Big Hungarian health databases

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- The list of databases
- Common features of these databases
- Privacy protection issues concerning to these personal health data
- Ethical considerations
- Interdependence between databases
- Presenting databases one by one
- International examples of such databases
List of databases

- Accounting data at the National Health Insurance Fund
- Coded version of the above database (TEA, Itemized Health Database)
- National Cancer Registry
- National Registry of Newborns with Congenital Development Disorder (VRONy)
- National Vaccination Registry (EFRIR)
- National Screening Registry (OSzR)
- National Guthrie blood sample database
Personal Identification

- Natural personal identifiers: personal name, birth name, place and date of birth, mother’s name, home address (according to the Act XVLII of 1997 on Protection and processing of health data, section 3, point b)

- National Social Insurance ID (TAJ): a lifelong unique identifier of any citizen in Hungary, 8+1 digit (the last digit is a control number). It is used in context of pension and health insurance plus family allowance, benefits, aids, and subsidies. Maintains and issues by the National Health Insurance Fund (OEP, http://www.oep.hu).

- Computerized and standardized population register: whenever TAJ cannot be used – the standardized natural identifiers are enough for identification.
Common Features

- Transferring personal health data to these databases is a legal obligation
- Patients are not informed about data transfer
- Patients cannot consent to the data transfer
- Patients may not require data deletion
- Right to objection is not implemented
- Data processing cannot be disputed before Courts
- Data retention time is not specified (OEP is an exception)
- Joining databases is easy by making use of the National Health ID (TAJ)
- Anonymization is not an issue because processing personal data is provided for by law
Privacy issues I.

- Data are not anonymized
- Data processors have full control of personal data (identified by person name, date of birth, many times living address)
- Data are retained for unspecified time
- The itemized health database (TEA) is coded, therefore considered not containing personal data, but it can be re-identified with a tiny piece of medical information anybody can be looked after patients (they secretly monitoring us)
- Data are used for medical research without consent
- Possibility of selling data or giving them to [pharmaceutical] industrial partners, friends, etc.
Privacy issues II.

- TAJ (National Health ID) is not considered as a personal identifier – since for the first look, one cannot determine the person name, address, etc. belonging to a certain TAJ.
- In the health system, data identified by only a TAJ is not considered as personal data, although this identifier is lifelong, never changing, and data are retained for unspecified time.
- Data can be accessed and transferred by the medical staff without obstacles, no penalties and fines (limiting access needs special education, extra efforts, legal knowledge and courage from the patients).
- There is no obligation to report (publicize) data protection incidents, breaches, or losses.
- No effective data protection officers (several hospitals and the OEP are exceptions).
- There is no standard operating procedures for complaints.
Medical Ethics Issues I.

  - Processing identifiable personal data (or tissue) IS medical research
  - All medical research has to be described in a research protocol and has to be approved by an ethics committee
  - All approved medical research protocol have to be publicized
  - No one can be involved in a medical research against his/her will
  - The declaration is not legally binding.
Medical Ethics Issues II.

The Council of Europe’s Ovideo Treaty (CETS-164, 1997) is legally binding, Law VI. of 2002 on Announcement of the Ovideo Treaty

- Patient interest always prevails research or scientific interests
- All medical research requires ethical approval
- All medical research requires preliminary information, explanation
- All medical research requires consent
- Any time, consent can be revoked
- In Hungary, research on existing personal data does not require providing preliminary information, and obtaining consent. Right to objection in the DPA?
- Medical authorities think so that when data processing is done in accordance with a law – then they do not need to undergo ethical revision (they are above the ethics).
European Law I.

- The Council of Europe’s Rome Treaty or ECHR (European Convention on Human Rights) ETS-005, 1950, is legally binding, Law XXXI. of 1993 on Announcement of the Rome Treaty
  - Article 8. introduced the concept of private and family life
  - The signing states declared that the public authorities keep themselves off from the citizens private and family life with the exception „in accordance with the law and it is necessary in a democratic society in the interests of national security, public safety or the economic well-being of the country, for the prevention of disorder or crime, for the protection of health or morals, or for the protection of the rights and freedoms of others”
  - ECtHR (Strasbourg Court) set out in 1980’s that self health state DOES belong to the private and family life.
European Law II.

- Council of Europe, R(97) No 5. Recommendation on Medical Data Protection
  - Article 4.3. Medical data may be collected and processed:
    - a. if provided for by law for:
      - i. public health reasons; or
      - ii. subject to Principle 4.8, the prevention of a real danger or the suppression of a specific criminal offence; or
      - iii. another important public interest; or
    - b. if permitted by law:
      - i. for preventive medical purposes or for diagnostic or for therapeutic purposes with regard to the data subject or a relative in the genetic line; or
      - ii. to safeguard the vital interests of the data subject or of a third person; or
      - iii. for the fulfilment of specific contractual obligations; or
      - iv. to establish, exercise or defend a legal claim; or
    - c. if the data subject or his/her legal representative or an authority or any person or body provided for by law has given his/her consent for one or more purposes, and in so far as domestic law does not provide otherwise.
European Practice

- Normal medical data processing is done by permission of a law and not as a legal obligation.
- Patients are always given data protection explanation, they have to consent to the data processing.
- Anytime, anywhere data subjects may object.
- Data subjects have right to dispute data processing before Courts.
- Medical data is processed as a legal obligation ONLY for the purposes of prevention and punishment of serious crimes and in life interest of others (preventing epidemics, etc. i.e. for public health reasons).
- Medical data is retained for the minimal time while legal responsibilities are expire, then anyone can ask for deletion (generally after 5 years, lab results are automatically deleted after 2 years).
- Medical health insurance and provision of care are distinguished, insurance is used when patients like to do so.
- Data subjects have the right to remain unidentifiable in any health data transfer in the public interests.
Look at databases one by one
National Health Insurance Fund

- For 10 million people, from January 1, 1998, all consumed medical care events, all medical prescription data
- Really three databases:
  - General practitioners’ (B300) and private doctors’ (prescription) reports
  - Pharmacies prescription reports
  - In and outpatient clinics/hospital reports
- The above three sources can be joined by using TAJ
- A reduced view of the last two can be reached electronically
  - By the patients through eGovernment Portal (http://www.magyarorszag.hu)
  - By the General Practitioners via the OEP portal

National Health Insurance Fund

Legal basis:
- Act LXXXIII of 1997 on Benefits of obligatory social insurance
- Act XLVII of 1997 on Protection and processing of health data, section 22.
- Decree of the Government 43 of the 1999 on Financing medical care provisions from the Health Insurance Fund
- Decree of the Government 134 of the 1999 on Accounting and payment of subsidies to medicines and medical aids
- Decree of the government 217 of the 1997 on Execution of the act LXXXIII of 1997 on Benefits of obligatory social insurance
National Health Insurance Fund

- Primary purpose: provision, planning and accounting benefits for insured ones, and financial inspection of contractual care providers
- Secondary purposes: epidemics, statistics, medical research (suitability of medicines, care protocols, procedures)
- Ternary purposes: prevention and punishment of crime, provide personal data on request of police, courts, national security (thousands of requests per year)
- Retention time: unspecified (until December 31th, 2006); 5 years (from January 1st, 2007 until 24th July 2007); 10 years (from 25th July 2007 until December 31th 2008); 15 years (from January 1st, 2009).
Medical research:
- Hard to distinguish administration from research
- They think: any data processing is administration, even it is required by researchers for the purposes of a research
- No medical ethics supervision
- No independent data protection supervision
- Anyone can request data of public interests upon payment
- The fund can join together longitudinal data from anybody back to 1998 independently from the place of the provision of care
- The fund can join together family data (parents and children, wives and husbands)
Itemized Health Database (TEA)

- Obtained from the National Health Insurance Fund’s database by replacing TAJ with a pseudonym (a code which is different from TAJ)
- The pseudonym remains always the same – a means to collect lifelong medical history about 10 million people
- Retention time: unspecified
- The database is considered not being personal, because pseudonym correspondence are known only by the OEP
- Therefore no data protection rights (information, copy, right to correction, objection, deletion) are provided
- No data protection measures are applied when data are processed (e.g. data can be sold)
Itemized Health Database

- Legal basis: Decree of the Health Minister 76 of 2004 on processing and transfer unidentifiable health data
- The philosophy is: since data is not personal, therefore a decree of the minister can serve as a suitable legal basis
- Beneficiaries: Ministry of Health, Institute for Strategic Health Research, Center for Medical Audit and Inspection, Public Health and Medical Officer Service
- Data containing: exact dates (hours, minutes), ICD-10 (BNO) codes of diagnoses and diseases, medical institutions, medical professionals, prescribed medicine, gender, age, exact postal code. (A medical institution can easily break the database.)
National Cancer Registry I.

- Legal basis:
  - Act XLVII of 1997 on Protection and processing of health data, section 16.
  - Decree of the Health Minister 24 of 1999 on Reporting cancer cases to the National Cancer Registry
- Data content of the report is defined in a decree (not in a law)
- Data subjects are identified by name, date of birth, address, and TAJ, after the death the name, date of birth and address are removed from records (TAJ remains)
- Data is retained forever, deletion is not permitted by decree
National Cancer Registry II.

- Data can be accessed by the data processor (OOI, National Institute of Oncology, [http://www.oncol.hu](http://www.oncol.hu)) and transferred only anonymously (perhaps).
- Data subjects do not get preliminary explanation.
- Data subjects are not allowed to object.
- Data processing and research access is controlled by an Advisory Committee (that is not independent and one sided, quasi ethics committee).
- Reporting doctors may get a copy of all data they have previously sent.
Legal basis:
- Act XLVII of 1997 on Protection and processing of health data, section 16.

Data Processor is: National Centre for Healthcare Audit and Inspection, [http://www.oszmk.hu](http://www.oszmk.hu)

Data subjects (mothers) are identified by name, address, age, and the name and TAJ of the newborn.

Data content is not specified in a legal document.

Retention time is not specified.
Registry of Congenital Development Disorders II.

- Many data subjects do not get preliminary explanation
- Data subjects may not object
- Data subjects cannot dispute processing before the Courts
- Reveals Assisted Reproduction information and genetic data – conflicts with the Law XXI of 2008 on Human genetic assessment and research
- No ethics and data protection supervision
- No publicized access policy and explanation
National Vaccination Database I.

- Legal basis:
  - Act CLIV of 1997 on Healthcare, section 58, paragraph 5

- Data Processor is: National Public Health and Medical Officer Service, [http://www.antsz.hu](http://www.antsz.hu)

- Data content is not specified in a legal document

- Data subjects (children) are identified by name, date of birth and TAJ (has not been published anywhere)

- Retention time is not specified
National Vaccination Database II.

- Data subjects do not get any information
- Data subjects may not object
- Data subjects cannot dispute processing before the Courts
- Data can be accessed in a nationwide network, access policy is not specified
- No ethics supervision
- No data processing supervision
National Screening Database I.

- Legal basis:
  - Act XLVII of 1997 on Protection and processing of health data, section 16/A.
- Under planning
- Data processor is: National Public Health and Medical Officer Service, [http://www.antsz.hu](http://www.antsz.hu)
- Monitors cancer screening: participation, results, follow-ups, efficiency
- Cancer registry provides necessary data
- Data content is not specified in any legal document
National Screening Database II.

- Data subjects do not get any information
- Data subjects may not object
- Data subjects cannot dispute processing before the Courts
- Data can be accessed in a nationwide network, access policy is not specified
- No ethics supervision
- No data processing supervision
National Guthrie strips database I.

- Legal basis:
  - Decree of the Ministry of population welfare 51 of 1997, on Medical screening services of the obligatory health insurance
- Data processors: Pediatrics Clinic of University of Szeged, Pediatrics Clinic of Semmelweis University Budapest
- Screening metabolic diseases from blood samples
- Detecting proteins indicating deficiencies in metabolic system
- Sometimes reveals hereditary genetic information (from parents as well)
- Database contains samples from 1990’s, i.e. about 2 million youngsters because samples are not destroyed
National Guthrie strips database II.

- Data subjects are identified by mother’s name, date and place of birth, and TAJ
- Data content is not specified in any legal document
- Conflicts with the Law XXI of 2008 on Human genetic assessments and research (voluntarily or not, preliminary explanation)
- There is ethical supervision
- There is some kind of data protection supervision
- Right to object, delete sample and data are guaranteed in the law but not implemented yet
Foreign Examples
Privacy Considerations I.

- Coded data – can be broken (can be reidentified)
  - Double coding
  - Include an uninterested third party
  - Prevent reidentification (coded data is never sent to somebody who has means for reidentification)

- Treat coded data as personal data
- Coding or pseudonymizing
- Hash codes (uncertainty, more people may have the same code)
- Destroy code correspondence tables
Privacy Considerations II.

- Data protection supervision of medical research
- Include privacy experts in ethics committees
- Openness, include all stakeholders in decisions
- Prevent collection of longitudinal (long term) data from data subjects
- Use random samples and not complete data sets
SUS (Secondary Use Service) I.

- NHS (UK) data set from all citizens
- Legal obligation – UK did not sign the Ovideo Treaty (UK was aware why)
- Independent organization
- Stores personal data (by NHS id), and provides all data protection rights (copy, information, rectification) excepting deletion and objection
- Under data protection supervision NIGB, National Information Governance Board, [http://www.nigb.nhs.uk](http://www.nigb.nhs.uk)
SUS (Secondary Use Service) II.

- Do not contain information about private care
- Ethics Committee include public members (50%+1, including the chair)
- Publicize information about all approved data uses
- Never provides personally identifiable information (excepting legally well based cases for the purposes of crime prevention or punishment)
- DPC’s office gave license to work for 1 year and renews it on yearly basis
- Implementation of right to object is being considered
German and French Patient Registries

- All German (and French) data subjects have the right being anonymous when processing health data for secondary purposes by the DPA.
- Germany did not sign the Oviedo Treaty.
- RKI (Robert Koch Institute) ID: letters from the personal name, year and month of birth, gender, several beginning digits from ZIP code (hash).
- Cancer Registry and other epidemiological databases use RKI identification.
SNIR-AM France

- Multiple insurance organization (Système National Inter-Regimès)
- France did not sign Ovideo Treaty
- Independent organization
- Double coding (by the help of an uninterested party)
- Retention time is: 3 years
- Data protection supervision (CNIL, La Commission Nationale de l'Informatique et des Libertés)
- A long term (20 years) database from random 1% of population is made by special permission of CNIL
Cases before the Constitutional Court

- 237/D/2009: against universally, obligatory retention of medical data for 30 years
- 134/B/2011: against breaching medical confidentiality in public interests or in the interests of the state by making laws
- 129/B/2008: against medical research without consent and being informed
- 997/B/2010: against section 3 of the DPA, a law is always required for data processing, and therefore a law is always passed
- 1249/E/2008: Hungarian DPA does not contain relevant right to object, right to appeal, and getting legal remedy
- 1065/B/2009: against patient registries functioning as criminal databases – on the basis of legal obligation
- 800/B/2009: against universal employment medical surveillance implemented as an uncontrolled and uncontrollable legal obligation
In Hungary, medical data processing is a repression
- Ethical and data protection issues concerning to these databases do nothing, no one cares
- Ethics committees are unbalanced (members are mainly doctors)
- Privacy means: data is processed by medical professionals (that is all)
- Privacy breaches cannot be sanctioned
- Data that are processed is not limited by law
- Data retention time is not limited by law
- Joining data together is not limited by law
- Long term surveillance is enabled
- Private life is not considered
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