Implementation of an expanded point-of-care site inspection checklist in an academic medical center: An eight year experience

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ABSTRACT

Background: We evaluated the effectiveness of an expanded point-of-care (POCT) site inspection checklist over an extended 8-y period.
Methods: A retrospective review of site inspection deficiency reports in a large academic medical center from 2010 to 2017 (year to date).
Results: There was a significant decrease in the number of cited deficiencies per site/inspection from 2010 (3.17) to 2017 (0.27) ($p < 0.001$). The percentage of sites without deficiencies steadily increased from 2010 (8.7%) to 2017 (80.7%) ($p < 0.001$). The most common citation was documentation of competency assessment followed by results documentation and annual procedure review.
Conclusions: Regular inspections of sites performing POCT are necessary to maintain regulatory compliance. Over time significant improvements in compliance are achievable.

1. Introduction

Maintaining quality testing and regulatory compliance for point-of-care testing (POCT) has traditionally been a challenge particularly in large academic medical centers [1]. This results in part from the large size of these institutions and from the diverse test menu that they may perform at the point-of-care [2]. The overall approach to managing POCT in hospital settings has been previously described [3]. In most large hospitals, there exists a POCT management team with representatives from the clinical laboratory (POCT Director, POCT Co-ordinator(s)) working in conjunction with representatives from nursing, hospital administration and various clinical services in which testing is performed [3]. In many POCT programs the POCT coordinators perform site inspections to verify regulatory compliance with Clinical Laboratory Improvement Amendment (CLIA-88) requirements. These typically take the form of "mock" College of American Pathologists (CAP) or Joint Commission (JC) inspections. In a previous study, we reported on the implementation of an expanded POCT site inspection checklist and described results over a 2 year period [4]. The checklist included all CLIA-related requirements and additional elements such as environment of care and safety as shown in Fig. 1. In that study, we showed that the use of a site inspection checklist decreased the number of citations per POCT site from 3.17 in 2010 (from a possible range of 42) to 2.37 in 2011 ($p = 0.04$). The percent of sites with no citations

also increased from 8.7% to 18.0%. We have since continued to use the checklist to guide our POCT site inspections. Here we report our results over a longer period of time (2010–2017 year to date) to evaluate the long-term effectiveness of the site inspection checklist strategy on regulatory compliance, environment of care and safety.

2. Methods and materials

The Massachusetts General Hospital (MGH) is a 999-bed academic medical center. The hospital provides comprehensive medical services including primary care to the region with approximately 48,000 admissions, 1.5 million outpatient visits and over 100,000 emergency department visits per year. The hospital point of care program including organizational structure, test menu and testing volumes have been previously described [2]. There have been no significant changes to the overall program since that time. The program administration includes a medical director (partial effort), an associate director for operations and two POCT coordinators. The program oversees both on-site and off-site locations. Each testing location has an assigned person on-site who is responsible for regulatory compliance (usually a physician or nurse manager). In addition to a hospital wide bedside glucose testing program, there are 21 additional sites performing waived testing, 13 sites performing provider performed microscopy and 11 sites performing non-waived testing. To ensure regulatory compliance the

Indicator:	Compliance Yes, No or N/A	Findings:
EOC -		
- Under sink storage, no patient supplies		
- Supplies not stored on floors/ in shipping containers		
- Clean/Dirty sinks labeled		
- Microscope/centrifuge maintenance up to date		
- Centrifuge has a safety lock		
Safety -		
- Hand hygiene before and after glove use		
- Gloves used for blood draw/point of care testing		
- Needle boxes (¾ full or less)		
- No food or drink in testing area		
- Eye wash/shower checks performed weekly		
- Chemicals and reagents properly labeled/stored		
- Frig/RT logs maintained/remedial action if needed /monthly review by director/designee of non-waived sites		
- Min/max temperatures documented for sites closed on weekends/holidays		
- Fire extinguishers properly inspected		
- Biohazardous waste placed in appropriate containers		
- Reagents stored with meds appropriately segregated		
Procedures -		
- Reviewed annually by site director		
- Procedures in use are current and approved		
- Log sheets in use are current and approved		
- Order or protocol for test available		
- Valid CLIA certificate available or posted		
- Documents retained/retrievable for 4 years		
Training/Competencies -		
- New hire training documented <u>prior</u> to patient testing		
- 6 month competency for non-waived tests		
- Annual competencies available for all staff/each test		
- waived tests – two methods of competency		
- non-waived tests – 6 methods		

Fig. 1. Point-of-care site inspection checklist.

POCT coordinators perform site inspections at regular intervals utilizing a POCT checklist to guide the elements of the inspection as shown in Fig. 1. The checklist includes the following categories: 1) environment of care, 2) safety, 3) procedures, 4) training/competencies, 5) quality controls/proficiency testing, 6) specimen collection/identification, 7) result documentation, and *8) examination room inspection.

For this study the inspection checklists were reviewed from 2010 to 2017 (calendar year July to date). The number and type of each citation per site was tabulated by the calendar year. Site inspections occurred on a rotating basis such that all sites were not necessarily inspected in any given calendar year. Excluding 2010 and 2011 for which inspection data has already been reported [4] the number of site inspections per year varied from 86 to 31 (31 being 2017 calendar year to date).

Following each inspection, the sites received a written report of the findings including the standards that could be cited and requirements for remedial action. An example of a site inspection report is shown in Fig. 2. The local site director is responsible for documentation of remedial action such that the responsibility for ensuring compliance is shifted to the level of the individual testing site.

We performed statistical analysis using R (R Core Team. (2014). R: A Language and Environment for Statistical Computing. http://www.R-project.org/). The mean number of citations per site was compared between 2010 and 2017 using a two-tailed permutation test with 5000 replicates. The proportion of sites with no citations was compared between 2010 and 2017 using a two-tailed fisher exact test.

3. Results

Fig. 3 shows the average number of citations per site inspection (out of a possible 42) from 2010 to 2017. The number of citations per site varied from a high of 3.17 in 2010 to a low of 0.27 in 2017 with a distinct downward trend from 2010 to 2017. The difference from 2010 to 2017 was statistically significant ($p < 0.001$). There did not appear to be any correlation between the number of citations per site with the dates of the laboratory Joint Commission inspections (8/2009, 8/2011, 7/2013, 4/2015, 4/2017). Fig. 4 shows the percentage of sites with no citations from 2010 to 2017. There was a steady increase in the percentage of sites with no citations from a low of 8.7% in 2010 to a high of 80.65 in 2017 indicating overall improvement in compliance ($p < 0.001$). Table 1 shows the most frequent categories of citations per year over the duration of the study. Data from our previous study in 2010 and 2011 were combined. The most common citations varied some from year to year but overall the most frequent categories were policies and procedures, quality control/proficiency testing, result