Health Data Governance: Privacy, monitoring and Research. OECD projects, international debate and implications for research, policy and practice

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The Organization for Economic Cooperation and Development (OECD) is a forum where governments of 34 Member States work together with 70 non-member States to promote economic growth, prosperity and sustainable development. The OECD Health Division is the hub where various groups meet to conduct collaborative health projects.

In 2010, Health Ministers called for more effective use of data already collected to provide evidence to improve health care quality.

Between 2010-2016, the OECD Health Committee supported the following projects:

- Health data availability and use (linkage)
- Development and use of EHR data
- Health data governance
- Recommendations on Health Data Governance
OECD Strengthening Health Information Infrastructure
Planning impact on governance of health data


May 2013

International Advisory Panel on Health Information Infrastructure


September 2015

Advisory Group to Develop an OECD Recommendation on the Use of Personal Health Data

OECD Council Recommendation

Ministerial Conference 2017
High priority data – care pathways and outcomes
Oderkirk J, Ronchi E, Klazinga N. Health Policy. 2013 Sep;112(1-2):9-18

Data for scientific knowledge generation and intelligence for health care management and policy can describe *pathways of care* for each patient and *outcomes and costs* of specific pathways.
From care pathway data to high quality and efficient health care
Oderkirk J, Ronchi E, Klazinga N. Health Policy. 2013 Sep;112(1-2):9-18

• Timely and accurate post-market surveillance for adverse drug events
• Timely monitoring of adherence to clinical care quality guidelines and guideline revision
• With administrative data:
  – Timely monitoring of health care pathways, costs and outcomes
  – Evaluate and improve care pathways
• With predictive analytical modelling tools:
  – Support physicians in identifying the most appropriate care
  – Enable health care managers to plan, optimise care provision and minimise costs
• Stratifying patients into groups that share common characteristics (age, sex, disease history, medications, lab or image results) has been difficult.

• With large national databases and international cooperation it becomes possible to:
  – Identify the treatment pathways that are effective for different types of patients
  – Combine with bio-bank data to further stratify the patients and personalise therapies
  – Efficiently select large and homogenous groups of patients for clinical trials of new therapies

From Pathways to Scientific Discovery
Oderkirk J, Ronchi E, Klazinga N. Health Policy. 2013 Sep;112(1-2):9-18
How to build care pathway data?
Oderkirk J, Ronchi E, Klazinga N. Health Policy. 2013 Sep;112(1-2):9-18

• Two key prerequisites
  – Data at the level of individual patients/persons
  – Capacity to follow patients through the cycle of care to relate care to outcomes

• Often requires data linkage because few databases have all of the information needed

• Could be based on electronic health records
Success stories: national and international projects
Oderkirk J, Ronchi E, Klazinga N. Health Policy. 2013 Sep;112(1-2):9-18

• Finland, Korea and Singapore: Cost effectiveness and clinical appropriateness of care reported
• Sweden: Quality and efficiency assessment of clinical guidelines
• Israel and UK: Quality of surgical outcomes
• Australia and Canada: Care transitions for chronic conditions
• Denmark: Waiting times in cancer care
• USA: Monitor safety of medicines, medical devices and biologics; detect and deter insurance fraud
• EU Projects: EUBIROD, EuroHOPE, ECHO, ADR
Independent Evaluation
Euroreach WP2: Coordination with International Health Data Initiatives
http://www.euroreach.net/activities/workpackages/w2

“Based on the success factors and key facts of Best Practice examples....

**Recommendation: use of BIRO technology**

“Establishment of nationwide databases with multiple administrative registry linkages at individual level...

**Recommendation: BIRO can be extended to further diseases and has even been specifically conceived and realized for that, since the entire platform may be parameterized to allow the computation of health indicators for a wide range of diseases”

B.Zander, R.Busse (TUB Berlin) 2011
Privacy enhancing technologies

• Increased availability of large datasets require new technologies to minimize the potential impact of privacy risks and maximise the benefit

• New technologies aimed at safeguarding the statistical and epidemiological information content are needed to make best use of the available information
Architecture of the BIRO system

http://jme.bmj.com/content/35/12/753.full.pdf

BIRO = Best Information through Regional Outcomes
Designed and implemented to report on quality of care and outcomes in diabetes in Europe

Result of the BIRO Delphi panel:
best alternative identified to balance privacy protection and information content
EUBIROD Privacy Performance Assessment


Low average (median):
A5: Disclosure and Disposition (40%)
A9: Individual Access (50%)
A3: Consent (75%)
A4: Use of Personal Information (75%)
A6: Accuracy (75%)

High Variability (standard deviation, range):
A10: Challenging Compliance (39%, 0-100%)
A11: Anonymisation (35%, 45-100%)
A8: Openness (30%, 0-100%)
A3: Consent (28%, 17-100%)
A6: Accuracy (26%, 17-100%)
A9: Individual Access (25%, 0-100%)
Each register can compare own practice against the average of the overall sample and the maximum attainable score.

Example:
- Maximum score in terms of accountability and anonymisation
- Acceptable levels for collection, consent, use and disclosure
- All other factors show poor privacy performance
<table>
<thead>
<tr>
<th>1. DEMOGRAPHIC CHARACTERISTICS</th>
<th>1.1 Basic demographics</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.1 Diabetes status</td>
<td></td>
</tr>
<tr>
<td>2.2 Risk factors for diabetes complications</td>
<td>2.2.1 Obesity and Growth (most recent value in the last 12 months)</td>
</tr>
<tr>
<td></td>
<td>2.2.2 Lifestyle</td>
</tr>
<tr>
<td></td>
<td>2.2.3 Clinical measurements (most recent value in the last 12 months)</td>
</tr>
<tr>
<td>2.3 Diabetes complications</td>
<td></td>
</tr>
<tr>
<td>3. HEALTH SYSTEM</td>
<td></td>
</tr>
<tr>
<td>3.1 Structure (provider level)</td>
<td></td>
</tr>
<tr>
<td>3.2 Structural quality</td>
<td></td>
</tr>
<tr>
<td>3.3 Processes</td>
<td>3.3.1 Foot examination</td>
</tr>
<tr>
<td></td>
<td>3.3.2 Eye examination</td>
</tr>
<tr>
<td></td>
<td>3.3.3 Measurement done (in the last 12 months)</td>
</tr>
<tr>
<td></td>
<td>3.3.4 Treatment (at least one prescription in the last 12 months)</td>
</tr>
<tr>
<td></td>
<td>3.3.5 Management</td>
</tr>
<tr>
<td>4. POPULATION</td>
<td>4.1 Area level</td>
</tr>
<tr>
<td>5. RISK ADJUSTED INDICATORS</td>
<td>5.1 Epidemiology</td>
</tr>
<tr>
<td></td>
<td>5.2 Process quality (in adults with diabetes in the last 12 months)</td>
</tr>
<tr>
<td></td>
<td>5.3 Outcome Quality: Intermediate outcomes (in adults with diabetes in the last 12 months)</td>
</tr>
<tr>
<td></td>
<td>5.4 Outcome Quality: Terminal outcomes (in the last 12 months)</td>
</tr>
</tbody>
</table>
Architecture of the Neo software

(shaded architecture based on the BIRO system)
Patient-based Composite Indicator of Quality of Care in Multimorbidity

Average Percentage: number of processes observed over the number of those expected for each individual profile (N=13,428; Overall mean=45.27)
The EUBIROD Network
http://www.hirs-research.eu/eubirod/members.html

**Coordinating Centre**
Hub for International Health Research (HIRS), Italy

**Members**
Joanneum Research, Austria
Scientific Institute of Public Health, Belgium
National Institute of Public Health, Croatia
University of Zagreb, Croatia
Ministry of Health, Cyprus
National diabetes register, Steno Centre, Denmark
University of Debrecen, Hungary
Ministry of Health, Israel
HIRS, Italy
Serectrix, Italy
Ministry of Health, Latvia
University of Malta, Malta
NOKLUS, Norway
Silesian University of Technology, Poland
Teledmedica Consulting, Romania
University of Ljubljana, Slovenia
IDIBAPS, Spain
Foundation for Care Information, The Netherlands
University of Dundee, UK
University of Surrey, UK

**Partner**
www.bridge-health.eu

**Associated Project**
www.parentregistries.eu

**Joint Action addressing chronic diseases and promoting healthy ageing across the life cycle**
www.chrodis.eu

**Invited Project to discuss a potential ERIC on Health Information**
Commentary

Revision of the European Data Protection Directive: opportunity or threat for public health monitoring?

The link between public health monitoring on one hand and data protection legislation on the other may not be immediately clear to all. Nevertheless, it has a strong relation with the conditions required to build and correctly operate high quality, sustainable public health information systems.

A comprehensive framework for data protection is fundamental to create the best conditions to harmonize access to accurate, complete and up-to-date data. Results of an ad hoc survey conducted by a Work Group of the Network of Competent Authorities [an advisory body in the field of health information] open consultation launched by the EC to gather input for the DPD revision.

The scarcity of responses received from the public health field seems to indicate that experts may be not completely aware of the relevance that privacy legislation in general, and the EU Directive in particular, have for their activities.

Current controversy

Health research and systems’ governance are at risk: should the right to data protection override health?

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ABSTRACT

The European Union (EU) Data Protection Regulation will have profound implications for public health, health services research and statistics in Europe. The EU Commission’s Proposal was a breakthrough in balancing privacy rights and rights to health and healthcare. The European Parliament, however, has proposed extensive amendments. This paper reviews the amendments proposed by the European Parliament Committee on Civil Liberties, Justice and Home Affairs and their implications for health research and statistics. The amendments eliminate most innovations brought by the data protection. On this basis, the Commission is undergoing a revision of the EU Data Protection Directive (DPD).

A “Communication on a comprehensive approach on personal data protection in the European Union” was enacted in 2010. The Communication acknowledged that privacy and data protection rights should not unnecessarily limit other fundamental rights enshrined in EU Treaties, including the right to health/healthcare; thus, confirming that the right to privacy is not an absolute right. It also highlighted that, despite a common EU legal frame-
OECD Workshops

• Joint Consultation of the OECD Health Care Quality Indicators Expert Group and the Working Party on Information Security and Privacy, 11th May 2012


http://www.oecd.org/health/health-systems/health-meetings-presentations.htm
Current situation

• Most countries have national data covering many of the key elements of the health care pathway
  – hospitalisations, emergency care, primary care, long-term care, prescribed medicines, registries (cancer, diabetes, CVD) deaths, population health, PROMs, census/population registry
• Often data are in silos (separate and disconnected)
• Too few countries are linking across databases for research or to improve the quality of care
OECD study to improve data governance

• Project of the Health Care Quality Indicators Expert Group in 2013/14 to:
  – Uncover and document governance practices and
  – Identify governance mechanisms to enable privacy-respectful data use

• Guided by experts in law, privacy regulation, IT, policy, statistics, and research

• 22 countries participated
### Advisory Panel Members

<table>
<thead>
<tr>
<th>Members</th>
<th>Area of expertise</th>
<th>Countries</th>
<th>Level of engagement</th>
</tr>
</thead>
<tbody>
<tr>
<td>6</td>
<td>Privacy law</td>
<td>Australia, Italy, USA, UK***</td>
<td>High</td>
</tr>
<tr>
<td>5</td>
<td>Health Statistics</td>
<td>Canada, Finland*, Italy*, Korea*, Switzerland*</td>
<td>High</td>
</tr>
<tr>
<td>2</td>
<td>Health Research</td>
<td>Finland, USA</td>
<td>High</td>
</tr>
<tr>
<td>3</td>
<td>Health IT</td>
<td>Canada, Netherlands, USA</td>
<td>High</td>
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<tr>
<td>5</td>
<td>Health Policy</td>
<td>EC, Israel**, Japan*</td>
<td>High</td>
</tr>
<tr>
<td>7</td>
<td></td>
<td></td>
<td>Low</td>
</tr>
</tbody>
</table>

*HCQI Expert Group members
**Health Committee member
***Security and Privacy in the Digital Economy member
Study framework

Data Governance Framework

Proposed data use

Benefits:
- Individuals' rights to health
- Societal values:
  - Health
  - Care quality
  - Care accessibility
  - Care affordability
  - Safe care
  - Scientific discovery
  - Efficient public services
  - Patient benefits:
    - Health
    - Care quality
    - Coordination of care
    - Health system benefits:
      - Savings in data collection costs
      - Efficiency gains
      - Market share
      - Innovation/discovery

Decision to process personal health data

Maximises Benefits and Minimises Risks

Proposed data use

Risks:
- Individuals' rights to privacy
- Societal trust in:
  - Government
  - Health care providers
- Societal values:
  - Privacy
  - Sharing data
  - Patient risks:
    - Lost privacy
    - Discrimination
    - Identity theft
    - Health system risks:
      - Lost privacy
      - Decreased trust
      - Lost market share
Interviews with experts

- Question sets tailored to each type of expert
- Experts in data privacy, project approval, data processing, access, routine use and analysis
- Interviews to understand current practices to:
  - Govern data
  - Initiate and approve projects
  - Protect data security
  - Process data
  - Provide access to data
- Interviews completed with 50 experts
  - Legal experts in 11 countries and operational experts in 15 countries
Analysis

- APHII reviewed draft findings from the country survey and expert interviews in spring 2014
- APHII participated in a modified Delphi survey to identify elements of:
  - Data governance framework that maximises societal benefits and minimises risks
  - Taxonomy to guide evaluation of risks and benefits
- APHII met on 21 May 2014 to discuss and revise aspects of the recommendations where views diverged and outline the structure of the report
Key health data availability, maturity and use

Score is the sum of the percentage of national datasets meeting seven dataset content and use factors (Highest score = 7)

Source: OECD HCQI Country Survey, 2013/14
<table>
<thead>
<tr>
<th>National health data linkage projects conducted on a regular basis…</th>
<th>Country</th>
</tr>
</thead>
<tbody>
<tr>
<td>With 7+ national datasets</td>
<td>Canada, Finland, Israel, Korea, Singapore, Sweden, United Kingdom (England, Scotland and Wales)</td>
</tr>
<tr>
<td>With 5-6 national datasets</td>
<td>Australia*, Belgium*, Denmark, France*, New Zealand, Netherlands, United States</td>
</tr>
<tr>
<td>With 3-4 national datasets</td>
<td>Czech Republic, Iceland, Norway, Spain, Malta*</td>
</tr>
<tr>
<td>With 1-2 national databases</td>
<td>Ireland, Italy, Switzerland, Portugal*</td>
</tr>
<tr>
<td>None</td>
<td>Germany*, Japan, Poland*, Turkey</td>
</tr>
</tbody>
</table>
OECD 2015 - Health Information Infrastructure
State of play of data linkage


- Hospital in-patient data
- Cancer registry data
- Mortality data
- Emergency health care data
- Mental hospital in-patient data
- CVD registry data
- Prescription medicines data
- Population census/registry
- Population health survey data
- Formal long-term care data
- Primary care data
- Patient reported outcomes
- Diabetes registry
- Patient experiences survey data

Record linkage to regularly monitor health care quality and system performance
Unique ID included and used consistently
National personal health data available
## Thirteen countries regularly linking across pathways of care

<table>
<thead>
<tr>
<th>A</th>
<th>B</th>
<th>C</th>
<th>D</th>
<th>E</th>
</tr>
</thead>
<tbody>
<tr>
<td>Canada</td>
<td>Canada</td>
<td>Canada</td>
<td>Canada</td>
<td>Korea</td>
</tr>
<tr>
<td>Czech Republic</td>
<td>Israel</td>
<td>Denmark</td>
<td>Finland</td>
<td>Singapore</td>
</tr>
<tr>
<td>Denmark</td>
<td>Korea</td>
<td>Finland</td>
<td>Israel</td>
<td>UK (Wales)</td>
</tr>
<tr>
<td>Finland</td>
<td>New Zealand</td>
<td>Korea</td>
<td>Korea</td>
<td></td>
</tr>
<tr>
<td>Israel</td>
<td>Norway</td>
<td>New Zealand</td>
<td>Singapore</td>
<td></td>
</tr>
<tr>
<td>Korea</td>
<td>Singapore</td>
<td>Sweden</td>
<td>UK (Wales)</td>
<td></td>
</tr>
<tr>
<td>New Zealand</td>
<td>Sweden</td>
<td>UK (Scot. &amp; Wales)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Norway</td>
<td>UK (Eng., Scot. &amp; Wales)</td>
<td></td>
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<tr>
<td>Singapore</td>
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<tr>
<td>Sweden</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>UK (Eng., Scot. &amp; Wales)</td>
<td></td>
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<td></td>
<td></td>
</tr>
</tbody>
</table>

Source: OECD HCQI Country Survey, 2013/14
Sharing and accessibility of data

- Score is the sum of the percentage of national datasets meeting 6 accessibility factors (Highest score =6)

22 Countries

Source: OECD HCQI Country Survey, 2013/14
## Number of national dataset custodians

<table>
<thead>
<tr>
<th>Number of Custodians</th>
<th>Countries</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-2 custodians</td>
<td>Czech Republic, Iceland, Italy, Japan, Switzerland, Turkey, UK England &amp; Scotland</td>
</tr>
<tr>
<td>3-4 custodians</td>
<td>Canada, Denmark, Finland, Israel, New Zealand, Singapore, Spain, Sweden, United States</td>
</tr>
<tr>
<td>5-6 custodians</td>
<td>Korea, UK Wales</td>
</tr>
<tr>
<td>7 or more custodians</td>
<td>Ireland, Netherlands, Norway</td>
</tr>
</tbody>
</table>
Sharing identifiable data among national data custodians for research or statistics (dataset linkages)

<table>
<thead>
<tr>
<th>Custodians</th>
<th>Countries</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-2 custodians</td>
<td>Czech Republic, Iceland, Italy, Japan, Switzerland, Turkey, UK England, UK Scotland</td>
</tr>
<tr>
<td>3-4 custodians</td>
<td>Canada, Denmark, Finland, Israel, New Zealand, Singapore, Spain, Sweden, United States</td>
</tr>
<tr>
<td>5-6 custodians</td>
<td>Korea, UK Wales</td>
</tr>
<tr>
<td>7+ custodians</td>
<td>Ireland, Netherlands, Norway</td>
</tr>
</tbody>
</table>

Sharing identifiable health data among national custodians:
Permitted
Not permitted (unless consent or legal authorisation)
Not permitted but linkages still occur through consistent encryption of identifiers or trusted 3rd party
Other challenges sharing identifiable data

Among public authorities in general:
- Data collection authority uncertainty (Czech Republic)
- Trouble negotiating transfers (Singapore, Turkey)
- Slow negotiations (Canada, USA)

Among health and statistical authorities:
- Netherlands, Switzerland and USA have linkages take place within the NSO
- Iceland negotiated method for bi-directional sharing
- UK NSO legally authorised to share

Among health care providers and public authorities:
- Trouble negotiating sharing with private providers
  (Canada, Netherlands, Iceland, UK)
# Sharing de-identified micro data

<table>
<thead>
<tr>
<th></th>
<th>Academic and non-profit researchers</th>
<th>Commercial sector researchers</th>
<th>Foreign Researchers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Permitted</td>
<td>16</td>
<td>10</td>
<td>15</td>
</tr>
<tr>
<td>Permitted only for unlinked data</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Not permitted but access still occurs through secure portals</td>
<td>3</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Not permitted (unless consent is obtained)</td>
<td>2</td>
<td>10</td>
<td>6</td>
</tr>
</tbody>
</table>
Big data and project-specific consent

» Future research and statistical uses of data are not known in a detailed way at the time data is collected (hospitalisation, primary care visit, insurance claim etc.)

» Some data are specifically collected to support future, and not yet specified research – bio banks

» Costs of administering project specific consent questions retrospectively are prohibitive

» Validity of the research results is compromised – known bias toward younger/healthier and less mobile

» Public acceptability of numerous requests is doubtful – robust programs have 1000’s of projects annually
Promising practices

» Project-specific consent for purpose-specific studies (invitation to a survey or a clinical trial)

» Exemptions to patient consent requirements when complete patient data is essential

» Broader consent questions
  » Can be framed as an option to opt-out of datasets that will be used for research and statistics
  » Can be asked by health care providers at the first visit or
  » Can be asked within patient portals (where patients access their own data) as these become more widely available

» Decisions on exemptions or use of data under a broad consent are taken by a credible arms-length approval body
Volumes and recovering costs

» Highest volume of approved access requests in:
  » Denmark with 2000 applications from external researchers per year (40% linkages)
  » New Zealand with 2500 applications (5% linkages)
  » 100’s of requests in Canada, Finland, USA – about 6-10% are linkages - UK England is preparing for high volume

» Cost recovery models used – marginal cost (staff time)
  » Costs much higher where probabilistic matching is needed (lack of consistent ID number)
  » Strategies to lower costs
    » Secure storage of linkage keys to not re-do established links (Statistics Canada)
    » Automation of linkages (UK HSCIC)
Data security environments surrounding data use

Common approaches of national data processors:

» Physical security, separation of duties, staff obligations and training, secure channels for data sharing

» Contractual obligations + follow-up and penalties

Alternatives to transferring data from processors to recipients

» Secure research data centres and remote data access systems
  » Data use limited to within a secure physical or virtual facility
  » Facilities offer analytical software, tools and good processing speeds
  » No ability to print or otherwise remove data or results from the facility until the release is approved by a qualified reviewer

» RDCs in Canada, Japan, Singapore, Netherlands and USA and RDA’s in Canada (Ontario), UK (Scotland and Wales), Netherlands, USA, Korea (pilot) and Denmark (in development)
## Views about the next five years

<table>
<thead>
<tr>
<th>Country</th>
<th>Likelihood that <strong>linked data</strong> are used to regularly monitor care quality</th>
<th>Likelihood that <strong>data from EHRs</strong> are used to regularly monitor care quality</th>
</tr>
</thead>
<tbody>
<tr>
<td>Canada</td>
<td>Likely</td>
<td>Very likely</td>
</tr>
<tr>
<td>Czech Republic</td>
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<td>Very unlikely</td>
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<tr>
<td>Denmark</td>
<td>Very likely</td>
<td>Unsure</td>
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<tr>
<td>Finland</td>
<td>Unsure</td>
<td>Very likely</td>
</tr>
<tr>
<td>Iceland</td>
<td>Likely</td>
<td>Likely</td>
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<tr>
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<td>Likely</td>
<td>Likely</td>
</tr>
<tr>
<td>Israel</td>
<td>Likely</td>
<td>Likely</td>
</tr>
<tr>
<td>Italy</td>
<td>Very likely</td>
<td>Likely</td>
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<td>Japan</td>
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<td>Likely</td>
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<td>Likely</td>
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<td>Singapore</td>
<td>Likely</td>
<td>Likely</td>
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<tr>
<td>Spain</td>
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<td>Very likely*</td>
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<td>Unsure</td>
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<td>Switzerland</td>
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<td>Unsure</td>
</tr>
<tr>
<td>Turkey</td>
<td>Unlikely</td>
<td>Very unlikely</td>
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<td>United States</td>
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<tr>
<td>UK Wales</td>
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<td>No opinion</td>
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</tbody>
</table>
Progress and obstacles

Progress

» Strengthening of legislative frameworks governing health information privacy and use or reforms are underway
» Greater clarity about the interpretation of legislation in practice
» Improvements data quality and tools for data processing
» Progress in developing and standardising EHR systems
» Monitoring and research uses of data have started

Obstacles

» Uncertainty about the impact of the European DPR
» Lack of government priority on solving data use challenges
» Need for more time to implement EHR systems
OECD Health Policy Studies

Health Data Governance
PRIVACY, MONITORING AND RESEARCH
Data governance framework is aligned to maximise benefits and minimise risks:

1. Health information system
2. Legal framework
3. Public communication plan
4. Certification or accreditation of processors
5. Project approval process
6. Data de-identification steps
7. Data security and management
8. Data governance review cycle

Benefits and risks of proposed data uses are evaluated:

**Benefits:** Rights to health, Societal values toward health, health care quality & efficiency, and scientific discovery & innovation

**Risks:** Rights to privacy, Societal trust in government & institutions, Societal values toward privacy & sharing data

Informed decisions to process personal health data are taken
#1 Coordinated development of high-value, privacy protective health information systems

#2 Legislative framework permits privacy-protective data use

#3 Open and transparent information system that builds trust

#4 Accreditation/certification of data processors to promote data security and access

#5 Transparent and fair project approval processes

#6 Data de-identification practices that consider “the big picture” – data protection, security and utility

#7 Data security practices that meet legal requirements and public expectations

#8 Data governance practices that are continuously assessed and renewed
Australia is already well organized to respond to these recommendations...

...but...

- did not participate to the OECD HII Survey

- did not deliver patient-based data for the OECD Health Care Quality Indicators in 2015

  • Mortality after AMI
  • Mortality after Stroke
  • Amputation rates in diabetes
  • Etc...

- does not seem to play a strong role in these discussions...

ALL GOOD?
Major lower extremity amputation in adults with diabetes, 2013

Source: OECD Health at a Glance 2015
http://www.oecd.org/health/health-systems/health-at-a-glance-19991312.htm
8.10. Thirty-day mortality after admission to hospital for AMI based on admission data, 2003 to 2013 (or nearest years)
Mortality after Stroke

Source: OECD Health at a Glance 2015

http://www.oecd.org/health/health-systems/health-at-a-glance-19991312.htm

8.12. Thirty-day mortality after admission to hospital for ischemic stroke based on admission data, 2003 to 2013 (or nearest years)

Note: 95% confidence intervals represented by H. Three-year average for Iceland and Luxembourg.
1. Admissions resulting in a transfer are included.
1. **The health information system supports the monitoring and improvement of health care quality and system performance, as well as research innovations for better health care and outcomes.**

- Is accessible for statistics and research, subject to safeguards
- Data governance protects health information privacy
- Developed by establishing information priorities, data collection requirements and data content standards through formal and open consultation with key stakeholders
- Includes datasets of patient-level data for complete or representative national patient populations for all key health and social care services and for patient characteristics, behaviours and health outcomes
- Includes data from clinical, administrative, laboratory, device and survey sources that can be linked and analysed for approved statistics and research projects
- Includes the collection of consistent, patient identifiers for datasets where identification and/or data linkage is in the public interest
- Follows international standards for the coding of terminology and data interoperability
- Is routinely audited for information content quality and usability for research and statistics
- Enables datasets to be routinely linked for approved on-going monitoring of population health, health care quality and system performance in the public interest
- Enables datasets to be routinely linked for approved research projects in the public interest
Data governance mechanisms
Health Data Governance: Privacy, Monitoring and Research, OECD Health Policy Studies, Paris 2015

2. The processing and the secondary use of data for public health, research and statistical purposes are permitted, subject to safeguards specified in the legislative framework for data protection

The legislative framework should:
- Reflect the basic principles for privacy protection and cover all data sources and custodians
- Require a fair and transparent project approval process including an independent, multi-disciplinary project approval body – publicly report applications for approval and decisions
- Permit use of personal health data for public health, research and statistics in the public interest
- Allow the processing of data, whether by consent, exceptions to consent or specific authorisation, for further approved statistical and research projects
- When given, provide practical means for patients to exercise a right to opt-out of having their data included in a dataset used for future approved research and statistics
- Allow personal health datasets to be linked for approved uses (record linkage).
- Permit the sharing of linkable data among public authorities for approved research and stats
- Permit public authorities and/or trusted third parties to securely store keys to the re-identification of data to enable future approved data linkage projects and government statistics
- Allow sharing and access to de-identified person-level health data for research or statistical projects
  - by applicants from all sectors of society, subject to approval
  - by foreign applicants, where the legislative framework in the foreign country adequately meets the standard for data protection of the home country and subject to approval
Data governance mechanisms
Health Data Governance: Privacy, Monitoring and Research, OECD Health Policy Studies, Paris 2015

3. **The public should be consulted upon and informed about the collection and processing of personal health data**
   - Regular, clear and transparent communication about the collection and processing of personal health data and the benefits, risks and risk mitigations
   - Website describes national personal health datasets, applications for approval to process them and approval decisions

4. **A certification/accreditation process for the processing of health data for research and statistics could be implemented**
   - Comply with data governance norms, support appropriate cooperation for data sharing that minimises barriers, act as a secure national archive, be resourced and required to support fair fees, be accountable for data governance, quality and timeliness

5. **The project approval process should be fair and transparent and decision-making should be supported by an independent, multidisciplinary project review body**
   - Follow an approval criteria that considers both risks and benefits, avoid discrimination, process to apply and criteria for approval are public, summary of applications and approval decisions are public
   - Approval body consults with data custodians, is publicly identified and is accountable for timeliness and quality
6. **Best practices in data de-identification should be applied to protect patient data privacy**
   - Document and audit, create pseudonyms from direct identifiers, retain the mapping, do not disclose pseudonyms, have general rules for data masking that consider “the big picture” — the usability of the data for the purpose and the security around the data use

7. **Best practices in data security and management should be applied to reduce re-identification and breach risks**
   - Basic security including physical and IT security, staff subject to data confidentiality rules, secure channels of data transmission
   - Legally binding contracts with data recipients, mandatory and periodic training for both staff and data recipients, review the physical and IT security of data recipients before transferring data, audit data recipients and any parties involved in data transfers, follow-up to ensure contractual obligations are met, Implement penalties
   - Offer alternatives to transferring data — Research Data Centres, Secure Real-Time Remote Data Access Systems

8. **Governance mechanisms are periodically reviewed at an international level to maximise societal benefits and minimise societal risks as new data sources and new technologies are introduced.**
OECD Council Recommendations are a moral force representing the political will of Member countries.

Expectation that Member countries will do their utmost to fully implement a Recommendation.

Implementation of Recommendations is regularly monitored.

Must be approved of by the Health Committee and the Committee on Digital Economy Policy and then by the OECD Council.

Guidance provided by HCQI and the Working Party on Security and Privacy in the Digital Economy.
Advisory Expert Group

• Advisory expert group co-chairs
  – Jennifer Stoddart, former Privacy Commissioner of Canada, Canada
  – Päivi Hämäläinen, National Institute for Health and Welfare (THL), Finland

• Members with expertise in privacy, law, statistics, research, IT and health policy from government, industry, academia and civil society

• Providing regular input to the draft since September

• In depth discussion on 30th November 2015 at a Paris meeting
## Rationale, purpose and scope

<table>
<thead>
<tr>
<th><strong>Rationale</strong></th>
<th>The twin objectives of maximising societal benefits while minimising privacy risks to the individual require the careful development of strong health information privacy protections and governance.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Purpose</strong></td>
<td>To provide countries with guidance when developing governance frameworks and engaging in legal reforms relevant to health data governance.</td>
</tr>
<tr>
<td><strong>Scope</strong></td>
<td>Applicable to the use of personal health data for promoting health and wellbeing, and to serve other public objectives, including health care quality and system performance monitoring and research.</td>
</tr>
</tbody>
</table>
Three main recommendations are proposed

- Respect individuals’ privacy, data protection and data sharing
  - Recognises the value and importance of rigorous protection of fundamental rights and freedoms, in the context of health data collection, processing and use
  - Builds from existing legal frameworks and OECD Privacy Guidelines

- Implement Ethical and Proportionate Governance
  - Describes a health data governance framework appropriately tailored to the real risks posed
  - Builds from the OECD Privacy Guidelines. The data governance mechanisms put forward in the OECD Health Data Governance report are considered for inclusion.
Three main recommendations are proposed

• Ensure Security and Risk Management
  – Provides general principles of security and risk management appropriate to support data collection, processing and use and to reduce the risk of unwanted data destruction, re-identification or breach
  – Builds from 2015 OECD Recommendation on Digital Security Risk Management. The data governance mechanisms in the OECD Health Data Governance report are considered for inclusion
Challenges

• Develop a Recommendation that will be applicable in the era of “big data” in health care. Expressed in general language for high level decision making, seeking approval of OECD Committees/Council for the Health Ministerial meeting in January 2017

• Data should serve multiple purposes and be governed in a way that will protect patients’ fundamental rights.

• For example:
  – Scope must be relevant today and relevant as new data sources emerge in the future
  – Wording to encompass the possibility of exemptions to patient consent requirements subject to suitable safeguards
  – Describing data de-identification and digital security risk management processes in a way that will be relevant in the future as new technologies emerge
OECD Strengthening Health Information Infrastructure
Planning impact on governance of health data


May 2013


September 2015

International Advisory Panel on Health Information Infrastructure

Advisory Group to Develop an OECD Recommendation on the Use of Personal Health Data

OECD Council Recommendation

Ministerial Conference 2017
Thanks for your attention!