Findings of innovation research applied to quality management principles for health care

David H. Gustafson
and
Ann Schoofs Hundt

We asked health care professionals to identify and prioritize barriers to implementing TQM in their organizations. Lack of evidence of TQM success was a commonly listed barrier. In response, we drew from research in the innovation literature that identifies factors that distinguish successful from failed efforts to innovate and improve. Applied to TQM principles, innovation findings overwhelmingly support customer and quality mindedness. To a lesser degree other principles are upheld, suggesting future research in the area.

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In the last few years, total quality management (TQM) and one of its key elements, continuous quality improvement (CQI),[1–3] have gained increasing attention from health care leaders.[4–6] [We find that TQM and CQI are frequently used interchangeably. It helps to see total quality management as being a set of management principles that manifest themselves in four strategies: (1) continuous quality improvement (the ongoing effort to make things a little better); (2) innovation, e.g., quality function deployment (strategies for designing completely new ways to meet a certain customer need); (3) quality in daily work life (strategies for integrating the management principles into the way all employees live); and (4) strategic quality planning (the means by which the principles influence the long- and short-term directions of the organization). Typically TQM implementation begins with CQI, but over time evolves to include the three other strategies.] Some contend that the tenets of TQM are substantially different from practices of quality assurance and offer a unique means of improving the quality of health services.[4]

In response to this and related contentions and also due to directives from regulatory and accrediting bodies, thousands of health care providers have now been trained in TQM. At least one journal is devoted to reporting the accomplishments of TQM in the health field and other journals have published many articles on the subject. Conferences on TQM in health care draw hundreds of people. Many hospitals and health maintenance organizations (HMOs) claim to have a CQI program, and some have begun other elements of TQM, such as quality function deployment and strategic quality planning. Networks of health care providers committed to CQI and TQM meet regularly to share experiences and plan how to improve their implementation.

It makes sense that TQM has been so widely received. Its principles make sense, at least on the surface. In addition, there are numerous success stories from other industries. In fact, some corporate custom-

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David H. Gustafson, *Ph.D., is Professor of Industrial Engineering and Preventive Medicine, Center for Health Systems Research and Analysis, University of Wisconsin, Madison, Wisconsin.*

Ann Schoofs Hundt, *M.S., is a doctoral student in Industrial Engineering, Center for Health Systems Research and Analysis, University of Wisconsin, Madison, Wisconsin.*

ers insist that their health care providers adopt CQI. Yet we get the impression that many efforts to implement have been halfhearted: a little training, a few teams (and fewer successes), a steering committee that meets irregularly, a top management that says the right things but whose real attention is elsewhere. TQM seems to be more than a fad (partly due to external pressures from corporate and now government customers) but far from the success story that many had hoped. What has held back wholehearted commitment to CQI?

A SURVEY OF BARRIERS TO IMPLEMENTATION

In an effort to understand what top managers need to fully embrace TQM and make it the central focus of their work, we telephone interviewed 23 health care leaders who, with varying levels of success, have attempted TQM implementation. We asked them what barriers they found to wide acceptance of TQM. After eliminating duplicates, we identified 44 possible reasons. Table 1 lists those reasons.

We then created a survey and distributed it to 100 health care leaders from 32 health care organizations who were attempting to implement CQI, and another 120 leaders attending a nationally offered introductory course on quality improvement. The survey asked these leaders to set priorities for addressing the barriers. Each barrier was scored on a 1–5 scale, with 5 being the most important. Column 3 of Table 1 lists the average priority score for each barrier.

While many of the barriers related to lack of knowledge about how to implement CQI (how to involve physicians, how to empower employees, how to learn customer needs), 5 of the top 15 barriers related to a lack of evidence of TQM success. They include:

- Ways to measure success of CQI.
- Evidence of CQI effectiveness and the conditions under which it is effective.
- Knowledge of what factors promote successful organizational transformation.
- Outcome and process measures for evaluating CQI success.
- Knowledge of which TQM principles really promote success.

HOW TO PROVIDE EVIDENCE OF TQM EFFECTIVENESS?

Ultimately, the measure of TQM success will be whether customer needs are more efficiently and effectively met. Ideally, this would involve a study where organizations, randomly assigned to either adopt TQM or to be in a control group, are studied over the years to assess their success in meeting customer needs. A key aspect of the study would be to measure how well the principles of TQM were adopted. However, a controlled study of this type is impractical and sets a standard to which no other management philosophy has been subjected. Yet the effort to adopt and implement TQM principles is complex and difficult and it is reasonable to require some sort of evidence before a wholehearted commitment can be expected.

An alternative means of gathering evidence would be to search for the structural and process predictors of successful improvement and then determine which were consistent with TQM principles. That is, (a) we would identify a large number of organizations that had implemented formal efforts to improve; (b) we would then identify the principles and practices (some TQM based and some not) that might explain the difference between successful and failed improvement efforts; (c) subsequently, we would collect data on the extent to which each principle and practice was present in the successes and failures; and (d) finally, we would determine which principles and practices were the best predictors of success and failure. If the TQM principles were the best differentiators, this would provide evidence of their validity.

TQM does not advocate simply copying a good process but rather identifying those key process variables (KPV) that make the difference between success and failure.

As it turns out, those studies have been done. Not in health care and not with the intention of validating TQM, but they have been done. Over the last 30 years, researchers in business[7–23] have been searching for the factors that distinguish between successful and failed efforts to innovate and improve. We believe this literature contributes to our understanding of TQM/CQI because there are numerous parallels between the two:

- there is an intent to improve a product or service;
- sometimes the improvement comes in *design* or *redesign* of the product/service; other times, by

TABLE 1

QUESTIONNAIRE RESULTS

Rank	Question	Average score
1	How to measure success of QI**	4.7
	How to involve physicians in improving processes for getting care to the patient	4.7
3	Evidence of QI effectiveness and when effective**	4.6
	How to involve/get leadership from CEOs	4.6
5	What factors promote successful organizational transformation**	4.5
	How to empower employees to contribute to QI	4.5
	Outcome and process measures for evaluating QI**	4.5
8	How to integrate QI values and concepts (e.g., process thinking, variation) in life of people	4.4
	How to measure quality	4.4
	How to use data already available for QI	4.4
	How to obtain and use customer judgments of quality	4.4
	How to use customer needs to promote design of services	4.4
13	How to best involve middle management in QI	4.3
	What QI principles and techniques really promote success**	4.3
15	Effect of clinical guidelines on quality	4.2
	What are most important gaps in knowledge, attitude, skills that inhibit QI	4.2
	What care processes need to be improved to deliver best care	4.2
	How to better manage relationships with customers	4.2
	How to identify key processes in meeting customer needs	4.2
	How to link customer judgments to QI	4.2
21	Essential characteristics of good QI training program	4.1
	How stable and useful are customer judgments of quality	4.1
	How to construct information systems to facilitate QI	4.1
	Case studies of successful QI teams and organizations	4.1
	How to develop and continually improve QI plans	4.1
	How to integrate QI and clinical epidemiology and outcomes research	4.1
27	How to use clinical guidelines without stifling judgment	4.0
	How to capture needs—not expectations	4.0
	How to develop low-cost but effective means to learn QI	4.0
	How to select improvement activities that will do most good	4.0
	How to build and maintain effective QI teams	4.0
32	Optimal relationship between QI and QC	3.9
	How to integrate QI and QC	3.9
34	How to assess organizational readiness for QI	3.8
35	What are costs of implementing QI	3.7
	How to improve awareness of national leaders regarding QI	3.7
	How to conduct error-free design	3.7
	How to design a system to reduce total cycle time	3.7
	How to promote continuous improvement of QI research	3.7
40	How to decide what QI tools to use when	3.6
	Costs vs. benefits of QI training	3.6
42	Effect of multiinstitutional collaboration on QI success	3.5
43	What types of control charts to use when	3.3
44	Effect of publishing Health Care Finance Administration (HCFA) mortality data on hospital behavior	2.4

**Barriers relating to lack of evidence of TQM success.

improving the process for producing a product or service;
- a specific decision is made to initiate an improvement effort;
- there are organizational, technical, professional, and procedural changes that influence the success of both.

As a result of these similarities, one might expect that if TQM is effective, its key elements would emerge as key success predictors in examinations of health care improvements.

To date, most studies of process and product innovation have been conducted in manufacturing industries. However, just as insights for implementing and applying TQM in health care are drawn from similar experience in manufacturing, we believe further useful insights can be gained from the results of empirical industrial innovation studies.

This article reports on our review of the research on product innovation and process improvement to determine what TQM principles are supported by the findings.

TQM PRINCIPLES

One health-care-oriented characterization of Deming's TQM principles is provided by Batalden.[6] In this section, we introduce each principle using Batalden's characterization. In the subsequent sections we present the evidence we found from key innovation studies that supports or refutes each of these principles.

Constancy of purpose implies that people within an organization know why the organization exists and in turn operate within the bounds of the fundamental mission. Constancy prevents an organization from entering into ventures that deviate from its purpose or basic reason for existence. Constancy also implies that an organization's customers have been carefully chosen to meet the underlying ethical precepts of the organization.

Customer mindedness calls for a continued commitment to understand the needs and expectations of people who can benefit from the products and/or services produced by the organization. Both internal and external customers are targeted for these efforts. In all cases, the underlying concept is that a successful innovation originates because the organization thoroughly understands customer needs, and designs services to meet those needs.

Quality mindedness defines quality as the design and production of products and services that meet customer needs. A high quality design means the product or service (if produced as intended) will meet customer needs without requiring adaptations by the customer. The production aspect implies that the product or service is produced in such a way that it works as designed—the first time—with no "bugs" or defects. Through effective product or service design and production, waste, rework, duplication, and needless complexity are reduced.

Process mindedness begins with the belief that a vast majority (e.g., 85%) of the problems in an organization are caused by the processes of producing a product or service and thus only a minority (e.g., 15%) are due to individuals.[2] It follows, that to improve, most of the effort should be concentrated on improving processes and not identifying and blaming people. Advocates of TQM in health care don't deny that some providers of care deserve to be identified and punished. Rather, they argue that improvement is more likely to occur if more resources are allocated to process improvements.

A methodological outgrowth of this position is the need to fully understand the process being addressed. This is achieved (in part) by encouraging workers to use tools such as flow process charts and cause and effect diagrams, as well as simple data collection and display tools, to more fully understand the process and help identify opportunities for improvement.

Statistical mindedness means that data need to be used to confirm the existence of problems, identify opportunities for improvement, and evaluate the effectiveness of a process improvement. This is based on the premise that decisions should not be made based on intuition alone. Information-gathering and data-collection studies are initiated to ensure that improvement projects address the areas of need. Emphasis is placed on observing process performance over time and studying variation in product and/or service characteristics. Once adequate data are collected, the process for improvement can be clearly defined, and efforts to begin addressing the specific improvement can occur. Techniques such as statistical process control (a) are used to ensure that individual events are responded to only when they are almost certain to be caused by forces not typically present and (b) guide efforts to minimize variation in health care. Experimentation is advocated as a way to design products and services that meet needs under a variety of conditions. Monitoring of performance is then encouraged to ensure that a process performs as intended.

Employee mindedness argues that employees who are directly involved with the process are best qualified to improve it. Therefore, quality improvement teams composed of employees associated with the process under scrutiny form the foundation for improvement efforts. TQM organizations attempt to equip all employees with appropriate skills in group processes, statistics, and process analysis. Increasing the process improvement skills of all employees allows those with special expertise in process improvement (e.g., management/industrial engineers) to provide educational roles and engage less directly (e.g., as staff support) in process improvement.[24]

Management leadership implies that the overall responsibility for and commitment to quality cannot be delegated and that if TQM is to succeed, the chief executive officer (CEO) and other top managers must not only practice its principles but also lead the implementation. Some top managers of TQM organizations argue that quality is their only responsibility.[25]

Benchmarking promotes a search for process improvement ideas that extend beyond the boundaries of the organization.[26] Not only does one seek ideas from the best versions of the particular process within the industry but one is encouraged to search for ideas in other industries as well. For example, a hospital interested in improving its operating room scheduling process not only searches for the best scheduling systems in health care but also seeks ideas from airlines, hotels, and other "scheduling" industries. TQM does not advocate simply copying a good process but rather identifying those key process variables (KPV) that make the difference between success and failure. The underlying rationale is that processes rarely transfer completely. The unique aspects of one environment need to be considered in the design of a process, but there remains a set of characteristics that must be present in a process for it to succeed. These are the kernels of the process that must be identified and implemented when benchmarking.

Continuous improvement addresses two principles: (a) ongoing efforts to get better—which in turn implies (b) no goal other than perfection. In this context, no improvement is the "end of the line," and no improvement is too small. Efforts are aimed at the never-ending pursuit of excellence. In addition, some TQM advocates strongly encourage continuous improvement and the exclusion of "problem solving." To them solving a problem implies an end point, while process improvement is continuous. By focusing on problem solving, one is forced to admit (in extreme cases) that the underlying process is inadequate, thus deserving of criticism and potentially open to sanction. As a result, the natural reaction in a regulated industry such as health care is to hide problems, to pretend that everything is good enough. Process improvement has no such negative implication. All processes (even the best) can be improved. It is acceptable, and in fact desirable, to get better.

Suppliers as partners suggests that (a) organizations should form long-term relationships with a few suppliers, (b) the choice of a supplier should be based on its ability to deliver a quality product, and (c) the supplier should also be committed to continuous improvement. Therefore, suppliers are not chosen solely on low price. The result is that the purchaser avoids waste, rework, delays, and other costs associated with poor quality supplies. The long-term impact of this principle allows a supplier to concentrate on achieving a high quality product or service while worrying less about selling or defending a poor one. When improvements can be made, both parties—purchaser and supplier—work together in a spirit of collaboration.

With these principles in mind, we examined the literature to determine whether there is evidence to support that adherence to these principles is empirically associated with successful innovation and improvement.

REVIEW OF INNOVATION AND IMPROVEMENT LITERATURE

Methods employed by investigations reviewed

While the methods employed in the investigations we reviewed vary to some degree, many follow the same basic pattern. Producers of goods and services in many industries were approached by researchers and asked to think of both a successful and an unsuccessful effort to innovate or improve. Criteria for success used by the studies varied but generally related to the innovation's impact on the producer's profitability, market share, and/or image. Investigators then described each successful and/or unsuccessful project in terms of a number of factors that seemed to influence the outcome. Various statistical techniques such as factor analysis, least squares analysis, and other correlation techniques were then used to analyze the data. Some studies, such as those by Cooper,[8] Freeman,[10] and Maidique and Zirger[13] examine similar predictive factors and employ similar data collection methods. Others concentrate on a smaller set of predictive factors and tend to define success nar-

rowly. For instance, one study[11] looked at the extent of innovations categorized as "demand pull" (innovation introduced at the "demand" of customers) versus "technology push" (innovation introduced by the producers that were not previously solicited by customers) and the outcome of the respective type of innovation. Generally, then, a key measure of importance was the extent to which the presence of a factor or factors distinguished between successful and unsuccessful attempts to innovate or improve.

We include in this review only research examining *both* successful and unsuccessful attempts at innovation because it is otherwise impossible to determine how well factors distinguish success from failure. Therefore we did not include the classic innovation study by Myers and Marquis,[15] which examined only successful innovations, as well as other studies that examined only successes or failures.

Findings from past research studies

In an attempt to uncover whether past innovation research provided evidence supporting the principles of TQM, we interviewed leading theoreticians and empirical researchers to assess the state of the art in innovation and improvement research. From these interviews, we obtained nominations for outstanding empirical investigations. We supplemented these nominations with our own review of the literature, preferably with empirical evidence, addressing *both* success and failure in innovation. We include here only those works with empirical data, as well as one narrative study containing no data, but a thorough summary of study findings.

The measure of influence we use is the "success/failure ratio." This measure is the degree to which a certain characteristic was present in a successful project (the numerator) versus the degree to which it was present in an unsuccessful project (the denominator). For example, one indicator of the extent to which customer mindedness is practiced is the effort put into educating customers of a project on how to use the improved product or service. Suppose, in comparing 29 pairs of successful and unsuccessful projects, the successful project placed greater effort on user education in 14 cases; in one case the unsuccessful project put more effort into it; and in the remaining 14 cases there was no difference in education effort. Our measure of difference yields a success/failure ratio of 14/1, implying that every time an unsuccessful project invests considerably in user education there are 14 instances of a successful project investing considerably in user education. The remainder of this section summarizes findings from eight research studies of successful and failed innovations.

Project SAPPHO[10,17,23]

The purpose of Project SAPPHO (both I and II), was to create a profile of successful innovations. The research team defined innovation as "the commercial application of the results of previous inventive work and experimental development."[23] Successes were defined as *commercial* successes (innovations making a profit and/or significant market penetration) whereas failures were the converse.

The group twice studied chemical (process-related) and scientific instrument (product-related) industries in the United States and Europe by conducting retrospective interviews with representatives from the respective firms. Pairs of innovations—one success to each failure—were selected. The pairs were similar in terms of the market being studied. Generally, however, the paired innovations were developed by different producers. SAPPHO I included 29 pairs, and SAPPHO II included 43 pairs of innovations. The findings of SAPPHO II (conducted several years later) were similar and confirmed the major results of SAPPHO I.

During the data collection (in this case, interview) process, validity checks of the variables assessed were performed via internal data "cross checks," coding of the data and team member follow-up of the process to identify potential mistakes, inconsistencies, or unfounded conclusions made by the interviewer. Statistical analyses were based on 122 variables.[10] The categories into which the 122 variables were grouped include: (a) the degree of organizational risk in pursuing the innovation, (b) the management techniques practiced by the organization, (c) the strength of the respective organization, (d) its organizational structure, (e) the extent that customer requirements were understood, (f) knowledge of the technical problems the innovation presented, (g) the organization's research and development strength, (h) the extent to which the organization communicated with the external scientific and technical community, (i) the organization's competitive environment, and (j) the extent of the organization's marketing effort.

Overall the research team concluded that five factors consistently distinguished between success and failure. They are[23]:

1. Understanding user needs—successful projects have a much better understanding of user needs.
2. Marketing—successful projects give more attention to marketing.
3. Efficiency of development—successful projects perform their development work more efficiently.
4. Effectiveness of communication—successful projects make better use of external technology and scientific advice.
5. Strength of management and characteristics of managers—the responsible individuals in successful projects are generally more senior and have more authority than their counterparts who do not succeed.

Several of the studies' findings coincide with and support TQM principles—some more so than others. For example, customer mindedness was overwhelmingly supported by both versions of this study. In only two of 216 question pairs (72 paired projects with three questions each) did the failed project claim more customer mindedness than the successful project, whereas successful projects were more customer minded in 132 question pairs. More effort was put into educating users and selling them on the merits of the product or service. (In the remaining 82 question pairs, there was no difference between the successful and unsuccessful paired products.)

Similarly, successful projects produced a higher quality product in 178, compared to 19 (for the unsuccessful) question pairs. This was evidenced by fewer modifications being made after introduction of successful products and fewer production bugs, adjustments, and fewer after-sales problems incurred.

Management leadership was stronger in 154 of the successful question pairs compared to 30 of the unsuccessful ones. The leader of the innovation tended to have more experience, higher status, more authority, and more responsibility in successful innovations than in failed ones.

Benchmarking related to the specific product occurred in 64 successful question pairs versus 7 unsuccessful question pairs. The successful project had better external communication systems and better linkages to external experts.

There were few projects where employee incentives to innovate (consistent with the employee mindedness principle of TQM) were more common in successful than unsuccessful cases. In the nine cases where differences did occur, they favored successful projects 8/1, although it was not a statistically significant difference.

Only one aspect of statistical mindedness was examined in project SAPPHO—the presence of systematic forecasting efforts. Successful cases led unsuccessful 25/14.

In the area of constancy of purpose, there was a tendency, though not statistically significant, for successful projects to adhere to their organizational mission (20/10).

The empirical findings for these studies are listed in Table 2. As in all tables, all questions related to a principle are listed regardless of whether the result is significant or not. Numbers in parentheses indicate Project SAPPHO II results.

Hungarian SAPPHO[16]

After SAPPHO I and II, a similar study was conducted in Hungary using a slightly different approach; however, the same kinds of industries and variables were assessed. The methodological differences between SAPPHO and Hungarian SAPPHO included the following:

- In the Hungarian study the pairs assessed were, whenever possible, innovations developed by the same organization;
- The innovation pairs were technically (rather than commercially) similar (i.e., the products were similar despite the similarity or dissimilarity of the product market); and
- The statistical techniques used differed: SAPPHO "results were based on a somewhat more rigorous and varied statistical foundation than were those of the Hungarian work."[16(p33)]

Despite these differences (as well as the differences in the respective economies), the Hungarian work resulted in similar findings. The significant findings are listed in Table 3. No numerical findings were reported.

Stanford Innovation Project[13]

Another SAPPHO-like study, the Stanford Innovation Project, was conducted in the United States on 118 (59 pairs of) new products in the electronics industry in an attempt to develop a "new product process" model. As in the SAPPHO studies, pairs of products were evaluated to identify variables that distinguish between success and failure. Although terms were not defined, the researchers appeared to use the

TABLE 2

SAPPHO I AND II FINDINGS

TQM principle	Study question	Success/failure statistic[1]	
Customer mindedness	• Were user *needs* more fully *understood* by the innovators in one case than in the other?	24/0	(33/0)[2]
	• Was the *sales effort* a major factor in the success or failure of the innovation?	16/0	(22/0)
	• Were any steps taken to *educate* the *users*?	14/1	(23/1)
Quality mindedness	• Did *innovation* have to be *adapted* by users?	0/12	(0/15)
	• Were there any *after sales problems*?	1/22	(1/31)
	• Did any *"bugs"* have to be dealt with in the early production stage?	2/16	(1/25)
	• Were there unexpected *production adjustments*?	2/13	(2/21)
	• Were *modifications* introduced *after* commercial sales (as a result of user experience)?	3/12	(7/11)
Constancy of purpose	• Was the innovation *part* of the general marketing policy?	7/5[NS]	(8/8)[NS]
	• Did the *firm view* the innovation as being part of its *natural business*?	11/9[NS]	(9/17)[NS]
	• Was the innovation *radical* for the firm?	9/10[NS]	
Employee mindedness	• Were there any *incentive* schemes to encourage innovative efforts?	2/0[NS]	(6/1)[NS]
Management leadership	• Did the innovator have a great degree of management *responsibility*?	14/3	(18/4)
	• Did the innovator have substantial *authority* (power)?	15/3	(20/4)
	• Did the innovator have diverse *experience*?	16/3	(20/5)
	• Did the innovator have *higher status*?	13/4	(18/4)
Benchmarking	• What was the *coupling* with the outside scientific and technological community in the *specialized* field involved?	13/1	(23/1)
	• How adequate was the *external communication network*?	10/2	(18/3)
	• What was the *coupling* with the outside scientific and technological community *in general*?	4/5[NS]	
Data/information	• Was any systematic *forecasting* by the marketing or sales department involved in the decision to adopt the innovation?	11/6	(14/8)

NS = Not significant (unless otherwise indicated by NS, the result is statistically significant).

[1] The success/failure statistic is the number of pairs where a successful project possessed the characteristic divided by the number of pairs where the failure possessed it.

[2] Numbers in parentheses are results of the second SAPPHO study.

same definitions as SAPPHO since numerous parallels were drawn and references were made to that study. In the surveys (rather than interviews, as in SAPPHO) distributed in this study, a high percentage of the respondents (85%) consisted of the president/CEO/general manager or vice president/functional manager related to the innovation.

The general findings of the study revealed that successful innovations:

- better coincided with user needs;
- were planned more effectively and efficiently;
- were more efficiently developed;
- were marketed and sold more actively;
- generally fell within the realm of the firm's expertise; and
- were introduced prior to similar efforts of the competing firms.

Table 4 contains the findings of this study, which coincide with the principles of TQM.

The differences between successful and unsuccessful projects are less distinct here than in the SAPPHO project, but results favor the same interpretation. Successful projects were more customer minded in 105 versus 42 question pairs. Also, they better understood

TABLE 3

COMPARISON OF FINDINGS BETWEEN SAPPHO I AND II AND HUNGARIAN SAPPHO

TQM principle	Hungarian SAPPHO findings	SAPPHO findings
Customer mindedness	• Knowledge of *consumer demands* existed • Successful operations were furthered by adequate *preparation of consumers* • Where *no deliberate marketing* was practiced in the interest of successful development, this circumstance had a decisive role in *failure*	• *User* needs understood • Successful firms pay more attention to *user education* • Successful firms pay more attention to *marketing* • Successful firms pay more attention to *publicity and sales*
Benchmarking	• Probability of success enhanced by improved *internal and external* communication *network*	• Successful firms have better *internal communications* • Successful firms have better *external communications*

user needs, put more effort into educating users, and tended to involve users more in design. However, successful projects often took longer to be accepted than unsuccessful ones.

Quality design and production were more evident in successful projects (91 versus 26 question pairs). Product design also matched customer needs better, required less adaptation, and had fewer bugs.

Management leadership was stronger in successful projects (67 versus 34 question pairs). Senior management was more supportive and the project leader was more senior and had more authority and power.

TABLE 4

STANFORD INNOVATION PROJECT FINDINGS

TQM principle	Study question: Innovation . . .	Success/failure statistic
Customer mindedness	• was matched to *customer needs*	40/4
	• coupled with a marketing effort to *educate users*	26/11
	• required more *interaction* with users in *development stage*	24/17^{NS}
	• required fewer new *marketing channels*	6/19
Quality mindedness	• was less plagued by *after-sales problems*	6/29
	• required *less adaptation by users*	16/22^{NS}
Constancy of purpose	• was closer to the *main business* area of the firm	22/8
	• required less change in *firm's strategy*	17/16^{NS}
Management leadership	• was supported more by *senior management*	24/7
	• was developed with more *senior project leader*	24/15
	• project was directed by *individual with* more *power and authority*	19/12^{NS}
Benchmarking	• project team *interfaced* with *external resources*	17/15^{NS}
	• had *fewer external advisors*	15/18^{NS}

NS = Not significant.

Successful projects were more customer minded in 105 versus 42 question pairs. Also, they better understood user needs, put more effort into educating users, and tended to involve users more in design.

Benchmarking did not prove to be an important predictor of success. However, a product was more likely to be successful if it followed the firm's line of business (constancy of purpose).

Gerstenfeld study[11]

In Gerstenfeld's work, the research team attempted to identify qualities of successes and failures (as well as projects in progress, that we do not include in this review) that contributed to their respective outcomes in 22 innovations in the chemical, electrotechnical, and automotive industries. Eleven of the projects were categorized as failures and 11 were successes. The major areas addressed were: the source of the innovation (i.e., technology push [producer] versus customer pull [demand]), the number of people involved in the project, and the total time spent on development. The team defined terms in the following manner[11]:

- Successful: An innovation with a minimum of one person-year between the origin of the idea and its introduction to the market with the innovation showing ongoing success.
- Unsuccessful: An innovation with a minimum of one person-year effort resulting in termination of the innovation/project and showing no sign of continuation.

All data for the successful and unsuccessful innovations were collected retrospectively via interview.

The main finding of the group was that 8 of the 11 successes and only 2 of the failures were demand pull. Neither of the other two variables (number of people involved or total time spent) differentiated success from failure. As this relates to TQM principles, it suggests that going outside the organization for ideas on how to meet customer needs is significant in relation to the success of a project. The study findings are listed in Table 5.

Project NewProd[8]

The Project NewProd study, undertaken by Robert Cooper of McGill University, attempted to understand the factors that distinguish successful from failed attempts to introduce new products. Success was defined as a product or service that was profitable, expanded market share, or positioned the organization to play a more significant role in the industry. In this research, a random sample of 177 Canadian industrial goods (e.g., electrical, heavy equipment, chemical, pharmaceutical) firms were selected for study, of which 103 agreed to participate. Almost all of the firms provided examples of both clearly successful (102) and clearly failed (93) innovations. Corporate development officers were asked to select the respective successful and/or failed projects within their firm, and finally, asked to complete a 77-item questionnaire on each project they selected. Using a measurement approach different from SAPPHO or the Stanford Innovation Project, responses were rated on a 1 to 10 scale ranging from strongly disagree to strongly agree with the respective questionnaire statement. The results then were analyzed using factor analysis, regression analysis, and discriminant analysis.

Three major areas differentiated success from failure. These areas are[8]:

1. *The uniqueness and superiority of the product*—for example, being better than the competing prod-

TABLE 5

GERSTENFELD STUDY

TQM principle	Study finding	Success/failure statistic
Customer mindedness	• *Demand pull* innovations were associated with success in the innovation	8/2

ucts at meeting customer needs, offering unique features or attributes compared to the competition, having higher quality, costing less, or reducing customer costs.

2. *Market knowledge and marketing proficiency*—for example, conducting a well-thought-out market study of customer needs, having an initial test or trial prior to market launch, and having a well-directed sales force and/or distribution effort when the product is released.
3. *Technical and production proficiency and synergy*—for example, conducting initial technical assessments, having in-house prototype testing, and possessing staff with exceptional engineering skills.

A summary of Cooper's findings related to the TQM principles is found in Table 6. Unlike the other principles, low scores are favorable for "constancy of purpose" due to the wording of the question.

The measures used (1–10 scale) made it difficult to compare numerical findings with previous studies. However, the essence of the results is similar. Successful projects are more likely to result when the producer understands its customers, and their needs and

TABLE 6

NEWPROD

TQM principle	Study factor	Average success/failure scores*
Customer mindedness	• Prototype *testing* with customer	7.62/5.30
	• Knew *customer needs* better	7.69/5.61
	• Preliminary *market assessment*	7.07/5.23
	• Knew customer *price sensitivity*	7.66/5.68
	• Knew *buyer behavior*	7.13/5.30
	• Permitted customer to do *unique task*	6.27/4.73
	• Amount of *need for product*	7.40/5.78
	• Product had *unique features* for customer	7.63/6.00
	• Conducted *preliminary assessment* of need	7.22/5.98
	• Knew *market* size	6.93/5.26
	• *Specifications* defined by *marketplace*	6.62/6.09
	• *Idea* is *market driven*	7.19/7.00
Quality mindedness	• Product met *customer needs* better	7.78/4.77
	• Product has *higher quality/tighter specs*	7.25/5.00
	• Product *design*	7.82/6.06
	• Prototype *testing in-house*	7.83/6.22
	• All design *bugs out*	6.42/5.15
Process mindedness	• *Know production* process well	7.73/6.63
Constancy of purpose	• Newness of:	
	customer needs	4.46/6.10
	competitors	3.54/4.59
	product class	4.46/5.95
	customers	2.97/3.88
Management/leadership	• *Compatibility of mgt.* skills with project	7.78/6.53
Data/information	• *Test marketing*	5.22/3.28
	• Formal *market study*	6.21/4.20
	• *Financial analysis*	6.75/5.19
	• Prototype *testing in-house*	7.83/6.22

*1 to 10 scale; 1 = strongly disagree, 10 = strongly agree.

behaviors (supporting TQM's customer-mindedness principle). The resulting product then better meets customer needs and has fewer bugs and/or requires less modification or adaptation by the user (supporting the TQM focus on quality).

The concept of statistical mindedness was supported via systematic studies of markets, product effectiveness, and financial issues. Constancy of purpose is supported by findings that encourage innovation directed to an established customer base, between established competitors, and/or within an established product class. Cooper examined process mindedness by evaluating how well people understood the production process with the results supporting that TQM principle.

Utterback Innovation Studies[18–22]

The purpose of Utterback's work was to understand the effect of environmental influences on sources and outcomes of research and development projects. Successful projects were defined as being at least a moderate technical success that met or exceeded sales and profit expectations with few cost overruns in development. In this research, 164 projects (66 successes, 51 failures, and 47 ongoing) were selected from 59 firms in Germany, the United Kingdom, France, Japan, and the Netherlands. The firms specialized in computers, consumer electronics, automobiles, chemicals, or textiles. Information about the projects was obtained from interviews with senior managers, project managers, and key project personnel.

Utterback's research supports the TQM principle of commitment to quality of product design and production. By an 8 to 1 margin, successful products were more likely to have fewer "bugs," require less adaptation by users to meet their needs, and lead to fewer after-sales modifications in design or production based on consumer feedback.

Customer mindedness was also an important distinction between successful and unsuccessful products. User opinions of the product were assessed and users were more likely to see real advantages in successful products. Although users did not identify the need alone, producers of successful products had a very clear understanding of the customer for whom they were producing the product. Customer contact during the design and initial pilot tests was more frequent in successful projects. Utterback found that some of the most successful commercial innovations were designed to meet the need of a specific customer.

Successful innovations were more likely than unsuccessful ones to be incremental improvements to an existing product instead of a radical innovation that required developing a new niche in the marketplace. This supports the TQM concept of continuous improvement in products or services.

Utterback's research also supports the importance of benchmarking and data-driven improvements. His research found that structured and sophisticated planning was more likely to occur in successful projects and that outside consultants were more likely to be a source of information and support.

Regarding top management leadership, Utterback found that projects were more likely to be initiated by top management in successful cases, however the relationship was not statistically significant.

A summary of Utterback's findings related to TQM principles is found in Table 7.

Delbecq and Mills[9]

We found that "Managerial Practices that Enhance Innovation" offered significant findings related to our review of innovation, although no empirical data were included. In this article, the authors summarize the results of a study they performed on "several hundred" managers in high-tech and health service organizations where they (the authors) attempted to determine characteristics of high- and low-innovation organizations. As they state, the two different types (high-tech versus health service) of "organizations were markedly different and reflected two very different structural contexts."[9]

In this article, high-innovation firms tend to operate under conditions or premises similar to that of TQM organizations. Although the authors did not offer definitions for high and low innovation, the reader can deduce that high-innovation firms are those that tend to pursue and be successful at introducing innovations to the market. Low-innovation firms are the converse—innovations are less common and frequently unsuccessful when introduced to the market.

The authors analyze the organizations in relation to the types of activities performed in the four phases of

High-innovation firms are those that tend to pursue and be successful at introducing innovations to the market.

TABLE 7

UTTERBACK STUDIES

TQM principle	Study factor	Percent having factor (success/failure)
Customer mindedness	• There was no difficulty in *marketing* the product	80.0/10.2
	• The product was designed with a *specific user* in mind	40.6/20.4
	• The project had great *competitive advantage*	63.3/37.5
	• The *need* was *identified* before a solution	59.3/48.9*
	• *Users identified need*	67.2/63.8*
	• There was frequent *contact with users* during design	54.1/45.7
Management/leadership	• The project was *initiated by top management*	43.6/30.0
Benchmarking	• Outside *consultants* provided information and advice on the project	36.5/26.0
Data/information	• The product was a result of a structured and "sophisticated" *planning* process	40.0/31.3
Continuous improvement	• The product was an *incremental improvement* of an existing product with little market or technical uncertainty	59.1/40.9

*Not statistically significant.

the innovation sequence: (1) idea generation and initial mandate, (2) preliminary analysis, (3) decision to adopt, and (4) implementation.[9]

Overall, the TQM principles of constancy of purpose, belief in the worker, customer orientation, and a need for meaningful information/data significantly distinguish between high- and low-innovation organizations in this study. One particularly interesting finding related to TQM comes in the leadership category. Top management in successful firms was more likely to formally select and support innovation and improvement projects. This supports the need for a steering committee to control what quality improvement projects are selected. There were no differences between the results of health delivery organizations and high-tech firms. A summary of the authors' findings is found in Table 8.

DISCUSSION AND CONCLUSIONS

Because the studies reviewed different TQM principles and different strategies for measuring effect, we believe it would be inappropriate to use a meta-analytic approach aggregating the findings across studies. Summarizing the results here is the most we can do. We now discuss what we learned about each principle. See Table 9 for a summary of which innovation studies did or did not support each TQM principle.

Constancy of purpose

Results of five of the studies relate to this principle, including SAPPHO I and II, the Stanford Innovation Project, Project NewProd, and Delbecq and Mills. In most of these studies, findings support the principle of adhering to the organization's fundamental mission, with success to failure ratios ranging from 3:1 to 1.1:1. The studies identified successful projects as having a direction that is consistent with the firm's history and introducing innovations that are not radically different from past production and/or service commitments. Overall, successful innovation organizations retained their organization's customer and product traditions.

Customer mindedness

This principle was overwhelmingly supported by all of the studies that examined it. Understanding user needs had a favorable success to failure ratio ranging from 33:0 to 1.4:1, with the majority of the study results clustered toward the higher end. User involvement in the development process, however,

TABLE 8

DELBECQ AND MILLS

TQM principle	Innovation phase*	High- or low-innovation firm?	Study finding
Customer mindedness	2	low	• Underestimated market differences result in *customer* frequently being *overlooked*
	2	low	• Complex designs *intimidating* many *customers*
	2	high	• Feasibility studies include considerable *interaction with customer*
	2	low	• Insufficient thought paid to *orientation and training* to all but initial users
Employee mindedness	1	low	• *Risk* is assumed by the *individual* alone
	3	low	• *Employee lacks involvement* in decision to adopt
Management/leadership	1	low	• *Sponsorship* is obtained by getting resources currently allocated for *existing or other purposes*
	1	low	• *Inconsistent or vague support from organization*
	1	high	• *Funds* are *designated* for innovation
	2	high	• *Sponsorship* is *organizational*
	3	low	• *Lack* of formal *commitment* from organization
	3	low	• Approval to proceed given despite *insufficient resources*
	3	high	• *Sufficient* human and financial *resources* are allocated
	3	high	• *Implementation*, as well as *risk*, is *organizational*
Benchmarking	2	high	• Extensive *dialogue with persons external* to organizations occur
Data/information	1	low	• *Support* is based on *subjective* beliefs and/or *interests*
	2	low	• *Demand* is *overestimated*, resulting in unrealistic revenue expectations

* 1: Ideas generation and initial mandate; 2: preliminary analysis; 3: decision to adopt; (these are the phases the authors associate with the innovation process).

marginally distinguished between success and failure (ratios clustered close to 1.4:1), while attention to user education and marketing had a greater influence on success (ranges of 23:1 to 2.3:1 were reported). No distinction between internal and external customers was made. Overall, however, findings supported the fact that innovations must meet customer needs that are clearly identified and reinforced through user education and customer use of the new product. The results also emphasize how important it is to let the external customer know about the improvements and innovations produced by TQM.

Quality mindedness

Both design and product quality were strongly supported by the findings of these studies. Studies favoring design quality for successful innovations had success/failure ratios ranging from 25:1 to 1.1:1, whereas product quality had success/failure ratios ranging from 31:1 to 1.45:1. For successful innovations, these studies demonstrate that bugs are eliminated before the introduction of a new product or process. Fewer user complaints are received, and products are less likely to require adaptation to meet user needs. It is apparent in this research that quality is a very significant factor that discriminates between success and failure.

Process mindedness

This factor was addressed only by Cooper, and only one of his findings offered significant results. Overall, results do not allow one to claim or refute that process mindedness distinguishes successful from failed innovations.

TABLE 9

SUMMARY OF RESEARCH FINDINGS

TQM principle	SAPPHO I	SAPPHO II	Hungarian SAPPHO	Stanford Innovation Project	Gerstenfeld	Project NewProd*	Utterback	Delbecq and Mills
Constancy of purpose	0/3/0	0/2/0	—	1/1/0	—	4/0/0	—	1/0/0
Customer mindedness	3/0/0	3/0/0	3/0/0	2/1/2	1/0/0	12/0/0	4/2/0	4/0/0
Quality mindedness	5/0/0	5/0/0	—	1/1/0	—	5/0/0	—	—
Process mindedness	—	—	—	—	—	1/0/0	—	—
Data/information	1/0/0	1/0/0	—	—	—	4/0/0	1/0/0	2/0/0
Employee mindedness	0/1/0	0/1/0	—	—	—	—	—	2/0/0
Management/leadership	4/0/0	4/0/0	—	2/1/0	—	1/0/0	1/0/0	8/0/0
Benchmarking	2/1/0	2/0/0	1/0/0	0/2/0	—	—	1/0/0	1/0/0
Continuous improvement	—	—	—	—	—	—	1/0/0	—
Suppliers as customers	—	—	—	—	—	—	—	—

*No information on statistical significance.
Information is presented in the following fashion: Number of factors with statistical significance favoring the TQM principle versus number of factors supporting the TQM principle but without statistical significance versus number of factors *not* favoring the TQM principle.

Data mindedness

TQM suggests using data to: (a) understand and demonstrate needs, (b) understand underlying causes of problems, (c) test solutions, and (d) monitor performance. The only data we could find related to this principle address the use of formal empirical studies.

Formal studies of customer needs and product effectiveness were addressed in two studies, and both were significantly more evident in successes versus failures. Formal studies of needs (e.g., identifying and assessing the magnitude of needs) as well as formal prototype tests were important, although the strength of their importance in these studies was not great. Statistical process control was not addressed in these studies.

Employee mindedness

Neither participation in improvement efforts nor formal training in improvement processes, TQM philosophy, or tools were examined in these studies. Therefore we are unable to draw any conclusions concerning this principle.

Management leadership

These studies support the TQM principle that change is more likely to occur if top management is involved in both the overall TQM program and specific project management. Six studies supported this principle. However, the presence of top management in the improvement effort seems to be more indirectly than directly associated with improvement. For example, a commitment to producing a "bug-free" product or service probably requires top management support. Thus influence of leadership is reflected in the other principles.

Benchmarking

These studies examined two ways in which ideas may be pursued outside the organization:

1. establishing general external advisors or consultants in areas such as management, and
2. getting outside ideas on specific projects.

The first strategy (general external advisor) has no support based on any study findings (ratio of 1:1.07) and calls into question the value of employing a TQM mentor to advise on general TQM issues. However, there is evidence to support the importance of benchmarking in specific projects. Ratios favor specific networking at 6:1 and 5:1.

Continuous improvement

Utterback addresses continuous improvement in his support of incremental (in comparison to radical) innovation on a 1.5:1 basis. Utterback's findings support the slower, less radical improvement of a product or process (as encouraged in CQI), as opposed to introduction of a "brand new" service or product. This is not to suggest that radical projects should be rejected. Their success is less likely but their benefits may be much greater.

Supplier mindedness

No aspect of this principle was addressed in any of the studies. This principle, to the best of our knowledge, is unique to TQM.[27]

In summary, we conclude the following points based on our review of significant success/failure studies in the innovation literature concerning product and/or service firms:

- The innovating firm must know its customers' needs and behaviors (customer mindedness);
- Improvements must be designed to readily meet and exceed customer needs (quality design), and customers must receive sufficient education concerning the improvement (customer mindedness);
- The product or service must work as designed when it reaches the marketplace (quality production);
- The innovating firm, on occasion, must reach outside the organization to get specific ideas on how to meet needs and/or solve problems (benchmarking);
- The innovating firm must develop a network of resources to quickly and easily obtain outsiders' insights regarding a project (benchmarking);
- Top management must lead and be involved in improvement activities (management leadership);
- The innovating firm must know who it wants to serve and hold to its basic mission (constancy of purpose).

FUTURE RESEARCH

Since a sufficient number of health care organizations now espouse TQM and have progressed substantially in implementing its various principles, empirical data could be collected from their activities

and conclusions could be drawn from the findings. Particular attention, however, should be paid to examining the salience of TQM principles not examined in other studies. As far as we can tell, the principles needing the most study are the importance of:

- employee training in tools of improvement and innovation,
- forming partnerships with suppliers,
- using data to reduce variation,
- focusing on process, not people, as the source of problems, and
- pursuing continuous, small improvements instead of innovations.

While these principles make sense, we found limited empirical assessments of their value in the review of the innovation literature.

Conversely, if we had to predict the success of improvement efforts based on what we know now, we would examine how well an organization:

- understands its customer needs,
- designs a service to meet their needs in unique ways,
- provides that service in an error-free fashion,
- goes outside the organization to get ideas for improvement, and
- gets top management involved not only in supporting but also in leading specific improvement projects.

• • •

One of the valuable aspects of the studies reported here was that the researchers were not limited to examining TQM principles. In fact, the investigators looked at many other issues (such as the effect of external regulation on innovation), yet virtually all of the factors that differentiated between success and failure were encompassed by the TQM principles.

This research is, by necessity, focused on studies unrelated to health care. Certainly we need empirical research on factors affecting successful improvement and innovation in health care. However, we should not ignore the results of previous research simply because they do not emanate from health care. We can learn much from their experiences.

We conclude from this research that TQM promotes many principles shown to be central to successful innovation and improvement, although not all principles are of equal importance in predicting success. Because TQM is a very difficult management strategy to adopt, the principles that must be followed should be reduced as much as possible to make implementation as easy as possible. Therefore, further research is necessary, preferably in health care, to assess the principles lacking support from the innovation and improvement studies reported here. At the same time, the principles supported here could be further confirmed.

REFERENCES

1. Deming, W.E. *Out of the Crisis.* Cambridge, MA: The MIT Press, 1986.
2. Juran, J.M. *Juran on Leadership for Quality.* New York, NY: The Free Press, 1989.
3. Crosby, P.E. *Quality is Free.* New York, NY: McGraw Hill, 1979.
4. Berwick, D.M., Godfrey A.B., and Roessner, J. *Curing Health Care.* San Francisco, CA: Jossey-Bass, 1990.
5. Batalden, P., and Nolan, T. In *The AUPHA Manual of Health Services Management,* edited by R.J. Taylor and S.B. Taylor. Gaithersburg, MD: Aspen Publishers, 1994.
6. Batalden, P. Personal communications with author (DHG), 1989–1992.
7. Cochran, B., and Thompson, G. "Why New Products Fail." *The Conference Board Record,* October 1964.
8. Cooper, R. *Project NewProd: What Makes a New Product a Winner? An Empirical Study of Successful versus Unsuccessful Industrial Innovation.* Montreal, Quebec: Quebec Industrial Innovation Centre, 1980.
9. Delbecq, A., and Mills, P. "Managerial Practices that Enhance Innovation." *Organizational Dynamics* 14, no. 1 (1985): 24–34.
10. Freeman, C. "Chapter 5: Success and Failure in Industrial Innovation." *The Economics of Industrial Innovation,* 2d ed. Cambridge, MA: The MIT Press, 1982.
11. Gerstenfeld, A. "A Study of Successful Projects, Unsuccessful Projects and Projects in Progress in West Germany." *IEEE Transactions on Engineering Management* EM-23, no. 3 (1976): 116–23.
12. Hopkins, D., and Bailey, E. "New Product Pressures." *The Conference Board Record* (June 1971): 16–24.
13. Maidique, M., and Zirger, B.J. "A Study of Success and Failure in Product Innovation: The Case of the U.S. Electronics Industry." *IEEE Transactions on Engineering Management* EM-31, no. 4 (1984): 192–203.
14. Meyer, A., and Goes, J. "Organizational Assimilation of Innovations: A Multi-level Contextual Analysis." *Academy of Management Journal* 31, no. 4 (1988): 897–923.
15. Myers, S., and Marquis, D. *Successful Industrial Innovations: A Study of Factors Underlying Innovation in Successful Firms.* NSF (1969): 69–117.

16. Rothwell, R. "The Hungarian SAPPHO: Some Comments and Comparisons." *Research Policy* 3 (1974): 30–38.
17. Rothwell, R., Freeman, C., Horsley, A., Jervis, V.T.P., Robertson, A., and Townsend, J. "SAPPHO Updated—Project SAPPHO Phase II." *Research Policy* 3 (1974): 258–91.
18. Utterback, J. "The Process of Technological Innovation Within the Firm." *Academy of Management Journal* 14 (1971): 75–88.
19. Utterback, J. "The Process of Innovation: A Study of the Origination and Development of Ideas for New Scientific Instruments." *IEEE Transactions on Engineering Management* EM-18, no. 4 (1971): 124–31.
20. Utterback, J. "Innovation in Industry and the Diffusion of Technology." *Science* 183 (1974): 620–26.
21. Utterback, J. "Successful Industrial Innovations: A Multivariate Analysis." *Decision Sciences* 6 (1975): 65–77.
22. Utterback, J., Allen, T., Holloman, J., and Sirbus, M. "The Process of Innovation in Five Industries in Europe and Japan." *IEEE Transactions on Engineering Management* EM-23, no. 1 (1976): 3–9.
23. Science Policy Research Unit, University of Sussex. *Success and Failure in Industrial Innovation.* Edinburgh: Bishop and Sons, 1972.
24. Dasbach, E., and Gustafson, D.H. "Impacting Quality in Health Care—The Role of the Health Systems Engineer." *Journal of Society of Health Systems* 1, no. 1 (1989): 75–84.
25. Caldwell, C. Personal communication with author (DHG), 1990.
26. Camp, R. *Benchmarking: The Search for Industry Best Practices That Lead to Superior Performance.* Milwaukee, WI: ASQC Press, 1989.
27. Hundt, A.S. *The Roots of Quality Improvement and Changes in Health Care Management.* Unpublished paper, 1991.