

119: USING THE ISO INDUSTRY WORKSHOP AGREEMENT (IWA 1) TO SPAN THE HEALTH CARE QUALITY CHASM

Author:

Reid R.D.

Objective:

This paper shows how the International Organization for Standardization (ISO) Industry Workshop Agreement (IWA 1) was developed and how its practical guidance can be used to implement Institute of Medicine (IOM) recommendations.

Methods:

Last year the IOM published "Crossing the Quality Chasm: A New Health System for the 21st Century". It describes how the health care delivery system can be redesigned to improve care and proposes an "agenda" supported by concrete 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-based documents. Agreement was reached in 2000 to work 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. In September 2000 ISO approved their proposal. An international workshop was convened in January 2001. Agreement was subsequently reached, and IWA 1 was released in September 2001.

ISO 9000 was developed to assist organizations of all types and sizes to implement and operate a quality management system. Since 1994, several industries, including medical devices and food services, have implemented ISO 9000-based requirements.

Some say that quality improvement principles widely applied in other industries with significant success are not applicable to health care. However, the IOM report states that application of these principles to the health care sector is the critical first step in improving patient safety. It recommends that the Agency for Healthcare Research and Quality with others convene workshops involving representatives from health care and other industries to identify and implement state-of-the-art approaches to address the challenges of redesigning healthcare delivery.

The intent of IWA 1 is to:

- Improve delivered health service quality and safety through: 1) complementing 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 ISO 9000 sector-specific documents, e.g. medical devices (*ISO 13485*), 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.

This abstract is submitted for consideration as an oral presentation directly addressing Stream 3 topics.

Results:

AIAG and ASQ surveys report that a similar ISO 9000-based document (QS-9000) provided a 3:1 return for all costs to implementing organizations, and nearly 17:1 return for "out-of-pocket" certification costs. Organizations averaging US \$130 million in sales reported average savings of 6% of sales (US \$8 million). About half of these reported quality improvement of nearly 50% in the first three years of implementation. In addition to cost and quality, they also reported 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 more years. To date, health care organizations who have implemented an ISO-9000-based system have reported benefits including increased customer satisfaction, standardized operations, faster through-put, reduced cost and continuous improvement.

Conclusion:

Change and improvement do not come easy. To improve we must continually change. ISO 9000 is largely unknown to the health care sector. Using principles successfully implemented outside of health care, IWA 1 can be used to guide the redesign of health care delivery systems and processes the IOM calls for.