Interoperability and Security: Design and Development of a Clinical Documents Repository Digitally Signed using CDA standard.

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Departament of Medical Informatics

Introduction

- Medical documents can be shared and exchanged
  - →Growth of hospital information systems
  - →Information exchange needs
  - →Proliferation of Internet technologies
- Standard formats - semantic and syntactic interoperability
  - →HL7, CDA

Introduction (cont.)

- Handwritten Signature
  - →Traditionally guaranteed authorship and integrity of paper documents
  - →Is written at the end of the document to prove that what is authenticated has not been modified
  - →Medical setting works by this same modality
- Impossibility of physically signing digital documents
  - →Simple electronic signatures can't replace handwritten signature
- Digital Signature guarantees authorship and integrity of digital documents
  - →Giving them the same validity of those signed in paper
  - →Uses mathematical processes to relate the signed document with information from the signing person

Objectives

- Describe the design, development and process of implementation of a clinical electronic documents repository digitally signed, using CDA standard and the asymmetric key infrastructure (PKI - Public Key Infrastructure).

Materials and Methods – Scenario

- Hospital Italiano de Buenos Aires (HIBA)
  - →Tertiary care, teaching and research hospital with a 150 year old history
  - →Since 1998 a full scale HIS has been gradually implemented
    - Including Ambulatory Electronic Health Record (EHR)
    - Several health informatics standards had been implemented, including HL7, CDA 2.0, ICD-9CM, DRG and ICD10

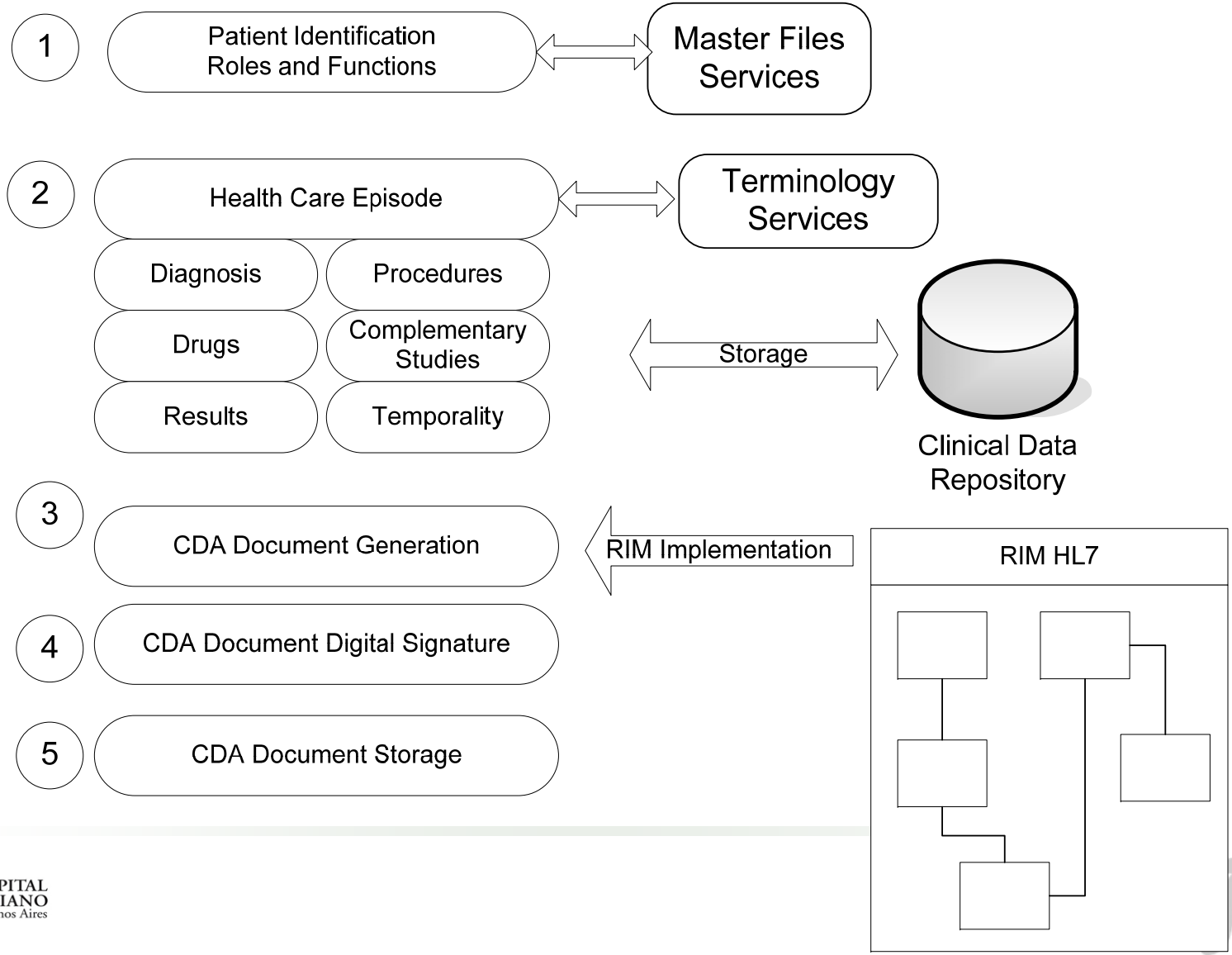
Digital Signature Legislation in Argentina

- In 2001, Bill 25506 of "Digital Signature" was sanctioned
  - →Recognizes the use of digital signature, and its legal validity
  - →Allows truthfully identification of individuals making electronic transactions
  - →When a document requires a handwritten signature, that exigency is also satisfied by a digital signature.
  - →Also describes the figure of electronic signature as an integrated electronic data set, related in a logical way to other electronic data, used by the signatory like his means of identification, which lacks some of the legal requirements to be considered digital signature

Medical Information Security

- Key issue
  - →Development of security mechanisms needed to operate and maintain a decentralized medical record system
  - →Based on five fundamental aspects:
    - Privacy
    - No Disavowal
    - Authenticity
    - Integrity
    - Chronology

CDA documents creation



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Signature of Medical Documents

- "In house" application, with own PKI
  - → Creation and administration of public and private keys and digital certificates.
- Three basic characteristics of digital documents:
  - → Having a HASH to guarantee the document's integrity.
  - → Been signed with private and public key system, to guarantee its authorship.
  - → Having a Time Stamping service, that guarantees document's temporality.
- Public and private keys are stored in a cryptographic USB E-Token given to providers
- Each XML clinical document created, has a single HASH value and is encrypted using the private key stored in the E-token
  - → This encrypted file maintains its original information and the digital certificate
- A process of time stamping stores a digitally signed time registry with the document signed by the user

Discussion

- Trustworthy and unique registry of the medical acts, allowed by:
  - →Documents in single XML files that summarizes providers work,
  - →Digital and Electronic Signature, provided by the E-token
- Current graphical interfaces
  - →Provide improvements in usability and information visualization
  - →But...
  - →Does not correspond with the traditional charts in paper.
- Traditionally the professionals records their observations and findings in documents and then sign them
  - →The implementation of CDA and Digital/Electronic Signature maintains this sequence.

Conclusion

- Users can access laboratory results, imaging reporting, referral notes, discharge letters, progress notes, diagnoses, procedures and medical prescriptions, in a fully legible format…
  - →and the possibility of information processing for its later inclusion in other information systems or related health care applications.
- Documents visualization was personalized using XSL style sheets
- A time stamping service (also digitally signed), will allow temporality to this unique registry of medical acts.
- CDA standard implementation with the aggregate of digital/electronic signature in an electronic health record is a true challenge
  - →it entails an important technological and organizational impact.

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