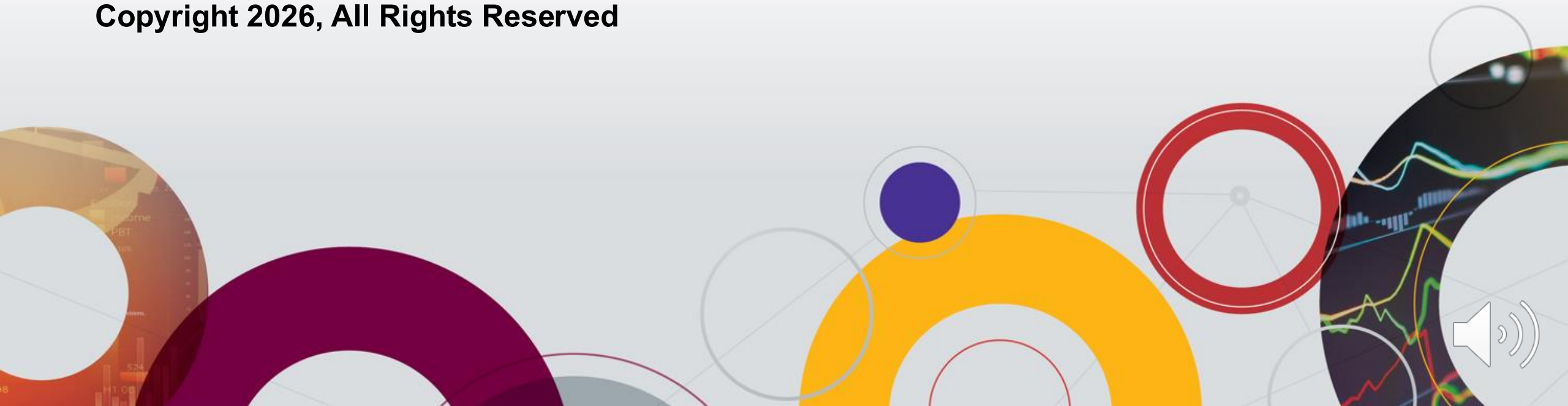


4.1 Standards and Interoperability: Basic Concepts

10x10 – Introduction to Biomedical Informatics & Artificial Intelligence
William Hersh, MD, FACMI, FAMIA, FIAHSI
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Why are standards important in biomedical and health informatics?

Promote consistent naming of individuals, events, diagnoses, treatments, etc.

Allow better use of data for patient care as well as re-use in quality measurement and improvement, research, public health, etc.

Enhance ability to transfer data among applications, allowing better system integration

Facilitate interoperability among information systems and users

Time is ripe for standards and interoperability

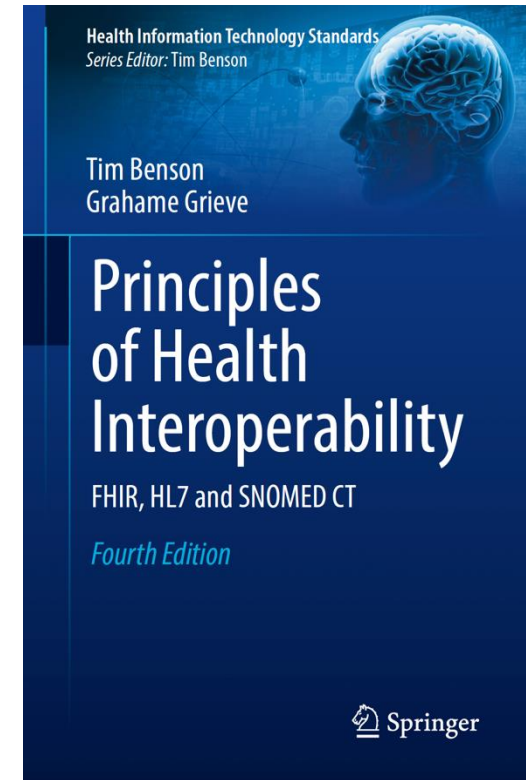
Advocacy for value and need not new (McDonald, 1989)

After massive investment in electronic health records (EHRs) through HITECH Act, there was insufficient requirement for interoperability (Adler-Milstein, 2017; Pronovost, 2018)

Particularly problematic between vendors but even a problem within vendors (Bernstam, 2022)

Also hindered by lack of policy and regulation (Szarfman, 2022)

Facilitated in US by 21st Century Cures Act (Federal Register, 2020; Blumenthal, 2022)



(Benson, 2021)

What is a standard?

There's a standard for that!

From ISO, 2004 (emphasized by Benson, 2021)

- A 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 optimum degree of order in a given context

Standards facilitate interoperability

IEEE original definition, widely cited (1990)

- “The ability of two or more systems or components to exchange information and to use the information that has been exchanged”

Revised IEEE definition (AHA, 2017)

- “Ability of a system or a product to work with other systems or products without special effort on the part of the customer. Interoperability is made possible by the implementation of standards.”

Interoperability in healthcare

In recognition of inadequate interoperability, 21st Century Cures Act specified definition for healthcare (Tripathi, 2022)

Interoperability defined as

- Enables the secure exchange of electronic health information with, and use of electronic health information from, other health information technology without special effort on the part of the user
- Allows for complete access, exchange, and use of all electronically accessible health information for authorized use under applicable State or Federal law
- Does not constitute information blocking

Levels of interoperability for healthcare (Walker, 2005)

Level 1 – no interoperability

- e.g., mail, fax, phone, etc.

Level 2 – machine-transportable (structural)

- Information cannot be manipulated
- e.g., scanned document, image, PDF

Level 3 – machine-organizable (syntactic)

- Sender and receiver must understand vocabulary
- e.g., email, files in proprietary format

Level 4 – machine-interpretable (semantic)

- Structured messages with standardized and coded data
- e.g., coded results from structured notes, lab, problem list, etc.

Value of standards throughout history

Roman chariots

Railroad tracks

Telephones

ASCII text in computers

Wi-Fi to connect computers, smartphones, tablets, etc. wirelessly to the Internet

Global financial transactions

Other examples?

Benefits and limitations of standards

Benefits

- Interoperability
- May allow innovation based on common foundation

Limitations

- Dominance by one segment of industry
- May stifle innovation

May be a mixed bag

- Microsoft “standards,” e.g., Windows, Office, etc.
- Ever hear of Esperanto? Why did English prevail? (Patterson, 1999)
- “The nice thing about standards is that there are so many of them to choose from.” (Tanenbaum, 2010 – disputed)

Standards development process – four approaches (Hammond, 2014)

Ad hoc – groups agree to informal specifications

De facto – single vendor controls industry

Government mandate – government agency creates standard and mandates its use

Consensus – interested parties work in open process

Some US standards bodies (private, non-profit)

[American National Standards Institute \(ANSI\)](#) that accredits standards development organizations (SDOs), including in healthcare

- Accredited Standards Committee (ASC) X12
- Health Level 7 (HL7)
- [American Society for Testing and Materials \(ASTM\)](#), which has a Committee E31 on Healthcare Informatics

International standards bodies

International Organization for Standardization (ISO)

- Technical Committee 215 (TC 215) focuses on health informatics standards

European Committee for Standardization (CEN)

- CEN/TC 251 is health informatics standards body for Europe

International Telecommunication Union (ITU) – UN agency focused on telecommunications standards (general, not medical)

ASTP/ONC Interoperability Standards Platform

HealthIT.gov

Interoperability
Standards
Platform

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Interoperability Standards Platform

The Interoperability Standards Platform (ISP) is the Assistant Secretary for Technology Policy and the Office of the National Coordinator for Health IT's (ASTP/ONC) repository for standards initiatives that advance health data interoperability nationwide.

ISA



Look Up Interoperability Standards

USCDI



Reference Core Data Elements for
Interoperability

Standards Bulletin



ONC Standards Bulletin

SVAP



Find Newest Standards For Certification

USCDI+



Go Beyond USCDI

Draft FHIR® Action Plan



Draft Federal FHIR® Action Plan



Banking can do worldwide standards; why not healthcare (Bernstam, 2009)?

ISO 8583

	Banking Data	Health Data
Concepts and descriptions	Precise <i>Example</i> Account 123 balance = \$15.98	General, subjective <i>Example</i> Sick patient
Actions	Usually (not always) reversible <i>Example</i> Move money A → B	Often not easily reversible <i>Example</i> Give a medication Perform a procedure
Context	Precise, constant, or irrelevant to the task <i>Example</i> US \$	Vague, variable <i>Example</i> Normal lab values differ by lab. No two cells, organs, tumors, or patients are identical.
User autonomy	Well-defined and constrained <i>Example</i> What I can do with my checking account = what you can do with yours	Variable and dependent on circumstance <i>Example</i> Clinical privileges depend on training, changes over time, and circumstances
Users	Clerical staff, account holder	Varied, including highly trained professionals
Workflow	Well-defined, documented, and explicit	Highly variable, implicit with many undocumented tasks and exceptions

No discussion of standards is complete without mentioning HIPAA

Health information standards were a key focus of the Health Insurance Portability and Accountability Act of 1996 (HIPAA; aka, the Kennedy-Kassebaum Bill)

Main focus of legislation, however, was health insurance issues

- Reducing denial based on pre-existing conditions
- Improving portability across jobs

But now HIPAA is best known for its addressing of

- Standards for financial transactions and code sets
- Unique identifiers for patients, healthcare providers, and employers
- Development of privacy and security standards for transmission of electronic health data

HIPAA privacy and security regulations expanded in HITECH

More in 4.2 and Unit 7

Important concerns for standards and interoperability going forward

Overview of benefits for all stakeholders from lens of universal health coverage (World Bank, 2023)

Specific issues in many specialties, e.g., pediatrics (Shafi, 2023) and ophthalmology (Goetz, 2023)

Streamlining functions, e.g., prior authorization (CMS, 2024)

Important foundation for optimal use of AI (Mandl, 2024)

- Interoperability more important than standards (Coiera, 2023)?
- Early work shows generative AI can generate standardized output (Li, 2024; Brat, 2024)

Engagement with industry via APIs essential (Adler-Milstein, 2023; Barker, 2024)

Biomedical and health informatics standards

Identifiers (4.2)

Transactions (4.2)

Message exchange (4.3)

Terminology (4.4)

SMART on FHIR (4.5)