

The Case for Using Industrial Quality Management Science in Health Care Organizations

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In an effort to provide health care of optimal quality, providers traditionally assess or measure performance and then assure that it conforms to standards. In cases where performance fails to conform, providers attempt to modify or improve physician behavior. The analytic scope of this traditional paradigm may not be broad enough to allow modern health care organizations to provide optimal care. At a theoretical and practical level, many conceptual limitations inherent in the traditional approach are addressed in modern industrial quality science. A fundamental principle of industrial quality control is the recognition, analysis, and elimination of variation. Based on rigorous analysis of variation in outcomes and processes, industrial quality experts have developed principles and techniques for quality improvement. Health care organizations may well make important advances in the quality of care and service through the application of these principles and techniques.

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SINCE Codman¹ first systematically audited medical records at the Massachusetts General Hospital (Boston) in 1915, scholars and practitioners have made considerable progress in defining and assessing the quality of medical care.² Nevertheless, it is argued herein that current theory and practice have limitations that must be remedied before complex, modern health care organizations will be able to develop effective quality improvement programs. It is further argued that industrial quality science appears to address some of these deficiencies and thus might enhance the ability of health care facilities to provide care of optimal quality.

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QUALITY OF CARE: CURRENT THEORY AND PRACTICE

Donabedian,^{3,4,5} the leading thinker in modern medical quality assurance, formulated the classic definition of quality of care in medicine: it is "that kind of care which is expected to maximize an inclusive measure of patient welfare, after one has taken account of the balance of expected gains and losses that attend the process of care in all its parts." High-quality medical care is traditionally thought to consist of a scientific or technical component and an interpersonal component that together enable the patient to attain the highest possible functional state and psychosocial result.⁶

Consistent with this definition, health care organizations' quality programs generally have three major foci: assessing or measuring performance,

determining whether performance conforms to standards, and improving performance when standards are not met.^{6,7}

This traditional approach to quality has several important limitations. To begin with, the classic definition of quality of care seems too narrow to meet the needs of modern health care providers. Donabedian's formulation emphasizes quite appropriately the extent to which health care providers improve the physical and psychological health of individual patients. The needs of patients should always be paramount, but health care organizations are increasingly called on to meet the needs of other individuals and groups, such as patients' families, referring physicians, and third parties. For example, teaching hospitals can achieve high-quality care in part by meeting the educational needs of interns.

Second, traditional medical quality assurance features a static approach to quality. Its goal is conformance to standards. This can be distinguished from the professional ethic of physicians to continuously improve on existing practices. The approach implicitly assumes that some rate of poor outcomes is acceptable and that little information can be obtained from the analysis of cases in which prevailing standards are met. Furthermore, should standards be set too low, quality assurance programs may breed complacency and thus contribute to poor quality. Should they be set unrealistically high, they may alienate or frustrate providers.

A third limitation of the current approach is that it tends to focus on physician performance and to underemphasize the contributions of nonphysicians and organizational processes generally. For example, consider what happens when a physician concludes that his patient has bacterial sepsis. The physician must choose an appropriate antibiotic and communicate this decision appropriately. These activities trigger subsequent processes by which the pharmacy department dispenses and nurses administer the antibiotic (Fig 1).

As it relates to this example, a traditional quality program might evaluate the physician's diagnostic skills and choice of antibiotic. However, errors may occur at any step in the subsequent processes and they, too, may cause the patient to receive suboptimal care. Unfortunately, most health care organizations do not routinely analyze the performance of such critical processes. In those that do, the data may be perceived to be less important than evaluations of physician performance.

Traditional techniques for quality improvement in health care also tend to focus on physicians and changing physician behavior.¹¹⁻¹⁶ However, it is likely that quality improvement in modern health care organizations will require complex, simultaneous changes involving employees and professionals in many departments. In many industries, the transformation of the production process from one dominated by artisans to one involving complex interactions among many specialized divisions has necessitated the development of new methods for quality improvement. Health care delivery, which is undergoing similar transformation, may require similar reform in its approach to quality improvement.

The fourth limitation of the current approach is that it tends to emphasize certain aspects of physician performance: technical expertise and interpersonal relations. Other aspects of physician performance have a bearing on quality. One of the most important is the physician's ability to mobilize an organization's resources so as to meet the needs of individual patients and the goals of the organization.

Consider a physician who has expertly diagnosed and treated a patient with chest pain. On the first hospital day, the physician fails to properly specify the roentgenogram he wants, so the patient must return to radiology. On the second day, he forgets to sign his verbal orders for pain medication. This delays pharmacy and nursing and, of course, prolongs his patient's discomfort. On the day of discharge, he decides to evaluate

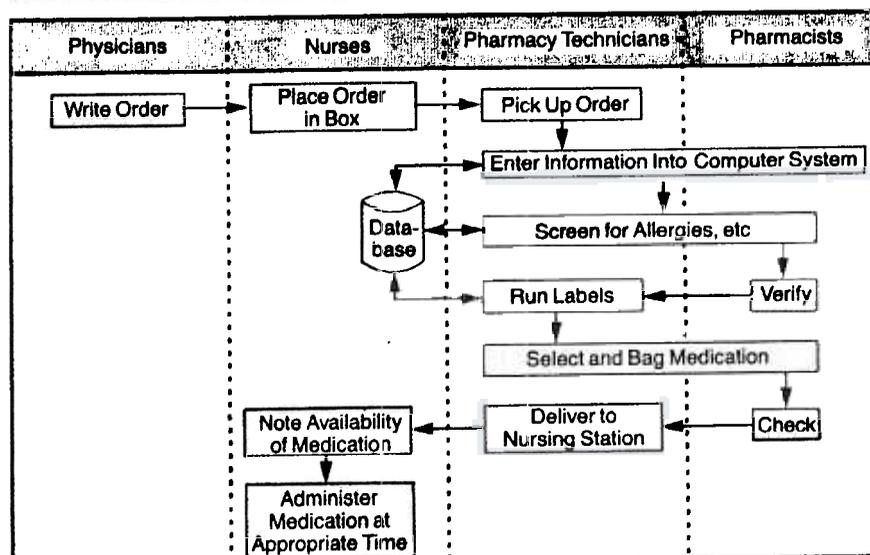


Fig 1.—Flowchart: dispensing medications at Brigham and Women's Hospital, Boston, Mass.

an ancillary problem. This delays the patient and his family and prevents the hospital from accepting a patient awaiting transfer from another hospital. Has high-quality care been given?

A NEW APPROACH TO QUALITY

Problems with traditional approaches to medical quality have led recently to a search for alternative methods and strategies. Modern quality science, a discipline in which statistical techniques are used to assist decision making concerning product quality and production processes, is one such alternative. Modern quality science has been adopted on a large scale outside health care, and it has led to demonstrable improvements in the quality of products and services, improved productivity and efficiency, and, in many cases, improved profitability as well.

Redefining Quality

Industrial quality experts suggest that quality be defined as a continuous effort by all members of an organization to meet the needs and expectations of the customer. For health care purposes, this definition might be modified to substitute "patients and other customers" for the word "customer."

The advantages of this definition are several. The reference to "continuous effort" emphasizes the value of striving to exceed prevailing standards, rather than accepting them even temporarily as limits on performance. The term "all members of an organization" suggests an imperative to study the organizational processes by which health care is pro-

duced and provided. The reference to "expectations" recognizes that patients' reports of their experiences and their assessments of results are valid indicators of quality, including some of its technical aspects.^{16,17}

By singling out the patient from other customers, this definition acknowledges the ethical primacy of the individual patient's needs and expectations. However, one advantage of acknowledging openly the existence of other customers is that this may encourage frank discussion within health care organizations of the reality that they are constantly engaged in complex efforts to satisfy many parties. The needs and expectations of differing clients sometimes conflict, and such conflicts must always be resolved in the patient's favor.

Measuring Quality

The recognition and analysis of *variation* is fundamental to modern industrial thinking about quality measurement. All aspects of medical care display variation. For example, in a series of patients with sepsis, the etiologic agent and its antibiotic sensitivities vary. Patients themselves have unique combinations of coexisting conditions, clinical presentations, and expectations. The particular mix of physicians, nurses, and support personnel varies, as does the availability of diagnostic tests and the accuracy with which they are performed. Antibiotic batches vary in potency and bioavailability.

Furthermore, all these sources of variation combine at random during the

care of each patient with sepsis. It is thus not surprising that the outcomes of a sequence of seemingly similar clinical encounters can themselves display variation.

When multiple sources of variation are present, isolated observations provide insufficient information on which to base objective decision making.¹⁸ Optimal decision making requires the application of some basic statistics to a series of observations so that recognizable and predictable patterns can be appreciated. The control chart (Fig 2) can be used to accomplish this. Control charts have been used in industrial settings for 60 years to understand patterns and types of variation and to provide a rational framework on which to formulate and evaluate quality improvement efforts. They are particularly effective when used to evaluate an unusual observation or sequence of observations. In such settings, control charts are used to determine the probability that these observations have a truly unique cause.

This fundamental thinking about multiple sources of variation and their combined impact on the measures of quality is not commonly applied in traditional medical quality programs. Instead, it is common to attribute poor outcomes to an individual or some other isolated cause. For example, an "unanticipated" death may be attributed to physician negligence, or a high rate of wound infections may be attributed to a particular technique.

Improving Quality

Having used control charts and other statistical tools for decades to study production and service provision, quality experts have more recently begun to suggest a set of managerial principles directed at quality improvement. They include (1) active, visible support from clinical and managerial leadership for the continuous improvement of quality; (2) a focus on processes as the objects of improvement; (3) the elimination of unnecessary variation; and (4) revised strategies for personnel management.

As it applies to health care organizations, quality experts' central principle of quality improvement is that *senior administrative and clinical leaders should explicitly and actively pursue an ethic of continuous improvement in the quality of care and service.* This is deceptively difficult to achieve. The very issues that have thrust quality to the top of health care leaders' agenda—cost containment, the nursing shortage, malpractice, and others—all beg for short-term solutions at the expense of a long-term commitment toward quality improvement. A most salient example

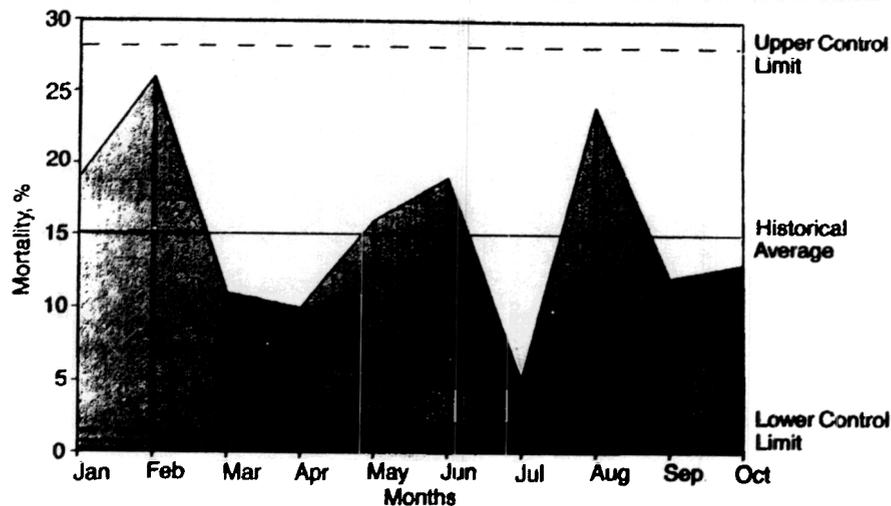


Fig 2—Control chart demonstrating mortality rates in bacterial sepsis.

of this occurs in health care organizations that face serious financial crises. In this setting, many leaders are unwilling to commit the resources and time to initiate quality improvement efforts.

In addition to committing resources, quality experts suggest that leadership must direct the effort, evaluate it, implement process changes where indicated, provide training, and recognize those who participate. This would require uncommon leadership in health care settings, because quality management principles have yet to be empirically proved in health care as they have in industry.

As a second fundamental principle of quality improvement, quality experts suggest that *processes, not individuals, should be the objects of quality improvement.* In industry, the word "process" refers to a sequence of activities that transforms inputs into final products, or outputs. This definition should be distinguished from the definition used in the medical quality assurance literature. In the latter, "process" refers to the "set of activities that go on within and between practitioners and patients."^{19,20,21} This traditional medical definition of process has become an important conceptual link in the analytic framework that supports traditional medical quality assurance, and it has been of great value for many years.

It is also readily apparent, however, that modern health care organizations provide medical care and ancillary services by implementing processes of the type described by industrial quality experts. There are processes by which we admit and discharge patients. There is a process by which pharmacy dispenses

medications (Fig 1). And, to be sure, there are clinical decision-making processes as well.

Industrial quality experts have made several observations about process that can assist quality improvement efforts. The first is that processes are complex. During a recent demonstration project at Brigham and Women's Hospital (Boston, Mass), for example, we observed that the process by which cardiac catheterization laboratories are "turned over" between cases includes four individuals who carry out over 50 separate activities. The activities of each individual are linked to those of the other three through an exquisitely timed series of interactions, handoffs, and dependencies. This process is repeated 10 times each day at our hospital, but it is only one of dozens that take place in the catheterization laboratory, and it is only one of hundreds that a patient might be part of during even the most routine hospitalization. This suggests that health care organizations could benefit from a systematic approach to the analysis and improvement of process, as outlined in the industrial quality science literature.

Second, industrial quality experts have observed that processes are frequently characterized by unnecessary rework and waste, and process modifications that reduce these features may simultaneously improve quality and reduce cost. These observations would seem applicable to health care organizations as well. We repeat tests because they are not performed correctly the first time. We rewrite requisitions because they are lost or filled out incorrectly. We look for lost charts and reschedule appointments. Because the

time required for such activities reduces that available for direct patient care, there is a strong rationale to improve the execution of such processes.

Quality experts' third observation is that organizations can substantially improve their final products or service by training personnel at all levels to use simple analytic techniques and graphical methods^{19,22} for the study of process. The implication for health care organizations is that with proper training in quality improvement methods, physicians, nurses, technicians, and other hospital employees are well positioned to contribute to quality improvement. All have important perspectives on the processes involved in health care delivery, and all can identify sources of variation in these processes.

The Elimination of Unnecessary Variation.—Many sources of variation in medical care should not be controlled. For example, it is often necessary to develop treatment plans that are customized to meet the needs and expectations of individual patients. Nevertheless, quality experts suggest that substantial quality improvement can be achieved by eliminating unnecessary variation in the execution of the processes by which these treatment plans are implemented.

In the management of all patients with sepsis, for example, quality may be improved if technicians use the same techniques for obtaining, handling, and interpreting blood cultures and if nurses use the same techniques and equipment for measuring patients' temperature and applying wound dressings. The benefits of eliminating unnecessary variation in this way include rapid acquisition of technical skills through frequent repetition and consequent reduction in procedural errors. They include improved turnaround times on diagnostic information and improved reliability of this information.

The elimination of unnecessary variation in clinical practice may similarly improve the quality of care. In the above example, for instance, should physicians choose to follow similar procedures for determining the source of infection and for selecting and then modifying antibiotic coverage, it is likely that the hospital would be able to implement their care plans more efficiently and accurately. This is because allied health personnel would become familiar with the procedures and protocols physicians expect them to perform. These potential improvements in the quality of care need to be balanced against the physician's need to preserve discretion in many aspects of clinical practice.

The proposition that unnecessary variation in clinical practice causes poor quality provides an important justification to develop consensus about "best practices" and to encourage adherence to these practices. "Best practices" might be developed at the institutional level based on the medical literature and local needs and constraints, and they should be updated as necessary. They are to be distinguished from mandatory adherence to externally imposed, static guidelines or standards.

The elimination of variation in clinical practice is highly desirable even in the common circumstance where physicians must make treatment decisions without clear guidance from the results of clinical trials. In such settings, widespread uncontrolled variation may inhibit the advancement of medical knowledge by confounding the interpretation of outcomes. In fact, research and development are best accomplished in circumstances where sources of variation have been identified and controlled. When this is the case, differences between control and treatment groups can more accurately be attributed to the treatment.

Industrial quality management science's intense focus on process and its improvement effectively complements current trends in medical quality assurance that increasingly rely on outcome measures. Outcome measures will always have a role in medical quality programs because there will always be a need to know when poor outcomes are occurring. However, because outcome measures do not generally provide insight into the causes of defects, they may be most useful when used in conjunction with process technology as described above.

Personnel Management.—Quality experts recommend a personnel management strategy that centers around the treatment of employees and professionals as valuable resources with a central role in quality improvement. The strategy features increased training, the elimination of work standards and numerical goals, and new approaches to employee evaluation.

Quality experts suggest greatly intensified training for all hospital professionals and employees. They suggest that training be directed at the acquisition and perfection of job-specific skills and at the principles and techniques of quality improvement. Consider, for example, how new physicians learn to perform invasive procedures such as lumbar puncture and thoracentesis. When a patient develops an indication for such a procedure, the resident demonstrates his technique to the intern. The next

time a patient on that intern's service requires that procedure, the intern does it himself. As the year goes on, interns continue to gain unsupervised experience with these techniques. For their part, each resident had learned his technique from a different resident the year before. This paradigm considerably increases variation in technique and increases the chance for procedural error and complications. If the training program emphasized supervision and if it formulated optimal approaches for the performance of such procedures, negative outcomes might well be reduced.

In industrial settings, employee training programs also frequently include clear statements of organizational commitment to quality improvement. Employees are shown how the organization defines and measures quality, and *how they can participate in its improvement*. This generally requires several days of instruction in communication skills, elementary statistics, and graphical techniques. Such training has become increasingly common outside health care, and it appears to be effective despite variations in employee educational levels.^{19,22}

As part of their new personnel management strategy, quality experts also recommend the elimination of work standards and numerical goals. Standards and goals stimulate behavior narrowly directed at their achievement, and this may lead to impaired performance in other areas. In addition, standards may be perceived as maximal attainable levels of performance. Such perceptions may discourage creativity and risk taking, which are required to substantially improve quality.

Quality experts also suggest alternatives for employee evaluation. These are based on the assumption that employees and professionals generally want to do their best, and that variations in output should not routinely be attributed to their behavior, as there are many other equally plausible explanations for such variation.

CONCLUSIONS

The focus of most quality assurance programs in health care remains the technical expertise and interpersonal skills of physicians. Their ability to mobilize the resources of complex health care organizations remains unassessed. Health care organizations themselves contribute to overall quality in ways that have yet to be measured. In addition, regulatory and legal demands to define standards of care encourage or force physicians to pursue conformance rather than the possibility that continuous improvement is possible.

Modern industrial quality science appears to offer solutions to these conceptual problems. It includes the use of statistics to analyze production and service provision processes. It is based on the assumption that employees and top leadership should continuously strive to improve these processes. It stresses interdepartmental cooperation, training, and experimentation.

These techniques have been associated with improved product quality in many Japanese and American industries, but they have yet to be widely implemented in health care. It is an appropriate time for the health care industry to begin experimentation with these techniques.

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