

Quality in radiation oncology

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(Received 19 January 2007; revised 7 March 2007; accepted for publication 15 March 2007; published 17 April 2007)

A modern approach to quality was developed in the United States at Bell Telephone Laboratories during the first part of the 20th century. Over the years, those quality techniques have been adopted and extended by almost every industry. Medicine in general and radiation oncology in particular have been slow to adopt modern quality techniques. This work contains a brief description of the history of research on quality that led to the development of organization-wide quality programs such as Six Sigma. The aim is to discuss the current approach to quality in radiation oncology as well as where quality should be in the future. A strategy is suggested with the goal to provide a threshold improvement in quality over the next 10 years. © 2007 American Association of Physicists in Medicine. [DOI: [10.1118/1.2727748](https://doi.org/10.1118/1.2727748)]

Key words: quality, variation, process improvement, quality management

I. BACKGROUND AND INTRODUCTION

The industrial revolution resulted in notable worldwide contributions including mass production. In the early part of the 20th century, the emphasis was to bring as much product to market as possible in the shortest period of time, often with little attention to quality. The primary method to ensure quality was by inspection. Each component that created the final product was inspected to verify it was within the specifications set by product engineers. If a component was outside specifications, then it was either scrapped or sent back for rework and subsequent reinspection.

During this period, American Telephone & Telegraph (AT&T) was hard at work building facilities to support a universal telephone service. Western Electric Company (created by AT&T as a constant source of supply) was struggling with problems of mass production, including the interchange of parts, precision, and reliability.¹ Scientists and engineers at Bell Telephone Laboratories (Bell Labs), a subsidiary of AT&T, were engaged in product research as well as research on problems of quality associated with mass production. A major emphasis was on the application of probability and statistics to quality.

By the mid 1940s, significant progress was being made on new approaches to quality. Researchers at Bell Labs realized that product inspection was not adequate to ensure a high-quality product.¹ It was much more important to control the variation in the process that created the product. A significant invention was the control chart where data acquired by inspection was plotted sequentially to characterize process variation.² Based in part on this work, W. Edwards Deming, Joseph M. Juran, Kaoru Ishikawa, and others were creating new approaches to quality that extended beyond the manufactured product.³ Unfortunately for AT&T, much of this research did not translate into their production efforts.

After entering World War II in December 1941, the U.S. enacted legislation to gear the civilian economy to enhance military production. The armed forces also helped suppliers by sponsoring training courses on ways to improve quality.

In early 1942, Deming was invited to the Stanford University Statistics Department to lecture on potential ways they could contribute to the war effort. Deming gave a series of lectures on using probability and statistics to provide a basis for action in creating high-quality manufactured products.⁴ Attendees at these lectures and at others that followed included engineers from U.S. industries contributing to the war effort. Most quality programs based on probability and statistics were terminated once the government contracts ended. Deming and others realized that quality can be no better than the intent and commitment of senior management.

After the war, Deming went to Japan in 1950 to lecture on quality to the Union of Japanese Scientists and Engineers (JUSE).⁵ Juran was to follow in 1954 where he raised the issue of quality from the factory to the total organization. Japanese industry readily adopted these new quality practices and Japanese researchers played an integral role in the development of quality. For example, Ishikawa of Tokyo University emphasized seven quality tools now used in most quality programs³ (Table I). In 1976, the JUSE developed and promoted a list of seven quality tools for management and planning³ (Table II).

By the late 1970s, several U.S. industrial sectors including automobiles and electronics had been hit hard by Japan's high-quality competition. Japanese products were flowing into the U.S. that were less expensive and of much better quality. This situation was highlighted to the U.S. public in the 1980 NBC television documentary, "If Japan can...why can't we?"⁶ In many ways, the start of the quality movement in U.S. industry came as a direct response to the quality revolution in Japan. Senior managers of U.S. companies were now eagerly learning quality techniques introduced to the Japanese, many first developed in the U.S. 40 years earlier.

During the past half-century, progress in health care has been made by medical science and technology breakthroughs. While this has led to improvements in radiation oncology, a new focus on quality will continue to provide

TABLE I. Seven basic tools of quality. Optimal use of these tools is within a comprehensive quality program.

Tool	Description
Cause-and-effect diagram ^a	Identify many possible causes of a problem
Check sheet	Structured form to collect data on frequency of events
Control chart ^b	Quantify and predict variation in output of a process
Histogram	Document or communicate the distribution of data
Pareto chart	Data analysis to show which situations are more significant
Scatter diagram	Plotting method to determine if two variables are related
Stratification ^c	Data separation so that patterns or conditions can be identified

^aAlso known as the fishbone diagram or Ishikawa diagram.

^bAlso known as the process behavior chart.

^cSometimes replaced with the flowchart or run chart.

opportunities to improve patient care. In the next section, we present the current approach to quality in radiation oncology, which is followed by where we believe quality practices should be over the next decade with suggested pathways to achieve these goals.

II. WHERE ARE WE NOW?

Quality in healthcare has two dimensions: (1) high-quality decision making and (2) high-quality performance.⁷ One aspect of high-quality decision making is consistency of practice. Professional judgment and peer review are current methods to achieve consistency.⁸ Consistent decision making is also achieved by studying patterns of care,⁹ and by clinical trials.¹⁰ However, results of clinical trials can be confounded by inconsistent interpretation and implementation of the trial criteria.¹¹ A related problem with results published in the literature is that the reported efficacy may not be generally applicable if different levels of quality are used at different institutions. With regard to high-quality performance, reported error rates for significant events in radiation oncology are low.^{12,13} The actual error rates are probably higher with even more nonsignificant events that are never reported.¹⁴ There is theoretical evidence that even those nonsignificant events can play a role in the degree that radiotherapy is a benefit to patients.¹⁵

The focus of research on quality in radiation oncology is on breakthrough innovation. The emphasis is largely on new hardware or software products or on methods to utilize such new equipment. Over the last several years, a limited number of research papers have been devoted to adapting modern quality techniques to the radiation oncology environment.^{16–20} The consensus seems to be that automation, new machinery, and new computer systems will ensure optimal quality. It has been shown, however, that record and verify systems do not remove all possible sources of error.¹³ In fact, entirely new failure modes are possible using such systems.²¹ Effective use of record and verify systems for improving quality requires a change in staff functions within the new electronic environment. As a general rule, continued efforts on new equipment and software alone will not improve quality beyond its current level.²²

The current approach to radiation oncology quality is to investigate incidents once they have occurred rather than investigating processes for potential problems. Within some departments or staff, the primary aim is making it through the day, with no thought about the system or the future. This approach to quality is summed up in the old adage, “If it ain’t broke, don’t fix it.” Such a philosophy can lead to latent errors in a process that can be manifested long into the future.²³ Hard work and best efforts in radiation oncology are

TABLE II. Seven quality tools for management and planning. These tools are used for abstract analysis as well as detailed planning.

Tool	Description
Affinity diagram	Organizes a large number of ideas into natural relationships
Relations diagram	Understand cause and effect relationships
Tree diagram	Move the thought process from generalities to specifics
Matrix diagram	Understand how groups of items relate to one another
Matrix data analysis ^a	Compares options to criteria in order to choose the best option
Arrow diagram	Schedule and monitor tasks within a complex project
Process decision program chart	Systematically identify what might go wrong in a plan under development

^aSometimes replaced with the prioritization matrix.

the main mode of operation to improve quality. An example of this is the requirement to perform a measurement for every IMRT case prior to treatment. Whether this actually improves quality is still a point of debate.²⁴ However, independent anthropomorphic-based IMRT plan verification can bring user errors to light and thus lead to improvements in quality.²⁵ When quality is in doubt, the response is to give best efforts and check more parameters. This approach is also applied to people and processes when a mistake occurs. But, simply paying closer attention to people can create what is known as the "Hawthorne effect".² That is, by just paying closer attention, people do a better job. Nevertheless, it is impossible to check everything. There are limited resources and limited time to do all the work. Current appropriate staffing levels for physicists can be found in the Abt Report,²⁶ but may need to be modified with new requirements and approaches to quality.

III. WHERE SHOULD WE BE IN 10 YEARS?

The International Organization for Standardization (ISO) created a set of international standards for quality known as ISO 9000. Originally issued in 1987, a major revision was presented in 2000.²⁷ Elements of ISO 9000 include modern quality techniques such as the responsibility of senior management and requirements of continuous improvement, which can be implemented using a comprehensive quality program.²⁸ The ISO standards have already been suggested for use in radiation oncology.¹⁶ The Joint Commission (www.jointcommission.org) is partly responsible for encouraging radiation oncology departments into action. The quality mandate from the Joint Commission is specific to describing a comprehensive quality program rather than a detailed prescriptive emphasis focused on capability.²⁹ A first step should be to take action on those recommendations. Modern quality tools and organization-wide quality programs are already used in other hospital environments.^{30,31}

Quality should depend more on the assessment of process data and less on the assessment of a patient's health status post treatment (outcomes data). Patient outcome is a misleading quality metric because differences in patients' characteristics may lead to different results, even for the same delivery of care. A system view of department processes should be adopted with a focus on reducing variation through the people who use them. Within a radiation oncology department, each job or group of workers is not simply additive; their efforts are interdependent. One process of the system, in achieving some numeric goals, may inhibit the function of another process. Some process(es) may operate at a loss to optimize the system as a whole. An example of this is in treatment planning where a dosimetrist may have down time waiting for the physician to draw contours on a computed tomography scan. Working to understand variation allows one to first control a process and then to achieve real process improvement. High-quality means minimizing process variation and moving the average closer to the optimum value. But what is the optimum value and what are acceptable limits of variation? These questions are answered by a

consistent and up-to-date set of specifications for our procedures and equipment. Task Group reports that contain specifications (e.g., TG-40,³² TG-53,³³ etc.) can be several years behind technology implementation and not easily updated. Furthermore, independent checks of subsystems are becoming more difficult as newer technologies, such as Tomotherapy HiArt and Accuracy CyberKnife, are self-contained planning and delivery systems. Specifications are needed for these new systems as well.

Error reporting mechanisms (e.g., the ROSIS database, www.clin.radfys.lu.se) need continual development to allow optimal sharing of information, which will help to understand clinical processes, equipment, and their failure modes. Quality and error reduction should go hand-in-hand. When a process is predictable, one can consider an error as being built into the process, i.e., a given number of errors are guaranteed to occur. If high-quality processes with minimal variation are developed and implemented, then fewer errors should result. Variation, for example in a repeated set of measurements, is an easy concept to appreciate. What may not be so obvious is that clinical processes also contain variation. Without an appreciation of variation, it is difficult to predict the future of process operation or understand past performance. It is also easy to blame others for errors over which they have little control.

There are, however, situations where even a single error may result in catastrophic loss, for example a miscalibration of a new linear accelerator during acceptance or delivery errors in a single-fraction radiosurgery treatment. A different set of modern quality and error reduction tools are required in these cases.³⁴ Tools that can be useful are repeatability and reproducibility studies, checklists, mistake-proofing, and the usual independent verification checks.

High-quality patient service is a necessity. A goal should be to understand and also believe what patients want and use that as a compass to define optimal quality. Quality and error reduction programs should consist of process design, process implementation with statistical evaluation, and design improvement based on the data the process provides. Vague statements on quality should no longer be acceptable such as "I think we are doing OK" or "things seem to be getting better." The new requirement should be the evaluation and documentation of process behavior based on the data.

IV. HOW DO WE GET THERE?

A modern approach to quality as found in most industries must be implemented in radiation oncology. Modern quality techniques developed in industry have already been suggested as important to healthcare.^{35,36} The concept of measurement and an appreciation of a system are essential to achieve optimal quality. Measures of improvement should be created together with a focus on specific projects that are critical to a department's success. Quality should be restricted to problems of loss caused by variability of function and related harmful side effects, or it will slip out of the domain of medical physics into the psychological domain of cultural or personal values.³⁷ Facets of a modern approach to

quality include senior management leadership, employee involvement and empowerment, patient defined quality (patient satisfaction), a view of work as a system consisting of different processes, and continuous improvement. Such models should help with gathering information and taking action efficiently and effectively. In-depth education on quality is needed along with skills transfer that will give a team and individuals the power to lead sustainable change. Relevant projects must be incorporated with broad training that is tied to an overall vision. Picking out a single quality tool or technique will lead to unimpressive results and ultimately not work. We believe the following six objectives are necessary to achieve the goal of optimal quality.

A. Encourage research on quality

All technology research in radiation oncology is geared toward improving the efficacy of radiation therapy. The vast majority of that research, which is specific to quality, is focused on new equipment and new procedures using the equipment, i.e., breakthrough innovation. For example, in the November 2006 issue of *Medical Physics*, there are seven papers devoted to this type of research.^{38–44} There are no papers in that issue devoted to modern industrial approaches to quality. Research sessions at the annual American Association of Physicists in Medicine (AAPM) and American Society for Therapeutic Radiology and Oncology (ASTRO) meetings that are specific to techniques of quality and error reduction need to be instituted. This will provide an academic incentive for physicists and physicians to focus on implementing and demonstrating the benefit of modern industrial quality techniques. Discussions at the annual meetings on quality and error reduction are inappropriately relegated to the professional (nonacademic) tracks at the annual meetings. Research on modern approaches to quality may be undervalued because it can be seen as not scientific or only incrementally innovative and lacking hard results. Incremental innovation, however, can be just as important to our field as breakthrough innovation.⁴⁵ This type of research on quality needs to be done with the same academic requirements as any scientific study.⁴⁶ It will take a focused effort to sift through the many quality techniques for applicability to radiation oncology. This includes metrics for process behavior charts, appropriate staffing levels, financial implications, and organization-wide approaches such as Total Quality Management, Quality Function Deployment, Six Sigma, Lean, etc. Lean thinking, for example, is a system of methods that is geared toward identifying and eliminating all non-value-adding activities. How Lean a process can be made without making it prone to errors is an area that requires research. Research is also necessary to determine which metrics or criteria are reliable to characterize a process and minimize variation. Interesting quality techniques such as situational awareness are themselves being investigated for optimal application to medicine and this type of work needs to be encouraged.⁴⁷ Novel approaches such as Web-based audit systems may improve high-quality decision making in the future.⁴⁸ Process control techniques may even play a role in

the physician care of patients.⁴⁹ All of these aspects argue for dedicated research sessions on quality and error reduction at the AAPM and ASTRO annual meetings.

B. Educate radiation oncology leadership

Cultural change and strong management are necessary to achieve optimal quality.⁵⁰ Educating leadership does not refer to continuing education but rather an initial education on what optimal quality means and what methods and resources are needed to achieve it. Success of new quality programs will hinge on the ability to obtain endorsement of and commitment to the process from departmental senior managers and hospital leadership. A delineated vision and goals for the department and commitment of resources to support the process is necessary along with department-wide communication to spread the initiative and tools. Quality committees should report directly to departmental leadership. Early physician and physicist buy-in to any program will be essential for success. Department chairs, physics directors, and administrators need to be informed on modern quality and error reduction techniques. Successful continuation of new quality programs will then depend on staff education. This should not be left to the annual meetings but rather be Web based and easily accessible to anyone. Medical and physics residency programs should teach modern industrial quality techniques and these should be tested for at the ABR board exams. The most efficient way education can be achieved is through AAPM and ASTRO initiatives.

C. New approach for AAPM QA task groups

Specification of operating limits for equipment and procedures is an essential part of developing a quality program. A consistent, up-to-date specification document for all aspects of radiation oncology is required. At the rate of new technology development and implementation, specifications will be changing rapidly. The first step is to collate existing specifications (e.g., Table II of TG-40) into one place. These documents should be condensed to the minimum necessary specifications rather than an exhaustive list of all possible things to check. The specifications should be contained in a single document (or Web pages) for all aspects of radiation oncology. This document should be “live” and readily available to departments and vendors. A system of regular updates can be accomplished by a joint organization with appointments from the AAPM and ASTRO that has the authority to make necessary changes. The organization or committee will discuss specifications for new equipment and procedures or revisit antiquated specifications. For brand new equipment, the committee can recommend temporary specifications based on the experience and input from early adopters. A start in this direction is the AAPM Therapy Committee’s assignment of a Quality Assurance and Outcome Improvement Subcommittee that is working to fast track recommendations for new devices in the form of short Task Group reports. A subsequent initiative, after considerable research has been done, is for the AAPM Task Groups to make recommendations on organization- or department-wide quality programs and the

use of modern quality tools. This step has begun with the formation of TG-100, which has taken the approach to develop a framework for designing quality management activities. Specifically, TG-100 will investigate and present the technique of Failure Modes and Effects Analysis with specific examples to IMRT and HDR brachytherapy. Lastly, clear guidelines are needed for what constitutes quality, what constitutes an error, and how to report errors. Other fields have also been plagued with confusing nomenclature.⁵¹

D. Close collaboration with vendors

A closer and more formal collaboration with vendors should be fostered to provide equipment and procedures to customers. A first step is to facilitate data transfer between competitive vendors' systems, which has begun to be addressed by the Integrating the Healthcare Enterprise (IHE) Radiation Oncology (RO) Task Force. Vendor and user collaboration should also be more than mere financial support. The vendor's expertise of their product should be combined with the user's clinical knowledge to create optimal products and processes. New equipment should be delivered with process behavior limits rather than specification limits. It is the physicist's responsibility to set specification limits and the vendor's responsibility to produce a product that meets those specifications. Long-term relationships should be developed with vendors to reduce variation in product output and create a steady stream of incremental innovations. Vendors should be encouraged to work closely with clinicians and reward their employees for participating in peer-reviewed publications. Collaborative research, even vendor initiated research, should be encouraged and receive the same level of academic scrutiny and standards as any other type of research work.⁵² This type of collaborative research should not be seen as inferior to pure academic pursuits. After all, discoveries or innovations that never make it to market are of little benefit to patients.

E. Utilize resources outside radiation oncology

Collaboration with other professional societies that have expertise in quality and error reduction is needed. For example, the American Society for Quality (www.asq.org), the National Quality Forum (www.qualityforum.org), the Institute for Healthcare Improvement (www.ihl.org), and the National Patient Safety Foundation (www.npsf.org) provide valuable information and contacts on how to improve quality. These societies may provide the opportunity to identify researchers interested in improving quality in healthcare. Similarly, contact with colleagues in schools of management or departments of industrial and systems engineering may provide needed expertise from fields outside medical physics and medicine. Collaborating with these researchers will provide new opportunities to learn about current quality opportunities that may be applicable to radiation oncology. There is also much to learn from other journals such as *Quality Management Journal*, *Quality Engineering*, *Quality and Safety in Healthcare*, and *Quality Progress* just to name a few.

F. Adopt a patient view of quality

The highest bar one can set is to treat patients as customers. It is easy for physicians and physicists to discount the patient's expectations of health quality. The science of quality is making its way into healthcare and patients may be the greatest resource to determine what needs to be improved.⁵³ Patient requirements should be related to quality characteristics of the service being provided. A way to achieve this is to have patient advocates on departmental quality committees as well as on AAPM and ASTRO quality committees. Quality characteristics identified with patient input should be targeted for improvement and translated into necessary functions of staff and equipment. Patient survey data will be an important tool to learn about the patient's perception of care. But surveys must be used carefully as the potential for error and bias can be significant.³⁰ Quality improvement capacity needs to be aligned with professional receptiveness, leadership, technical expertise, and survey data.⁵⁴ It is important to remember that the patient is the greatest beneficiary of an optimal quality program.

V. CONCLUSION

Medical physicists and radiation oncologists have readily harnessed new technologies and have made many significant contributions to radiation oncology over the years. Much like medicine, quality is also an art and there is a need for investigation. Scientific training leads physicists and oncologists to wait for convincing evidence for the effectiveness of new techniques before incorporating any change of procedures to treat patients. However, our field should not quickly dismiss approaches to quality that have roots in probability and statistics with many years of practical experience and demonstrated benefit in other fields.

ACKNOWLEDGMENTS

The authors would like to thank the Associate Editor and referees for many constructive comments that made their way into the final version of this manuscript.

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