

Call to Action: The Future ISO 7101 Healthcare Quality Management Systems Standard

Angela McCaskill, Independent Researcher, USA*

ABSTRACT

Low quality healthcare services can hinder economic and social development, result in premature death and disability, and waste human capital. To compound pre-pandemic healthcare access and equity issues, the quality of care that is delivered in low, lower-middle, as well as in high-income OECD countries can be uneven, poorly funded, and without adherence to standardization. COVID-19 has highlighted the importance of high-quality healthcare, while exacerbating many challenges. How services are delivered and the underlying guidance or standards that support the delivery of high-quality care are not necessarily a part of the regular healthcare reform dialog. This position paper introduces a new standard, ISO CD 7101, that seeks to address problems and offer solutions for the quality of healthcare delivered globally. This paper describes the need for such a standard, its history, advantages, and how it answers the global call to action set forth by the OECD, the World Bank, and the World Health Organization.

KEYWORDS

COVID, Effectiveness, Efficiency, Equity, Health Systems Strengthening, ISQua, LMICs, OECD, Patient Safety, People-Centered Care, SDGs, Standardization, UN, WHO, World Health Organization

INTRODUCTION

Throughout much of the world access to, and provision of, high-quality healthcare has been scarce or unavailable, but the COVID-19 pandemic has pushed that challenge to a new and unprecedented level. Low quality healthcare services can hinder economic and social development, result in premature death and disability, and wastes human capital, which is the economic engine of many low- and middle-income countries (LMICs). According to a 2018 report from the Lancet Global Health Commission, “high-quality health systems could save over 8 million lives each year in LMICs” (Kruk et al, 2018, p. 1196). To compound pre-pandemic healthcare access and equity issues, the quality of care that is delivered in both LMICs, as well as in high-income OECD countries, can be uneven, poorly funded and without adherence to standardization. How services are delivered and the underlying guidance or standards that support the delivery of high-quality care is not necessarily a part of the regular healthcare reform dialog.

The Organization for Economic Co-operation and Development (OECD) is an intergovernmental organization with 38 member countries. These countries and their key partners represent approximately

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*Corresponding Author

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80% of world trade and investment (OECD, n.d.). In their publication *Health at a Glance 2019*, the OECD reports U.S. health spending data that raises cause for concern. In 2018, overall spending on health care in the U.S. was estimated to be the equivalent of more than \$10,000 for each resident. This amount was higher than all other OECD countries by a notable margin. This is an estimated 17% of the U.S. GDP, well above the 8.8% average of other OECD countries. Unfortunately, the increased spending did not yield considerably higher health outcomes when compared to its counterparts. The U.S. reports a lower life expectancy and worse avoidable mortality rates than the OECD average (OECD, 2019). The OECD later published a report on the European Union in 2020 stating, “In 2017, over 1 million premature deaths across EU countries could have been avoided through better prevention and health care interventions” (OECD/European Union, 2020, p. 176). The statistics for countries at all levels of economic rankings indicate a need for improved health systems and healthcare quality.

To compound the statistics for low quality healthcare globally, another significant and equally daunting challenge for all health systems throughout the world is the impending deficit of qualified and supported clinical providers. The WHO predicts a shortfall of 18 million health workers by 2030, mostly in LMICs. Their report warns that “countries at all levels of socioeconomic development face, to varying degrees, difficulties in the education, employment, deployment, retention, and performance of their workforce” (World Health Organization, n.d.-a). Increasingly healthcare organizations will have to explore new strategies, such as task shifting, increasing medical and nursing school admissions and practicums, and rethinking how to educate and upskill future healthcare providers (OECD, 2019). Ensuring that all clinical staff is working to their highest level of licensure and are in a supported work environment also drives the need for standard setting as it is one of the tenets of a high-quality health system.

Since the beginning of the COVID- 19 pandemic, quality of care continues to be a challenge. Health systems are overwhelmed and healthcare workers are in short supply. An article by Winkelmann et al. (2021) explains that the pandemic has put stress on staffing for multiple reasons. Some reasons include more workers needed to provide longer term care for patients in the ICU, workers often cannot find childcare and are forced to stay at home, some take a leave of absence or quit because of stress or burnout, and healthcare workers were more apt to be exposed to the virus and be forced to stay at home to recuperate. They state that “in April 2020, up to 20% and 13% of all recorded COVID19 cases in Spain and Bulgaria respectively were in health care workers” (Winkelmann et al., 2021, p. 6). The quality of care rendered is consequential when staffing is not adequate to meet patient loads.

While COVID-19 has stretched some healthcare systems to an uncomfortable inflection point, the post-pandemic recovery provides an opportunity to embrace new ways of delivering care (telehealth, utilizing real time reporting systems to inform public health authorities about disease patterns and decision making, etc.). The healthcare sector has reacted quickly, finding creative ways to deliver care. Unfortunately quality and patient safety are often sacrificed in the process (Braithwaite, 2021). These opportunities to apply new knowledge and strategies learned in a post pandemic world is exciting. However, if this work is not based on measurable standards that can be verified and internationally disseminated, much of the new technologies and lessons learned during the past two years could be lost. As COVID-19 has repeatedly demonstrated, the virus respects no international borders, and thus developing stronger, standards-driven healthcare systems that can truly deliver high-quality care can help minimize future pandemic risks, and lead to stronger health systems and improved population health and well-being.

History of a New ISO Standard for Healthcare Quality Management

The International Organization for Standardization (ISO) is an independent, non-governmental international organization that develops voluntary consensus standards. ISO was founded in 1946 and at that time, represented 25 countries. Today, it has a membership of 165 national standards bodies (representing 165 countries), and it is through collaboration between these standards bodies that ideas and research become globally adopted guidelines and standards (ISO, n.d.-a). As of 2021, ISO has

developed over 24,115 International Standards that cover everything from manufactured products and technology to environmental management systems (ISO, n.d.-b).

ISO is not an accreditation body nor a certification body, and as such it does not offer consulting or assessment services. ISO is purely an international consensus standards developer. This is important because it removes the bias or financial interest that may be inherent in organizations that create guidelines and standards, while at the same time offering consulting and certification or accreditation services. This neutrality is a noteworthy differentiator between ISO and other standards developers.

Standards are created through the work of specialized technical committees (TC). Guided by their strategic business plan, members of each TC collaborate to write standards within the defined scope. As of December 2021, there are 255 TCs. Technical Committee (TC) 304 Healthcare Organization Management was developed to create standards that focus on the non-clinical aspects of healthcare delivery (ISO, n.d.-c).

While there are ongoing discussions about the organization and financing of health services across nations, agreed upon standards of how to manage delivery of care has not been previously disseminated in-depth. As such, underpinning the work of TC 304 is the need to strengthen health systems through improved quality of care. With the goal of equipping organizations with tools needed to improve healthcare quality worldwide, ISO TC 304 submitted a new work item proposal and justification study to the ISO Technical Management Board (TMB) for the creation of a Healthcare Quality Management System Standard. In November of 2020, the justification study was approved by the ISO Technical Management Board, and the new work item proposal was approved by TC 304 member countries.

In accordance with the ISO process for the creation of standards, Work Group (WG) 5 was established to write the standard. Work groups are formed by experts who are nominated by their country's standards body to contribute to the work of a specific standard. WG 5 is comprised of global health experts from ministries of health, the International Society for Quality in Health Care (ISQua), WHO consultants, leaders in patient safety, healthcare accreditation, risk management and people-centred care. Members represent government, private, and non-profit interests. Some of the members are practicing physicians and/or healthcare quality managers and directors of their organizations. Diversity is at the core of the group with members spanning the globe from Chile to Nigeria to Japan. According to the World Bank's July 2021 classification of countries into low, lower-middle, upper-middle-, and high-income categories, the work group has representatives from all of the identified income categories.

ISO numbered the standard 7101 and it currently has the designation of Committee Draft (CD). As the standard passes through the required stages of approval, the designation of "CD" changes, but the number remains the same. The first draft of CD 7101 was submitted for vote on August 19, 2021. The draft was approved by member countries on October 15, 2021; however, numerous comments were received that, per ISO standard requirements, must be addressed before the standard can proceed to the next stage. WG 5 is currently addressing those comments and will begin the edited draft in January of 2022.

Advantages of the ISO 7101 Healthcare Quality Management System Standard

International Recognition and Acceptance

The ISO 9001 Quality Management Systems Standard (MSS) is arguably the most recognized standard of all time, and currently there are over one million organizations in over 170 countries certified to ISO 9001 (ISO, n.d.-d). With its roots in the widely recognized management technique called the Deming Cycle, the standard is based on a four-step iterative process that allows management to "plan-do-study-act" (also referred to as PDSA) to ensure organizations meet the needs of their customers and other stakeholders more effectively (The Deming Institute, n.d.). The ISO 9001 standard requires participation and endorsement of top management to support the development of quality systems

based on a process approach that involves planning, risk management, monitoring, evaluation, correct action and continual improvement.

The currently proposed ISO standard CD 7101 builds on the foundation of ISO 9001, with a sizable number of additional requirements unique to the healthcare sector. Like ISO 9001, CD 7101 is a Management Systems Standard (MSS). All ISO MSS follow a similar structure so that they address critical management system requirements such as top management commitment, a quality policy and objectives, planning, risk management, a nonconformance and corrective action mechanism, internal audits, management review, and continual improvement.

The MSS also have a similar structure so that they can be assessed simultaneously (ISO, n.d.-e). One of the benefits of using this structure is it allows organizations to undergo simultaneous assessments to multiple ISO standards. For example, an organization can be audited to ISO 14000 Environmental Management Systems and ISO 9001 Quality Management Systems at the same time, which allows for improved resource utilization and continuity. Following the MSS structure, CD 7101 allows for the same type of joint assessments in existing ISO certified organizations. This will also allow entities seeking initial certification status to strengthen multiple operating systems in the same period of time to ensure an optimal outcome to all systems. Thus, the addition of ISO 7101 is a welcome addition the internationally recognized ISO community.

Global Collaboration, Holistic Focus

While there are several healthcare quality standards that are internationally or nationally recognized, the more widely adopted guidelines and standards often originate in western, high-income countries. Frequently these standards are adopted by LMICs and may or may not be relevant as per the health system in which the provider operates. These standards were authored for countries with high insurance penetration as well as safety-net care which ensure that most people have some type of access to care, regardless of their ability to pay. There is often limited international input and collaboration when creating healthcare standards that are viable in many international settings.

Moreover, many existing healthcare related standards have an intentionally narrow focus by type or setting of services. Examples include accredited palliative care programs, cardiac catheterization laboratories, emergency management, and behavioral health units. While these types of service line programs are important, there is still an overarching need for a comprehensive, holistic set of standards that take the ISO MSS approach which can be applied across the entire organization.

Global Consensus and Understanding

ISO standards are created by country member bodies. Any country that is a member of ISO can create a technical committee to write and vote on potential standards. This means that technical committee members from each country are the individuals who meet to discuss, collaborate, and create the content of standards. Once a proposed standard is presented for vote, each country gets one vote, regardless of its size, GDP or other defining feature. Currently, ISO TC 304 Healthcare Organization Management, has 48 member countries who have a voice in the creation of CD 7101. The 48 member countries are a subset of ISO's 165 member countries and any of these countries may create a TC 304 and contribute to CD 7101 (ISO, n.d.-a).

ISO standards create an agreed upon vocabulary and are international reference points for talking about a subject matter. This mutual understanding breaks down borders, encourages trust, and fortifies collaboration. The ISO process for creation of standards is an open dialog to facilitate commonly understood best practices for quality healthcare across the globe and helps develop interoperability in healthcare organizations.

Content in Agreement With Leading Expertise

CD 7101 was strategically created based on the most current literature and expertise from global health leaders. In July of 2020, the World Health Organization (WHO) published that, while multiple quality

elements have been described over the past decades, there is a clear consensus that quality health services should be: effective, safe, people-centred, timely, equitable, integrated and efficient (World Health Organization, n.d.-b). CD 7101 addresses all of the above WHO criteria, outlining requirements for health systems that are: efficient, effective, people-centred, timely, safe and equitable. The only subject the standard does not specifically address by the same name is that of “integrated.” However, the standard does address aspects of integrated care such as communication among healthcare workers, specialists, referrals, hand-off between providers, and transport to other care facilities.

Further in agreement with timely, expert thought, a recent article about healthcare quality describes a multidimensional model of care. The model outlines domains of quality for the new era of health: safe, effective, efficient, accessible and timely, equity and eco-friendly. (Lachman et al., 2021). It is significant to note that ISO CD 7101 includes all of these dimensions of the quality of care model.

United Nations Sustainable Development Goals (SDGs)

The UN Sustainable Development Goals (SDGs) are “a universal call to action to end poverty, protect the planet and ensure that all people enjoy peace and prosperity” (United Nations Development Program, n.d., center of page). The goals were adopted in 2015 and have a target obtainment date of 2030. CD 7101 encourages the inclusion and obtainment of the SDGs. When submitting a new work item proposal for a standard, ISO requires that the proposer indicate how the standard will strive to address the SDGs. CD 7101 addresses the following SDGs: 3 Good Health and Well-being, 8 Decent Work and Economic Growth, 9 Industry Innovation and Infrastructure, 10 Reduced Inequalities, and 11 Sustainable Cities and Communities (ISO, n.d.-f). CD 7101 also makes an innovative reference to the UN SDGs stating that organizations should consider the SDGs when planning quality objectives.

CONCLUSION

The OECD, The World Bank, and WHO (2018) joint published, *Delivering quality health service. A global imperative for universal health coverage*. In this report they argue, “But even if the world achieved essential health coverage and financial protection, health outcomes would still be poor if services were low-quality and unsafe” (p.5). They issue a “call to action” to achieve high quality, people-centred health services, and for stakeholders to work together with a sense of urgency to obtain the SDGs for better, safer health care. I submit that the implementation of ISO 7101 by ministries of health, health systems, hospitals, clinics and any organization providing health services, is a notable response to the global call to action.

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APPENDIX

See Figure 1 for the process for drafting ISO CD 7101 healthcare quality management system.

1. A Justification Study is required by ISO when a new Management System Standard is proposed. The study ensures need, relevancy, and helps identify overlaps or potential conflicts with existing standards.
2. A detailed proposal called a New Work Item Proposal (NWIP) is required prior to writing a standard. It is used to confirm that a new International Standard in the subject area is needed and globally relevant. The NWIP was approved on November 20, 2020.
3. An official Work Group (WG) was formed of experts who are writing the standard. Each new WG is given a number. The Healthcare Quality Management group is WG 5, and it has a roster of 61 committee members and expert liaisons, representing 23 countries, and five continents.

Figure 1. Process for drafting ISO CD 7101 healthcare quality management systems standard



4. In order to facilitate focused writing by experts in specific topics, WG 5 divided into seven subgroups. Each subgroup addressed one of the main themes of the standard: Governance, Patient Safety, Efficiency and Effectiveness, People-Centered Care, Risk Management, Performance Evaluation and Information Management Systems.
5. Once subgroups were formed, the experts started a 3-month writing process during which subgroups met weekly, and sometimes biweekly.
6. On August 19, 2021, CD 7101 was sent to TC 304 member countries for vote. At that time, member countries could reject, accept, or abstain. They also had the opportunity to make comments on the draft, using a commenting template provided by ISO. The draft was approved by member countries on October 15, 2021; however, numerous comments were received that, per ISO standard requirements, must be addressed before the standard can proceed to Draft International Standard (DIS) stage.
7. At the time of submission of this article, WG 5 is meeting every two to three weeks to respond to the comments received by member country experts. Comments may be technical, general or editorial.
8. Once WG 5 has consensus on the changes made to the draft, the draft will be sent back out for vote by member countries. As in the previous vote, comments can be made, and must be addressed by WG 5. This Draft (DIS) vote is a 12-week ballot.
9. WG 5 will once again respond to any comments received in the above ballot process.
10. When the DIS is approved and no more substantive comments are received, the standard proceeds to the Final Draft (FDIS) stage. FDIS vote is an eight-week ballot.
11. If the Final Draft is approved with no substantive comments, it becomes an official ISO publication and is translated into English, French, and Russian.

Angela McCaskill is a Registered Nurse with a master's degree in Global Health. Throughout her career she has delivered patient care in a variety of settings including medical-surgical, family clinics, the emergency department, rehabilitation, and hospice care. Ms. McCaskill is a specialist in the management of non-transmissible chronic conditions and has worked as a patient educator for diabetes, hypertension, metabolic syndrome, and rare, genetic disorders. She is an advocate for high quality healthcare and leads a team of 60 global health experts who are writing an innovate healthcare quality management standard for the International Organization for Standardization (ISO) based in Geneva. Angela's passion is to collaborate with individuals in low and low-middle income countries to empower healthcare workers and strengthen health systems.