# Chapter 7
# Health Informatics Standards

**Anne Casey**

**Abstract** Health informatics standards help to ensure that health specific applications used by clinicians, patients and citizens are safe, usable, and fit for purpose. They support interoperability between systems so that information communicated electronically can be accurately interpreted and used for decision-making, continuity of care, and other purposes. This chapter covers HI practice standards, guiding the integration of ICT into clinical practice, and HI specialist standards including standards for semantic content, data structures, data interchange, security and safety. Examples of professional and technical HI standards are provided to demonstrate how each type of standard is dependent on the other to help nurses deliver safe, effective care and to communicate across boundaries.

**Keywords** eHealth • Nursing informatics • Informatics standards • Nursing systems

**Key Concepts**

eHealth
Nursing informatics
Informatics standards
Nursing systems

## 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

The online version of this chapter (doi:10.1007/978-1-4471-2999-8_7) contains supplementary material, which is available to authorized users.

A. Casey, RN, MSc, FRCN
Knowledge and Information Service, Royal College of Nursing, London, UK
e-mail: tbacasey@hotmail.co.uk



K.J. Hannah et al. (eds.), *Introduction to Nursing Informatics*,
Health Informatics, DOI 10.1007/978-1-4471-2999-8_7

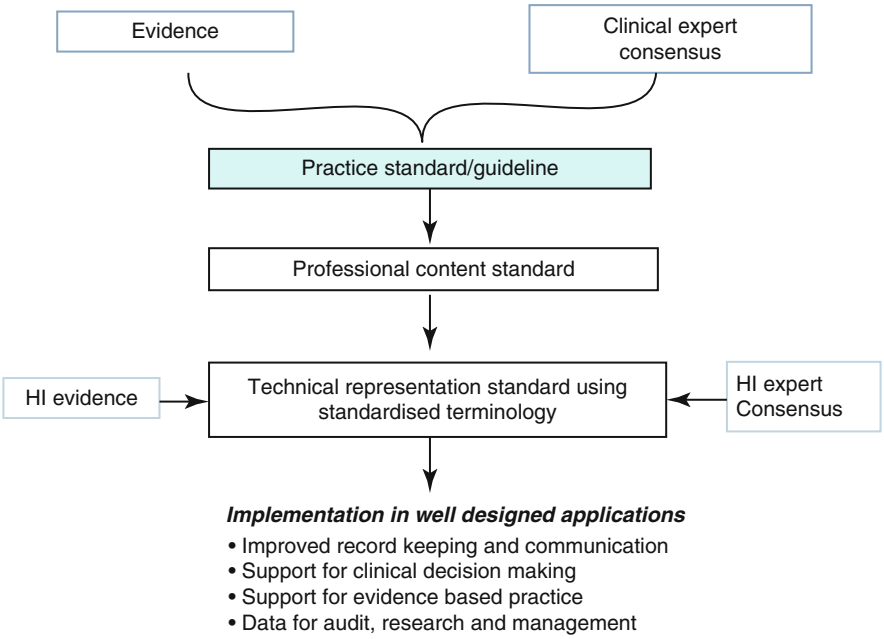


**Fig. 7.1** Relationship between evidence based and consensus practice standards, HI practice standards and HI specialist standards

conditions increases and the number of qualified nurses continues to fall [1]. 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. Using the example of record content standards, Fig. 7.1 shows the relationship between evidence based and consensus practice standards, HI practice standards and HI specialist standards. This theme will be revisited throughout the chapter.

In this chapter, the nature of standards in health informatics is explained and key concepts such as conformance and consensus are explored. Table 7.1 provides definitions of relevant terms, some of which are also explained in the text. HI practice standards and HI specialist 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 – Table 7.2 explains how to obtain copies of all ISO standards. Examples of HI practice 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.

**Table 7.1** Terms and definitions

| | | |
|---|---|---|
| **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 (International Organisation for Standardisation) [94] | |
| **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 | |
| **Default 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 | |
| **Regulation** | Legal or professional rule or principle that directs activities or their results; also known as 'regulatory standard' | |
| **Clinical guideline** | Systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances [15] | |
| **Mandation** | Term that groups the categories of conformance requirement specified in standards: 'mandatory', 'conditional' and 'optional' | |
| | Mandatory: | Always required |
| | Conditional: | Required under certain specified conditions. Anything specified as Conditional … shall be treated as Mandatory if the associated condition is satisfied, and shall otherwise be not present |
| | Optional: | Permitted but not required |
| | | (ISO/IEC 11179–3 2003) [95] |
| **Conformance** | Degree to which the requirements in a standard specification are met | |
| **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 | |
| **Conformity assessment** | Process used to show that a product, service or system meets specified requirements (International Organization for Standardization) [96] | |
| **Recognized body** | Legal or administrative entity that has specific tasks and composition, with acknowledged authority for publishing standards (International Organization for Standardization) [96] | |
| **Interoperability** | Ability of two or more systems or components to exchange information and to use the information that has been exchanged (Institute of Electrical and Electronics Engineers, 1990) [7] | |
| | Functional interoperability – capability to reliably exchange information without error | |
| | Semantic interoperability – ability to interpret, and, therefore, to make effective use of the information so exchanged. (Health Level Seven International HL7) | |
| **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; concerns keeping, obtaining, recording, using and sharing such information [97, p9] | |

(continued)

**Table 7.1** (continued)

| | |
|---|---|
| **UMLS** | Unified medical language system – a terminological resource from the National Library of Medicine – www.nlm.nih.gov/research/umls/about_umls.html |
| **Clinical LOINC** | A universal code system for identifying laboratory and clinical observations – www.loinc.org |
| **SNOMED Clinical Terms** | A terminological resource maintained by the International Health Terminology Standards Development Organization – www.ihtsdo.org |

**Table 7.2** Standards Development Organizations (SDOs)

| | | |
|---|---|---|
| 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 162 countries. It has published more than 19,500 International Standards and has around 3,400 technical groups 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 33 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 on SDO Global Health Informatics Standardization was formed to address gaps, overlaps, and counterproductive HI standardization efforts. Members include ISO TC215, CEN TC 215, HL7, CDISC, IHTSDO |
| 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 2,300 members. 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' |

**Table 7.2** (continued)

| | | |
|---|---|---|
| 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. |
| 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. |

NOTE: Hammond et al. [98] provide a helpful overview of standards development with a diagram showing how US and international SDOs relate to each other

In the final section of the chapter, the standards lifecycle is described and approaches to standards development and review are explained. After reading this chapter, the reader should be able to:

- Identify and access standards that are relevant to one's context (clinical practice, education, informatics specialist etc.)
- Use appropriate standards to assess conformance of HI practices, processes and applications
- Participate in standards development, conformance assessment and review.

## Defining Standards and Related Concepts

### *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. This chapter uses ISO 690, the international standard for bibliographic referencing, which is embedded in the word processing software.

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

- Help to make the development, manufacturing and supply of goods more efficient, safer and cleaner.
- Make trade between countries easier and fairer.
- Support national technical regulations. For example, ISO 14971, *Application of Risk Management to Medical Devices*, has been adopted in the USA, Europe, and Japan [2].

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. [2]

Put more simply, a standard is '*an agreed way of doing something*' [3]

Both of these definitions conform to international standards for formulating good definitions [4] in that they state what the concept is without using the word that is being defined. The second definition conforms very well in that it is concise, unambiguous and states the essential meaning of the concept. The first definition includes a purpose ('*..aimed at the achievement of …*') which goes against the recommendation that a good definition should '*be expressed without embedding rationale*, *functional usage*, *domain information*, *or procedural information*' [4; p7]. However, in order to understand HI standards we need to consider both their purpose and their 'functional usage', particularly conformance assessment.

Before discussing these topics however, there is one other aspect of the definition of a standard that needs to be considered, most easily understood as the difference between a noun and an adjective. ISO sees a standard as a **document** but people often refer to **things** as standards, 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 9919 is a family of standards that specify the characteristics of medical electrical equipment such as pulse oximeters so that these can be assessed for safety and performance; ISO/TS 17117 sets out the essential features of controlled health terminologies to support evaluation as well as development. Supporting safety and evaluation are just two of the purposes of HI standards summarised below.

## *Purpose of HI Standards*

At a general level, HI standards support clinical practice and the management, delivery, and evaluation of health services [5]. According to ISO, their specific purpose is '*to promote interoperability between independent systems*, *to enable compatibility and consistency for health information and data*, *as well as to reduce duplication of effort and redundancies*' [6].

Interoperability is '*the ability of two or more systems or components to exchange information and to use the information that has been exchanged*' [7]. Expanding on this definition, Health Level Seven International (HL7), a standards development organization (SDO), talks about functional and semantic interoperability:

- 'Functional interoperability is the capability to reliably exchange information without error.
- Semantic interoperability is the ability to interpret, and, therefore, to make effective use of the information so exchanged.' [8]

In all healthcare settings across the globe, 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 and that is 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 [9]. 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, discussed next.

## *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 7.1 for definitions of conformance and compliance. In the two definitions above, I was able to evaluate the degree to which the definitions conform to the statements in the ISO standard for the formulation of data definitions [4].

A good test of the quality of a standard is whether it is specified in a way that makes assessment of conformance possible. Consider the two statements below related to on-screen display of medication:

1. '*Ensure that numbers and units of measure can be clearly distinguished*'
2. '*Leave a space between numbers and units of measure. Ensure that spacing is adequate by always leaving one blank, non-breaking space between a number and its unit of measure. In addition, use full English words instead of symbols and always use the standard abbreviation for units of measure*.' [10]

Imagine the process of evaluating a new medication administration system before it is introduced in the hospital. A subjective assessment is necessary against Statement 1 above, but Statement 2 allows for an objective and replicable measurement i.e. either there is 'one blank, non-breaking space' etc. or there is not.

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 (ISO/IEC 11179–3). These terms are explained further in Table 7.1 but an example is given below from the *End of Life Care Co-ordination Information Standard* published by the English National Health Service (NHS) [11].

This standard specifies the required format for core content of the record to communicate a person's end of life care decisions and preferences. One of the requirements in the standard is that *Clinical governance and IT safety leads in each organization 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 Resuscitation orders. Some content elements such as demographic details are mandatory in every 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 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 [12] and a Code of Ethics for Nurses is published by the American Nurses Association [13]. In the UK, the Nursing and Midwifery Council is the regulatory body established in law that sets standards for education, conduct, performance and ethics [14].

In contrast, clinical guidelines are '*Systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances*' [15; p38]. '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 Regulations if they are to continue to practise. 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 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 Quality Standard* published by the English National Institute for Health and Clinical Excellence (NICE) [16]. NICE has the same kind of authority as the US Agency for Healthcare Research and Quality (AHRQ) [17] – 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* [18] 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.

## *Consensus Or Evidence?*

Consensus building by experts, technical committees and national standards bodies is used by most international HI standards organizations to prepare new standards. However, 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 is more difficult to obtain. Personal Health Records (PHRs), for example, are not yet widespread in most countries so ISO's Health Informatics Technical Committee (TC215) published a Technical Report (TR) to summarise current knowledge on this topic and establish some definitions and principles (ISO/TR 14292). A 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, ISO's experts may agree to publish a Technical Specification (TS) – 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 and the TS will most likely be updated and promoted to a full standard based on their feedback.

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. Until recently, fitness for purpose and implementation evaluations have not been sufficiently accounted for in the consensus approach to development and review of HI standards. More attention is being paid now to questions such as costs 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?

## *'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 [19].

A small but growing number of HI practice 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 7.2 but perhaps more relevant to readers of this chapter are the national standards organizations in each country that 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' [20]. Many national organizations of this kind will also develop standards for their own country, which they can then contribute to the international arena when other countries identify a similar need.

The standards produced by these organizations may be entirely consistent, differing only in presentation such as when different versions are published for technical experts and for clinicians. Unfortunately, consistency across SDOs is not always the case. A very basic example is the spelling of the word 'organisation'. The European standards organisation (CEN) uses 's' whereas ISO uses 'z'. There are

similar trivial examples specific to health informatics: the HI technical committee of ISO is called TC 215 – the equivalent committee in Europe is called 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 on SDO Global Health Informatics Standardization (see Table 7.2) [21]. Members of these SDOs consist mainly of HI experts and industry representatives. However, there is recognition that clinicians and health consumers should be part of standards development activity. In a presentation to the Joint Initiative Council meeting in October 2012, Professor Steven Kay emphasised the need for HI standards organizations to focus on 'usability' [22]. He cited the definition of usability from ISO 9241, a multi-part ISO standard covering ergonomics of human-computer interaction, i.e. usability is '*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*'. According to Kay, 'users' are presently seen as representatives and experts from organizations with a vested interest in the standard under development, not the clinicians and patients who are often the ultimate 'consumer' of the standard [23].

ISO has recognised the importance of consumer participation: '*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*' [24]. 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. Standards have a clear and defined development lifecycle or development process. In 2012, Canada Health Infoway [25] articulated a pan-Canadian Standards Product Life Cycle, which identified the four-stage development process for standards (Fig. 7.2). These include needs identification, options analysis, specification (standard) development, and maintenance [25; p.18].

This lifecycle is follows a traditional development process of identifying a health care challenge or 'business need' that requires a standards-based solution, exploring various options or potential standards solutions, proceeding to the adaptation of an existing standard or to developing a new standard, and finally reaching the stage of stability and on-going maintenance of that solution.

As standards progress through the development process, they may be awarded specific labels indicating their levels of maturity and readiness for use in health information applications [25]. These levels of maturity are intricately tied to the development process, as illustrated in Fig. 7.3. The *Canadian Strategy Selection* is the most introductory label of potential suitability for use as solution to a clinical challenge. The *Canadian Draft for Use* label is one that tells early adopters that this standard has undergone sufficient testing and validation to proceed with use but that future changes can still occur. The most important label is the *Canadian Approved Standards*, which designates the highest label of stability and that the standards is fully endorsed by the Infoway-sponsored inter-professional authorizing committees. When standards no longer meet business needs, they may become *Canadian Deprecated* or withdrawn from use.

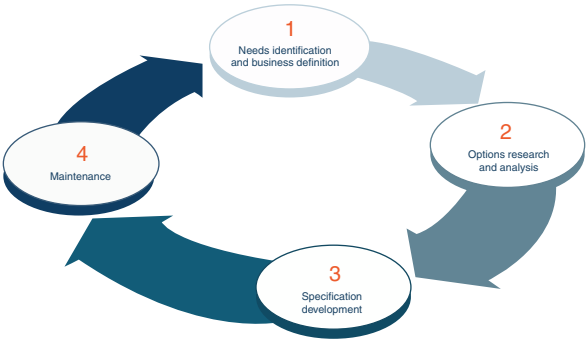


**Fig. 7.2** The pan-Canadian Standards Product Life Cycle [25]

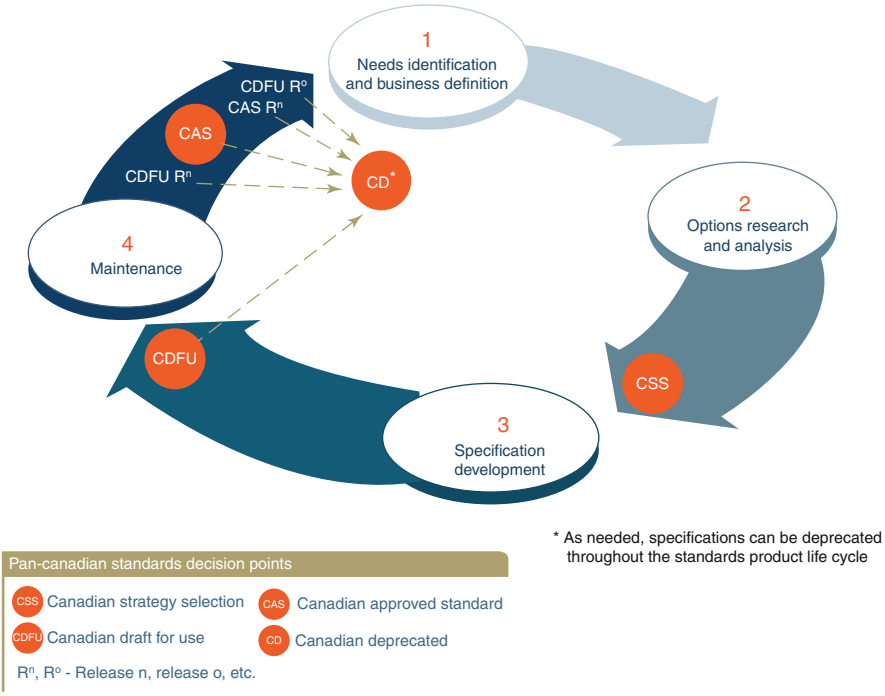


**Fig. 7.3** The Pan-Canadian Standards Development Process and Decision Points [25]

Development, approval and adoption of standards follows a recognised standards lifecycle one example of which is given below with further detail in a later section.

## *Summary – 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 to conclude that 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 HI standards is 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. Clinicians and consumers of health care should be involved in the development, implementation and review of HI standards.

## HI Practice Standards

### *Scope of the Requirement for 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 the scope of health care i.e. healthcare delivery; disease prevention and wellness promotion; public health and surveillance; clinical research [6].

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, so the focus here will be on the standards that are available to support clinicians in their everyday practice including their support for healthcare consumers.

### *HI Standards for Clinicians*

The term 'eHealth' is often used in place of 'health informatics' to convey a more general meaning i.e. '*healthcare practice which is supported by electronic processes and communication*' [26; p42] – see also Chap. 2. This definition places ICT in perspective – it is a support for practice rather than a separate subject, at last for the non-specialist. This is why, as mentioned in the introduction, HI standards must be so closely related to 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 practice standards for all nurses and other clinical staff are given below, organised according to clinical eHealth themes identified by the NHS [26; p5]:

- Protection of individuals – confidentiality, privacy and security
- Data, information and knowledge
- Communication and information transfer
- Health and care records
- Terminology
- Clinical systems and applications
- Standards for Competence and Education

**Protection of Individuals**

Across the globe, nurse Practice Acts, Regulations and ethical 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' [22]. Health departments and professional associations are the main sources of practice standards for Information Governance – see definition in Table 7.1. 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 [27; p3].

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 as an Information Governance Review in England has found [28]. This report cites data from sentinel reviews in the US and a number of UK cases where professionals did not share confidential information about children who were at risk and were subsequently killed. Table 7.3 lists examples of standards for information sharing as well as for maintaining privacy and confidentiality.

Although there is plenty of guidance for seeking consent for information sharing, there do not seem to be any standards for recording consent or refusal, a necessary precursor for designing appropriate structure and content for electronic recording. However, ISO TC215 is currently collating international best practice to develop 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 17915). Work is also progressing on *Data protection in transborder flows of personal health information* (ISO 16864). 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 7.3).

**Table 7.3** 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 (2013) | http://www.cdc.gov/mmwr/preview/mmwrhtml/m2e411a1.htm |
| College of Registered Nurses of British Columbia | Practice Standard – Privacy and Confidentiality (2010) | https://crnbc.ca/Standards/PracticeStandards/Lists/GeneralResources/400ConfidentialityPracStd.pdf |
| Department for Education (England) | Information Sharing: How to judge a child or young person's capacity to give consent to sharing of personal information (2011) | http://media.education.gov.uk/assets/files/pdf/h/how%20to%20judge%20capacity%20to%20give%20consent.pdf |
| Nursing and Midwifery Council (UK) | Regulation in Practice: Confidentiality (2012) | http://www.nmc-uk.org/Nurses-and-midwives/Advice-by-topic/A/Advice/Confidentiality/ |
| Palo Alto Medical Foundation | Privacy of Information (teens) | http://www.pamf.org/teen/sex/righttoknow.html |
| Royal College of Nursing (UK) | Consent to create, amend, access and share eHealth records (2012) | http://www.rcn.org.uk/__data/assets/pdf_file/0003/328926/003593.pdf |

**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. However, health information literacy for clinicians is one area that has been extensively developed, recognizing 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.

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 data set 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* [29] 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*' [29; p6]. The TVS proposed a UK standard using the definitions agreed by the US and EU Pressure Ulcer Advisory Panels – the professional 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 then 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': Levy and Heyes [30] argue that, "the best way to ensure patients do not access poor quality or inaccurate information online is for healthcare professionals to act as 'information brokers' and guide users to high quality web resources" [30; p22]. This means that nurses must themselves have the skills needed 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 [31] 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 [31].

Table 7.4 lists examples of standards guiding practice related to information literacy (for clinicians and consumers) and to information quality. Note that information literacy of health consumers is one part of wider 'health literacy'. The National Network of Libraries of Medicine uses the Institute of Medicine definition of health literacy: '*the degree to which individuals have the capacity to obtain*, *process*, *and understand basic health information and services needed to make appropriate health decisions*' [32]. What this means for nurses is well illustrated by guidance on how to improve health literacy from the New Zealand Nurses' Organization [33].

**Table 7.4** Examples of practice standards – Information Literacy and Information Quality

| Organization | Title and year | URL |
|---|---|---|
| DISCERN (UK) | Quality criteria for consumer health information (includes a questionnaire to help users to assess information quality) | http://www.discern.org.uk/ |
| National Library of Medicine. MedlinePLus | Evaluating Internet Health Information: A Tutorial from the National Library of Medicine | http://www.nlm.nih.gov/medlineplus/webeval/webeval.html |
| New Zealand Nurses Organization | Health Literacy Practice Position Statement (includes strategies for nurses to help improve consumer health literacy) (2012) | http://www.nzno.org.nz/LinkClick.aspx?fileticket=GPbcXpviZxM%3D |
| Royal College of Nursing (UK) | Finding, using and managing information – Nursing, midwifery, health and social care information literacy competences (2011) | http://www.rcn.org.uk/__data/assets/pdf_file/0007/357019/003847.pdf |
| US Dept of Health and Human Services. Office of Disease Prevention and Health Promotion | Quick Guide to Health Literacy (includes section on improving the usability of health information) | http://www.health.gov/communication/literacy/quickguide/ |

### Communication and Information Transfer – Standards for What and How We Should Communicate

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 Practice Acts and Codes and in national and international standards and benchmarks [34].

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.

In recent years there has been a major focus 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 [35]. 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] [36].
- 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 [35–37].

A single standard format for the information to be transferred would not be appropriate in all care settings, but there are elements common to all handovers, including the patient's name, diagnosis and problems, plans and tasks to be done [35]. Guidelines developed for the NHS by the Centre for Health Care Informatics Design [38] identified a core data set for electronic handover communications that must be used in every electronic clinical handover, recognising that each healthcare

**Table 7.5** Examples of practice standards – Communication and Information transfer

| Organization | Title and year | URL |
|---|---|---|
| Agency for Healthcare Research and Quality (AHRQ) Patient safety Network | Transitions of Care (TOC) Portal (Joint Commission) | http://www.psnet.ahrq.gov/resource.aspx?resourceID=25778 |
| Association of periOperative Registered Nurses (AORN) and the U.S. Department of Defense Patient Safety Program | Patient Hand Off Tool Kit (2012) | http://www.aorn.org/Clinical_Practice/ToolKits/Patient_Hand_Off_Tool_Kit/Patient_Hand_Off_Tool_Kit.aspx |
| British Geriatric Society | Transfer of Care for Frail Older People (2010) | http://www.bgs.org.uk/index.php/topresources/publicationfind/goodpractice |
| Royal Pharmaceutical Society | Keeping patients safe when they transfer between care providers – getting the medicines right.<br>Good practice guidance for healthcare professions (2011) | http://www.rpharms.com/current-campaigns-pdfs/1303---rps---transfer-of-care-10pp-professional-guidance---final-final.pdf |
| World Health Organization | Communication During Patient Hand-Overs | http://www.who.int/patientsafety/solutions/patientsafety/PS-Solution3.pdf |

setting will have its own, additional set of essential data. The content elements that are being considered for recognition as a national NHS handover standard are:

- Name, date of birth, unique identifying number (national identifier such as the NHS number).
- What is wrong with the patient e.g. active clinical problems.
- What has been done e.g. relevant investigations and treatments to date.
- What needs to be done e.g. action plan — including when and by whom.
- Anything else that is essential to inform the receiving clinician about e.g. risks, allergies, statuses, disability.
- Clinician making the handover.
- Clinician to whom the handover is being made.
- Current medications [39].

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* [40]. The rationale for this review was the absence of any evidence base for interventions to improve patient safety around handover. It is hoped that the review will provide the basis for more directive practice standards although it may be that further research is required to move from consensus to truly evidence based standards for information transfer.

There are too many examples of practice standards for good communication and information transfer to list in this chapter. A few examples are listed in Table 7.5.

### Health and Care Records – Standards for Record Keeping and Record Content

Nurses are required to maintain up-to-date and accurate records of assessments, risks and problems, care, arrangements for ongoing care and any information provided to the patient [41, 42]. 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 [43].

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' [41; p3]. However, many studies have identified that there is room for improvement in the quality of nursing documentation [43]. This will not happen unless records are valued and used rather than being viewed as a 'necessary evil' in case of litigation [34]. 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. [43] indicate that electronic applications and standardized documentation systems had the potential to improve documentation. However, a Cochrane Review of nursing record systems [44] 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*' [44; p2]. 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 (for example, as in Northern Ireland) [45], they provide a good basis for improving the quality of nurses' record keeping and for supporting the design of applications. It should be noted however, 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*' [46].

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. report that the Danish national guideline lists 12 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*' [47].

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 [46]. 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; limb movements; pupil size and reactivity; blood oxygen saturation; respiratory rate; heart rate; blood pressure; temperature [48]. 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 [49]. 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 7.6 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.

**Table 7.6** 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. |

**Table 7.7** Examples of professional record content standards

| Organization | Title and year | URL |
|---|---|---|
| Patient Safety Organization Privacy Protection Center (US) | Hospital Common Formats (for adverse event reporting – including technical specifications) | https://www.psoppc.org/web/patientsafety/hospital-common-formats |
| Royal College of Physicians (UK) | Standards for the structure and content of medical records and communications when patients are admitted to hospital. (2008) | http://www.rcplondon.ac.uk/sites/default/files/documents/clinicians-guide-part-2-standards.pdf |
| NHS National End of Life Care Programme (England) | End of life care co-ordination record keeping guidance (2012) (includes practice principles and a technical specification – the 'national information standard') | http://www.endoflifecare.nhs.uk/search-resources/resources-search/publications/information-standard-record-keeping-guidance.aspx |
| Academy of Medical Royal Colleges, Royal College of Nursing, British Pharmaceutical Society (UK) | Standards for the design of hospital in-patient prescription charts (2011) – (includes content and format requirements) | http://www.aomrc.org.uk/projects/standards-in-patient-prescription-charts.html |

- Are specified or endorsed by clinical professional organizations.
- Are the basis for related technical standards or specifications that support content design for clinical applications (refer back to Fig. 7.1 and see examples in Table 7.7).

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 few

professional standards for the structure and content of records – some examples are provided in Table 7.7.

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

## Terminology

Nursing has a relatively long history of terminology development and use. The American Nurses' Association (ANA) was the first to recognise the importance of standardised terminologies for supporting nursing practice, education, management and research [50]. 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) programme which 'serves as a unifying nursing language system for international nursing based on state-of-the-art terminology standards' (Fig. 7.4) [51].

A systematic review in 2006 suggested that use of standardised terminology improved documentation [52] 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 publi-


**Fig. 7.4** ICNP® 7-Axis Model (With permission from the International Council of Nurses. ©2013 International Council of Nurses, 3, place Jean-Marteau, 1201 Geneva, Switzerland -All rights reserved)

cations 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. For example, evaluation of the Canadian Health Outcomes for Better Information and Care (C-HOBIC) project [53] indicated that use of the C-HOBIC approach to assessment using standardized terminology had a positive impact on professional practice, enabling nurses to share information and focus on patient outcomes. Benefits were more evident where C-HOBIC was integrated with existing systems, workflow and nursing processes [53; p5].

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 ANA recognised nursing terminologies 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. (See Table 7.1 for further description of these terminology resources.)

These latter resources 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 only for use in computer applications. Several international standards developed by ISO TC215 focus on terminological resources for health informatics applications. These semantic content standards are introduced in the section below entitled Standards for Informatics Specialists.

### Using Clinical Systems and Applications (see Also Chap. 8)

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 been subjected to the same evidence based/ risk management

approaches – they should be no different. 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. These two example illustrate what can go wrong:

- Implementation of an administration system resulted in 20 % of patients having duplicate records. This increased the workload for staff, and created the potential for a patient being seen with wrong/ missing information.
- When prescribing data were migrated to a new system, a number of patients were issued prescriptions for discontinued repeat medications. During the data migration, these repeat prescriptions were incorrectly migrated as 'current' repeat prescriptions [54].

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 [55]. 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 [56]. The principle behind these standards is that proactive safety risk management will help to reduce the likelihood of adverse events. According to these standards, healthcare organizations must have:

- A named lead for IT clinical risk who is independent from an implementation project manager or IT lead i.e. this is a clinical safety role.
- A clearly documented set of procedures covering clinical risk management of IT systems. This will include procedures for identifying and addressing hazards, and audit procedures to ensure the safety procedures are followed and are effective.
- Clear lines of escalation for safety concerns within the organization – linked to existing systems for raising concerns about clinical practice and existing routes for reporting adverse events/ near misses [57].

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. This responsibility extends to those who work for the companies that design and supply systems [57].

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 7.8. 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.

**Table 7.8** 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 (2008) | http://www.crnns.ca/documents/TelenursingPractice2008.pdf |
| National Council of State Boards of Nursing (NCSBN) (US) | White Paper: A Nurse's Guide to the Use of Social Media (2011) | https://www.ncsbn.org/2930.htm |
| Royal College of Nursing (UK) | Using text messaging services (2012). | http://www.rcn.org.uk/__data/assets/pdf_file/0003/450246/004_230_Using_text_messaging_V2.pdf |
| Royal College of Nursing (UK) | Using technology to complement nursing practice: an RCN guide for health care practitioners (2012). | http://www.rcn.org.uk/__data/assets/pdf_file/0019/450244/004_228_e--Health_Using_technology_V3.pdf |
| Royal College of Nursing (UK) | Using telehealth to monitor patients remotely (2012). | http://www.rcn.org.uk/__data/assets/pdf_file/0018/450252/004_232_Using_telehealth_V3.pdf |
| Telecare Services Association (UK) | Telecare code of practice (2010). | http://www.telecare.org.uk/standards/telecare-code-of-practice/executive-summary |

### Standards for HI Competence and Education for Clinical Nurses (see Chaps. 20 and 21)

Chapters 20 and 21 cover HI educational needs so this brief mention is included for completeness. Given the widespread use of ICT in health care, 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* [58], the TIGER (Technology Informatics Guiding Educational Reform) Initiative competencies [59] and the Canadian Association of Schools of Nursing (CASN) Informatics Competencies, 2012. However, in this rapidly evolving area of practice where new terms like cloud computing and mHealth are almost immediately integrated into everyday use, it is doubtful that faculty everywhere will have the skills to successfully integrate new technologies and the latest standards into their programs. The National League for Nursing provides an Informatics Education Toolkit [60], as does CASN, to assist educators to achieve this integration and there is a similar resource from the NHS [26]. However, few such resources cite national or international HI standards with the exception of the TIGER Initiative report [59]. Raising awareness of HI practice standards is one way that informatics specialists could help to improve the education of non-specialists such as students and faculty.

### *Consumer Health Information Standards*

The concept of consumer health informatics has been around for some time. It is defined as "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" [61]. In 2009, an invitational workshop entitled Personal Health Information Management: Tools and Strategies for Citizens' Engagement, was held in Finland in association with the 10th International Nursing Informatics Congress (NI2009). The report of this workshop included a discussion of the standards that are required to support people who wish to use technology as part of their approach to personal health management [62]. To support interoperability and safe, effective applications requires standards related to functionality, behaviour, work flow, information modelling, terminology, data, access control, identity, security and privacy. The authors concluded that there was much work to be done to identify which of the existing HI standards are relevant to consumer health applications and what gaps need to be filled.

A number of consumer-specific standards have been developed ranging from the international definition for personal health records (ISO/TR 14292) to guidance for nurses on how to support patients using technology [63] and guidance for patients on keeping their online records safe [64]. As more people engage with health information applications, they are becoming more involved with development of standards and dissemination to fellow consumers. We are already seeing a move away from health professionals and industry partners defining these standards to development in collaboration with patient organizations as well as consumer-led developments. However, there is still a need for national and international regulation and standardization. For example, rapid production of mobile apps for every conceivable health condition has led the U.S. Food and Drug Administration (FDA) to prepare guidelines for the regulation of medical apps, based on risk levels [65].

Interoperability among the many innovative applications that are improving personal health management, particularly in developing countries, also needs to be addressed. In 2012, a joint workshop hosted by the International Telecommunications Union and the World Health Organization considered what e-Health standards were needed in future to "leverage today's advanced communications capabilities to achieve more efficient, cost-effective and equitable health services worldwide" [66]. The roadmap discussed at that meeting informed a resolution by the World Health Organization in January 2013 on eHealth standardization and interoperability [67]. Standards development organizations such as HL7 are already actively working in this area, publishing regular updates from its Mobile Health Work Group.

## *HI Standards for Informatics Specialists*

In 2011, the top three job responsibilities for nursing informatics specialists were:

- Systems implementation – preparing users, training and providing support;
- Systems development – customizing and/or updating a vendor system or an in-house system;
- Quality initiatives – including system evaluations/problem solving, quality improvement and patient safety [68].

Health informatics specialists support improvements in health outcomes, healthcare system performance and health knowledge discovery and management, through the application of technology [69]. 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 very familiar with the practice and behavioural standards that support safe use of clinical systems and applications in order to educate and support their clinical colleagues.

One of the most important competencies for HI specialists is use of HI standards. In its 2009 report on Competencies for Public Health Informaticians, the US Department of Health and Human Services [70] listed four performance criteria to support this core competency:

- 'Communicates the origin and role of standards relevant to informatics projects and information systems within the enterprise
- Uses informatics standards in all projects and systems, where relevant standards exist
- Contributes to standards development efforts
- Supports orderly migration to a standards-based framework' ([70], Appendix p4-5).

To support better understanding of 'the origin and role of HI standards', this section considers the different kinds of specialist HI standards, i.e. those that are required to ensure safety and interoperability between systems: where two or more systems or components can exchange information (securely) and use the information that has been exchanged [7]. This requires standards for:

- Semantic content.
- Data structures.
- Data interchange.
- Security
- Safety.

A topic that seems to have received little attention outside the UK is user interface standards specific to healthcare so these are also introduced here. The scope of these areas and examples of standards are presented below; more detail can be found on the websites of the various standards organizations listed in Table 7.2.

### Semantic Content

Semantics is the study of meaning – HI standards for semantic content aim to ensure that health information is meaningful and well-formed so that:

- Information in records is comprehensible and can be communicated between systems.
- Data can be re-used through consistent data aggregation and summary.
- Information in records can be linked to knowledge in decision support systems.

Working Group 3 of ISO TC215 and Working Group 2 of CEN TC251 address these goals by publishing standards and guidelines for the structure and format of HI terminologies (properly know as 'terminological systems'). They are not concerned with standardization of the content of terminologies, i.e. the individual terms within a terminology. In addition, these groups publish standards and guidance for the maintenance of terminologies, mapping between terminologies and classifications, and other related activities. ISO and CEN standards in the terminology space can be described as 'standards for terminology standardization'. They do not specify which terminology to use, nor do they include lists of terms. For example, the purposes of ISO 18104 *Categorial structures for representation of nursing diagnoses and nursing actions in terminological systems* are to promote interoperability by supporting:

- Analysis of the features of different terminologies and to establish the nature of the relationship between them.
- Development of terminologies for representing nursing diagnoses and nursing actions that are able to be related to each other.
- Identification of relationships between terminology models, information models and ontologies in the nursing domain.

The main target audience for ISO 18104 are developers of terminologies but it is also used by developers of models for health information systems such as electronic health records and decision support systems to describe the expected content of terminological value domains for particular attributes and data elements in the information models. Other semantic content standards of relevance to nursing include: EN/ISO 13940 *System of concepts to support continuity of care*; ISO/TS 22789 *Conceptual framework for patient findings and problems in terminologies*; ISO 13119 *Clinical knowledge resources — Metadata*; and standards in development for representing traditional medicine concepts in health records.

National standards are more likely to specify which specific terms to record in a given circumstance, for example, the NHS End of Life Care Coordination Standard includes terms and codes for content items where structured data rather than free text is required [11]. Iterative dialogue between clinical experts, terminology experts and system designers is required to develop and maintain these detailed terminology subset standards. This requires considerable resource and commitment which may be one reason why detailed content standards have been slow to emerge, the other reason being that the focus until recently has been on data sets for reporting rather than on clinical content of systems.

**Data Structure Standards**

According to ISO, the challenge for interoperability in health care is to be able to represent the structure of every kind of health information in a consistent way [71; p6]. At the most basic level, if we do not have common names for elements of electronic records and messages, we cannot expect them to be successfully communicated between systems. Standards for data types, record architecture, reference information models, detailed clinical models and other information components are developed by a number of organizations including ISO, CEN, HL7 and Open EHR (see Table 7.2).

ISO 18308 is a foundational structure standard that defines the requirements to be met by the architecture of systems and services that process, manage and communicate EHR information. It does not address the specific requirements of individual/localized applications but only the common set of requirements that all need to meet so that their EHR data can be safely communicated and combined. This is one standard that I would recommend all nursing informatics specialists to obtain and use as it defines core terms and covers essential system requirements (in plain English!) such as:

- Requirements for the representation of clinical information, including terms, quantities, numeric data and time.
- Representation and support of clinical processes and workflow including care planning.
- Communication and interoperability requirements.
- Ethical and legal requirements.

A complementary standard, ISO/HL7 10781, defines the requirements that must be met by individual EHR systems – a good example of international standards organizations working together to harmonise potentially conflicting standards and reduce duplication.

Multiple organizations are working together on standards to support detailed clinical models (DCMs), a way of structuring healthcare information that combines clinical knowledge, data specifications and terminology [72]. Once validated by clinical and technical experts, DCMs can be re-used multiple times in different applications – they are set to become content building blocks for clinical systems in the future. Experience with DCMs in nursing is just beginning: Park et al. [73] reported the development and validation of 429 DCMs for nursing assessments and 52 DCMs for nursing interventions as well as a test of an electronic nursing record system for perinatal care that is based on detailed clinical models and clinical practice guidelines [74].

The focus of international standards to support this kind of development is currently on how they should be represented and the quality criteria they must meet. ISO 13972 (in development) covers the following:

- Assuring clinician engagement and endorsement.
- Quality of the content that forms a proper DCM including metadata and appropriate terminology binding.

- Guidance on modeling of DCMs.
- Quality measures for repositories of DCMs – to be able to store, index, find, retrieve, update and maintain DCMs.
- Assuring patient safety in DCM specifications.

HL7's website [75] has a helpful summary of all aspects of detailed clinical models.

### Data Interchange Standards (and Beyond)

In addition to consistency of representation using conformant terminologies and data structures, there needs to be consistency in the format of messages used to exchange health data electronically i.e. for communication transactions. This core aspect of interoperability has been a primary focus of HL7 standards and those of working group 2 of ISO TC215 although the latter's more recent role has been to enhance cooperation between the many different organizations involved in data interchange standards. Other examples of the vast array of standards in this space include:

- Basic standards that are used in exchanges of all information on the Internet e.g. HTTP (Hypertext Transfer Protocol).
- DICOM – Digital Imaging and Communication in Medicine.
- Interoperability profiles and specifications such as Health Information Technology Standard Panel (HITSP) Interoperability Specifications and Integrating the Healthcare Enterprise (IHE) Integration Profiles.

HL7 Version 2 messaging standards are widely used across the US and in many other countries. Version 3 standards, based on HL7's Reference Information Model (RIM), '*represent a new approach to clinical information exchange based on a model driven methodology that produces messages and electronic documents expressed in XML syntax*' [76]. Version 3 standards are developed across a range of domains from Care Provision to Order Sets, Public Health and Clinical Genomics. By combining structure, content and syntax, they bring together all of the elements needed for achieving interoperability as illustrated in the description of the standard for order sets:

> This document proposes a multi-layered standard that supports the publication and maintenance of order set libraries, the sharing of order sets between collaborating institutions and entities, the structuring of order sets to support effective presentation and clinical use, and the importing and interoperation of order sets within advanced clinical guideline and care planning software [77].

Because these standards rely heavily on clinical expertise, HL7 encourages individuals and professional organizations to become members. There is a special membership category (with a much reduced cost) for clinical professionals such as physicians, nurses and pharmacists who are working for healthcare provider organizations and are directly engaged in providing care to patients – see Table 7.2.

### Security Standards – Technical Safeguards

In the Security Rule adopted to implement provisions of the US Health Insurance Portability and Accountability Act of 1996 (HIPAA) technical safeguards are defined as '*the technology and the policy and procedures for its use that protect electronic protected health information and control access to it*' [78]. Related standards illustrate the scope of the controls required to ensure that electronic personal health data is not only protected but also made available when needed. This latter purpose is equally important so that privacy and confidentiality are not used as excuses to prevent data and information being communicated and used fairly and lawfully. These standards are:

- Access control standards covering unique user identification, emergency access procedure, automatic logoff and encryption.
- Audit controls.
- Integrity i.e. that the data or information have not been altered or destroyed in an unauthorized manner.
- Person or entity authentication.
- Transmission security. [78] – NOTE: this reference includes helpful checklists for people to check their organization's compliance to the standards.

In the UK, the Data Protection Act 1998 covers similar ground and requires that '*appropriate technical and organizational measures shall be taken against unauthorised or unlawful processing of personal data and against accidental loss or destruction of, or damage to, personal data*' [78]. This requirement covers any organization processing data and information, not just healthcare providers, as is the case with most ISO standards related to information security. ISO 27799 takes one of these overarching standards (ISO/IEC 27002) and specialises it for information security management in health, including practical actions for anyone seeking to implement 27002 in health care.

### Safety

Health IT (HIT) is seen as a means for improving safety but it can also introduce new safety risks as illustrated in the preceding section on use of clinical systems and applications. The Institute of Medicine has produced a number of reports on HIT safety issues, identifying significant gaps in the HIT standards portfolio and infrastructure [79, 80]. In December 2012, the US government published a draft *Health IT Patient Safety Action & Surveillance Plan* which included two safety goals: 'use health IT to make care safer' and 'continuously improve the safety of health IT' [81]. Although the majority of actions related to the second goal were focused on standardised reporting and reduction of safety incidents, the proposals did include establishing safety standards and certification criteria for HIT applications.

The approach taken in the UK has been to focus on safety risk management throughout the application lifecycle – from design and manufacture to deployment and use, including decommissioning [82]. The UK standards draw heavily on a

Technical Specification from ISO *Application of clinical risk management to the manufacture of health software* (ISO/TS 29321). More standards and infrastructure will be established in the next few years as governments decide on what regulations are practical and necessary to ensure safe systems without stifling innovation or creating other barriers to development and implementation.

The importance of safety risk management and safety processes is at last being recognised in career frameworks for clinicians in health informatics roles. For example, one NHS health informatics career framework places the clinical risk management role at advanced practitioner level with the patient safety facilitator role at senior practitioner level [83]. Informatics specialists have a key role in raising awareness and educating non-clinical colleagues about safety risk assessment and mitigation as well as using and promoting existing safety standards and guidance throughout the system lifecycle.

**Interface Design – Evidence-Based Safety Standards and Guidance**

Good user or human interface design is based on usability principles/standards and makes application interfaces intuitive, easily learned, and consistent. A common 'look and feel' across multiple applications requires the same visual design and the same behaviour of elements such as buttons, icons and dialogue boxes. Anyone who switches between applications from major software vendors understands what 'intuitive use' means but most people never have to consider interface design – demonstrating its success.

General standards and guidelines for interface design range from legal requirements for accessibility such as large font size for the visually impaired to parts of NASA's 'human-systems integration design considerations' for the development of manned space stations [84]. Many of these general considerations are applicable to health care however there are some user interface issues that are specific to health care. In 2007, the NHS in England teamed up with Microsoft Health to develop a set of evidence-based guidance documents aimed at ensuring safe input and display of clinical information [85]. In the Medication Line guidance, for example, detailed guidance points are provided for: formatting drug names, displaying dose, strength, volume, rate and duration, wrapping, truncation, use of abbreviations and symbols [86].

A number of these guidance documents have been adopted as NHS Information Standards, including several apparently simple guides such as those for displaying dates [87]. The purpose of this guide is to achieve the important safety features of certainty (or removal of ambiguity), clarity and readability by:

- Eliminating confusion between the month and day values.
- Minimising the space required to display dates on a screen.
- Maintaining a reading pattern that is natural to users.
- Eliminating opportunities for misinterpreting the date as representing some other data.
- Promoting consistency across clinical applications by defining a set of two permissible date formats [88].

Another safety critical feature of interface design has been considered by ISO TC215: display of alert symbols as part of decision support. This is an area where consensus is difficult i.e. there may never be a global symbol for screen display of alerts and warnings in electronic health records. However, it is possible to draw up principles for the design and use of alert symbols and warning information, a task that TC215 is currently undertaking. Rather than producing an International Standard (IS) on this topic, ISO will publish either a Technical Report (TR) summarising the current state of knowledge or a Technical Specification (TS) with agreed principles and a limited set of universal rules. Sometimes the decision to develop a TR or TS rather than an IS cannot be made until well into the standards development lifecycle (described in the next section) when it becomes clear that the subject area is less mature than initially thought or that consensus will not be possible.

## 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: www.iso.org/iso/home/standards_development.htm. 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.

### *The ISO Standards Lifecycle*

#### Proposal

This stage begins with identification of stakeholders who can contribute to clarifying the requirement and the scope and purpose of a standard. Then a global scan is 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:

(a) **Adopt** or **adapt** an existing international or national standard OR
(b) **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 [89]. 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 [21].

If a decision is made to adapt or develop 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 is looking for 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 [90]. 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 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 – another challenge discussed below.

**Preparatory Stage**

The nominated experts from the 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. Extracts from 18104 below illustrate the differences in content and the formality of the language used.

Definition example

**4.1 concept**

Unit of knowledge created by a unique combination of **characteristic**s

NOTE: a **concept** can have one or more names. It can be represented using one or more terms, pictures, icons or sounds.

Normative content example

A nursing action expression (in a terminology) shall have a descriptor for **action** and at least one descriptor for **target**, except where the **target** is the **subject of record** and implied in the expression.

Informative discussion content example

'Nesting' refers to relationships between concepts where one or more concepts can be parts of another concept. For example, *eye care* may be made up of a number of sub-actions such as *assessment of eye*, *cleansing of eye* and *instillation of eye drops*.

## Committee Stage

The Committee Draft is registered by the ISO Central Secretariat and distributed for comment and voting by the P-members of the TC. 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). One of the issues with this voting process is that it is based on ISO's national member body structure and other stakeholders such as the three international nursing groups mentioned above have no say in the formal comment and voting rounds. During the revision of 18104 in 2011/12, we got round this challenge by requesting comments from international stakeholders and including them in the formal feedback.

ISO and many other SDOs use a structured and very helpful approach to feedback 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 any comments and 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 DIS enquiry stage.

### Enquiry Stage

Next the Draft International Standard (DIS) is circulated 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 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 2 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 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. Again, if these approval criteria are not met, the standard is referred back to the originating TC for reconsideration in light of the technical reasons submitted in support of the negative votes. 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.

Figure 7.5 identifies the various stages of balloting or review and feedback cycles employed by the International Organization for Standardization (ISO) in the standards development lifecycle.

### Implementation

Regions and countries have different approaches to the adoption and implementation of international standards. For example, every country uses ISO 3166 – country codes – exactly as it is published. Some countries take a particular international standard and build it into their national standards, for example ISO ISO/IEC 5218 – Codes for the representation of human sexes – is the basis for a more extensive entry

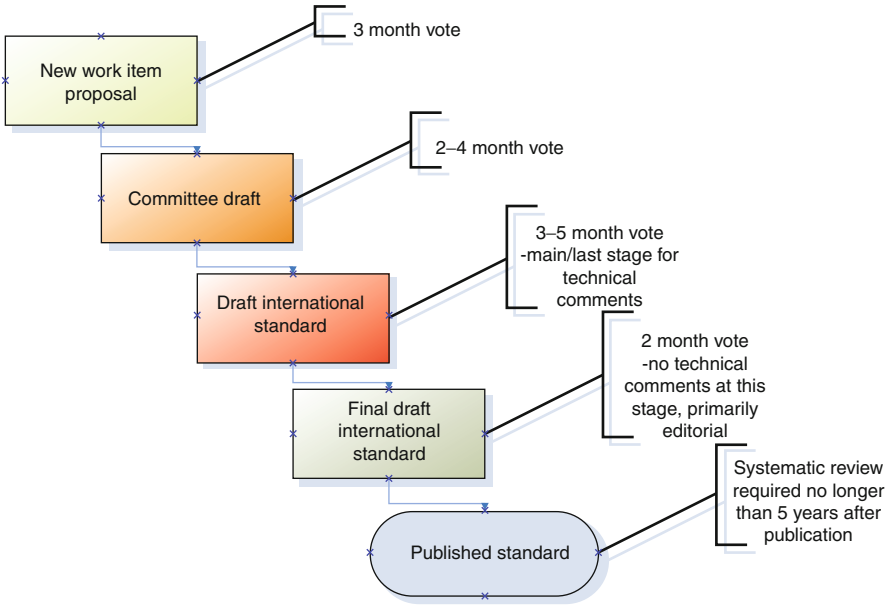


**Fig. 7.5** The various stages of balloting or review and feedback cycles employed by the International Organization for Standardization (ISO) in the standards development lifecycle. *NOTE*: *Certain stages may be omitted depending on development needs* (*e.g. Committee Draft or Final Draft International Standard stages*). *Further information*: *ISO/IEC Directives*, *Part 1 Consolidated ISO Supplement — Procedures specific to ISO Fourth edition*, *2013*

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 as 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.

A few 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 [91].

**Review of International Standards (Confirmation, Revision, Withdrawal)**

International Standards are reviewed at least every 5 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.

When the revision of ISO 18104 was due, the initial request for comment identified that it had been used in at least 11 member countries and by several international terminology development organizations. Inputs from those countries and from the original professional stakeholder organizations identified several areas that needed to be addressed in a revision including:

1. Updating normative references and definitions and considering more recent international terminology developments.
2. Consideration of a model for outcomes (in addition to models for diagnoses and actions)
3. Adding an informative annex to clarify the relationship between the model for diagnoses and the model for actions as well as points of intersection between terminology models and information models.
4. Adding implementation guidance/ examples, and simplifying the language used in the document so that it is better understood by target groups.

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 used to restructure 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 have been taken forward to the next version.

## *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 multi-disciplinary 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 (ISO/TR 11487). Progress has been slow on these recommendations which included:

- 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 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 6 % of the world's population*' [92]; p2]. It has been good to see the active engagement of 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. Global policy making organizations such as the European Union (EU), the Joint Initiative Council, WHO and HITSP have all identified the need for improved and coherent action to address the healthcare interoperability requirements of the future. The European eHealth Interoperability Roadmap was published in December 2010 with a number of standards related key actions for EU member states:

- Equip Europeans with secure online access to their health data and achieve widespread deployment of telemedicine services
- Define a minimum common set of patient data for interoperability of patient records to be accessed or exchanged electronically across Member States
- Foster EU-wide standards, interoperability testing and certification of eHealth systems.

Similar objectives are being addressed in the US by HITSP whose members '*work together to define the necessary functional components and standards – as well as gaps in standards – which must be resolved to enable the interoperability of healthcare data*' [93]. 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.

## *Participation in Standards Development and Review*

There are a number of routes and opportunities for nurses to engage in the development of HI practice 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 through education, practice audit and change management. Individual nurses can engage by contacting their professional organizations some of which may need to be made aware of the need for HI practice standards but may welcome interested volunteers.

Participating in the development and review of national and international HI specialist standards is less 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 HI 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; 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 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.

There is plenty of entry-level material on the websites of the major SDOs to inform anyone of the 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 but there is a fee to join some organizations including ANSI and HL7. Before signing up, consider some of the factors that support those who are involved:

- Employer's support: time to undertake reviews and attend meetings.
- Payment of expenses and employer's support for time.
- Learning opportunities provided at meetings.
- Dialogue/ interaction with other nurses engaged in the work.
- Direct mentorship by more experienced nurse or other clinician.

## Conclusion

A 2013 Kings Fund report on the future of UK health and social care [1] estimated that by 2016 the majority of the population will access the web through mobile devices. Routine use of electronic records will be achieved by 2017; by 2021 there will be a shortfall of between 40,000 and 100,000 nurses – teleconsultations and remote monitoring will become routine to manage the growing number of elderly people with multiple chronic conditions and the million or more people with dementia. Information and communications technology, including robots in health care settings and homes, 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 practice standards are needed to support integration of information management and ICT into clinical practice. They will 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 lacking and are 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 practice 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.

## Downloads

Available from extras.springer.com:

Educational Template (PDF 103 kb)
Educational Template (PPTX 116 kb)

## References

1. King's Fund. The Future of ehealth and social care timeline 2013–2033. [Online] [Cited 4 Mar 2013] http://www.kingsfund.org.uk/time-to-think-differently/timeline.
2. International Organisation for Standardisation. What are standards and how do they help? [Online] [Cited: 13 Feb 2013] http://www.iso.org/sites/ConsumersStandards/en/1-1-what-standards-context.htm.
3. British Standards Institute. Information about standards. [Online] [Cited: 14 Feb 2013] http://www.bsigroup.co.uk/en-GB/standards/Information-about-standards/.
4. ISO/IEC. Information technology — Metadata registries (MDR) — Part 4 Formulation of data definitions. Geneva: ISO; 2004. ISO/IEC 11179–4:2004.
5. Health Level Seven International. Introduction to HL7 standards. [Online] [Cited: 20 Feb 2013] http://www.hl7.org/implement/standards/index.cfm.
6. International Organisation for Standardisation. TC 215 Health Informatics. [Online] [Cited: 20 Feb 2013] http://www.iso.org/iso/iso_technical_committee?commid=54960.
7. Institute of Electrical and Electronics Engineers. IEEE Standard Computer Dictionary: a compilation of IEEE standard computer glossaries. New York: Institute of Electrical and Electronics Engineers; 1990.
8. Health Level Seven International HL7. HL7 FAQs. [Online] [Cited: 20 Feb 2013] http://www.hl7.org/about/FAQs/index.cfm.
9. IMIA Special Interest Group on Nursing Informatics. cited in Working Group Nursing Informatics. AMIA. [Online] 2009. [Cited: 20 Feb 2013] http://www.amia.org/programs/working-groups/nursing-informatics.
10. National Patient Safety Agency. Design for patient safety: guidelines for the safe on-screen display of medication information. [Online] 2010. [Cited: 20 Feb 2013] http://www.nrls.npsa.nhs.uk/resources/collections/design-for-patient-safety/?entryid45=66713.
11. NHS Information Standards Board. End of life care co-ordination: core content standard specification. [Online] Oct 2012. [Cited: 20 Feb 2013] http://www.isb.nhs.uk/documents/isb-1580/amd-29-2012/1580292012spec.pdf.
12. National Council of State Boards of Nursing. About NCSBN. [Online] [Cited: 20 Feb 2013] https://www.ncsbn.org/about.htm.
13. American Nurses Association. Code of ethics for nurses. [Online] [Cited: 20 Feb 2013] http://www.nursingworld.org/codeofethics.

14. Nursing and Midwifery Council. The code: standards of conduct, performance and ethics for nurses and midwives. [Online] [Cited: 20 Feb 2013] http://www.nmc-uk.org/Publications/Standards/The-code/Introduction/.
15. Feild MJ, Lohr KN, editors. Clinical practice guidelines: directions for a new program. Washington, DC: National Academy Press; 1990.
16. National Institue for Health and Clinical Excellence. QS13 Quality standard for end of life care for adults. [Online] Aug 2011. [Cited 20 February 2013.] http://publications.nice.org.uk/quality-standard-for-end-of-life-care-for-adults-qs13.
17. Agency for Health Research and Quality. Agency for Health Research and Quality (AHQR). [Online] [Cited: 20 Feb 2013] http://www.ahrq.gov/.
18. Registered Nurses' Association of Ontario. Guideline summary end-of-life care during the last days and hours. Agency for Healthcare Research and Quality. [Online] Oct 2011. [Cited: 20 Feb 2013] http://www.guideline.gov/content.aspx?id=34759&search=palliative+and+end+of+life.
19. World Health Organisation. International Classification of Functioning, Disability and Health (ICF). [Online] http://www.who.int/classifications/icf/en/.
20. American National Standards Institute. About ANSI. ANSI. [Online] [Cited: 20 Feb 2013] http://www.ansi.org/about_ansi/overview/overview.aspx?menuid=1.
21. Joint Initiative Council. Joint initiative on SDO global health informatics standardization. [Online] [Cited: 20 Feb 2013] http://www.jointinitiativecouncil.org/.
22. International Council of Nurses. Code of ethics for nurses. International Council of Nurses. [Online] 2012. [Cited: 20 Feb 2013] http://www.icn.ch/about-icn/code-of-ethics-for-nurses/.
23. Kay S. Presentation and discussion by Steven Kay on usability of health informatics standards. Joint Initiative Council. [Online] October 2012. [Cited: 20 Feb 2013] http://www.jointinitiativecouncil.org/.
24. International Organisation for Standardisation. Why consumer participation in standards improves products and services improves products and services. ISO. [Online] [Cited: 20 Feb 2013] http://www.iso.org/sites/ConsumersStandards/en/2-4-consumer-participation.htm.
25. Canada Health Infoway. pan-Canadian Standards Decision Making Process Version 2.2. 2012. https://www.infoway-inforoute.ca/index.php/programs-services/standards-collaborative/pan-canadian-standards.
26. National Health Service (NHS). Learning to manage health information: a theme for clinical education 2012. Embedding information in clinical education . [Online] April 2012. [Cited: 20 Feb 2013] http://www.cln.nhs.uk/eice/images/learningtomanage_12.pdf.
27. Royal College of Nursing. Consent to create, amend, access and share eHealth records. [Online] 2012. [Cited: 20 Feb 2013] http://www.rcn.org.uk/__data/assets/pdf_file/0003/328926/003593.pdf.
28. Severs M. Failure to share – meeting of Information Governance Review. [Online] 28 Feb 2012. [Cited: 20 Feb 2013] https://www.wp.dh.gov.uk/caldicott2/files/2012/06/Failure-to-share.pdf.
29. Tissue Viability Society. Achieving Consensus in Pressure Ulcer Reporting. [Online] 2012. [Cited: 8 Mar 2013] http://www.tvs.org.uk/sitedocument/TVSConsensusPUReporting.pdf.
30. Levy S, Heyes B. Information systems that support effective clinical decision making. Nurs Manage. 2012;19(7):20–2.
31. Agency for Healthcare Research and Quality. Assessing the quality of internet health information . [Online] 1999. [Cited: 20 Feb 2013] http://www.ahrq.gov/data/infoqual.htm.
32. National Network of Libraries of Medicine. Health literacy. [Online] [Cited: 20 Feb 2013] http://nnlm.gov/outreach/consumer/hlthlit.html.
33. New Zealand Nurses' Organisation (NZNO). Health literacy practice position statement. NZNO. [Online] 2012. [Cited: 20 Feb 2013] http://www.nzno.org.nz/LinkClick.aspx?fileticket=GPbcXpviZxM%3D.
34. Casey A, Wallis A. Effective communication: principle of nursing practice E. Nurs Stand. 2011;25(32):35–7.
35. British Medical Association. Safe handover: safe patients. Guidance on clinical handover for clinicians and managers. London: BMA; 2004.

36. World Health Organization. Communication during patient hand-overs. [Online] 2007. [Cited: 20 Feb 2013] http://www.who.int/patientsafety/solutions/patientsafety/PS-Solution3.pdf.
37. Joint Commission Center for Transforming Healthcare. Hand-off communications. [Online] [Cited: 20 Feb 2013] http://www.centerfortransforminghealthcare.org/projects/detail.aspx?Project=1.
38. Centre for Health Care Informatics Design, City University. NHS Connecting for Health Safer Handover Project: ER-08-0300. Final Report on Safer Handover. London: Centre for Health Care Informatics Design, City University; 2009.
39. Galliers J, Wilson S, Randell R, Woodward P. NHS Connecting for Health Safer Handover Project: ER-08-0300. Final Report on Safer Handover. London: Centre for Health Care Informatics Design, City University; 2009.
40. Smeulers M, van Tellingen IC, Lucas C, Vermeulen H. Effectiveness of different nursing handover styles for ensuring continuity of information in hospitalised patients (Protocol). Cochrane Database of Systematic Reviews. 2012;(7):CD009979. doi:10.1002/14651858.CD009979.
41. Nursing and Midwifery Council. Record keeping: guidance for nurses and midwives. [Online] 2009. [Cited: 1 Mar 2013] http://www.nmc-uk.org/Documents/NMC-Publications/NMC-Record-Keeping-Guidance.pdf.
42. Royal College of Nursing. Nursing content of eHealth records . [Online] 2012. [Cited: 1 Mar 2013] http://www.rcn.org.uk/__data/assets/pdf_file/0005/328928/003596.pdf.
43. Wang N, Hailey D, Yu P. Quality of nursing documentation and approaches to its evaluation. J Adv Nurs. 2011;67(9):1858–75.
44. Urquhart C, Currell R, Grant MJ, Hardiker NR. Nursing record systems: effects on nursing practice and healthcare outcomes (Review). [Online] 2010. [Cited: 8 Mar 2013] http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD002099.pub2/pdf/standard.
45. Northern Ireland Practice and Education Committee. NIPEC improving record keeping. [Online] [Cited: 1 Mar 2013] http://www.nipec.hscni.net/recordkeeping/.
46. Royal College of Physicians. Developing standards for health and social care: report of the Joint Working Group. [Online] 2012. [Cited: 1 Mar 2013] http://www.rcplondon.ac.uk/sites/default/files/devoloping-standards-for-social-care-records-report-of-joint-working-group.pdf.
47. Hakonsen S, Madsen I, Bjerrum M, Pedersen P. Danish national framework for collecting information about patients' nutritional status. Nursing Minimum Dataset (N-MDS). Online J Nurs Inform. [Online] 03 Nov 2012. [Cited: 1 Mar 2013] http://ojni.org/issues/?p=2044.
48. (NICE), National Institute for health and Clinical Excellence. Head injury: triage, assessment, investigation and early management of head injury in infants, children and adults. [Online] 2007. [Cited: 1 Mar 2013] http://publications.nice.org.uk/head-injury-cg56.
49. Royal College of Nursing. Standards for the weighing of infants, children and young people in the acute health care setting. [Online] 2010. [Cited: 1 Mar 2013] http://www.rcn.org.uk/__data/assets/pdf_file/0009/351972/003828.pdf.
50. Rutherford M. Standardized nursing language: what does it mean for nursing practice? Online J Issues Nurs. [Online] 31 January 2008. [Cited: 1 Mar 2013] http://www.nursingworld.org/MainMenuCategories/ANAMarketplace/ANAPeriodicals/OJIN/TableofContents/vol132008/No1Jan08/ArticlePreviousTopic/StandardizedNursingLanguage.html.
51. International Council of Nurses. Vision, goals & benefits of ICNP. [Online] [Cited: 1 Mar 2013] http://www.icn.ch/pillarsprograms/vision-goals-a-benefits-of-icnpr/.
52. Muller-Staub M, Lavin M. Nursing diagnoses, interventions and outcomes – application and impact on nursing practice: systematic review. J Adv Nurs. 2006;56(5):514–31.
53. Praxia Health Informatics Research. C-HOBIC Initiative Benefits Evaluation Final Report. [Online] 20 October 2009. [Cited: 1 Mar 2013] http://www2.cna-aiic.ca/c-hobic/documents/pdf/Evaluation_Final_Report_2009_e.pdf.
54. NHS Connecting for Health. Nine steps for safer implementation. [Online] 2009. [Cited: 1 Mar 2013] http://www.isb.nhs.uk/documents/isb-0160/dscn-18-2009/0160182009guidance.pdf.
55. Information Standards Board for Health and Social Care. Clinical risk management: its application in the deployment and use of health IT systems version 2 – specification. [Online] 2013. [Cited: 1 Mar 2013] http://www.isb.nhs.uk/documents/isb-0160/amd-38-2012/0160382012spec.pdf.

56. Clinical risk management: its application in the manufacture of health IT systems version 2 – specification. [Online] 2013. [Cited: 1 Mar 2013] http://www.isb.nhs.uk/documents/isb-0129/amd-39-2012/0129392012spec.pdf.
57. Royal College of Nursing. Making IT SAFER. [Online] 2011. [Cited: 1 Mar 2013] http://www.rcn.org.uk/__data/assets/pdf_file/0004/328927/003594.pdf.
58. American Nurses' Association. Nursing Informatics: Practice Scope and Standards of Practice. Silver Spring, MD: Nursesbooks.org; 2008.
59. TIGER Collaborative. Informatics competencies for every practicing nurse: recommendations from the TIGER Collaborative. [Online] nd. [Cited: 1 Mar 2013] http://tigersummit.com/uploads/3.Tiger.Report_Competencies_final.pdf.
60. Nursing, National League for. NLN competencies for nursing education: informatics. [Online] [Cited: 1 Mar 2013] http://www.nln.org/facultyprograms/facultyresources/informatics.htm.
61. International Medical Informatics Association. Consumer health informatics. [Online] [Cited: 1 Mar 2013] http://www.imia-medinfo.org/new2/node/137.
62. Goossen W, Casey A, Juntilla K, Newbold S, Park H-A. Technical and infrastructure requirements for personal health information management systems. [book auth.] Brennan PF, Casey A, Saranto K, editors. Personal health information management, tools and strategies for citizens' engagement. Kuopio: University of Kuopio; 2009.
63. Royal College of Nursing. Personal health records and information management: helping patients, clients and parents/carers to make the most of information. [Online] 2012. [Cited: 1 Mar 2013] http://www.rcn.org.uk/__data/assets/pdf_file/0005/465458/16.12_Personal_Health_Records_Briefing_-_18_July_2012.pdf.
64. British Computer Society and Department of Health. Keeping your online health and social care records safe and secure. [Online] 2013. [Cited: 1 Mar 2013] http://www.bcs.org/category/17485.
65. Strickland E. The FDA takes on Mobile Health Apps. IEEE Spectrum. [Online] 2012. [Cited: 1 Mar 2013] http://spectrum.ieee.org/biomedical/devices/the-fda-takes-on-mobile-health-apps.
66. International Telecommunications Union. ITU-WHO Workshop produces roadmap to guide the development of global e-health standards. [Online] 2012. [Cited: 1 Mar 2013] http://www.itu.int/ITU-T/newslog/ITUWHO+Workshop+Produces+Roadmap+To+Guide+The+Development+Of+Global+Ehealth+Standards.aspx.
67. World Health Organisation. eHealth standardization and interoperability. [Online] 28 January 2013. [Cited: 8 Mar 2013] http://apps.who.int/gb/ebwha/pdf_files/EB132/B132_R8-en.pdf.
68. HIMSS. 2011 HIMSS nursing informatics workforce survey. [Online] 2011. http://himss.files.cms-plus.com/HIMSSorg/content/files/2011HIMSSNursingInformaticsWorkforceSurvey.pdf.
69. Australian Health Informatics Education Council. Health informatics: scope, careers and competencies. [Online] November 2011. [Cited: 1 Mar 2013] http://www.ahiec.org.au/docs/AHIEC_HI_Scope_Careers_and_Competencies_V1-9.pdf.
70. US Department of Health and Human Services. Competencies for Public Health Informaticians. [Online] 2009. [Cited: 1 Mar 2013] http://www.cdc.gov/informaticscompetencies/downloads/PHI_Competencies.pdf.
71. European Committee for Standardization (CEN). EN 13606–1 health informatics – electronic health record communication – part 1: reference model. Brussels: CEN; 2007.
72. Goossens W, Goossen-Baremans A, van der Zel M. Detailed clinical models: a review. Healthc Inform Res. 2010;16(4):201–14.
73. Park H-A, Min Y, Kim Y, Lee M, Lee Y. Development of detailed clinical models for nursing assessments and nursing interventions. Healthc Inform Res. 2011;17(4):244–52.
74. Park HA, Min YH, Jeon E, Chung E. Integration of evidence into a detailed clinical model-based electronic nursing record system. Healthc Inform Res. 2012;18(2):136–44.
75. Health Level 7 (HL7). Detailed clinical models. [Online] [Cited: 4 Mar 2013] http://wiki.hl7.org/index.php?title=Detailed_Clinical_Models.
76. HL7. HL7 Version 3 product suite. [Online] [Cited: 1 Mar 2013] http://www.hl7.org/implement/standards/product_brief.cfm?product_id=186.

77. HL7 Version 3 Standard: Order Set Publication, Release 1. [Online] [Cited: 4 Mar 2013] http://www.hl7.org/implement/standards/product_brief.cfm?product_id=287.
78. Department of Health and Human Services. HIPPA security series – security standards: technical safeguards. [Online] 2007. [Cited: 4 Mar 2013] http://www.hhs.gov/ocr/privacy/hipaa/administrative/securityrule/techsafeguards.pdf.
79. Information Commissioner's Office. Data protection principles. [Online] [Cited: 4 Mar 2013.] http://www.ico.gov.uk/for_organisations/data_protection/the_guide/the_principles.aspx.
80. Institute of Medicine. Health IT and patient safety: building safer systems for better care. [Online] 2011. [Cited: 8 Mar 2013] http://www.iom.edu/~/media/Files/Report%20Files/2011/Health-IT/HealthITandPatientSafetyreportbrieffinal_new.pdf.
81. Office of the National Coordinator of Health Information Technology. Health IT patient safety action & surveillance plan for public comment. [Online] 2012. [Cited: 8 Mar 2013] http://www.healthit.gov/sites/default/files/safetyplanhhspubliccomment.pdf.
82. NHS Information Standards Board for Health and Social Care. Patient safety. [Online] [Cited: 8 Mar 2013] http://www.isb.nhs.uk/use/baselines/safety.
83. NHS Wales Informatics Service. Health informatics career framework. [Online] [Cited: 8 Mar 2013] https://www.hicf.org.uk/.
84. (NASA), National Aeronautics and Space Administration. Man-systems integration standards. [Online] [Cited: 4 Mar 2013] http://msis.jsc.nasa.gov/Volume1.htm.
85. Microsoft Health. Common user interface. [Online] [Cited: 4 Mar 2013] http://www.mscui.net/.
86. Microsoft Health. Design guidance: medication line. [Online] 2009. [Cited: 4 Mar 2013] http://www.mscui.net/DesignGuide/Pdfs/Design%20Guidance%20--%20Medication%20Line.pdf.
87. National Health Service (NHS). NHS common user interface. [Online] [Cited: 4 Mar 2013] http://www.cui.nhs.uk/Pages/NHSCommonUserInterface.aspx.
88. Microsoft Health. Design guidance: date display. [Online] [Cited: 4 Mar 2013] http://www.mscui.net/DesignGuide/Pdfs/Design%20Guidance%20--%20Date%20Display.pdf.
89. International Organisation for Standardization (ISO). Cooperation with CEN (Vienna Agreement). [Online] [Cited: 4 Mar 2013] www.iso.org/iso/standards_development/processes_and_procedures/cooperation_with_cen.htm.
90. American National Standards Institute (ANSI). Introduction to ANSI. [Online] [Cited: 4 Mar 2013] www.ansi.org/about_ansi/introduction/introduction.aspx.
91. Integrating the Healthcare Enterprise (IHE). About IHE. [Online] [Cited: 4 Mar 2013] http://www.ihe.net/About/.
92. Morikawa M, Morrison J. Who develops ISO standards? A survey of participation in ISO's international standards development processes. [Online] October 2004. [Cited: 4 Mar 2013] http://www.pacinst.org/reports/iso_participation/iso_participation_study.pdf.
93. Healthcare Information Technology Standards Panel (HITSP. Welcome to www.HITSP.org. [Online] [Cited: 4 Mar 2013] http://www.hitsp.org/.
94. International Organization for Standardisation ISO. Standards catalogue TC215 health informatics. ISO. [Online] [Cited: 20 Feb 2013] http://www.iso.org/iso/home/store/catalogue_tc/home/store/catalogue_tc/home/store/catalogue_tc/catalogue_tc_browse.htm?commid=54960&published=on.
95. ISO. What are standards and how do they help? [Online] [Cited: 13 Feb 2013] http://www.iso.org/sites/ConsumersStandards/en/1-1-what-standards-context.htm.
96. International Organization for Standardization. What is conformity assessment? [Online] [Cited: 8 Mar 2013] http://www.iso.org/iso/home/about/conformity-assessment.htm.
97. European Commission. EU eHealth Interoperability Roadmap. [Online] 2010. [Cited: 4 Mar 2013] http://www.ehgi.eu/Download/European%20eHealth%20Interoperability%20Roadmap%20%5bCALLIOPE%20-%20published%20by%20DG%20INFSO%5d.pdf.
98. Hammond WE, Jaffe C, Kush RD. Healthcare standards development: the value of nurturing collaboration. J AHIMA. 2009;80(7):44–50. Available at http://library.ahima.org/xpedio/groups/public/documents/ahima/bok1_043995.hcsp?dDocName=bok1_043995.

## Additional Reading

International Organization for Standardization. Glossary of terms and abbreviations. [Online] [Cited: 8 Mar 2013] http://www.iso.org/sites/ConsumersStandards/en/5-glossary-terms.htm.

National Guideline Clearinghouse. Inclusion criteria. [Online] [Cited: 20 Feb 2013] http://www.guideline.gov/about/inclusion-criteria.aspx.

Nursing, National Council of State Boards of. About NCSBN. [Online] [Cited: 20 Feb 2013] https://www.ncsbn.org/about.htm.

Agency for Health Research and Quality (AHQR). [Online] [Cited: 20 Feb 2013] http://www.ahrq.gov/.

Feild MJ, Lohr KN, editors. Clinical practice guidelines: directions for a new program. Washington, DC: National Academy Press; 1990.

ISO. TC 215 Health Informatics . [Online] [Cited: 20 Feb 2013] http://www.iso.org/iso/iso_technical_committee?commid=54960.

Kay S. Presentation and discussion by Steven Kay on usability of health informatics standards. Joint Initiative Council. [Online] October 2012. [Cited: 20 Feb 2013] http://www.jointinitiativecouncil.org/.

International Organisation for Standardisation. ISO/TS 17117:2002 health informatics – controlled health terminology – structure and high-level indicators. Geneva: ISO; 2002.

Kind A, Smith M. Documentation of mandated discharge summary components in transitions from acute to subacute care. [Online] nd. [Cited: 1 Mar 2013] http://www.ahrq.gov/downloads/pub/advances2/vol2/advances-kind_31.pdf.

Royal College of Nursing. Delegating record keeping and countersigning records. [Online] October 2012. [Cited: 1 Mar 2013] http://www.rcn.org.uk/__data/assets/pdf_file/0005/486662/004337.pdf.

College of Nurses of Ontario. Practice standard: documentation. [Online] 2008. [Cited: 1 Mar 2013] http://www.cno.org/Global/docs/prac/41001_documentation.pdf.

Hardiker NR, Casey A, Coenan A, Konicek D. Mutual enhancement of diverse terminologies. AMIA annual symposium proceedings, 2006. pp. 319–23.

Nursing and Midwifery Council. Standards of proficiency for nurse and midewife prescribers. [Online] 2006. [Cited: 1 Mar 2013] http://www.nmc-uk.org/Documents/NMC-Publications/NMC-Standards-proficiency-nurse-and-midwife-prescribers.pdf.

Eysenbach G. Consumer health informatics. Br Med J. 2000;320:1713.

European Committee for Standardization (CEN). European Standards (EN). [Online] [Cited: 4 Mar 2013] http://www.cen.eu/cen/products/en/pages/default.aspx.

Health Level 7 International (HL7). About HL7. [Online] [Cited: 4 Mar 2013] http://www.hl7.org/about/index.cfm?ref=nav.

Union, World Health Organisation and International Telecommunications. [Online]

Goossen W. Personal health records: infrastructure and standards. [book auth.] Brennan PF, Casey A, Saranto K, editors. Personal health information management, tools and strategies for citizens' engagement. Kuopio: University of Kuopio; 2009.