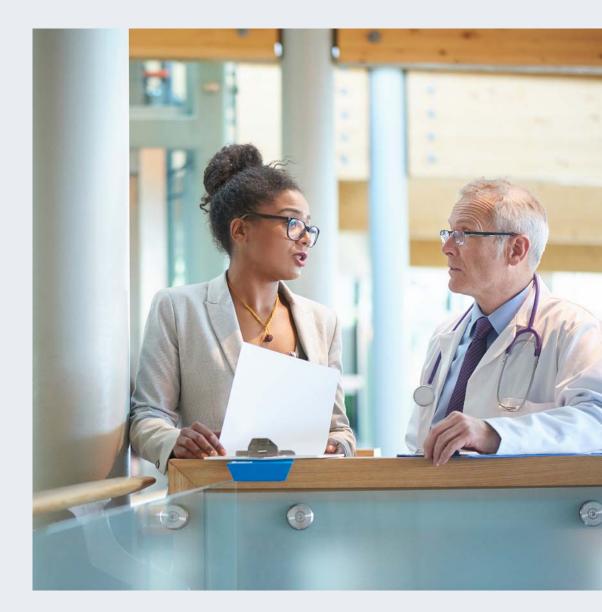# ● BS ISO 7101:2023

Healthcare organization management – Management systems for quality in healthcare organizations – Requirements

A BSI executive briefing

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By Royal Charter

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Contents

Overview

Healthcare is facing three sustained threats and has done for many years. Increasing demand from aging populations, decreasing funding in comparison to this demand, and an international workforce shortage.

This triple threat is only anticipated to become more problematic with multi-morbidities being prominent across an ever-aging population (The Health Foundation, 2023). Since 2020 healthcare organizations around the world have faced a fourth and terrifying threat, COVID-19. This resulted in excess deaths and changes to ways of working which require a balance between finances and quality. Whilst no organization would ever wish to consciously diminish the quality of service they provide, this is an inevitable fact of operating with these threats without a continuous focus on quality.

Quality is therefore expected to be protected across organizations, and mechanisms are required to safeguard this approach.

BS ISO 7101:2023 has been developed to initiate a movement that improves the quality of healthcare around the world through a structured management system, providing key quality metrics which organizations can implement to achieve higher and better quality.

When considering healthcare quality, there are several attributes that are the fundamental building blocks to critique and identify whether quality has a focus within a healthcare organization. These attributes described by the World Health Organisation (WHO, n.d.), and enhanced by Lachman et al (2020), are:

- **Effectiveness** – Healthcare that is effective is based on scientific evidence and produces the desired pre-identified outcomes, and ultimately improves the lives of patients, or a population, or the working environment for the workforce.

- **Safety** – The minimization and elimination of any forms of harm to a patient, a population, or the workforce.

- **Accessibility and timeliness** – Healthcare is easily accessible to those who need it, and available when it is needed.

- **Efficiency** – Resources are used well to provide maximum value to the payer (whether that is funded through taxation, insurance, or individually paid) and that waste is minimized across the organization.

- **Equity** – Services are provided to all patients regardless of their personal characteristics, such as race, religion, ethnicity or socioeconomic status.

BS ISO 7101:2023 identifies critical areas to support these attributes, improving the management approach to quality. The areas assist the development of an organization focused on healthcare quality and include:

- leadership, including healthcare policy;

- planning, including risk;

- communication;

- documentation, including audits to check implementation and effectiveness;

- operational aspects such as facilities, waste, management and technology;

- people-centred care, such as inclusivity, diversity, co-production and wellbeing;

- education and training;

- patient safety mechanisms;

- performance evaluations, including methods and reviews; and

- continuous improvement, including conformity.

Overall, this standard is designed to improve the wellbeing of patients, populations and the healthcare workforce by taking a systematic approach that requires healthcare organizations to have the tools, procedures, and processes to support quality outcomes.

Target audience

This standard identifies quality as a critical component for the improvement of the management of healthcare organizations, therefore its target audience in the first instance is top management and quality experts, with the wider audience of commissioners of healthcare services, insurance companies and regulators who want assurance of the quality of organizations providing healthcare.

The standard can be utilized by any healthcare organization, regardless of size or location, and is just as applicable across healthcare systems of multiple healthcare organizations combined, i.e. integrated care systems and those involved in the care continuum.

Academics and consulting services can use this standard to support the improvement of healthcare quality, either through research or interactions.

Commissioners of healthcare have often considered the quality aspects for delivering a service, and the introduction of BS ISO 7101:2023 will provide a framework for implementing quality approaches which can specify certification against the standard as part of a commissioning and contracting process.

This is the first international standard specifically designed for healthcare quality that identifies additional areas not addressed by iterations of other standards adapted for healthcare.

Benefits of using the standard

The accessibility and outcomes of healthcare interventions have a significant impact on the economic environment of a locality and country. If access and outcomes from healthcare are poor, then there is a reduced working population contributing economically.

This standard creates the conditions for any size of healthcare organization to implement actions that, when met, ensure the provision of a quality service, thus improving the experience and outcomes of patients and populations.

Successful implementation and certification of the standard is likely to improve patient experience and satisfaction, therefore making the organization more attractive to patients, whilst improving its overall reputation among the public. This can also improve workforce recruitment and retention, including the improvement of wellbeing of the workforce across an organization. The improvements for patients and the workforce suggest a well-led, effective, safe, responsive and caring (Care Quality Commission) organization indicating that the organization is more likely to be performing against all pre-defined metrics required by healthcare organizations.

Achieving this can permit more devolved responsibility from commissioners or governments, which reduces bureaucracy on organizations where this resource can then be reinvested into improving quality and service delivery across healthcare. Additionally, these improvements could then allow for increased funding opportunities from research institutes and the trial of new pioneering services for patients and populations.

How to implement BS ISO 7101:2023

The introduction of this standard will be transformational in the healthcare environment. The ability for organizations to implement the standard will be based on where they consider their current quality approach to be, which is likely to be within one of three areas: emerging, developing or matured.

Where organizations are emerging in their quality approach, the implementation of the standard would give clarity on direction and provides a structured approach to implementing quality changes overall and removes the guesswork of what to include.

If an organization is developing their quality approach, the suggested methodology is to match the standard to their current approach to produce a gap analysis, which will indicate current areas of overlap or areas requiring further action. This will allow for the organization to develop its approach and to comply with the standard.

Where an organization has a matured approach to quality, the implementation of the standard provides a good assessment of the maturity of the organization's quality system. BS ISO 7101:2023 can be utilized as an audit tool and, following the audit, an action plan can be developed which supports ongoing improvements to attain full compliance with the standard. Considering that this standard contains the latest evidence on quality, it is expected that organizations will have opportunity to identify this new practice for their own implementation.

The standard is underpinned by the quality improvement cycle: Plan, Do, Study, Act (PDSA). This is also a methodology for implementing the standard in healthcare organizations, regardless of their size or location. Utilizing the PDSA model takes a logical approach for implementation whether the organization is emerging, developing, or matured, and would evidence an appropriate approach for standard compliance.

Challenges and limitations

Healthcare organizations have a multitude of priorities issued to them from regulators, policy makers and governments.

This therefore restricts a concerted effort of focus on quality, particularly whilst threats exist as outlined earlier in this briefing. Some of these requirements would contain a quality priority which this standard supports.

Given that healthcare is primarily about the outcome of services, there is sometimes a mixed understanding of what constitutes a quality approach and it can often be subjective to individuals. This standard identifies the key criteria which inform a quality approach and is based on current evidence as well as being developed by a considerable number of international healthcare experts, therefore minimizing any mixed understanding.

Each organization might have their own approach to quality, and the adoption of this standard could require a significant investment of time and resources. Similarly, some organizations could be in a better position with a mature approach to quality, which only requires certification of the standard.

The standard does not go into detail for each aspect identified as a mechanism to achieve quality, as it sets out a systematic approach to quality, and therefore links to other international standards which would require consideration by potential adopters.

Wider context

The new standard is written within the harmonized structure for management system standards and provides a consistent approach with other management system standards.

The threats outlined earlier in this briefing highlight the importance of quality across healthcare, with organizations, regulators and commissioners seeking solutions that can recover healthcare following the impact of the pandemic.

Across healthcare there are additional strains as well as the sustained threats. These strains include ongoing industrial action (in the UK) by healthcare professionals which further exacerbates the threats, and diminishes quality for patients, populations, and the wider workforce too. Furthermore, there are risks identified for viruses that could result in epidemics or pandemics, which would impact significantly on healthcare and further reduce the ability for

resourced efforts on quality due to the necessity of being responsive to higher volumes of patients

Additionally, anti-microbial resistance is a concern internationally as this can impact the effectiveness of medicine, resulting in more people being unwell or hospitalised with traditionally treatable issues. International effort is concentrated on this matter and the improvement to general infection prevention controls. Standards continue to be developed for pandemic preparations which are designed to provide a mechanism for better preparedness that reduces the negative impact on wider healthcare outcomes.

Next steps

This standard presents the opportunity to enhance the healthcare experience of many people, and therefore improve communities and populations as a whole. It is suggested that users communicate this standard and its publication to leaders across healthcare organizations, regardless of their size, as well as to healthcare regulators, healthcare insurance companies, quality experts and aspiring leaders. Universities teach quality to all healthcare students, as part of leadership development and this standard would be beneficial to that sector, as well. Organizations can then undertake a review of their quality management approach against the standard and make improvements where required to reach compliance, identifying the actions required to do this.

It is suggested that organizations benchmark their current quality metrics before implementing the actions, to measure the effectiveness of introducing the standard and review their quality metrics at appropriate intervals on successful implementation.

Further reading

WHO. (n.d). **Quality of care**. *Overview. Available at: https://www.who.int/health-topics/quality-of-care#tab=tab_1*

Care Quality Commission (nd) **The five key questions we ask** *available from: https://www.cqc.org.uk/about-us/how-we-do-our-job/five-key-questions-we-ask [Accessed 31 July 2023]*

BS EN ISO 19011:2018, *Guidelines for auditing management systems*

BS ISO 22886:2020, *Healthcare organization management — Vocabulary*

*Lachman, P., et al. (2020) "***A multidimensional quality model: an opportunity for patients, their kin, healthcare providers and professionals to coproduce health***." F1000Research, 9, 1140.*

The Health Foundation (2023) REAL Centre – **Health in 2040: projected patterns of illness in England**.

The power of standards, *https://www.bsigroup.com/en-GB/standards/explore-standards/the-power-of-standards/overview-guide-to-implementation/*

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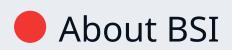
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