HEALTH INFORMATICS STANDARD

Corso di Informatica Medica

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The healthcare heterogeneous scenario
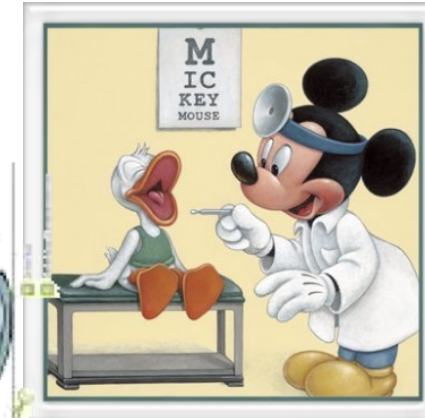
Interoperability

Ability of different systems to work cooperatively allowing different users to share information and resources

Why standards?

INTEROPERABILITY TYPE	HOW TO ADDRESS IT
Technological	Technological Standards
Structural	Communication Standards
Semantic	Terminologies and ontologies
Organizational	Processi
Governance	Frameworks and agreements
Legal	International legislation

Health Information Exchange

According to healthit.gov, the official US site for Health IT information:

"Electronic health information exchange (HIE) allows doctors, nurses, pharmacists, other health care providers and patients to appropriately access and securely share a patient's vital medical information electronically—improving the speed, quality, safety and cost of patient care"

HIE =
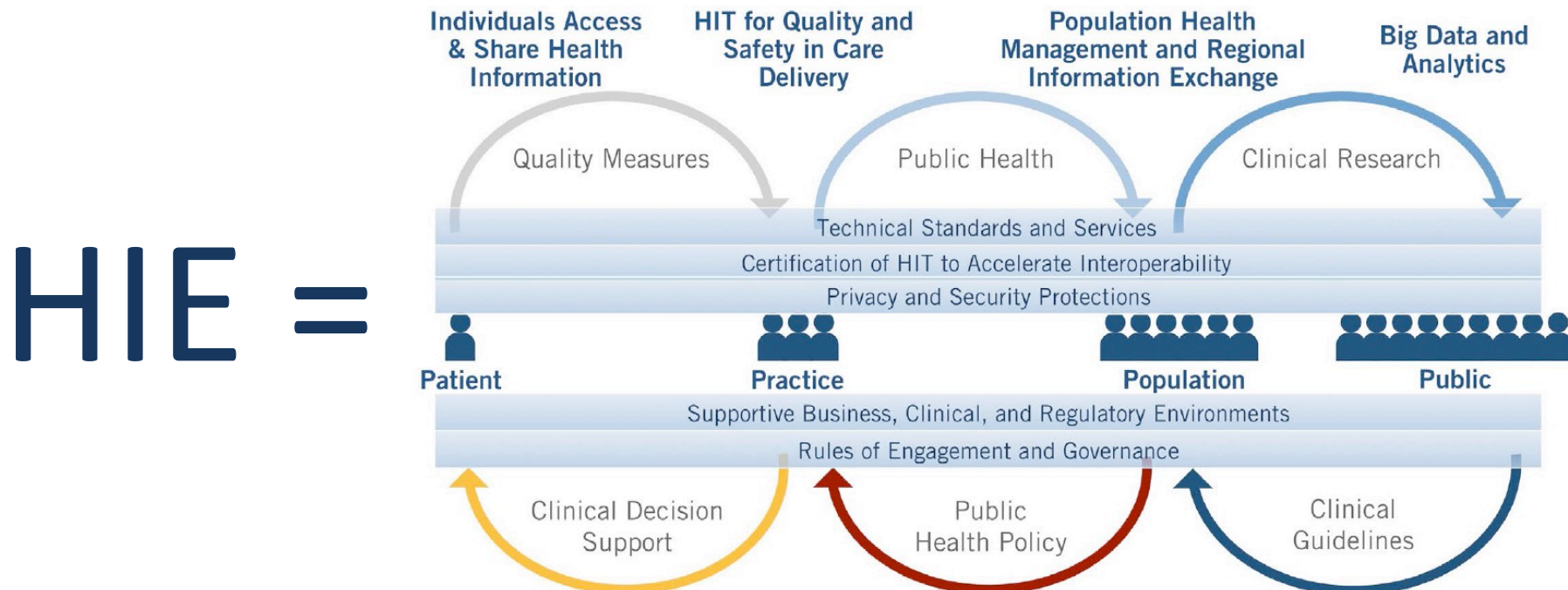
From: "Connecting Health and Care for the Nation: A Ten Year Vision to Achieve Interoperable Health IT Infrastructure" – ONC 2014

HIE expected scenario

- Exchange data among providers
- Provide secure access to healthcare documents for patients
- **Based on interoperability (technology/standards and semantic/archetypes-terminologies)**

Standards: definition and scopes

- **Set of rules and definitions that specify how to carry out a process or produce a product**

- 1987 Technical report from the International Standards Organization → "Any **meaningful exchange of utterances** depends upon the prior existence of an **agreed** upon set of **semantic and syntactic rules**"

- Standards →

  - created and used to **make things or processes work** more easily and economically (sometimes, to work at all)

  - permit two or more disassociated people/parts to **work** in some **cooperative** way

Computers and standards

- The first computers were built without standards

- Hardware and software standards were quicly developed for humans who need a more readable language →

  - standard character sets (ASCII, EBCDIC)
  - first standard computer language (COBOL)
  - hardware components depend on standards for exchanging information

The standards development process: methods

Ad hoc method

- A group of interested people and organizations agree on a standard specification.
- These specifications are informal and are accepted as standards through mutual agreement of the participating groups.
- Example: DICOM standard for medical imaging (American College of Radiology/National Electrical Manufacturers Association, ACR/NEMA)

De facto method

- A single vendor controls a large enough portion of the market to make its product the market standard.
- Example: Microsoft Windows.

Government-mandate method

- A government agency creates a standard and legislates its use.
- Example is HCFA's UB92 insurance-claim form.

Consensus method

- A group of volunteers representing interested parties work in an open process to create a standard.
- Example: Health Level 7 (HL7) standard for clinical-data interchange.

The development process

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IDENTIFICATION: someone becomes aware that there exists a need for a standard

CONCEPTUALIZATION: definition of the characteristics of the standard

DISCUSSION: outline creation to define content, identification of critical issues, and time line

DRAFTING: few dedicated individuals, typically vendors)

REVISION: balance between moving forward and being open: open policy where anyone can be heard and open balloting policy where the draft is made available to all interested parties to be duscussed

IMPLEMENTATION: guidelines are released. The early stage are the most critical for acceptance and future adoption

Conformance and Certification

CONFORMANCE

- Compliance with the standard
- Specific agreements among users of the standard who affirm specific rules will be followed.
- The conformance document identifies specifically what rules are followed in the process/system implementaion
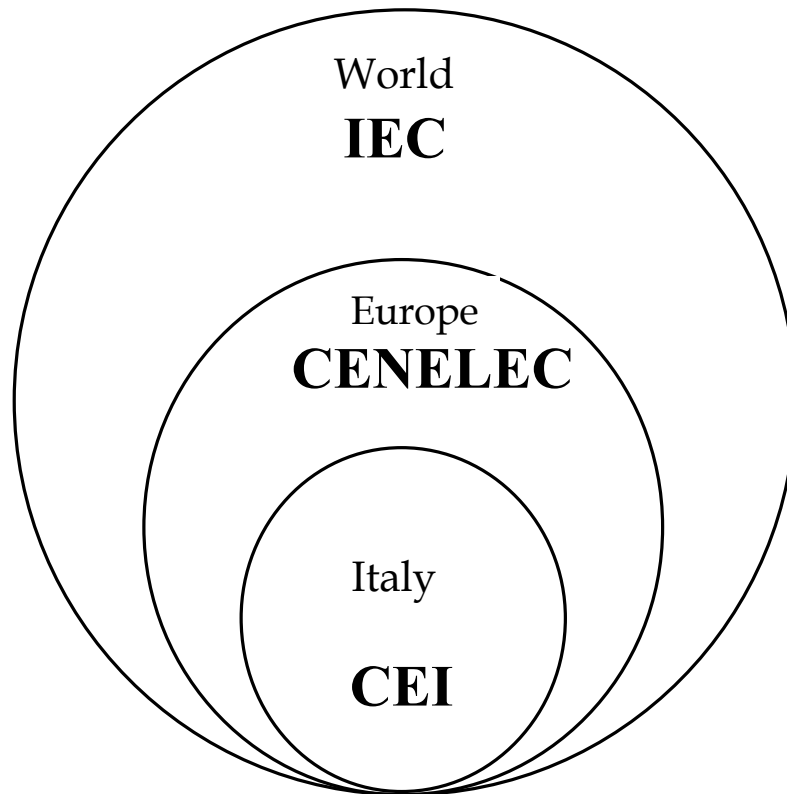
CERTIFICATION

- A neutral body certifies that a vendor's product in fact does comply and conform with the standard.
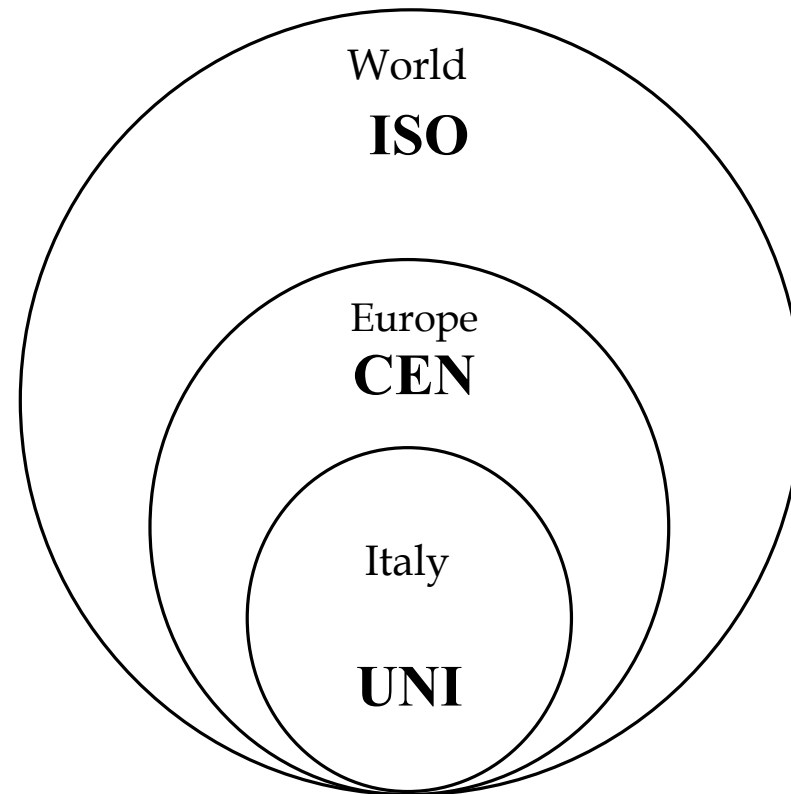- There is a verification stage that provides a "certificate"

Standards characteristics

- The standard definition process ensures that:

- AGREEMENT → Standards are created upon agreement because there was a consensus among who participated to the working group.

- DEMOCRACY → all the interested stakeholders can participate to the working groups and make observations and suggestions

- TRANSPARENCY → standardization bodies make the process and the diffrent steps avaiable to the poublic who is interested

- VOLUNTARY→ Norms atre a reference that the interested stakeholders voluntary adopt.

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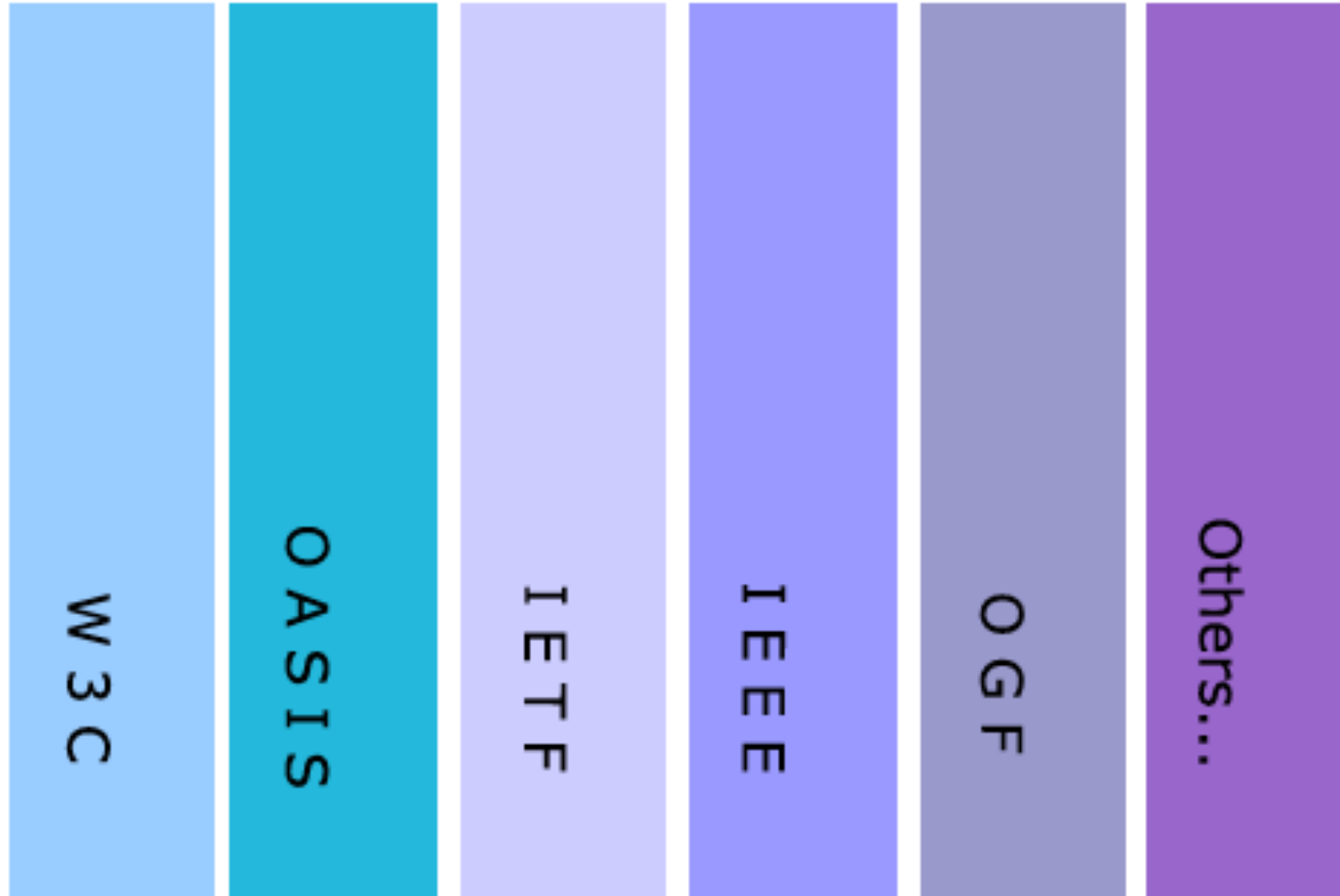ELECTRICAL AREA

OTHER AREAS

World
IEC

Europe
CENELEC

Italy

CEI

World
ISO

Europe
CEN

Italy

UNI

Standardization bodies for ICT

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W 3 C

O A S I S

I E T F

I E E E

O G F

Others…

Standardization bodies for Medical Informatics

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INTERNAZIONAL LEVEL

- **CDISC** - Clinical Data Interchange Standards Consortium
- **CEN TC 251** – Health Informatics
- **GS-1** - Supply chain standards system
- **HL7** – Health level 7
- **IHTSDO** - Not-for-profit association that owns and maintains SNOMED CT
- **ISO TC215** – Health Informatics

NATIONAL LEVEL

CTI
Termotecnica

CIG
Gas

CUNA
Automobili

UNICHIM
Chimica

UNSIDER
Ferro e Metalli

UNINFO
Informatica

UNIPLAST
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"Informatica Medica"

"**UNINFO** è una libera Associazione a carattere tecnico-scientifico e divulgativo senza fine di lucro (diretto o indiretto) che si prefigge di promuovere, realizzare e diffondere la normazione tecnica nel settore delle tecnologie dell'informazione e delle comunicazioni (in breve ICT) e delle loro applicazioni, sia a livello nazionale che europeo ed internazionale."

HIPAA: a first law on standard adoption in medical informatics

- 1996 → Health Insurance Portability and Accountability Act (HIPAA)

- Signed into law → HIPAA requires that the Secretary of Health and Human Services (HHS) adopt standards for the electronic transmission of specific administrative transactions.

- These standards will apply to health plans, health-care clearinghouses, and health-care providers who transmit any health information in electronic form;

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Health Level 7 (HL7)

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Health Level Seven
International

www.hl7.org

Founded in 1987, Health Level Seven International (HL7) is a not-for-profit, ANSI-accredited standards developing organization dedicated to providing a **comprehensive framework and related 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's 2,300+ members include approximately 500 corporate members who represent more than 90% of the information systems vendors serving healthcare.

What is HL7

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Health Level Seven (HL7)

►► An international standard development organization established more than 20 years ago

►► Enables interoperability of healthcare information

►► Creates standards for the exchange, management, and integration of electronic healthcare information

►► Develops specifications, e.g., a messaging standard that enables disparate healthcare applications to exchange key sets of clinical and administrative data

HL7: meaning

OSI Model
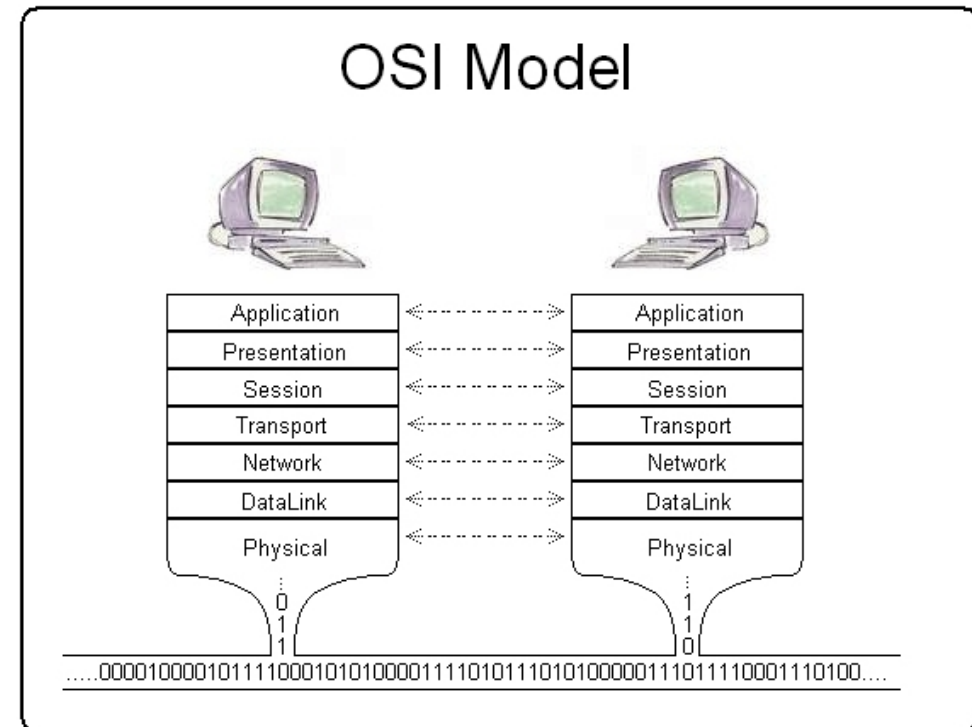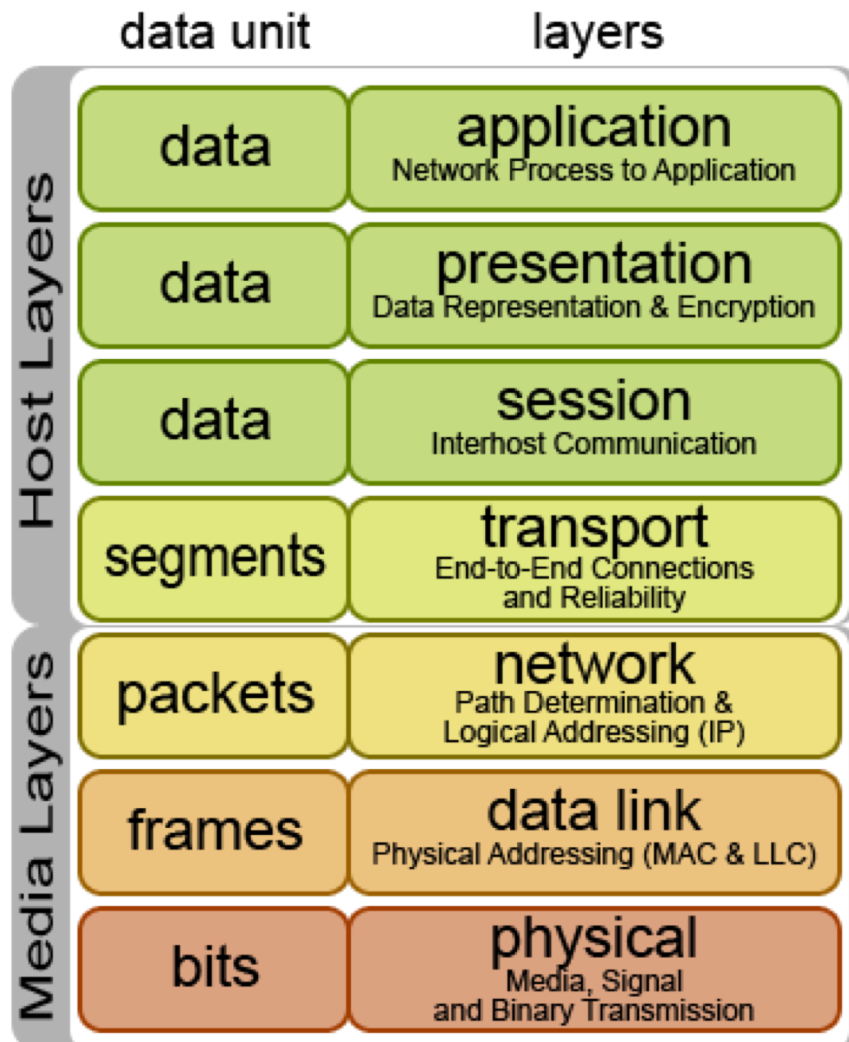
"Level 7" refers to the ISO-OSI application level (Open System Interconnection)

HL7 standard aims (1/2)

HL7 creates healthcare standards to enable interoperability of healthcare information.

►► Messages and documents move healthcare information in a standardized way to the point of patient care.

►► Standards assist in moving information within and beyond the four walls of hospitals and clinics among all healthcare stakeholders.

►► Standards assist in the sharing of public health information.

►► Standards help enable the electronic health record and creation of a National Health Information Network.

►► HL7 assists in using genomic data in conjunction with other clinical information.

HL7 standard aims (2/2)

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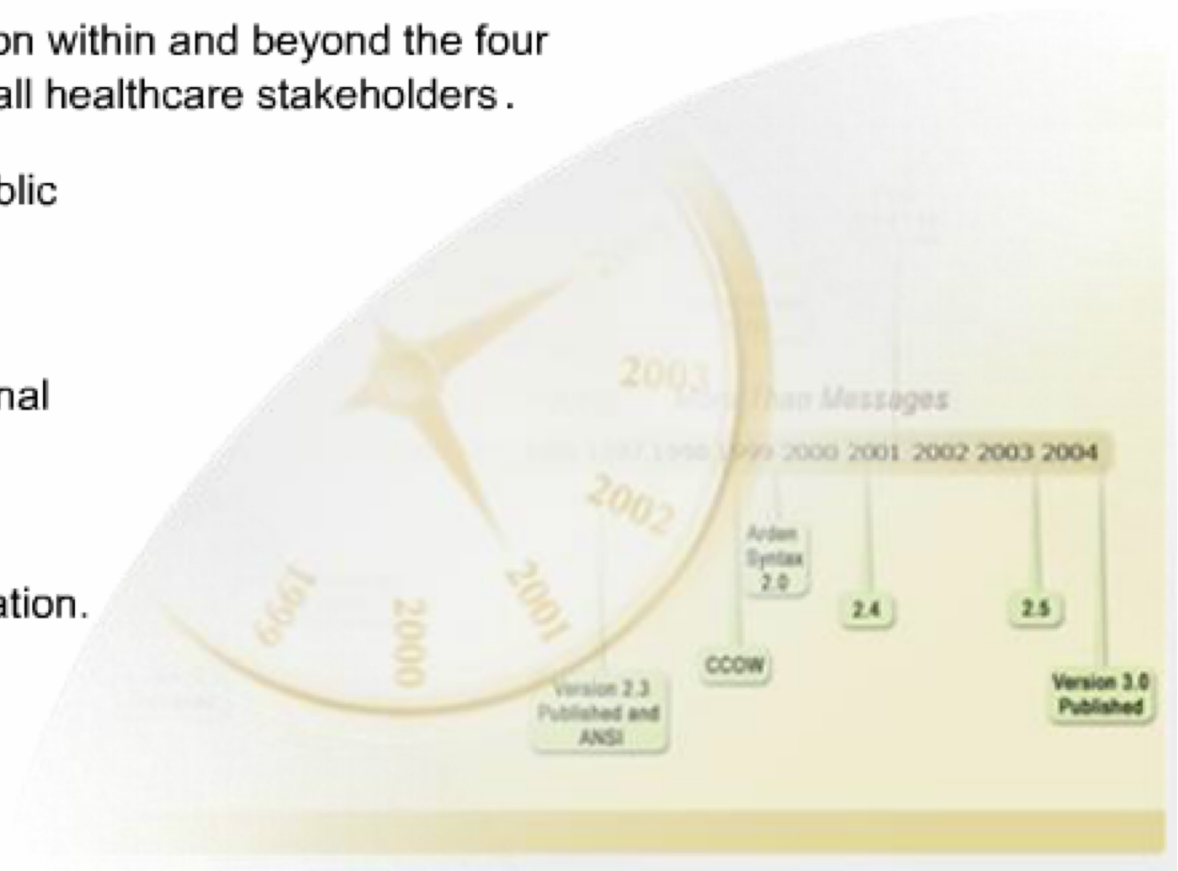
> ❗ HL7 does not create or provide any sort of software. It does provide healthcare organizations with specifications for making their systems interoperable.

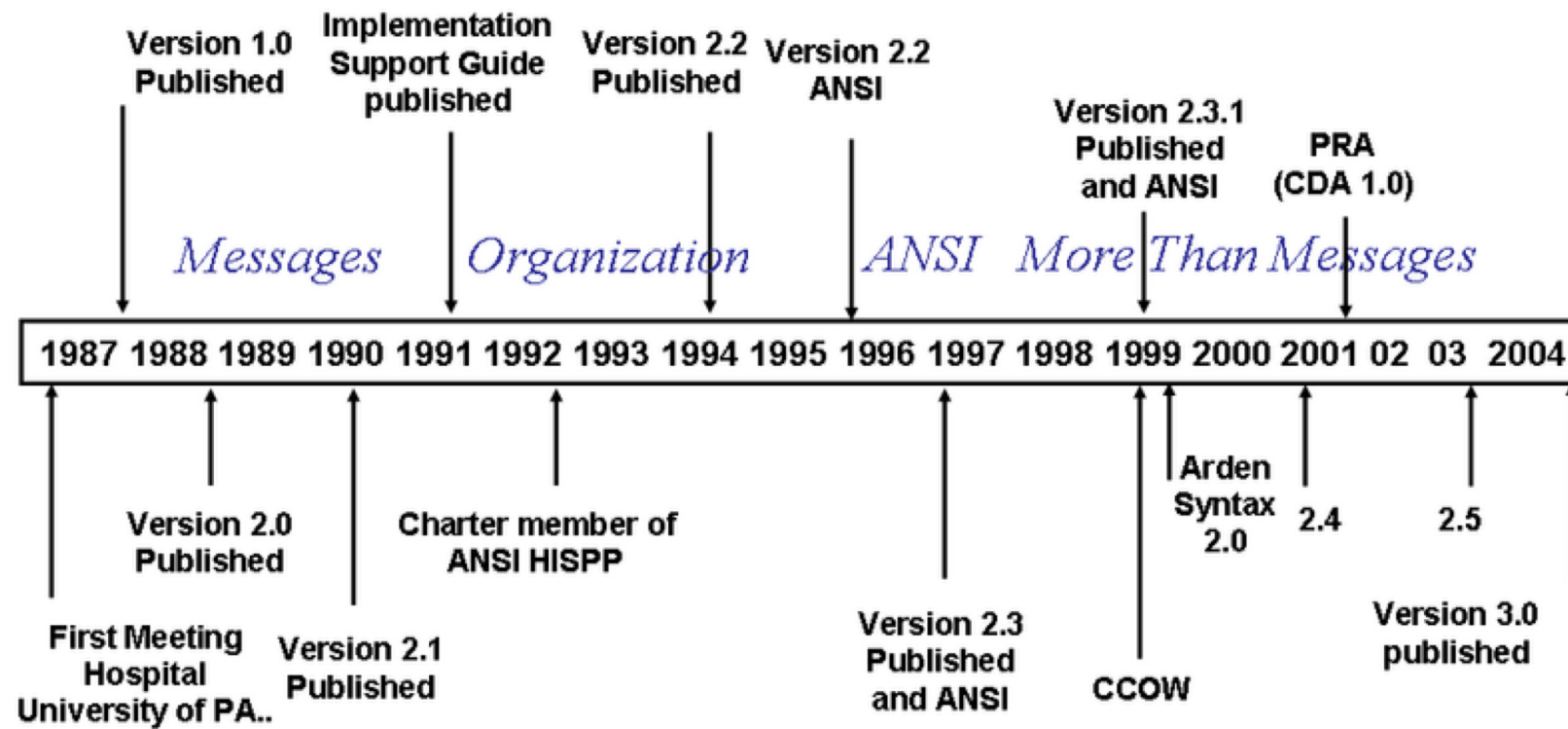**HL7 adopted strategies to develop specifications for making healthcare systems interoperable.**

►► Develop coherent, extendible standards and a formal methodology.

►► Collaborate with healthcare information users and other standards development organizations.

►► Promote the use of HL7 standards worldwide.

►► Educate the healthcare industry and policy makers.

►► Enable domain experts from the healthcare industry to develop healthcare information standards in their areas

HL7 history

History of HL7

Version 1.0 Published

Implementation Support Guide published

Version 2.2 Published

Version 2.2 ANSI

Version 2.3.1 Published and ANSI

PRA (CDA 1.0)

Messages   *Organization*   *ANSI* *More Than Messages*

1987 1988 1989 1990 1991 1992 1993 1994 1995 1996 1997 1998 1999 2000 2001 02 03 2004

Version 2.0 Published

Charter member of ANSI HISPP

Arden Syntax 2.0

2.4

2.5

First Meeting Hospital University of PA..

Version 2.1 Published

Version 2.3 Published and ANSI

CCOW

Version 3.0 published

Designed by David Marotta

Sept. 10 and 12, 2006

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HL7 reference categories

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HL7 standards are grouped into reference categories:

Section 1: Primary Standards - Primary standards are considered the most popular standards integral for system integrations, inter-operability and compliance. Our most frequently used and in-demand standards are in this category.

Section 2: Foundational Standards - Foundational standards define the fundamental tools and building blocks used to build the standards, and the technology infrastructure that implementers of HL7 standards must manage.

Section 3: Clinical and Administrative Domains - Messaging and document standards for clinical specialties and groups are found in this section. These standards are usually implemented once primary standards for the organization are in place.

Section 4: EHR Profiles - These standards provide functional models and profiles that enable the constructs for management of electronic health records.

Section 5: Implementation Guides - This section is for implementation guides and/or support documents created to be used in conjunction with an existing standard. All documents in this section serve as supplemental material for a parent standard.

Section 6: Rules and References - Technical specifications, programming structures and guidelines for software and standards development.

Section 7: Education & Awareness - Find HL7's Draft Standards for Trial Use (DSTUs) and current projects here, as well as helpful resources and tools to further supplement understanding and adoption of HL7 standards.

HL7 v2: communication workflow

- The data exchange protocol is based on ASCII-coded messages delimited by "separators";

- Two actors (sender and receiver) communicate throgh the exchange of bi-directional messages;

- The message content is validated by a parser before the transmission: first, the parser adds missing parts, then the message is transmitted;

- The receiver decodes the message accoridng to the protocol rules and interprets the data type extracting all the relevant information from the message;

- Messages are independent from the system implementations → heterogeneous systems can communicate withouth knowing each other;

- The receiver always sends an Acknowledge (ACK) message to confirm the reception.

Trigger events
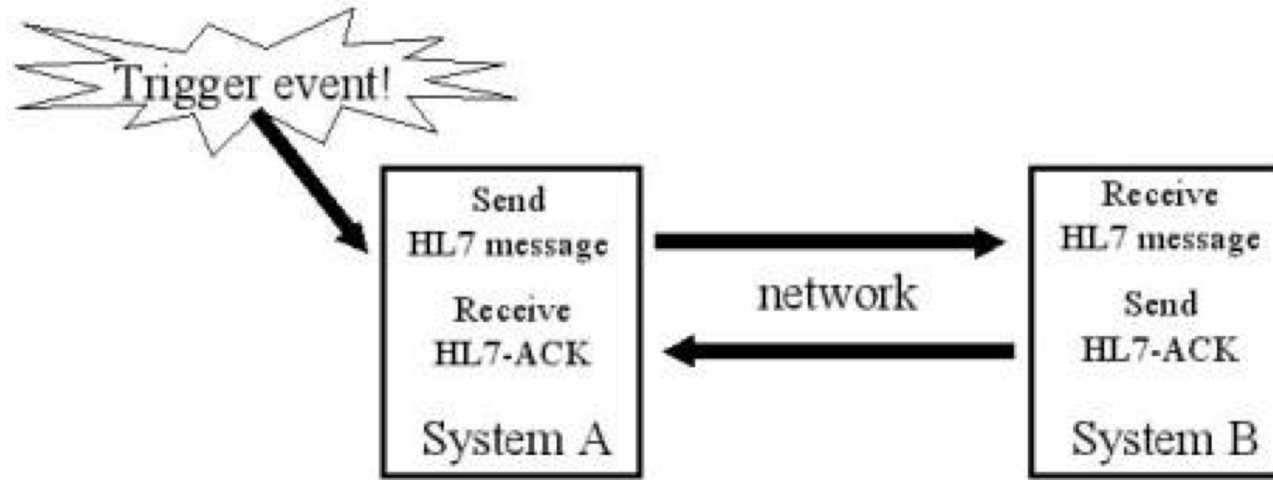
- The HL7 vs communication workflow is activated by a **trigger event: an explicit set of conditions that initiate the transfer of information between system components (real world event)**
- Examples: the placing of a laboratory order or drug order.
- The Trigger Event may be caused by one of the following reasons:
    - User Request Based (the trigger event that prompts a system to send all accumulated data to a tracking system every 12 hours; a user pressing a button in a user-interface)
    - State Transition (the trigger for canceling a document)
    - Interaction Based (the response to a query)

HL7 v2 message structure

- **Message** →
  - Delimited ASCII text
  - Composed by one or more **Segments**.

- **Segment** →
  - Text line delimited by the carriage-return (hexadecimal 0D).
  - Can be optional
  - Composed by one or more **Fields** delmited by the pipe character "|".

- **Fields** →
  - Composed by data or strings separated by " ^ ".
  - They can be empty
  - The NULL value is the empty string "".

HL7 v2 message separators

(x0D)		Segment separator
|		Field separator, aka pipe
^		Component separator, aka hat
&		Sub-component separator
~		Field repeat separator
\		Escape character

HL7 vs message example: order placer
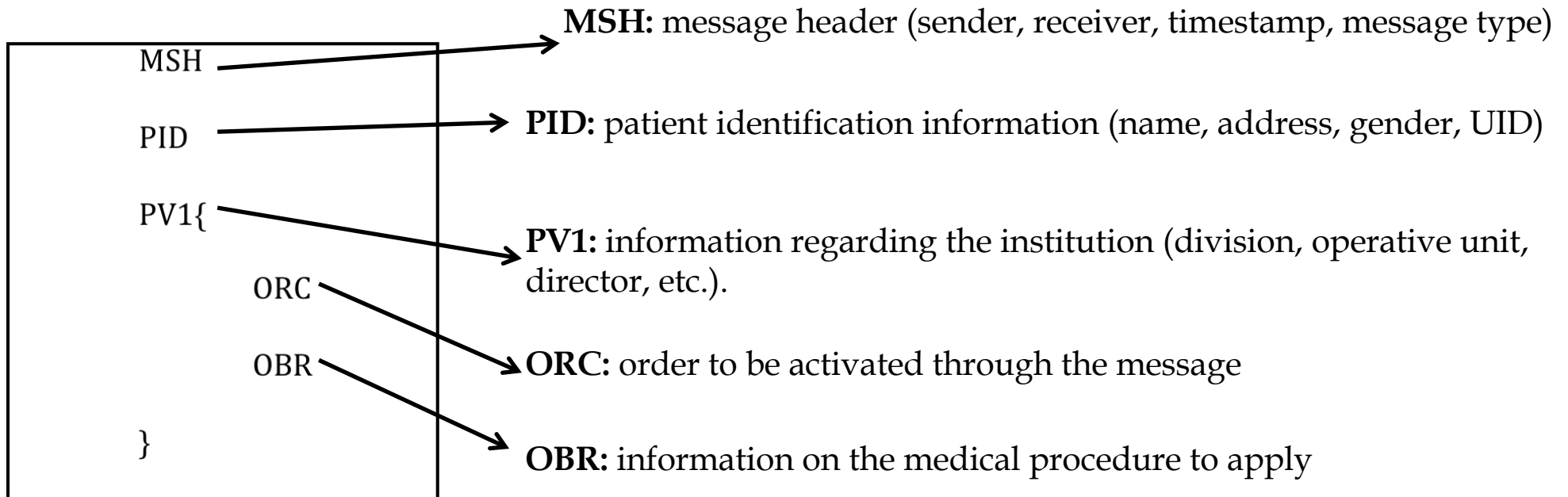
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ORM^O01 New Order

MSH|^~\&|RIS|SIEMENS|SCREENING|DEDALUS|20131001134643||ORM^O01|20240061|P|2.3.1|||||||8859/1<cr>
PID||59530^^^RIS|""||ROSSI^MARIA||19540101<cr>
PV1||O|||||||||||||||||SCR2013156803
ORC|SC|0000000000034466^DEDALUS|4399598^RA2000||CM
OBR||||4399598|||20131001131042

Segment desciption

MSH: message header (sender, receiver, timestamp, message type)

MSH

PID

PID: patient identification information (name, address, gender, UID)

PV1{

ORC

PV1: information regarding the institution (division, operative unit, director, etc.).

OBR

ORC: order to be activated through the message

}

OBR: information on the medical procedure to apply

HL7 vs message example: Acknowledge

```
MSH|^~\&|RIS|SIEMENS|EUROSOFT|EU|20131001134643||ACK^O01|MSGID12345678|P|2.3.
1<cr>
MSA|AA|MSGID12345678
```

Acknowledge message

- Composed by two segments→ **MSH** e **MSA**
- **MSH:** message header
- **MSA** →
  - ID of the message that is acknowledged;
  - A code describing the result of the message→
    - AA (Application Accept): success;
    - AE (Application Error): rejected for application error;
    - AR (Application Reject): rejected ffor data error.