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Health informatics — Clinical stakeholder participation in the work of ISO TC 215

Informatique de santé — Participation clinique du dépositaire dans les travaux du TC 215

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Foreword

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

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

In exceptional circumstances, when a technical committee has collected data of a different kind from that which is normally published as an International Standard ("state of the art", for example), it may decide by a simple majority vote of its participating members to publish a Technical Report. A Technical Report is entirely informative in nature and does not have to be reviewed until the data it provides are considered to be no longer valid or useful.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO/TR 11487 was prepared by Technical Committee ISO/TC 215, *Health informatics*.

Introduction

According to the ISO Code of Ethics [1], the development of International Standards is a consensus-based process that relies on “the contributions of the relevant experts and the participation of the concerned stakeholders”. ISO members (i.e. national standardization organizations) are expected to take “appropriate measures to facilitate the participation of consumers and other affected parties from civil society, SMEs and public authorities”. Objective 2 of ISO Strategic Plan 2005-2010 [2] specifically addresses actions that national members should be taking to ensure the involvement of stakeholders. Stakeholder participation is seen as key to both the market relevance and effective use of standards. See Reference [3].

Building on an initial enquiry into the participation of nursing experts and stakeholders in the work of TC 215, a multi-disciplinary task force was formed to review clinical stakeholder participation in TC 215 in broader and more general terms. This review is undertaken in the context of increasingly widespread deployment of health information technologies, renewed demands on TC 215 to respond rapidly to the business needs of national members and improved harmonization with other international standards organizations.

Health informatics — Clinical stakeholder participation in the work of ISO TC 215

1 Scope

This Technical Report is structured around four review areas:

— stakeholder groups concerned with the work of TC 215;

— potential benefits/outcomes of clinical stakeholder participation;

— current nature of stakeholder participation;

— recommendations for improving clinical stakeholder participation.

The review is limited to clinical stakeholder groups. Stakeholders from industry, consumer groups and other non-clinical groups are outside the scope of this Technical Report, as are the specific issues related to participation of clinical stakeholders in developing countries.

The content of this Technical Report is based on informal consultation among delegates attending TC 215 meetings and e-mail communication with interested individuals. Opportunities to comment on the draft report were provided prior to and during the 2007 Montreal plenary meeting in accordance with the TC Resolution at the 2006 Jeju plenary.

The purposes of this Technical Report are:

a) to clarify and confirm TC 215 support for clinical stakeholder participation;

b) to make recommendations to the TC and to national member organizations on approaches to improving clinical stakeholder participation based on examples of existing effective participation models.

2 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

2.1
TC 215 stakeholder
person, group or organization with a legitimate interest in the activities and outputs of TC 215; those who will direct the use of the standards and those who will use or be affected by the use of the standards

NOTE The scope of TC 215 is “Standardization in the field of information for health, and Health Information and Communications Technology (ICT) to achieve compatibility and interoperability between independent systems. Also, to ensure compatibility of data for comparative statistical purposes (e.g. classifications), and to reduce duplication of effort and redundancies”.

2.2
clinician
healthcare professional who delivers healthcare services directly to a patient/consumer

[ISO/TS 18308:2004, definition 3.12]

2.3
clinical stakeholder
representative of a health care professional organization (see 3.3)

2.4
health care professional
person authorized by a nationally-defined mechanism to be involved in the direct provision of certain health care activities

[EN 13940-1]

EXAMPLE General medical practitioner, medical consultant, therapist, dentist, nurse, social worker, radiographer.

3 TC 215 stakeholders

3.1 Those developing consensus-based standards in the field of health informatics should solicit and take account of the views of those who will use the standards or be affected by their use, i.e. the stakeholders. The preamble to each standard normally includes a list of target groups for the standard. The target group will depend on the scope and purpose of the specific standard, but examples include:

— developers of other health informatics standards;

— developers and purchasers of health information systems;

— national governments;

— clinical work flow experts;

— end users of health information systems such as health care professionals and teams, health care funding organizations, managers, subjects of care (patients, clients) and health care provider organizations.

3.2 TC 215 needs the active participation of experts in health informatics standards and in related general standards; e.g. standards for devices in general and standards for terminology in general. The work also requires understanding of evolving information and communication technologies related to healthcare, i.e. the expectations and feedback of the supplier community need to be captured. Health informatics standards must be responsive to evolving health service policy and management, i.e. the “business” requirements for health informatics standards must be captured and feedback obtained from policymakers, health care providers and purchasers of health information systems.

3.3 Individual end users of health information systems would not generally be directly involved in the development and review of health informatics standards. Clinical participation for many enterprises is usually sought through representative organizations for each of the professional disciplines. For the purposes of this Technical Report, clinical stakeholders equate to representatives of health care professional organizations. At the international level, membership of such organizations is usually made up of national organizations, for example, the International Pediatric Association comprises national pediatric associations of many countries.

3.4 At present, individual clinicians may participate in the work of TC 215 but generally do so as experts in health informatics standards or health informatics, bringing their specific clinical expertise into the work when relevant. They may “speak as” a clinician (with acknowledgement of the currency of their clinical expertise) but they do not “speak for” a specific clinical discipline.

3.5 For TC 215 purposes, a distinction needs to be made between:

— clinical experts/clinical workflow experts who may or may not have health informatics expertise;

— health informatics standards experts with clinical backgrounds who may or may not have current clinical expertise;

— clinical stakeholders, who are representatives from health care professional organizations who may or may not have health informatics expertise.

3.6 The complex nature of most health informatics standards at the international level means that even clinicians with health informatics expertise can find standards development and review challenging. If clinicians develop an interest and can participate regularly, they develop the necessary expertise to contribute informed views to the standards process, but regular participation and interest cannot be relied upon as a route for involving all clinical stakeholder groups. Other ways may need to be found of engaging clinicians and clinical stakeholders more widely and in a more representative way, but it is important to balance the challenges of doing this with the benefits of such participation.

4 Potential benefits of clinical stakeholder participation

4.1 Input and feedback from clinical stakeholders could be of benefit in the development of any health informatics standard that will have an impact on clinical practice. Even the “standards for standards” that TC 215 most often produces require knowledge of clinical practice and could have an impact on clinical practice and patient safety. Therefore, both individual clinicians and clinical stakeholders should be involved in the development and review of health informatics standards at the international level and in testing at the local (national, state, provincial) level.

4.2 The requirement for clinical input will vary depending on the type of standard and the stage of the standard lifecycle. Clinical knowledge, clinical risk assessment, up-to-date understanding of clinical processes and the realities of ICT use in different clinical environments may be beneficial at all stages, from requirement specification through to review/revision of an existing standard based on post-deployment experience.

4.3 The extent to which clinical stakeholders can help ensure the market relevance of health informatics standards is limited by the stakeholders’ understanding of the specific topic of the standard. This, in turn, is affected by the way in which information about international health informatics standards is generally communicated. For example, the International Pediatric Association might not be concerned to see an International Standard for vocabulary of terminology but would recognise the relevance of a standard to ensure the consistent capture of details about the provenance of health information on the web.

4.4 Clinical stakeholders could have a greater role in promoting effective use of standards. Through active participation, representative organizations would better understand the importance of health informatics standards and use their influence to promote the adoption of appropriate standards by national and other health enterprises. Individual clinicians involved in international health informatics standards can also use their skills and knowledge in being mentor to roles and peer-to-peer networks to “spread the word” amongst their colleagues and enhance the circle of knowledge, understanding and adoption.

4.5 Overall, participation that helps ensure the quality of clinical aspects of international health informatics standards will have benefits in the longer term with respect to improvements in clinical efficiency, data capture and data utilization, clinical decision-making, patient outcomes, etc. These benefits are of major concern to clinical stakeholders and the organizations that advance the science (and art) of the health care professions.

5 Current participation models

5.1 The member organization of ISO is the organization most broadly representative of standardization in each country. That organization is expected to organize national input "in a timely and effective manner taking into account all relevant interests at national level". See Reference [1].

5.2 Countries that participate in TC 215 organize their national input in different ways. The most common model seems to be:

— open participation of volunteers in national working groups from which one or more individuals are delegated to attend TC 215 meetings. Participants may be self-funding or receive some financial support from their employers or from the national standards organization.

5.3 Less common models include:

— participation through subscription of national working groups – attendance at TC 215 meetings is restricted to national group members who may be self-funded or receive some financial support from their employers or from the national standards organization;

— employees or representatives of the national standards organization or an academic institute with a standards remit are supported to attend TC 215 meetings.

5.4 At the national level, a health care professional organization may participate through an active national working group member, but this is not usually a formal arrangement. Australia has a formal representative structure: open working groups input to a national standards group that is representative of all major stakeholders. The national group sponsors delegates to the TC 215 meetings. In Canada, the Infoway Standards Collaborative has a governance structure that includes clinical representation across disciplines (e.g. physicians, nurses, pharmacists, laboratory professionals) at various levels, ranging from the strategic level where national priorities are determined to the working group level where content is developed and reviewed.

5.5 Ways that international clinical stakeholders participate in TC 215 work include:

— a representative of the international professional organization is an active member of the national group in a host country;

— a targeted invitation to contribute to a specific work item, for example, ISO 18104 involved the Nursing Terminology Summit, the International Council of Nurses and representatives of national nursing associations such as the American Nurses Association;

— Working Group 6 *Pharmacy and medicines business*, which provides a specific focus for pharmacy professionals within the TC structure, many of whom have formal or informal links to professional representative organizations (and most of whom work as pharmacists).

6 Barriers to participation

6.1 The ISO Strategic Plan [2] identifies the need to "optimise liaisons and involvement with representative international organizations of stakeholders", but unfortunately many of the health professions do not have representative international organizations, and where such organizations exist, they may not have the capacity or expertise to contribute to standards activity. Investment in the development of expertise and participation by such organizations at national and international levels first requires recognition of the importance of the activity. At present, there is no systematic communication from the TC to such stakeholder organizations, thus it is likely that many do not know that international health informatics standardization activity is underway.

6.2 A further barrier to involvement of international clinical stakeholder organizations is the voluntary nature of ISO activity. There may not be the capacity among the volunteers to inform and consult with relevant stakeholder groups.

7 Conclusions

7.1 Objective 2 of ISO Strategic Plan 2005-2010 requires technical committees to ensure the involvement of stakeholders.

7.2 Involvement of clinical stakeholder groups in TC 215 activity at both national and international levels is generally *ad hoc* and informal (with a few exceptions).

7.3 The benefits of clinical stakeholder involvement in TC 215 activities are unproven but potentially include improved safety and utility of health information systems as well as improved market relevance and uptake of health informatics standards.

7.4 The national membership structure of ISO TCs does not support an official role for international stakeholder groups other than as liaisons. This means they can contribute but cannot vote, unless they do this through a willing host country.

7.5 Barriers to effective clinical stakeholder participation include:

— in the professional organizations: lack of awareness of health informatics standards and their relevance; lack of capacity to participate; unclear route for participation;

— in TC 215: the ISO model of national, voluntary participation; lack of resources for stakeholder consultation and communication.

8 Recommendations for improving involvement of clinical stakeholders in TC 215

The TC should:

8.1 Identify and establish communications with international health professional organizations, particularly those that have a health informatics profile/component. This communication could include regular information exchanges and invitation for liaisons to attend TC 215 meetings.

8.2 Explore mechanisms by which input of such international stakeholder organizations can be recognised within formal TC 215 processes, including lessons from other ISO domains (engineering, chemical, etc).

8.3 Add to the new work item proposal template a section that requires identification of relevant clinical and other stakeholder groups, their input to the proposal and how they may be involved in the work item.

8.4 Identify and support dissemination of “training and educational material on the nature and practice of voluntary standardization” (see Reference [2]) in general and on health informatics standardization in particular to increase awareness of the importance of this activity and facilitate wider clinical stakeholder participation.

8.5 Establish a requirement on TC 215 delegates to state the currency of their credentials when speaking as a clinician or speaking as a health professional organization representative in committees and working groups.

8.6 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. This could include information and suggestions on possible funding support approaches/models for clinicians to participate and whether/how health informatics standards are addressed in clinical career paths, starting with undergraduate curricula.

8.7 Request national member bodies to initiate ongoing efforts to identify and establish communications with national clinical stakeholder representative organizations, particularly organizations that have a health informatics profile/component.