

L'evoluzione degli Standard di Laboratorio: dalle norme ISO al WEB

Marco Pradella
Castelfranco Veneto (TV)

Milano, 17 settembre 2004
ore 8:30/18,00 Corso di aggiornamento su:
Il Problema degli Standard
in Medicina di Laboratorio

I Sessione
Il Laboratorio di Analici tra
esamificio ed esami diagnostici

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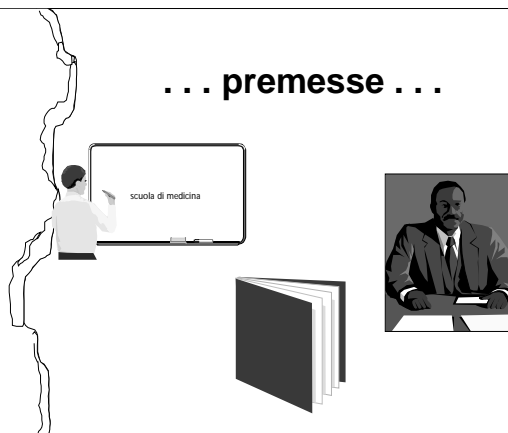
- gruppo Informatica
- news: standard - linee guida

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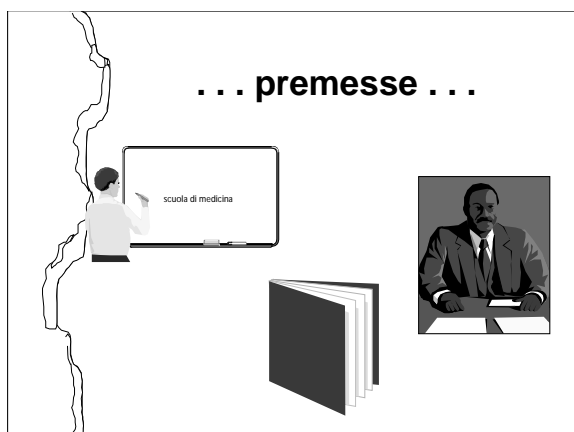
- sottocomitati
- cismelnews



... premesse ...



... premesse ...



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a.C.



Sommario

- | sigle e acronimi
- | esempi: qualità
- | il metodo di produzione degli standard
- | esempi: clinica
- | esempi: informatica automazione

la realtà degli standard

- | UNI
- | ISO TC 12 - TC 176 - TC 210 - TC 212 - TC 215
- | CEN TC
- | CEN TC 251
- | COWS of WASPaLM
- | NCCLS - HSI (?)
- | ASTM



geografia della normazione

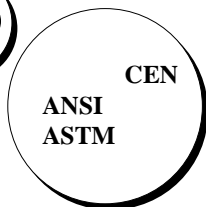
www.ANSI.org

www.ASTM.org

www.ISO.org

www.CENORM.be

www.UNI.com



CISMEL

Comitato Italiano
per la
Standardizzazione
dei Metodi
Ematologici e di
Laboratorio



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| - immunologia | - patrocini |
| - informatica | - Membri |
| - trombosi | Segretariato |
| - microbiologia | - NEWSLETTER |



COMMISSIONE INFORMATICA MEDICA

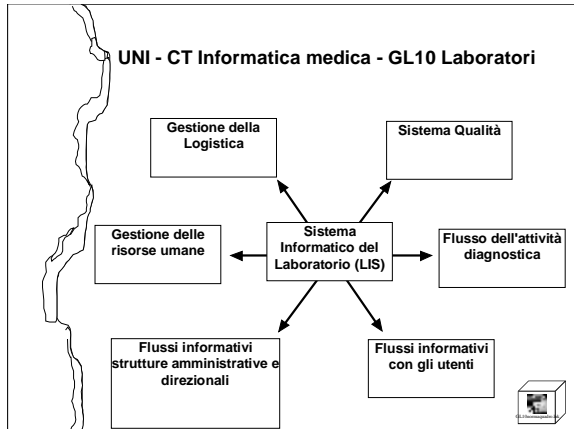
<http://web.uni.com/settoretecnico/ct/informaticamedica/home.shtml>

CAMPO DI ATTIVITÀ

Aspetti tecnico-informatici nel settore medico, con particolare riguardo a terminologia, modello dei dati, formato dei messaggi, strumentazione, strategie e aspetti non tecnologici, tipo etico-legali, sicurezza, riservatezza e qualità

TC CEN DI COMPETENZA TC 251 Informatica medica

TC ISO DI COMPETENZA TC 215 Informatica medica



linee guida per linee guida?

COGS: The Conference On Guideline Standardization

- to define a standard for guideline reporting that will promote guideline quality and facilitate implementation.
- The COGS statement was produced following an invitational meeting of experts - bringing together developers, disseminators, and implementers -- held in New Haven, Connecticut on April 26, 2002.
- 18 items that are critical for understanding a guideline's development process, its recommendation statements, and potential issues in its application.

COGS: The Conference On Guideline Standardization

<http://ycmi.med.yale.edu/COGS>

THE LANCET Volume 362, Number 9388 20 September 2003

<http://www.thelancet.com/journal/vol362/iss9388/full/lan.362.9388.news.27254.1>

Last updated: August 28, 2003

Qualità

ISO technical programme: TC 212 Clinical laboratory testing and in vitro diagnostic test systems

Projects

- ISO/CD 17593 Specifications and standards for instruments for self testing in monitoring of anticoagulation treatment
- ISO/CD TR 18112 In vitro diagnostic medical devices -- Information supplied by the manufacturer
- ISO/AWI 20776 Susceptibility testing of infectious agents and evaluation of performance of antimicrobial susceptibility devices
- ISO/WD TR 22367 Medical laboratories -- Reduction of error through risk management and continual improvement
- ISO/PRF TR 22869 Clinical laboratory testing -- Guidance on application of ISO 15189
- ISO/DIS 22870 Point-of-care testing (POCT) -- Requirements for quality and competence

ISO/PDTR 22869: Guidance on laboratory implementation of ISO 15189

ISO TC 212/SC N118 Date: 2003-07-25

ISO/PDTR 22869

ISO TC 212/SC /WG 1

Secretariat: ANSI

Technical Report: Medical laboratories — Guidance on laboratory implementation of ISO 15189

Élément introductif — Élément central — Élément complémentaire

ICS: 11.100 - Laboratory medicine

Stage: 50.00 FDIS registered for formal approval

Stage date: 2004-08-12

Obiettivo ISO/PDTR 22869?

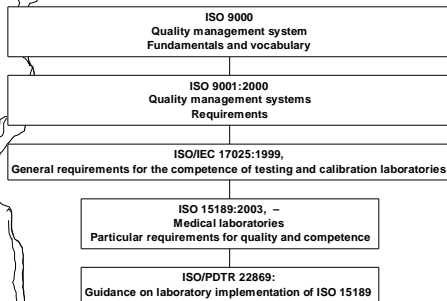
The object of this Technical Report is to provide guidance for complying with ISO 15189:2003 Medical laboratories – Particular requirements for quality and competence, which was drafted in accordance with the rules given in the ISO/IEC Directives, Part 2. This report was prepared by Technical Committee ISO/TC 212, *Clinical laboratory testing and in vitro diagnostic test systems*.

This Technical Report provides a link between establishment of a quality system for medical laboratory operations and the international standard describing the managerial and technical requirements for assuring quality and competence in medical laboratory operations.

riferimenti ISO/PDTR 22869

- ISO 31 (all parts), Standardisation and related activities — General vocabulary
- ISO Guide 31, Quantities and units
- ISO/IEC Guide 43-1, Proficiency testing by interlaboratory comparisons — Part 1: Development and operation of proficiency testing schemes
- ISO 9000, Quality management systems — Fundamentals and vocabulary
- ISO 9001:2000, Quality management systems — Requirements
- ISO/IEC 17025:1999, General requirements for the competence of testing and calibration laboratories,
- International vocabulary of basic and general terms in metrology (VIM). BIPM, IEC, IFCC, ISO, IUPAC, IUPAP, OIML
- ISO 15189:2003, Medical laboratories – Particular requirements for quality and competence

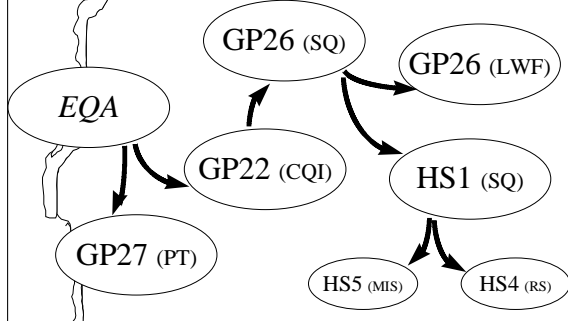
catena degli standard



ISO/PDTR 22869 Bibliography

- [1] CDC, Core Functions and Capabilities of State Public Health Laboratories. MMWR September 20, 2002/51(RR14);1-8.
- [2] McCloskey LA, Collet DN. TQM: A Primer Guide to Total Quality Management. Methuen, MA:Goal/QPC; 1993.
- [3] Dveyrin Z, Ben-David H, Mates A. Proficiency testing as tool for ISO 17025 implementation in National Public Health Laboratory: a means for improving efficiency. Accred Qual Assur (2001) 6:190-194. Springer Verlag, Germany.
- [4] Kalmin ND, Myers LK, Fisk MB. ISO 9000 model ideally suited for quality plan for blood centers. Transfusion 1998; 38:79-85.
- [5] Deming WE, Out of the Crisis. Cambridge, MA: MIT Center for Advanced Engineering Study; 1986.
- [6] Juran JM. Juran On Leadership for Quality. New York, NY: The Free Press; 1989.
- [7] NCCLS GP2-A4: Clinical Laboratory Technical Procedure Manuals-Fourth Edition. NCCLS; Wayne, PA., 2002.
- [8] NCCLS GP22-A: Continuous Quality Improvement: Essential Management Approaches; Approved Guideline. NCCLS: Wayne, PA., 1999.
- [9] NCCLS GP26-A2: Application of a Quality System Model for Laboratory Services; Approved Guideline – Second Edition. NCCLS: Wayne, PA., 2003.

strumenti per la qualità in NCCLS



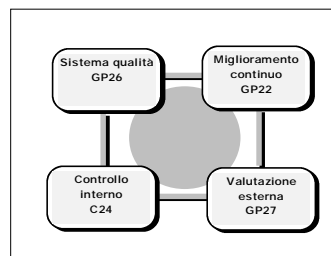
NCCLS - logo



NCCLS CATALOG

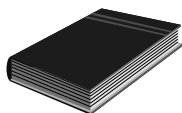
Documents:	Immunology and Ligand Assay
Automation and Informatics	ISO TC/212 and TC/76
Clinical Chemistry and Toxicology	Microbiology
Evaluation Protocols	Molecular Methods
General Laboratory Practices	National Reference System for the Clinical Laboratory
Healthcare Services	Complete Library
Hematology	Projects in Development
	Reports

NCCLS - i pilastri per la qualità



NCCLS - mission

enhances the value of medical testing and healthcare services through the development and dissemination of consensus standards, guidelines and best practices



NCCLS - standard e linee guida

Uno standard o una linea-guida è un documento che promuove l'uniformità di prodotti, materiali, metodi o procedure. In particolare, uno **standard** può contenere elementi discrezionali, ma in generale specifica i requisiti essenziali di un prodotto, un materiale etc... La **linea-guida**, invece, può essere modificata, entro certi criteri stabiliti, per adattarsi a specifiche necessità dell'utilizzatore.

NCCLS - metodo

- *aperto*
- *rappresentanze indipendenti*
- *bilanciamento industria-governo-professione*
- *onestà-equità, nel considerare tutte le opinioni ed evitare conflitti di interessi*
- *volontarietà*
- *praticità*



NCCLS - il consensus

Il **consensus** è un particolare tipo di processo in cui tutti gli interessati hanno la possibilità di intervenire.

Ogni gruppo di lavoro, inizialmente individuato dal NCCLS, è aperto alla partecipazione di esperti nominati da tutte le organizzazioni interessate.

Ciascun sottocomitato prepara versioni successive del documento, che vengono sottoposte alla revisione pubblica ed aperta, più ampia possibile.

Tutti i commenti vengono presi in considerazione.

Il documento finale, per essere approvato, deve essere votato a 4 livelli.



NCCLS - il *consensus*

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6.4 The ISO Consensus Process

Stage Associated Document Abbreviation

1 - Proposal stage New work item proposal NP

2 - Preparatory stage Working draft(s) WD

3 - Committee stage Committee draft(s) CD

4 - Enquiry stage Enquiry draft, i.e.,

Draft International Standard (ISO) ISO

Committee Draft for Vote (IEC) CDV

5 - Approval stage Final Draft International Standard FDIS

~~6 - Publication stage International Standard ISO, IEC or ISO/IEC~~

6.4 The ISO Consensus Process

Stage	Associated Document	Abbreviation
1 - Proposal stage	New work item proposal	NP
2 - Preparatory stage	Working draft(s)	WD
3 - Committee stage	Committee draft(s)	CD
4 - Enquiry stage	Enquiry draft, i.e., Draft International Standard (ISO) ISO Committee Draft for Vote (IEC)	CDV
5 - Approval stage	Final Draft International Standard	FDIS
6 - Publication stage	International Standard	ISO, IEC or ISO/IEC

NCCLS: gruppo di lavoro (ex sottocomitato) sul Controllo di Qualità Interno (C24)

- | James O. Westgard, Università del Wisconsin.
 - | T.L. Hearn del Center for Disease Control di Atlanta.
 - | W.G. Cooper della Bio-Rad Laboratories
 - | G.A. Graham della Ortho Clinical Diagnostics
 - | C.A. Parvin, della Washington School of Medicine
 - | R.W. Burnett, Hartford Hospital.
- + 8 *advisors*, di cui 3 internazionali

clinica

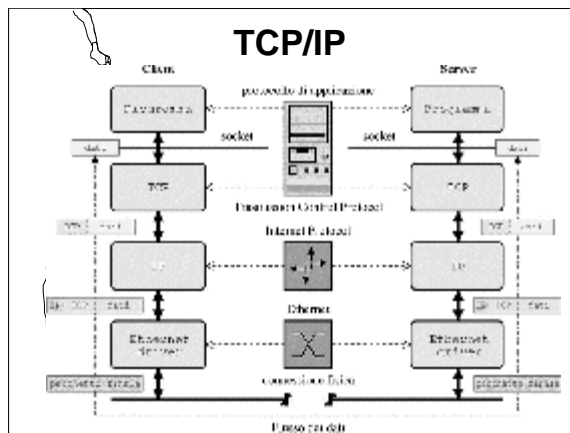
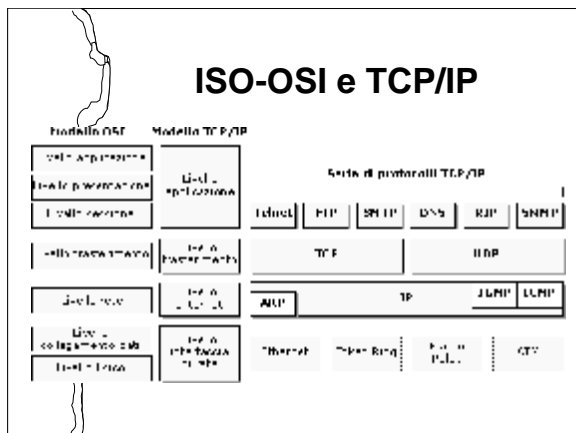
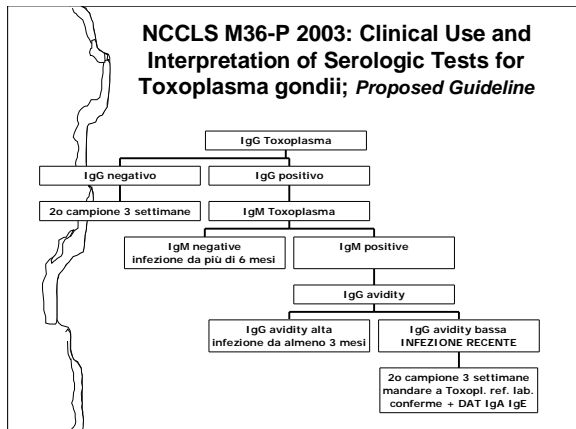


NCCLS M36-P Clinical Use and Interpretation of Serologic Tests for *Toxoplasma gondii*; Proposed Guideline

This document is intended to serve as a guide to aid in the interpretation of tests for the diagnosis of *Toxoplasma infection*.

Lynne S. Garcia, M.S., F(AAM) LSG and Associates, 2003

Member Price: \$25 Non-Member Price: \$35



WWW

World Wide Web

Il WorldWideWeb (W3) è un'iniziativa per il recupero di informazioni ipermediali in area vasta, che mira a dare l'accesso universale ad un grande universo dei documenti.

<http://www.w3.org/History/19921103-hypertext/hypertext/WWW/TheProject.html>

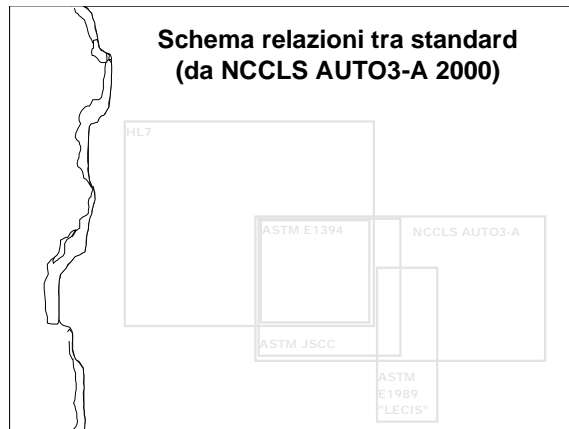
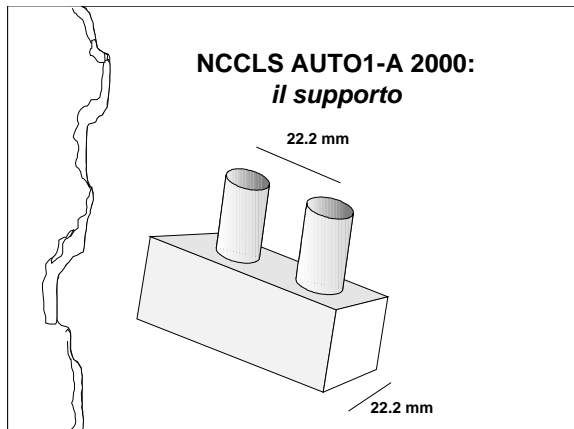
ENQUIRE era il primo programma che Tim Berners-Lee ha scritto con le caratteristiche del web. Fu una delle ispirazioni principali alla radice del WWW. Il nome "ENQUIRE" viene da un libro "Enquire Within Upon Everything" che TimBL lesse nella sua infanzia.

NCCLS AUTO2-A

Proposed Standard for Laboratory Automation: Bar Codes for Specimen Container Identification

Razionale della proposta

- codice 128: più denso, sicuro, largamente usato, robusto per la stampa
- altezza min. 10 mm: garantisce sicurezza nella posizione del contenitore, anche un po' obliqua
- barra sottile min. 0.191 mm: con stampanti moderne
- zona morta min 10 x 0.191; raccomandato 3.5 mm
- minimo 3 caratteri: la trasposizione deve essere rivelata da un checksum
- no caratteri o spazi in più
- area riservata del contenitore: 20 mm dal fondo e 14 mm dall'apertura
- max 4 etichette per contenitore
- larghezza etichetta min 5 mm meno della circonferenza del contenitore



E1238-97 Standard Specification for Transferring Clinical Observations Between Independent Computer Systems
Developed by ASTM Subcommittee: E31.13

<p>10 Record dei risultati</p> <p>10.1 contenuti</p> <p>10.1.1 tipo record: R</p> <p>10.1.2 sequenza: numero del paziente nel messaggio</p> <p>10.1.3 ID dell'esame</p> <p>10.1.3.1 codice internazionale</p> <p>10.1.3.2 nome (associato al codice)</p> <p>10.1.3.3 schema di codificazione</p> <p>10.1.3.4 codice locale o del produttore</p> <p>10.1.4 risultato: uno per record (di regola)</p> <p>10.1.5 unità: ISO 2955</p> <p>10.1.6 intervallo di riferimento:</p> <p>10.1.6.1 da XX a YY (precedente: XX-YY)</p> <p>10.1.6.2 intervalli multipli: delimitatori di ripetizione (l) con descrizione (sotto-campo: ^)</p>	<p>10.1.7 segno di normalità (N, A, >, <, H, L, HH, LL, U, D, B, W)</p> <p>10.1.8 tipo di intervallo di riferimento: età (A), sesso (S), razza ®</p> <p>10.1.9 stato del risultato: finale F, preliminare P, correzione C, non eseguibile X, parziale S, ripetizione R, per reflex N, MIC M, su richiesta Q, validato V, dubbio W</p> <p>10.1.10 data di variazione dell'intervallo di riferimento</p> <p>10.1.11 operatori:</p> <p>10.1.11.1 esecutore</p> <p>10.1.11.2 validatore</p> <p>10.1.12 ora inizio dell'analisi</p> <p>10.1.13 ora completamento dell'analisi</p> <p>10.1.14 identificativo strumento</p>
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Logical Observation Identifier Names and Codes (LOINC®)
Updated June 13, 2000

Table 21: Columns Appearing on Printed Reports

Status	Method
Class	Related Names
Loinc Number	Exact Core Component
Map To	Synonym
Analyte/Component Name	Date Last Changed
Type of Property	Reason for Change
Time Aspect	Answer List
System/Specimen	EUCLIDES Code
Type of Scale	IUPAC Analyte Code
	Molar Mass

complete table: 49 columns

Logical Observation Identifiers Names and Codes (LOINC®)

The purpose of the LOINC database is to facilitate the **exchange and pooling of results**, such as blood hemoglobin, serum potassium, or vital signs, for clinical care, outcomes management, and research.

Currently, most laboratories and other diagnostic services use **HL7** to send their results electronically from their reporting systems to their care systems. However, most laboratories and other diagnostic care services identify tests in these messages by means of their internal and idiosyncratic code values. Thus, the care system cannot fully "understand" and properly file the results they receive unless they either adopt the producer's laboratory codes (which is impossible if they receive results from multiple sources), or invest in the work to map each result producer's code system to their internal code system.

LOINC codes are universal identifiers for laboratory and other clinical observations that solve this problem

www.loinc.org

LOINC® 2003

- 30.000 voci (LOINC 2.10, released October 6, 2003)
- RELMA™ REgenstrief LOINC Mapping Assistant (RELMA 3.9.15, released October 8, 2003)

LOINC, a Universal Standard for Identifying Laboratory Observations: A 5-Year Update
Clement J. McDonald,1,2* Stanley M. Huff,3 Jeffrey G. Suico,1,2 Gilbert Hill,4
Dennis Leavelle,5 Raymond Aller,6 Arden Forrey,7 Kathy Mercer,1 Georges DeMoor,8 John
Hook,1 Warren Williams,9 James Case,10 and Pat Maloney11 for the Laboratory LOINC
Developers†
Clinical Chemistry 49:4 624-633 (2003) <http://www.loinc.org/news/whitepaper>

Esempi di codici LOINC per laboratorio

LOINC code LOINC name
(component:property:timing:specimen:scale)

- | 2951-2 SODIUM:SCNC:PT:SER/PLAS:QN
- | 2955-3 SODIUM:SCNC:PT:UR:QN
- | 2956-1 SODIUM:SRAT:24H:UR:QN
- | 2164-2 CREATININE RENAL CLEARANCE:VRAT:24H:UR:QN
- | 1514-9 GLUCOSE 2H POST 100 G GLUCOSE
- | PO:MCNC:PT:SER/PLAS:QN
- | 3665-7 GENTAMICIN TROUGH:MCNC:PT:SER/PLAS:QN
- | 17863-2 CALCIUM IONIZED:MCNC:PT:SER/PLAS:QN
- | 2863-9 ALBUMIN:MCNC:PT:SNV:QN:ELECTROPHORESIS

SNOMED RT Integration with LOINC - Defining Characteristics

With LOINC there's hope for mining lab data

*The LOINC-SNOMED connection
In British Columbia, LOINC is the answer*

Eric Skjei

Archive: June 1999
Feature Story



SNOMED Clinical Terms® aggiunti a UMLS® Metathesaurus®

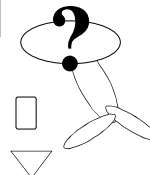


Tommy G. Thompson, Secretary of Health and Human Services, announced on July 1, 2003, (press release) an agreement with the **College of American Pathologists (CAP)** that will make SNOMED Clinical Terms (SNOMED CT®) available to U.S. users at no cost through the **National Library of Medicine's Unified Medical Language System® (UMLS)**.



Produced by the College of American Pathologists (CAP), SNOMED CT (Systematized Nomenclature of Medicine--Clinical Terms) was formed by the convergence of SNOMED RT® and the **United Kingdom's Clinical Terms Version 3** (formerly known as the **Read Codes**). With terms for more than 344,000 concepts, SNOMED CT is the most comprehensive clinical terminology available. It is being implemented throughout the **National Health Service** in the **United Kingdom**.

... SNOMED Terminologia clinica® ...



SNOMED RT Integration with LOINC - Defining Characteristics

- | "is-a" relationships
- | "has-measured component"
- | "has property"
- | "has-time-aspect"
- | "has-scale-type"
- | "has specimen"
- | Standardize data dictionary variables using SNOMED
- | Encode clinical findings, diagnoses, and other "results" using SNOMED
- | Encode the name of tests and test attributes using LOINC, if desired
- | Retrieve using SNOMED functionality

http://www.snomed.org/benefits/LOINC_txt.html



CDC

PHIN Presentations: May 14, 2003

- | Session 4C: PHIN and Data Routing for Health Departments and Public Health Labs
- | Session 5E: PHIN and Public Health Laboratories - Meeting the Challenges of Electronic Information Exchange with Multiple Partners

*1st Public Health Information Network Stakeholders' Conference
Atlanta, Georgia May 13 - 15, 2003*

http://www.cdc.gov/phn/conference_presentations/05-14-03/

Electronic Laboratory Reporting and Communication

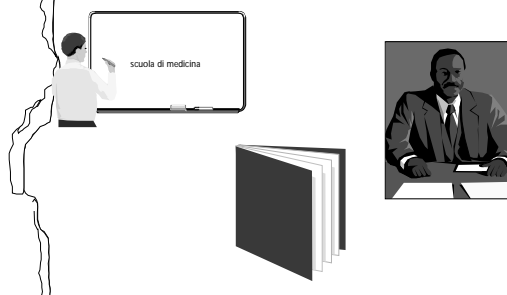
The Massachusetts State Laboratory Institute - A Conceptual Design
Dina Caloggero

Electronic Laboratory Communication and Reporting Component (ELR)

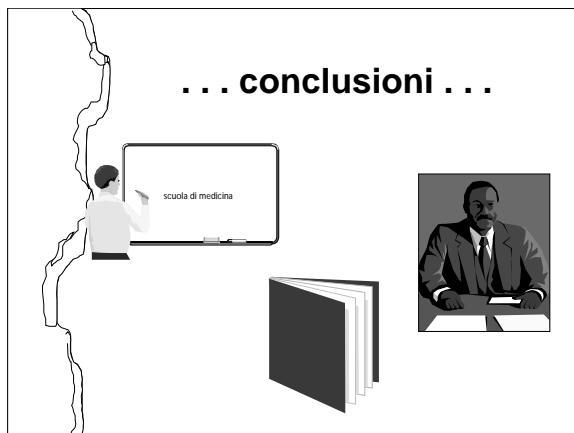
- An extranet application that extends SLIS functionality securely to the Internet
- Remote Order Entry (ROE) and Reporting
- Standardized data exchange with organizations (HL7, LOINC, SNOMED)
- Reception of remote orders from hospitals sending specimen batches to the State Laboratory Institute (SLI) (HL7)

http://www.cdc.gov/phin/conference_presentations/05-14-03/

... conclusioni ...



... conclusioni ...



Sommario

- | sigle e acronimi
- | esempi: qualità
- | il metodo di produzione degli standard
- | esempi: clinica
- | esempi: informatica automazione

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www.snomed.org

- | On May 9, 2000 SNOMED® International launched the next generation of its clinical reference terminology to thousands of healthcare professionals participating in the TEPR 2000 (**Toward an Electronic Patient Record**) meeting at the Moscone Convention Center.
- | SNOMED® RT (Systematized Nomenclature of Medicine Reference Terminology) will facilitate the health care field's transition from paper records to electronic records.
- | With over **340,000 explicit relationships**, SNOMED RT will provide a common reference point for comparison and aggregation of data throughout the entire health care process. It will also facilitate the transmission of patient-related information across diverse information systems.



www.snomed.org

- | The CAP has entered into a collaboration with the United Kingdom's Secretary for Health on behalf of the National Health Service Executive (NHS) to combine **SNOMED RT** and **Clinical Terms Version 3** of the NHS thesaurus of health care terms. The agreement creates an international approach for computerizing scientific terms that physicians, nurses, and other health professionals use for the effective management of patient records and medical communication.
- | The new work, named **SNOMED Clinical Terms** (abbreviated **SNOMED CT**), combines the strengths of the two existing terminologies: the robust strength of SNOMED RT in specialty medicine, including pathology, and the richness of Clinical Terms Version 3 (also known as Read Codes V3) in primary care.