

## Public Good versus Privacy Two National Health Database Projects in Japan

Jan. 31 2016 WMA WG for Ethical cord for Health Database and Biobank  
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## Brief History of Healthcare ICT in JAPAN

- > 1970s Computerized financial systems
- > 1980s Order Entry systems of large scale hospitals
- > 1990s Electronic Medical Record systems
  - Just started to developing experimental systems
- > 1999 Government determined requirements for paperless EMR.
- > 2001 “Grand Design for Healthcare ICT in Japan”
- > 2005 Act for personal data protection
- > 2006 “New IT Reform Strategy”
- > 2010 “A New Strategy in Information and Communications Technology”
- > 2014 “Japan revival strategy”
- > 2015 “Japan revival strategy 2015”

2

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## New IT Reform Strategy (2006)

### > Realizing Ubiquitous and Universal Network Society Where Everyone Can Enjoy the Benefits of IT

1. Structural reform of healthcare through IT
2. An environmentally-friendly society that utilizes IT
3. The world's leading safe and secure society
4. The world's safest road traffic environment
5. The world's most convenient and efficient e-Government
6. Enhanced business competitiveness through establishment of management by utilizing IT
7. Prosperous lifestyle throughout people's lifetime

3

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## Action Plan 2006 (Health field)

### > Make New Grand Design for Healthcare ITC

MHLW announced first draft and emphasizing constructing Japanese EHR

### > Common Infrastructure

Healthcare PKI, Secure Network, and Healthcare smart card

### > ITC Based Healthcare Network

Regional and inter-regional healthcare network

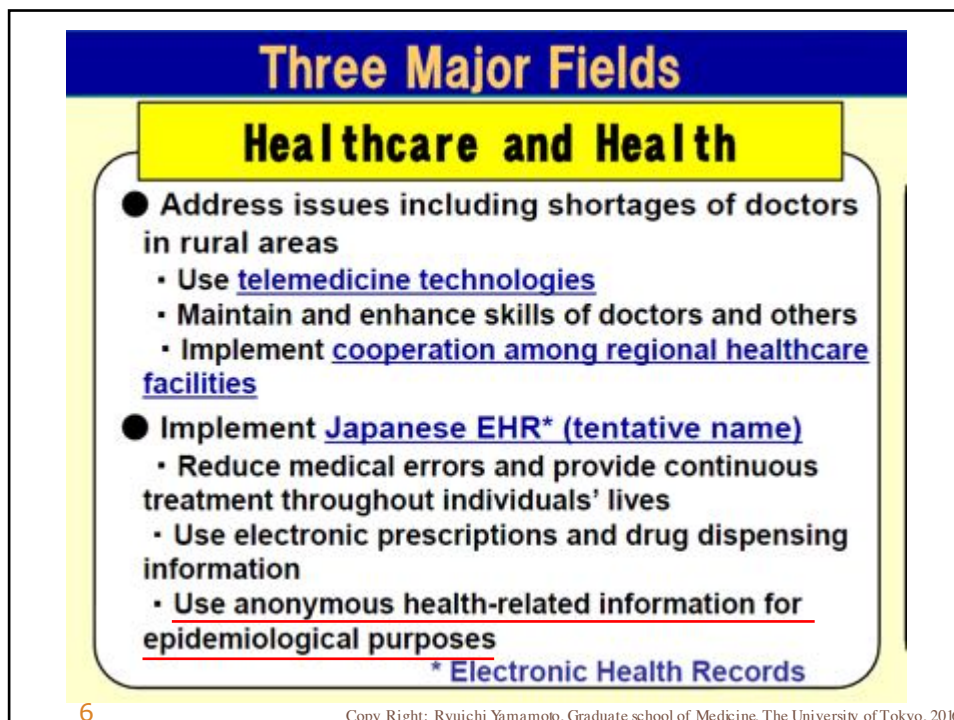
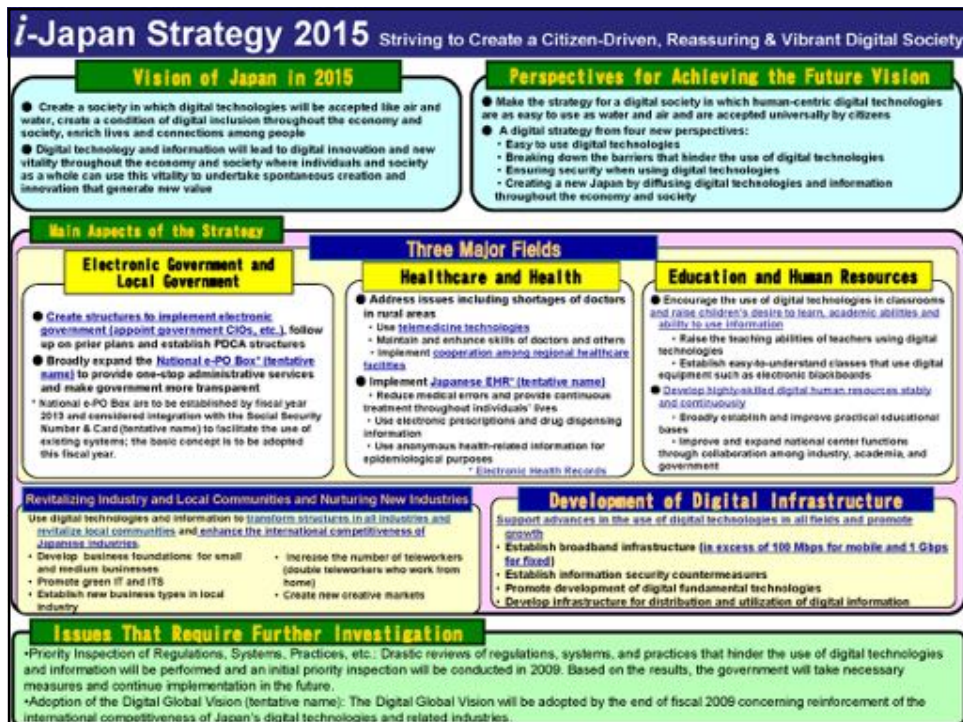
### > Gathering nation-wide health data and analysis.

Developing healthcare terminology and ontology

### > Full Online Handling of Insurance Claims

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## A New Strategy in Information and Communications Technology (May 2010)

> 1. Delivering a citizen-oriented electronic administration

Initiating a citizen identification (ID) system

> 2. Recreating bonding in local communities

A national-level information service shall be created to allow the citizens to electronically manage and utilize their own medical and health-related information in order to create an environment where the citizens may receive medical care based on their medical records anywhere in the country and undertake their own health management. As the first step toward this end we shall create a mechanism enabling individuals to electronically manage their own medication and other information. We shall also create a mechanism wherein anonymized medical insurance claims are listed in databases so that they may be utilized in the process of standardizing and improving the efficiency and quality of services related to medical care.

> 3. Creating new markets and expanding internationally

7

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## Recreating bonding in local communities

> “My Hospital Everywhere”

(Japan’s Personal Health Record service)

> Seamless community-collaborated medical services

(Advanced Healthcare information network)

> **Planning for efficient medical services using medical insurance claim data and others**

**(National medical insurance and health checkup DB)**

> **Promoting pharmaceutical safety through the use of medical information database**

**(Large scale medical information DB)**

> Advancing in-home medical, care, watching, and other services for the aged

8

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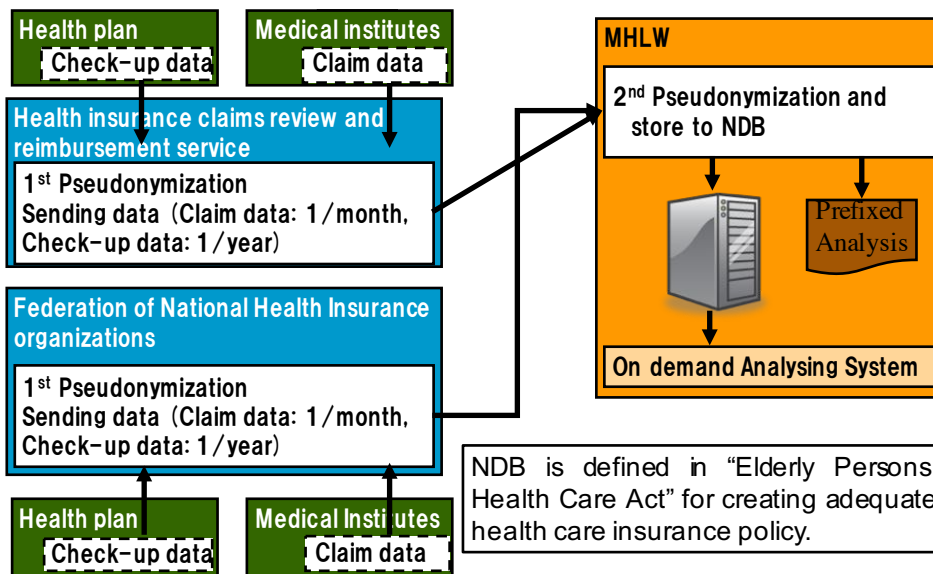
## Major Health databases

Database	Nation	Scale (million )	data	memo
GPRD	UK	6.57	Medical Records	MHRA' DB Derived from 488 general clinics
THIN	UK	5	Medical Records with Pt. identifier	EPIC' DB for replacement with GPRD Derived from 300 GPs
PHARMO	Netherland	> 2	Medical Records	DB of Utrecht Univ. and Rotterdam Univ.
IMS Disease Analyzer	UK, German, France, Australia	15.7	Medical Records	DB of IMS Health inc. Derived from 3600 GPs
i3 Aperio	US	> 39	Claim data, Laboratory test result	DB of i3, a member of United Health Group
Kaiser Permanente	US	> 8.6	Claim data, Laboratory exam result	DB of NPO Kaiser Permanente, Kaiser Permanente has seven research centers and each center has own DB
HMO research network	US	> 40	Claim data	DB of 14 health plans including Kaiser Permanente
Medicare, Medicaid	US	42.3 + 49.3	Claim data EHR data in planning	DB of CMS
Health Services Databases in Saskatchewan	Canada	1	Claim data	DB of local health department of Saskatchewan state of Canada
HIRA	Korea	45 (beneficiaries)	Claim data	Since July 2000
NHI Research DB	Taiwan	23 (beneficiaries)	Claim data	Since January 1996

9

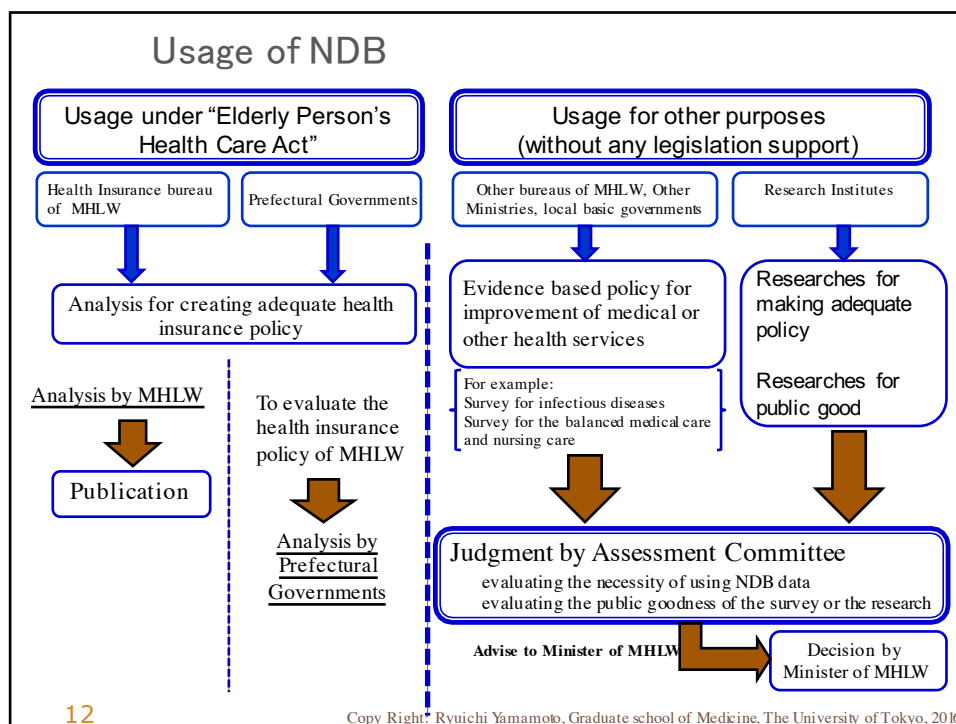
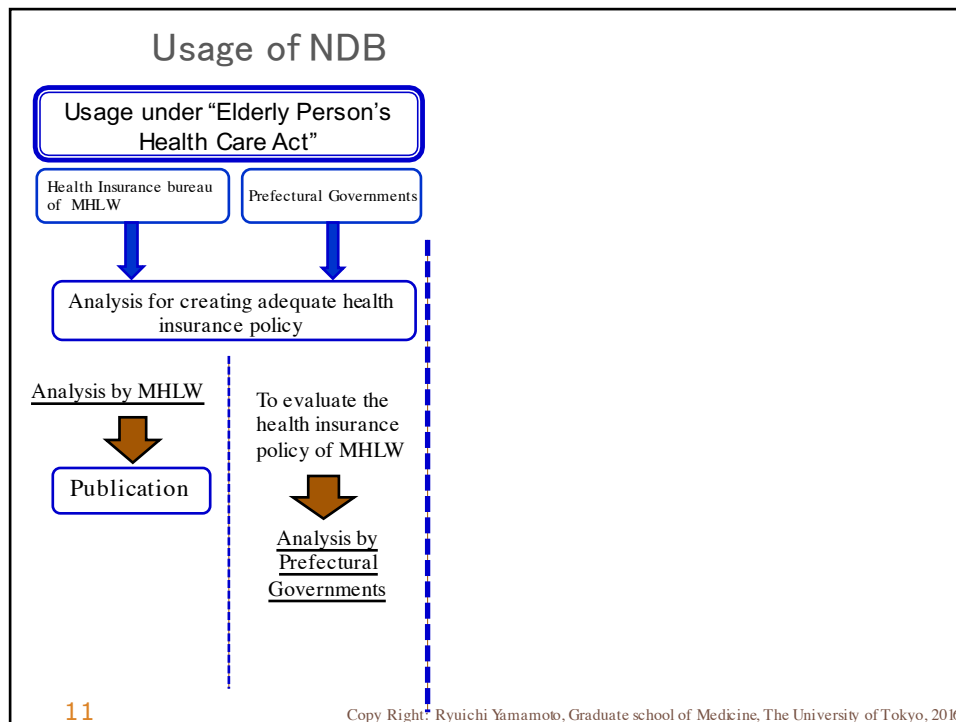
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## National Claims and specific screening information database system of Japan (NDB)



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## Present Status of NDB Japan

- > Over 10 billions insurance claim data and 120 millions of special health checkup related data stored
- > Sampling dataset was released and provided to some researchers.
  - 1% of out patients, 10% of in patients
  - One month (Oct. of 2011)
  - Rare disease name and name of medial procedure was replaced to dummy one up to 0.1% of all claim data.
- > Basic dataset will be released in a couple of year. (DM, malignant disease, renal failure, ..)
- > On-site research center placed at Tokyo and Kyoto.
- > NDB Open Data (a few hundreds simple stastical tables) will be released in a couple of months.

13

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## Insurance Claim data

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Date of birth (only month and year values)  
Diagnosis  
Data of beginning of care and number of days for care  
Health institute ID  
Kind of visit  
Existence of educational guidance  
Prescriptions with drug code, Injections with drug code  
Codes of medical procedures, Codes of Surgical Operations  
Codes of laboratory, physiological and radiological examination (without results)  
Codes of Imaging diagnosis  
Total costs  
Double hashed value of Insurance claim ID, birth date and gender  
Double hashed value of Name, birth date and gender

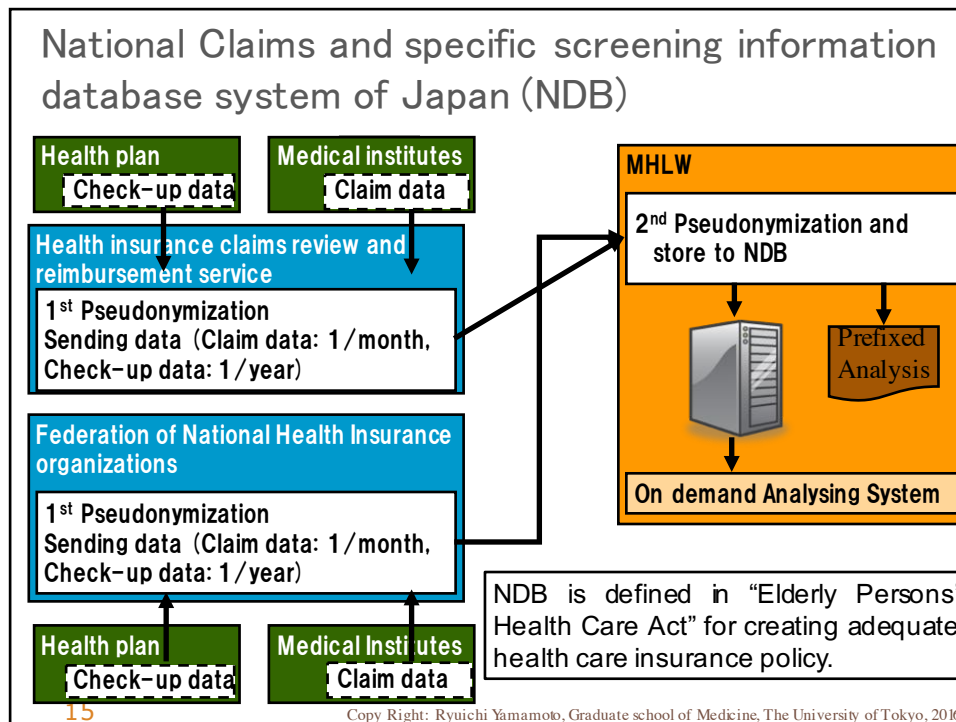
## Health check-up data for life style related diseases

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Date of check-up or educational guidance  
Code of Health plan  
Code of examination institute  
Gender and postal code  
Results of examinations and educational guidance  
Level of educational guidance  
Double hashed value of Insurance claim ID, birth date and gender  
Double hashed value of Name, birth date and gender

14

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Insurance Claim data
Date of birth (only month and year values) Diagnosis Data of beginning of care and number of days for care Health institute ID Kind of visit Existence of educational guidance Prescriptions with drug code, Injections with drug code Codes of medical procedures, Codes of Surgical Operations Codes of laboratory, physiological and radiological examination (without results) Codes of Imaging diagnosis Total costs Double hashed value of Insurance claim ID, birth date and gender Double hashed value of Name, birth date and gender
Health check-up data for life style related diseases
Date of check-up or educational guidance Code of Health plan Code of examination institute Gender and postal code Results of examinations and educational guidance Level of educational guidance Double hashed value of Insurance claim ID, birth date and gender Double hashed value of Name, birth date and gender

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## NDB users policy

- > The purpose of data use shall be exact public benefit.
- > Requested data set shall be minimal required.
- > Data security shall be achieved by the level of Information Security guidelines of MHLW by Information security management system.
- > **Publication policy:**  
 if any table field have more than 20,000 population, any bullets shall contains more than 10 patients.  
 If one table filed have 2,000 – 19,999 population, any bullets shall containd more than 20 patients.  
 Researchers is not allowed to analyze fields less than 2,000 population.

17

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## Korean HIRA DB, Taiwan's NHI Research DB, Japanese NDB

	Korea	Taiwan	Japan
Name of DB	HIRA DB	NHI Research DB	Claims and specific screening information DB
General description	Nationwide insurance claims database (nearly 100% coverage) (Japanese NDB includes health check-up for LRD data)		
Other linkable data sources	Not allowed	Partially allowed if patient consent was provided	Not allowed
Data starting	Since July 2000	Since January 1996	Since April 2009
Number of beneficiaries	48 million	23 million	128 million
Data availability /application for research	Open to restricted researchers who are performing national projects (HIRA Claims Data Providing Review Committee) approval is needed)	Open to academic researchers through application, review for purpose and size of population	Open to researchers through application, review for purpose (under discussion, pilot period from April 2011, and available from April 2013)

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Korean HIRA DB, Taiwan's NHI Research DB, Japanese NDB

	Korea	Taiwan	Japan
Timing of data update	Monthly	Annually	Monthly for claims, annually for health checkup
Latest data	Last month	Previous year	2 months ago for claims
Birth year/month/date	Yes/yes/yes	Yes/yes/yes	Yes/yes/no
Body height /weight	No/no	No/no	Limited to health check data and/or DPC data
Prescriptions			
Prescription month /day	Yes/yes	No/no	Yes/yes
Dispensing month/day	Yes/yes	Yes/yes	Yes/yes
Dose / strength /quantity	Yes/yes/yes	Yes/yes/yes	Yes/yes/yes
Vaccine	No	Yes	Limited to officially reimbursed vaccines

19

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Korean HIRA DB, Taiwan's NHI Research DB, Japanese NDB

	Korea	Taiwan	Japan
Procedures, surgical operations codes	Korea Ministry of Health and Welfare standardized reimbursement coding system	ICD-9 procedure codes	Japan original standardized reimbursement coding system
Hospitalization			
Admission date	Yes	Yes	Yes
Medication while hospitalized	Yes	Yes	Yes
Discharge diagnosis	Yes	No	Yes
Diagnosis code	ICD-10	ICD-9	ICD-10
Laboratory test order/result	Yes/no	Yes/no	Limited to annual health check data

20

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## Unsolved issues of NDB Japan

- > Making legislative basement to use for public good.
- > More open access in case no fear to infringe privacy
- > Establish safe connection to other databases.
  - Cancer registration database
  - Nursing care databases
  - National clinical database (Surgical operation DB)

21

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## Another National Health Database projects: Japanese Sentinel Project

電子化された医療情報データベースの活用による  
医薬品等の安全・安心に関する提言  
(日本のセンチネル・プロジェクト)

概要

平成22年8月

医薬品の安全対策等における医療関係データベース  
の活用方策に関する懇談会

1

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## Japanese Sentinel Project

- > Primarily for drug safety, So, MHLW and Pharmaceuticals and Medical Devices Agency (PMDA) of Japan has significant role in projects.
- > 10 million cohort in 5 years, 8 university hospitals and 2 large hospital groups.
- > Data will be gathered from EMR systems, claim systems, and laboratory systems, so that enough information will be available for drug safety research.
- > Now under construction, on Mar. 2012 first database will start to work.

24

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## The Epidemiologist's Dream: Denmark

Lone Frank

- Epidemiologists in Denmark finished enrolling a cohort of 100,000 pregnant women into a mother-and-child research project last September and expect to finish collecting data from the children over the next year. The entire survey—which is large for this country of 70,000 annual births—is to be completed in 2005 for about \$15 million, a tiny fraction of what the cost would be in the United States.

(Science 2003; vol. 301, no. 5630, p.163)

27

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The screenshot shows the website of The Academy of Medical Sciences. The header includes the logo and the word 'Policy'. A sidebar on the left contains navigation links: Homepage, About us, Support us, Fellows, Policy, Academic careers, The FORUM, Publications, Events, Press, and Contact us. Below the sidebar is a search bar. The main content area is titled 'Previous projects' and lists two years: 2009 and 2008. Under 2009, there are three projects: 'Genome-wide association studies: understanding the genetics of common disease', 'Global health diagnostics: research, development and regulation', and 'Global mental health'. Under 2008, there are four projects: 'Brain science, addiction and drugs', 'Inter-species embryos', 'The role of teaching in academic careers', and 'Building clinical academic capacity and the allocation of resources across'. To the right of the project list is a 'Project Details' section for 'Personal data for public good: using health information in medical research'. It includes a summary, a list of links (Summary, Working Group Membership, Terms of Reference, Review Group Membership, Project Downloads), and a small image of a group of people.

28

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# INSTITUTE OF MEDICINE

REPORT BRIEF • FEBRUARY 2009

## BEYOND THE HIPAA PRIVACY RULE: ENHANCING PRIVACY, IMPROVING HEALTH THROUGH RESEARCH

Our modern electronic world has many benefits and conveniences; emails can be checked from a mobile device and patients provide their medical histories online. But this free flow of information also creates privacy concerns; the risks of data security breaches, identity theft, and discrimination are real. Privacy protections are needed, but they can also impede the flow of information, with negative consequences. In health research, access to patient health information is vital for making medical advances such as new therapies, improved diagnostics, and more effective ways to prevent illness and deliver care. At the same time, effective privacy protections permit health care and research activities to be carried out in ways that preserve patients' dignity, and help protect individuals from harms like discrimination. Thus, privacy protections and ethically-conducted health research provide valuable, interrelated benefits to society and society should strive to support both.

In 1996, Congress enacted the Health Insurance Portability and Accountability Act (HIPAA), which called for a set of federal standards, now known as the HIPAA Privacy Rule, for protecting the privacy of personally identifiable health information. One major goal of the Privacy Rule is to ensure that individuals' privacy is properly protected



In its report, the committee concludes that the HIPAA Privacy Rule does not

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## Using Health data for public good (versus Privacy? )

For balancing privacy and public good, We should discuss about:

- > Future consent and opt out system
- > Simplifying the process of assessing proposals so that researchers can get clear and timely decisions about their projects.
- > Ensure the database security.
- > Patients should participate these discussions.

We need well acceptable ethical cord.

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## WMA Declaration on Ethical Considerations regarding Health Databases and Biobanks

### > PREAMBLE

### > ETHICAL PRINCIPLES

The right to privacy.

Confidentiality is essential.

Informed consent.

Individuals right to be informed, to correct mistakes or to omit.

Individuals have the right to withdraw.

Anonymous data

Independent ethics committee.

Intellectual property

31

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## WMA Declaration on Ethical Considerations regarding Health Databases and Biobanks

### > GOVERNANCE

Management with safeguarded.

Contribution of health professionals

An appropriately qualified physician's appointment

Requirements for Governance:

- **Purpose**
- **Length of time for which the data or material will be stored**
- **Obtaining appropriate consent or other legal basis for data collection;**
- **Arrangements for protecting privacy, confidentiality and autonomy;**
- **How the health data or human material will be accessed;**
- **The person or persons who are responsible for the governance;**
- **The procedures for receiving and addressing enquiries and complaints;**
- **The security measures to prevent inappropriate or unauthorized access;**

32

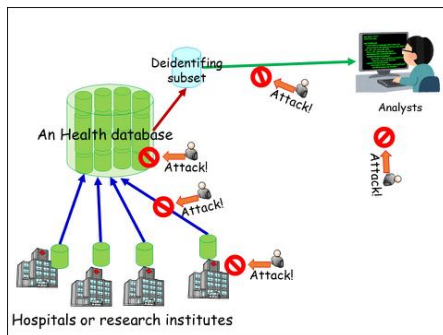
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Biobank

Deep Freezer is so heavy and easily locked.



Health database

“Database” includes:

- > gathering data from various institutes
- > indexing or preprocessing native data
- > send subset to various analysts
- > .....

There are many attack points!

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Thank you for your attention!



34

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