

Il POCT e le soluzioni di Risk Assessment
27 e 28 Novembre 2007 - Hotel Leon D Oro - Verona

Martedì, 27 Novembre ASPETTI GESTIONALI E MEDICO-LEGALI
Moderatori: Marco Caputo (Bussolengo) - Michele Schinella (Rovereto)

SOLUZIONI DI RISK ASSESSMENT PER IL POCT

8 Maggio 2008 - Azienda Ospedaliera
'G. SALVINI' - Garbagnate Milanese
Sala Conferenze
prima sessione: ASPETTI GESTIONALI E MEDICO-LEGALI

26 settembre 2008
Aula Magna P.O. Manerbio (BS)

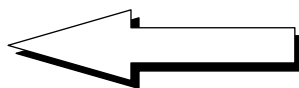
seconda sessione: STRATEGIE ED ORGANIZZAZIONE

Il valore della risposta POCT: regole di gestione dei dati

Marco Pradella, Asolo

Sommario

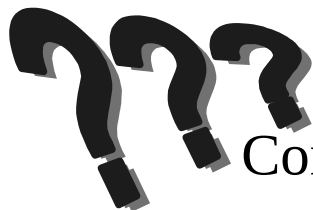
- applicabile?
- chi sviluppa?
- chi adotta?
- cosa contiene?
- come si applica?
- da teoria a pratica
- multe, arresti e reclusioni



domande ECM

1. Il trattamento informatico degli esami in point-of-care

- a) non è applicabile, a differenza degli esami di laboratorio
- b) è applicabile solo se si utilizza il sistema informatico fornito con gli strumenti
- c) è applicabile solo se consentito dagli utilizzatori
- d) va previsto come per tutti gli esami di laboratorio
- e) nessuna delle precedenti



Connectivity Industry Consortium Membership - 1

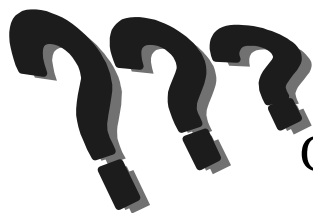
CORE VENDORS

Abbott Laboratories
Agilent Technologies
Bayer Diagnostics
BD John Hopkins
Instrumentation Laboratory
Lifescan/J&J
Medical Automation Systems
Radiometer Medical
Roche Diagnostics
Sunquest Information Systems

CORE PROVIDERS

Banner Health System
Bradford Royal Infirmary
Geisinger Healthcare System
Medical Institutions
Kaiser Permanente
Mayo Clinic
Profil GmbH
St. Vincent Mercy Medical Center
The Mount Sinai Hospital
University of Iowa Healthcare





Connectivity Industry Consortium Membership - 2

SUPPORTING VENDORS

Abaxis Maurice

Avocet Medical

Cerner

Clarinet Systems

Control Corporation

First Medical/Sigma Diagnostics

GE Medical Systems Information Technologies

HemoCue

HemoSense

InterComponentWare

i-STAT Corporation

International Technidyne Corporation (ITC)

Lantronix

Medtronic

Motorola

Orasure Technologies, Inc.

Pharmacia & Upjohn

SMS/Siemens

TELCOR Inc

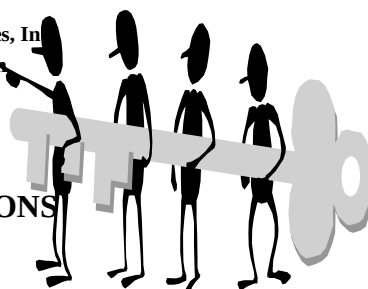
LIAISONS

AACC

COLA

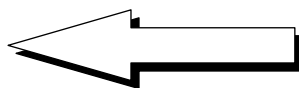
IFCC Scientific Division

Medical Devices Agency



Sommario

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domande

2. lo standard informatico per gli esami in esami in point-of-care

- a) è stato sviluppato da un consorzio di produttori di strumenti analitici
- b) è stato sviluppato da ISO
- c) è stato sviluppato da CLSI (ex NCCLS)
- d) è frutto di un accordo tra USA e UE
- e) nessuna delle precedenti



Connectivity Industry Consortium (CIC)

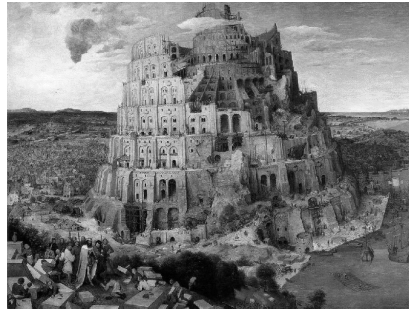


- On **October 20, 1999**, inaugural meeting (start-up) in Redwood City, Calif.
 - point-of-care testing division of the AACC
 - Agilent Technologies (formerly Hewlett-Packard Laboratories, Palo Alto, Calif),
 - Enterprise Analysis Corporation (Stamford, Conn)
- In **February 2000**, 49 healthcare institutions, point-of-care diagnostic vendors, diagnostic test system vendors, and system integrators formed the Connectivity Industry Consortium (CIC) to address this point-of-care diagnostic integration problem. The CIC Board of Directors created the following statement to guide the CIC work teams:

“The vision of the CIC is to **expeditiously develop, pilot, and transfer the foundation for a set of seamless ‘plug-and-play’ POC communication standards** ensuring fulfillment of the critical user requirements of bidirectionality, device connection commonality, commercial software interoperability, security, and QC / regulatory compliance.”

Connectivity: The millennium challenge for point-of-care testing
Kost, Gerald J Arch Pathol Lab Med. 2000;124:1108-1110

da Babel a CIC



<http://www.devicelink.com/mddi/archive/01/04/001.html>

<http://www.poct.fraunhofer.de/about/index.html>

<http://www.aacc.org/AACC/members/divisions/lis/midconcons/>

IVD Industry Connectivity Consortium IICC

October 16-17, 2007, Tarrytown, NY

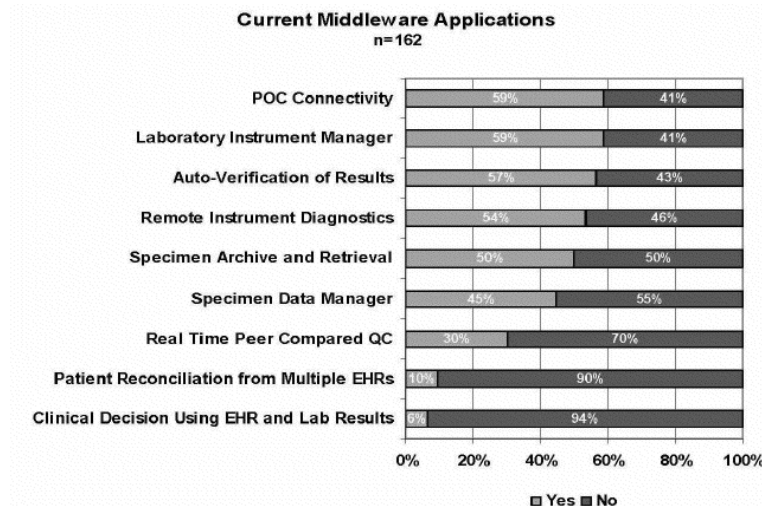


The focus of the organizing meeting was to **create an industry consortium to improve IT connectivity standards** in the IVD industry, with the goal of reducing complexity and variability when linking IVD systems and software.

Connectivity Industry Consortium

March 2007 Survey

Al Jekelis, PhD, Chair LISMI Division, of Informatics, New Jersey Institute of Technology
 Jay Jones, PhD, Director of Regional Labs and Chemistry, Geisinger Medical Center



Connettività POCT in Italia

?



IVD Industry Connectivity Consortium IICC

October 16-17, 2007, Tarrytown, NY



The overall result of the consortium was a **high degree of consensus** among participants that improved connectivity is needed, and that the IVD industry is ready to create and fund a consortium to meet this need. ...

In the **next few months**, the consortium will be incorporated, officers will be appointed, and founding members will fund the organization.

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domande ECM

**3. lo standard informatico per gli esami
in esami in point-of-care**

- a) è stato adottato da CLSI (ex NCCLS)
- b) è stato adottato da ISO
- c) entrambe le precedenti
- d) è stato approvato dalle società scientifiche
- e) nessuna delle precedenti



da CIC a
NCCLS-CLSI

POCT - Point-of-Care Connectivity; Approved Standard.

Lou Dunka, PhD, Bryan Allen, Todd Cooper, Christopher Feters, Wayne Mullins, James Nichols, PhD, Thomas Norgall, Paul Schluter, PhD, Robert Uleski

*NCCLS. Point-of-Care Connectivity; Approved Standard. NCCLS document **POCT1-A** (ISBN 1-56238-450-3). NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898, USA 2001.*

*Clinical and Laboratory Standards Institute. Point-of-Care Connectivity; Approved Standard—Second Edition. CLSI document **POCT1-A2** [ISBN 1-56238-000-0]. Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2006.)*

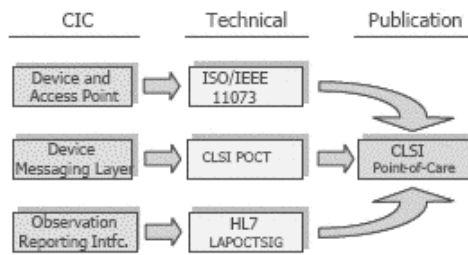


Institute of Electrical and Electronics Engineers, Inc.



Health Level Seven

CIC, IEEE, HL7, CLSI



CLINICAL AND
LABORATORY
STANDARDS
INSTITUTE®



CLINICAL AND
LABORATORY
STANDARDS
INSTITUTE®



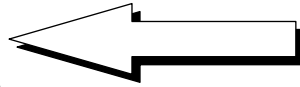
International
Organization for
Standardization

CIC - CLSI - ISO ISO/FDIS 11073-90101:2007

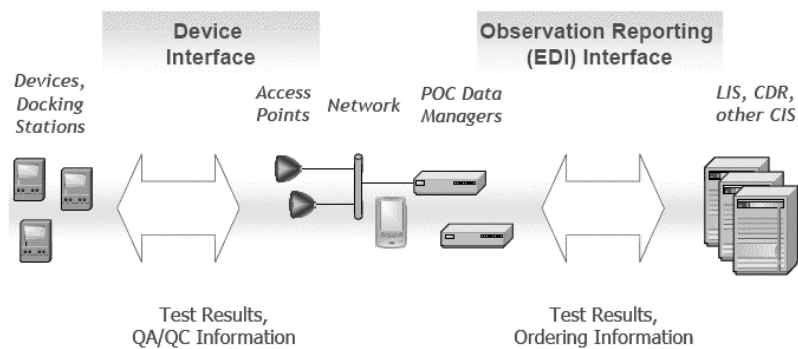
- ISO 11073-90101 was prepared by the Clinical and Laboratory Standards Institute (as POCT1-A2) and was adopted, under a special “fast-track procedure”, by Technical Committee ISO/TC 215, *Health informatics*, in parallel with its approval by the ISO member bodies.

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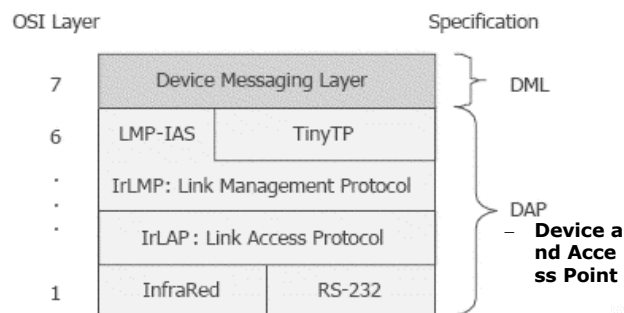
ISO/FDIS 11073-90101:2007 CLSI POCT1-A2 The Two Interfaces





International
Organization for
Standardization

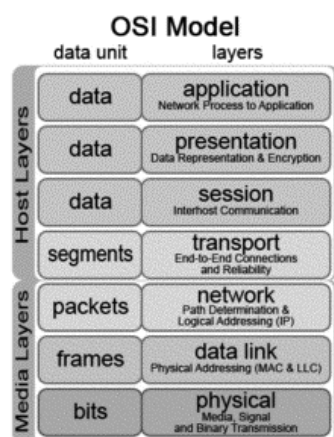
Device Interface Layers



International
Organization for
Standardization

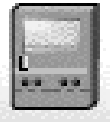
Open Systems Interconnection

Il modello di riferimento OSI

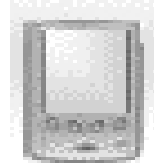


L'Open Systems Interconnection (meglio conosciuto come Modello ISO/OSI) è uno standard stabilito nel 1978 dall'International Organization for Standardization, il principale ente di standardizzazione internazionale, (ISO), che stabilisce una pila di protocolli in 7 livelli.

DAP - DML

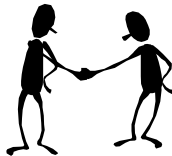


- **Device and Access Point interface (DAP)** – specifies the interface between a device and an Access Point or **concentrator**.



- **Device Messaging Layer (DML)** – the DML describes a complete messaging protocol (message types and message flow) to exchange results and quality information (quality assurance and quality control) between a Device and an Observation Reviewer;

***NOTE:** This protocol may sit on top of any robust, reliable transport, such as the one described by the POCT1 Device and Access Point specification.*



dialog between a Device (DEV) and an Observation Reviewer (OR):

DEV: Hello Observation Reviewer, I'm device 'xyz'. I'm on-line.

OR: Hello 'xyz'. You are a registered device. Please proceed.

DEV: Here is my device status. What else would you like me to do?

OR: Device 'xyz', please report your observations.

DEV: Here are my observations. What else would you like me to do?

OR: Device 'xyz', please report your device events.

DEV: Here are my device events. What else would you like me to do?

OR: Device 'xyz', please accept this Directive: 'xxx'.

DEV: I can perform directive 'xxx'. What else would you like me to do?

OR: Device 'xyz', please accept this vendor-specific communication: 'yyy'.

DEV: I have received vendor-specific communication 'yyy'. What else would you like me to do?

OR: Device 'xyz', please terminate this conversation.

DEV: Goodbye, Observation Reviewer.

POCT1: example of the observation message used to report a glucose test result.

```

<?xml version="1.0" encoding="UTF-8"?>
<!DOCTYPE OBS.R01 SYSTEM "OBS.R01.dtd">
...
<PT.patient_id V="PT222-55-7777"/>
<PT.location V="ICU-4"/>
<PT.name V="Jan Patient">
<GIV V="Janet"/>
<FAM V="Patient"/>
</PT.name>
<PT.birth_date V="1960-08-29"/>
...

<OBS.observation_id V="1517-2" SN="LN" DN="Glucose"/>
<OBS.value V="85" U="mg/dL"/>
<OBS.method_cd V="M"/>
<OBS.status_cd V="A"/>
<OBS.interpretation_cd V="N"/>
<OBS.normal_lo_hi_limit V="[80;120]" U="mg/dL"/>
<OBS.critical_lo_hi_limit V="[30;160]" U="mg/dL"/>
...

<OPR.operator_id V="OP777-88-9999"/>
<OPR.name V="Pat Operator">
...
<GIV V="Patrick"/>
<RGT.name V="GlucoseControl"/>
<RGT.lot_number V="123456" SN="BCHMX" SV="1.0"/>
<RGT.expiration_date V="2002-05-31"/>

```

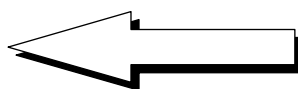
POCT1-A2: Appendix B. Device Messaging Layer

Table 51. Specimen Source Field Values^{aaa}

CODE	DESCRIPTION	CODE	DESCRIPTION
BE	Bilateral Ears	LVL	Left Vastus Lateralis
OU	Bilateral Eyes	NB	Nebulized
BN	Bilateral Nares	PA	Perianal
BU	Buttock	PERIN	Perineal
CT	Chest Tube	RA	Right Arm
LA	Left Arm	RAC	Right Anterior Chest
LAC	Left Anterior Chest	RACF	Right Antecubital Fossa
LACF	Left Antecubital Fossa	RD	Right Deltoid
LD	Left Deltoid	RE	Right Ear
LE	Left Ear	REJ	Right External Jugular
LEJ	Left External Jugular	OD	Right Eye
OS	Left Eye	RF	Right Foot
LF	Left Foot	RG	Right Gluteus Medius
LG	Left Gluteus Medius	RH	Right Hand

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POCT2: la linea guida

Clinical and Laboratory Standards Institute (CLSI
) *Implementation Guide of POC
T1 for Healthcare Providers; P
roposed Guideline.*

CLSI document POCT2-P (ISBN 1-56238-630-1). Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2007.

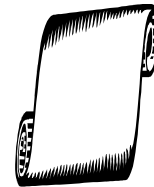
Vote due by Monday, 7 May 2007



POCT2: solo per utilizzatori

- *[POCT1] is very technical, there is some **lack of understanding**, even **confusion**, as to its practicality.*
- *[POCT2] ... is intended for use by **healthcare providers** and end users responsible for point-of-care testing. It will present **some background** on the rationale behind POCT1 and will describe the practical manner in which application of the standard to the POCT device/system should permit the flow of data between the testing system, the data manager and the LIS/HIS.*
- *... A separate guideline, intended to assist device **manufacturers**, will also be available.*

POCT2: contenuti



4 Descriptions and Ideal Characteristics

4.1 General Principles

4.2 Primary Requirements

4.3 Secondary Requirements

4.4 Future Characteristics

4.5 Description of POCT System

4.6 Software and Interfaces

4.7 Possible Mechanisms of Information Transfer

5 Security

5.1 Risk Management and Risk Analysis

6 Information That Can Be Transferred

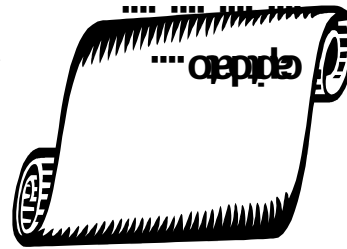
6.1 Obligatory Information Items

6.2 Optional Information Items

7 Questions to Be Asked

Appendix. Risk Identification

POCT2: 4 Descriptions and Ideal Characteristics



4.1 General Principles

4.1.1 Use Existing Infrastructure

4.1.2 Security

4.1.3 International Needs

4.1.4 Individualized Data Access

4.1.5 Desirable Features

4.2 Primary Requirements.

4.2.1 Bidirectional Connectivity

4.2.2 Standardized Device Connections, Plug and Play

4.2.3 Use Existing Infrastructure

4.2.4 Conservation of IP Addresses

4.2.5 Ability to Meet Regulatory Guidelines

4.2.6 Compatibility With LIS Order Generation

4.2.7 Interoperability With Commercial Software

4.2.8 Security

4.2.9 Connectivity Doesn't Impede a Timely Result

4.2.10 Easy to Use

4.3 Secondary Requirements

4.3.1 Configurable User Model

4.3.2 Instrument Dock Integration

4.3.4 Ability to Qualify Results

4.3.5 Manual Data Entry

4.3.6 Remote Access

4.3.7 Result and Test Menu Blocking

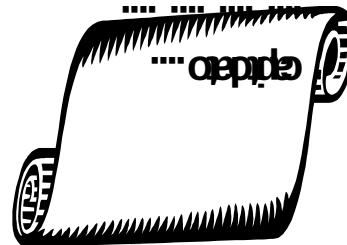
4.3.8 Data Utilization

4.4 Future Characteristics

4.4.1 "Expert System" Analysis

4.4.2 Locator Capability

POCT2: importanti



4.2 Primary Requirements.

...

4.2.3 Use Existing Infrastructure

4.2.4 Conservation of IP Addresses

4.2.5 Ability to Meet Regulatory Guidelines

4.2.6 Compatibility With LIS Order Generation

4.2.7 Interoperability With Commercial Software

4.2.8 Security

4.2.9 Connectivity Doesn't Impede a Timely Result

4.2.10 Easy to Use

4.3 Secondary Requirements

...

4.3.4 Ability to Qualify Results

4.3.5 Manual Data Entry

...

POCT2: analisi dei rischi

Appendix. Risk Identification

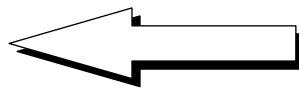
Basis for identification of risks and risk controls should be a matrix to be filled

Severity					Probability of Occurrence
Critical	High	HL	HM	HH	
Moderate	Medium	ML	MM	MH	
Insignificant	Low	LL	LM	LH	
		Low	Medium	High	
		Unlikely	Sporadically	Probable	

- **Red area**—Unacceptable, risk control measures are to be defined and validated
- **Yellow area**—Control measures are recommended, the total count of yellow risks is to be minimized
- **Green area**—Acceptable area

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domande

4. una applicazione commerciale dello standard informatico per POCT

- a) va provata sul campo nella sede di installazione
- b) può essere provata e validata in un connectathon IHE
- c) va certificata secondo ISO
- d) non esistono applicazioni commerciali
- e) nessuna delle precedenti

GMSIH, HL7 France H⁷, SFIL, HL7 Germany, IHE-J, JAHIS, IHE Italy
Integrating the Healthcare Enterprise



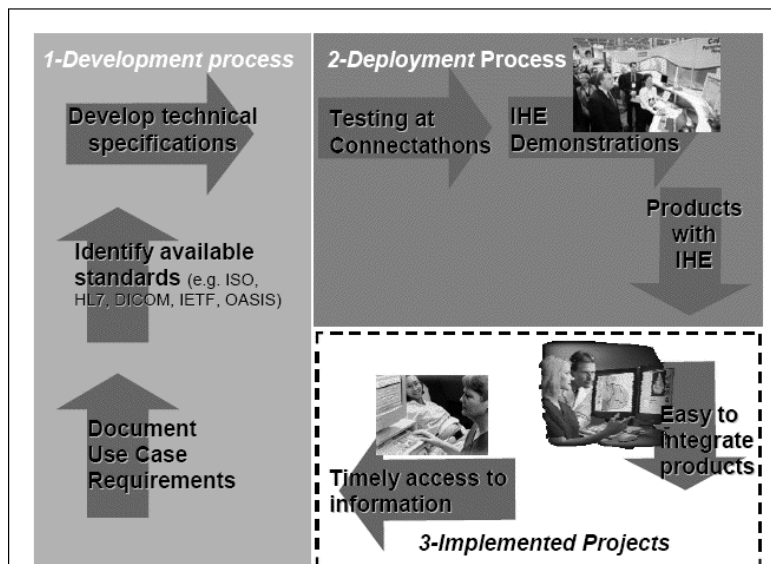
**IHE Laboratory Technical
Framework
Supplement 2005-2006**

**Laboratory Point Of Care Testing
(LPOCT) Integration Profile**

2007-03-27 **ISO DTR 28380-1**

Closing date for voting
2007-07-23

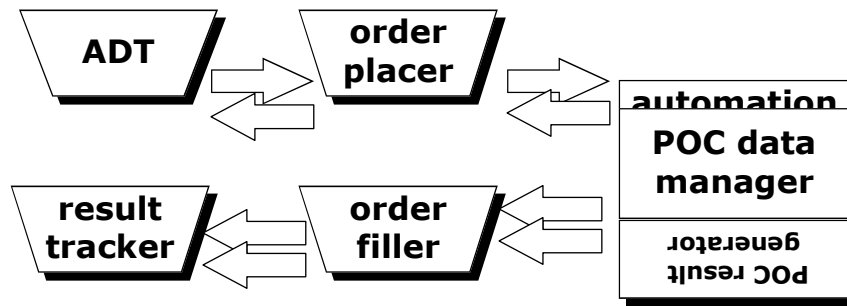
Health Informatics - IHE Global Standards Adoption – Part 1: Process



Laboratory Technical Framework Integration Profiles

- Laboratory **Scheduled Workflow (LSWF)**: covers the workflow related to tests performed by a clinical laboratory, fulfilling an order for a well-identified patient .
- Laboratory **Device Automation (LDA)** describes the workflow between the Automation Manager and a set of laboratory equipment involved in the testing process.
- Laboratory **Point Of Care Testing (LPOCT)** covers the workflow related to clinical laboratory tests performed on the point of care or on patient's bedside, by ward staff.
- Laboratory **Information Reconciliation (LIR)**: covers the workflow related to tests performed by a clinical laboratory under exceptional situation: patient unidentified or misidentified, order not existing...
- Laboratory **Code Set Distribution (LCSD)** provides a way for an application owning a code set in the domain of clinical laboratory (battery, test and observation codes) to send it to other applications.

attori IHE



Core difference between LPOCT and LDA

When the clinical testing **workflow is initiated by the a nalytic testing** producing a set of observations, and when there is neither significant pre-analytic nor post-analytic process, then the analytic part of this workflow will be treated within the Laboratory Point Of Care Testing profile.

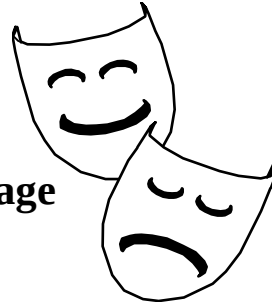
In all other cases the analytic workflow is covered by Laboratory Device Automation profile. This LDA profile supports the clinical testing workflow when it is initiated by an order, irrespective of whether this order is created at the Order Placer level or at the Order Filler level, and wherever the analyzers are located (on the point of care or in a laboratory).

2.4 Actors in Laboratory Technical Framework

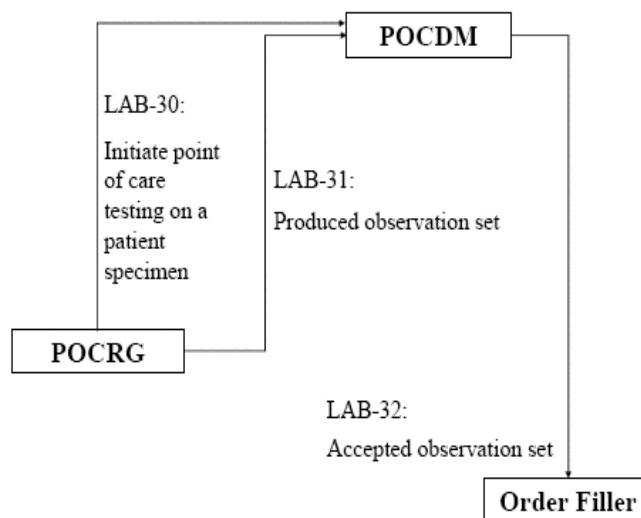
- **Point Of Care Result Generator (POCRG)**

- **Point Of Care Data Manager (POCDM)**

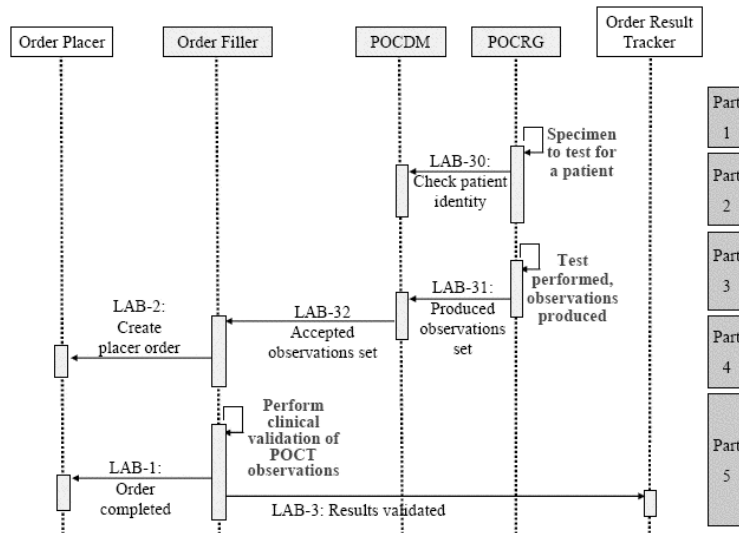
- **Order Filler**



LPOCT Profile: Actors/Transactions Diagram

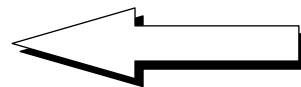


Unordered observations with patient identity checking

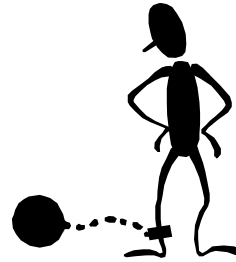


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Sanzioni 196/03



- **Violazioni amministrative**

- 161. 3-18000 €, 5-30000 € (aum. fino 3 volte)

- 162. 5-30000 € 500-3000 €

- 163 10-60000 € + diffusion e media

- 164. 4-24000 €

- 165. 161 162 164 event. di ffusione media



- **Illeciti penali**

- 167. 6-18m / 6-24m / 1-3a

- 168. 6m-3a

- 169. 0-2a / 10-50000 €

- 170. 3m-2a

- 171. Legge 300/70 art. 38

- 172. + diffusione medi a

196/03 Art. 4 Definizioni

dati personali

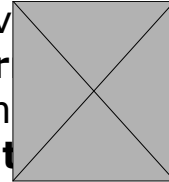
c. "**dati identificativi**", i dati personali che permettono l'identificazione diretta dell'interessato;

d. "**dati sensibili**", i dati personali idonei a rivelare l'origine razziale ed etnica, le convinzioni religiose, filosofiche o di altro genere, le opinioni politiche, l'adesione a partiti, sindacati, associazioni od organizzazioni a carattere religioso, filosofico, politico o sindacale, nonché i dati personali idonei a rivelare lo stato di salute e la vita sessuale;

e. "**dati giudiziari**", i dati personali idonei a rivelare provvedimenti di cui all'articolo 3, comma 1, lettere da a) a o) e da r) a u), del d.P.R. 14 novembre 2002, n. 313, in materia di casellario giudiziale, di anagrafe delle sanzioni amministrative dipendenti da reato e dei relativi carichi pendenti, o la qualità di imputato o di indagato ai sensi degli articoli 60 e 61 del codice di procedura penale;

Illeciti penali **196/03** Art. 169
Misure di sicurezza

- Chiunque, essendovi tenuto, omette di adottare le misure minime previste dall'articolo 33 è punito con **l'arresto sino a due anni** o con l'ammenda da **diecimila euro a cinquanta mila euro**



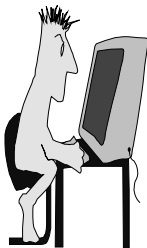
- **Art. 33 Misure minime**



- 1. Nel quadro dei più generali obblighi di sicurezza di cui all'articolo 31, o previsti da speciali disposizioni, i titolari del trattamento sono comunque tenuti ad adottare le misure minime individuate nel **presente capo** o ai sensi dell'articolo 58, comma 3, volte ad assicurare un livello minimo di protezione dei dati personali.

196/03 Art. 34 Trattamenti
con strumenti elettronici

- 1. Il trattamento di dati personali effettuato con strumenti elettronici è consentito solo se sono adottate, nei modi previsti dal disciplinare tecnico contenuto nell'allegato B), le seguenti **misure minime**:
 - a. **autenticazione** informatica;
 - b. adozione di procedure di **gestione delle credenziali** di autenticazione;
 - c. utilizzazione di un sistema di **autorizzazione**;
 - d. **aggiornamento** periodico dell'individuazione dell'ambito del trattamento consentito ai singoli incaricati e addetti alla gestione o alla manutenzione degli strumenti elettronici;
 - e. **protezione** degli strumenti elettronici e dei dati rispetto a trattamenti illeciti di dati, ad accessi non consentiti e a determinati programmi informatici;
 - f. adozione di procedure per la custodia di **copie** di sicurezza, il **ripristino** della disponibilità dei dati e dei sistemi;
 - g. tenuta di un aggiornato **documento programmatico** sulla sicurezza;
 - h. adozione di tecniche di **cifratura** o di codici identificativi per determinati trattamenti di dati idonei a rivelare lo stato di salute o la vita sessuale effettuati da organismi sanitari.



196/03 Art. 35 Trattamenti senza l'ausilio di strumenti elettronici

- Il trattamento di dati personali effettuato senza l'ausilio di strumenti elettronici è consentito solo se sono adottate, nei modi previsti dal disciplinare tecnico contenuto nell'allegato B), le seguenti misure minime:

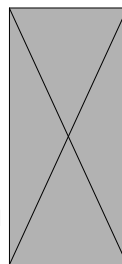


- a. **aggiornamento** periodico dell'individuazione dell'ambito del trattamento consentito ai singoli incaricati o alle unità organizzative;
- b. previsione di procedure per un'idonea **custodia** di atti e documenti affidati agli incaricati per lo svolgimento dei relativi compiti;
- c. previsione di procedure per la conservazione di determinati atti in archivi ad **accesso selezionato** e disciplina delle modalità di accesso finalizzata all'identificazione degli incaricati.

196/03 Art. 4 Definizioni

autenticazione informatica

- c. "**autenticazione informatica**", l'insieme degli strumenti elettronici e delle procedure per la verifica anche indiretta dell'identità;
- d. "**credenziali di autenticazione**", i dati ed i dispositivi, in possesso di una persona, da questa conosciuti o ad essa univocamente correlati, utilizzati per l'autenticazione informatica;
- e. "**parola chiave**", componente di una credenziale di autenticazione associata ad una persona ed a questa nota, costituita da una sequenza di caratteri o altri dati in forma elettronica;
- f. "**profilo di autorizzazione**", l'insieme delle informazioni, univocamente associate ad una persona, che consente di individuare a quali dati essa può accedere, nonché i trattamenti ad essa consentiti;
- g. "**sistema di autorizzazione**", l'insieme degli strumenti e delle procedure che abilitano l'accesso ai dati e alle modalità di trattamento degli stessi, in funzione del profilo di autorizzazione del richiedente.



POCT1-A2 Appendix D. Requirements

1.1 General Principles

1.1.2 Security

1.1.2.1 Point-of-Care User's Issue

*Maintaining the security of data and access is essential. POCT data contains confidential patient information. **Encryption** should be further considered, particularly with communication outside the user's intranet and wide area network. Using the same security that LIS vendors do should be adequate.*

Sommario

- applicabile?
- chi sviluppa?
- chi adotta?
- cosa contiene?
- come si applica?
- da teoria a pratica
- multe, arresti e reclusioni

