



Магистърска програма “ Регламенти и стандарти в медицината”

Kурс MEDM 620 „Стандарти при експлоатация на МИС”

Лекция № 13

Меню “Европейски стандарти в eHealth и медицинската информатика”

Както е видно от предложения текст, темата за стандартите в медицинската информатика е обект на много сериозна работа и представлява област с високи постижения:

ISO/IEC обединен технически комитет 1

Общ брой *стандарти свързани с информационни технологии* – 2227 и 549 работещи програми, с 15 субкомитета .

Официално комитетът се занимава с разработване, управление, промоциране и подобряване на стандарти в информационните технологии, с цел удовлетворяване изискванията на глобалния пазар и бизнес изискванията относно:

- Дизайн и разработване на системи и средства в информационните технологии
- Изпълнение и качество на продукти и системи в информационните технологии
- Сигурност на IT системи и информация
- Преносимост и съвместимост на приложните програми
- Интероперабилност на IT продукти и системи
- Унифициране на средства и работна среда
- Хармонизиране на IT речниковите панели и
- Потребителски интерфейс и ергономичен дизайн на приложенията

За регулиране и обслужване на здравните стандарти и инициативи има различни здравни сегменти, ефективно доставящи нужната информация между системите.

- **HL7** - Health Level Seven – осигурява стандарти за обмен на клинични данни.
- **DICOM** - Digital Imaging and Communications in Medicine – отговаря за съхранение, разпечатване и трансмисия на информация в медицинския имиджинг.
- **HL7 CDA** - Clinical Document Architecture – модел на обмен (XML-базиран) за клинични документи; познат като Patient Record Architecture (PRA).
- **CCR** - Continuity of Care Record – кореспондира за необходимостта за организиране и пренос на базисна информация относно пациентска грижа, достъпна за лекари и пациенти.
- **CCOW** - Clinical Context Management Specification – позволява клинични приложения да споделя информация в необходимия момент.
- **LOINC** - Logical Observation Identifiers Names and Codes – прилага универсални кодови наименования и идентификатори на медицинската терминология, свързани с Електронното

Здравно Досие (ЕЗД) и асистира при електронната обмяна и събиране на клинични резултати (като лабораторни тестове, клинични наблюдения, управление на изходите от заболяването и изследвания).

- **ELINCS** - EHR-Lab Interoperability and Connectivity Standards – стандарт за докладване на лабораторни изследвания.
- **X12** – осигурява електронна обмяна на бизнес транзакции – електронни данни.
- **SNOMED** - Systematized Nomenclature of Medicine Clinical Terms – осигурява изчерпателна компютъризирана клинична терминология, покриваща клинични данни за заболявания, клинични открития и процедури.
- **NCPDP** - National Council for Prescription Drug Programs – управлява транзакции за лекарства.
- **IHE** - Integrating the Healthcare Enterprise – промотира координираната употреба за употреба на здравни интеграционни стандарти, като DICOM и HL7, адресирайки специфични клинични потребности за поддръжка на оптимална пациентска грижа.
- **CC HIT** - Certification Commission for Healthcare Information Technology – лужи за US сертифицираща власт за ЕЗД и мрежи.
- **HITSP** - Healthcare Information Technology Standards Panel – подпомага разработването и разпространението на консесусно-базирани стандарти за интероперабилност и взаимоотношения между здравните информационни технологии.

Международната организация за стандартизация ISO разработва група стандарти за здравни смарт-карти, каквито в момента се внедряват повсеместно и обещават да доведат до революция в здравните услуги. Стандартизираните карти биха могли да осигурят достъп на здравните работници до медицинските досиета на пациентите, независимо къде по света се намират.

Стандартите ще определят какви данни и в каква структура да се съдържат в смарт-картите, които ще са носители на здравните досиета на хората: данни за връзка с лекар и застрахователи, всички заболявания и операции, кръвна група, жизнени функции, история на заболявания, приемани към момента лекарства, алергии и други данни. Картите ще са с микрочип и ще са защитени с пароли, а информацията ще е достъпна само за пациентите и медицинските специалисти, предвиждат стандартите.

Съдържанието на здравната карта ще осигурява четири общи типа данни на пациента:

- данни за устройството
- идентификатор на человека, за когото се отнасят данните
- административни данни (например тип застраховка)
- клинични данни (например информация относно здравето на картопритеjателя и здравни събития)

ISO 21549 се състои от осем части със заглавие “Здравна информатика – Здравна карта с данни на пациента”.

Стандартът предлага единен набор от указания, които да гарантират, че здравната карта може да се чете от медицински персонал в различните страни и от различни здравни организации чрез преносими електронни четящи устройства. Първите три части са вече готови. Останалите предстои да бъдат публикувани.

Първата част, ISO 21549-1:2004 дефинира структурата на данните на пациентската здравна смарт-карта. Тази част не се отнася за многофункционалните чип-карти. Втората част определя базовата структура на данните за притеjателя на картата. Третата част, ISO 21549-3:2004, определя базовата структура на ограничен обем клинични данни за пациента. Това се прави с цел осигуряване на най-необходимата информация за в случаи на нужда от спешна медицинска помощ, но далеч не предоставя всичката налична информация за лицето.

Working Groups(WG I) - CEN/TC251

Работна група I (Информационни модели)

Разработване на Европейски стандарти за подобряване комуникацията между независими информационни системи в една организация

Работен код	Работен акроним	Описание
WI 086	BTR-PAT	Здравна информатика – съобщения относно кръвна трансфузия Част 1:

		съобщения, свързани с пациенти
WI 097	BTR-PROD	Health informatics - Blood Transfusion Related Messages, Part 2: Product Related Messages
WI 088	MESSMAINT	Health informatics - Maintenance of the Message Standards produced by CEN/TC 251
WI 098	LABMES	Health informatics - Messages for exchange of laboratory information
WI 102	PATCARDS	Health informatics - Patient healthcard data Part 1: General structure Part 2: Common objects Part 3: Limited clinical data Part 4: Extended clinical data Part 5: Identification data Part 6: Administrative data Part 7: Electronic prescription Part 8: Linkage and reference data
WI 109	HIF	Health Informatics - Medical informatics Healthcare Information Framework (HIF)
WI 110	RDS	Health Informatics - Registration of information objects used for EDI in healthcare - Part 1: The Register
WI 111	RDS	Health Informatics - Registration of information objects used for EDI in healthcare - Part 2: Procedures for the registration of information objects used for electronic data interchange (EDI) in healthcare
WI 112	MPRD	Health Informatics - Messages for patient referral and discharge
WI 113	DIAMES	Health Informatics - Request and report messages for diagnostic service departments
WI 116	ADMES	Health Informatics - Messages for the exchange of healthcare administrative information
WI 127	SUPINFMES1	Health Informatics - Messages for Maintenance of Supporting Information in Healthcare Systems Part 1. Updating of Coding Schemes
WI 129	GCOM	Health Informatics - General purpose components for messages - Part 1: Overview Part 2: Non Clinical Part 3: Clinical PT-41
WI 130	SSR-MES	Health Informatics - Service request and report messages Part 1 - Basic services including referral and discharge
WI 131	CTRL-MES	Health informatics - Control messages
WI 132	XML-MAP	Health informatics - Mapping of hierarchical messages descriptions to XML
WI 133	DOM	Health informatics - General domain model
WI 151 WI 152 WI 153 WI 154		Health informatics - Electronic health record communication Part 1: Reference architecture Part 2: Methodology for clinical domain modelling Part 3: Security requirements and distribution rules Part 4: Methods for the exchange of information
WI 178	EAQ	Health informatics - Messages for reporting results from external quality assessments in clinical laboratories

Работна група II (Терминология и бази от знания)

Semantic organisation of information and knowledge so as to make it of practical use in the domains of health informatics and telematics. Provision of information and criteria to support harmonisation in health care and terminological consistency within TC251.

Work Item Code	Work Item Acronym	Title
WI 108	UNITS	Health informatics - Expression of the results of measurements in health sciences

WI 146	MOSE-1	Health informatics - Categorical structures for systems of concepts
WI 106	TIME	Health informatics - Time standards for healthcare specific problems
WI 099	UNITS	Health informatics - Structure for nomenclature, classification and coding of properties in clinical laboratory sciences
WI 114	DRUGSID	Health informatics - Medicinal product identification
WI 115	DEVCON	Health informatics - Categorical structure of systems of concepts - Medical devices
WI 149		Health informatics - Registration of coding schemes
WI 083	CONTSYS	Health informatics - System of Concepts to Support Continuity of Care
WI 084	SELIM	Health informatics - System of Semantic Links in Medicine
WI 085	NURSYS	Health informatics - System of Concepts to Support Nursing
WI 082	IM-PROC	Health informatics - Categorical Structure for a Concept System for Imaging Procedures
WI 145	METAVOC	Health informatics - Vocabulary for terminological systems
WI 079	T&C-base	Health informatics - Vocabulary - Maintenance Procedure
WI 142	CLAML	Health informatics - A syntax to represent the content of medical classification systems
WI 148	METKNOW	Health informatics - Clinical knowledge resources - Metadata
WI 143	CATANAT	Health informatics - Categorical structure for anatomy
WI 155	CATFIND	Health informatics - Categorical structure for documentation of patient findings and problems
WI 156	CATERMCON	Health informatics - Categorical structure of representation of conditions, coding systems and clinical terminologies

Working Groups(WG III) - CEN/TC251

WG III (Security, Safety and Quality)

Techniques for technical protection of confidentiality, integrity, availability and accountability as well as guidelines for security management.

Work Item Code	Item	Work Item Acronym	Title
WI 069		SECREQ-ICD	Health informatics - Security Requirements for Intermittently Connected Devices
WI 096		SAFE-ID	Health informatics - Safety Procedures for Identification of Patients and Related Objects
WI 107			Health informatics - Algorithm for Digital Signature Services in Health Care
WI 119			Health informatics - Security Categorisation and Protection for Healthcare Information Systems
WI 124		FM-HSP/FR	Health informatics - Framework for Formal Modelling of Healthcare Security Policies
WI 134		ACCOUNT/AUDIT	Accountability and audit trail mechanism for healthcare information systems
WI 140		ANONYM	Health informatics - Anonymity user requirements for trusted anonymisation facilities
WI 147		ACCESS	Health informatics - Access control policy bridging
WI 141		FSPM	Health Informatics - Formal security policy modelling
WI 139		RISK	Health informatics - Risk assessment procedures
WI NEW		DPCGUIDE	Health Informatics - Data Protection Contract Guidance
WI 150		POLITRANS	Health Informatics - International transfer of personal health data covered by the EU data protection directive- High level security policy

WG IV (Technology for Interoperability)

Work on middleware and most of the work on medical imaging and multimedia (although the focus in this area is on international standards) and medical device communication in integrated healthcare.

Work Item Code	Work Item Acronym	Title
WI 050	EPAS	Health informatics - Evaluation of Physiological Analysis Systems
WI 063	MULTIMED	Interoperability of Healthcare Multimedia Report Systems
WI 103	MEDICOM	Health informatics - Medical Imaging Communication
WI 117		Health informatics - Media Interchange in Medical Imaging Communications
WI 118		Health informatics - Medical Image Management - Part 1: Storage Commitment Service Class
WI 120	HISA	Health informatics - Healthcare Information System Architecture - Part 1: Healthcare Middleware Layer
WI 121		Health informatics - Standard communication protocol - Computer-assisted electrocardiography
WI 136	EFDI	Health informatics - Descriptive elements for interoperability of device data file formats and application invocation
WI 135	VITAL-FILE	Health informatics - File exchange format for Vital Signs
WI 137		Health informatics - Interoperability of patient connected medical devices - Optional packages
		Health informatics - Point-of-Care medical devices - Framework and overview
		Health informatics - Point-of-Care medical devices - Domain Information Model
		Health informatics - Point-of-Care medical devices - Nomenclature
		Health informatics - Point-of-Care medical devices - Transport Profile - Cable Connected
		Health informatics - Point-of-Care medical devices - Physical Layer - Cable Connected
		Health informatics - Point-of-Care medical devices - Transport Profile - Infra-Red Based Protocol
		Health informatics - Standardized computer protocols for ECG
		Health informatics - Instrument interfaces to laboratory information systems

ISO/TC215

International Organization for Standardization - Health Informatics(Homepage)

Working Groups - ISO/TC215

Committee	Title	Convenor
WG 1	Health records and modelling coordination	SCC
WG 2	Messaging and communication	ANSI
WG 3	Health concept representation	ANSI
WG 4	Security	SIS
WG 5	Health cards	DIN
WG 6	E-pharmacy and medicines business	BSI

Working Items(TS,TR) - ISO/TC215

TS (Technical Specification), TR (Technical Report)

Work Item Code	Stage Code(*)	Stage Date	Title	Abstract
ISO/TS 17090-1:2002	#60.60	2002-10-03	Health informatics -- Public key infrastructure - - Part 1: Framework and overview	ISO/TS 17090-1 defines the basic concepts of a healthcare public key infrastructure (PKI) and provides a scheme of interoperability requirements to establish a PKI enabled secure communication of health information. It also identifies the major stakeholders who are communicating in health, as well as the main security services required for health communication where PKI may be required. ISO/TS 17090-1 gives a brief introduction to public key cryptography and the basic components of a healthcare PKI. It further introduces different types of certificates, public key identity certificates and associated attribute certificates, for relying parties, self-signed certification authority (CA) certificates, and CA hierarchies and bridging structures.
ISO/TS 17090-2:2002	#60.60	2002-10-03	Health informatics -- Public key infrastructure - - Part 2: Certificate profile	ISO/TS 17090-2 specifies the certificate profiles required to interchange healthcare information within a single organization, between different organizations and across jurisdictional boundaries. It details the use made of public key infrastructure (PKI) digital certificates in the health industry and focuses, in particular, on specific healthcare issues relating to certificate profiles.
ISO/TS 17090-3:2002	#60.60	2002-10-03	Health informatics -- Public key infrastructure - - Part 3: Policy management of certification authority	ISO/TS 17090-3 gives guidelines for certificate management issues involved in implementing and operating a healthcare public key infrastructure (PKI). It specifies a structure and minimum requirements for certificate policies, as well as a structure for associated certification practice statements. ISO/TS 17090-3 also identifies the principles needed in a healthcare security policy for cross-border communication and defines the minimum levels of security required, concentrating on aspects unique to healthcare.
ISO/TS 17117:2002	#60.60	2002-03-07	Health informatics -- Controlled health terminology -- Structure and high-level indicators	
ISO/TR 18307:2001	#60.60	2001-12-20	Health informatics -- Interoperability and compatibility in messaging and communication standards -- Key characteristics	

Working Items(FDIS) - ISO/TC215

FDIS (Final draft International Standard)

Work Item Code	Stage Code(*)	Stage Date	Title
ISO/FDIS 18812	#50.20	2002-11-18	Health informatics -- Clinical analyser interfaces to laboratory information systems -- Use profiles

Working Items(DIS) - ISO/TC215

DIS (Draft International Standard)

Work Item Code	Title
ISO/DIS 17113	Health informatics -- Exchange of information between healthcare information systems -- Development of messages

ISO/DIS 17120	Health informatics -- Country identifier standards
ISO/DIS 18104	Health Informatics -- Integration of a reference terminology model for nursing
ISO/DIS 21549-1	Health informatics -- Patient healthcard data -- Part 1: General structure
ISO/DIS 21549-2	Health informatics -- Patient healthcard data -- Part 2: Common objects
ISO/DIS 21549-3	Health informatics -- Patient healthcard data -- Part 3: Limited clinical data

Working Items(CD) - ISO/TC215

CD (Committee draft)

Work Item Code	Title
ISO/CD 17115	Health informatics -- Vocabulary on terminological systems
ISO/CD TR 17119	Health information modelling framework
ISO/CD TR 21089	Health Informatics -- Trusted end-to-end information flows
ISO/CD 21549-7	Health informatics -- Patient healthcare data -- Part 7: Electronic prescriptions
ISO/CD TS 21667	Health informatics -- Health indicators conceptual framework
ISO/CD 22857	Health informatics -- Guidelines on data protection to facilitate trans-border flows of personal health information

Working Items(AWI) - ISO/TC215

AWI (Approved work item)

Work Item Code	Title
ISO/AWI TR 16056-1	Health informatics -- Interoperability of telehealth systems and networks -- Part 1: Introduction and definitions
ISO/AWI TR 16056-2	Health informatics -- Interoperability of telehealth systems and networks -- Part 2: Real-time systems
ISO/AWI TS 16058	Health informatics -- Interoperability of telelearning systems
ISO/AWI 21091	Health informatics -- Directory services for security, communications and identification of professionals and patients
ISO/AWI 21547-1	Health informatics -- Security requirements for archiving and backup -- Part 1: Archiving of health record

Водещи и групирани

Уеб адреси на органи и асоциации по медицинска информатика

American Health Information Management Association

<http://www.ahima.org>

American Medical Association

<http://www.ama.assn.org>

American Medical Informatics Association/General Health & Medical Web Resources

<http://amia2.ami.org/lkres.html>

ANSI - American National Standards Institute

<http://www.ansi.org>

Asociación Argentina de Informática Médica (AAIM)

<http://www.pccp.com.ar/aaim>

ASTM - American Society for Testing and Materials

<http://www.astm.org>

AVICENNA – The Medical Information Supersite of the WWW

<http://www.avicenna.com>

BioMedNet-For Biological and Medical Researchers

<http://www.biomednet.com/home>

BIREME – Regional Library of Medicine PAHO/WHO

<http://www.bireme.br/>

Brazilian Society for Health Informatics(SBIS)

<http://www.sbis.epm.br/sbis/index.html>

- British Medical Informatics Society (BMIS)
<http://www.cs.man.ac.uk/mig/people/medicine/bmis>
- British Medical Journal
<http://www.bmj.com>
- CEN/TC 251 – European Standardization Activities in Medical Informatics
<http://www.centc251.org>
- Health Informatics Center, School of Medicine, Federal University of São Paulo, Brazil
<http://www.epm.br/cis/CIS1.HTM>
- CIHI - Canadian Institute for Health Information
<http://www.cihi.ca>
- CMA CPGInfobase/Canadian Medical Association
<http://www.cma.ca/cpgs/index.htm>
- Cyberspace Hospital – access to health information resources on the Internet via a virtual hospital setting
<http://ch.nus.sg/CH/ch.html>
- Cyberspace Telemedical Office – gateway to healthcare information, products, and services
<http://www.telemedical.com>
- Data Interchange Standards Association
<http://www.disa.org/>
- DICOM - Digital Imaging and Communications in Medicine Standard
http://www.xray.hmc.psu.edu/dicom/dicom_intro/DICOMIntro.html
- Duke University Medical Center Division of Medical Informatics
<http://dmi-www.mc.duke.edu/dukemi/misc/links.html>
- EDI – Electronic Data Interchange
<http://www.premenos.com>
- European Federation for Medical Informatics (EFMI)
http://www.cxwms.ac.uk:80/Academic/AGPU/staffpag/robinson/interest/efmi_wg7/efmiaims.html#Index
- European Health Telematics Observatory
<http://www.ehto.be>
- European Telecommunications Standards Institute (ETSI)
www.etsi.fr
- Grateful Med - search the National Library of Medicine
<http://igm.nlm.nih.gov>
- GT Saude, Brazil
http://gts1.incor.usp.br/news_eng.html
- Health Care Information Systems Directory of U.S. Services and Product Vendors
<http://www.health-infosys-dir.com/>
- Health Care IT Services-Wales
<http://www.gwent.nhs.gov/PubMed/medline.html>
- Health Gate-medical research
<http://www.healthgate.com>
- Health Industry Bar Code Supplier Labeling Standard
<http://www.hibcc.org>
- Health Informatics Center – Federal University of São Paulo (in Portuguese)
<http://www.epm.br/cis>
- Health Informatics Worldwide - links to Medical Informatics activities at universities and other institutions around the world
http://www.imbi.uni-freiburg.de/medinf/mi_list.htm
- Health Market International Implementing ICD-10
<http://www.healthmkt.com/hmi/icd10.htm>
- Health on the Net Foundation
<http://www.hon.ch>
- Health Web/Health Information
<http://healthweb.org>
- Healthcare Informatics Standards Guide
<http://www.mcis.duke.edu/standards/guide.htm>
- HIMSS Health Care Information and Management Systems Society
<http://www.himss.org>
- HL7 - Health Level Seven
<http://www.hl7.org>
- International Electrotechnical Commission
www.iec.ch
- International Medical Informatics Association (IMIA)
www.imia.org

- International Medical Informatics Association (IMIA) Federation for Latin American and the Caribbean
http://www.imia-lac.org/what_e.htm
- International Telecommunication Union
www.itu.ch
- Internet Medical Terminology Resources
http://www.gsf.de/MEDWIS/activity/med_term.html
- Internet Mental Health
<http://www.mentalhealthhelp.com>
- Internet Resources In Medical Informatics - Health Sciences Information Service, University of California, Berkeley
<http://www.lib.berkeley.edu/HSIS/medin.html>
- Inventory of Standards
http://www.ehto.be/scripts/imiawg16/see_standards.cfm
- ISO – International Standards Organization
<http://www.iso.ch>
- Joint Commission on Accreditation of Health Care Organizations
<http://www.jcaho.org/>
- Journal of Medical Internet Research (JMIR)
<http://www.sympoison.com/jmir/>
- LOINC - Duke University-Logical Observation Identifiers
<http://www.mcis.duke.edu/standards/tercode/loinc.htm>
- MedExplorer-Health Medical Internet Search
<http://www.medexplorer.com>
- Medical Informatics Institutions – World Wide. This is a comprehensive Home Page with links to all countries in the world, maintained by the Department of Medical Informatics, University of Freiburg, Germany.
http://www.imbi.uni-freiburg.de/medinf/mi_list.htm
- Medical Records Institute
<http://www.medrecinst.com/>
- Medical World Search- Medical Intelligence
<http://www.mwsearch.com>
- Medline PubMed
<http://www.ncbi.nlm.nih.gov/pubmed/>
- National Center for Emergency Medicine Informatics
<http://ncemi.org>
- U.S. National Library of Medicine
<http://www.nlm.nih.gov>
- New England Journal of Medicine
<http://www.nejm.org>
- NSW Health Enterprise Information Model – Australia
<http://www.health.nsw.gov.au>
- Object Management Group (OMG)
www.omg.org
- Organizing Medical Networked Information (OMNI Biomedical Internet Resources)
<http://omni.ac.uk>
- Pan American Health Organization
<http://www.paho.org>
- PaperChase-Access to Medline and more
<http://www.paperchase.com>
- Primary Health Care Informatics Home Page
<http://s1.cwxms.ac.uk/Academic/AGPU/staffpag/robinson/interest/medcomp/homepage.html>
- References About the Quality of Medical Information /Mnegri
<http://www.irfmn.mnegri.it/oncocare/it/quality.htm>
- SLACK Incorporated-Medical Information
<http://www.slackinc.com/chilidchome.html>
- SNOMED International
<http://www.snomed.org>
- Society for Internet in Medicine (SIM)
<http://www.mednet.org.uk/mednet/contents.html>
- Technology in Medical Education – Centre of Medical Informatics, Monash University
<http://www.monash.edu.au/informatics/techme/index.htm>
- Telemedicine Glossary and Links
<http://www.hscsyr.edu/telemed/glossary.html>
- The Combined Health Information Database-NIH
<http://www.chid.nih.gov>

The Community Health Management Information Systems (CHMIS) Resource Center - an information clearinghouse with downloadable documents on a variety of subjects

<http://www.chmis.org>

The Lancet

<http://www.thelancet.com>

The Medical Information System Development Center – Japan

http://www.medis.or.jp/e_index.html

United States Department of Health and Human Services – Agency for Health Care Policy and Research

<http://www.ahcpr.gov>

Univ. of Sheffield School of Health Related Research

<http://www.shef.ac.uk/scharr/ir/netting.html>

University of Hull Medical Informatics Group(MIG)

<http://www.enc.hull.ac.uk/CS/Medicine>

Uruguayan Health Informatics Society

<http://www.chasque.apc.org/suis/>

VA Veteran's Health Administration-Decentralized Hospital Computer Program

<http://www.va.gov/dhcp.htm>

World Health Organization

<http://www.who.ch>

World Journal Association-open peer review

<http://www.journalclub.org>

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