AHIMA Leading and Influencing International Standards for HIM Practices

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AHIMA has been leading the development of international standards for health information management (HIM) practices at the International Organization for Standardization (ISO)—the world's largest developer of international standards.

In the AHIMA comments on the 21st Century Cures Act Trusted Exchange Framework and Common Agreement, AHIMA representatives emphasized that "technical standards, policies and best practices around use of and adherence to technical standards are imperative to a trusted exchange framework and to a common agreement for trusted exchange[1]. These technical standards are chiefly focused on transmission and security. While these standards are of course imperative, they alone do not ensure the accuracy/trustworthiness of exchanged data and information. Adoption of standards critical to the "use" side of the interoperability equation held within Section 4003 of the 21st Century Cures Act definition of interoperability must be required.[2]

About the International Organization for Standardization (ISO)

Working as a global federation, ISO brings together public and private sectors in more than 160 countries to create consensus standards. To date, nearly 20,000 ISO standards have been published representing the work of more than 250 Technical Committees (TC) and thousands of subject matter experts providing standard-based solutions and meaningful benefits for global development.

About ISO/TC215 Health Informatics

Established in 1998, ISO Technical Committee 215, Health Informatics (ISO/TC215) has over 70 member countries and liaisons representing millions of healthcare stakeholders worldwide. The ISO/TC215 mission is standardization in the field of health informatics to facilitate the capture, interchange, and use of health-related data, information, and knowledge to support and enable all aspects of the health system. The US delegation at ISO/TC215 is represented by the Technical Advisory Group (ISO/TC215 USTAG), a committee accredited by the American National Standards Institute that develops US national positions on international standards. AHIMA serves as the designated Secretariat for ISO Technical Committee 215 Health Informatics (ISO/TC215) (Global Health Informatics Standards) and Administrator of the US Technical Advisory Group to TC215 (ISO/TC215 USTAG).

Standards that support the "use" of exchanged information include those falling into the categories of:

- Functional Interoperability (Business, Functional, and Safety Standards)
- Semantic Interoperability (Data and Information Content Standards)
- Technical Interoperability (Transport and Security Standards)[3]

Figure 1 below shows AHIMA's standards development activities and its partners—standards development organizations (SDOs).

Figure 1: AHIMA Standards Development Activities Scope and Collaborating SDOs: ISO, IHE, and HL7

- Enabling **functional interoperability** by standardizing information management practices in healthcare

- Enabling **semantic interoperability** by creating trusted information via semantic content standardization

- Collaborating with vendors in SDOs to support **technical interoperability**

At the level of a National Trusted Exchange Framework, the healthcare industry will be exchanging enormous amounts of granular data and individual record sets generated/captured at the local level by thousands of electronic health record (EHR) systems, ancillary systems, and mobile applications, largely without best practices for data and information governance in place —according to the results of AHIMA's information governance (IG) surveys in 2014, 2015, and 2017. If the industry does not address standards and best practices for data and information capture, use, exchange, and reuse (i.e., functional, semantic, and technical interoperability standards all together), then providers cannot trust information for safe, quality care of the individual or for use in improving the health of patient populations.

AHIMA is focused on standards for trusted information sharing—standards for functional, semantic, and technical interoperability. These health informatics standards categories, as defined by the US Healthcare Information Technology Standards Panel in 2006, include:

- **Functional Interoperability (Shared Rules)**

  - Business Standards (business rules, guidelines, practice checklists)
  - Functional Standards (interoperability use cases, HIM practice standards)

- **Semantic Interoperability (Shared Content)**

  - Data Standards
  - Information Content Standards
  - Identifiers Standards

- **Technical Interoperability (Shared Infrastructure)**

  - Information Exchange Standards
  - Privacy and Security Standards
  - Health Information Technology (HIT) Safety Standards

Why AHIMA is a Leader at ISO

In 2011, AHIMA was designated by the American National Standards Institute (ANSI) to serve as a Secretariat to ISO/TC215 and the ISO/TC215 USTAG. AHIMA was selected by ANSI because AHIMA's best practices for coding, information management, IG, clinical documentation improvement (CDI), operational informatics, and data analytics serve as invaluable resources for standardization of HIM practices and HIT products that support these practices at both the national

and international level. AHIMA was also selected because the association has an established record of participation in various standards development organizations (SDOs), such as:

- Health Level Seven (HL7), where AHIMA develops standards for EHRs, personal health records (PHRs), and mHealth
- Integrating the Healthcare Enterprise (IHE), a collaborative of HIT vendors, users, and associations of healthcare professionals, where AHIMA develops US standards for HIM practices
- ISO/TC215, where AHIMA has elevated the US HIM, HIT, and informatics standards into international standards

AHIMA's standards development activities are carried out in collaboration with the SDOs listed above. Informed by the Practice Briefs and best practices identified under the Volunteer Leadership Development (VLD) activities (AHIMA Practice Councils (PCs), Task Forces (TFs), and Ad Hoc Committees), the AHIMA Standards Task Force of over 60 volunteer HIM subject matter experts (SMEs) work on developing HIM, HIT, and informatics standards, as depicted in Figure 2 below.

Figure 2: AHIMA Standards Development Activities: Collaboration with VLD and SDOs
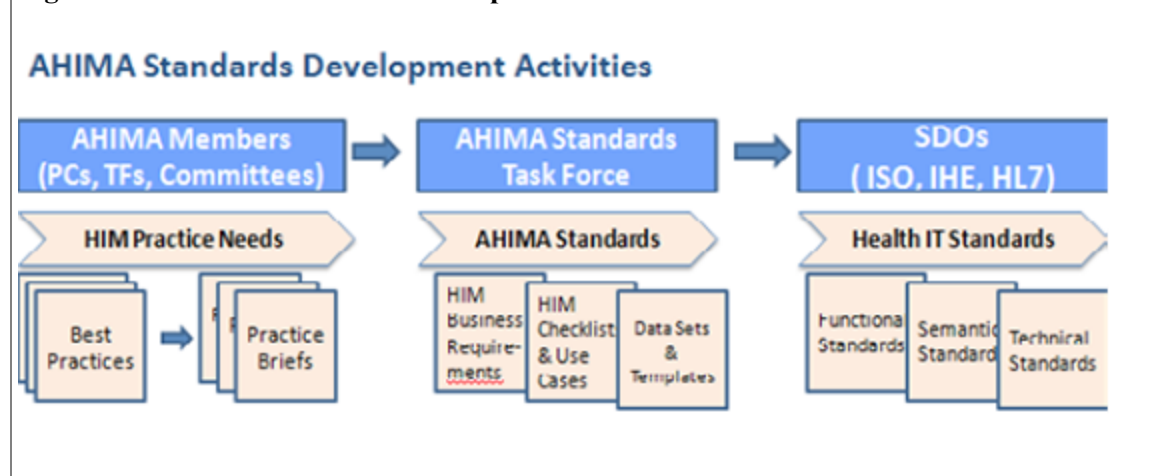
Through these efforts AHIMA has positioned itself as an important participant in the national and international HIT standardization activities and has built institutional competencies for standards development and use to support trusted information exchanges for providers, information managers, and researchers.

Why AHIMA Focuses on ISO/TC215

The AHIMA Standards Task Force and Practice Councils have become the drivers to identify the need for standards and to develop HIM standards for electronic information exchanges nationally and globally (see Figure 2 above). Understanding that multi-stakeholder collaboration is needed to build and adopt standards, AHIMA, through multi-national and multi-sector cross-collaboration offered by the ISO/TC215, focuses on the effective proliferation of standards-based HIM practices in the US as well as in the global healthcare market. The stakeholders for ISO/TC215 standards include governmental agencies, healthcare organizations, clinical practitioners, health information managers, public health and research organizations, academia, developers and integrators of HIT applications and services, and various SDOs.

AHIMA selected ISO/TC215 as a primary partner in AHIMA standards development efforts because of its high visibility across SDOs, international focus, HIT users as a primary target audience, and unique role in developing interoperability standards that combines all three components of interoperability (semantic, technical, and functional), as well as for AHIMA's established leadership role in various workgroups and overall Secretariat role to both the US delegation (USTAG) and the ISO/TC215 at large.

AHIMA Priorities at ISO/TC215

AHIMA standards development efforts at ISO/TC215 are focused to address interoperability challenges experienced today by HIM professionals, clinicians, researchers, and public health professionals who continue to face overwhelming difficulties with

usability of the health information systems due to their shortcomings in supporting user needs.[4,5,6,7] Specific examples of some challenges when using health IT are provided in Table 1 below.

Table 1: Challenges Using Health IT[8,9]	
Issues	**Examples**
Data design and capture issues	- Inconsistent data definition across/between systems - Inability to tag and capture high value data elements - Inconsistencies between data in structured and unstructured notes
Information integrity and quality issues	- Lack of trust in data (impedes ability to utilize for analytics) - Impact on safety and quality of care - Patient identification and patient data from devices, other records - Lack of data quality management efforts/tools - Process breaks/redundancies (shadow records) - Errors found at the health record "end of the line" in patient portals
Inability to use data for analytics/advanced reporting	- Insufficient knowledge and skill of analysts - Errors found in data are not traced back to source - Siloed ownership at business or clinical level - Little or no ability to report across systems
Lack of interoperability	- Cost of interoperability - System ability to trade data and information - Trust in inbound information from other organizations

A five-year study published by the US National Institute of Standards and Technology on usability of EHR systems identified the following four issues with adoption that may negatively impact patient safety:

1. Clinically relevant information is not available for the task at hand
2. Inadequate documentation
3. Inaccurate information
4. Irretrievable information[10]

Healthcare is moving to greater patient participation and personalization in care that requires trusted information capture, sharing, use, and reuse between patients, providers, and healthcare organizations. This must occur during not just information access but also scheduling, referral, decision-making, and general management of the patient's health and care. Standards-based interoperable HIT solutions are becoming fundamental building blocks and are driving healthcare delivery transformation to enable a financially sustainable and well-resourced healthcare system. In addition, the need for a competent workforce to support standards development as well as implementation, operation, and use of standards-based HIT solutions is overwhelming—specifically, for workers skilled in standards-based services integration, cloud computing, cybersecurity, and information safety.[11] AHIMA standards development efforts at ISO/TC215 are focused on addressing the challenges summarized above, all of which are semantic, technical, and functional interoperability challenges.

To date, ISO/TC215's portfolio of standards and projects (standards under development) includes over 230 health informatics standards: International Standards (IS), Technical Specifications (TS), and Technical Reports (TR).[12] These standards are developed by the ISO/TC215 Work Groups (WG) and Joint Work Groups (JWG) as follows:

- WG1 – Architecture, Frameworks and Models
- WG2 – Systems and Device Interoperability
- WG3 – Semantic Content
- WG4 – Security, Safety and Privacy
- WG6 – Pharmacy and Medicines Business
- JWG1 – Traditional Chinese Medicine
- JWG7 – Health Software, HIT Systems and Medical Devices (abbreviated name)

AHIMA standards development activities are mainly conducted in WG3 (semantic interoperability standards), WG4 (functional interoperability standards), and WG2 (technical interoperability standards).

Workforce standards have been developed in WG3 and WG4, while HIT safety standards have been developed in JWG7. Table 2 below provides examples of standards developed with AHIMA participation.

Table 2: Examples of ISO/TC215 Health Informatics Standards Developed with AHIMA Participation	
Functional Interoperability Standards	
Business Standards	
ISO/TR 12773	Business requirements for health summary records
ISO/IS 18308	Requirements for an electronic health record architecture
ISO/TS 14265	Classification of purposes for processing personal health information
ISO/TS 13131	Telehealth services — Quality planning guidelines
ISO/TR 17522	Provisions for health applications on mobile/smart devices
Functional Standards	
ISO/TR 21089	Trusted end-to-end information flows
ISO/IS 27789	Audit trails for electronic health records
ISO/IS 21091	Directory services for healthcare providers, subjects of care, and other entities
ISO/TS 17975	Principles and data requirements for consent in the collection, use, or disclosure of personal health information
ISO/HL7 10781	HL7 electronic health records system functional model, Release 2 (EHR FM)
HIT Safety Standards	
ISO/TS 25238	Classification of safety risks from health software
ISO/TR 27809	Measures for ensuring patient safety of health software
ISO/TR 17791	Guidance on standards for enabling safety in health software

IEC/IS 82304	Health software – Part 1: General requirements for product safety

Semantic Interoperability Standards

Data Standards

ISO/HL7 27951	Common terminology services, Release 1
ISO/IS 13119	Clinical knowledge resources – Metadata
ISO/TR 12300	Principles of mapping between terminological systems
ISO/TR 12310	Principles and guidelines for the measurement of conformance in the implementation of terminological systems
ISO/IS 13120	Syntax to represent the content of healthcare classification systems – Classification markup language (ClaML)
ISO/TS 21526	Metadata Repository Requirements
ISO/TS 21564	Terminology Resource Map Quality Measures
ISO/TS 22287	Workforce Tasks and Capabilities for Terminology Services in Healthcare

Information Content Standards

ISO/TR 20514	Electronic health record – Definition, scope and context
ISO/HL7 27932	Data Exchange Standards – HL7 clinical document architecture, Release 2
ISO/TR 14292	Personal health records – Definition, scope, and context
ISO/HL7 21731	HL7 Version 3 – Reference information model, Release 4
ISO/IS 20301	Health cards – General characteristics
ISO/TS 13972	Detailed clinical models, characteristics, and processes
ISO/IS 14199	Information models – Biomedical research integrated domain group (BRIDG) model
ISO/TS 20440	IDMP – Implementation guide for ISO 11239 data elements and structures for the unique identification and exchange of regulated information on pharmaceutical dose forms, units of presentation, routes of administration, and packaging

Technical Interoperability Standards

Identifier Standards

ISO/TS 27527	Provider identification
ISO/IS 20302	Health cards – Numbering system and registration procedure for issuer identifiers

ISO/TS 18530	Automatic identification and data capture marking and labeling – Subject of care and individual provider identification
ISO/TS 16791	Requirements for international machine-readable coding of medicinal product package identifiers
Information Exchange Standards	
ISO/TR 18307	Interoperability and compatibility in messaging and communication standards – Key characteristics
ISO/TR 16056	Interoperability of telehealth systems and networks
ISO/IS 12052	Digital imaging and communication in medicine (DICOM) including workflow and data management
ISO/HL7 27931	Data Exchange Standards – Health Level Seven Version 2.5 – An application protocol for electronic data exchange in healthcare environments
ISO/TR 28380	IHE global standards adoption
ISO/IEEE 11073	Personal health device communication – Part 00103: Overview
Privacy and Security Standards	
ISO/TS 13606-4	Electronic health record communication – Part 4: Security
ISO/TS 21547	Security requirements for archiving of electronic health records – Principles
ISO/TR 21548	Security requirements for archiving of electronic health records – Guidelines
ISO/IS 17090-4	Public key infrastructure – Part 4: Digital signatures for healthcare documents
ISO/IS 22600	Privilege management and access control
ISO/IS 27799	Information security management in health using ISO/IEC 27002
ISO/IS 25237	Pseudonymization
ISO/TR 18638	Guidance on health information privacy education in healthcare organizations
ISO/TC215 Interoperability Standards	
ISO/TS 21860	Reference standards portfolio (RSP): Clinical Imaging RSP-CI)

Source: ISO/TC215. "ISO/TC 215 Health Informatics Standards Catalog." 2017.

AHIMA Partners at the US Delegation to ISO/TC215

AHIMA's partners in developing interoperable HIM, HIT, and informatics standards at the US delegation (US Technical Advisory Group) to ISO/TC215 include various SDOs and national leaders in HIT adoption, including but not limited to (in alphabetical order):

- Association for the Advancement of Medical Instrumentation
- American Dental Association
- BD
- Clinical Data Interchange Standards Consortium
- Experian Healthcare
- Health Level Seven
- Healthcare Information and Management Systems Society
- Kaiser Permanente
- Medtronic
- National Council for Prescription Drug Programs
- Philips Healthcare
- US Department of Veterans Affairs
- US Food and Drug Administration

AHIMA built a foundation for ensuring ISO/TC215 standardization efforts have direct value for AHIMA members and HIM professionals at large. AHIMA is working with its members to be recognized as the national and global leader to influence the US position on HIM, HIT, and informatics standards across the globe. AHIMA's goal is to help set the national and international HIT standardization agenda and establish HIM leadership and influence on standardization of electronic health data, information, and knowledge.

Resources

Those interested in learning more about ISO/TC215 standards development can visit the following resource links for additional information:

- ISO/TC215 Standards and Project Catalog
- ISO/TC215 Website at AHIMA
- ISO/TC215 Website at ISO

Notes

[1] AHIMA. "AHIMA Comments on 21st Century Cures Act Trusted Exchange Framework and Common Agreement." August, 25, 2017.

[2] House.gov. "21st Century Cures Act." November 25, 2016.

[3] Orlova, Anna. "Overview of Health IT Standards." *Journal of AHIMA* 86, no. 3 (March 2015): 38-40.

[4] Bowman, Sue. "Impact of electronic health record systems on information integrity: Quality and safety implications." *Perspectives in Health Information Management* (Fall 2013).

[5] Nguyen, L., E. Bellucci, and L.T. Nguyen. "Electronic health records implementation: An evaluation of information system impact and contingency factors." *International Journal of Medical Informatics* 83, no. 11 (2014): 779-796.

[6] Kuhn, Thomson et al. "Clinical Documentation in the 21st Century: Executive Summary of a Policy Position Paper from the American College of Physicians." *Annals of Internal Medicine*. February 17, 2015.

[7] Bouamrane, Matt-Mouley and Frances S. Mair. "A study of general practitioners' perspectives on electronic medical records systems in NHS Scotland." *BMC Medical Informatics and Decision Making* 13, no. 58 (2013).

[8] Mitcheff, M. "A Case Study: The Association of Interoperability of Health Information and Potential Patient Safety Concerns." Presentation at 2016 AHIMA Convention, October 15 to October 19, Baltimore, MD.

[9] Miller, M. and D. Young. "Supporting Functional Interoperability through Standards for Information Management Practices for Healthcare." Presentation at 2016 AHIMA Convention, October 15 to October 19, Baltimore, MD.

[10] Lowry, Svetlana Z. et al. "Technical Evaluation, Testing, and Validation of the Usability of Electronic Health Records: Empirically Based Use Cases for Validating Safety-Enhanced Usability and Guidelines for Standardization." US National Institute of Standardization and Technology (NIST). October 7, 2015.

[11] International Organization for Standardization (ISO) Technical Committee 215, Health Informatics (ISO/TC215). "Strategic Business Plan."

[12] AHIMA and ISO/TC215. "ISC/TC 215 Health Informatics Standards Catalog." 2017.

DOWNLOAD
Join the United States Delegation at ISO/TC215 USTAG

www.ahima.org/~/media/AHIMA/Files/AHIMA-and-Our-Work/ISOMember.ashx?la=en

Are you interested in participating in health informatics standards development with AHIMA and ISO? Contact Diana Warner, secretary, ISO/TC215 Health Informatics and Administrator, USTAG, ISO/TC215 at diana.warner@ahima.org, or Sheryl Reyes, deputy-secretary, ISO/TC215 Health Informatics and deputy-administrator, USTAG, ISO/TC215, at sheryl.reyes@ahima.org for more information. Review qualifications, membership levels, and apply by downloading and completing a membership application—either follow the URL above, or scan this QR code:

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