

INTRODUCTION

BACKGROUND

The Mayo Clinic Comprehensive Cancer Center (MCCCC) serves investigators and research participants in Arizona, Florida, Minnesota, and Health System (Minnesota, Wisconsin, and Iowa) academic medical centers. Organizational complexity and geographic distribution contributed to a lack of standardization within training programs and core business processes.

Staff reported ineffective and inconsistent workflow despite multiple resources. Therefore, a robust Quality Management System (QMS) was needed to sustain infrastructure required for training, communication, and resources

PURPOSE

To develop and implement a continuously improving system of policies, procedures, processes, and training within a QMS to sustain and fortify Clinical Team Resources and Training.

FIGURE 1

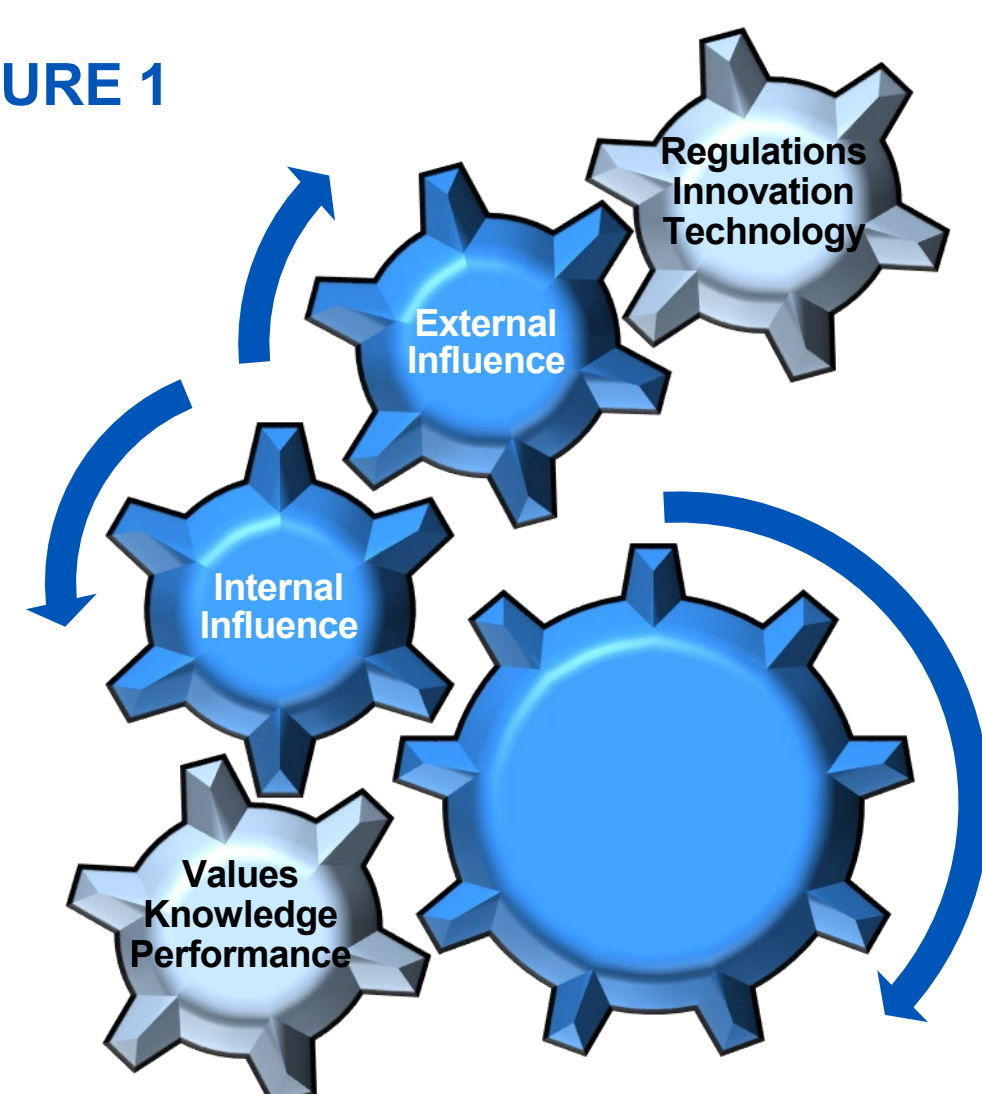


Figure 1. Relationship of internal, external and organizational influences

FIGURE 2



Figure 2. Process development model

METHODS

HOW WE ACHIEVE THIS GOAL

- **Identify and establish governance and oversight for the QMS:** Development of an incremental role, Quality Management Coordinator (QMC), responsible for the development, management, and continuous improvement of the MCCCC QMS.
- **Specific QMS Structure:** Specific to MCCCC's needs, ensuring effectiveness and value added. To achieve this, QMCs implemented quality system essentials (QSE), based off ISO 9001:2015.

IMPLEMENTATION

Condense site-specific documents into overarching enterprise resources, including:

- **Feedback:** Work with site staff to determine gaps and ensure unit needs are met
- **Assessment:** Existing MCCCC resources to identify scope and needs for each unit
- **Communication:** Create new or use existing communication pathways
- **Metrics:** Establish key performance metrics to easily determine trends and gaps
- **Sustain initiatives** through monitoring and continuous improvement cycle

FIGURE 3



Figure 3. Quality Management System based on ISO 9001:2015, organized by quality system essentials (QSEs)

RESULTS AND DISCUSSION

WHERE ARE WE WITH IMPLEMENTATION

DESIGN: Assess existing documentation (archive, update, gap)

- **Defined/developed core business functions with SIPOC-R methodology.** Continuous re-assessment process to capture changes
- **Created document control practices** along with Enterprise Education and Resource teams to reduce redundancy and drive teamwork

DEPLOY: Implement education/training communication

- **Engaged Enterprise Research** via monthly Newsletter articles and website blog posts
- **Enterprise Workgroups** addressed new gaps
- **Developed eLearnings** and drop-in trainings

CONTROL: Establish key performance metrics

- **Subject Matter Experts (SMEs) and Leadership** created new resources to easily capture data with REDCap racking and Tableau dashboards

MEASURE: Sustain with monitoring and continuous improvement cycles

- Drafted QMS Plan and Manual with risk-based approach following ISO 9000-9001

IMPROVE: Revised/archived documents initially built as best-case scenarios.

- Engaged dedicated SMEs on critical projects
- Implemented automated request system. Increased transparency, automated notifications, and dashboard functionality.

CONCLUSIONS

- **Involving the end-users is essential.** A feedback loop is vital to have end-user support, buy-in, and overall moral.
- **Acknowledge past failures.** The current QMS was not the first iteration. Addressing the previous program's failure helps build moral and engage staff at all levels.
- **Support from business unit leadership** is vital to successful implementation
- A culture of quality and competency in quality management is essential for MCCCC staff while maintaining a QMS.

NEXT STEPS

- Continue to mature the QMS
- Employ change management tools with process and resource revisions
- Continue staff engagement, reinforce QMS principles, and heighten adoption/learning
- Maintain cycle of continuous improvement

ACKNOWLEDGEMENT

- Special thank you to study teams, supervisors, and leadership for continued partnership, feedback, volunteered time, and effort to support QMS

REFERENCES

1. ISO, <https://www.iso.org/obp/ui/#iso:std:iso:9000:en>.
2. REDCap 12.4.25 - © 2023 Vanderbilt University