Chapter 6
Health Informatics Standards

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Abstract This chapter introduces readers to the world of health information standards and standards development organizations. The chapter provides insight into the relationship between standards and nursing practice and how they relate to evidence in practice. The definitions and purpose of standards are explored, as well as the development and approval processes of international standards development organizations. Conformance and relevance to nursing practice are also covered from an international perspective.

Keywords Nursing · Informatics · eHealth · Standard · Interoperability
Electronic health record · Terminology

Learning Objectives for the Chapter

1. Articulate the value of standards for Health Informatics and for nursing practice.
2. Identify and access standards that are relevant to their context (clinical practice, education, informatics, etc.).
3. Use appropriate standards to assess conformance of Health Informatics practices, processes and applications.
4. Participate in standards development, conformance assessment and review.

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6.1 Introduction

Nursing informatics and health informatics are no longer the domain of specialists. As this book demonstrates, information management and the use of information and communication technology (ICT) are an integral part of the delivery of quality health care. In future, ICT will become even more essential for the delivery of affordable health and nursing care, as the number of people living with multiple chronic conditions increases and the number of qualified nurses continues to fall.

The integration of health informatics (HI) practice with nursing practice is a key theme of this chapter on HI standards. Standards for nursing practice and standards for the information and communication technologies (ICT) that support nursing practice are intertwined, each dependent on the other to help nurses deliver safe, effective care and to communicate across boundaries.

This chapter represents a revision of a chapter, authored by Anne Casey, RN, MSc, FRCN, which appeared in a previous edition of this book. In this chapter, the nature of standards in health informatics is explained and key concepts such as conformance and consensus are explored. Table 6.1 provides definitions of relevant terms, some of which are also explained in the text. HI standards are described in the context of clinical nursing. Examples of standards from different countries are used to demonstrate how standards guide practice and support interoperability. Many of the examples are standards published by the International Organization for Standardization (ISO). These are referred to by number and not fully referenced.

Examples of HI standards are mostly drawn from the UK partly because the author is more familiar with these but also to encourage readers to look beyond local policies and state or national standards to international sources. This is not only necessary, given that there are significant gaps in national standards portfolios, but also relatively easy to do with the potential of internet searching to identify appropriate resources from across the globe.

In the final section of the chapter, the standards lifecycle is described and approaches to standards development and review are explained. Readers are encouraged to consolidate their understanding by reviewing relevant additional resources on the topic, for example the educational materials produced by ETSI (ETSI 2020)

6.2 Defining Standards and Related Concepts

6.2.1 What Is a Standard?

Standards are relevant to every aspect of our daily lives, from the way we drive, to the food we eat. International standards are especially important. Consider the Automatic Teller Machine (ATM): people can use a personalized card to obtain money almost anywhere in the world because the banking systems have all adopted relevant international standards. In contrast, when travelling abroad, people have to carry an adaptor plug because different countries do not have the same standard for electricity power points.

Table 6.1 Terms and descriptions

Term	Description
Clinical guideline	Systematically developed statements to assist practitioners and patient decisions about appropriate health care for specific circumstances (Feild and Lohr 1990)
Compliance	Used interchangeably with 'conformance' but with a flavour of a mandatory regulation. Conformance implies some degree of choice whereas compliance suggests sanctions for not complying.
Conformance	Degree to which the requirements in a standard specification are met
Conformity assessment	Process used to show that a product, service or system meets specified requirements (ISO 2020a)
De facto standard	Way of doing things or artefact that is widely accepted as best practice/gold standard even though it has not been officially recognised or documented by a recognized body
HI standard	Document, established from evidence and by consensus and approved by a recognized body, that provides rules, guidelines or characteristics for activities or their results, in the field of information for health, and health information and communications technology
Information Governance	Framework of policies and procedures for handling personal health information in a confidential, secure and accurate manner to appropriate professional, ethical and quality standards
Interoperability	Ability of two or more systems or components to exchange information and to use the information that has been exchanged (United Nations 2020)
Mandation	Term that groups the categories of conformance requirement specified in standards: 'mandatory', 'conditional' and 'optional'
Recognized body	Legal or administrative entity that has specific tasks and composition, with acknowledged authority for publishing standards (ISO. 5 2020)
Regulation	Legal or professional rule or principle that directs activities or their results; also known as 'regulatory standard'
Standard	Document established by consensus and approved by a recognized body that provides for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context (ISO. 1 2020)

Aside from personal convenience, international standards benefit us in numerous ways.

They:

- Help businesses reduce costs, better meet the needs of customers, and improve environmental performance.
- Open up access to new markets and reduce barriers to international trade.
- Provide a basis for better regulation, both nationally and internationally (ISO 2020b).

ISO defines a standard as:

> *A document established by consensus and approved by a recognized body that provides for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context*. (International Electrotechnical Commission 2020)

Put more simply, a standard is '*an agreed way of doing something*' (BSI 2020).

In order to understand HI standards we need to consider both their purpose and their 'functional usage', particularly conformance assessment (Chap. 5 demonstrated through the Euro CAS project, which completed in 2018, how conformance may be acheived (European Commission 2020)).

Before discussing these topics however, there is one other aspect of standards that needs to be considered. ISO views a standard as a set of guidelines presented in a **document**; people on the other hand often view standards as **things**. For example: 'the Braden scale is the standard assessment tool for pressure ulcer risk in our organization'; 'we use a standard terminology in our electronic record system'; 'the X monitor is the standard device for measuring blood pressure in neonates'. In these examples, the Braden scale, the terminology and the device have been adopted by a clinical team, an organization or other body as their standard approach. In order to ensure quality and consistency, staff would be expected to use only these artefacts in the situations for which they have been adopted.

This meaning of the word 'standard' (i.e. as a descriptor that gives an artefact additional status) is not covered further in this chapter—here we focus on standards as documents that state 'rules, guidelines or characteristics'. Interestingly, many standards support the selection of artefacts for preferred use by describing the characteristics that make them safe, effective and useful. For example, ISO/IEEE 11073 Medical/Health Device Communication Standards represent a family of standards for interoperability between medical devices, such as blood glucose monitors.

6.2.2 Purpose of HI Standards

At a general level, HI standards support clinical practice and the management, delivery, and evaluation of health services. More specifically, their purpose is to promote interoperability between independent systems (as discussed in Chap. 5).

In all healthcare settings around the World, we need to be able to exchange information reliably and then interpret and use it effectively: interoperability is essential. Reducing duplication of effort and redundancy are also important goals, as are making manufacture, supply and trade easier. However, there is something missing from this list of purposes for HI standards—the safe, effective integration of information management and ICT into clinical practice. This purpose fits well with definitions of nursing informatics, which emphasise the integration of the science and art of nursing with information management and ICT (American Nurses Association 2014).

This leads to the conclusion that HI standards have two main purposes: to support interoperability and to guide safe, effective HI practice. However, it is their 'functional usage' which is perhaps most important—we use standards to guide what we do and to measure conformance.

6.2.3 Conformance

In the same way that we use practice standards to audit the quality of nursing care, we use HI standards to ensure that HI systems and the way we use them conform to agreed 'best practice'. The word 'conform' is key: a standard is something against which conformance or compliance can be measured—see Table 6.1.

Closely related to conformance is the idea of 'levels of mandation'—a term that groups the categories of 'mandatory', 'conditional' and 'optional'. Mandatory statements in a standard are those that must be complied with. Conditional ones must be complied with if certain specified conditions are met and optional ones are recommended but not required for conformance. An example is given below from the Palliative Care Co-ordination Information Standard published by NHS Digital in the UK (NHS Digital 2020a)

This standard specifies the content of electronic palliative care co-ordination systems (EPaCCS). One of the requirements in the standard is that *Clinical governance and IT safety leads in each organisation where the standard is implemented MUST ensure that the editing rights for specified clinical content elements are limited to the appropriate clinicians*. This mandatory (MUST) requirement aims to ensure that only the lead clinician records or amends critical information such as Do Not Attempt Cardiopulmonary Resuscitation orders. Some content elements such as person name are mandatory in each record. Others should be recorded once the person has made a decision (conditional), for example, 'Preferred place of death'.

There are some similarities between these levels of mandation and the way we talk about professional standards. In health care, we use terms like 'requirements', 'recommendations' and 'principles' which are found in Regulations, Clinical Guidelines and Practice Guidance. Regulations are legal or professional requirements for practising nurses mainly aimed at protecting the public. In the US, education and licensure requirements are set by the State Boards of Nursing (NCSBN 2020) and a Code of Ethics for Nurses is published by the American Nurses Association (American Nurses Association 2020a).

In the UK, the Nursing and Midwifery Council is the regulatory body established in law that sets standards for education, conduct, performance and ethics (Nursing and Midwifery Council 2020a).

In contrast, clinical guidelines are:

> *systematically developed statements to assist practitioners and patient decisions about appropriate health care for specific circumstances*. (Feild and Lohr 1990, p. 38)

'Systematically developed' means that a systematic literature search and review of research evidence have been undertaken using agreed criteria and rigor. Practice guidance is generally evidence based but has not been systematically developed, depending rather on consensus among practice experts. The terms guideline, guidance, practice standard, practice parameter, quality standard and others are

frequently used interchangeably. They are all standards in that they are 'agreed ways of doing something'. No matter what they are called, the important thing is to know how they were developed and who approved or endorsed them so that users can decide whether to comply with the recommendations made.

All nurses must comply with relevant regulations if they are to continue to practice. However, the degree to which a nurse is expected to comply with clinical guidelines or practice guidance will depend on national and local polices but it often comes down to (a) the strength of the evidence that supports the recommendations and (b) the authority of the organization that has published or adopted the standard.

Continuing the example of End of Life Care, all clinicians would be expected to comply with the *End of life care for adults* quality standard, published by the English National Institute for Health and Clinical Excellence (NICE) (National Institute for Health and Care Excellence 2020a). NICE has the same kind of authority as the US Agency for Healthcare Research and Quality (AHRQ) (Agency for Healthcare Research and Quality 2020a)—clinicians would have to give a very good reason for not complying with guidelines from these organizations, for example, in a court of law or fitness-to-practise hearing.

Standards produced by less well known organizations can be equally authoritative provided the evidence cited is strong enough and the recommendations fit with nursing principles and best practice. The Registered Nurses' Association of Ontario's guideline on *End-of-life care during the last days and hours* (Registered Nurses' Association of Ontario 2020) has good research evidence for many of its recommendations with the remainder being supported by consensus from leading experts in palliative care nursing. This balance of evidence and consensus is required in many areas of nursing where there is little empirical research to guide recommendations. However, as can be seen in the ISO definition of a standard in the introduction to this chapter, consensus rather than evidence seems to be the basis for the development of HI standards.

6.2.4 Consensus or Evidence?

Most international HI standards organizations prepare new standards through a process of consensus by experts, technical committees and national standards bodies. The initial drafting process also includes consideration of evidence such as what standards already exist in the area under consideration and how effective these are. Many standards are developed using the experience and lessons from applications that are well advanced in some settings. For example, the ISO standard for patient health card medication data (ISO 21549-7) was agreed among a number of countries that had implemented and evaluated health cards. The standard is therefore based on consensus underpinned by experience of what works but not necessarily from formal evaluation studies or other empirical evidence. For other applications and supporting processes there is less experience, and consensus may be more difficult to obtain. For example, as Personal Health Records (PHRs) are not yet

widespread in most countries, ISO's Health Informatics Technical Committee (TC215) published a Technical Report (TR) (ISO/TR 14292) to summarise current knowledge on this topic and establish some definitions and principles. An International Standard may be developed for PHRs when more is known about any interoperability, safety or other requirements that would benefit from standardization.

If there is insufficient support for a full standard (International Standard or Technical Report), ISO's experts may agree to publish a Technical Specification (TS)—unlike a TR this can be used as a standard but only has consensus within the Technical Committee, not across all the national standards organizations. For example, ISO/TS 21547 specifies principles for security requirements for archiving electronic health records—these have been adopted by a number of countries. The TS was reviewed and updated in 2017 and therefore remains current. However, it is possible that the TS will be promoted to a full standard based on feedback from practical use.

After a published standard has been in use for several years it will be reviewed. Evidence is collated on how it is being used, whether it is achieving its objectives and whether it needs to be revised or withdrawn. Previously, fitness for purpose and implement evaluation may not have been sufficiently accounted for in the consensus approach to development and review of HI standards. More attention is now being paid to questions such as cost and outcomes of standards implementation, implications for staff, patients, application providers and others.

A combination of consensus and evidence should be used for the development and review of HI standards but there is still a question about how they are approved and adopted i.e. who are the HI standards 'authorities' equivalent to AHRQ and NICE?

6.2.5 'Recognized Body'

One of the greatest challenges in the standards world is that there are multiple sources for standards. Many different 'recognized bodies' and other organizations publish rules, guidelines and 'agreed ways of doing things', even in the specialised field of health informatics. Governments, health departments, regulators and others adopt or develop their own HI standards for use in their countries and regions. Other organizations, such as the World Health Organization (WHO) and the International Council of Nurses (ICN), produce artefacts that are adopted as HI standards. For example, the WHO International Classification of Functioning Disability and Health (ICF) has been adopted in a number of countries as the standard to describe and measure health and disability (World Health Organization 2020).

A small but growing number of HI standards are developed by national and international professional bodies. Where no authoritative standard is available, the practice that is in common use may become known as the 'default standard' or 'de facto'

i.e. it is widely accepted as best practice even though it has not been officially recognised or documented by a recognized body.

The most widely known HI SDOs are listed in Table 6.2 but perhaps more relevant to readers of this chapter are the national standards organizations in each country, which contribute on their behalf to international developments and decide which standards should be adopted and promoted in their country. ANSI, the American National Standards Institute, is a good example of a national 'recognized body'. Founded in 1918, ANSI is 'the voice of the US standards and conformity assessment system' (American National Standards Institute 2020).

Many national organizations of this kind will develop standards for their own country, but then share these internationally when other countries identify a similar need. The standards produced by different organizations may be entirely consistent, differing only in presentation such as when different versions are published for technical experts and for clinicians. Unfortunately, there are inconsistencies across SDOs. A trivial example is the spelling of the word 'organisation'. The European standards organisation (CEN) uses 's' whereas ISO uses 'z'. There are similar examples specific to health informatics: the HI technical committee of ISO is labelled TC 215—the equivalent committee in Europe is labelled TC 251. At best, multiple HI standards lead to confusion; at worst they result in wasted resources and increase the risk of poor communication and unsafe practice and, concomitantly, risk to patient safety. To address existing inconsistencies and to prevent development of new competing standards, international HI standards organizations have established the Joint Initiative Council for Global Health Informatics Standardization (see Table 6.2) (Joint Initiative Council 2020).

Members of SDOs comprise mainly HI experts and industry representatives. However, there is recognition that clinicians and health consumers should also be part of standards development activity.

ISO has recognised the importance of consumer participation, for example in their own learning materials: '*a "good" standard means one that creates a good product—a product that you will want to use because it is safe, fit for purpose, and easy to operate*' (ISO. 2 2020).

This sounds exactly what nurses, patients and public want from the systems and applications they use in health care. It is therefore essential that organizations representing, nurses, other clinicians and patients are an integral part of the 'recognised bodies' that develop, approve and adopt HI standards.

In the US, the Interoperability Standards Advisory (ISA) provides a framework for the Office of the National Coordinator for Health Information Technology (ONC) to identify, evaluate and raise awareness on standards to support interoperability. Stakeholders are encouraged by ONC to implement and test existing and emerging standards identified in the ISA. Standards that are relevant to nursing practice include those relating to:

Table 6.2 Standards Development Organizations

Acronym	Organization	Description
ISO	International Organization for Standard (also known as the International Standards Organization) www.iso.org	ISO is an independent, non-governmental organization made up of members from the national standards bodies of 164 countries. It has published more than 23,188 International Standards and has 784 technical committees and subcommittees developing standards. Technical Committee TC 215 is responsible for ISO Health Informatics standards. ISO standards can be purchased from the online ISO store or through the national standards body.
CEN	European Committee for Standardization www.cen.eu	CEN is an international non-profit association based in Brussels. It has 34 members (national standards bodies) who develop voluntary European Standards (ENs), which are then adopted as national standards in the member countries. It has formal arrangements for working with ISO to avoid duplication and promote harmonisation. Technical Committee TC 251 is responsible for CEN Health Informatics standards. CEN standards can be purchased from national member bodies.
JIC	JIC for Global Health Informatics Standardization www.jointinitiativecouncil.org	The Joint Initiative Council for Global Health Informatics Standardization was formed to address gaps, overlaps, and counterproductive HI standardization efforts. Members include ISO TC215, CEN TC 251, HL7, CDISC, GS1, DICOM, SNOMED International and IHE.
HL7	Health Level Seven International www.hl7.org	Health Level Seven International is a not-for-profit, ANSI-accredited SDO providing a framework and standards for the exchange, integration, sharing, and retrieval of electronic health information that supports clinical practice and the management, delivery and evaluation of health services. HL7 has over 1600 members from over 50 countries. Membership is open to individuals and organizations for a fee—with a special low cost for health care professionals. HL7 standards are free to members and can be purchased from the HL7 online store.
openEHR	Open EHR Foundation www.openehr.org	The openEHR Foundation is a not-for-profit company providing 'an open domain-driven platform for developing flexible e-health systems'.
CDISC	Clinical Data Interchange Standards Consortium www.cdisc.org	CDISC is a global, multidisciplinary, non-profit organization developing standards to support the acquisition, exchange, submission and archive of clinical research data and metadata. CDISC standards can be downloaded for free from the CDISC website.

(continued)

Table 6.2 (continued)

Acronym	Organization	Description
ANSI	American National Standards Institute www.ansi.org	ANSI facilitates the development of National Standards (ANS) by accrediting the procedures of SDOs—groups working cooperatively to develop voluntary national consensus standards. It is the US national standards body member of ISO and encourages the adoption of international standards as national standards where they meet the needs of the user community. Membership is open to individuals and organizations. ANSI standards can be purchased from the online store.

- Representing Clinical/Nursing Assessments—https://www.healthit.gov/isa/representing-clinicalnursing-assessments.
- Representing Patient Problems for Nursing—https://www.healthit.gov/isa/representing-patient-problems-nursing.
- Representing Nursing Interventions—https://www.healthit.gov/isa/representing-nursing-interventions.
- Representing Outcomes for Nursing—https://www.healthit.gov/isa/representing-outcomes-nursing.

A range of contexts, and their accompanying standards, are also included in the ISA standard for care plans that might be relevant to nursing (https://www.healthit.gov/isa/care-plan).

6.2.6 Definition of an HI Standard

From the preceding discussion, we can adapt the ISO definition of a standard, and extend it with notes about purpose and functional usage as follows:

An HI standard is a document, established from evidence and by consensus and approved by a recognized body, that provides rules, guidelines or characteristics for activities or their results, in the field of information for health, and Health Information and Communications Technology (ICT).

The purpose of an HI standard includes to:

- *Support safe, effective HI practice*
- *Promote interoperability between independent systems*
- *Enable compatibility and consistency for health information and data*
- *Reduce duplication of effort and redundancies.*

HI standards should meet the needs of users, be practical to implement and be sufficiently well specified to enable assessment of conformance. Standards should have a clear and defined development lifecycle or development process. Clinicians and consumers of health care should be involved in the development, implementation and review of HI standards.

6.3 HI Standards

6.3.1 The Scope of Standards

In this section, we consider the 'rules, guidelines and characteristics of activities or their results' that are needed to integrate information management and ICT into health care, particularly into nursing practice. For this purpose, the scope of health informatics can be considered as covering all aspects of the health system (ISO. ISO/TC 215 2020).

HI also covers the use of information and ICT by patients, clinicians, managers, researchers and others. Many standards will be common to all, for example, anyone providing health care could be expected to have some level of competence in using technology, in accessing, understanding and using information to make decisions and in the secure management of information. Other chapters in this book go into more detail about specific topics such as education and competence, clinical and administrative applications, documentation systems, security, etc. and the focus here will be on the standards that are available to support clinicians in their everyday practice, including their support for healthcare consumers.

6.3.2 HI Standards for Clinicians

As indicated the introduction to this chapter, HI standards are closely related to clinical practice standards. Take the example of record content standards, which specify what must or should be recorded about the care of a patient in a particular context. It is impossible to talk about standardizing the content of a document used for handing over care between shifts, for example, without first defining best practice for shift handover. In the same way it is impossible to have a standard for recording falls risk assessment without reference to the evidence based guideline for assessing a person's risk for falls.

Examples of HI standards for nurses and other clinical staff are given below, organised into a number of HI themes (NHS Networks 2020):

- Protection of individuals and organisations
- Data, information and knowledge
- Communications and information transfer
- Health and care records
- Clinical coding and terminology
- Clinical systems and applications
- The future direction of healthcare

Protection of Individuals and Organisations

Around the World, laws (including practice acts), regulations and codes require nurses to ensure confidentiality, privacy and security of information, irrespective of whether it is held and communicated on paper or electronically. The International Council of Nurses (ICN) requires National Nursing Associations to 'incorporate issues of confidentiality and privacy into a national code of ethics for nurses' (International Council of Nurses 2012).

Health departments and professional associations are the main sources of practice standards associated with information governance. Such guidance documents range from statements of law and principles through to example templates and other tools to support implementation of these standards in practice. For example, the Royal College of Nursing provides a summary of the scope of the conversation that should be had with the patient regarding their health record, including:

- the kinds of information that is being recorded and retained
- the purposes for which the information is being recorded and retained
- the protections that are in place to ensure non-disclosure of their information
- the kinds of information sharing that will usually occur
- the choices available to them about how their information may be used and disclosed
- their rights to access and where necessary to correct the information held about them on paper or electronic records (Royal College of Nursing 2009, p. 3).

When and how to share patient information with others is a major issue for clinicians, including sharing with law enforcement and other non-health agencies. Legal requirements for obtaining consent to disclose patient information and for disclosing without consent differ between and even within countries, leading to confusion and communication failures. Failure to share information can result in significant harm. Table 6.3 lists examples of standards for information sharing as well as for maintaining privacy and confidentiality.

Table 6.3 Examples of practice standards—Confidentiality, privacy and information security

Organization	Title and year	URL
Centre for Disease Control (CDC) and the US Department of Health and Human Services	HIPAA Privacy Rule and Public Health (2003)	http://www.cdc.gov/mmwr/preview/mmwrhtml/m2e411a1.htm
British Columbia College of Nursing Professionals	Privacy and Confidentiality	https://www.bccnp.ca/Standards/RN_NP/PracticeStandards/Pages/privacy.aspx
Sutter Health	Privacy of Information	https://www.sutterhealth.org/pamf/health/teens/sexual/privacy-of-information
Royal College of Nursing (UK)	Consent to access, share and create eHealth records (2008)	https://www.rcn.org.uk/-/media/royal-college-of-nursing/documents/policies-and-briefings/uk-wide/policies/2008/0908.pdf

The International Standard *ISO 22857 Provides guidelines on data protection to facilitate trans-border flows of personal health information*. This kind of standard brings together practice and technical aspects but at a general level so that countries can extend the international provisions with content relevant to their different legal and professional jurisdictions (Table 6.3).

Although guidance may be available for seeking consent for information sharing, there do not appear to be any standards for recording consent or refusal, a necessary precursor for designing appropriate structure and content for electronic recording. However, ISO TC215 has been collating international best practice and is developing a Technical Specification (not yet a standard) for *Principles and data structures for consent in the Collection, Use, or Disclosure of personal health information—Patient consent* (ISO/AWI TS 17975).

Data, Information and Knowledge

Nurses and other clinicians access and use data, information and knowledge in every aspect of their work, from checking the normal range of a laboratory result to performing an organizational audit or carrying out a nationwide research study. There is a vast array of standards to support these activities, most of them not specific to health informatics.

Health information literacy for clinicians is one area that has been extensively developed, recognising firstly that they must be lifelong learners and secondly that they cannot retain all the information and knowledge required to practise health care in the modern age. Specifications of information literacy competencies by national organizations (including health library science organizations) provide default standards for healthcare staff in the various roles they may fulfil, including researchers and managers. Health information literacy is related to digital literacy which is discussed is Chap. 3.

Standards for the data that are required to monitor healthcare quality and manage services are one of the most common HI standards available at local and national levels. These dataset specifications are another example of how HI standards cannot be divorced from practice standards if they are to be an accurate reflection of care and outcomes and, most importantly, if the data are to be extracted from care records—the 'record once, use many times' principle. The UK Tissue Viability Society (TVS) publication *Achieving Consensus in Pressure Ulcer Reporting* (Tissue Viability Society 2012) is a good example.

Tissue viability specialist nurses had recognised that data about pressure ulcer incidence '*has little value if it is not collected in a rigorous and practical way, and that comparisons between organizations are pointless as there is no standardised data set used across the country*' (Tissue Viability Society 2012, p. 6). The TVS proposed a UK standard using the definitions agreed by the US and EU Pressure Ulcer Advisory Panels i.e. a practice standard. Integrating the reporting of pressure ulcers with adverse event reporting and root cause analysis is a key part of the TVS standard, which specifies what should be reported, when and how. Being able to

report and then to access, interpret and use data of this kind for quality improvement are core competencies for all qualified nurses.

Another core competency is supporting patients and health consumers to access, understand and use health related information. Nurses are frequently described as 'information brokers'. This means that nurses must themselves have the skills needed for example to critique the accuracy, quality and authority of health-related websites.

There a number of standards and guidelines for ensuring the quality, readability and usability of health information. Specifications of the characteristics of good health information are used by accrediting organizations to indicate that the information itself or the organization producing the information meets specified quality standards. In 1999, the Agency for Healthcare Quality and Research (AHQR) in the U.S. identified seven quality criteria to guide evaluation of health information on the internet (Agency for Healthcare Research and Quality 2020b) which have been the basis for standards set by other organizations since then. These are:

- *Credibility*: includes the source, currency, relevance and editorial review process
- *Content*: accuracy and completeness
- *Disclosure*: informs the user of the purpose of the site, as well as any profiling or collection of information associated with using the site
- *Links*: evaluated according to selection, architecture, content, and back linkages
- *Design*: accessibility, logical organization (navigability) and internal search capability
- *Interactivity*: feedback mechanisms and means for exchange of information among users
- *Caveats*: whether site function is to market products and services or is a primary information content provider (Agency for Healthcare Research and Quality 2020b).

Table 6.4 lists examples of standards guiding practice related to information literacy (for clinicians and consumers) and to information quality. Note that

Table 6.4 Examples of practice standards—Information literacy and information quality

Organization	Title and year	URL
DISCERN (UK)	Quality criteria for consumer health information	http://www.discern.org.uk/
National Library of Medicine. MedlinePLus	Evaluating Internet Health Information: A Tutorial from the National Library of Medicine	https://medlineplus.gov/webeval/webeval.html
New Zealand Nurses Organization	Health Literacy (2011)	https://www.nzno.org.nz/LinkClick.aspx?fileticket=vL8p8cbHY-o%3D&tabid=109&portalid=0&mid=4918
US Department of Health and Human Services	Health Literacy (includes guide to improving the usability of health information)	https://health.gov/our-work/health-literacy/health-literacy-online

information literacy of health consumers is one part of wider 'health literacy' as discussed in Chap. 2.

Communication and Information Transfer

One of the most basic goals of nursing is that patients and those who care for them experience effective communication. The importance of good communication and information transfer is demonstrated when things go wrong, as almost every review of sentinel events/critical incidents illustrates. Good quality information about care and treatment must be communicated to patients so they can make sense of what is happening and participate in decision-making and self care. Staff must communicate effectively with each other to ensure continuity, safety and quality of health care for all. These principles are enshrined in laws, regulations and codes and in national and international standards and benchmarks (Casey and Wallis 2011).

Alongside face-to-face and telephone conversations, nurses are now using a greater range of communication tools such as SMS texting, social media and video links. Standards for use of these technologies to communicate with patients and with other clinicians are considered below in the section on applications and clinical systems.

There has been a focus for many years on hand-off/handover communications involving the transfer of information between shifts, between agencies and between professionals when a patient is transferred from one setting to another, for example, from hospital to home or from the critical care unit to the operating room. In these circumstances, incomplete or delayed information can compromise safety, quality and the patient's experience of health care (British Medical Association 2004). A number of principles have emerged that inform guidance for nurses and others on safe handover. These include:

- A standardized approach to handover communication
- Use of a structured format for the information to be handed over [WHO recommends the SBAR (Situation, Background, Assessment, and Recommendation) technique] (World Health Organization 2007)
- Allocation of sufficient time for communicating and a location where staff won't be interrupted
- Limiting the information to that which is necessary to provide safe care.
- Use of technologies and methods that can improve handover effectiveness, such as electronic records
- Ensuring that processes, which use electronic technology are interactive and allow for questions or updates (British Medical Association 2004; World Health Organization 2007; Joint Commission Center for Transforming Healthcare 2020).

In 2012, the Cochrane Collaboration began a systematic review of the growing literature on handover, specifically focused on the *Effectiveness of different nursing handover styles for ensuring continuity of information in hospitalised patients* (Smeulers et al. 2014). Disappointingly the review found insufficient robust

Table 6.5 Examples of practice standards—Communication and information transfer

Organization	Title and year	URL
Royal Pharmaceutical Society	Keeping patients safe when they transfer between care providers—getting the medicines right (2012)	https://www.rpharms.com/Portals/0/RPS%20document%20library/Open%20access/Publications/Keeping%20patients%20safe%20transfer%20of%20care%20report.pdf
World Health Organization	Communication During Patient Hand-Overs (2007)	https://www.who.int/patientsafety/solutions/patientsafety/PS-Solution3.pdf

evidence to make any conclusions about effectiveness of different handover styles and studies with greater methodological rigour are needed.

There are more examples of practice standards for good communication and information transfer than could be listed in this chapter. A selection is provided in Table 6.5.

Health and Care Records

Nurses are required to maintain clear and accurate records and to ensure that all records are kept securely (Nursing and Midwifery Council 2020b).

They must be able to record elements of the nursing process in a manner that reflects nursing practice including:

- the patient's views, expectations and preferences
- results of assessments
- judgments about the patient's needs and problems
- decisions made
- care planned and provided
- expected and actual outcomes
- communications with patients and carers and other professionals/agencies (Wang et al. 2011).

Records should reflect core nursing values such as being patient focused, supporting patient decision making and self care. Their primary purpose is to support high quality care, effective decision-making and communication. Record keeping by nurses is supposed to be an integral part of practice, not 'an optional extra to be fitted in if circumstances allow' (NHS Digital 2020b, p. 3). However, many studies have identified that there is room for improvement in the quality of nursing documentation (Wang et al. 2011).

This will not happen unless records are valued and used rather than being viewed as a 'necessary evil' in case of litigation (Casey and Wallis 2011). Although nurses are blamed for poor record keeping, it may be that the records themselves need to become more useful and usable as communication tools, a challenge for health informatics. A number of the studies cited in the review by Wang et al. (2011) indicate that electronic applications and standardized documentation systems had the

potential to improve documentation. However, a Cochrane Review of nursing record systems (Urquhart et al. 2018) concluded that there is a fundamental problem to be solved before both paper and electronic records can be improved: '*there needs to be more work with the nursing professions to understand exactly what needs to be recorded and how it will be used*' (Urquhart et al. 2018, p. 2).

The development of standards for the nursing content of patient records is a challenge that must be taken up by the profession, with support from informatics and terminology specialists.

Knowledge of standards for both record keeping practice and record content are essential for informatics specialists as these dictate the regulatory and professional requirements that must be incorporated into applications supporting record keeping and communication. Where national or regional standards exist, they provide a good basis for improving the quality of nurses' record keeping and for supporting the design of applications. It should be noted that uni-disciplinary standards are becoming less relevant as more provider organizations move to single patient records. Professional bodies and others who set practice standards need to collaborate more widely to ensure that there are clinical record standards common to all specialties and clinical disciplines. According to a UK joint professional working group, multi-professional standards: '*will provide the foundation upon which to base the collection, storage, communication, aggregation and reuse of structured clinical information across organizational boundaries throughout health and social care*' (Royal College of Physicians 2020).

Standards for recording, storing and retention/destruction of records are not further addressed in this chapter. Instead we will now focus on the major gap in standards related to record keeping, that is: record content—the 'what' of record keeping, as distinct from the 'how, when and by whom'.

Nurses know in principle what they should be recording but may struggle with exactly what makes a good care record, either on paper or in electronic systems. In some countries, there are national requirements for what nurses should record but these are often at too high a level to direct practice. For example, Håkonsen et al. reported in 2012 that the Danish national guideline at that time listed twelve areas about which nurses must document but it does not specify exactly what they have to document: '*It is an empty framework where nurses themselves must assess what is relevant to document … in the specific patient situations*' (Håkonsen et al. 2012).

As well as supporting best practice, detailed record content standards are needed to inform the design of electronic records and communications. As the UK Joint Working Group noted, technical standards alone do not ensure the communication of interpretable health data; professionally agreed 'standard representations' for content are also needed (Royal College of Physicians 2020). Record content standards specify information elements that must and should be present for a specified record or communication context e.g. a discharge summary. Interestingly, these record content specifications can be found in some clinical practice guidelines. For example, a clinical guideline for managing head injury includes 'minimum acceptable documented neurological observations' such as: Glasgow coma score; pupil size and reactivity; limb movements; respiratory rate; heart rate; blood pressure;

Table 6.6 Examples of information elements that could be part of a content set for a discharge summary

Heading	Description
Information/advice given to the patient	Detail of the verbal or written information or advice given to the patient and the patient's preferred form for such information. May be in the form a structured list of patient information leaflets or web links for a specific clinical context.
Advance decisions about treatment	List of and location of advance decisions i.e. written documents completed and signed when a person is legally competent, that explain a person's wishes in advance, allowing someone else to make treatment decisions on his or her behalf late in the disease process.

temperature and blood oxygen saturation (National Institute for Health and Care Excellence 2020b).

Another example is the RCN's guidance on weighing infants and children in hospital which includes a section on standards and quality criteria for recording their weight (Royal College of Nursing 2020). If the recording practice standard were to be included routinely in practice guidelines there would be less need for separate content standards.

When content standards are separately specified, each information element in a record content set usually has a heading and a description with examples to ensure consistent use—Table 6.6 illustrates the structural (heading) and indicative content which may be a list of terms, numerical values or free text.

In summary, content standards:

- Are based on best/evidence based clinical practice and Regulatory Standards.
- May (and should) be integrated with clinical practice guidelines
- Define structural headings and may describe indicative content to populate the headings; they may define restricted content sets, for example, a list of terms and codes.
- May take account of what data is required for analysis (for example, to monitor and improve quality) but this is secondary to the primary purpose of supporting clinical care, communication and decision making.
- Are specified or endorsed by clinical professional organizations.
- Are the basis for related technical standards or specifications that support content design for clinical applications (see examples in Table 6.7).

Replicating paper record formats in electronic systems is not good user interface design therefore most content standards do not specify a layout of the content on a page, template or screen as these depend on the context of use and on good user interface design/standards. Where necessary for safety or consistency, standards may specify a standard layout or include examples to demonstrate good practice. Wherever possible, content standards should also be independent of any specific technical or clinical implementation context. Again, a standard may reference good practice examples and implementation resources/audit tools. To date, there are

Table 6.7 Examples of professional record content standards

Organization	Title and year	URL
Patient Safety Organization Privacy Protection Center (US)	Common formats for event reporting—hospital version 1.2 (2020)	https://www.psoppc.org/psoppc_web/publicpages/commonFormatsV1.2
Professional Records Standards Body (UK)	PRSB Standards for the Structure and Content of Health and Care Records (2018)	https://www.rcplondon.ac.uk/file/10682/download
NHS Digital (England)	SCCI1580: Palliative Care Co-ordination: Core Content (2015)	https://digital.nhs.uk/data-and-information/information-standards/information-standards-and-data-collections-including-extractions/publications-and-notifications/standards-and-collections/scci1580-palliative-care-co-ordination-core-content
Academy of Medical Royal Colleges, Royal College of Nursing, British Pharmaceutical Society (UK)	Standards for the design of hospital in-patient prescription charts (2011)	https://www.aomrc.org.uk/reports-guidance/standards-design-hospital-prescription-charts-0411/

professional standards for the structure and content of records—examples are provided in Table 6.7.

A number of related standards are required as building blocks for content standards and their related technical specifications, including terminologies, data dictionaries, data sets and detailed clinical models as well as interoperability resources such as terminology subsets and message specifications.

Clinical Coding and Terminology

Nursing has a relatively long history of terminology development and use. The American Nurses' Association (ANA) was among the first to highlight the importance of standardised terminologies for supporting nursing practice, education, management and research (Rutherford 2008); ANA formally recognized early in their adoption a number of nursing-specific terminologies, multi-disciplinary terminologies and datasets. Nurses in other countries have adopted terminologies developed in the US or have established their own to meet the specific needs of their populations. The International Council of Nurses has contributed to these efforts through the International Classification for Nursing Practice (ICNP) in order to develop a 'common language for nursing practice' (Rutherford 2008).

A systematic review in 2006 suggested that use of standardised terminology improved documentation (Muller-Staub and Lavin 2006) but there has been no

systematic review of the effect of standardized terminology on patient outcomes and experience of care.

However, the International Journal of Nursing Terminology and Classification and other publications do provide good examples of how standardised terminologies are used, and the ways in which they could benefit nursing and patients. There are also examples of the positive effects of national initiatives to standardise the terminology used in practice instruments such as assessment scales, such as the Canadian Health Outcomes for Better Information and Care (C-HOBIC) (C-HOBIC 2020).

In recent years, the main challenge for terminology developers and application designers has been to incorporate adequate representations of nursing care into computer and digital applications. It is this aspect of terminology which concerns us here but it should be noted that any professionally-endorsed terminology can add value to the ongoing work to develop and maintain the advanced terminological systems required in current and future healthcare applications. Many of the nursing terminologies previously recognised by ANA have informed the integration of nursing content into major international multi-disciplinary terminological resources such as the Unified Medical Language System (UMLS), Clinical LOINC and SNOMED Clinical Terms.

In 2018, ANA reaffirmed its support, through a position statement, of the use of recognized terminologies to support nursing practice and facilitate interoperability between systems (American Nurses Association 2020b).

In the position statement, ANA more closely aligned its support with data representation and exchange and interoperability standards included in the US Interoperability Standards Advisory (ISA) (described previously in this chapter). It recommended to each setting type the adoption of a standard terminology 'that best suits their needs and and select that terminology for their EHR, either individually or collectively as a group' (American Nurses Association 2020b). However, except in cases where settings are using the same terminology, ANA recommended that when exchanging data with another setting, SNOMED Clinical Terms (for problems, interventions and observation findings) and LOINC (for nursing assessments and outcomes) should be used. In some cases this might require mapping from the source nursing terminology to either SNOMED CT or LOINC. SNOMED CT and LOINC are designed to support the entry and retrieval of clinical concepts in electronic record systems and their communication in messages. They are built using logical definitions, rather than definitions drawn from practice knowledge and evidence, and are intended for use in computer applications.

Several international standards developed by ISO TC215 focus on terminological resources for health informatics applications. For example, ISO/TR 12300 *Principles of mapping between terminological resources* provides guidance on mapping between different terminologies and ISO/TS 21564 *Terminology resource map quality measures (MapQual)* provides guidance on how to assess the quality and utility of mappings.

Clinical Systems and Applications

Guidance and training for nurses in the use of specific applications has traditionally been the responsibility of the supplier or the employing organization. However, the spread and variety of applications means that it is now possible to draw together practice principles that build on evidence and lessons learnt from evaluations of system implementations. There are many gaps in this relatively new area of standards development but where they exist, nurses and provider organizations can use agreed standards or adapt them (with caution) for their local context. This will help prevent duplication and ensure consistency and safety. Approaches to system safety and risk management are perhaps the most important standards for both informatics specialists and clinical nurses when considering clinical systems and applications.

Risk management and patient safety processes are core aspects of all clinical practice. Any new intervention, device or health technology will have undergone rigorous testing up to and including formal clinical trials. It is surprising then that HI technologies have not generally been subjected to the same evidence based/risk management approaches. Serious harm can arise from the way systems are designed or the way they are used in practice, and any risk of harm must be identified and managed.

ISO has published a classification of safety risks from health software (TS 25238) citing concerns about the growing potential for harm to patients as the number, variety and sophistication of applications increases. Initial concerns focused on decision support systems with their obvious risks of errors, but have now spread to all types of health software.

The NHS in England requires all healthcare organizations to comply with its standards for the application of clinical risk management to deployment and use of health IT systems (NHS Digital 2020b). Note that in April 2020, it was agreed that due to the COVID-19 pandemic, organisations were able to defer full compliance with (NHS Digital 2020b), but there was an expectation that they would adhere to the fundamental principles of the standard and work towards compliance.

There is a related standard for those who design and manufacture systems, including processes for handover of responsibility for clinical safety when a system is deployed or upgraded (NHS Digital 2020c).

The principle behind these standards is that proactive safety risk management will help to reduce the likelihood of adverse events. According to the standard for manufacturers:

- The health care organisation must nominate a suitably qualified lead for clinical safety (a clinician).
- Manufacturers must have a documented clinical risk management process (approved by the clinical safety lead).
- Manufacturers must implement a clinical risk analysis process, including hazard identification with risk estimation, with ongoing monitoring and reporting (NHS Digital 2020c).

Table 6.8 Examples of professional standards and guidance for use of clinical systems and applications

Organization	Title and year	URL
College of Registered Nurses of Nova Scotia	Telenursing Practice Guidelines (2019)	https://cdn1.nscn.ca/sites/default/files/documents/resources/Telenursing.pdf
National Council of State Boards of Nursing (NCSBN) (US)	A Nurse's Guide to the Use of Social Media (2018)	https://www.ncsbn.org/3739.htm
Royal College of Nursing (UK)	Using text messaging services (2012)	https://www.rcn.org.uk/-/media/royal-college-of-nursing/documents/publications/2012/may/pub-004230.pdf
TEC Quality (UK)	TEC Quality Standards Framework (2020)	https://www.tsa-voice.org.uk/standards/

This last point is essential if nurses are to protect patients and fulfil the requirements of their ethical codes; if they have concerns about the safety of clinical systems and applications or the way these are being used they have a duty to act on their concerns (Nursing and Midwifery Council 2020b). This responsibility extends to those who work for the companies that design and supply systems.

Safety standards apply to all systems and applications and are supplemented by specific standards and guidance for integrating mobile technology (mHealth), telehealth applications, social media, SMS text messaging, decision support and other clinical systems into practice. Examples of these types of standards, written for practitioners rather than informatics specialists, are given in Table 6.8. Over the coming years we should see more examples where telehealth and other applications are integrated into clinical practice guidelines as just another kind of intervention or mode of care delivery.

The Future Direction of Healthcare

Given the widespread use of ICT in health care, in order to support contemporary nursing practice and the future direction of healthcare, a natural assumption is that all national and international standards of nursing proficiency or competence include the knowledge and skills necessary to manage information and to use ICT in daily clinical practice. Well known examples of such standards include the American Nurses' Association's *Nursing Informatics: Practice Scope and Standards of Practice* (American Nurses Association 2014), the TIGER (Technology Informatics Guiding Educational Reform) Initiative competencies (HIMSS 2020) and the Canadian Association of Schools of Nursing (CASN) Entry-to-Practice Nursing Informatics Competencies (Canadian Association of Schools of Nursing 2012).

However, in this rapidly evolving area of practice where new terms like big data and mHealth rapidly become broadly recognized in everyday use, it is doubtful that

faculty everywhere will have the skills to successfully integrate new technologies and the latest standards into their programs. In common with other organisations, the National League for Nursing for example provides an Informatics Teaching resource (National League for Nursing 2020). However, not all such resources cite national or international HI standards. Raising awareness of HI standards is one way that informatics specialists could help to improve the education of non-specialists such as students and faculty.

6.3.3 Consumer Health Information Standards

The concept of consumer health informatics has been around for some time. It has been defined as "the branch of medical informatics that analyses consumers' needs for information; studies and implements methods of making information accessible to consumers; and models and integrates consumers' preferences into medical information systems." (Eysenbach 2000).

A number of consumer-specific standards have been developed ranging from the international definition, scope and context for personal health records (ISO/TR 14292) to guidance for nurses on how to support patients using technology (Royal College of Nursing 2012) and guidance for patients on keeping their online records safe and secure (BCS/NHS 2013). As more people engage with health information applications, they are becoming more involved with the development of standards and dissemination to fellow consumers. We are already seeing a move away health professionals and industry partners defining these standards and towards development in collaboration with patient organizations, as well as consumer-led developments. However, there is an ongoing a need for further national and international regulation and standardization.

6.3.4 HI Standards for Informatics Specialists

In 2017, the top three job responsibilities for nursing informatics specialists were:

1. Systems implementation—including preparing users, training and providing support
2. System optimisation
3. Systems development (HIMSS 2017).

It is interesting to note that responsibilities around regulatory initiatives also featured strongly.

Health informatics specialists support improvements in health outcomes, healthcare system performance and health knowledge discovery and management, through the application of technology (Australian Health Informatics Education Council 2011).

In order to fulfil their responsibilities, HI specialists need to be clinical professionals and meet the standards of education and competence set by their professional organizations or government agencies. They also need to be familiar with standards that support safe use of clinical systems and applications in order to educate and support their clinical colleagues.

These include standards for:

- Semantic content—covering the structure and content of HI terminologies through standards. For example, ISO 18104 *Categorial structures for representation of nursing diagnoses and nursing actions in terminological systems*
- Data structures—covering data types, record architecture, reference information models, detailed clinical models and other information components. For example, ISO 18308 *Requirements for an electronic health record architecture*
- Data interchange—covering the format of messages used to exchange health data electronically. For example, HL7 *Fast Healthcare Interoperability Resources (FHIR®)*
- Security—For example, ISO 27799 *Information security management in health using ISO/IEC 27002*
- Safety—For example, IEC 82304-1 *Health software—Part 1: General requirements for product safety*.

6.4 Standards Development and Review

Structured development processes always begin with statement of need or requirements, i.e. what is the problem, who is affected by it and what is needed to solve it. Standards development is no different and begins with industry or other stakeholders identifying a gap in the standards portfolio that needs to be filled at a national or international level. In this section, the steps in the ISO standards lifecycle are summarised, including the essential steps of dissemination and review. A useful summary of the process is provided on the ISO site: https://www.iso.org/developing-standards.html. Other standards developers follow similar pathways involving multiple stakeholders in a consensus process based on expert opinion.

Challenges for HI standards development are discussed before moving on to the final section which considers how nurses can participate in the many activities required to promote safe, effective HI practice, the development of safe usable systems and to support interoperability.

6.4.1 The ISO Standards Lifecycle

The ISO standards lifecycle can be divided into 7 main stages, given below:

1. Proposal
2. Preparatory stage

3. Committee stage
4. Enquiry stage
5. Approval and publication
6. Implementation
7. Review

Proposal

This stage begins with the identification of stakeholders who can contribute to clarifying the requirement and the scope and purpose of a standard. A global scan is also undertaken to identify what standards already exist and where there is recognised expertise in the area under discussion. At the end of this stage a decision is made whether to:

- **Adopt** or **adapt** an existing international or national standard OR
- **Develop** a new standard, drawing on what is already known to work.

The adopt/adapt/develop decision is an important ISO principle: standards should not duplicate each other and should build on what is already known. ISO may adopt a standard produced by CEN, HL7 or another standards body through a fast track process; joint working across standards development organizations is common. For example, work on ISO 18104 began in CEN as ENV 14032 *System of concepts to support nursing*. It was moved to ISO under an arrangement called the Vienna Agreement, a formal route for cooperation between ISO and CEN (ISO/CEN 2001). Ensuring harmonisation across all HI standards is the goal of the Joint Initiative Council for Global Health Informatics Standardization which now coordinates standards strategies and plans with the aim of making all future standards available through ISO (Joint Initiative Council 2020).

If a decision is made to adapt or develop a standard, an expert group then begins a preliminary draft document and puts a proposal forward to the governance structures of the standards organization. At ISO, a new work item proposal is submitted to the relevant Technical Committee (TC 215 for health informatics) where a vote by TC members determines whether this should become an ISO programme of work. The TC seeks a clear international justification that reflects the benefits of implementing the proposed standard and/or the loss or disadvantage if a standard is not made available. At least five 'P-members' must commit to provide active support for the work in order for it to be approved (P- or Participating members are national member bodies rather than organizations with ISO Observer status—'O-members').

Countries that put forward experts usually have a domestic standards infrastructure that mirrors ISO working groups. For example, ANSI's HI Technical Advisory Groups (TAGs) manage US contributions, including ballot responses (American National Standards Institute (ANSI) 2020). They also promote the use of US standards internationally, advocating US policy and technical positions so that international and regional standards are more likely to align with domestic requirements.

Similar structures exist in all member countries so that, for example, health informatics experts in the Japan can actively engage with relevant work items and send delegations to TC 215 working group meetings to represent consensus views from that country. In the US and UK, these experts are normally volunteers from industry, government, academia or healthcare provider organizations. The success of standards efforts is therefore dependent on the willingness of these bodies to commit the resources required for experts to participate.

Preparatory Stage

The nominated experts from five (or more) supporting countries form the core of a working group/task force to prepare a working draft of the standard with a volunteer leader/convenor to plan and coordinate the work. Development is open so the working group will often involve other experts. For ISO 18104, stakeholders that were involved from the beginning included the International Council of Nurses (ICN), the Nursing Specialist Group of the International Medical Informatics Association (IMIA-NI) and ACENDIO, the Association for Common European Nursing Diagnoses, Interventions and Outcomes. Once the experts are satisfied with the draft, it goes as a Committee Draft (CD) to the parent working group and then to the TC for the consensus-building phase. At this stage the document must be structured according to ISO rules with sections for Definitions, Normative References and Normative Content, and Conformance requirements. Explanatory information, discussion, implementation examples, additional references etc. are contained in Informative Annexes i.e. they are not included in the Normative (mandatory) provisions of the standard.

Committee Stage

The Committee Draft is registered by the ISO Central Secretariat and distributed for comment and voting within the TC by its P-members. Successive Committee Drafts may be considered until consensus is reached on the technical content. Once consensus has been attained, the text is finalized for submission as a Draft International Standard (DIS). The voting process is limited to ISO's national member bodies (i.e. P-members); other stakeholders, such as the three international nursing groups mentioned (i.e. O-members) above have no formal role in the commenting and voting rounds (although it is hoped that their feedback would be considered).

ISO and many other SDOs use a structured approach to feeding back comments. This requires the country making the comments to categorise them to indicate whether they are editorial (such as spelling and format) or technical (e.g. errors in definitions or unclear/unsupported Normative content) and to include a suggested amendment to the relevant part of the document. The expert group is required to respond to every comment made and must provide a rationale for each response (including suggested amendments that are not accepted). Any contentious issues are

taken back to the wider TC so that other experts can provide input and reach consensus before the enquiry stage.

Enquiry Stage

The Draft International Standard (DIS) is circulated outside the TC to all ISO member bodies by the ISO Central Secretariat for voting and comment. It is approved for submission as a Final Draft International Standard (FDIS) if a two-thirds majority of the votes are in favour and not more than one-quarter of the total number of votes cast are negative. If the approval criteria are not met, the text is returned to the originating TC for further work following which a revised document will be sent out voting and comment again as a Draft International Standard.

Approval and Publication

In the last development stage, the FDIS is circulated to all ISO member bodies requesting a final Yes/No vote within a period of two months. If further technical comments are received during this period, they are not considered but are registered for consideration during a future revision. The document is approved as an International Standard again if a two-thirds majority of the members is in favour and not more than one-quarter of the total number of votes cast are negative. And once again, if these approval criteria are not met, the standard is referred back to the originating TC for reconsideration. Once the FDIS has been approved, only minor editorial changes are permitted before the final text is sent to the ISO Central Secretariat for translation into the three official languages of ISO (English, French and Russian) and publication.

Implementation

Regions and countries have different approaches to the adoption and implementation of International Standards. For example, while every country uses ISO 3166 *Country codes* exactly as it is published, the UK takes ISO/IEC 5218 *Codes for the representation of human sexes* as the basis for a more extensive entry in the NHS data dictionary that defines ‘person sex’ for use in all health data reporting data sets.

In some European countries, CEN standards automatically become national standards whereas in the UK a decision will be made whether or not to adopt a standard as a mandatory/contractual requirement for those supplying HI solutions to the NHS. The specification of relevant standards in national laws/regulations (e.g. medical devices regulations) and vendor contracts are the major implementation drivers. For other standards, a number of approaches may be required including: endorsement by organizations such as professional associations; awareness raising; education; supported change management; and incentives.

Some organizations support a coherent, user driven approach to implementing proven standards. One example is IHE which brings together users and developers of healthcare applications in a four-step process:

1. Clinical and technical experts define critical use cases for information sharing
2. Technical experts create detailed specifications for communication among systems to address these use cases, selecting and optimizing established standards
3. Industry implements these specifications called IHE Profiles in their systems
4. IHE tests vendors' systems (Integrating the Healthcare Enterprise 2020).

Review (Confirmation, Revision, Withdrawal)

International Standards are reviewed at least every five years and a decision made by a majority vote of the P-members on whether the standard should be confirmed, revised or withdrawn. Countries are asked to indicate whether they use the standard and if they have any issues with it that would require revision or withdrawal. Revised standards follow a similar pathway with an expert group steering the work through ballot/voting stages, seeking international consensus, approval and publication.

Some reviews will elicit more concrete technical requirements, based on live use of a standard in multiple systems or settings. For example, EN/ISO 13940 *System of concepts to support continuity of care* was referenced by the NHS Data Dictionary in England. This work validated the provisions of the standard and confirmed its value but also identified a number of issues with relationships between data elements as they were specified in the standard. These were taken forward to the next version.

6.4.2 Standards Development Challenges

The core principles for national and international standards development are that this activity is voluntary, open to all, consensus based and stakeholder driven. However, there are a number of challenges with achieving these goals, particularly at the international level. The 'open standards' process must balance the interests of those who will implement the standard with the interests and voluntary cooperation of experts who may own intellectual property rights (IPR) associated with it. The word 'open' does not imply free—there may be a need for some form of licensing to protect IPR and often there is a fee to obtain a copy of the standard which offsets the costs of the development and maintenance process.

Volunteer effort sometimes limits the level and type of expertise available and means that a standard can take longer to develop than is required in a rapidly developing field like health informatics. Organizations such as HL7 have made significant advances in the way it engages stakeholders and develops standards in an effort to be more responsive to the urgent demands of the industry. However, end users of

health informatics standards such as health professionals and health care consumers are still not actively engaging to the extent that ISO would expect. In 2008, a multidisciplinary task group led by nursing members of TC 215 made a number of recommendations for improving clinical stakeholder engagement in international HI standards development and review, and embodied these within a TR (ISO/TR 11487). The recommendations within the TR still hold, including:

- Establish communications with international health professional organizations, particularly those that have a health informatics profile/component. This could include regular information exchanges and invitation for liaisons to attend TC 215 meetings
- Explore mechanisms by which input of such international stakeholder organizations can be recognized within formal TC215 processes, including lessons from other ISO domains (engineering, chemical, etc.)
- Require that proposers of new work items identify relevant clinical and other stakeholder groups, their input to the proposal and how they may be involved in the work item
- Request national member bodies to report on the measures being taken to engage and facilitate the participation of clinical stakeholders at the domestic level as a basis for further action and to identify models of good practice that other members could adopt.

Participation of developing countries and non-English speaking members in HI standards development has also been limited, although this is changing slowly. In 2004, a survey of participation in ISO's standards development processes reported that Western Europe represented '*almost half the voting base in ISO's standards development work, despite representing approximately six percent of the world's population*' (92, p. 2), although there has been increased engagement of non-European countries such as Korea, Japan and China in TC215 meetings in recent years.

Given these challenges, it is no surprise that there are significant gaps in the HI standards portfolio. International policy making organizations such as the European Union (EU), the Joint Initiative Council and WHO have all identified the need for improved and coherent action to address the healthcare interoperability requirements of the future.

The high profile of HI standards and the huge amount of national and international standards-related activity presents a particular challenge for nursing as we will see in the final section below.

6.4.3 Participation in Standards Development and Review

There are a number of routes and opportunities for nurses to engage in the development of HI standards. Researchers, practising nurses, policy leaders and others can collaborate to influence what standards get developed, creating and collating

evidence to support standard/guideline development and promoting their use, for example through education. Individual nurses can engage by contacting their professional organizations some of which may need to be made aware of the need for HI standards but may welcome interested volunteers.

Participating in the development and review of national and international HI standards themselves is not straightforward. There are very few clinicians involved in general and too few nurses in particular. Those who are involved come in several guises:

- The practising clinician who has an interest in a specific aspect of health information and participates on a part time basis. Many of these people do this work in their own time although some employers recognise the value of this activity and provide varying levels of support to attend events and undertake development/review work
- The health informatics specialist i.e. someone who has developed a career in health informatics. This person can have a significant role in helping technical people understand the clinical world and vice versa. However, unless he/she maintains clinical networks, this person may become distanced from the world of practice
- The practising clinician who becomes involved for a short time on a particular project. Facilitation of this input can result in new skills for this person who could be encouraged to participate further.

A major area of interest for nurses is terminology and content standards, but only a few are involved in this kind of international standards activity, mainly at HL7, ISO and CEN. It is a complex world for new members to enter at any level; and time and support are needed to develop sufficient understanding to participate effectively. Efforts to recruit and develop new participants have had little success for a number of reasons including:

- Lack of time and financial support to participate—some countries provide funding but this is often limited to national delegates
- Perceived lack of relevance to nursing practice and therefore to managers
- Perceived complexity of the domain: jargon, technical knowledge requirements, etc.
- Lack of awareness of the need or of how to get involved.

Entry-level material is available on the websites of the major SDOs with information on need, relevance and development processes. Each country that has a participating organization will include on its website information about how to participate and many provide online training opportunities. Willing volunteers are usually welcomed with open arms. However, there may be a fee to join some organizations, and before signing up it is important to consider whether support is available (such as for time to undertake reviews and attend meetings, payment of expenses, peer support, etc.).

6.5 Conclusion

Information and communications technology are central to the future of health and social care. To support the rapid advances needed for future solutions, health information standards are being developed and implemented across the globe. These will have a profound impact on nursing, patient care and outcomes. HI standards are needed to support integration of information management and ICT into clinical practice. They provide guidance for clinicians, patients and public on how to make best use of information and technology and are closely linked to standards for practice, including record keeping. Specialist HI standards are also required to ensure that applications are safe, usable and fit for purpose. They must support interoperability between systems so that information that is communicated electronically can be accurately interpreted and used for decision-making, continuity of care and other purposes.

Although the number of nurses working in health informatics roles is increasing, the number participating in standards development and review is, if anything, decreasing. Health informatics specialists need to work with their clinical colleagues, professional organizations and developers of clinical guidelines to produce, maintain and measure conformance to HI standards. They should also engage with national and international HI standards organizations, helping to fill gaps in the standards portfolio and promoting the use of standards in their own organizations. New approaches to participation that do not involve expensive and time consuming travel must be found so that nursing can continue to have an active, leadership role in this important activity.

6.6 Clinical Pearls

- Nurses are required to maintain clear and accurate records and to ensure that all records are kept securely
- HI standards provide a foundation so that nurses can have more confidence in the systems they use in practice.

6.7 Review Questions

6.7.1 Questions

1. Describe the role that HI standards play in nursing practice.
2. Identify the aspects of nursing practice that are covered by HI Standards.
3. Describe the lifecycle of an HI standard.

6.7.2 Answers

1. HI standards support the integration of information management and ICT into clinical practice. They provide guidance for clinicians, patients and public on how to make best use of information and technology and are closely linked to standards for practice, including record keeping. Specialist HI standards are also required to ensure that applications are safe, usable and fit for purpose. They must support interoperability between systems so that information that is communicated electronically can be accurately interpreted and used for decision-making, continuity of care and other purposes.
2. It might be useful for respondents to present the answer to this review question as a set of use cases drawn from their own practice. They may also find it useful to refer also to generic use cases, for example, those developed for eHealth by ETSI (https://www.etsi.org/deliver/etsi_tr/103400_103499/103477/01.01.01_60/tr_103477v010101p.pdf).
3. A useful approach to framing the HI standards lifecycle is by describing the 7 stages of the approach taken in ISO:
   Proposal
   Preparatory stage
   Committee stage
   Enquiry stage
   Approval and publication
   Implementation
   Review

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Glossary

AHQR Agency for Healthcare Research and Quality
ANA American Nurses Association
ANSI American National Standards Institute
CEN European Standards Organisation
Consumer Informatics The use of modern computers and telecommunications to support consumers in obtaining information, analyzing unique health care needs and helping them make decisions about their own health
Clinical guidelines Systematically developed statements to assist practitioners and patient decisions about appropriate health care for specific circumstance
HI standard A document, established from evidence and by consensus and approved by a recognized body, that provides rules, guidelines or characteristics

for activities or their results, in the field of information for health, and Health Information and Communications Technology (ICT)

HIPAA Health Insurance Portability and Accountability Act of 1996

HL7 Health Level Seven

HL7 RIM Reference Information Model Represent an approach to clinical information exchange based on a model driven methodology that produces messages and electronic documents expressed in XML syntax

ICF International Classification of Functioning Disability and Health

ICN The International Council of Nurses

ICNP International Classification of Nursing Practice

ISA Interoperability Standards Advisory (ISA) is a process which represents the model by which the Office of the National Coordinator for Health Information Technology (ONC) will coordinate the identification, assessment, and determination of "recognized" interoperability standards and implementation specifications for industry use to fulfill specific clinical health IT interoperability needs.

ISO International Organization of Standardization

ISO defines a standard as A document established by consensus and approved by a recognized body that provides for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context

JIC Joint Initiative Council

LOINC Logical Observation Identifiers Names and Codes

NHS National Health Service

RIM Reference Information Model

SMS Short Message Service

SNOMED Clinical Terms Systematized Nomenclature of Medicine a systematic computer processable collection of medical terms in human and veterinary medicine

TVS Tissue Viability Society

UMLS Unified Medical Language System

Usability The extent to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency and satisfaction in a specified context of use

WHO World Health Organisation

XML Extensible Mark Up Language is a computer markup language that defines a set of rules for encoding documents in a format that is both human-readable and machine-readable

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