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JOURNEY TO CAP 15189

National Jewish Health
Advanced Diagnostic Laboratories

Abstract

National Jewish Health Advanced Diagnostic Laboratories strives for excellence in quality and competence for its laboratory services. In an effort to foster continual quality improvement across the organization, the lab's management and staff sought to maintain and enhance its CAP 15189 accreditation. In September 2013, the lab's management team, which was new to the organization, was tasked with preparing the lab for a full CAP 15189 surveillance inspection, to include both the management and technical sections, in a very aggressive six month timeframe. All lab sections involved in the total testing process participated in these accreditation efforts. This included phlebotomy, pre-analytical processing, immunology, flow cytometry, complement, beryllium, microbiology, mycobacteriology, pharmacokinetics, molecular and client services. A laboratory-wide Quality Manual was developed to provide the appropriate framework on which to build the quality system. A variety of tools were utilized to determine areas for improvement, including Lean Six Sigma, heat maps, metric development, quality reports, root cause analysis, internal auditing by peers, customer satisfaction surveys and a Plan-Do-Check-Act approach. Focused training was provided where opportunities for improvement were identified. Action plans were developed with timelines assigned established through a visual heat map and internal audit approach. A variety of quality committees, including staff of all levels, were formed in order to enable communication of ideas, foster collaboration between lab sections and to disseminate information. Leadership focused heavily on fostering a culture of quality throughout the organization. In addition, to enhance the participation at grass roots levels of the organization an employee recognition program was established to positively reinforce this culture. Progress on initiatives was assessed through the ongoing utilization of heat maps, follow-up audits which culminated in a March 2013 with successful CAP 15189 surveillance visit. Most importantly, through the CAP 15189 accreditation process the organization realized incredible, measurable improvement in the level of quality and patient safety of laboratory services it provides.

Introduction

National Jewish Health Advanced Diagnostic Laboratories (ADx Labs) is a highly esoteric laboratory offering both clinical and research testing. The laboratory is comprised of phlebotomy, pre-analytical processing, immunology, flow cytometry, complement, metal hypersensitivity, core, microbiology, mycobacteriology, pharmacokinetics, molecular and client services sections. The organization strives for excellence in quality and competence for its laboratory services. In an effort to foster continual quality improvement across the organization, the lab's management and staff established and supported a formal quality framework based on the Clinical and Laboratory Standard Institute's 12 Quality System Essentials (QSE's). Through these efforts, the laboratory management sought to achieve, maintain and enhance its voluntary CAP 15189 accreditation while increasing the level of compliance, standardization, efficiency and most importantly to improve the level of patient safety for all lab services.

Materials & Methods

A number of approaches were utilized in the organization-wide journey to CAP 15189 beginning in September 2012. A formal quality manual was written in compliance with the ISO 15189:2007 standard, which addressed all aspects of establishing and maintaining an effective Quality Management System (QMS) utilizing the 12 QSE framework. All staff were trained and tested on this manual to facilitate understanding and to encourage buy-in for the quality program from Director to Bench Technologist level. A graphic depiction, or "map", of the components of the QMS was developed, presented and posted in each laboratory section. Two committees were responsible for all CAP 15189 related initiatives, which were established and led by the Quality Manager. The Quality Council consisted of Lab Section Directors and the Quality Improvement Crew (QuIC), consisted of staff and supervisor level volunteers from each Lab Section. Thorough training on the ISO 15189:2007 standard was developed and delivered to these committees. Each lab section was then required to employ a "train the trainer" approach to share this information in their respective area. Internal audits were conducted in each lab section by the Quality Manager and peer auditors against the ISO 15189:2007 standard. Gap analysis reports were prepared and issued to each lab section in a formal close-out meeting. Responses and action plans for all deficiencies were due within 30 days. A formal audit schedule was then developed to address critical areas of deficiency and repeat findings for Lab Sections. A heatmap template (Fig.1), named the ISO Assessment Tool, was developed and deployed to assess status and track progress for all components of the ADx QMS framework. Heatmaps were completed monthly by each lab section and the laboratory as a whole monthly until the inspection in March 2013 and then quarterly thereafter. Consensus was reached between all lab staff, supervisors, Lab Directors and the Quality Department for all Lab Section heatmaps. For ADx wide heatmaps, consensus was achieved between all senior managers, including the Executive Director, Medical Director, Lab Directors and Quality Manager. A template for a Quarterly Quality Report (QQR) was developed by translating the stated Quality policy into Quality objectives and metrics. Examples of metrics spanning the Total Testing Process (TTP) were provided as a starting point for each lab section's metrics. Control boards and value stream maps were developed and Lean initiatives were completed in each lab section under the direction of the Director of Operations (Master Black Belt). A formal "Focus on Quality" employee recognition program was established to recognize staff members who made significant contributions to quality in the lab. Each lab section nominates an employee at the quarterly quality committee meeting and staff vote on who will be awarded the "Quality Star" trophy. All nominees receive a framed certificate signed by the Chief Operating Officer of the hospital and senior laboratory leaders. A PDCA approach was utilized for all initiatives and adjustments were made as necessary.

Figure 1. Example of QSE Consensus Heatmap ("ISO Assessment Tool")

58	30	2

Organization (ISO 15189 Section 4.1, 4.2, 4.15, annex C1, C10)								
Org Structure	Resource Allocation	Planning	Quality Policies	Ethics	Management Review	Mission/Vision/ Values	Communication	Executive Management

Facilities/Safety (ISO 15189 5.2, Annex2)								
Safety Training	Biosafety	Chemical Hygiene & Hazcom	Radiation Safety	Regulatory Compliance	Access	Emergency Management	Design & Allocation	Use & Maintenance

Personnel (ISO 15189 Section 5.1)						
Job Descriptions	Personnel Qualifications	Orientation/ Onboarding	Personnel Files	Competency Assessment	CE & Professional Development	Performance Evaluation

Purchasing/Inventory (ISO 15189 Section 4.4, 4.5, 4.6)						
Vendor Selection	Vendor Qualification	Inspection & Verification	Inventory Management	Storage & Handling	Market Recall	Critical Materials & Services

Figure 2. Focus on Quality Awards

Results

The laboratory was successful in gaining and maintaining CAP 15189 accreditation. Performance on QSE consensus heatmaps is shown in Figure 3. This initiative resulted in a 45% decrease in the number non-conformities (events), a 70% reduction in the Cost of Poor Quality (CoPQ)/event and an 84% decrease in overall CoPQ from 2012 to 2013 (Figures 4-7).

Figure 3. QSE Heatmap Performance 12/1/2012 - 9/1/2013

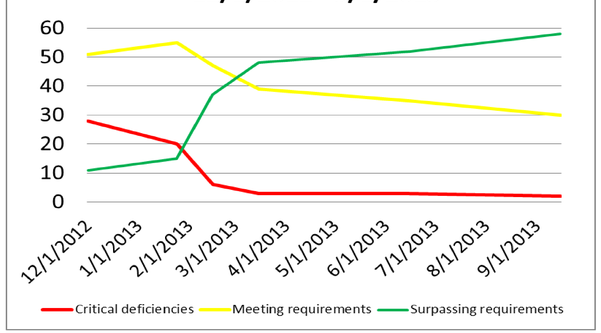

Figure 4. # of Events Reported 1/1/2012 - 8/31/2013

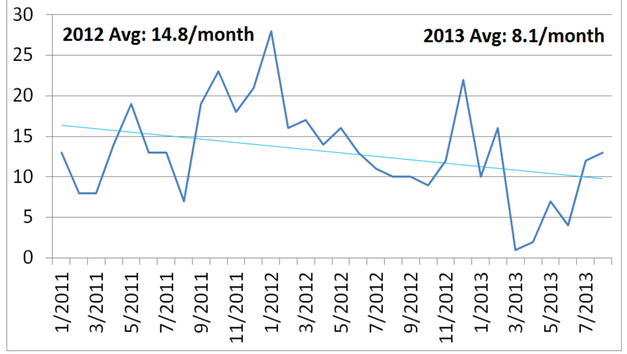

Figure 5. Avg Cost of Poor Quality per Event 1/1/2013 - 8/31/2013

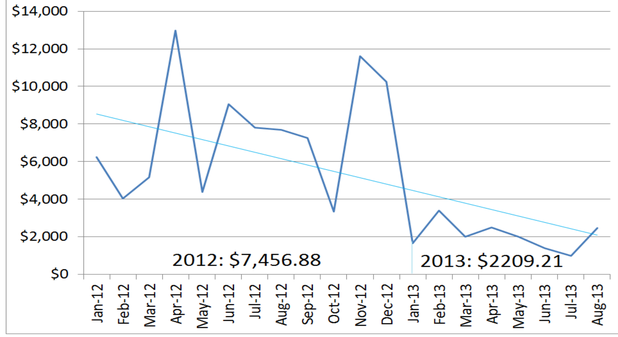

Figure 6. Monthly Cost of Poor Quality 1/1/2013 - 8/31/2013

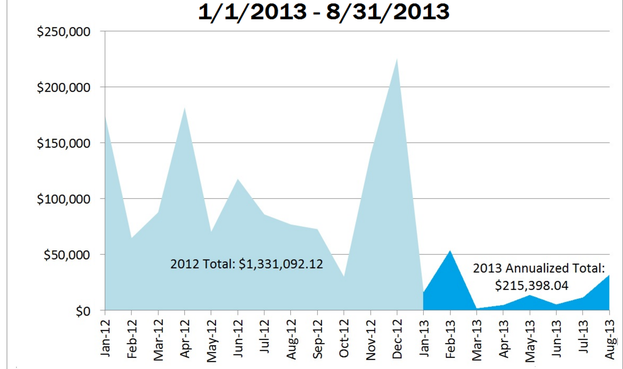

Figure 7. Summary of Results

CoPQ 2012 Total	$1,331,092.12	# of Events - 2012	178	Avg. CoQP/Event - 2012	$7,456.88
CoPQ 2013 Total (Annualized)	$215,398.04	# of Events - 2013 (Annualized)	98	Avg. CoQP/Event - 2013	$2,209.21
% Improvement - CoPQ	84%	% Improvement - # of Events	45%	% Improvement - Avg. CoPQ/Event	70%

Key Words

Quality System Essentials (QSEs): There are twelve essential elements of a quality system, called 'Quality System Essentials' (QSE's). The QSEs are a set of coordinated activities that function as building blocks for an effective quality management system. Each QSE must be formally addressed in order to produce quality lab results. The twelve QSEs defined by CLSI are: 1) Documents & Records 2)Organization 3)Personnel 4)Equipment 5)Purchasing and Inventory 6)Process Control 7)Information Management 8)Occurrence Management 9)Assessment 10)Process Improvement 11)Customer Service 12)Facilities and Safety[1]

ISO 15189: A standard developed by the International Organization for Standardization that specifies requirements for quality and competence in medical laboratories. ISO 15189 can be used by medical laboratories in developing their quality management systems and assessing their own competence. It can also be used for confirming or recognizing the competence of medical laboratories by laboratory customers, regulating authorities and accreditation bodies. (Note: While ISO 15189:2007 was used for this project, there is now a newer version available, ISO 15189:2012)[2].

CAP 15189 Accreditation: CAP 15189 is a voluntary accreditation program that provides accreditation to ISO 15189. It is a process management approach to running a laboratory. CAP 15189 builds on the gold standard technical requirements of the CAP Laboratory Accreditation Program. However, it makes additional requirements of the quality management system, including the following:

- Demonstrated understanding of processes and their interactions (Process mapping)
- Expansion of quality policy into quality objectives and corresponding metrics
- Management review
- Quality manual summarizing the QMS
- Evaluation of referral labs and suppliers
- Internal audits
- Proficiency testing for all tests
- Continuous process improvement
- Designated quality manager
- Contract review[3]

Cost of Poor Quality (CoPQ): Those costs incurred because of poor quality that would not have been incurred if every aspect of a product or service were perfectly correct the first time and every time. (Figure 8)[4]. This includes:
1. Failure costs
2. Appraisal costs
3. Prevention costs[5]

Figure 8: Cost of Poor Quality in the Lab

Conclusions

1) The QSEs provide an effective quality framework for use in conjunction with ISO 15189.

2) Heatmaps, internal auditing and quality metric development are effective ways to identify and track progress for quality improvement initiatives and CAP 15189 accreditation efforts.

3) Peer auditing, ISO 15189 training for all levels of staff and grassroots quality committees assist ISO 15189 implementation in the lab by providing in depth knowledge of the standard and its deployment which increases understanding and buy in.

4) Employee recognition programs improve employee morale and positively reinforce participation in quality activities.

5) CAP 15189 accreditation, although voluntary and costly to implement, provides significant quality, patient safety and financial benefits to participating laboratories.

Bibliography

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