Closing the Gap: Developing a Comprehensive Laboratory Quality Program for a Large Healthcare System

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Background

- HealthPartners, a large integrated healthcare organization based in Minnesota and western Wisconsin, operates eight hospital laboratories, over 60 clinic labs, and a standalone high-throughput lab performing over 10 million tests annually. In 2021, the laboratory service line was restructured to a central leadership team, including a Laboratory Director of Quality, Patient Safety, and Accreditation.
- Prior to creating a system quality team, our laboratories had standardized operational processes but lacked standard quality system essentials. A standardized laboratory quality program is critical to measure performance, identify deviations from standard practice, and make improvements.

Methods

- In November 2021, a gap analysis was completed to compare our quality program to best practices and assess the amount of internal standardization in practice. Clinical and Laboratory Standards Institute (CLSI), published literature, and interviews with external quality leaders were used as sources for best practice. Laboratory leaders assessed 37 program elements through a guided structured review process. The analysis showed areas of moderate variation, major variation, as well as gaps compared to both best practice and internal assessment of standardization. Action items were created, incorporated into the annual planning process, and tasked to newly created workgroups to address the variations identified.

Results

Program Section	Element	2021 Assessment	2025 Assessment
Quality	Quality Indicators	Moderate	None
Quality	Test Utilization	Large	None
Quality	Benchmarking	Program Gap	None
Quality	Quality Management Systems	Moderate	Minor
Quality	Daily Management Systems	Large	Large
Quality	Leader Management Systems	Program Gap	Program Gap
Quality	Annual Planning Process	Minor	None
Quality	Quality Manual/ Charter	Large	Minor
Quality	Quality Plan Assessment	Moderate	Moderate
Quality	Internal FTE Support	Large	None
Quality	External FTE Support/ Programs	Large	Moderate
Quality	IQCP Program	Moderate	Moderate
Quality	CLSI Membership and Participation	Large	Moderate
Patient Safety	Event Reporting	Large	None
Patient Safety	Event Review	Large	None
Patient Safety	Event Trend Analysis/ Reports	Large	Moderate
Regulatory	Accrediting Organization	Large	None
Regulatory	Document Control	Moderate	Minor
Regulatory	Mock Surveys/Self-inspection	Moderate	None
Regulatory	Compliance Monitoring/Audits	Large	Moderate
Regulatory	FDA Reporting	Moderate	Minor
Regulatory	Accreditation Reporting	Large	None
Regulatory	Laboratory-Developed Tests	Large	None
Education	Students	Moderate	None
Education	Competency Assessment	Large	Minor
Education	New Employee Orientation	Moderate	Minor
Education	Employee Right to Know Education	Moderate	Minor
Education	CEU Requirements	Moderate	None
Education	CEU Support	Moderate	None
Education	Career Development	Large	Moderate
Staff Safety	Environmental Safety (Chemical, Ergonomic, Biological)	Large	Minor
Staff Safety	Emotional Safety (Workplace Violence, Culture of Safety)	Large	Minor
Research	Grants/ Research Partnerships	Large	Minor
Data Analytics	Dashboards	Program Gap	None
Data Analytics	Scorecards	Program Gap	None
Informatics	LIS Optimization	Program Gap	Minor
Informatics	LIS Modules (i.e. QC module)	Large	Moderate

The author has nothing to disclose concerning possible financial or personal relationships with commercial entities that may have a direct or indirect interest in the subject matter of this poster.

Discussion

- In January 2025, the program was reassessed, and significant improvements were made to standardize practices across locations and to best practice compared to 2021 ($p<0.01$). 33 out of 37 program elements saw improvement, while four program elements had no change in the level of variation.
- The gap analysis tool is commonly used in improvement science to assess the difference between an organization's current state and its desired future state. In our organization, it has helped clarify and prioritize the actions needed to create an efficient and cohesive laboratory quality program.

Conclusion

- Laboratories undergoing quality program changes should consider using a gap analysis tool to identify organizational needs and create a roadmap to future success.

References

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