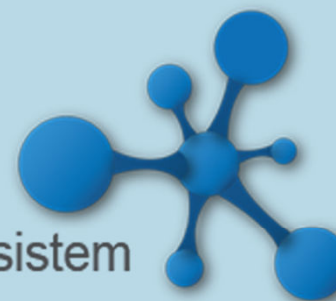




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Ministarstvo zdravlja

Workshop

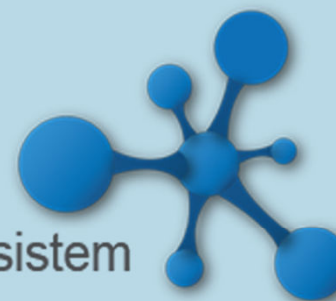
Health Information Think Tank

Hotel Izvor, Arandjelovac
28 and 29 November 2012



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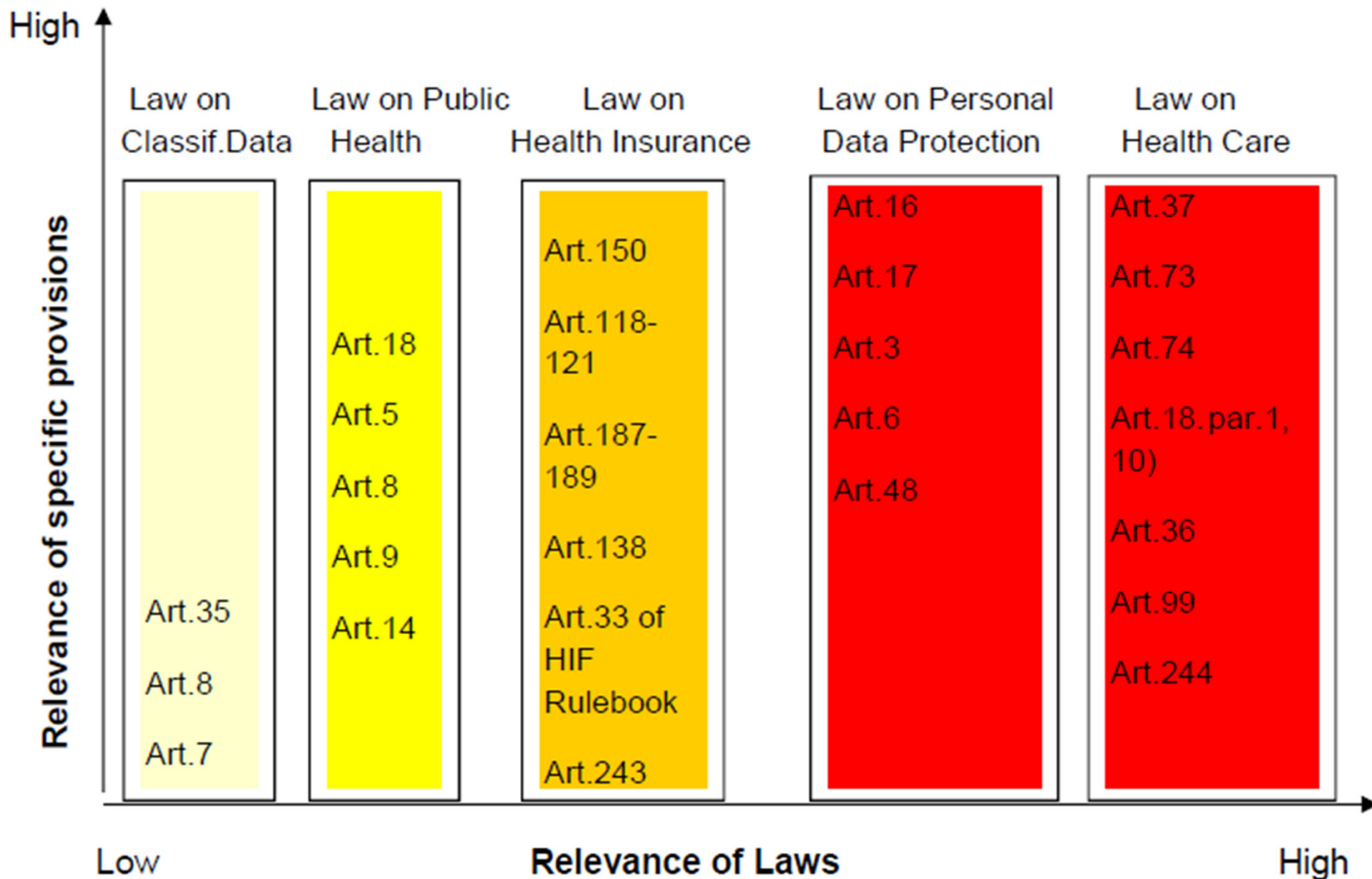
Ministarstvo zdravlja

Legal Framework for IHIS and EHR

Aleksandar Zavišić

- Short overview of relevant legislation
- Challenges in front of EHR with possible answers and actions to be taken
- Summary of recommendations and conclusions

Overview of relevant laws



1. Definitions from the realm of personal data protection and how **medical data** are defined?
2. What is the existing legal basis for regulating EHR and IHIS?

3. What is the **data set** to be included in EHR, that is which personal data are to be mandatorily included in the new law on health records?

Could these data serve as the basis for obtaining important health indicators?

4. „**Collision**“ between the protection of the right to privacy and the idea of EHR:

- a) Who has the right to access the (medical) data from EHR and access level of the authorized persons?

- b) When does the patient's consent is not needed, that is what are the data to be processed without his/her consent?

It is important as problems may occur in practice!

5. What are the **patient's rights** in relation to medical personal data?

6. Personal data which are transferred for **statistical and scientific purposes** and the role of key institutions?

7. Protection of medical data - official (professional) secret or classified data and connection to that, personal liability of health professionals?

8. Connecting Health Insurance Data Base with EHR?

9. Limitations of the Law on Medical Records and Regulation on Medical Record Keeping

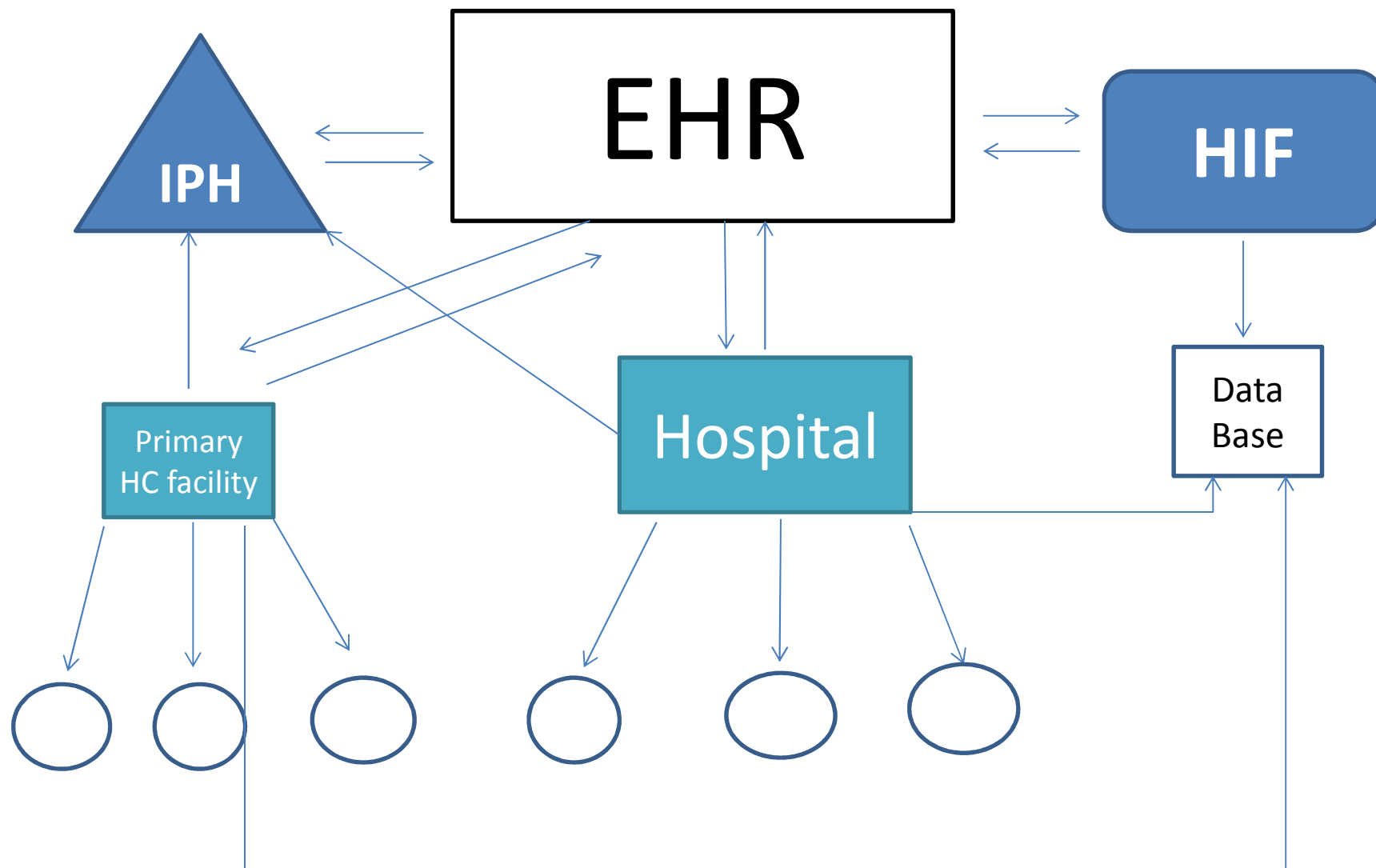
1. Definitions

- Personal Data ≠ Identity Data (bad example: Article 138 of Law on Mandatory Health Insurance)
- Article 3 of Law on Personal Data Protection – personal data, controller, processor, user

Medical data - major gaps:

- Article 16 of PDPL – “particularly sensitive data“
Vs.
- Article 37 of Law on Health Care – “classified data”
- Absence of the definition of “health documentation and records”

Relations in the new system and flow of medical personal data





2. Legal Basis for the Introduction of EHR and IHIS

In a narrow sense:

- Article 18 + Article + Article 74 of Law on HC

In a wider sense:

- Strategy of the development of Information Society until 2020
- Government Decree „e-Health“

3. Data to be included in EHR

- Set of high-quality health information...
 - from both, an individual and a society perspective
- Aligned with the obligations from the systemic Law on Health Care, Law on Personal Data Protection and other legislation



4. „Collision course“ of the two systems: a) Who has the right to access the data

Selected physician \longleftrightarrow Physician from 2nd & 3rd level

- Excludes all the other physicians and third parties...

unless a patient gives his/her consent or the law provides differently (that the data can be processed without an explicit consent)

4. b) When the patient's consent is not required, that is which data can be processed without a consent?

- According to PDPL, consent is not required if the law provides so (Art. 12, par. 3 and Art. 16, par. 2 PDPL)
- Thus, the question of the patient's consent in the EHR context should be addressed
- If the decision is made to ask the patient every time if he/she agrees to authorize access to his EHR, such a consent should be specific and in relation to a concrete situation (with an explanation about the consequences of refusing it); no *à la carte* consent is allowed



5. Prava pacijenta povodom (medicinskih) podataka o ličnosti

- Right to insight \rightleftarrows Right to information
- Right to copy (Article 33 of the HIF Regulation)
- Rights of data subject regarding insight performed: correction, amendment, update, deletion of data, termination and temporary recess of processing.
- Clarify where the request for obtaining information, having insight and receiving a copy of the medical data stored in EHR is submitted –
recommendation: through a primary health facility

6. Collection of data for statistical and scientific purposes

- Article 6, par. 2 + Article 16, par. 3 of the PDPL
- Article 37, par. 12. of the Law on Health Care
- Article 138, par. 3 of the Law on Health Insurance
- Article 2 of the Law on Health Records



6. Collection of data for statistical and scientific purposes

But:

1) Law on Public Health does not elaborate on measures of data protection,
in contrast to Law on Health Insurance

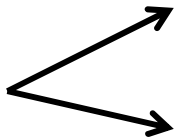


6. Collection of data for statistical and scientific purposes

2) For the sake of consistency of EHR system, a question about the need of receiving most of personal(ized) for public health purposes should be asked

Law on Public Health states „ ...monitoring of the population’s health“, which may lead to conclusion that **anonymous, or pseudonimized personal data** are sufficient

- Similarly, Article 231 of the Law on Health Care refers to research conducted by health faculties

- **On the individual level**, through:
 - Hippocratic oath
 - Professional association
 - Laws 
 - in principle, Article 37 and 73 LHC
 - concretely, misdemeanors & crim.off.
- **On the level of technical solutions** – safeguard measures



8. Connecting data base of HIF with EHR

- Primary focus is on keeping records for mandatory health insurance, which is an obstacle for a better quality of health services;
- Access level of EHR data by HIF (control of invoicing)?
- Access level of the relevant HIF's health data by EHR (identity of persons, services, prescriptions)?
- Potentially: To define a subset of HIF data about delivered health services - relevant for EHR



9. Anachronism of the existing Law on Records and Rulebook

- Adopted in 1981
- Currently, double record keeping
- Additional effort and expense with an administrative burden of health professionals
- Example: manual handling of protocols
- Hampers the introduction of IT solutions in the health sector, which is a prerequisite for EHR

- Prepare and adopt a new law on health record and a by-law, which will to a great extent give answers to open questions and challenges and, thus, facilitate modernization of health sector and enhancement of the quality of health care