An Ethical Approach to Healthcare Data Privacy and Management

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Ministry of Social Affairs and Health, Finland
Speaker Bio and Learning Objectives

Special thanks to colleagues: Maritta Korhonen, Hannu Hämäläinen, Anne Kallio, Ulla Närhi, Pauliina Puustjärvi, and others

- Director of Health Care (CMO), MSAH 2010-; Senior Medical Adviser of the Finnish Association of Local and Regional Authorities 2004-2009
- Chief of Acute Care, Helsinki University Hospital District 2000-2004
- Vice Chair, European Observatory on Health Systems and Policies
- Specialist in internal medicine and cardiology
- >100 original papers in cardiovascular medicine

Learning objectives:
- **Ethical** and legal frameworks and practical solutions to ensure safe electronic health data: case Finland
- How to incorporate new data into clinical databases: R&D
- How to include patients, physicians and other healthcare professionals in the development and use of e/mHealth
CASE FINLAND
Population 1970

Population 2007

Inhabitant per square kilometer

- 1 - 5
- >5 - 20
- >20 - 100
- >100 - 1000
- >1000 - 190146
- Uninhabited area

Uninhabited area

Aineisto: Tilastokeskus
Kartta: Oulun yliopisto, maantieteet laitos

MINISTRY OF SOCIAL AFFAIRS AND HEALTH
Residence-based, universal and equal right

The public authorities shall guarantee for everyone adequate social, health and medical services and promote the health of the population.

*The Constitution of Finland (731/99), 19 §*
Government norms (legislation) money strategic guidance monitoring

research, education €

 Hospitals Hospital districts

€

Municipalities tax money; autonomous operators of service delivery

Health care centers (primary care)

€

Modified after Professor Martti Kekomäki
Distribution of social expenditure in Finland in 2012 - the common European categorization

Total expenditure in 2012 was 60.0 billion euro, 31.2% of the GDP.

Total health expenditure was 17.5 billion euro, 3229 € per capita, 9.1% of GDP.

Source: National Institute for Health and Welfare and Local and Regional Authorities

MINISTRY OF SOCIAL AFFAIRS AND HEALTH
Infant mortality in EU countries in 2012, per 1000 live births

- Romania: 9
- Bulgaria: 7.8
- Latvia: 6.3
- Slovakia: 5.8
- Malta: 5.3
- Hungary: 4.9
- Poland: 4.6
- UK: 4.1
- Lithuania: 3.9
- Belgium: 3.8
- Netherlands: 3.7
- Estonia: 3.6
- Croatia: 3.6
- Ireland: 3.5
- France: 3.5
- Cyprus: 3.5
- Portugal: 3.4
- Denmark: 3.4
- Germany: 3.3
- Austria: 3.2
- Spain: 3.1
- Italy: 2.9
- Greece: 2.9
- Sweden: 2.6
- Czech Republic: 2.6
- Luxembourg: 2.6
- Finland: 2.5
- Slovenia: 1.6

Source: Eurostat
Challenges

• Ageing population
  – Increased need of services due to multi-morbidity

• Accumulation of social and health problems; poverty, unemployment, poor health, poor mental health, mostly but not exclusively in rural areas
  – 10 % of the population is using almost 80 % of public social and health care resources
  – 2/3 of them need both social and health care

• Increasing socioeconomic / health inequalities

• Increased demand of services due to
  – access to information
  – new technologies
Phases of the economic and needs pressure

- Building phase of the welfare society
- Pensions on the increase
- Increasing need of care
- Economic burden

70 children and elderly per 100 persons in working age
Social welfare and health care reform in the new Government Programme

- Prime Minister Juha Sipilä’s Government Programme was published in May 27th 2015
- Responsibility of all social and health services will be given to 5-19 regional authorities by 2019
- Main targets:
  - reducing socioeconomic inequity
  - improving cost containment
- Main tools:
  - full integration of primary, secondary and tertiary health care as well as public health services with social services
  - maximal digitalization of all services
  - decisions of steering the digital solutions by 12/2015
> 4 M persons have medical documents in Kanta-repository 9/2015
(population 5,4 M)
Monthly visits and different visitors in My Kanta service

<table>
<thead>
<tr>
<th></th>
<th>2010</th>
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<th>2012</th>
<th>2013</th>
<th>2014</th>
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<td>All visits</td>
<td>500 000</td>
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<td>Different visitors</td>
<td>500 000</td>
<td>450 000</td>
<td>400 000</td>
<td>350 000</td>
<td>300 000</td>
<td>250 000</td>
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Kela

8.10.2
ePrescription

National Prescription centre
- ePrescriptions sent by local EHR-systems
- Information of medicine dispensed in pharmacies
- Viewing allowed with patient’s consent

Implementation nearly 100 %
- Pharmacies OK
- Public sector OK
- Private sector 85 %
  - Appr 95% of all prescriptions are ePrescriptions

By legislation obligatory
- For doctors and pharmacies
- Patients can refuse ePrescription till 31.12.2016
- Obligatory 1.1.2017
eDeliveries from pharmacies compared to reimbursed prescriptions years 2009–2015

Million prescriptions

Pharmacies
31.03.2012

Public health care
31.03.2013

Private health care
31.12.2014 (>5000 res/v)

2014 ePrescription for 3,64 M persons (pop 5,4 M)

Kela®

8.10.2015
What about privacy management and data security?

- Prescription data and patient records are sensitive medical information. The KanTa services allow the information to be handled confidentially and securely.

- All communication of data between health care providers, pharmacies, the electronic archive of patient records, and the Prescription Centre is encrypted between authenticated users.

- All users of the Prescription Centre and the electronic archive of patient records must pass an identity check based on a strong authentication scheme.
Data security cnt

- The Prescription Centre is accessible to HC professionals only in relation to their professional duties and requires a professional card issued by Population Register Centre (PRC).

- Electronic signatures are used to verify the signer’s identity and that the information has not changed during transmission or storage.

- Privacy protection and the legality of the information processing are monitored by the health care organisations, pharmacies and Kela (Kanta database manager).

- To enable retrospective checks, log files are kept about the use and release of data.
Patients can check how their personal information is used

- Patients can check the use and release of their personal health information.

- Through the eAccess portal, patients can monitor which organisations access or process their personal information and to which organisations the information is released.

- Patients can also request the register authority to detail who have accessed and processed the data.
### Log files

**Yhteenveto sähköisen reseptin 12.12.2009 tietojen luovutuksista**

**TIESTI ANNA**

- **Lääke**: CIPRAMIL 10 mg
- **Määräaja**: Lääkäri Lars
- **Maarayspaiva**: 12.12.2009

**Reseptin tietoja on käsitelty seuraavissa terveydenhuollon toimintayksiköissä ja apteekissa:**

<table>
<thead>
<tr>
<th>Sijainti</th>
<th>Päivitysajan</th>
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<tr>
<td>Kuopion uusi apteekki</td>
<td>12.12.2009</td>
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</table>
The national health information archive - a success story (?)

**eHealth study 2011***
- Electronic Health Record (EHR) coverage 100 % in the public and 80 % in the private health care
- EHR information exchange 90 % (public, hospital districts)
- Electronical referrals and discharge letters 95 %

**Negative publicity**
- Forerunners dilemma: old EHR systems, poor interoperability
- “Doctors talk to their computers, not to me!”

- Critical features of the new business model:
  - **National criteria for the usability of information systems**
  - Decision-making support for professionals
  - **Active user involvement in the development and adoption of information systems and operating models**
  - Training

# National eHealth and eSocial strategy 2020

Information to support well-being and service renewal

<table>
<thead>
<tr>
<th>Focus area</th>
<th>How to get it done</th>
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<tr>
<td><strong>Citizens</strong></td>
<td>Taking own responsibility - doing it yourself</td>
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<tr>
<td>Professionals</td>
<td>Smart systems for capable users</td>
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<tr>
<td>Service system</td>
<td>Effective utilisation of limited resources</td>
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<tr>
<td>Information use</td>
<td>Knowledge-based management</td>
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<tr>
<td>Refinement of information and knowledge management</td>
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<tr>
<td>Steering and co-operation</td>
<td><strong>From soloists to harmony</strong></td>
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<tr>
<td>Infostructure</td>
<td>Ensuring a solid foundation</td>
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How to incorporate new data into clinical databases?
EHR privacy and consent legislation

- Patient records are sensitive personal information which can only be created and handled according to specific legislation.
- A general consent is used (patient rights act).
- Information of data disclosures between the local provider’s and the Hospital District’s register as well as the Kanta Patient Data Repository must be given upon first contact with the pt.
- Pts must be informed that they can refuse to have their records passed between registers, in whole or partially.
- The Kanta PDR keeps up-to-date information of consent limitations => no retrieval by another unit.
- Refusal is rare; availability of data is expected if not demanded.
- Digital information is generally considered safe.
Citizens as service users - doing it yourself
Strategic objectives by 2020

- Citizens use online services and produce data for their own use and for the professionals.
- Reliable information on well-being easily at hand
- Information on the quality and availability of services is available in all parts of Finland
Public healthcare providers
- Hospital districts (20)
- Primary care org. (192)
- Private healthcare providers (4000)
- Pharmacies (~800)

Other national services
- Kanta services
  - ePrescription service
  - Prescriptions
  - Dispensations
  - Logs
  - Metadata
  - Logs
  - Radiology
  - DICOM studies
  - Health records repository
    - Health records, legacy (CDA R2 L1)
    - Health records, structured (CDA R2 L3)
  - Patient data management service
    - Patient summary management
      - Diagnoses
      - Vaccinations
      - Radiology
      - Procedures
      - Lab
      - Physical findings
      - Risks
      - Health and care plan
      - Medication
  - Pharmaceutical database
  - Service for HCPs
  - Personal Health and Social Record
    - Disability services
    - Other NCPs not yet connected

Main standards
- HL7 V3: CDA R2 Level 3 and Medical Records
- IHE IT-I Profiles
- W3C XML DSig
- WS Addressing, WS-I
- TLS, X.509

Other national services
- National code server
  - Code lists and terminologies
- Form and document structures
- Healthcare and social care organizations register
- Pharmacies register
- Certification services
- Health care professionals register

6.9.2011
SOSIAALI- JA TERVEYSMINISTERIÖ
EU legal framework applicable to lifestyle and wellbeing apps

- EU Data Protection Directive is transposed by national legislations; e.g. EHR legislation
- Some mHealth apps may fall under the definition of medical devices; guidelines available since 2012
- App developers, unaware of data protection requirements, may create unwanted threats to the privacy and reputation of users of smart devices
- As soon as the national own care/self care app will be available in the next few years, discussion on the confidentiality of self-gathered data vs. consumer rights is to be expected
- **Who owns my data?**
Business opportunities in digital health

- Early detection of diseases
- Wellbeing services
- Genetic data
- Environmental data
- Lifestyle data
- Patient data
- Personalised healthcare

- Diagnostics industry
- Social media
- Game industry
- BioIT industry
- Big data
- Remote care
- Biobanks
- Population health management

- PPolar
- Orion
- Nokia
- Microsoft
- Pfizer
- Roche
- Novartis
- Planmeca
- Medieta
- AURIA
- GE Healthcare
- Tekes

Global digital health market EUR 47 bn in 2018
Knowledge management: Knowledge first, then decisions
- Knowledge to support Wellbeing and reformed Services

Real time data and information systems supporting health care
• policy making and managing -> effective, cost effective and high-quality social and health care
• research, development, innovation

⇒ secondary use of personal data (apart from official authorised registries)

EHTEL peer review 2013
Finland will be sitting on a gold mine of information
National Health Sector Growth Strategy for Research and Innovation activities

- Joint strategy created and implemented by 3 ministries
  - Min. Employment and the Economy
  - Min. Social Affairs and Health
  - Min. Education and Culture

- For the first time the strategy examines the health sector from the perspective of innovation and business growth.

- Use of health data and genomic information for drug development and personalized medicine

More information:
Biobanks and health registers are increasingly used for R & D purposes

- National healthcare registers and large clinical & population sample collections provide invaluable information for medical research and innovation.
- Biobanks are established for collecting data and for multiple future research studies ("wide consent").
- Explicit consent from sample donors for every study is not feasible => other safeguarding methods are needed (ethical oversight, pseudonymisation, etc).
- Biobanking and the secondary use of personal data, such as register-based research, should be secured with sufficiently flexible regulation (in the EU).
- Consent withdrawal remains a difficult legal issue.
Finland’s strengths in Personalized Medicine

- Reliable and comprehensive registries and population databases since the 1950’s
- Existence of a legal framework for biobanking and willingness to further develop the legislative framework
- Nationwide electronic patient data repository and MyData
- New interest in nationwide research collaboration
  - Biobanks (BBMRI.fi)
  - Oncology, neurosience
- Very positive attitude of the population towards research
The key is to improve the operating environment of the whole ecosystem
National Biobank ICT-infrastructure

**Biobanks’ own registries & tools:**
- Code registry
- Sample and data registry
- Event registry
- Availability tools
- Consent registry

**BBMRI.fi joint services:**
- Catalogs of different sample collections
- KITE availability tools for collections & variables
- REMS Data Access

**Kanta:** Consents and My Data

**BBMRI-ERIC catalogs**

**Researchers**

**Sample donors**
Dream Big

National health registries

Functional imaging

Lifestyle data

Family history

Microbiome

Reference database

Clinical measurements & imaging

Metabolomics

DNA and RNA Analyses

Dream Big

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The Kanta EHR Repository is not enough!

1. **Data harmonization**
   - Match variables across datasets
   - Create an ontology
   - Add metadata descriptions, keywords…
2. **Technical interface to source**
3. **Pseudo/Anonymization process**
4. **Access policy harmonization**
5. **Sample Locator database**
6. **Operating infrastructure**
BBMRI.fi IT development

› Availability and discovery database for Biobanks (KITE by FIMM)
› Consent and coding management for biobanking and research projects (CORE by FIMM)
› Information management systems (SamWise by THL)
› Resource Entitlement Management (REMS by CSC)
› https://opensource.thl.fi/wiki05/x/4YBb

BBMRI.FI - IT Collaboration

Donor
TERVEYDEN JA HYVINVOINNIN LAITOS

Researcher

ID 1
ID 2
ID 3

Consent
Samples
Data

Consent
ID Recoding
Anonymization
Authorization

SamWise
CORE
KITE
REMS
Discovery

Biobank Internal
National Operator for Health and Well-being Information combined with new legislation on the secondary use of sensitive health data and other sensitive personal information 2015-

1. **Data Creation**
   - Individual
   - Bio-banks “My Kanta” / personal online service for medical details
   - EHR database
   - Genome database
   - Other data sources

2. **Data Gathering and Refining**
   - Integrated and analysed data
   - Data anonymization
   - National Operator

3. **Value Added Services**
   - Analytic services
   - End-user applications
   - Services containing anonymized data
   - Etc.
   - Ecosystem and Partner Network

4. **Utilization of Information**
   - Individual
   - National Centres of Expertise
   - Public Research Institutes
   - Private Research Institutes
   - Pharmaceutical Industry
   - Individual

**Revenue Stream**

**Information Enrichment and Increased Customer Value**

**Audit Trail and Securing Information Reliability**

Sitra • 28.9.2015
The Role of a National Operator

Service operator is responsible for gathering big data on health and well-being information while ensuring the reliability of the data.

- Co-operation with data owners in order to enable data transfer from administrative and technical perspective
- Continuous data gathering from different data sources using appointed interfaces and methods
- Integration of gathered data
- Integrating audit trail into data content

- Data structuring
- Ensuring data quality
- Creating integrated data structure
- Creating technical architecture for providing services
- Enabling the utilization of Big Data and its datasets

- Defining, documenting and providing basic services e.g. standard interfaces together with the ecosystem
- “Made to order” customized interfaces
- Data anonymization depending on usage purpose
- Guidance and support on utilization of basic services
Working Group on National Genome Strategy:
By the year 2020, genomic data will be effectively used in the Finnish healthcare and in the promotion of health and wellbeing

- Ethical principles and legal framework are available for the application of genomics
- Genomics research is integrated into healthcare
- Healthcare workforce have the knowledge and skill to apply genomic information
- Informatics infrastructure is in place for effective application of genomics

- Genomic information is widely used in healthcare to meet the needs of individuals and the population
- People understand and are able to make effective use of genomic information to improve their own health
- In genomics, Finland is an attractive research and innovation environment for collaboration and investment
Regulatory nightmare or protection of patient privacy and safety?
How to include patients, physicians and other healthcare professionals in the development and use of eHealth and mHealth?
WHO 2007: Everybody's Business. Strengthening health systems to improve health outcomes
Service network in Northern Finland
We believe that in times of rapid demographic change (and austerity)

- Uniform social and health services in the case of Finland can still improve population health, promote social inclusion and prevent marginalisation
- A well designed health system *can* provide both adequate benefits and be financially sustainable
- Digitalization is not a goal in itself but key to success
- Digital health care needs good governance and its components should not be adopted randomly
- In particular, citizen involvement and empowerment by mHealth needs data protection and guidance because of the sensitive nature of the personal data
Questions we must be able to answer to maintain people’s trust

- Data & consent management: who can see and who has used my data:
  - my caregivers and service providers
  - biobanks, for what?
  - commercial companies?

- Self-care and self-analysis services
  - who will evaluate and use my data?
  - evidence for better care experience and impact on outcome

- Service modelling & communication tools
  - respect of patient interest & satisfaction
  - maintain the human touch when needed
The age structure is changing among the elderly as well:
the number of elderly people by age group in the current Finnish demographic forecast

Source: Statistics Finland
Healthcare everywhere

THANK YOU!

liisa-maria.voipio-pulkki@stm.fi

Active, vital, healthy individual

Lähde: Modified S. Bialoja, Ernst&Young ; BSF 2014;
Tekesin aineistot

DM 1381236
Disclosure of Relevant Financial Relationships
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**Commercial Interest:** A commercial interest is considered any entity producing, marketing, re-selling, or distributing goods or services.

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Name: Liisa-Maria Voipio-Pulkki, MD, PhD, Director, Health Care Group Ministry of Social Affairs and Health
Event Title: IHF 39th World Hospital Congress, Wednesday Oct. 7, 2015, 1:00 p.m. – 2:00 p.m.
Program Title: Ethics in relation to privacy and management of health data in the context of healthcare delivery.
Relationship: Plenary Speaker

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If Yes, please identify the company and the nature of the financial relationships and compensation below.

<table>
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<tr>
<th>Self and/or Immediate Family Member</th>
<th>Commercial Interest</th>
<th>Type of Relationship</th>
<th>Nature of Compensation</th>
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Please fax or email this document to Megan Angelini by March 6th, 2015 at (312) 424-0023 or mangelini@ache.org