

# Italian guidelines on Electronic Health Record: CHALLENGES FOR RE



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# Outline

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- Introduction (EHR and Nómos I )
  - Analysis: purpose and method
  - Results
  - Details and challenges
  - Conclusions
- NP
  - LS
  - Motivations
  - Properties of resources
  - Examples and Extension of domain
  - Conditional situations

# Introduction

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## ■ Motivation

Complete modeling language for the domain

## ■ Guidelines on Electronic Health Records/Health File

- 2009
- “Appendix” for the Italian Privacy Law [Decree n.178, June 2003]
- Issued by the Italian Data Privacy Authority (*Garante*)
- *“initial set of precautionary measures to timely highlight specific safeguard and responsibilities and outline the applicable rights”*

## ■ Nómos I



### **Normative Proposition**

most atomic piece of law able to carry normative meaning

### **Legal Subject**

Subject addressed by the law



# Analysis: purpose and method

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- Purpose
  1. Evaluate existing concepts
  2. Identify concepts and entities for new modeling language for a certain domain
- Method

NP

LS

§4.1. **“Processing of personal data** via an EHR/HF [...] should only be performed by **health care practitioners** - which does not include technical experts, [...]. Nor are the **medical staff** acting in their capacity as forensic medicine experts included - e.g. when examining an individual to establish whether he or she is fit to work and/or drive. The underlying rationale is that the functions discharged by the said professionals - which are nevertheless health care practitioners - are not aimed at treating the data subject, but rather at establishing the data subject's fitness and/or conditions.”

© Conditional Situation

Motivation

# Results

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<b>Legal Subjects</b>	<b>23</b>
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<b>Normative Propositions (NPs)</b>	<b>111</b>
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<b>Paragraphs</b>	<b>91</b>
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NP-able	72
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Not NP-able	19
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- <i>Introduction</i>	52.63%
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- <i>Examples</i>	31.58%
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- <i>Extension of domain</i>	15.79%
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		with respect to all (identified) NPs	with respect to the NP-able paragraphs
<b>Extension of domain</b>	10	9.01%	13.89%
<b>Motivations</b>	24	21.62%	33.33%
<b>Example</b>	34	30.63%	47.22%
<b>Properties of resources</b>	6	5.41%	8.33%
<b>Conditional Situation</b>	41	36.94%	56.94%

# Details and challenges #1

5



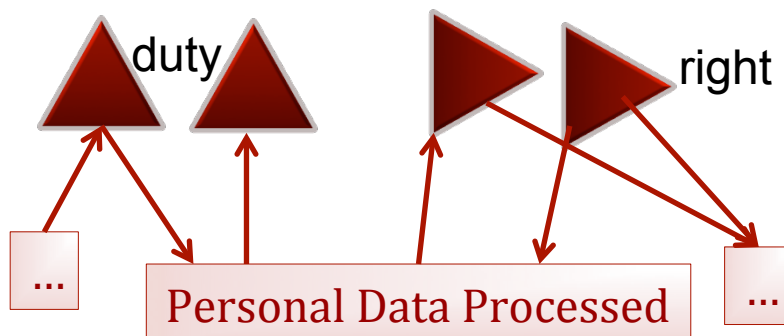
NP	111
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## NORMATIVE PROPOSITION

### ■ Redundancy of NP

- Same action in different NPs
- This redundancy is what delineates the variability for that event/situation/action

### ■ Our modular approach with *Situations*



§4.1 “Processing of personal data via an EHR/HF [...] should only be performed by health care practitioners - which does not include technical experts, insurance companies, [...]”.

NP<sub>1</sub> Health Care Practitioners  
“Process Personal Data”

NP<sub>2</sub> Technical experts  
“DO NOT Process Personal Data”

NP<sub>3</sub> Insurance Companies  
“DO NOT Process Personal Data”

...

§4.4 “Appoint the natural person in charge of *this processing*”

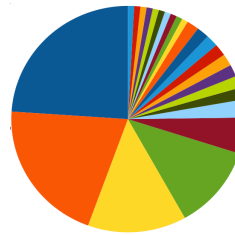
NP<sub>x</sub>

# Details and challenges #2

6

Legal subjects

23



## LEGAL SUBJECT



- Holder not explicit

12%

§2.6 “the appropriate measures should be taken to allow tracing back the entities responsible for creating and collecting the data”.

- Correlative not expressed

91%

§3.7 “The consent must be given on a separate, specific basis [...]”

- General/Instance level specification

§9.4 “Entities coordinating EHR projects that covers a small area”

§5.12 “the health care practitioner that is or will be treating the DS”

# Details and challenges #3

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## MOTIVATIONS

Motivations	24
with respect to the identified NPs	21%
with respect to the NP-able paragraphs	33%

### ■ Purpose

... aimed at...  
... the purpose is...

37.5%

§4.1 *“Processing of personal data via an EHR/HF is only aimed at prevention, diagnosis and treatment activities in respect of the data subject”*

### ■ Reason

Why? For what reason?

62.5%

§2.6 *“**since** the medical data and documents contained in a EHR are collected from different sources*

*take appropriate measures to allow tracing back the entities responsible for creating and collecting data and making them available via the EHR”*

### ■ Is a *reason* enough for compliance?

What if my EHR does not collect info from multiple sources?



# Details and challenges #4

8



Prop. Resources	6
with respect to identified NP	5%
with respect to the NP-able paragraphs	8%

## PROPERTIES OF RESOURCES

### ■ Resources

- Information Notice
- Patient Consent

§8.4 “***The information notice** should clearly specify [...] the entities (or categories of entities) that, when treating the data subject, may access the EHR/HF as well as the possibility for the data subject to only allow part of those entities to access the EHR/HF*”

# Details and challenges #5

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Examples	34
with respect to identified NP	30%
with respect to the NP-able paragraphs	47%

## EXAMPLES

“e.g.”, “i.e.”, “for example”, “for instance”,

- clarifications on information

64%

§3.15 “[...] *past clinical events (e.g. previous medical reports)*”

- with (strong) compliance meaning

36%

§3.12 “*empower data subjects to “blank” information via a sealed electronic envelope*”

## EXTENSION OF DOMAIN

§5.6 “*a data controller should comply with the legislation protecting anonymity of individuals*”  
§5.19 “*The legislation on access to administrative records (...) is obviously left unprejudiced*”

Extension of domain	10
with respect to identified NP	13%
with respect to the NP-able paragraphs	9%

# Details and challenges #6

10



Conditional Situation	41
with respect to identified NP	37%
with respect to the NP-able paragraphs	57%

## CONDITIONAL SITUATIONS

### ■ Element *influencing* the normative

- Influences the applicability
- Affects the legal subject
- The environment
- Temporal dimension

§8.6 the record of a DS can be accessed without his/her consent “if this is found to be indispensable to protect a third party's and/or the public health”

§2.2 If the medical staff is acting as forensic medicine expert then he has no right to process the patients record

§3.18 “[..] when the Data subjects first gets in touch with the Data Controller...”

§3.14 “[..] the DC is free to require that DSs exercise the said right in the presence of the physician...”

# Conclusions

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## ■ Concepts [we identified] in these guidelines

Normative Proposition

– Conditional situations



– Examples



Legal Subjects

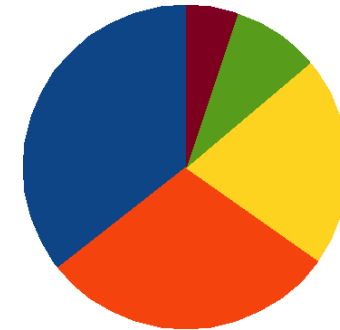
– Motivations



– Extension of domain



– Properties of resources



## ■ Challenges [we identified] for RE

1. Variability ☒

2. Missing subjects ☐

3. Abstraction levels ☐

4. Motivations ☐

5. Temporality ☐

# Conclusions

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## ■ ... but

1. “low level” technical regulation
  - “higher level” laws might have different traits?
2. short document (91 paragraphs)
  - longer laws have a different element distributions?
3. advantage of using situations?
  - new modeling language, new analysis 😊

# Questions?

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