
**Healthcare organization
management — Requirements for
patient-centred staffing**

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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 304, *Healthcare organization management*.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

0.1 General

Healthcare personnel work in highly complex environments characterized by multiple competing challenges, including interdependent processes, a growing population of older, more acutely ill hospitalized patients, the need to stay current with rapid advances in medical knowledge and technology, and a multigenerational and multi-cultural workforce. The ever-changing demands of the new healthcare delivery models exacerbate the complexity by orders of magnitude.

Healthcare personnel work across all sectors and settings and are integral to the delivery of a range of health services. They monitor and respond to changes in patients' health status, develop care plans, deliver interventions and educate patients about self-care. As key players on the front lines of healthcare delivery, they play a critical role in providing care, coordinating care, preventing adverse events and optimizing patient outcomes.

Adopting a healthcare standard for patient-centred staffing is a strategic decision for healthcare organizations; it can assist health services in improving overall performance. This document provides a robust set of requirements which support sustainable development initiatives within a managed framework. Patient-centred staffing has emerged as a globally important area within health services.

Patient satisfaction is an important underpinning concept associated with the implementation of this document. Organizations monitor patients' perceptions and views about their experiences, and whether their needs and expectations have been met. They determine the methods for obtaining, monitoring and reviewing this information, including:

- service-specific or general patient surveys;
- patient focus group and quality circles;
- written expressions or comments and concerns.

Healthcare organizations are encouraged to cooperate with interested parties (see 4.2) in the development, deployment and execution of patient-centred staffing standards. Interested parties can have valuable input and feedback to improve the effectiveness of these standards, and a cooperative relationship can improve satisfaction among interested parties. Likewise, healthcare organizations are encouraged to share with interested parties relevant information regarding patient-centred staffing standards, for example the processes and procedures that are important to these parties.

0.2 Patient-centred staffing principles for healthcare

This document is based on healthcare management principles described in organization management or leadership healthcare literature and incorporates knowledge about effective quality management.

Patient-centred staffing in healthcare considers:

- workforce planning;
- evaluating staffing methodologies;
- internal and external resource allocation and management;
- forecasting and planning across the service;
- improving patient care and facilitating opportunities to enhance patient satisfaction;
- providing services that meet patient needs;
- meeting the range of applicable statutory, regulatory and guideline requirements;
- addressing risks and opportunities;

- enabling capacity planning in emergency situations.

Patient-centred staffing considers the requirements to match healthcare service personnel expertise with the needs of the patient. This expertise should include a full range of professional experience required to deliver holistic care and meet the needs of the patient. Those needs relate to age, family, home environment and personal circumstances, culture and kind of illness – acute or chronic.

Broadly speaking, the principles for patient-centred staffing are based on the following:

- considerations of patient safety;
- risk management;
- providing a seamless experience for patients;
- the practice environment;
- management of continuity in healthcare: in-patient (hospitalized) and out-patient (ambulatory) telemedicine and home hospitalization;
- quality of healthcare;
- organizational culture, leadership and people engagement;
- the deployment of a systematic process-based approach;
- evidence-based decision making;
- technology and innovation;
- governance;
- the patient and service context.

The benefits to an organization of implementing this document are:

- providing methods for reviewing and allocating resources for effective staffing;
- effectively meeting patients' needs;
- reviewing skill mix and workload fluctuations;
- managing patient flow and matching service provision with any wider service requirements.

0.3 Benefits of a standardized approach

Understanding the influences that contribute to or detract from an optimal work environment for healthcare professionals is essential for health systems seeking to better manage patient needs, reduce harm and improve value across the care continuum. This can be achieved through in-depth analysis of the relationships between the structure, process and outcomes measures that directly relate to patient care.

Healthcare personnel structure, process and outcome indicators are those elements of patient care that are directly affected by their care. Structure indicators include the supply, skill level, education and certification levels of staff. Process indicators measure methods of patient assessment and interventions. Outcome indicators reflect both patient clinical and experience outcomes, such as pressure ulcers and falls, and staff outcomes such as job satisfaction or turnover.

Benefits to the organization emerging from the implementation of this document include:

- enhanced patient experience;
- improved compliance with statutory, regulatory and professional requirements;

- increased transparency and increased accountability;
- greater opportunity for evidence-based decision making;
- reduced risk of reputational damage;
- increased flexibility;
- improved staffing outcomes (e.g. attrition, recruitment, loyalty and retention of talent, existing vacancies, staffing gaps, salaries, skill mix requirements);
- management of a range of clinical and other service risks;
- ability to benchmark across organizations;
- meets requirements and public health data, such as those of the World Health Organization (WHO).

Staff benefits include:

- reductions in fatigue, burnout and sickness rates;
- better staff retention and lowered attrition;
- improved job satisfaction.

Patient benefits include:

- greater visibility of staff at all levels;
- more effective meeting of needs;
- improvements in staff competences;
- better quality of service;
- improved outcomes (e.g. falls, healthcare-associated infection rates, public health data: medical and medication errors, patient mortality, hospital readmissions, lengths of stay).

This document offers an opportunity for organizations to better understand and manage the complex interrelated processes within healthcare. It will also contribute to a better understanding of healthcare organizations' effectiveness.

Incident feedback mechanisms and serious incident reporting data may be analysed to identify trends and highlight potential sources of prevention. Falls with or without fracture rates in hospital can provide an area for improvement if these are above national rates, or alternatively can offer other organizations an opportunity to learn and develop their services.

The following patient safety goals suggest that it is important to address specific areas of concern in patient safety:

- identify patients correctly;
- improve effective communication;
- ensure high-alert medications (using drugs which can cause significant harm or if maladministered cause devastating consequences for patients) are given according to guidance;
- ensure safe surgery;
- reduce the risk of healthcare-associated infections;
- reduce the risk of patient harm resulting from falls;
- prevent and treat pressure injuries.

Monitoring of the process's indicators in relation to the requirements of this document can indicate that an organization needs to plan and implement actions to address both risks and opportunities. Addressing both risks and opportunities for improvement establishes a basis for increasing the effectiveness and safety of the healthcare guidelines, achieving improved results and ameliorating possible negative events.

Opportunities can result from evaluating health technologies for the introduction of areas such as new drugs or treatment modalities; however, there can be inherent risks in terms of training. Actions to capitalize on opportunities should include consideration of associated risks, whereby a considered risk is the effect of an uncertain outcome. Risks can result in positive or negative effects. For example, a positive deviation arising from a risk such as a fall can also provide an opportunity: it is possible that a patient waiting for a hip replacement falls, requiring a hip replacement immediately. However, not all positive effects of risk result in opportunities. For example, death or surgical complications can also result from a fall.

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Healthcare organization management — Requirements for patient-centred staffing

1 Scope

This document provides requirements for patient-centred staffing in healthcare settings. It is generic and applicable to any healthcare organization.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 21001, *Educational organizations — Management systems for educational organizations — Requirements with guidance for use*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 21001 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <http://www.electropedia.org/>

3.1

patient

person seeking to receive or receiving healthcare

3.2

patient need

essential element of patient care

3.3

patient expectation

belief of what will happen before, during and after a healthcare experience

3.4

patient perception

patient belief or opinion

3.5

outcome-based

approach to ensure that healthcare services are focused on achieving the intended results

3.6

healthcare service

output of a healthcare organization with at least one activity performed between the organization and the patient

3.7

**person
people**

individual, family, patient, community or worker (individuals who are training, etc.)

3.8

staff

people who work for or within an organization

Note 1 to entry: The patient should require support, clinical intervention and/or treatment delivered by a healthcare organization. The patient-centred staffing requirements continue throughout patients' episodes of care and across their care pathway.

4 Determining the scope of the healthcare organization

4.1 General

The organization shall consider the services being provided to determine the scope, and monitor and review information about external and internal issues, including:

- a) Internal issues: positive and negative factors or conditions requiring consideration, such as patient age or patient clinical needs and staffing requirements, level of complexity of the healthcare services; organizational values, culture and performance.
- b) External issues: legal, technological, competitive, market, cultural, social and economic environments, weather, national, regional or local environments.

4.2 Interested parties

The interested parties with regards to this document include:

- a) patients, families and other support structures (who need services to optimize their health requirements);
- b) staff;
- c) communities (seeking reassurance about healthcare provision);
- d) external services providing healthcare staff;
- e) regulatory, collegiate and statutory organizations;
- f) unions and other professional bodies representing the interests of healthcare staff;
- g) those individuals or groups funding healthcare services (taxpayers, government, insurance);
- h) governmental and non-governmental organizations;
- i) top management;
- j) industry representatives (medical devices, pharma, insurance);
- k) other third parties, including WHO.

The interested parties have similar expectations of outcome-based healthcare staffing, although possibly view these from differing perspectives.

4.3 Documented information throughout the organization

The healthcare service shall:

- a) maintain documented information to support the operation of its processes, including electronic and all other records linked to patient care;
- b) retain documented information to ensure confidence that the processes are being adhered to as planned;
- c) facilitate staff access to appropriate clinical or other documentation according to their role requirements.

5 Leadership

5.1 General

Top management shall determine the knowledge and skills necessary for the operation of its processes and to achieve conformity of services. When addressing changing requirements for service developments, new needs and trends, the organization should determine how to acquire or access any necessary additional knowledge and required updates.

Top management shall demonstrate commitment to this document by:

- a) taking accountability for the effectiveness of implementing this document;
- b) ensuring that policy and objectives are established according to this document, and are compatible with the context and strategic direction of the organization;
- c) integrating this document's requirements into the organization's core business and care processes;
- d) promoting the use of the process approach and risk-based thinking within the healthcare environment;
- e) providing those resources needed to achieve patient-centred staffing;
- f) communicating the importance of effective healthcare management and of conforming to this document;
- g) ensuring this document achieves its intended results by requiring consistent measurement;
- h) engaging, directing and supporting people to contribute to the effectiveness of implementing this document;
- i) promoting improvement;
- j) supporting other relevant management roles to demonstrate their leadership within their areas of responsibility;
- k) ensuring the organization's management has systems and metrics in place to identify and ensure compliance with all relevant legislation, regulatory requirements, guidelines, standards and collective agreements, if in place;
- l) ensuring that regular staff meetings concerning the planning, implementation and evaluation of the care and support and associated questions are agreed upon and documented;
- m) ensuring the responsibilities and authorities for staff roles are assigned, communicated and understood within the organization, according to the communication policies of the organization;
- n) ensuring all staff have written job descriptions and a copy of the terms and conditions of their staffing relationship (employment or otherwise);

- o) ensure there is an up-to-date work schedule for all staff categories and that applicable schedules are available to each staff category, as appropriate.

5.2 Patient-focus

Top management shall demonstrate leadership and commitment to having a patient focus by ensuring that:

- a) statutory and regulatory requirements are determined, understood and consistently measured to ensure they meet patient requirements;
- b) patient satisfaction is enhanced;
- c) risks are managed;
- d) a sufficient number of suitably qualified healthcare staff are available according to the patient and the complexity of the process.

5.3 Traceability

The healthcare organization shall ensure the traceability of patient care processes, diagnostics and therapeutics, including: patients' unique identifiers; samples; complementary examinations; medication; surgical and medical devices; and prosthetics traceability.

Clinical records shall be maintained to a high standard to ensure that patients' care pathways can be followed and are evidence-based. Hand-written and electronic records shall be legible (if paper records), signed, timed and dated, and include the following important factors:

- intervention discussions;
- medication and treatment given;
- informed consent;
- discussions with families or carers.

6 Risks, opportunities, expectations and perceptions

6.1 Addressing risks and opportunities

This document considers the following as risks and opportunities:

- a) ongoing staff training and development requirements;
- b) a notable increase of healthcare personnel leaving the professions;
- c) increasing numbers of ageing health professions and the pipeline for staff;
- d) compensation packages, working hours and requirements;
- e) changing demographic patterns and an increase in those aged 65 and older as a percentage of the population;
- f) changing epidemiological patterns that impact rates of morbidity or mortality;
- g) emergency management during pandemics and catastrophes (e.g. passenger transport accidents with multiple victims);
- h) litigation trends and patterns;
- i) technological advances and IT infrastructure;

- j) other documentation or information systems;
- k) maintenance of environments and facilities;
- l) issues relating to clinical challenges linked to the complexities of different patients;
- m) low discharge rates;
- n) in extremis crises, such as terrorism or natural disaster;
- o) risks to the safety of patients and staff.

6.2 Risk assessment

Healthcare organizations shall have guidelines, standards, policies, procedures or all of these in place to:

- a) evaluate and/or analyse risks, opportunities and expectations on a continuous basis;
- b) address risks and gaps in expectations and realize opportunities for improvement;
- c) continuously monitor and, if needed, act to ensure risks and gaps in expectations are addressed;
- d) continuously improve and implement measures to realize opportunities;
- e) notify staff and patients of risks affecting their safety.

6.3 Gaps between expectations and perceptions — patients and staff

Patients and staff have expectations of health services, some of which are the same depending on the respective health system.

Patient expectations or perceptions of health services include:

- timely access into services and service delivery;
- getting what is needed in a reasonable time frame in non-emergency situations;
- getting expedited treatment in emergency situations;
- fit-for-purpose premises and equipment;
- suitably qualified healthcare staff;
- safe care without avoidable harm;
- empathy for patients and their families;
- a safe and welcoming environment;
- an integrated and continuous care pathway;
- minimal possibility of medical error;
- being treated with respect and having a say in decision making.

Staff expectations or perceptions of health services include:

- opportunities for career progression and personal or professional development;
- opportunities to develop technical skills and receive training;
- sufficient compensation and adequate work–life balance;

- recognition and unconditional positive regard;
- satisfaction and feeling appreciated;
- reasonable periods of time in the workplace;
- adequately maintained technical equipment;
- adequate resources to support effective role performance;
- a safe and welcoming environment, including occupational health and safety;
- constructive feedback from senior colleagues.

7 Resources

7.1 Environment for the operation of processes

The healthcare organization shall determine, provide and maintain a suitable environment which considers:

- a) epidemiological and societal impacts;
- b) psychological considerations (e.g. stress reduction, burnout prevention, emotional protection);
- c) physical requirements (e.g. treatment and care);
- d) service environment (e.g. temperature, heat, humidity, light, airflow, hygiene, noise).

These factors can differ substantially depending on the setting and services being provided.

7.2 Competence and key skills

In areas linked to staff, the healthcare organization shall:

- a) determine the competence and skill requirements;
- b) provide adequate focus on recruitment;
- c) ensure appropriate education, training, development and on-the-job experience;
- d) close any 'competence gaps' and evaluate the effectiveness of the actions taken;
- e) retain documented information.

The healthcare organization should also consider staff engagement and retention of talent.

Possible actions to ensure competence include:

- hiring the right skill set;
- the provision of training or implementation of education-based courses;
- mentoring and coaching;
- reassignment of currently employed people.