47th EPSO Network Meeting, 4th Sep 2024

TOPIC 3:
Update on the new ISO 7101 accreditation standards for healthcare

Shin Ushiro, M.D., Ph. D.
Japan Council for Quality Health Care (JQ)
Kyushu University Hospital
Accreditation Council, International Society for Quality in Healthcare (ISQua)

Contents

- History
- The Experts – Global Alliance for Developing ISO New Standard
- Overview of ISO 7101
- The harmonized structure
- Differences
- ISO 7101 in Japan’s local setting

History

- Created by TC* 304 Healthcare Organization Management, Work Group 5
- WG 5 experts from all six WHO regions and all World Bank income categories (low, lower-middle, middle and high)
- Expert liaison – International Society for Quality in Health Care (ISQua)
- Diverse team with vast knowledge: doctors and nurses, risk management and patient safety directors, quality consultants, professors, representatives from ministries of health, academia, private and public institutions, and WHO consultants and contributors

* TC: Technical committee

History (Cont'd)

- First WG 5 meeting: February 2021
- Last WG 5 meeting: March 2023
- Standard published: 2 October 2023

"For the world, by the world"

- WG 5 motto – Prof Adam Layland (UK), convenor

Working flow of International Standard

Adoption of new international standard proposal

Vote by P-member* and O-member* of TC/SC

i)2/3 or more of P-members* voted in favor, and ii) experts are nominated by 4 or more countries among 16 or less P-member* countries/5 or more countries among 17 or more countries in TC/SC *

WG：Development of Working document（WD）

WG member: Experts nominated by P-member*

Consensus by WG

TC/SC：Committee Document (CD) submission

Finalized by TC/SC P-member* and O-member*

Consensus by P-members * in TC/SC *

Invitation of organizations of member states for comments: Deliberation and approval of DIS/CDV(Draft International Standard/Committee Draft for Vote)*

All member organizations in national body

i) 2/3 or more votes in favor by P-members * in TC/SC *, and ii)1/4 or less objections.

Official vote for Final Draft of International Standard (FIDS)：Approval of FIDS

All member organizations in national body

2/3 or more votes in favor by P-members * in TC/SC *, and ¼ of less objections.

Release of International Standard (IS)

TC/SC*

Valid period of development; 3 years

National body

* P-members; active member, O-member observer, TC; Technical committee, SC; Sub-committee

Meet some of the experts

Pictured in photos: USA, India, Brazil, Chile, India, England, Switzerland, Portugal, China, Japan, Jordan, Cameroon, Canada, Ireland, Cyprus, Poland, Argentina, Malawi, Nigeria, Ghana

Overview ISO 7101: 2023

Healthcare organization management – Management system for quality in healthcare organizations - Requirements

- Requirements for management systems for quality in healthcare organisations.
- First ISO healthcare quality management systems standard (MSS).
- First international healthcare quality management consensus standard (based on extensive collaboration and voting).
- First MSS to include the new climate change requirement that is required to be in all ISO MSS.

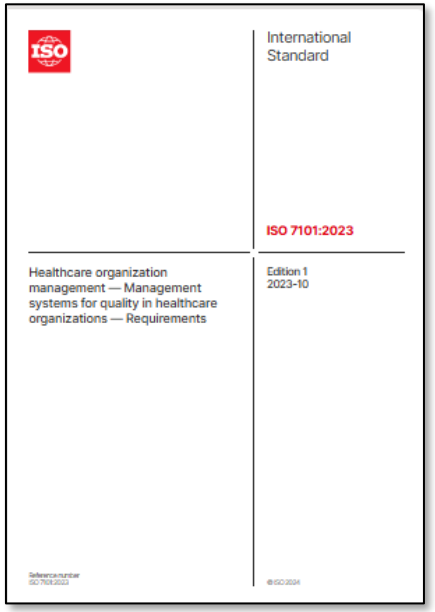
Overview ISO 7101: 2023 (cont'd)

Healthcare organization management – Management system for quality in healthcare organizations - Requirements

- An organization that wishes to demonstrate conformity with this document can do so by:
  a. making a self-determination and self-declaration;
  b. seeking confirmation of its conformity by parties having an interest in the healthcare organization, such as service users;
  c. seeking confirmation of its self-declaration by a party external to the organization; or
  d. seeking certification/registration of its management system for quality in the healthcare organization by an external organization.

Overview ISO 7101: 2023 (cont'd)

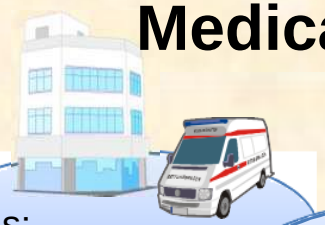
Healthcare organization management – Management system for quality in healthcare organizations - Requirements



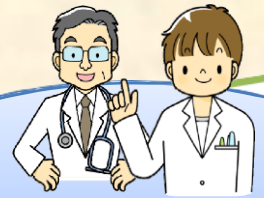
- Specifies requirements for healthcare quality management systems when an organization desires to:
  a. demonstrate its ability to consistently meet service user, stakeholder, and applicable statutory and regulatory requirements;
  b. enhance service user experience during the continuum of care and continually improve healthcare quality;
  c. create and maintain processes that ensure timely, safe, effective, efficient, equitable, and people-centered care.

Community-based Integrated Care System, Japan

Medical Care



Hospitals:
Acute phase,
recovery phase,
chronic phase



Daily health care:

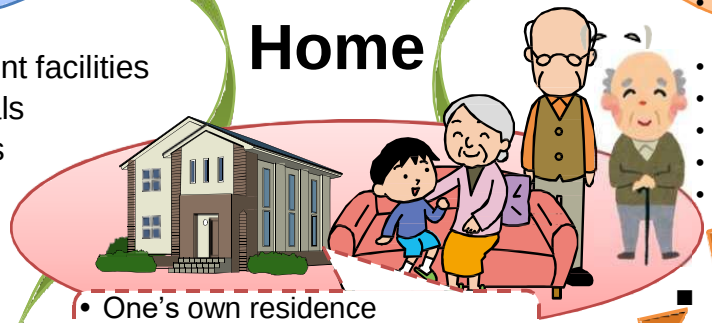
Outpatient/in-patient care

- PCP, clinics with in-patient facilities
- Regional affiliate hospitals
- Dental care, Pharmacies

- CommunityGeneral Support Center
- Care manager

Provides consultation service and service coordination.

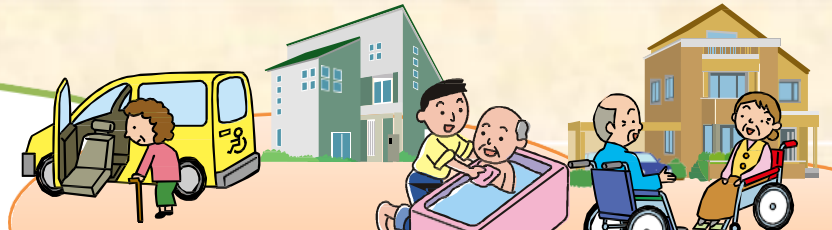
Home



- One's own residence
- Senior residence offering services, etc.

Visits / Moving in

Long-term Care



■ In-home services:

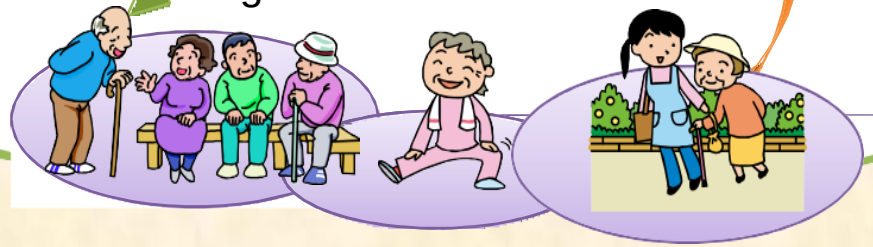
- Home-Visit Long-Term Care, Home-Visit Nursing, Outpatient Day Long-Term Care
- Multifunctional (Long-Term Care) Small Group Home
- Short-Term Admission for Daily Life Long-Term Care
- Equipment for Long-Term Care covered by Public Aid
- 24-hour Home-Visit Service
- Combined Multiple Service (Multifunctional Long-Term Care in a Small Group Home & Home-Visit Nursing)

■ Preventive Long-Term Care Services

■ Facility/Residence services:

- Nursing-care homes
- Geriatric health services facilities
- Communal-living care for patients with cognitive disorder
- Daily-life care for persons at government-designated facilities etc.

Livelihood support/ preventing long-term care



Senior clubs, residents' associations, volunteer groups, NPOs, etc.

* The Community-based Integrated Care System is conceived in units of every-day living areas (specifically equivalent to district divisions for junior high-schools) in which necessary services can be provided within approximately 30 minutes.

ISO/FDIS 7101:2022(E) 2 © ISO 2022 – All rights reserved

Highlights - 7 Major Clauses of the ISO 7101

4. Context of the organization

- Type of organisation, needs of stakeholders, determination of the scope of the healthcare quality management system

5. Leadership

- Commitment, quality policy, roles and responsibilities, focus on service user

6. Planning

- Risks and opportunities, quality objectives and plan to achieve them, planning for changes

7. Support

- Resources, competence, communication, information

Highlights - 7 Major Clauses of the ISO 7101 (contn'd)

8. Operation (largest clause)

- Planning, facility management, equipment, waste management, handling of materials, supplies and services, service provision, **people-centred care**, ethics, **patient safety**, workforce well being

9. Performance evaluation

- Monitoring, measurement, analysis & evaluation, quality indicators, internal audit, management review

10. Improvement

- Continual improvement, management of non-conformity and corrective actions

Features: “Harmonized Structure”

ISO 7101 follows the ISO Harmonized Structure, therefore can be easily combined with other ISO management systems standards (MSS) such as ISO 9001, ISO 14001 and ISO 27001

- Leadership and commitment
- Healthcare quality policy and objectives
- Planning
- Support
- Operations
- Performance evaluation (monitoring and measurement)
  a. Internal audit
  b. Management review
  c. Improvement

- ISO 9001: Quality Management Systems (QMS)
- ISO14001: Environmental Management System (EMS)
- ISO27001: Information Security, Cybersecurity and Privacy Protection - Information Security Management Systems

Features: “Differentiators – holistic standard”

Not just for hospitals!

Can be applied to any organization providing healthcare services (specialty clinics, ambulance transport, nonprofit health aid, etc.)

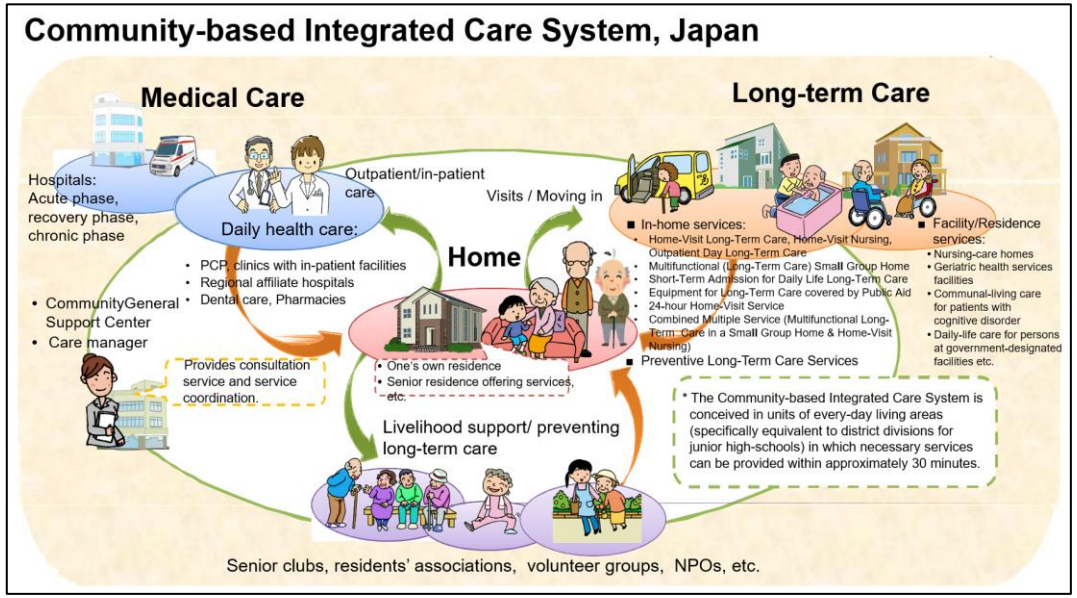
People-centered care:

- Service user experience
- Compassionate care
- Inclusivity and diversity
- Health literacy
- Co-production

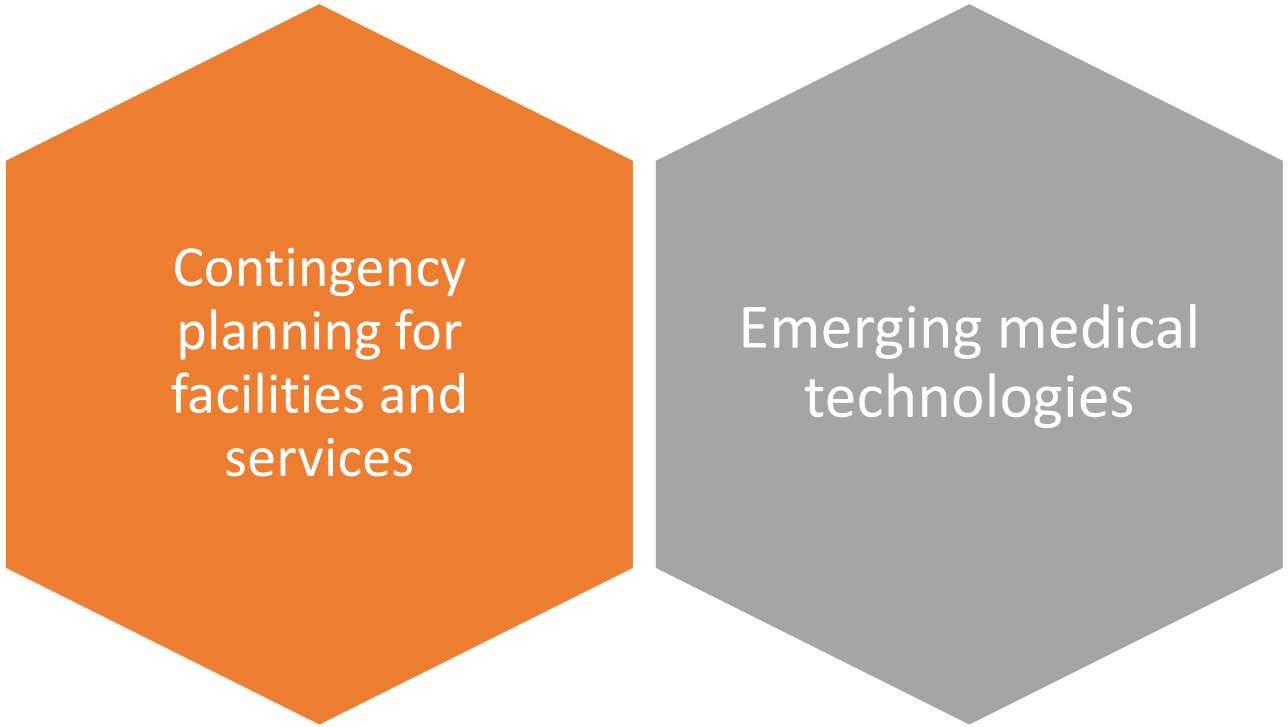
Workforce Wellbeing

Planetary Health

Waste reduction and environmental responsibility



Features: Differentiators - High risk management



- Business continuity to manage both natural events* and those caused by human beings**.

* *Earthquakes, typhoons, tornadoes, hurricanes, flooding, terrorism, pandemics, industrial accidents*

** *Profound adverse events caused by robotic surgery, genomic test, novel life-supporting/cardiac supporting devices and more.*

Annual disaster management drill, KUH

- KUH is designated as a “Fukuoka Regional Disaster Relief Hub Hospital” that practices disaster management drill every year on mandatory basis under the relevant law.
- Scenario (2022): **“Huge earthquake measuring magnitude 7.0 takes place due to a sudden slip of “KEGO” fault on 25th Oct, 2022.”**
- Disaster management headquarter is subsequently opened under the leadership of KUH director, getting hold of the latest picture of the earthquake and providing aid to inpatient and outpatient.
- Triage center is established to categorize outpatients into 4 levels i.e. Deceased, Immediate, Delayed, Monor depending on degree of injury.
- Tablet device is introduced for trial that works at frontlines in the hospital to share updates with the headquarter. Headquarter officials swiftly learn about the updates through a big monitor.

Dispatch of DMAT and DPAT to disaster affected area, KUH

DMAT (Disaster Medical Assistant Team)

DPAT (Disaster Psychiatric Assistance Team)

- KUH is designated as a “Fukuoka Regional Disaster Relief Hub Hospital” that practices disaster management drill every year on mandatory basis under the relevant law.
- **DMAT (Disaster Medical Assistant Team)** and **DPAT (Disaster Psychiatric Assistance Team)** swiftly visit affected areas in response to request from the local government through the Ministry of Health.
- **DMAT** comprises physician, dentist, nurse and pharmacist and visit evacuation sites/facilities to provide health check-up and primary care.
- **DPAT** provides is joined by psychiatrist, nurse and mental therapist and provides psychiatric check-up and care in affected areas.

Review and follow-up system for introducing a “Novel and risky surgery/procedure” – Government mandate for advanced care hospitals

Process **BEFORE** approval

Process **AFTER** approval

Administrator

- Installment of the division
- Publication of guideline
- Request the division in charge* to report on safety issues

Manager of clinical department

i) Application

Contents of the application form
Readiness on device, equipment, and trained staffers
Evidence of effectiveness and safety

vii) Monitoring and report

- **Compliance to the guidance**

Division of “Novel & High-risk Surgery/Procedure” control*

iv) Review committee

- **Approve? Yes/No**
- **Follow-up of the patient through EHR**

ii) hearing

iii) advice

- Physician with expertise on novel and risky surgery and procedure
- Staff engaged with operating theater

v) Notification of review result

Technical advisory committee

- Three or more members including staffers of the division on patient safety
- Physician, Dentist, Technician etc.

vii) Report on issues related to safety e.g. successful/failed operation, adverse event, fatal outcome

Manager of clinical department

vi) Implementation of “Novel & high-risk surgery”

Opportunities of ISO 7101 in Japan

- More than 8,200 hospitals are engaged in healthcare delivery in Japan.
- Hospitals with less than 300 beds (Small to mid sized hospitals) account for majority of them.
- Leading initiative of external evaluation by the Japan Council for Quality Healthcare (JQ) predominantly covers large sized hospitals, while there are many small to mid sized hospitals which are not evaluated eternally.
- ISO 7101 could be a tool for quality improvement for hospitals that have never been externally evaluated other than local government inspection.

Statistics on accreditation in 2022 (JQ's accreditation)

As of Oct 1, 2021

Bed number group	No. hospital *	Accredited	Accreditation ratio (%)	Accredited in 2021	No.hospital compared with 2021
100-	2,956	234	7.9	239	-5
100-199	2,786	583	20.9	602	-19
200-299	1,032	315	30.5	324	-9
300-399	674	330	49.0	330	0
400-499	366	237	64.8	232	+5
500-599	162	127	78.4	129	-2
600-699	110	92	83.6	88	+4
700-799	38	28	73.7	32	-4
800-899	29	27	93.1	26	+1
900-	52	40	76.9	41	-1
Total	8,205	2,013	24.5	2,043	-30

* Statistics from "Dynamic survey on healthcare institution 2021" by the Ministry of Health, Labour and Welfare

Thank you for your interest in ISO 7101, a first international healthcare quality management consensus standard.

Questions?