Electronic Non-conforming Event Management

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Introduction

Although the clinical laboratory industry continues to make strides in improving patient safety and the quality of services offered, opportunities for continuous improvement will always remain. Many of these opportunities present themselves as non-conforming events. A non-conforming event, put simply is an instance where things did not go as planned or failed to meet a requirement. Other terms frequently used include: accident, adverse event, error, event, incident, non-conformity, and occurrence. Non-conforming events do not conform with the organization's established policies, processes, or procedures; with applicable regulatory or accreditation requirements; or have the potential to affect (or have affected) patient safety, employee safety or the efficiency and effectiveness of laboratory operations. The purpose of non-conforming event management is to identify and characterize problem-prone processes so investigations can be carried out, root causes identified, and improvement projects initiated, thus eliminating reoccurrence.

Labs that conform with the ISO 15189 standard also perform an effectiveness check to ensure that the Corrective Action or Preventive Action (CAPA) implemented was effective in eliminating the root cause and that the event has not recurred. Thus, non-conforming event management is linked to risk management because it provides information on systemic service problems that could pose legal or financial risk issues for the organization. Non-conforming event management is an

Figure 1: Ticket Process and Statuses

START

Create QI Ticket (General, Equipment, Concern or Complaint)

Status: REPORT EVENT

Route to QM in Actions Log

Status: PENDING

QM Reviews and Assigns CAPA

Status: CAPA

Responsible Person Completes CAPA

Route to QM in Actions Log

Status: CAPA REVIEW

QM Routes Back for Correction as Necessary

Status: CAPA REVIEW

QM Closes QI Ticket

Status: CLOSED

Notify QM via Phone or Email

Status: COMPLETE

QM Reviews/Submits CAPA & Schedules Effectiveness Check

Responsible Person Performs and Documents Effectiveness Check as Planned

Effectiveness Check Successful?

Yes

Create New QI Ticket Referencing Ticket # with Failed Effectiveness Check

No

Provides information on systemic service problems that could pose legal or financial risk issues for the organization. Non-conforming event management is an

Courtesy of the author
integral part of Sonic Reference Laboratory’s (SRL) quality management system. SRL identifies systematic problems and demonstrates its management’s commitment to removing the causes. Removal of the root causes of non-conforming events leads to improved quality, which leads to improved patient safety and overall quality of services.

Materials & Methods

Sonic Reference Laboratory manages non-conforming events electronically utilizing a Web-based quality and compliance software called Omni-Assistant. The software was implemented at the time of the lab’s opening, December 1st, 2014. An algorithm—developed to assist employees in deciding when an event should be reported—directs employees to report all incidents that could result in patient harm, employee injury, or organizational loss. Both SRL’s Vice President of Quality and Quality Specialist underwent system administrator training on the use and configuration of the system via two 2-hour webinars. Training on use of the system was administered to all staff by SRL’s Quality Management (QM) department during initial quality onboarding training and lasted approximately 20 minutes. Two 20-minute follow-up training sessions were held to ensure all staff members were appropriately trained.

SRL collaborates with the vendor to continually customize and refine the non-conformity module for the laboratory’s use. SRL was able to fully configure the electronic workflow for event management (see FIGURE 1). The types of non-conformities to be reported were defined into four categories: General event, equipment event, employee concern, and client complaint. SRL also configured and customized CAPA forms, root cause classifications, event categories and subcategories, priority (risk/impact) categories, email alerts, and custom reports. The event reporting process was designed to include a description of the event, immediate action, assignment of a priority level, and classification of the event (see FIGURE 2). The CAPA form includes the investigation team, how the issue was discovered, an investigation summary, corrective action(s), preventive action(s), root cause, cost of poor quality (CoPQ) considerations and calculations, and a plan-for-effectiveness check.

Priority levels for events were defined and customized in the software based on risk and impact in order to quickly and effectively triage as events are reported. Priority levels are determined by calculating the cumulative effect of the event’s potential for harm (to the patient, employees, and/or the organization), and its impact (ie, the number of patients or employees affected, or financial loss). Various combinations of the items listed in TABLE 1 have been assigned priority levels that appear in a drop down menu in the software. Each priority level has been ranked and assigned a visual indicator color—red = high, yellow = medium, green = low, and blue = near miss—depending on the particular combination of risk and impact for each QI ticket.

Standardized root cause categories were established and configured (see TABLE 2). Reports were customized to display event number, priority with color coding, date reported, date action item is due, lab section, staff responsible, event classification, and status (see FIGURE 3). Ticket categories have been defined based on the phase of testing that the event occurred during and/or relevant department (see TABLE 3). Extensive

![Figure 2: Non-conforming Event Reporting Form](image)

**Table 1. Event Priority Categories**

<table>
<thead>
<tr>
<th>Risk</th>
<th>Impact</th>
<th>Business Considerations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serious Harm</td>
<td>1 patients or employees</td>
<td>Serious Financial Loss</td>
</tr>
<tr>
<td>Moderate Harm</td>
<td>5-10 patients or employees</td>
<td>Moderate Financial Loss</td>
</tr>
<tr>
<td>Minimal Harm</td>
<td>11-30 patients or employees</td>
<td>Low Financial Loss</td>
</tr>
<tr>
<td>No Harm</td>
<td>31-100 patients or employees</td>
<td>No Financial Loss</td>
</tr>
<tr>
<td>Harm Near Miss</td>
<td>100+ patients or employees</td>
<td>Near Miss for Financial Loss</td>
</tr>
</tbody>
</table>
innovative and comprehensive electronic non-conforming event management system and has become an integral part of SRL’s compliance with the Clinical Laboratory Improvement Amendments (CLIA) and College of American Pathologists (CAP), as well as voluntary ISO 15189 conformance. The laboratory also was able to incorporate cutting-edge quality principles (such as CoPQ) and best practices (such as effectiveness checks). SRL’s customization of the software allows the laboratory to ensure that it is capturing as many opportunities for improvement as possible in an efficient and user friendly manner. During the almost four-month period between go live in December 2014 and March 27th, 2015, approximately 200 QI tickets were entered into the system, 99.5% of which were successfully resolved after undergoing the standardized process.

The customized priority levels based on risk and impact allow the QM department to quickly triage events as well as effectively produce these metrics for management review. The CoPQ calculations have proven useful in justifying resources expended on QI initiatives to executive leadership and in proving the value of reporting to middle management and staff. The sub-categorization also was configured to enable effective trending (see TABLE 4). Each non-conforming event is entered into the system and goes through a standardized approach to risk management, which involves investigation, root cause analysis, and effectiveness checks (see FIGURE 1). The software is password protected and accessible by all laboratory staff from all workstations, and there is an audit trail within the system to track what actions are taken in the software, by whom, and the time and date.

The reports created for non-conformities were deemed as QI Tickets (Quality Improvement tickets) instead of events in order to aid in fostering a culture of reporting, as staff indicated that they felt the term event carries a negative connotation. The implementation of systems thinking and Just Culture™ have also fostered a culture of quality at SRL through which event reporting is encouraged.

### Results & Discussion

The laboratory-customized event module has evolved into an innovative and comprehensive electronic non-conforming event management system and has become an integral part of SRL’s compliance with the Clinical Laboratory Improvement Amendments (CLIA) and College of American Pathologists (CAP), as well as voluntary ISO 15189 conformance. The laboratory also was able to incorporate cutting-edge quality principles (such as CoPQ) and best practices (such as effectiveness checks). SRL’s customization of the software allows the laboratory to ensure that it is capturing as many opportunities for improvement as possible in an efficient and user friendly manner. During the almost four-month period between go live in December 2014 and March 27th, 2015, approximately 200 QI tickets were entered into the system, 99.5% of which were successfully resolved after undergoing the standardized process.

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### Table 4: Example Non-conforming Event Report

<table>
<thead>
<tr>
<th>Ticket #</th>
<th>Priority</th>
<th>Date of Occurrence</th>
<th>Department of Occurrence</th>
<th>Date Reported</th>
<th>Event Title</th>
<th>Category</th>
<th>Responsible Person</th>
<th>Status</th>
<th>Reporting Department</th>
</tr>
</thead>
<tbody>
<tr>
<td>75</td>
<td>Medium</td>
<td>4/15/16</td>
<td>Core</td>
<td>4/15/16</td>
<td>Alk Phos Reference Range</td>
<td>Analytical</td>
<td>J. Smith</td>
<td>Closed</td>
<td>Core</td>
</tr>
<tr>
<td>76</td>
<td>Medium</td>
<td>4/17/16</td>
<td>Immunology</td>
<td>4/17/16</td>
<td>Instrument Downtime</td>
<td>Analytical</td>
<td>C. Jones</td>
<td>Closed</td>
<td>Immunology</td>
</tr>
<tr>
<td>77</td>
<td>Low</td>
<td>4/17/16</td>
<td>Pre-analytical</td>
<td>4/17/16</td>
<td>HIV Specimen Misrouted</td>
<td>Pre-analytical</td>
<td>T. Walker</td>
<td>Complete</td>
<td>Pre-analytical</td>
</tr>
<tr>
<td>84</td>
<td>High</td>
<td>4/18/06</td>
<td>Pre-analytical</td>
<td>4/18/06</td>
<td>Lost Specimen</td>
<td>Pre-analytical</td>
<td>J. Kim</td>
<td>Pending</td>
<td>Pre-analytical</td>
</tr>
<tr>
<td>78</td>
<td>Low</td>
<td>4/18/16</td>
<td>Molecular</td>
<td>4/19/16</td>
<td>LIS Functionality - Shared Specimens</td>
<td>IT/IS</td>
<td>J. Dawson</td>
<td>Complete</td>
<td>Molecular</td>
</tr>
<tr>
<td>79</td>
<td>Medium</td>
<td>4/19/16</td>
<td>Hematology</td>
<td>4/19/16</td>
<td>Coag Testing TAT Delay</td>
<td>Analytical</td>
<td>A. Bauer</td>
<td>Complete</td>
<td>Hematology</td>
</tr>
<tr>
<td>80</td>
<td>Medium</td>
<td>4/20/06</td>
<td>Histology</td>
<td>4/20/06</td>
<td>Billing Problem Reported</td>
<td>Billing</td>
<td>F. Cruz</td>
<td>CAPA Review</td>
<td>Histology</td>
</tr>
<tr>
<td>81</td>
<td>Low</td>
<td>4/21/16</td>
<td>Pre-analytical</td>
<td>4/21/16</td>
<td>Duplicate Orders Received</td>
<td>Pre-analytical</td>
<td>L. Adams</td>
<td>Corrections Needed</td>
<td>Pre-analytical</td>
</tr>
<tr>
<td>82</td>
<td>Medium</td>
<td>4/21/16</td>
<td>Core</td>
<td>4/21/16</td>
<td>Ergonomic Mats Slipping</td>
<td>Safety</td>
<td>P. Garcia</td>
<td>Pending</td>
<td>Quality</td>
</tr>
<tr>
<td>83</td>
<td>High</td>
<td>4/22/16</td>
<td>Molecular</td>
<td>4/22/16</td>
<td>HCV Proficiency Testing Failure</td>
<td>Proficiency Testing</td>
<td>K. Fry</td>
<td>CAPA Review</td>
<td>Molecular</td>
</tr>
</tbody>
</table>
customized categories and sub-categories have helped streamline monthly and quarterly trending, and provided more useful data for management review and quality improvement. SRL also found that reporting increased by 20% once the term event was replaced by QI Ticket. The reporting algorithm, which did not exist when the laboratory first implemented the system, is necessary to aid employees in deciding when to file a QI ticket, especially for those employees who are not accustomed to reporting non-conforming events. Future initiatives will focus on ongoing training, timely and effective resolution of non-conformities, and evolution of CoPQ reporting.

Conclusion

Managing nonconforming events electronically allows the organization to:

● Save administrative time
● Ensure no issue falls off management’s radar
● Perform investigations and CAPAs for all applicable issues
● Assign statuses, due dates, priorities, and root causes
● Capture the cost of poor quality (CoPQ)
● Plan and document effectiveness checks
● Easily search data

Schedule email alerts to management/staff

Pull reports for trending, management review, and QI initiatives

This system has proven invaluable in increasing efficiency, decreasing cost of poor quality, and, most important, improving the quality of SRL’s services for our patients.

References

2. Omni-Tech Health. Available at: www.omnitechhealth.net/en

Jennifer Dawson, MHA, DLM(ASCP)SM, QLCSM, QIHCSTM, LSSBB, is the Vice President, Quality & Regulatory Affairs for Sonic Reference Laboratory in Austin, Texas. Having built the quality program from the ground up, she is responsible for oversight of a strategic approach to a robust, best-practice quality management system, as well as regulatory compliance for the lab. Jennifer serves on the CLMA Board of Directors, the ASCLS Patient Safety Committee, the AACC Management Sciences and Patient Safety Division, the CLSI Expert Panel on Quality Management Systems and General Practices, and the National Malcolm Baldrige Quality Award Board of Examiners.