



## Using The New “BOS” To Span The Healthcare Quality Chasm (PART 1 OF 3)



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### SUMMARY

In 2001 the Institute of Medicine (IOM) published “Crossing the Quality Chasm: A New Health System for the 21<sup>st</sup> Century” focusing on how the health care delivery system can be redesigned to improve care. The report proposed an “agenda” supported by concrete recommendations. The purpose of this paper is to define what the new hybrid standard “Business Operating Systems (BOS) for Health Care Organizations–[Requirements for Process Improvements to Achieve Excellence](#)” is and how it can be practically used to implement 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, AIAG 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 International Workshop Agreement (IWA), a new category of ISO document. In September 2000, ISO approved the proposal. An international workshop was convened in late January 2001. Agreement was subsequently reached, and IWA 1 was released in September 2001. ISO 9000 standards were developed to assist organizations of all types and sizes implement and operate a quality management system.*

ISO rules call for a six-year limit on IWA documents so in late 2006 AIAG elected to prepare a “hybrid” replacement document based on the Malcolm Baldrige Health Care Criteria for Performance Excellence, ISO 9001 as well as industry best practices applicable to the health care sector. The new document title is ‘Business Operating Systems (BOS) for Health Care Organizations – Requirements for Process Improvements to Achieve Excellence’. This hybrid approach has already resonated well with those who have reviewed it because it offers practical guidance to organizations of all maturity levels and provides a useful model for standards for other service sectors

### **WHY THE AUTOMOBILE INDUSTRY CARES...**

In its second major report, “Crossing the Quality Chasm: A New Health System for the 21<sup>st</sup> Century,” the Institute of Medicine (IOM) reported that Americans invest some \$1.1 trillion dollars annually (2001 data, but was \$2+ Trillion in

2008) in the health care sector. This represents over 13% of the Gross Domestic Product (2001 data, but was ~18% in 2008). General Motors in North America alone spent over \$5 billion per year on health care (Approximately \$5.2 Billion in 2001 and \$5.6 Billion in 2006). This cost is the largest purchased component of the vehicle. Health care costs the domestic automotive industry billions every year. Even a 1% reduction in cost would save millions annually. Subsequent to this, in January 2007, the McKinsey Global Institute published a report stating, “The United States spends more of its wealth on health care than any other developed country, and that share is rising. In 2005, the United States spent \$1.9 trillion or 16 percent of GDP, on health care, up from \$1.7 trillion, or 15 percent of GDP, in 2003.”

In late 1999, 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 in hospitals. This number reported is more than those who die from causes such as car accidents, guns, AIDS, workplace injuries or breast cancer. 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.

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 much worse.

The Centers for Medicare and Medicaid Services in 42 CFR Part 482 reports the health care 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 Golden, Colorado-based health care quality rating and advisory services company, published a report saying that approximately 192,000 patients lose their life due to errors in healthcare each year. 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 192,000 patients die annually in the U.S. because of preventable errors in 16 categories of patient-safety incidents. This puts deaths by errors in health care at approximately sixth on the list of causes of death. As a comparison, the number of military personnel who died in Iraq since the invasion in March 2003 until December 2006 was 3150. If this number is annualized and divided into the 192,000, it would take about 220 years of the war to kill as many as health care errors kill in one year.

In their Fourth Annual Study published in April 2007, Health Grades reported that approximately 1.16 million total patient safety incidents occurred in over 40 million hospitalizations in the Medicare population, which is almost a three-percent incident rate. These incidents were associated with \$8.6 billion of excess cost during 2003 through 2005. More than half (10 of 16) of the patient safety incident rates studied worsened from 2003 to 2005. These ten indicators worsened, on average, by over 11.5 percent while the other six indicators improved, on average, by eight percent. The total patient safety incident rate worsened by an additional 2.0 incidents per 1,000 hospitalizations in 2005 compared to 2003. Of the 284,798 deaths that occurred among patients who developed one or more patient safety incidents, 247,662 were potentially preventable.

### **BENEFITS OF THE “BOS”**

There are now over 700,000 organizations third party certified as compliant to ISO 9001 worldwide, but only a few are in the health care sector. In 1997, a senior GM executive asked if ISO 9000 could be applied to health care as it had been to the production materials supply chain with QS-9000 for significant improvements in quality and cost. (ISO literally means “equal” but is also known as the acronym for the International Organization for Standardization.) Surveys by the Automotive Industry Action Group (AIAG) and the American Society for Quality (ASQ) documented 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. (QS-9000 has been replaced with ISO TS 16949 and is based on ISO 9001.) 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 BOS 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 throughout the organization, through-put, cost, purchased product, documentation control, problem solving, patient communications, and control of measuring/monitoring equipment. The ISO-9000 based system also helps with regulatory compliance, risk management and consideration of new initiatives or innovation.

The health care organizations that have implemented Malcolm Baldrige National Quality Award health care criteria have also seen significant improvements. SSM Health Care in St. Louis was the first hospital to win the Baldrige Award. SSM Health Care representatives have published several articles or were interviewed for articles about the benefits achieved. Sister Mary Jean Ryan of SSM Health Care has made several appearances as a speaker on this subject. Mr. John Heer, North Mississippi Health Services, a winner of the Baldrige Award has also made several appearances as a speaker of this subject.

Baldrige Health Care criteria are better known and accepted in the USA than the ISO standards. As a result, the BOS document was developed based on 2006 Baldrige health care criteria with ISO 9001:2000 requirements and text from IWA-1 were inserted where applicable. The document went out to reviewers twice for review and comment to assure ease of use and understanding. Comments from these health care practitioners and others were added to improve the document.

## **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:

- 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 21<sup>st</sup> 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 health care on this scale.

The National Academy of Engineering and the IOM 2005 report “Building a Better Delivery System: A New Engineering/Health Care Partnership” suggest the following aims. The committee proposes six aims for improvement to address key dimensions in which today’s health care system functions at far lower levels than it can and should. Health care should be:

- Safe—avoiding injuries to patients from the care that is intended to help them.
- Effective—providing services based on scientific knowledge to all who could benefit and refraining from providing services to those not likely to benefit (avoiding underuse and overuse, respectively).
- Patient-centered—providing care that is respectful of and responsive to individual patient preferences, needs, and values and ensuring that patient values guide all clinical decisions.

- Efficient—avoiding waste, including waste of equipment, supplies, ideas, and energy.
- Equitable—providing care that does not vary in quality because of personal characteristics such as gender, ethnicity, geographic location, and socioeconomic status.

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 using standards based on ISO 9001. The acceptance by these industries should point the way for health care. By combining ISO 9001 and Baldrige with proven industry “best practices” for lean, quality and efficiency, the developers believe that a better management system can be achieved in organizations of any maturity level.

### **THE HARMONIZATION OF SIMILAR ISO 9001:2000 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 9001:2000 based application document for health care plans and providers. Also in 1998, the ASQ Health Care Division, made up of some 3000 health care professionals, decided that a committee should investigate the use of ISO 9000 series of standards in health care. The original goal was to develop a document that would help interpret ISO 9001:2000 for health care, but exempt those entities already covered by other national standards, e.g. pharmaceutical and durable medical equipment manufacturers. It was also decided to stay focused on humans and not animals. This does not say a veterinarian office should not consider the use of the BOS.

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. Most 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. The Baldrige criteria for health care were published a little later.

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 were accomplished as was called for in the new IOM report.

In September 2000, ISO approved an AIAG/ASQ proposal to develop an ISO Industry Workshop Agreement (IWA) [the document type name changed after this to International Workshop Agreement] document using the 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 health care “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 2001.

The IWA-1 was published and presentations were done to raise awareness. In Europe and Latin America, the document was accepted much better than in the USA. Therefore, after 5 years, a plan was developed to write a document that would be better accepted in the USA. This document was to be based on the Malcolm Baldrige National Quality Award health care criteria and have ISO 9001 and IWA-1 text inserted where appropriate. The AIAG undertook the role of sponsoring this document and was the publisher.

The BOS is a health care user-friendly guide to implementing or improving a management system. It does not tell a provider how to provide the care, but does give guidance on what elements of a system should be in place to manage all the processes associated with providing care to patients. The protocols and pathways should be adopted after review of known best practices for providing care. Dr. Donald Berwick once stated that it takes about 15 years for a new technology (protocol) to be deployed throughout the USA health care system. This means that by the time some of the later adopters get on board, the protocol may be obsolete. Organizations should benchmark the latest systems and methods, and implement “best known practices” to assure delivery of world-class care at the optimal efficiency and cost.