

Abstract

In 2009, Blanchard Valley Hospital Laboratory accepted the challenge of obtaining ISO 15189 accreditation, and now, four years later, continues to reap the benefits of an effective ISO 15189-based Quality Management System (QMS). The initial goal of attaining ISO 15189 accreditation was to challenge our laboratory to "raise the bar" on its existing quality operation.

The benefits of the QMS surpassed our expectations and were more extensive than first envisioned. Tangible results include improvement in both turnaround times and percentage of outliers for several of our Quality Assurance Performance Improvement studies. Evaluation of our pre-analytic processes resulted in increased efficiencies with our outreach specimens and improved relationships with our clients. Additional benefits include an engaged staff empowered to be part of the solutions, increased influence on the organization, structured occurrence management and problem solving, and sustained continual improvement. All of these advancements translate into improved patient care.

BACKGROUND

Blanchard Valley Health System (BVHS) is a non-profit, comprehensive health system offering the Northwest Ohio region a full continuum of care. Founded in 1891, BVHS is one of the largest employers in the region with more than 2,000 associates and serves an eight-county area. Blanchard Valley Hospital Laboratory, located within the 150-bed acute care hospital, provides clinical support for the patient pavilion as well as the emergency room and outpatient services consisting of approximately 43,000 ED visits and 304,000 outpatient encounters in 2012.



Introduction

After the decision to achieve ISO 15189 compliance came the task of figuring out the best way for our laboratory to realize the goal. The ISO 15189 standard outlines certain requirements of a quality management system (QMS) but is not prescriptive as to the methods used to meet them. The laboratory was already technically sound with consistently successful external assessments. Challenges existed in breaking down the departmental silos within the laboratory and standardizing processes in such a way that would bring common elements of each department to the laboratory level and drive performance improvement.

Benefits of Implementing an Effective ISO 15189-based Quality Management System: A 4-year Retrospective

Methods

Customer Service, Facilities and Safety. The following were of particular importance to our success.

DOCUMENT CONTROL

Maintaining written policies and procedures for all laboratory activity is the first step in standardization. Benefits of standardization include:

- Creating a common reference for staff
- Easing process evaluation and problem solving

OCCURRENCE MANAGEMENT and PERFORMANCE IMPROVEMENT

- documentation of patient outcome.
- Pareto chart analysis.

ASSESSMENT

- continually improve patient care.
- readiness.
- improvement and preventive measures.
- performance improvement.

PERSONNEL

- them to be part of the solution.







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