach
• Fully aligns with the Advocate Experience of:
  
  *Safety – Quality – Service*
  
  *Always*
Quality Management System
ISO 9001
Advocate Health Care’s Quality Management System (QMS) Vision

ISO 9001 is how Advocate will achieve high reliability system design resulting in highly reliable performance
Advocate’s QMS Approach

• Accountability through **Quality Management Review/Committee**

• **Controlled** Policies, Procedures and Protocols

• **Process Control** of Key Functions

• **Audits and Measurements** of Key Functions
Why key process audits so important:

- 95% accuracy at each step yields **77.4% accuracy** of final product

\[ \text{.95} \times \text{.95} \times \text{.95} \times \text{.95} \times \text{.95} = 0.774 \]
So What is Different?

<table>
<thead>
<tr>
<th>Traditional Quality Approach</th>
<th>QMS Approach</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quality Committees – Presentations of successful quality projects – physician led</td>
<td>Quality Management Oversight Committees – Focus on quality processes not meeting goal, accountability and resource assignment. Executive led</td>
</tr>
<tr>
<td>Auditing limited to Internal Audit Department – financial focus</td>
<td>Quality auditing of key high risk processes to identify variation + Internal Audits</td>
</tr>
<tr>
<td>Implementation effectiveness of P.I. projects or new procedures based only on outcome data or not assessed objectively</td>
<td>P.I. projects, key high risk processes audited to identify process variation and implementation effectiveness</td>
</tr>
<tr>
<td>Variable or informal corrective action process</td>
<td>Standardized formalized corrective action process that includes assessment of corrective action effectiveness</td>
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<tr>
<td>Quality owned by Quality Department/Committee</td>
<td>Quality owned by process owners</td>
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Transforming the Culture

- “QMS audits have transformed our culture by allowing us to detect process variation proactively through the use of quality management audits with objective auditors within our own organization” Comment by a hospital executive
QMS Audit Strategic Approach

The QMS audit process is a fundamental approach to support and validate continual improvement ensuring key processes are highly reliable.
Ask Four Questions...

1. Is There A Process?
   - Yes
   - No
     - Create A Process

2. Workforce Trained?
   - Yes
     - QMS Audit The Process!
   - No
     - Train To Process

3. Process Followed?
   - Yes
     - QMS Audit The Process!
   - No
     - Retrain/Coach

4. Results As Intended?
   - Yes
     - Done
   - No
     - Revisit Process
QMS Audit Program Components

- System trained QMS auditors – multiple areas
- Performed on key strategic high risk processes
- Standardized audit tools created with SMEs
- Standardized audit reports
- Assignment of Corrective Action/Preventive Actions (CAPAs) addressing non-conformities
- Executive sponsors and process owners of CAPAs – root causes and corrective action plans
- CAPA implementation assessed for effectiveness
## Standardized Approaches

<table>
<thead>
<tr>
<th>Key Components</th>
<th>Standardized Elements</th>
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<tbody>
<tr>
<td>QMS auditor training</td>
<td>✔ Auditor selection: Objective good communicators – clinical and non-clinical</td>
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<tr>
<td></td>
<td>✔ One day class taught by corporate trainers</td>
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<td></td>
<td>✔ Observe/shadow an experienced auditor</td>
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<td></td>
<td>✔ Conduct at least 3 audits before can serve as lead auditor</td>
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<tr>
<td>Conducting the QMS audit</td>
<td>✔ Audit areas not responsible for</td>
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<tr>
<td></td>
<td>✔ Some audit another site facility</td>
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<td></td>
<td>✔ Standardized audit topic specific training</td>
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<td></td>
<td>✔ Use standardized system audit tool</td>
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<td></td>
<td>✔ Adheres to audit tool – no change in direction or required response criteria</td>
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<tr>
<td></td>
<td>✔ Educational approach</td>
</tr>
<tr>
<td>Reporting of the QMS audit results</td>
<td>✔ Results entered in database</td>
</tr>
<tr>
<td></td>
<td>✔ Aggregated reports run and analyzed</td>
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QMS Audits and Key Result Performance Metrics

- **2015:** Incorporated QMS audits into a Key Result Area (KRA) metric tied to leadership performance goals
- **2016:** Incorporated QMS audit into two KRA metrics that could be cascaded to the frontline associates
- KRA audits conducted by trained QMS auditors from other sites
Objectivity = Accurate Results

- Hand Hygiene Unit Results: 99%
- Hand Hygiene Secret Shopper Results: 79%
- Hand Hygiene QMS Audit Results: 67%
Increased Reliability of Processes

• **CLABSI KRA audit:** 23% improvement in central line maintenance and 100% compliance with evidence based insertion practice

• **EVS Audit:** 24% improvement in environmental cleaning processes

• **Patient Falls Audit:** 100% improvement in nursing knowledge related to patient fall risks

• **Expired Products Audit:** 29% savings in expired products costs
CLABSI KRA Audit Drilldown

Phase 1
- Data not meeting goal for strategic metric
- Multidisciplinary group of experts created audit based on standardized evidence based P & P

Phase 2
- Unannounced audit conducted by trained clinical QMS auditors
- Key maintenance and insertion processes/steps were identified as non-compliant

Phase 3
- Corrective actions developed addressing root causes of non-compliance less than 75%
- Corrective actions implemented and re-audited
EVS Audit Drilldown

**Phase 1**
- Accreditation survey findings related to cleanliness
- Established cleaning process used as basis for audit tool development

**Phase 2**
- Audit conducted by non-clinical auditors with EVS partnership
- Results showed major discrepancy between EVS results and QMS audit results

**Phase 3**
- Corrective actions included redesigning cleaning standards and verification process by EVS
- Corrective actions audited quarterly for 3 quarters
Key Lessons Learned

• Standardized process definition and documentation **essential** for auditing and for high reliability of the QMS

• Good outcome results can hide process variations – **Swiss Cheese Potential**

• Audit benefits resulted in significant growth of audits requested and conducted requiring prioritization and tighter oversight

• Effective software support lacking
Scaling the QMS

• ISO 9001 QMS principles applicable to any size and type of organization
• QMS oversight starts with senior management
• QMS audit program applicable at system, operating site or department levels
• CAPAs applicable to system, operating site or department levels
• Additional staff not required but a different skill mix may be required
Questions/Comments