



2014 Italian
Presidency of the Council
of the European Union



CONFERENCE ON EHEALTH

MINISTERIAL CONFERENCE

Italian Presidency of the Council of the European Union

Sebastian Reimer, Ministry of Health AT

IMPLEMENTING ELECTRONIC HEALTH RECORDS IN AUSTRIA

7th- 8th October, 2014, Rome

STRATEGY

- Political discussion
- Wide involvement of relevant stakeholders
- Private law body as one of the main players
- Legislative process
- Implementation



MAJOR OBSTACLES

- Public opinion – especially resentments towards state-run EHR
- EHRs are regarded to
 - violate privacy
 - be disproportional
- No general standard, but many different ones
- Unnamed fears, e.g. of increased liability



MODEL

- Intra-State Treaty between Federal Government and Federal States since 2005 (Art 15a Austrian Federal Constitution)
- Private Limited Company of Federal Government, Federal States and National Insurance (ELGA-GmbH – www.elga.gv.at)
- DATA PROTECTION AS GUIDING PRINCIPLE
- Step-by-step implementation till 2022
- Easy-to-use web interface



WHAT MAKES THIS LAW OUTSTANDING?

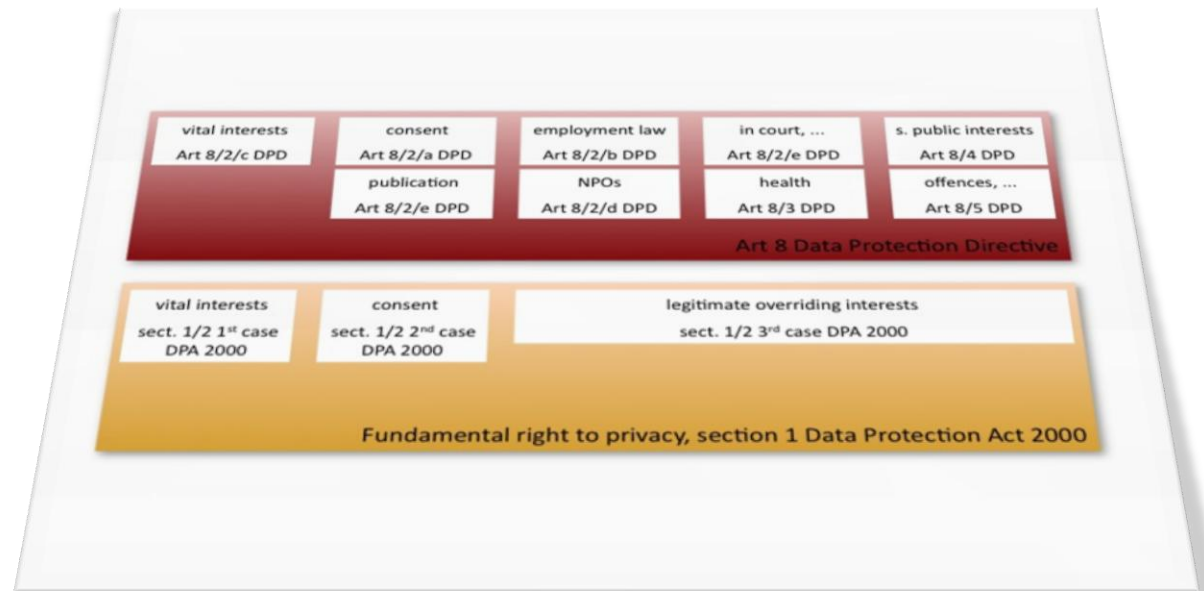
- First pure EHR Act in Europe
- Heavily discussed/criticized
- Opt-out
- very high level of data protection:
 - Ban on storages outside EU
 - De-facto-ban on cloud-storages (obligation to content encryption)
 - Mandatory unique identification
 - De-centralized approach
 - Transport encryption
 - Mandatory IT-security concept
 - Additional professional secrecy
 - Extended Patients' Rights
 - EHR Ombudsmen
 - ...

Electronic Health Records Act		
Art 1	Health Telematics Act 2012 (HTA 2012)	
	1 st Part (General Provisions)	
	Health data <ul style="list-style-type: none">- physical or psychological state of a person,- medical history,- accounting data,- ...	Healthcare Providers (HCP) <ul style="list-style-type: none">- dentists,- pharmacists,- hospitals,- healthcare institutions,- psychologists,- medical therapists,- Patients' ombudsmen,-
	2 nd Part (Data security)	
	3 rd Part (Information policy)	
	4 th Part (EHR [ELGA])	
	EHR-Health data <ul style="list-style-type: none">- Medication data,- laboratory findings,- X-Ray and MR- Hospital discharge reports,- living wills,- power of attorney und- data on transplants.	EHR Healthcare Providers <ul style="list-style-type: none">- dentists,- pharmacists,- hospitals and- healthcare institutions.
	5 th Part (Final Provisions)	
Art 2-5	Amendments to Social Security Laws	
Art 6	Amendment to the Gene Technology Act	
Art 7	Amendment to the Criminal Code	

IS THIS AUSTRIAN EHR ACT COMPLIANT?

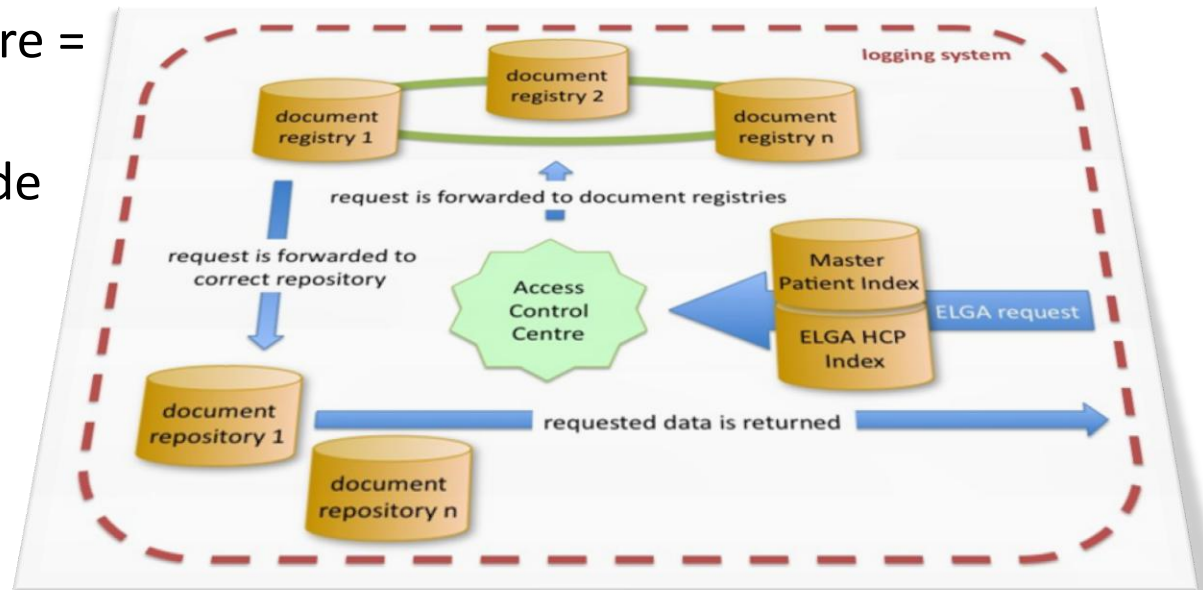
- ✓ Based upon Art 8 para 4 of the European Data Protection Directive 95/46/EC (DPD)
- ✓ Adheres to the standards of the DPD
- ✓ Implements Ombudsmen as supposed by Art-29 Working Party in their document WP 131 on Electronic Health Records

YES



RESULT

- De-centralized structure
- EXPLICIT BAN OF PUBLIC AUTHORITIES, EMPLOYERS, INSURANCE COMPANIES, ...
- Opt-Out for medical reasons (Swedish Study on Fatal Adverse Drug Reactions, 2008; ...)
- Access Control Centre = centrepiece
- Tightened Penal Code
- EHR-Ombudsmen
- Extended Patient Rights



RECOMMENDATIONS

1) Take care of **communication**

- be polite and objective
- explain
- emphasize benefits

2) Be **critical** and most importantly do not believe in scare stories!

3) Be **brave** – you will face a lot of opposition!



FURTHER READING

- *Clemens-Martin Auer/Carina Milisits/Sebastian Reimer*, ELGA-Handbuch (2014) **[German]**
- *Carina Milisits/Sebastian Reimer*, ELGA ist auf Schiene, Soziale Sicherheit 12/2012 **[German]**
- *Sebastian Reimer*, Current and Future Settings of Austrian Legislation Regarding Electronic Health Records (EHR), EJBI 2012; 8(2): 11-28 (http://www.ejbi.org/img/ejbi/2012/2/Reimer_en.pdf; 02.10.2014) **[English]**
- UNOFFICIAL English Translation of the Austrian Electronic Health Records Act (http://www.ilia.ch/wordpress/wp-content/uploads/2014/03/austrian_ehr-act_ILIA.pdf; 02.10.2014) **[English]**