

E-HEALTH: GRAND CHALLENGES AND LEGAL CONCERNS

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Electronic Health Record in Italy and Personal Data Protection

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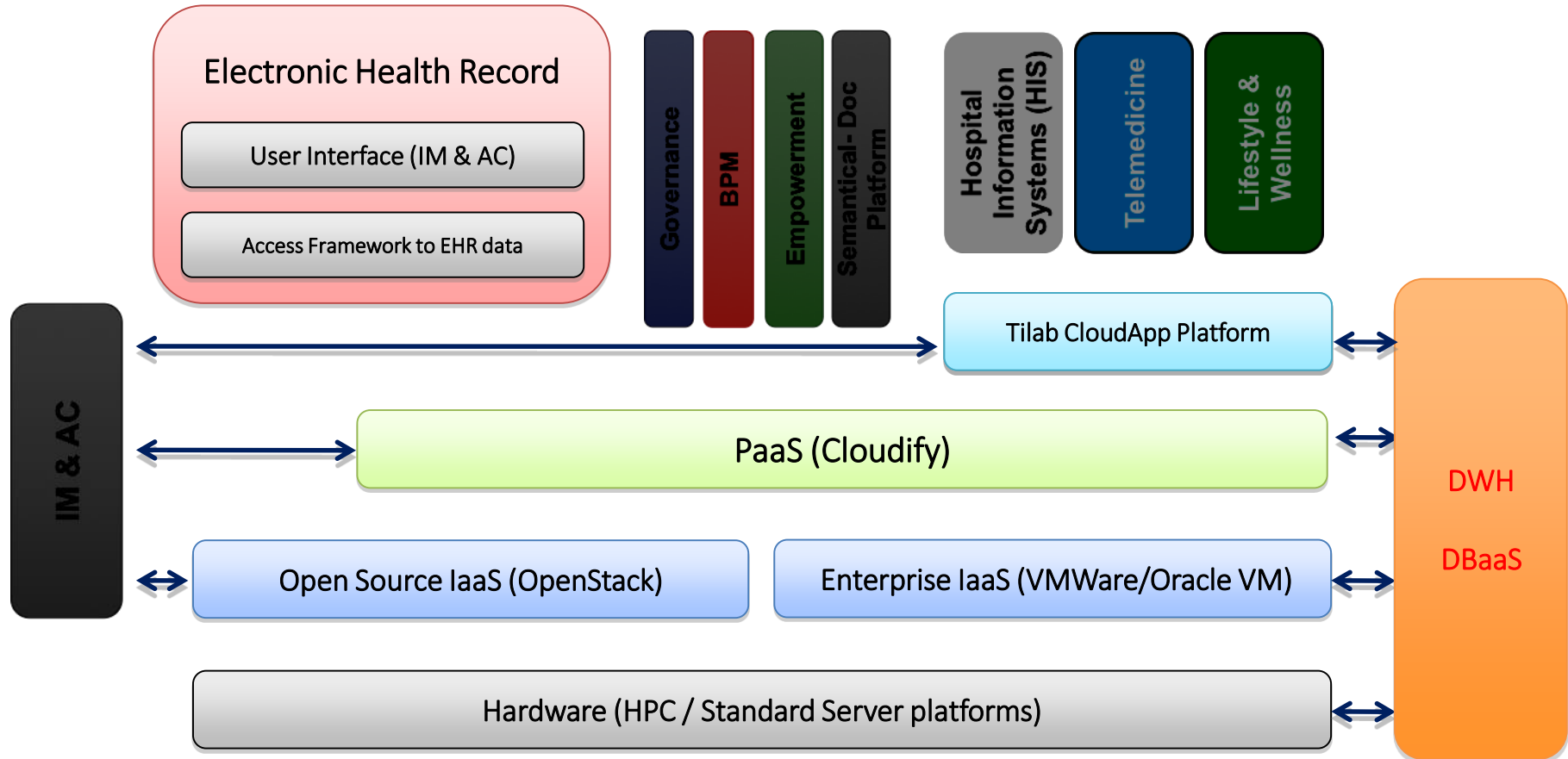
"Smart Health 2.0" Project

The project PON Smart Cities “*Smart Health 2.0*”, PON04a2_C, has been funded on the basis of the PON Smart Cities call 84/Ric of the Italian Ministry of Instruction, Education and Research of March 2nd, 2012.

It is aimed at implementing the following topics:

- enabling Cloud Computing Platform & Data Warehouse
- EHR of “second generation” for the Regione Siciliana
- Telemonitoring & Home Care services
- governance of health-care process
- tools for citizen empowerment
- experimentation & training

Enabling IT Platform



smart health
2.0



"Smart Health 2.0" partnership



EHR: Definition and Purposes

Act 221/2012:

- Art. 12.1: EHR is *"the set of data and digital documents related to health and socio-medical information generated by past and present clinical events about the patient"*
- Art. 12.2: EHR must be created only for aims of:
 - - prevention, diagnosis, treatment and rehabilitation
 - - study and scientific research
 - - health planning and evaluation of health care
- Art. 12.3: EHR allows citizens to have access to on-line health services

Main Italian Legal Sources on EHR

- Art. 12 Act 221/2012 (main principles on EHR)
- Act 82/2005 (Italy's Digital Administration Act)
- Act 276/2003 (Data Protection Code)
- AGID (Agency for Digital Italy) guidelines of 31st March 2014
- Scheme of Presidential Decree on EHR and Italian Data Protection Authority favourable pronouncement (22nd May 2014)
- Regions plans: EHR operative by 30th June 2015



Patient-Centered Model: the Consent

- Additional to consent provided for data processing for care purposes
- Autonomous, collected ad hoc, specific for EHR treatment, informed, free and aware (Artt. 13, 78 and 79 DP code)
- Double consent:
 - the first one is for feeding an EHR (data processed only for research and governance)
 - the second one allows practitioners to consult the EHR for care reasons
- Minors/incapacitated persons: consent given by whom exercises parental authority/guardian

General Principles on Data Processing

Artt. 3 DP Code and 6 Dir. 95/46/EC

- .Fairness, lawfulness
- .Purpose limitation
- .Proportionality and accuracy
- .Limited data retention period

Data Subject's Rights

• Art. 7 privacy code in e-health context: patient's rights to:

- access the data

- obtain their intelligible communication

- have the data supplemented, updated and/or rectified

• Medical data in EHR cannot be disseminated (unfettered circulation prohibited by DP Code ex artt. 22.8 and 26.5. Unlawful processing of health data allows criminal punishments ex art. 167 DP Code)

Data Subject's Rights, Data Controller and Data Processor

.Data Controller (art. 4.1 DP code): responsible for organizing the entire aspect of processing; main recipient of responsibility and the penalties prescribed by law on the processing of personal data

.Co-data controllership in EHR (art. 28 DP Code): suitable because the administrative architecture of public hospitals is on provincial basis. Same treatment shared by different hospitals

.Data Processor: optional figure, chosen by Data Controller *“among entities that can appropriately ensure, on account of their experience, capabilities and reliability, thorough compliance with the provisions in force applying to processing as also related to security matter”* (Art. 29 DP Code)

Privacy and open aspects in a Cloud-based EHR

- .Cloud Electronic Health Record (CEHR) using of Multitenancy and Big Data Analytics
- .Achieving a system centered-approach in the data processing: central implementation of services; reduction of costs and efforts by centrally managing the entire platform; supporting cross-sectional views for purposes of both governance and scientific research
- .Cloud and threats to privacy: Public Cloud; company located in a no-EU country (data transfer outside Europe); data access: who is the Data Controller?
- .Lack of legal framework on Cloud at Italian and EU level
- .*De jure condendo*: Private Cloud owned by the Department of Health of each Region/community; datacenters hosted in Italy or in EU; open format for data portability

CONCLUSIONS

- .Looking for an e-health culture in Italy
- .Need for legal regulation on several privacy issues related to EHR (minors' supersensitive data, co-data controllership, CEHR, datatransfer to other EU countries for care reasons)
- .Need for public investment to form practitioners and clerks managing EHR

Let's get in touch

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