ISO 9000 Is Coming: The Use and Discoverability of Hospital TQM Documents

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The Joint Commission on Accreditation of Hospital Organizations (JCAHO), formed in 1951 as a joint venture between the American Hospital Association and the American College of Surgeons, accredits 97 percent of all hospitals receiving Medicare or Medicaid funds.[1] But things are changing, as it seems likely that JCAHO's monopoly on providing hospital accreditation is about to end. Increasingly hospitals are using the ISO 9000 system for quality assurance. Whereas in 1999 only four hospitals in the United States were using ISO 9000 certification,[2] there are presently over 150 hospitals that have achieved ISO 9000 certification.[3] And if TUV Healthcare Specialists, which is ultimately owned by the German TUV SUD Group, receives "deemer" status from the federal government,[4] ISO 9000 popularity will likely skyrocket.

Use of ISO 9000 as a total quality management (TQM) tool represents a fundamental paradigm shift in ideas about health care quality. Like any TQM tool, ISO 9000 is designed to identify and correct flaws in the operation of an organization. However, in the health care arena, ISO 9000 will produce volumes of physician-specific documentation concerning medical errors. Such information could have a devastating impact to a physician's defense in a medical malpractice action because as a general rule documents developed during the routing course of business, like TQM documents, are discoverable.

Accordingly, this article examines this paradigm shift in more detail to stimulate discussion. The article is divided into four sections: the basic philosophy behind TQM; the specifics aspects and advantaged of ISO 9000; the power that will virtually compel hospitals to implement ISO 9000 (or some other approach to TQM such as Six-Sigma); and discoverability of TQM documents. This article concludes with the observations that the recently enacted Patient Safety and Quality Improvement Act (PSQIA)[5] will provide health TQM documents with unique protection from discovery, thereby facilitating the acceptance of ISO 9000 by providers.

TQM, THE BASICS

TQM is a methodology for improving all aspects of an organization's operations and its relations with customers through the systematic collection and analysis of data through the elimination of variation.[6] (While there are some philosophic and technical differences between TQM and continuous quality improvement (CQI), for the purpose of this article they are not material.)[7] Originating from Shewhart's work on the use of statistical process controls in an industrial setting, and later expounded upon by Deming, TQM is predicated on a reiterated cycle of "Plan, Do, Study, Act" (PDSA). That is, TQM encourages business organizations to constantly monitor their operations for variations that produce errors, and based on the information obtained, take appropriate remedial action.

While all parts of the PDSA cycle are important, the outcome determining decision-making occurs during the study phase. During this phase of the cycle, quality managers apply two types of tools to analyze data. Statistical tools (including histograms, pareto diagrams, and control charts) are designed to determine causation, while analytic tools (brain storming, fishbone diagrams, matrix diagrams, and force field analysis) are designed to identify possible solutions.[8] How these tools are applied, their limitations, and the underlying philosophies give rise to several "schools" of TQM styles, for which ISO 9000 and Six Sigma are perhaps the best known.

Thus far, application of TQM to the health care arena has been limited for a number of reasons. When TQM was first introduced in the late 1980s, it was quickly sidelined because hospitals, suffering with major cash flow concerns, had little time for innovative management systems that lacked a cachet considered valuable to the industry. Culture-based concerns were also responsible for the health care sector's limited adoption of TQM activities. For example, physicians' fears of litigation served as a disincentive for physician involvement in TQM demonstration projects.[9] But perhaps the most significant barrier to acceptance of TQM by the health care sector was a practical concern. Application of statistical analyses requires an agreed-upon standard to judge deviation. Unfortunately, until recently, the health care sector was virtually devoid of any agreed-upon

standards because medical decision-making was almost universally idiosyncratic,[10] or worse, was compounded by incentives that created conflicts of interest.[11]

The value of TQM to clinical decision-making advanced significantly after the Institute of Medicine (IOM) launched the patient safety movement with its publication of *To Err Is Human*. In that report, the IOM announced that as many as 98,000 Americans die each year from iatrogenic causes.[12] In the intervening five years, the public has become almost obsessed with the reduction of medical errors. As senator and physician Bill Frist (R-Tenn.) observed while promoting the recently enacted PSQIA (which concerns the reporting of medical errors), "tragedy of all these deaths is compounded by the fact that these deaths and the many errors that result in prolonged hospitalization, more misery, greater cost, can be prevented, can absolutely be prevented."[13] In essence, what Senator Frist is calling for is the wide-spread application of TQM to the health care setting, because TQM has been demonstrated to reduce medical errors, thereby improving providers' outcomes.[14]

For example, consider St. Louis-based SSM Health Care's experience with TQM.[15] In the first three years of using TQM, SSM expanded its market share, expanded the volume of charity work it could provide, and in 2002 it became the first health care institution to win the Malcolm Baldrige National Quality Award.[16] Importantly, SSM's success with TQM has not been an isolated event.[17]

ISO 9000 THE SPECIFICS PREDICATED

Against this backdrop, in 1987, the International Organization for Standardization (ISO), the world's largest developer of standards,[18] released its 9000 series of standards for quality management. Founded in 1946 and centered in Switzerland, the ISO is a network of non-governmental organizations representing 156 countries which creates consensus-based technical standards to facilitate international trade. Today the ISO has issued over 15,000 technical standards that were developed according to a set of strict rules that govern its consensus decision-making process. Because of this strict decision-making process, ISO's standards are view as being transparent and fair. Today, ISO standards allow a country that wants to expand a sector of its economy to do so without having to reinvent the wheel.[19]

In contrast to its product-specific technical standards, ISO's 9000 series of quality standards were developed from eight management principles and are intended to be used to guild any business organization. These eight principles concern:

1. Customer focus;
2. Top-down leadership;
3. Involvement of the entire organization;
4. A process approach;
5. Systems management;
6. Continuous improvement;
7. Factual approach to decision-making; and
8. Mutually beneficial relationships with business partners. [20]

From these eight principles, ISO then derived a number of specific quality standards. For example, ISO 9001 is composed of 20 chapters covering issues such as management responsibility, document and data control, and audits.[21] These standards are to be applied to the three areas most important to an organization: customer satisfaction, performance measures, and program costs.[22]

Key to the ISO 9000 program is documentation. In fact the maxim behind ISO 9000 is "document what you do and do what you document." As with the JCAHO's accreditation system, ISO 9000 certification is only available after the organization submits to an external audit by an ISO-independent registrar organization like TUV Health Care Specialists. An organization will fail the ISO 9000 standards if the registrar (*i.e.,* auditor) finds:

1. Any inconsistencies or discrepancies in the documentation; or
2. Substantial numbers of the ISO requirements are not met.[23]

An organization that passes the registrar's review receives a written assurance (*i.e.*, certification) from the registrar that the organization's management system conforms to the requirements specified in ISO 9000.[24]

While ISO 9000 certification of a hospital is superficially similar to the JCAHO accreditation, significant differences between the two exist. JCAHO audits are perormed in a retrospective fashion that until recently were performed only at fixed intervals. As a result, JCAHO's accreditation system has the appearance of a system that is designed to preserve the *status quo.* Consequently, over a recent 17-year period, fewer than 1 percent of JCAHO accredited hospitals lost their accreditation status.[25] Although the JCAHO has been making attempts to modernize its system of evaluation,[26] the JCAHO's accreditation does not differentiate hospitals on quality. From a practical point of view, the primary value of JCAHO accreditation is that it provides a hospital with "deemer" status. In order to be eligible to receive Medicare funds, hospitals must be in compliance with Medicare's onerous Conditions of Participation.[27] But, because any hospital that has received JCAHO accreditation is deemed to be in compliance with the Conditions of Participation, most hospitals opt for JCAHO approval, which is considered easier to obtain.

On the other hand, ISO 9000 certification is not guaranteed. Auditing of ISO 9000 documents is prospective and ongoing. This approach has lead to the ability of the ISO 9000 process to differentiate organizations in the market based on profitability. Organizations that are ISO 9000 certified organizations out-performed their non-ISO 9000 certified competition.[28] The ability of ISO 9000 to enhance the performance of a business organization is undoubtedly a major reason so many hospitals have adopted this system of TQM in the last five years. It also points to why the federal government's decision to grant deemer status to TUV Healthcare Specialists is important. If a hospital could use ISO 9000 to be deemed in compliance with Medicare's Conditions of Participation and out-perform the competition, why would the hospital want to continue to participate in the JCAHO's accreditation process?

THE POWER BEHIND ISO 9000

Some providers may be skeptical about what TQM can do for their organizations. After all, substantial differences exist between the market for health care services and market for other goods or services.[29] Yet, ISO 9000 is exactly what is needed by health care professionals to reduce the number of iatrogenic injuries. In the five years since the first IOM report,[30] it has been demonstrated that as many as 85 percent of all malpractice cases are not due to bad physicians. Rather, the malpractice occurred because the hospital where the physician worked had a faulty or non-existent quality control system.[31]

Perhaps the best example illustrating this point is the case of Jesica Santillan, who died because she received a heart transplant from a donor with an incompatible blood type.[32] Retrospective analysis of Jesica's story, even if it is performed by a root cause analysis (popularized by the JCAHO in sentinel event reporting), yields an "I owe you" action plan. Unlike a TQM cycle, which raps around, JCAHO root cause analysis alone does not create a follow-up mechanism to see if the provider actually takes remedial action. On the other hand, had the hospital that treated Jesica been using ISO 9000, perhaps the problems that allowed Jesica to receive incompatible tissue may never have occurred, as the error would have been detected and treated at an earlier time.

So powerful is the notion that ISO 9000 can prospectively eliminate medical errors that cause patient harm that state Rep. Phyllis Mundy (Dem.) of Pennsylvania introduced a bill that would grant providers a 20 percent discount on their medical malpractice premiums if the provider would incorporate ISO 9000 (or some other TQM system) into their practice.[33] But even if discounted professional liability insurance is not enough to induce providers to adopt a TQM system, responsible hospital boards are likely to soon impose some form of TQM upon their hospital's operations.

Management of hospitals under some form of TQM is an idea whose time has come. In the IOM's most recent publication on health care, although it does use the term TQM, it's an implicit call for TQM.[34] In essence, when commenting on the plan to implement pay for performance, the IOM is calling for the implementation of the first large-scale "Plan, Do, Study, Act" cycle. As used here, the "plan" is pay for performance; the "do" is its actual implantation in the next few years; the "study" that will be done will concern providers' responses to the incentives created by pay for performance, and the "act" will be the response to the data gathered. By adopting the IOM's recommendations, the government will be able to lead, by example, the health care industry into a new era of hospital management by TQM.

Yet the most important reason why hospital boards will impose TQM on their organizations is that such behavior will be demanded of hospital boards. The National Quality Forum (NQF) is calling for hospitals boards [35] to voluntarily adopt the principles of management articulated in the Sarbanes-Oxley Act (SOX).[36] Enacted into law after the collapses of Enron, Worldcom, and Arthur Andersen, SOX is a far-reaching law designed to make the workings of major for-profit corporations more transparent.[37] While SOX is not technically applicable to most hospitals because they are operated as not-for-profit entities,[38] many reforms like the NQF see similarities between the hospital market today and Wall Street during the 1990s.

Thus, the NQF believes that SOX's top-down management style, coupled with holding board members personally responsible for what occurs in their organization, will improve the hospital industry. In particular, the NQF believes that hospital boards must ensure "that a system of performance measurements and quality improvement is in place,"[39] and the NQF has advanced standards regarding whose patient data is to be collected for TQM.[40] (Similarly the IOM has also weighed in on performance measures.)[41]

NQF recommendations are important because of what the NQF is and because of a somewhat obscure federal law. The NQF is a consensus organization whose membership includes individuals and major stakeholders in the health care industry who want to improve patient safety.[42] This means that any recommendations promulgated by the NQF are likely to be adopted by the major health care stakeholders who had a hand in writing the recommendations. In addition, the National Technology Transference Advance Act of 1995[43] requires the government to adopt standards of a consensus organization in the field. This means that if the government wants to adopt standards for hospital governance, it will likely adopt NQF's recommendations. So, given the unique position of the NQF in the health care sector, its recommendation that hospitals adopt the principles of SOX is going to act like a "high-voltage prod … to get many hospitals boards to take a hard look in the mirror."[44]

This hard look in the mirror will come whenever hospitals review their TQM data. If hospital boards are going to be held responsible, after the board reviews unflattering data generated by a PDSA cycle, the board will have to take action. In part, this action will concern the implementation of a remedial plan to improve quality. But in part, taking action will mean hospital boards will have to decide how, and how much of its TQM data to disseminate. At a minimum, the NQF wants hospitals to report data to the government. More radical views on hospital reporting of provider-specific data include:

1. Forthright disclosing of negative provider-specific information when references are checked;[45]
2. Formal training for whistleblowers;[46] and
3. The selling of such data for profit as the JCAHO has recently been discovered to be doing through one of its subsidiaries[47] (a practice that can only encourage providers to switch from JCAHO accreditation to ISO certification).

DATA AND DISCOVERY

Like any TQM system, ISO 9000 will generate a lot of provider-specific analysis of medical errors. While some of these errors will not result in patient harm (*e.g.*, failure to enter medical data in a timely fashion) some of the medical errors will involve patient harm from medical malpractice. So, an important question for physicians will be, in the event a malpractice lawsuit is filed against a physician, how much TQM data can a plaintiff's attorney discover? In general, documents are discoverable if they are "reasonably calculated" to lead to admissible evidence.[48] This is a very low standard to meet because evidence is any relevant information that makes an event more or less probable,[49] and statutes to the contrary are narrowly interpreted.[50] Accordingly, because the scope of discovery is broad, as a general rule, records kept in the ordinary course of business, like ISO documents, are discoverable.[51]

However, two exceptions to these rules allow businesses to shelter documents from discovery. The first exception concerns documents that are destroyed during the routine course of business.[52] For many businesses storing documents in perpetuity is expensive. So they implement a policy to destroy all documents over a certain age. A document destruction policy is perhaps the cheapest method to shelter records from discovery. However, a key provision of anti-discovery technique is that all documents, both those favorable and unfavorable, must be destroyed. The second method to protect business documents from discovery concerns the *Upjohn* test. [53] Predicated on the attorney-client principle, the *Upjohn* test holds that documents and information gathered by a corporate attorney, in anticipation of litigation against the corporation, are privileged. Key to using the *Upjohn* test to block discovery of a business record is the need for litigation to be imminent. Because documents do not become privileged merely because they are stored in an attorney's office, hospitals cannot shelter ISO 9000 documents by hiring an attorney to be the risk manager. In short, ISO documents not destroyed in the routing course of business are likely to be discoverable.

At this point many physicians are likely to be thinking that this cannot be true because of peer review protection. While good-faith participants in peer review activity are protected from antitrust and defamation actions brought by providers who are the target of a peer review inquiry, peer review documents are not privileged.[54] Discovery of peer review documents and TQM documents is not only permitted,[55] but also documents containing confidential information of non-party patients may be discoverable if it is deemed necessary in the interest of justice.[56] Key to discovering non-party patient data is that the patients' identity must be adequately protected,[57] (for example by redacting all "protected patient information" as defined by HIPPA[58]).

In the past, a few states have passed statutes that make it very difficult to discover to hospital TQM documents.[59] But not enough states have enacted protective legislation to slow down the potential avalanche of TQM documents into the courts. This is rather unfortunate because patient safety advocates are well aware that the "discoverability of data under legal proceedings encourages silence about errors committed or observed."[60] Moreover, the purpose of TQM is to improve an organization's quality without assessing liability or imputing blame. This means that to the extent that liberal discovery rules allow TQM documents to find their way into medical malpractice litigation, liberal discovery rules harm patients in the long run because they stifle the flow of TQM information.

Fortunately, for physicians and patients, help is on the way in the form of the newly enacted PSQIA. Focusing on the "patient safety work product," the intent of the PSQIA is to facilitate the reporting of medical errors by hindering the discovery of health care TQM documents. As defined by the act, the patient safety work product is any oral or written data reports records, or analyses that are:

1. Assembled or developed by a provider and are reported to a patient safety organization (PSO); or
2. Any document developed by a PSO to improve patient care/outcomes or as a report to a patient safety evaluation system (*i.e.*, an organization that pools data).

Under the PSQIA, all (with a few exceptions that are not relevant here) patient information that qualifies as patient safety work product is privileged and confidential. The protective reach of the patient safety work product privilege covers disclosure of negative actions taken against a physician, and the findings of the TQM process.[61] Importantly, this privilege applies in federal and state court for matters that are both criminal and civil. The confidentiality provision of the patient safety work product is applicable

to physicians, hospitals, PSOs, and those in positions to have access to work product information.[62] The PSQIA set the penalty for wrongful disclosure of patient safety work product information at $10,000 per disclosure.

While the PSQIA goes a long way to encourage that patient safety information is reported to a TQM manager, it does not resolve all TQM-related problems. For example, while the act protects employees who in good faith report medical errors from employer retaliations, it is unclear whether physicians will be able to admit exculpatory patient safety work product data as defense evidence in a medical malpractice action.[63] Nor does the act attempt to clarify for hospitals the myriad of reporting requirements to various state and federal agencies. On the other hand, PSQIA's requirements concerning what is needed to become a PSO are fairly clear. To become a PSO the organization must:

1. Have a mission to promote patient safety;
2. Have appropriately trained staff;
3. Contract with more than one provider;
4. Be independent of an insurance corporation;
5. Disclose any conflict of interest with a provider(s);
6. Collect provider data in a uniform manner; and
7. Provide feed back to the providers to improve the outcomes of patients.

This information is important, because without a PSO to receive a hospital's TQM data, the data cannot be sheltered for the judicial system. Accordingly, whether a hospital selects ISO 9000 or some other TQM system, it must simultaneously select a PSO to receive discovery protection.

CONCLUSIONS

JCAHO's alienation of providers, by selling its proprietary information to insurance companies, could not have come at a worse time. While presently only a small percentage of hospitals are ISO certified, this number is likely to grow substantially if ISO certification is granted deemer status, thereby facilitating payment from the federal government to the hospital. Not only does ISO 9000 certification provide a hospital with a cache of quality management that is recognized worldwide, but it also is becoming increasingly clear that hospitals with ISO 9000 certification outperform the competition. Because of these advantages, ISO 9000 certification is poised to supplant the JCAHO accreditation system. Yet once an ISO 9000 (or any TQM system) is up and running, it will create mountains of documents concerning provider-specific adverse events. And like documents created for the JCAHO, ISO 9000 documents are discoverable. However, newly enacted PSQIA provides broad-reaching protection of health care TQM documents. This act makes health care TQM documents privileged and confidential in federal and state court. However, to get the benefit of this protection the documents must be delivered to a PSO. Accordingly, any provider contemplating the use of ISO 9000 should simultaneously be looking for a PSO to do business with in order to avoid unwanted discovery.

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