

**ISO/TC 304 "Healthcare organization management"**Secretariat: **ANSI**Committee manager: **Webster Lee Mr****ISO/TC 304 Strategic Business Plan (Revised) 29 August 2022**

Document type	Related content	Document date	Expected action
Ballot / Reference document	Ballot: ISO/TC 304 Strategic Business Plan Approval Ballot (restricted access)	2022-08-30	VOTE by 2022-09-30

Description

The ISO/TC 304 TG1 respectfully submits this revised TC 304 Strategic Business Plan to the TC for review and approval. A ballot has been created. This ballot closes on 30 September 2022.



BUSINESS PLAN

ISO/TC 304

Healthcare Organization Management

Executive summary

Healthcare Organization Management (HOM) describes the leadership and general management of hospitals, hospital networks, and/or health care systems. The sheer size and complexity of varied international approaches to healthcare systems means that HOM may encompass everything from policy making, to human resources, to department management and beyond. Depending on the type and size of the healthcare system, HOM often involves numerous teams working in unison to manage the system at every level. Regardless of the organizational structure, the goal is the same: to ensure the coordinated delivery of healthcare, efficient management of resources, and effective, safe, people-centred care.

Recent and future health trends, including an aging world population, a shortfall in the number of needed healthcare workers, natural disasters and pandemic, changing healthcare payment systems, and digital health technology, all represent opportunities for new standards in the area of HOM.

The international standardization community has been instrumental in establishing standards for medical devices and laboratories; however, less work has taken place in the administrative/management space. The proper application of voluntary standards to HOM can help control the costs of the non-clinical functions that support principal operations, while improving service user satisfaction and outcomes. The goal of TC 304 is to provide the HOM tools that allow healthcare systems to build a firm foundation from which clinical practices might arise. The premise of HOM asserts that more financial and other resources can be liberated to serve clinical goals and patient care imperatives if the non-clinical aspects of the healthcare experience are better managed and focused on service user needs and outcomes.

Current TC 304 efforts may include, as examples, the following areas: healthcare supply chain, capital (financial) management, patient admission and discharge approaches, human resource and facilities management that are specific to healthcare facilities, new technologies, management of healthcare related data, and service user experience. For the purposes of the committee's work, healthcare entities are those organizations "whose principal operations consist of agreeing to provide health care services, and entities whose primary activities are the



planning, organization, and oversight of such entities, such as parent or holding companies of healthcare providers.”¹

Introduction

1. ISO technical committees and business planning

1.1. The extension of formal business planning to ISO Technical Committees (ISO/TCs) is an important measure which forms part of a major review of business. The aim is to align the ISO work programme with expressed business environment needs and trends and to allow ISO/TCs to prioritize among different projects, to identify the benefits expected from the availability of International Standards, and to ensure adequate resources for projects throughout their development.

1.2. International standardization and the role of ISO

The foremost aim of international standardization is to facilitate the exchange of goods and services through the elimination of technical barriers to trade.

Three bodies are responsible for the planning, development and adoption of International Standards: ISO (International Organization for Standardization) is responsible for all sectors excluding Electrotechnical, which is the responsibility of IEC (International Electrotechnical Committee), and most of the Telecommunications Technologies, which are largely the responsibility of ITU (International Telecommunication Union).

ISO is a legal association, the members of which are the National Standards Bodies (NSBs) of some 164 countries (organizations representing social and economic interests at the international level), supported by a Central Secretariat based in Geneva, Switzerland.

The principal deliverable of ISO is the International Standard.

An International Standard embodies the essential principles of global openness and transparency, consensus, and technical coherence. These are safeguarded through its development in an ISO Technical Committee (ISO/TC), representative of all interested parties, supported by a public comment phase (the ISO Technical Enquiry). ISO and its Technical Committees are also able to offer the ISO Technical Specification (ISO/TS), the ISO Public Available Specification (ISO/PAS) and the ISO Technical Report (ISO/TR) as solutions to market needs. These ISO products represent lower levels of consensus and have therefore not the same status as an International Standard.

ISO also offers the International Workshop Agreement (IWA) as a deliverable which aims to bridge the gap between the activities of consortia and the formal process of standardization represented by ISO and its national members. An important distinction

¹ Prince PhD, Thomas R. 1998. Strategic Management for Healthcare Entities. Chicago. American Hospital Association. p.4.



is that the IWA is developed by ISO workshops and fora, comprising only participants with direct interest, and so it is not accorded the status of an International Standard.

2. Business Environment of the ISO/TC

2.1. Description of the Business Environment

The following economic, technical, regulatory, and social dynamics describe the business environment of the industry sector, and disciplines or practices related to the scope of this ISO/TC, and they may significantly influence how the relevant standards development processes are conducted and the content of the resulting standards.

The scope of the technical committee is, “Standardization in the field of healthcare organization management including classification, terminology, nomenclature, management practices and metrics that comprise the non-clinical operations in healthcare entities.”

Dynamics of Healthcare Organization Management

The recent COVID-19 pandemic exposed fissures in current management support systems. Frequent delays in manufacturing, distribution, and maintaining sufficient personal protective equipment during the early stages of the pandemic risked the lives of healthcare workers and service users. Telemedicine systems were caught unprepared, as large numbers of caregivers and patients were quarantined, and unable to meet and share vital information. Payment systems have been slow to adjust to billing patients who must receive treatment virtually. Facilities have been overwhelmed with unprecedented volumes of COVID-19 patients in their emergency rooms, and necessary treatment for patients with chronic conditions were delayed.

Economic:

A 2021 report from the World Health Organization states that global spending on health has doubled in real terms over the past two decades, reaching \$8.5 trillion in 2019 and 9.8% of GDP (up from 8.5% in 2000). Administrative costs now make up about 34% of total health care expenditures in the United States. This compares with the healthcare expenditure of the UK (16%) and the Netherlands (20%). A 2019 report from the WHO states that the health sector “continues to expand faster than the economy. Between 2000 and 2017, global health spending in real terms grew by 3.9% a year while the economy grew 3.0% per year.”

A report from Deloitte in 2019 states that, Global health care expenditures continue to escalate, shining a light on health systems’ need to reduce costs and increase efficiency. Spending is projected to increase at an annual rate of 5.4 percent in 2017–2022, from USD \$7.724 trillion to USD \$10.059 trillion, although cost-containment efforts combined with faster economic growth should maintain the share of GDP devoted to health care at around 10.4 percent over the five-year period to 2022.”

Technical:



Current thought leaders in health care organization management include writings from the World Health Organization, the OECD, The Lancet Global Health Commission for High Quality Health System, the Institute for Healthcare Improvement, the International Society for Quality in Healthcare, amongst others. Currently healthcare management standards exist and vary from country to country. Even within countries, requirements can vary from states, to regions, to departments, and to cities.

Examples of technical work that support and collaborate the goals of TC 304 are:

- ISO 14001: 2015 Environmental Management Systems – Requirements with guidance for use
- ISO 22301: 2019 Security and Resilience- Business continuity management systems
- ISO 22525:2020 Tourism and related services — Medical tourism — Service requirements
- EN 15224:2016 Quality Management Systems for Healthcare
- ISO 13485 Medical devices -- Quality management systems -- Requirements for regulatory purposes
- ISO 9001: 2015 Quality management
- Kruk ME, Gage AD, Arsenault C, Jordan K, Leslie HH, Roder-DeWan S, et al. High-quality health systems in the Sustainable Development Goals era: time for a revolution. *Lancet Glob Health* [Internet]. 2018; 6(November):1196–252. Available from: <https://linkinghub.elsevier.com/retrieve/pii/S2214109X18303863>
- World Health Organization. Handbook For National Quality Policy and Strategy [Internet]. 2018. Available from: http://www.who.int/servicedeliverysafety/areas/qhc/nqps_handbook/en/
- World Health Organization, World Bank, OECD. Delivering quality health services. A global imperative for universal health coverage [Internet]. 2018. Available from: <https://www.worldbank.org/en/topic/universalhealthcoverage/publication/delivering-quality-health-services-a-global-imperative-for-universal-health-coverage>
- WHO Quality Toolkit (launched online June 2022): <https://qualityhealthservices.who.int/quality-toolkit/qt-home>

The unavoidable, essential, and life-impacting nature of healthcare management and delivery is most effectively addressed by standards. There are few similar industries where the lack of standards could be so detrimental to the economy, education systems, labor force, and the well-being of humanity. As ISO has done throughout history with numerous and varied types sectors, it must also have a resounding international voice in the area of HOM. The breadth of regulatory approaches to manage the administration of healthcare vary widely due to the complexity of healthcare delivery systems, the payment systems of each country, and the cultural and societal norms that arouse passionate interest by local populations. These localized views and actions concerning health management, as shown by the recent pandemic, can impede the ability of healthcare providers to respond quickly to shared needs for human, capital, and logistical resources. There is no supra-regulatory entity to that can develop and implement the cross-boarder solutions that



are needed here. ISO through its standardization methodology can close the gap by developing interoperable standards that can be voluntarily adopted among its members.

Societal:

Population ageing is a global phenomenon: virtually every country in the world is experiencing growth in the size and proportion of older persons in their population. There were 703 million persons aged 65 years or over in the world in 2019. Almost 400 million of the population will be aged 80+. The number of older persons is projected to double to 1.5 billion in 2050. Globally, the share of the population aged 65 years or over increased from 6 per cent in 1990 to 9 per cent in 2019. That proportion is projected to rise further to 16 per cent by 2050, so that one in six people in the world will be aged 65 years or over. Conventional indicators of population ageing that are based on chronological age (years since birth), with a fixed threshold of “old age” at age 65, show that populations are becoming older in all regions of the world.²

A recent publication from the United Nations in June 2019, predicts that the world's population is expected to increase by 2 billion persons in the next 30 years. With this increase, the world's population is growing older, with age group 65 and older being the fastest growing. Along with this growth comes an increased demand for social protections systems, including well-functioning healthcare systems. Therefore, it is vital that health systems adopt HOM principles that result in cost-effective, high quality, patient-centered care.

Climate Change

As the world continues to face the consequences of climate change, the impacts on health, well-being, and spending are significant. Climate change affects the social and environmental determinants of health – clean air, safe drinking water, sufficient food and secure shelter. As of October 2021, the WHO predicts, “The direct damage costs to health (i.e. excluding costs in health-determining sectors such as agriculture and water and sanitation), is estimated to be between USD 2-4 billion/year by 2030.” The WHO (2018), further estimates, “Exposure to air pollution causes 7 million deaths worldwide every year and costs an estimated US\$ 5.11 trillion in welfare losses globally. In the 15 countries that emit the most greenhouse gas emissions, the health impacts of air pollution are estimated to cost more than 4% of their GDP.” Standardization in healthcare is a valuable tool for addressing health risks and consequences associated with climate change.

Workforce shortages

The World Health Organization predicts a “shortfall of 18 million health workers by 2030, mostly in low- and lower-middle income countries.” They warn that “countries at all levels of socioeconomic development face, to varying degrees, difficulties in the education, employment, deployment, retention, and performance of their workforce.” The American Hospital Association projects that “America will face a shortage of up

² ISO/TC 314 Aging Societies Strategic Business Plan (2020-09-18)

to 124,000 physicians by 2033, and will need to hire at least 200,000 nurses per year to meet the demand and replace retiring nurses.” OECD Health at a Glance 2021 reports that the ageing of the healthcare workforce is a reason for concern. They highlight Italy as an example, with 56% of its doctors over the age of 55. As more healthcare workers move towards retirement, organizations will have to explore new strategies such as task shifting, increasing medical school admissions and rethinking the educational paradigm for future healthcare providers. Standards in HOM are tools that may help address this shortage through risk and resource management, focused planning, improved education of the healthcare workforce

Changes in payer systems

One trend gaining popularity in some countries is the “value-based payment system.” This method of payment rewards healthcare providers and health organizations on the quality of care provided, not just the quantity. Examples of value-based programs include: hospital-acquired conditions, readmission reduction programs, and home health value-base program. Value-based programs often require the collection of data to determine obtainment of goals and metrics. HOM standards are a necessary tool for the planning, management, monitoring, and improvement necessary for a value-based payment system.

New technologies

A healthcare trend that continues to increase in size and importance is digital health, A 2020 statistic suggests that, “The global market size for telemedicine is projected to increase from around 45 billion U.S. dollars in 2019 up to nearly 180 billion dollars by 2026.” As the use of digital health grows, healthcare organizations will require documented processes to guide the safe and effective use of digital data. The COVID-19 pandemic has unexpectedly accelerated this trend, underscoring the need for standardization to respond quickly to unpredictable changes in the market.

McKinsey & Company reports a threefold increase in venture capitalist investment in virtual care and digital health from 2017 to 2020. They also report that telehealth utilization has “stabilized” at levels 38 times higher than before the pandemic.” Uptake of telehealth continues to grow, with both patients and providers viewing it more favorably than they did prior to COVID-19. Healthcare organization management will play a pivotal role in defining safe, secure and effective telehealth processes. Deloitte’s Global Healthcare Outlook 2022 emphasizes the need for healthcare leaders to balance the benefits of medical technology with the practicalities of controlling healthcare spending.”

Artificial Intelligence (AI) is the present and future of health care. According to the third annual Optum Survey on AI in Health Care 2020, 83% of healthcare organizations have an AI strategy in place, and another 15% are planning on creating one. Frost & Sullivan project sales of healthcare AI-enabled products to generate more than \$34.83 billion globally by 2025. AI can be used in multiple areas of healthcare service delivery including pharmaceutical AI, chatbots, Genomics AI, operations/supply chains, research of complex diseases, disease prediction, social



AI such as contact tracing, and the use of robots. Standards can be used to ensure the efficacy and safety of many new technologies, while streamlining vital processes.

2.2 Quantitative Indicators of the Business Environment

According to a [joint document](#) from the WHO, World Bank Group, and the OECD (2018):

- *In high-income countries, one in 10 patients is adversely affected during treatment*
- *Unwarranted variations in health care provision and delivery persist, and a considerable proportion of patients do not receive appropriate, evidence-based care*
- *Globally, the cost associated with medication errors has been estimated at \$42 billion annually, not counting lost wages, foregone productivity or health care costs*
- *Approximately 15% of hospital expenditures in high-income countries is used to correct preventable complications of care and patient harm*
- *Up to a fifth of health resources could be deployed much more effectively*
- *A survey of patients with complex care needs in 11 high-income countries found coordination problems, such as test results or records not available at appointment time or duplicate tests ordered, providers failing to share important information with each other, and specialists not having information about medical history or regular doctors not informed about specialist care.*
- *The broader economic and social costs of patient harm caused by long-term disability, impairment and lost productivity amount to trillions of dollars each year*

3. Benefits expected from the work of TC 304

TC 304 works towards the following goals in support of the 2015 [United Nations Sustainable Development Goals](#).

- ☒ GOAL 1: No Poverty
- ☐ GOAL 2: Zero Hunger
- ☒ GOAL 3: Good Health and Well-being
- ☒ GOAL 4: Quality Education
- ☐ GOAL 5: Gender Equality
- ☒ GOAL 6: Clean Water and Sanitation
- ☐ GOAL 7: Affordable and Clean Energy
- ☒ GOAL 8: Decent Work and Economic Growth
- ☐ GOAL 9: Industry, Innovation and Infrastructure
- ☒ GOAL 10: Reduced Inequality
- ☒ GOAL 11: Sustainable Cities and Communities
- ☒ GOAL 12: Responsible Consumption and Production
- ☐ GOAL 13: Climate Action
- ☐ GOAL 14: Life Below Water
- ☐ GOAL 15: Life on Land
- ☐ GOAL 16: Peace and Justice Strong Institutions
- ☒ GOAL 17: Partnerships to achieve the Goal

Goal 1: Reduce Poverty

- Social protection systems help prevent and reduce poverty. A health system is considered by the World Health Organization to be a social protection system.



Goal 3: Ensure healthy lives and promote well-being for all at all ages

- All of the targets (3.1 – 3.9) are related

Goal 4: Ensure inclusive and equitable quality education and promote lifelong learning opportunities for all.

- By 2030, substantially increase the number of youth and adults who have relevant skills, including technical and vocational skills, for employment, decent jobs and entrepreneurship

Goal 8: Decent work and economic growth

- By 2030, achieve full and productive employment and decent work for all women and men, including for young people and persons with disabilities, and equal pay for work of equal value.

Goal 10: Reduce inequality within and among countries

- Implement the principle of special and differential treatment for developing countries, in particular least developed countries, in accordance with World Trade Organization agreements.
- By 2030, progressively achieve and sustain income growth of the bottom 40 percent of the population at a rate higher than the national average.
- By 2030, empower and promote the social, economic and political inclusion of all, irrespective of age, sex, disability, race, ethnicity, origin, religion or economic or other status.

Goal 12: Ensure sustainable consumption and production patterns

- By 2030, substantially reduce waste generation through prevention, reduction, recycling and reuse.

Goal 17: Partnerships to achieve the goal

- Enhance international support for implementing effective and targeted capacity-building in developing countries to support national plans to implement all the sustainable development goals, including through North-South, South-South and triangular cooperation.
- Encourage and promote effective public, public-private and civil society partnerships, building on the experience and resourcing strategies of partnership.

Sub-goal 3.8: Achieve universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all. The development of a quality management standard for health care organizations will provide a framework for more cost-effective procurement, financial management and information management, enabling a greater share of resources for direct patient care.

Additional benefits are also projected below:

Consumers/Patients
Consumers of healthcare will benefit from slower increases in the cost of health care and the



resulting access to care
Consumers will be better protected against risks such as financial ruin, and health emergencies like natural disasters and political unrest/violence
Society in general will be better informed about the effectiveness of the management of their healthcare systems and gain access to a better quality of care
Population health will increase which leads to a decrease in poverty, an increased access to education, increased spending capacity, and increased quality of life
Consumers will have a documented way to verbalize their concerns and report low-quality care
Health Systems
Organizations that provide healthcare benefits will enjoy either a reduction in their benefits costs or more predictable, slower increase in the costs of coverage as efficiencies in healthcare management are transferred to the policyholders
Insurance companies and national ministries of health will more accurately monitor and compare the quality of management and assess cost control as they determine which healthcare entity provides the best value for their customers and populations
Developing countries and rural healthcare providers will more easily access and adopt the most effective practices and metrics of more established and better-resourced healthcare systems
Healthcare entities will enjoy the sharing of effective management practices that will drive better outcomes for patients and will reduce the increase in spending of non-clinical services,
Establishing healthcare organization management standards will reduce the cost of providing healthcare through the widespread adoption of interoperable metrics and practice
Labor
Employees working in health care organizations will have better training, which results in higher quality of care
Employees will have safer working environments, leading to less work-related injury (both physical and psychological)
Employees will feel valued and be empowered, thus reducing employee turnover
Employees will receive documented training, which will help them find jobs in the future and maintain the ability to provide for themselves and their families
Employees will have established systems for reporting concerns and non-conformances

4. Representation and participation in TC 304

4.1. Membership

Membership of TC 304

The current membership, Chairman and Secretary, and ISO committees in liaison can be accessed at:

[TC 304 ISO website](#)

4.2. Analysis of the participation

All countries and regions of the world have healthcare entities that fall under the scope of this standards committee. Ministries of Health and equivalent organizations have a paramount interest in providing the highest quality healthcare at the best possible cost. Developing countries and rural communities, which do not have the resources to



experiment with management practices or to hire consultants to advise them on effective practices would directly benefit from the access of effective management practices and tools.

TC 304 seeks increased participation by South and Central America, Africa and Central Europe. The TC's goal is to increase participation from these regions by networking with experts from these areas and participate, where possible, in conferences and other third-party meetings where active recruitment can occur. TC 304 has partnered with DEVCO (the ISO Committee on Developing Country Matters) in initiatives to increase participation by DEVCO member countries.

TC 304 actively pursues liaisons relationships with other ISO committees and/or external standards developing organizations. TC 304 notably has internal liaison relationship with over 20 other ISO TCs. The TC notes that the number of external liaison organization remains low; however, TC 304 develops Task and other Ad Hoc groups as needed to advance the development of standards and the operation of the committee itself. Among other duties, these groups secure collaborations with experts, universities, institutions, NGOS, and fortify relationships with country standards' bodies. Committee members endeavour to grow the portfolio of technical items and nurture the health of the committee.

5. Objectives of TC 304 and strategies for their achievement

5.1. Defined objectives of TC 304

In accordance with ISO strategy, TC 304, develops HOM standards and other deliverables that:

- Support the United Nations Sustainable Development Goals
- Facilitate global sharing of best practices
- Involve experts from all willing countries, with a focus on encouraging participation from lower and lower-middle income countries
- Establishes a common healthcare management language that allows international stakeholders to have a mutual understanding
- Support improvement in quality, safety, security, employee, patient, and environmental protection, together with the rational use resources in the context of health systems
- Include service users voice and experience in the establishment of best practices

5.2. Identified strategies to achieve the ISO/TC's defined objectives

TC 304 works with its liaisons and collaborates with other standards organizations to help ensure that stakeholders in specific application areas have the requisite health care administration standardization tools to support the introduction of emergent technologies, such as biotechnologies and nanotechnologies.

TC 304 ensures that ISO deliverables developed by this Committee do not conflict with any relevant existing national or regional statutory or regulatory requirements or guidelines. In particular, TC 304 will not duplicate the work of established ISO Committees in clinical or medical equipment fields, such as TC 76 (blood processing), TC 84 (administration of medicinal products), TC 121 (anaesthetic and respiratory



equipment), TC 159 (surgical implants) and TC 170 (surgical instruments). Furthermore, it is noted that ISO deliverables do not supersede or substitute for any applicable legal requirements. TC 304 will not develop application-specific ISO deliverables, except where there is a clear gap in standardization efforts and a business demand, and where there is no existing ISO committee or other established international standards-setting body applying their expertise to related standards development.

Since all stakeholders in the healthcare environment depend on high quality products and services from their providers, TC 304 will develop a Management System Standard (MSS) that addresses the application of quality to HOM. This standard serves as the focal point standard, around which all other technical documents are organized. TC 304 also anticipates other technical items like Technical Specifications (TS), Publicly Available Specifications (PAS), Technical Reports (TR) and International Workshop Agreements (IAW) will also be developed, where appropriate, to address less rigorous healthcare management issues that can achieve global consensus. However, International Standards (IS) are the Committee's primary and default vehicle for communicating industry requirements and guidelines.

Since many of the standards which fall within TC 304's scope will involve technical and scholarship laden areas of management, there may be occasions where the TC pursues specific pre/co-normative research to support the ISO committee's work program. As these needs develop, we will require any NWIP submission to include research needs so that an analysis can be made to detect any timing or funding difficulties.

Besides the mentioned approaches, TC 304 follows these principles when pursuing healthcare standards projects:

- Adopt national developed standards as a basis whenever possible
- Sustain close relationships with healthcare providers so that the standards meet market needs
- Maintain an effective and simple structure of the committee
- Globalize any discovered regional healthcare organization management standards that have a global impact
- Select and prioritize new projects based on their perceived efficacy for the improvement of HOM practices

6. Factors affecting completion and implementation of TC 304 work programs

The delivery of the TC 304 work program depends on the willingness and availability of experts in varied work disciplines to draft technical documents. Although ISO standards are familiar in medical devices, quality management, safety, and scientific functions in healthcare environments, there is less awareness of standardization in other non-clinical functions. Potential experts are numerous but may not see the efficacy of creating HOMs. In addition, organizations may prefer to adapt their own national standards. Stakeholders may see the introduction of these standards as an additional burden or threat



to their own established ways of delivering support services. TC 304 endeavors to educate and promote awareness about the development of these standards.

In addition, the financial burden of attending international meetings may prevent adequate national representation at TC 304 meetings. Even when developing countries have been informed about subsidies that are available to support their in-person participation in international meetings, few have taken advantage of this support. Routinely, WG Convenors and Secretaries report to the Committee Managers that participation in WG activities is low and unreliable. Fortunately, increasing numbers of work groups are making use of virtual meeting platforms. Nonetheless, the global reach of membership inevitably places some members at a time zone disadvantage during such conferences.

7. Structure, current projects, and publications of the ISO/TC

7.1. Structure of the ISO committee

7.2. Current projects of the ISO technical committee and its subcommittees

7.3. Articles and news

7.4. Website