USING IWA 1 TO SPAN THE HEALTH CARE QUALITY CHASM

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SUMMARY

The Institute of Medicine (IOM) published "Crossing the Quality Chasm: A New Health System for the 21st Century". The focus of this IOM report is how the health care delivery system can be redesigned to improve care. The report proposes an "agenda" supported by concrete recommendations. This paper defines what ISO IWA 1 is and shows how its guidance can be practically used to implement some of the IOM recommendations.

In 1998, work groups from the American Society for Quality (ASQ) and the Automotive Industry Action Group (AIAG), representing a large group of payers, began work on similar ISO 9000:2000 series based applications documents. Agreement was reached in 2000 to work together on a common document, HC 1, released in January 2001. Interest from other countries led them to propose release of HC 1 under the auspices of ISO, the International Organization for Standardization, as an Industry Workshop Agreement (IWA), a new category of ISO document. In September 2000, ISO approved their proposal. An international workshop was convened in January 2001. Agreement was subsequently reached, and IWA 1 was released last September. ISO 9000 was developed to assist organizations of all types and size to implement and operate a quality management system.

In 2004, a three-year review of the document was to be conducted according to ISO rules regarding this type of document. Suggestions for improvement were solicited from healthcare providers and administrators from around the globe. These comments were considered and an IWA 1 revision was drafted. A change summary was posted on the Standards Council of Canada website for the original 2001 workshop attendees to vote on. The changes were approved unanimously and IWA 1, Version 2 was sent to ISO for publication in late 2004.

WHY THE AUTOMOBILE INDUSTRY CARES…

In its second major report, "Crossing the Quality Chasm: A New Health System for the 21st Century," the Institute of Medicine (IOM) reported that Americans invest some $1.1 trillion dollars annually in the health care sector. This represents over 13% of the Gross Domestic Product. General Motors in North America alone spends about $5 billion per year on health care. This cost is the largest purchased component of the vehicle. Health care costs the domestic automotive industry billions per year. Even a 1% reduction in cost would save millions annually.

In 2000, the initial IOM report, "To Err Is Human", which focused on patient safety, estimated that as many as 98,000 people die annually from preventable medical errors.[1] This number is reported to be more than those who die from causes such as car accidents, AIDS, workplace injuries or breast cancer. This data is limited to the hospital setting. The nursing shortage in the years since the release of the original IOM report has probably resulted in an even higher number of annual deaths.

[1] Error was defined as "the failure of a planned action to be completed as intended (i.e. proof of execution) or the use of a wrong plan to achieve an aim (i.e. error of planning).

In 2003, the National Committee for Quality Assurance reported 57,000 die annually due to "inappropriate care," such as care inconsistent with known medical science. These deaths are in addition to the deaths resulting from medical error. If you also add the deaths due to medical error that occur outside hospital admissions and then consider the near misses that do not result in death but create harm as a result of care, the picture is worse.

The Centers for Medicare and Medicaid Services in 42 CFR Part 482 report the healthcare community acknowledges errors are most likely underreported due to malpractice threats and practitioner confidentiality concerns. According to the U.S. Department of Health and Human Services, even though the majority of medical liability cases never come to trial, it costs an average of $24,669 to defend each claim.

In July 2004, Health Grades, a Lakewood, Colorado-based healthcare quality rating and advisory services company, published a report saying that approximately 195,000 patients lose their life due to errors in hospitals. The difference from the IOM reported statistic could be attributed to two areas of patient-safety problems not evaluated in earlier studies. Extrapolating from a study of 37 million Medicare patient records, researchers determined that about 195,000 patients die annually in the U.S. because of preventable errors in 16 categories of patient-safety incidents.

Significantly, a 2004 survey published by the American College of Healthcare Executives listed hospital CEO top concerns as reimbursement issues, personnel shortages and capacity. Items of least concern included quality, technology, patient safety, and patient satisfaction and bio-disaster preparedness.

BENEFITS OF ISO 9000

There are now about 600,000 organizations third party certified as compliant to ISO 9000 worldwide, but few are in the healthcare sector. In 1997, a senior GM executive asked if ISO 9000 could be applied to healthcare as it had been to the productive material supply chain with QS-9000[2] for significant gains in quality and cost. ISO literally means "equal" but is also known as the short name for the International Organization for Standardization. Surveys by the Automotive Industry Action Group (AIAG) and the American Society for Quality Control (ASQ) document that QS-9000 provided a 3:1 return for all (internal and external) compliance-related costs, and nearly 17:1 return for out-of-pocket certification costs. In the most recent survey, the suppliers, who averaged $130 million in annual sales, reported average savings of 6% of sales, or about $8 million as a result of QS-9000. About half of these suppliers reported an average quality improvement of about 50% (as measured by Parts Per Million defects) in the first three years of implementation. In addition to cost and quality, suppliers also reported as QS-9000 benefits: improved processes and delivery, better understanding of jobs and tasks, and improved morale.

These results took 2-3 years to quantify so it is expected that similar data from IWA 1 implementation will take several years. To date, health care organizations who have implemented an ISO-9000-based system have reported benefits including improvements in customer satisfaction, standardized operations, through-put, cost, purchased product, documentation control, problem solving, patient communications, control of measuring equipment. The ISO-9000 based system also helps with regulatory compliance, risk management and consideration of new initiatives or innovation.

HOW HEALTH CARE DELIVERY SYSTEM CAN BE IMPROVED

The Committee on the Quality of Health Care in America, formed in 1998 and which authored the IOM reports, summarized the current state of health care indicating that the delivery system:

[2] QS-9000 is the automotive industry supplier quality requirements document, which incorporates ISO 9001:1994 in its entirety.

- Is in need of fundamental change
- Harms too frequently
- Routinely fails to deliver its potential benefits
- Frequently delivers care which is not based on the best knowledge
- Has quality problems "everywhere"
- Has not just a gap but a "chasm" in terms of quality
- Does not make best use of its resources
- Has waste present
- Cannot achieve higher quality by further stressing the current systems.

The focus of the "Chasm" IOM report is on how the system can be redesigned to innovate and improve care. The Committee offers an "agenda" for redesigning the 21st Century health care system and proposes a series of aims supported by concrete recommendations, some of which will be addressed herein.

In discussing organizational supports for change, they note that some have said that quality improvement principles widely applied in other industries (with significant success) are not applicable to health care. They add that some people in these other industries have also said these principles do not apply to their own sector. Of course, neither view is correct. The Committee rightly states that application of these so-called "Engineering" principles to the health care sector is the critical first step in improving patient safety. They recommend that the Agency for Healthcare Research and Quality with others convene workshops involving representatives from health care **and other industries.** The objective would be to identify and implement state-of-the-art approaches to address the challenges of redesigning healthcare on this scale.

Since 1994, some industries, including automotive, aerospace, telecommunications, chemical, petroleum, and medical devices have pursued implementation of fundamental quality management systems based on the international generic ISO 9000 series of quality management system standards. Service sectors, such as food services and financial services, are now showing the same interest.

THE HARMONIZATION OF SIMILAR ISO 9000:2000 BASED HEALTH CARE INITIATIVES

In February 1998, representatives from DaimlerChrysler, Ford, GM and the UAW began discussions through the AIAG, which eventually led to the decision to publish an ISO 9000:2000 based application document for healthcare plans and providers. Also in 1998, Dr. David Simmons, Chair of the ASQ Health Care Division, made up of some 1500 health care professionals, decided that a committee should investigate the use of ISO 9000 series of standards in health care. In 1999, the Committee was re-engineered by Dr. Tom Reiley, the 1999 ASQ Health Care Division Chair. The original goal was to develop a document that would help interpret ISO 9001:2000 for human care, but exempt those entities already covered by other national standards, e.g. pharmaceutical and durable medical equipment manufacturers.

In early 2000, the initiatives of AIAG and ASQ were made known to each other. The two joined forces to develop a single document. The motives of both organizations were similar in that they were trying to provide consistent guidance on implementing or improving the quality management system in a health care organization. Many of the preventable errors identified in the IOM and other reports are system-based. An ISO 9000-based quality management system was viewed as something of value to health care providers.

A joint ASQ/AIAG document, HC 1, based on ISO 9004:2000 was published by both organizations in January 2001. This is an excellent example of what can be accomplished through cooperative efforts across industry sectors toward a common goal. New levels of cooperation and teamwork are also called for in the new IOM report.

In September 2000, ISO approved an AIAG/ASQ proposal to develop an ISO Industry Workshop Agreement (IWA) document using their HC 1 document as the base. The project was approved and an

international workshop was scheduled for January 2001 in Detroit. There were about 130 healthcare "experts" from at least 17 countries in attendance. The final document was subsequently approved by 89% of the voting participants and IWA 1 was published in September.

The stated intent of IWA 1 is to:

- Improve delivered health service quality and safety through: 1) complement existing accreditation and 2) process improvements to increase the value added to the organization and the customer;
- Improve the image of the organization, increase customer confidence and have a tool to reward quality;
- Maintain consistency in the global approach with *TS-16949* and other ISO 9000 sector-specific documents, e.g. aerospace (*AS9100*), medical devices (*ISO 13485*), telecommunications (*TL 9000*) and medical laboratories (*ISO 15189*);
- Develop/incorporate a process that is actionable;
- Include terminology and examples familiar to healthcare personnel;
- Minimize/reduce the burden on providers.

It is clearly stated in IWA 1 that it does **not** constitute a set of criteria for third party certification or registration purposes. In addition, the document is applicable to healthcare service providers, but not aimed for medical device manufacturers, clinical laboratories, or regulated sectors, e.g. FDA, which have specific standards. However, it can be used by health care organizations to implement a system that is certifiable to ISO 9001.

WHAT IS ISO 9000?

The ISO 9000 family of documents was released in 1987, then revised in 1994 and 2000. The current family consists of three main documents:

- ISO 9001 – generic minimum requirements for a fundamental and certifiable quality system;
- ISO 9004 – guidance for performance improvements beyond ISO 9001 requirements (which are included in ISO 9004 in their entirety) in order to address both effectiveness and efficiency of a quality management system;
- ISO 9000 – Quality Management System fundamentals and vocabulary.

The ISO 9000 series is "generic" which means that it is written to apply to all types and sizes of companies. The current version improves its applicability to service sectors, e.g. healthcare.

Standards and Guidelines published by ISO require a high level of international consensus and are developed using a 3-5 year rigorous and transparent international design and development process.

ISN'T HEALTHCARE ACCREDITATION ENOUGH?

IWA 1 indicates that ISO 9004:2000 should be used to define the fundamentals of the quality system and support the use of the existing relevant healthcare sector documents, e.g. accreditation criteria. There is concern that some healthcare organizations opting for ISO 9000 certification will use it as a substitute for accreditation. Both are required to address specific quality management needs of healthcare organizations. In fact, other criteria such as the Malcolm Baldrige Quality Award can also be added to the organization's quality system requirements in pursuit of world-class excellence.

In the USA, healthcare organizations are accustomed to accreditation. Considering the number of errors and variation in healthcare, implementation of the basic principles of process management is still a challenge. In the June 2000 issue of Quality Progress, Dr. Paul Schyve of the Joint Commission for Accreditation of Healthcare Organizations (JCAHO) wrote, "Quality approaches initially developed for other industries hold promise for improving the performance of healthcare organizations." ISO 9000 was specifically mentioned. Crosswalks between ISO 9001:1994 and the healthcare accreditation criteria, e.g. JCAHO, NCQA and URAC, have revealed

significant gaps in the healthcare criteria, e.g. document control, purchased product control, control of inspection, measuring and test equipment, inspection and test status, and internal auditing.

IOM NEW RULES: CONTINUALLY DECREASE WASTE

Reduction of organizational waste has been a focus of manufacturing sectors worldwide for many years. For the service sectors, the concept of waste reduction may not be as clear. The Committee has incorporated this modern concept into their new rules for redesigning health care for the 21st century. Emphasizing the current health care delivery systems will not produce the needed improvements. The U.S. automobile industry found itself in similar position in the mid 1970's. To compete, process re-engineering and redesign of the management system was necessary. There are documented gains in quality, efficiency and cost reduction from other industries that the IOM Committee recommends should be adopted by health care.

The IOM report lists typical forms of waste as:

- Overuse of services
- Waiting, e.g. lab test performed or getting results
- Transportation, e.g. patient has to go to a different floor for services during a visit
- Processing, e.g. excessive steps to accomplish results
- Stock, e.g. unused inventory or workforce skills
- Motion, e.g. lost energy or time
- Defects, e.g. mistakes in execution of a procedure

Waste is any activity that does not add value. Value-added activities are those activities that a patient/client/customer would be willing to pay for if they had an option. Waste is present in all organizations and at all levels. Significant improvement can be made when an organization declares all-out war on waste. "Problems" must be viewed as opportunities to improve. Everyone should be a "problem-solver" then rewarded accordingly. Unfortunately, in many companies, problems are "hidden" because the bearer of "bad" news is, as they proverbially say, "shot."

IWA 1 stresses this concept of waste reduction. For example:

> *Activities undertaken in product realization should focus on reduction or elimination of waste, e.g. cost of excess inventory, poorly utilized floor space, non-value adding processing, and waiting or lost motion.*
>
> *Increased benefits, improved customer satisfaction, improved use of resources and* ***reductions of waste are*** *examples of measurable results achieved by greater effectiveness and efficiency of processes.*

CRITICAL TERMINOLOGY - PRODUCT

The above clauses are in IWA 1, Clause 7, which addresses "Product Realization." This terminology has been a point of misunderstanding in the health services sector. The organization's "product" is an integral subject in ISO 9000. Most service sectors believe that they do not provide "product." However, ISO 9000:2000 defines "product" as the "result of a process," and identifies four generic product categories in a note: services, software, hardware and processed materials. Thus, it is clear that services are, in fact, addressed in the ISO 9000 family of documents. Further, healthcare clearly involves processes and the use of the term "process".

WASTE OF STOCK (INVENTORY)

IWA 1 incorporates most of the text of ISO 9004:2000 which addresses efficiency as well as effectiveness. One of the types of waste identified by the IOM is waste of stock, or inventory. In order to provide

services, an organization needs people, facilities, “know how”, customers and working capital. Working capital consists of:

- Cash + inventory + accounts receivable - accounts payable.

Since inventory is a key component of working capital, reduction in inventory frees up cash for investment and avoids interest expense. It also provides better use of floor space and facilities.

IWA 1 lists several recommendations for inventory management:

> *The organization should use an inventory management system to optimize inventory turns over time and ensure stock rotation.*
>
> *The organization should consider implementation of a “pull” system of inventory management for those supplies used for routine service.*

“PULL” SYSTEM OF INVENTORY MANAGEMENT

Practitioners have also identified another common problem in healthcare. Hospitals often run short of supplies on off shifts. The method of obtaining replacement supplies is not well understood. An effective method of inventory management, the “pull” system, has been implemented in other industries.

“Pull” is based upon replenishment of stock based upon consumption. In the automotive industry, “pull” has proved to be much more effective and efficient than the traditional “mass” production inventory management method, e.g. “push” or replenishment of stock based upon forecast. For organizations such as hospitals, it would be practical to set up a “pull” system for standard supplies, e.g. gauze, popular medications, bandages and the like. It is recognized that some inventory must be maintained, whether it is used or not, for certain critical supplies and medications.

Pull systems have many benefits to the organization. These include:

- Decision-making at appropriate levels
- Provision of only what is needed by the customer
- Improves communications of needs through visual controls
- Eliminates scheduling complexity
- Highlights quality issues quickly
- Organizes the workplace
- Leads to lower unit cost

IOM NEW RULES TO REDESIGN AND IMPROVE CARE

The “Chasm” IOM report points out that health care systems are complex and adaptive, meaning they can change as individuals in the system learn and adjust. This has, in part, been blamed for the large variation found in care delivery. Reduction in variation and standardized operations can still be successfully implemented however. Some actions need to be specified so they can be predicted and have a high reliability. The key for practitioners is to know when standardization is appropriate. As the IOM report finds, variation should be minimal when a level of certainty and clinical agreement are high, and where evidence is consistent.

Dr. Brent James of Intermountain Health Care Institute in Salt Lake City and a member of the Committee, who authored the 2001 IOM report, has stated that for physicians “it is more important that you do it the same than it is that you do it right.” When you have standardized operations, error rates fall due to less complexity. Costs fall due to increased efficiencies, and you can systematically improve.

Standardized work is work performed with tasks organized into the best sequence making the most effective use of resources. Until an organization has standardized operations, it cannot achieve process control. Without process control, it cannot achieve systematic continuous improvement. Worse, it cannot take efficient corrective action when something goes wrong. The root cause (s) must be searched for. If operations are standardized, then something goes wrong, corrective action can be taken swiftly and the results can be quickly verified. Operations should be engineered using flow charts, which show how work is to be accomplished. Processes should then be measured and monitored using visual controls. Some monitoring will have to be done indirectly, e.g. overall nosocomial infection rate rather than individual processes.

IWA 1 provides guidance in the effective use of documentation, e.g. procedures, flow charts, checklists, records, forms, tags, labels, work instructions. For health services, this documentation can include, for example, the most current relevant clinical guidelines, treatment techniques, protocols, and the patient/client health record, if any. Care selected should be recorded in the care plan.

IWA 1 notes that: "ISO 9000 does not specifically define 'what' needs to be done by a health professional. That is to be done by consensus of appropriate professionals. Rather, ISO9000 can be used to ensure that the right activities are carried out consistently and in a controlled manner." Training, use of quality system documentation/records, process monitoring, and management review and corrective/preventive action is how activities are controlled.

IOM: SAFETY AS A SYSTEM PROPERTY

The IOM report goes on to say that patients are frequently injured due to poor system designs. The system must be designed to deliver appropriate care reliably and without error. The current "rule" is that health care professionals do not, or should not make errors. The new IOM rule indicates that errors are the result of complex causes. The suggested way to improve is to understand the root cause of errors, then design systems of care to prevent error (e.g. error-proofing[3]) where possible, then to make errors visible when they do occur and mitigate the harm done when error reaches the patient.

Various types of documentation should be used as a sub-system to accomplish this. Start with making readily available the best practice protocols. Effects of potential failures or errors in care delivery design or execution can be evaluated or ranked in a risk management tool such as Failure Mode and Effects Analysis (FMEA). Once ranked, which the IOM report discusses as use of "Pareto", an "Engineering" principle, efforts should be taken to eliminate those potential risks using error-proofing techniques. Risks should then be re-evaluated. Where risk remains high, efforts to mitigate the consequences of the potential failures should be specified in standard procedures and/or work instructions. Procedures should be used where work crosses functions in an organization, while staff at individual workstations should use instructions. Any measuring or process monitoring required should be specified in the system documentation including the frequency, measurement type, device to be used, and acceptance criteria.

IWA 1 discusses the responsibility of management to systematically plan to mitigate the effects of loss to the organization. This should be based on data from appropriate sources, e.g. evaluation of historical data looking for trends. Plan output should generate quantitative data. The documentation method described above is one way to accomplish this.

IWA 1 agrees with the IOM recommendation that the organization should use error proofing in the planning of care, but adds that it should extend to the planning of processes and facilities. One technique widely

[3] Error proofing is defined in IWA 1 as "use of process or design features to prevent the acceptance or further processing of nonconforming product" which also includes "service."

used in many sectors is to organize inventory storage areas such that similar items are NOT stored close to each other. This eliminates inadvertent errors of "grabbing" the wrong item.

ERROR PROOFING IS NOT ENOUGH

Error proofing is important but it is not the "end game." As Edwards Deming points out in "The New Economics," organizations that are "error free" can still go out of business. The key is to have a long-term plan with measurable objectives. As Deming says, what service (s) would help customers more now and in the future? How could current services be improved to satisfy customers more? In IWA 1, this is the comprehensive Business Plan (clause 5.4.3). The plan should define where the organization is going in the next 5 -10 years, and indicate the method (s) by which it will "get there." This will include defined business objectives (including cost and quality) and appropriate metrics for management. The goal must be to provide consistently better value to customers/clients/patients than the competition.

If two competing organizations provide comparable quality of service, then the distinguishing factors move to features such as performance or style. Given a (hopefully short) wait for service, would a customer rather sit in a sterile waiting room with only a few brochures and aged magazines to read or one with warm colors, comfortable seating, and cable TV. Given an option with other things being equal, would a customer rather seek service from a provider with hours between 9 – 5 PM or one with evening hours several nights per week to accommodate working people? In a service sector, "soft" issues of this type are more critical.

CRITICAL TERMINOLOGY - DESIGN AND DEVELOPMENT

The IOM report discusses the design and redesign of care at length as we have already seen. If you consider the examples given in the IWA 1 definition of "product", it is clear that a primary product of the general healthcare provider is the care plan. The provider must diagnose the patient's problem, "design" and implement the care plan. A healthcare professional saying that they are not "design-responsible" is analogous to a chef saying that they are not design-responsible for the meal because they did not design the ingredients they chose to use in the recipe, e.g. "ketchup". This would be like an airline company saying it is not design-responsible for the flight service because they did not design the aircraft.

We have seen that the health service system is complex. Many processes and transactions can be involved in any one instance of care delivery. In order to make sense of the ISO 9001 standard, it is critical to identify the organization's product (service). From this, you can then easily identify the customer, and components of the process, e.g. the inputs and outputs. These should be defined within the context of each transaction, where multiple parties and/or products are involved. It is also necessary to understand this when seeking third party certification of the system, as it will be used to define the scope of registration on the certificate. True, the healthcare provider does not typically design the protocols used, but they design the product, e.g. healthcare, that they deliver and are compensated for. A scope of registration should accurately define what specific product/service is provided by the organization.

In the ISO 9000 series, the term "design" is tied with "development" in both context and definition. Further, it is defined broadly in ISO 9004, clause 3.4.4 as "a set of processes that transform requirements into specified characteristics or into the specification …" This makes it clear that "design and development" applies to services.

The issue of design control is often further confused with the issue of subcontracted design services. ISO 9001 has been used for contractual situations, e.g. customer and supplier. In this context, one has to be ultimately "design-responsible" for the product supplied in the transaction. If the customer is not design-responsible for the product they are procuring from the supplier, then the supplier must be. If the supplier chooses to sub-contract the design, they must still be responsible for the design to the customer. If, on the other hand, the customer selects a third party design provider as a condition of the transaction, they are then design-responsible in the contract. This

understanding can be particularly helpful in healthcare where physicians are typically not employees of the hospital where they practice, and where healthcare is provided to a given patient across a number of providers. This continuum of care can be understood within the ISO 9001 model when you understand the "product" that each provider offers across the continuum.

For example, a patient goes to the doctor with various complaints. The doctor provides a diagnosis, designs and implements a "care plan" for that patient and is compensated for that service. However the plan may call for X-rays and referrals to various other specialists, rehabilitation or homecare services. Each of these provides a service to the patient and is compensated for that service. Thus, each one provides a unique "product" to the customer, e.g. patient. This is a critical issue which goes well beyond the quality management system – that is, typically, no one practitioner is ultimately responsible for the coordination of the healthcare services across the continuum of care by a number of providers. With no one ultimately in charge of the "quality" of the total care across providers, there can be problems, e.g. prescriptions issued by different providers that have adverse effects when used in combination for the same patient.

IOM NEW RULES: COOPERATION AMONG CLINICIANS

The IOM report also points out that in the current system, there is too little teamwork. Each department or function does what is best for their department. This has been referred to as "sub-optimization." Patients have also reported that caregivers do not seem to coordinate their work or know what others are doing. In the IWA 1, the issue of the continuum of care discussed above is identified as a problem without proposing a solution. The IOM new rules say that in the new system people will understand the benefits of optimizing the system as a whole, at the organization level, not at the department or function level. There will be high levels of cooperation, coordination and standardization.

IWA 1 encourages the organization to involve and develop its people. Just with regard to cooperation and teamwork, it recommends establishing individual and team objectives, ensuring effective teamwork and communicating suggestions and opinions. Further, for its people, the organization should provide ongoing training and career planning, involve people in objective setting and decision making, continually review needs of its people, and measure their satisfaction.

Many organizations use a classic pyramid organization structure. This emphasizes the reporting relationships rather than depicting how work is actually accomplished, as is shown in flow charts. Some organizations have implemented a "matrix" organization structure. This requires coordination as employees typically have two direct supervisors. This structure can be used to more effectively deploy common protocols, processes and procedures as "left side" executives can champion specific processes, while "top side" executives can manage the functional resources day to day.

Dr. Brent James has also reported that the medical profession is changing from a "craft-based" practice to a "profession-based" practice. In the former, physicians working alone design a solution for each patient based on their personal knowledge gained from training and experience. As a "profession-based" practice, groups of peers are treating similar patients in a shared setting. They plan coordinated care delivery processes, but physicians adapt to specific patient needs. He reports from early experience that this new approach is less expensive (supply of core processes), less complex (which means fewer errors) and results in better patient outcomes.

IOM REPORT: ORGANIZATIONAL SUPPORTS FOR CHANGE

The Committee indicates that the first critical step to effect change is the application of so-called "Engineering" principles. The first mentioned is to redesign the system using the 80/20 rule, also known as the "Pareto" principle to exploit the existence of routine work. The more predictable the work, the more sense it makes to standardize the work. The IOM reports that between 15 - 25 common chronic conditions account for the majority of the health services delivered. These would lend themselves to standardization of common sets of

services, customized as necessary for individual patient needs, which is another of the "Engineering" principles mentioned in the report.

A third principle is design for safety. This is essentially designing the system to prevent errors, which is also an emphasis of IWA 1, and designing procedures to make errors visible when they occur and to mitigate the potential harm to patients and/or employees.

Production or service planning is the final principle described in the report. This is described as use of a repeating master schedule for repetitive patterns of work. This provides for better utilization of staff, training efficiencies and better quality of care.

IWA 1: MANAGE PATIENT CARE PROCESSES

One key clause in IWA 1 deals with management of the patient care processes. Clearly the organization should ensure compliance with specified requirements, e.g. care plans, government or customer imposed standards, health care accreditation criteria, but it should also benchmark processes inside and outside of the healthcare sector to discover improvement opportunities. As discussed earlier, the organization should also make use of tools such as flow charts to document how care processes are to be delivered. To help identify, understand and manage variation, appropriate statistical tools should be used. Care should be taken to use relevant statistical tools make appropriate use of data. Some of these tools are run charts, histograms, control charts and designed experiments.

Sadly, the IOM report states that few healthcare organizations have developed successful models that reliably deliver basic effective services. W. Edwards Deming, mentioned in the IOM report, has developed a model that has been successfully used for many years in other industries. In his 1982 book, "Out of the Crisis", Dr. Deming published a healthcare version of his now famous 14 Points for Management, adapted by several physicians at the Health Services Research Center in Minneapolis. Deming's model is now several decades old, yet despite its successes where implemented, many organizations have not yet embraced it. Use of this model addresses what he calls the central problem of management: to better understand the meaning of variation and to extract the information contained in variation. Clearly, there are common threads between Deming and the IOM reports and the IWA 1. Some examples include:

- Require statistical evidence of quality of incoming materials
- Restructure training
  - teach methods of SPC on the job
  - provide operational definitions for all jobs
- Drive out fear
  - break down class distinctions between types of workers
  - cease to blame employees for system problems
- Breakdown barriers between departments
- Institute a vigorous program of retraining people in new skills

IOM REPORT: PREPARING THE WORKFORCE

The U.S. healthcare sector is large, 6 million strong in 1998. The IOM report points out that professional hierarchies are well established. The Committee recommends that a multi-disciplinary summit of healthcare leaders should develop strategies for restructuring clinical education and other professional training to provide

new or enhanced skills for the 21st Century. While curriculum changes are viewed as essential, they are not viewed as sufficient alone.

In IWA 1, emphasis is placed on the competency of people. Management is charged with ensuring that the organization has competent people for the efficient and effective running of the organization. Further, the current and future competence needs of the organization should be analyzed and compared with the existing competence in the organization. IWA 1 further supports the Deming philosophy above by recommending that the organization should have people competent in quality management science. Concepts of variation and control should be well understood throughout the organization.

IOM REPORT: ALIGNING PAYMENT POLICIES WITH QUALITY IMPROVEMENT

The final IOM recommendation to be considered in this paper is that purchasers of healthcare find ways to recognize and reward quality and support quality improvement efforts. One of the stated intents of the IWA 1 is to improve organizations' image, increase customer confidence and have a tool available to reward quality. AIAG, in cooperation with JCAHO and NCQA are planning pilot implementation of IWA 1 to gather cost/benefit information to build the business case for use of an ISO 9000 based system in healthcare.

In the meantime, efforts of the LeapFrog Group of the Business Roundtable are working on specific initiatives along the lines of the IOM recommendations. The Leapfrog Group is a coalition of more than 90 organizations that provide healthcare benefits created to help save lives and reduce medical errors by mobilizing employer purchasing power to initiate breakthrough improvements in the safety of healthcare. See their website at www.leapfroggroup.org.

ISO 9000 VS. SIX SIGMA VS. AWARD CRITERIA

Many organizations are pursuing a program of Six Sigma to address quality improvement. Others are following an Award Criteria such as Malcolm Baldrige in the USA or the EFQM in Europe. Given the options, many do not know which to pursue. In reality, they all have a place and a differing role in quality management and improvement.

The ISO 9000 series provides rather prescriptive guidelines and requirements for the organization's quality management system. The system is the "umbrella" for all the other programs and initiatives. The system includes the people, procedures, equipment and policy specified to result in product and/or service quality. ISO 9000 and IWA 1 provide a system that the organization can use daily involving everybody to achieve quality and control processes. Accredited third party certification is an option that organizations can elect to provide customer assurances of implementation of an effective quality system. Customers in some industry sectors require such certification as a condition of doing business.

Six Sigma is one of several comprehensive problem-solving methodologies available to organizations. Problem solving is conducted project-by-project and relies on experts, e.g. certified quality practitioners of various levels – black belt, green belt. Six Sigma practitioners use methodologies and statistical tools developed since the 1930's to lead a team over several months to solve an identified problem. Results can be dramatic for a well-executed applicable project. Many consultants advertise Six Sigma, but with widely varying degrees of competency and experience. Six Sigma methodologies can be incorporated into an ISO 9001/IWA-1 system very easily and then it becomes institutionalized.

Award Criteria typically provides areas to address for an organization as well as scoring. Organizational "Results" is an element typically scored with a higher proportion of the total points than other elements. Award criteria for organizations with maturing quality systems can effectively be used for self assessment and target setting for improvement over time, e.g. year-to-year. They are generally "descriptive" by design so organizations

that need guidance with what to do to improve will not find as much help in award criteria as in ISO 9000 or IWA 1.

These methodologies, with the use of tools like Six Sigma, SPC, FMEA, the Pareto principle and others aid the organization's management in determining the areas where significant improvement may be achieved without taking the "shotgun" approach.

CONCLUSION

This paper was not meant to be an exhaustive treatment of the "Chasm" IOM report. It must be noted that change and improvement do not come easy. A basic premise is that in order to improve, we must continually change. A basic law of physics is that for every action (change), there is an equal and opposite reaction (resistance to change). By nature, people resist change. Change takes people out of their "comfort zones." Therefore, the more you change, the greater the resistance. The greater the resistance, the more difficult it is to improve. The Committee drafting the IOM report did well to quote Goethe: "Knowing is not enough, we must apply; willing is not enough, we must do." The job of redesigning the healthcare system for the 21st century is a tall order, but it is worth the doing. The writers of IWA 1 trust that their contribution will be beneficial in accomplishing the work.

To order copies IWA 1, contact ASQ at 1-800-248-1946 or AIAG at 248-358-3003.
To order copies of the IOM report, see http://www.nap.edu/catalog/10027.html

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