

Transforming Research Management Systems at Mayo Clinic

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ABSTRACT

In order for research programs at academic medical centers and universities to survive and thrive in the increasingly challenging economic, political and regulatory environment, successful transformation is extremely important. Transformation and quality management techniques are increasingly well established in medical practice organizations. In medical research organizations, the introduction of quality management systems is a more recent development. Mayo Clinic has now completed five years of implementing quality management systems in support of its national research organization. This article describes the quality management system under development within research at Mayo Clinic, key action steps taken in transforming the research management systems, results achieved to date in improving performance, and lessons learned.

INTRODUCTION

Mayo Clinic serves as an integrated, multispecialty group practice of medicine, with a mission to inspire hope and contribute to health and well-being by providing the best care to every patient through integrated clinical practice, education, and research. It operates a large and complex national research enterprise

that is ranked in the top 20 of all National Institutes of Health (NIH)-funded academic medical centers in the United States, operating on campuses in Arizona, Florida, and Minnesota. One important aspect of the Mayo Clinic research enterprise is the management system designed to advance discovery and the translation of these discoveries to the broader benefit of society. The management systems supporting

research have the potential to be transformed through the disciplined application of quality management systems.

Quality Management Systems in Research Organizations

In advance of introducing a quality management system into the research organization at Mayo Clinic, the authors reviewed the experience in the field through discussions with experienced research leaders and through a review of the literature. Discussions with experienced research leaders suggested there have been some early adopters of quality management techniques in research organizations. A review of the literature reported the experience of some of these early adopters, highlighting the application of quality management techniques in research organizations, including: Lean and Six Sigma applied to clinical and translational research (Schweikhart, 2009); quality improvement used to strengthen informed consent in human subject research (Foglia, Salsa, & Dieksma, 2009); Six Sigma deployed to optimize data entry processes in clinical research (Liu, 2006); and Continuous Quality Improvement, Lean and Six Sigma applied in pharmaceutical and biotechnology research and development organizations (Carleysmith, Dufton, & Altria, 2009; Johnson, 2002; Sollecito & Kaluzny, 2000). This experience as reported in the literature highlights some

of the benefits of applying quality management systems in research.

BACKGROUND

During the summer of 2005 Mayo Clinic launched a major initiative designed to create a world-class research management system to advance its research vision and strategic priorities. The initiative, called the Research Infrastructure Service Excellence (RISE) initiative, was designed to create a management system for research characterized by 'best-in-class' customer service, quality, performance, reliability, efficiency, and cost-effectiveness.

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The RISE initiative was organized into four phases: (1) Research Vision and Strategic Priorities, (2) Research Infrastructure Compliance, (3) Research Infrastructure Process Improvement, and (4) Research Infrastructure Service Excellence.

Research leadership recognized that to accomplish the goal of creating and implementing a world-class research

management system, simply improving current business practices was not going to bring about the transformational change that was essential. Leadership established as a high priority the creation of a new research management system built on proven quality management principles.

KEY ACTION STEPS

The key action steps were as follows: securing senior leadership support, establishing a clear research vision, securing resources, addressing infrastructure compliance requirements, achieving significant process improvement results, and pursuing service excellence.

Securing Senior Leadership Support

Early in the RISE initiative those involved realized that strong and unwavering senior leadership support was needed to achieve the transformational change required to establish 'best-in-class' performance. Research leadership launched their sponsorship efforts early in 2006 with a clear, easy-to-understand plan that was called the Mayo Clinic RISE Roadmap to Excellence.

Figure 1 shows the four phases of the initiative.

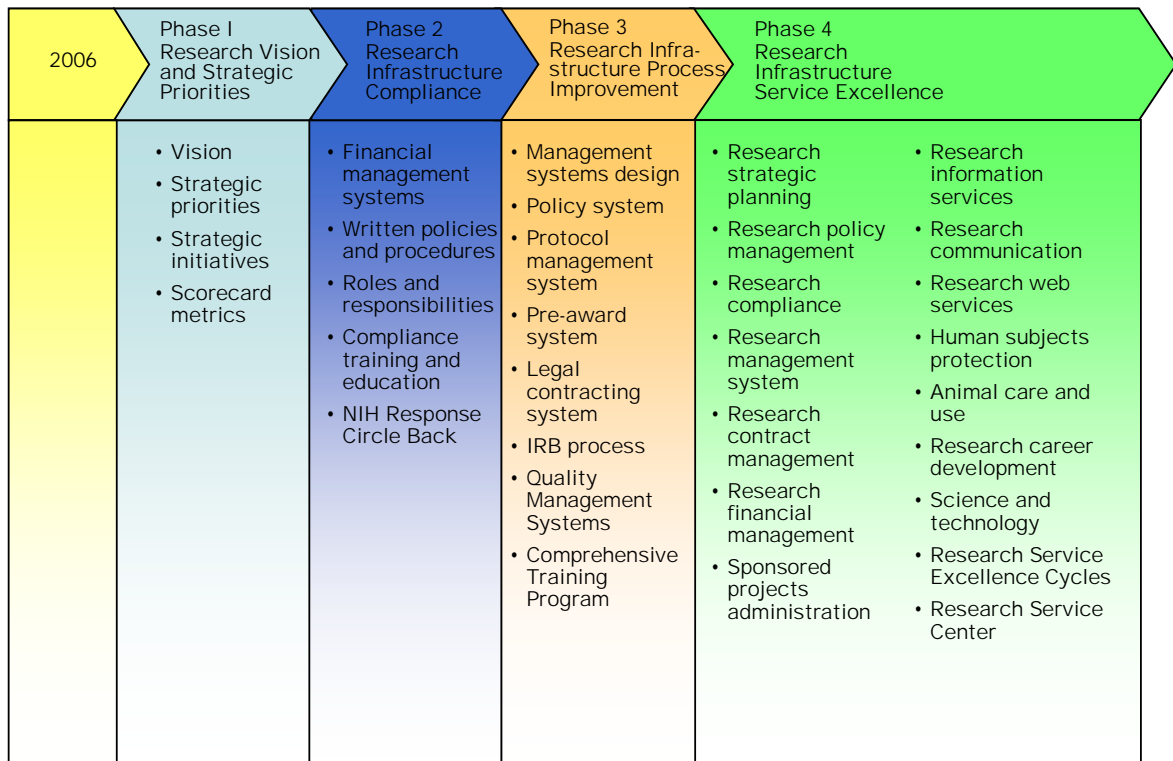


Figure 1. Mayo Clinic RISE Roadmap to Excellence

Research leadership used the Mayo Clinic RISE Roadmap to Excellence to articulate the vision of the RISE initiative, which was *“to create a world-class research management system to support Mayo’s world-class scientists.”* Of course, articulating the vision and creating the desire to make the transformational changes necessary to realize the vision are two different things.

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Phase 1—Establishing a Clear Research Vision

Research leadership first articulated a clear vision for research that set the direction for both scientific and administrative initiatives. The research vision at Mayo Clinic is *“Understand, predict, prevent, diagnose, optimally treat, and ultimately cure disease.”* This vision set the framework for the development of a research management system.

Phase 2—Addressing Infrastructure Compliance Requirements

Research leadership next addressed infrastructure compliance-related questions. The fundamental underpinning of a world-

class research management system includes ensuring that the research enterprise is operating within a fully compliant environment. Managers took a series of proactive steps in concert with internal audit services to survey the research enterprise and ensure that all appropriate steps were taken to verify that the research infrastructure components were operating in accordance with federal, state, and institutional requirements.

Phase 3—Achieving Significant Process Improvement Results

Research leadership then achieved significant process improvement results to address substantial operational inefficiencies and to demonstrate in tangible terms the transformational capability of quality management within a research enterprise. This phase had three primary objectives:

1. Improve the fundamental business processes
2. Build acceptance and understanding of process improvement and quality management
3. Create momentum for implementing a quality management system in research

The quality management system was designed based on ISO9000 standards to create the infrastructure necessary for sustainable and effective quality management. The four business processes

chosen for Phase 3 of the RISE initiative were selected based on input received from institutional and research leadership. The processes chosen were known to have chronic performance issues, resulting in substantial customer dissatisfaction. The four processes chosen were as follows:

1. Clinical trial protocol development
2. Institutional Review Board (IRB) protocol review
3. Office of Sponsored Projects Administration (OSPA) proposal development and negotiation of price and payment terms
4. Legal Contract Administration (LCA) contract negotiation

The overarching goal for each of the four process improvement teams was to establish best-in-class service levels, thereby making service improvements obvious and tangible. For example, all four process improvement teams focused on reducing the cycle times, in addition to other deliverables. Phase 3 of the RISE initiative included understanding the current state, designing a desired future state, and implementing the desired improvements effectively.

Current State

Research leadership first needed to understand how the existing research management system came into being. The system had evolved over several decades through a series of separate efforts conducted in attempts to meet the evolving

needs of the system's customers. When leadership for the RISE initiative started to assess the current state of the research infrastructure, several characteristics of the system started to become apparent:

- Processes and procedures were dispersed, variable, difficult to interpret, and in some circumstances conflicted with one another.
- Significant process variation and operational inefficiency characterized daily operations.
- Many basic tools necessary for effective day-to-day operations were not available.
- Performance data were not accessible, which forced managers to make decisions with a lack of verified data.
- Performance expectations were not established, which resulted in a lack of accountability.
- Management personnel had little exposure to fundamental quality principles.

All of this presented a major opportunity for senior research leadership to establish a comprehensive research management system designed to be best in class to support the world-class scientists at Mayo Clinic.

Future State

Next, each of the four process improvement teams designed a future 'ideal' state for each of these critical

research business processes. Each team used a variety of quality management tools, including attending quality training, using value stream mapping techniques, conducting idealized design sessions, and ultimately creating new process flows, standard operating procedures and work instructions in conjunction with training tools for each of these essential research business processes.

Change Management

To make improvements and move the organization from the “current state” to a more desirable “future state” required a change management process. The natural human response to change is resistance—the larger the change, the more it is resisted. The redesigning of the core business processes represented significant change for the personnel in the business units. The business unit leaders and quality office personnel had a good idea that there would be skepticism that the redesigned business processes could achieve the cycle time reductions being purported based on reactions from the process redesign teams themselves.

Communication, education, and training were the three tools utilized by the business unit leaders to prepare their business units for implementation of the redesigned processes. The business unit leaders communicated the need for change to all business unit personnel, with the goal being defined as improving customer

service. The business unit personnel were then educated at a high level concerning the quality tools and process improvement methodologies utilized to redesign their respective processes. After the need for change and credibility of the redesign processes had been established, the impacted personnel were trained on the redesigned processes so they could be effectively implemented.

Effective Implementation

Once the business units completed the implementation of the redesigned processes, each team demonstrated that it had achieved significant performance improvement results. Overall, the teams improved quality, service, and reliability. In addition, the teams standardized and removed variation from their processes, reduced waste, achieved cost savings, and improved cycle times dramatically. As illustrated in Figure 2:

- The **Protocol Development Team** succeeded in reducing its cycle time by 77%, from an average of 231 days to an average of 54 days, while at the same time reducing resources needed for the process by 2.5 full-time equivalents (FTEs).
- The **IRB Protocol Review Team** reduced its cycle time by 35%, from an average of 37 days to an average of 24 days, while at the same time reducing resources needed for the process by 4.0 FTEs.

- The **OSPA Team** reduced its cycle time by 72%, from an average of 95 days to an average of 27 days.
- The **LCA Team** reduced its cycle time by 88%, from an average of 105 days to an average of 12 days.

Overall, the four teams reduced cycle times by 75%, positioning our scientists to submit applications for funding up to 351 days faster than was previously possible at Mayo Clinic.

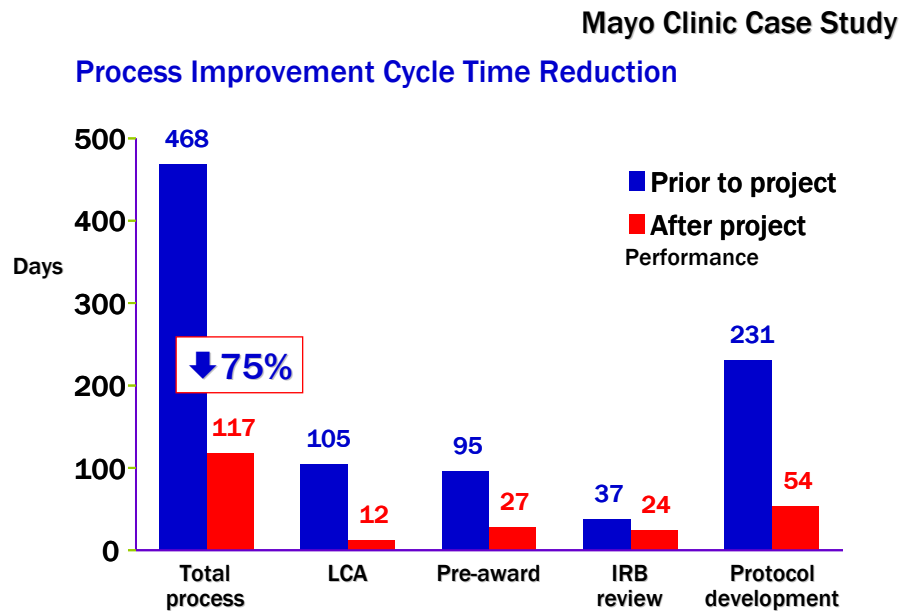


Figure 2. Mayo Clinic Research Cycle Time Reductions

The success of Phase 3 of the RISE initiative contributed to greater acceptance and understanding of the application of process improvement techniques and tools. It also created momentum for the initiative.

Phase 4—Pursuing Service Excellence

Finally, research leadership pursued service excellence through the disciplined application of quality management systems across the research infrastructure at Mayo Clinic. This phase of the RISE initiative was the result of Mayo's research leaders' understanding the critical difference

between achieving process improvement and sustaining quality management systems.

Creating a Research Quality Management System

There are eight fundamental elements of the quality management system in research at Mayo Clinic, as outlined in Figure 3. These eight elements are based on commonly accepted quality management principles, ISO9000 standards, a quality manual template from 9000World.com, and quality management concepts originating

from Joseph M. Juran (see, e.g., Juran, 1992, 1988, 1989) and W. Edwards Deming (see, e.g., Deming, 1986, 1989, 2000). A quality management system provides the means to apply the ISO Quality Management

Principles, empowers employees to pursue continuous improvement, and provides the framework necessary for process improvement sustainability.

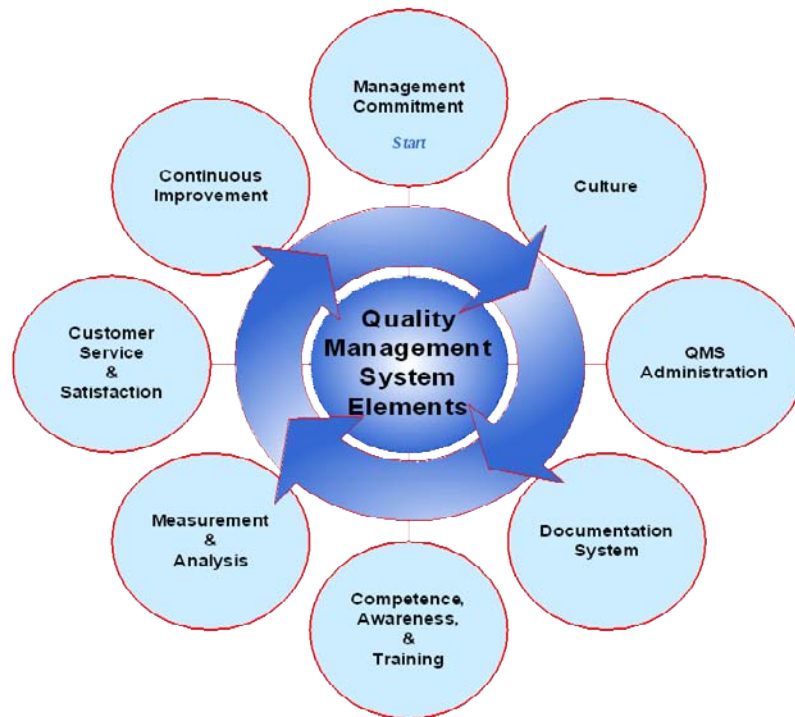


Figure 3. Mayo Clinic Research Quality Management System Model
Source: Data from 9000World.com

The logic behind the quality management system was simple. To bring about the desired transformational changes, quality management would have to be implemented in the work units that comprised Mayo's research management system. To improve quality management in a meaningful way, the personnel providing the services must be empowered to manage and improve the quality of their work and the services they provide. A quality

management system coupled with an understanding and practical application of the fundamental quality principles provide the means for proactive quality management and continuous improvement.
Creating an Office of Research Quality Management Services

In order to facilitate ongoing support for quality management, research leadership established an Office of Research Quality Management Services (ORQMS). This office

received requests from several work units volunteering to participate in the creation of quality management systems. Having work units volunteer meant that research leadership and the ORQMS had been successful in creating a “pull” (as opposed to “push”) environment for quality management, the former having a good chance for success and the latter being almost certainly destined for failure.

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Creating a Process for Implementing Quality Management Systems

The ORQMS created a process and sequence of events to help work units implement a quality management system. After the quality improvement advisors make certain that work unit leadership and management personnel are committed to improving quality and that a culture open to change and new ideas exists in the work unit, office personnel conduct training sessions for the work units to help them understand: (a) the nature of a quality management system, and (b) the benefits of

using a quality management system to manage quality for operational performance. Once this training is accomplished, the quality improvement advisor provides more detailed training on each element of the quality management system prior to implementation.

Obtaining the knowledge necessary to implement a quality management system does not necessarily mean work unit personnel buy into the concept that proactive management of quality will result in improvements in operational efficiency and increased capacity. As a result, some employees were hesitant to allocate the resources necessary to realize the benefits of their quality management system. Thankfully, a quality management system starts to sell itself even before it is fully implemented. Our experience has been that the act of documenting and standardizing the business unit’s processes alone creates significant efficiencies that result in newfound capacity within the work unit. The documentation and standardization of a process normally mean there will be less variation in the process, thereby allowing the process to be performed more efficiently. Often the opportunities for improvement become so evident during the business process documentation exercise that the improvements are simply worked into the new standardized process.

Creating Research Quality Coordinators at the Work Unit Level

In all circumstances the actions of standardizing processes and implementing each work unit's quality management system created new capacity in each work unit to redeploy existing resources. The new capacity represents an opportunity for the work unit to invest in personnel (quality coordinators) who are responsible for coordinating the work unit's quality management, planning, and reporting activities. The work units that have fully functional quality management systems have either hired quality coordinators from outside their work unit or assigned these responsibilities to existing personnel. Both scenarios are working well. The act of a business unit investing in personnel who have a defined responsibility for quality management coordination signifies to leadership that they understand that the benefits of managing quality proactively outweigh the modest investment in personnel necessary to ensure that their quality management efforts are effective. Quality coordinator positions may be full- or part-time depending on the size of the business unit. Responsibilities may also be shared among employees.

Sustaining Service Excellence

The RISE initiative designed to transform Mayo's research management system will never be complete. As progress is made, actions must be taken to protect

and sustain the gains that have been achieved by the initiative. To effectively sustain the gains and be able to utilize these gains to solidify the desire for change (nothing creates desire more than demonstrable success), the vision of the RISE initiative and the new concepts and methodologies for quality management and process improvement had to be reinforced. Reinforcement can, and in this case did, take multiple forms. The strategies and methodologies Mayo is using to sustain the gains already achieved by the initiative and to position the initiative for further sustainable transformation include the following:

- Leadership continues to clearly articulate the vision and provide visible support.
- Leadership reinforces the commitment to quality by supporting the ORQMS.
- Leadership expects work units to achieve best-in-class performance levels.

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A further example of research leadership’s commitment to quality is their support for the formation of a new program for Quality and Customer Service Oversight. The oversight group for this program has been charged with providing direction for quality and customer service activities, interacting with Mayo’s research community to “hear their voice” and to prioritize continuous improvement projects resulting from these interactions. A Quality Customer Service and Satisfaction Work Group is currently being implemented.

All of these actions have one thing in common: they were taken to ensure that all of the efforts by all of the people who have contributed to the RISE initiative and who are committed to its vision “*to create a world-class research management system to support Mayo’s world-class scientists*” result in this vision becoming a sustainable reality.

LESSONS LEARNED

At various points during the RISE Initiative, those most directly involved began to understand that these efforts do not have an end point, just as the pursuit of quality and excellence does not have an end point. Those involved also quickly came to the realization that transforming Mayo’s research management system would require a tremendous amount of work performed by dedicated and talented people, and that the work had to be conducted using well-thought-out strategies with a single, easily understandable vision in mind. Research and Office of Research Quality Leadership realized that in order to transform Mayo’s research management system, the fundamental quality principles had to become something more than abstract concepts to the work units supporting Mayo’s research enterprise. They had to become a real and meaningful component of their management philosophy. The most powerful lesson learned is that fundamental quality management principles may be effectively applied to a complex research enterprise and achieve transformational results within a relatively short timeframe.

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