Current Status of Databases in Japan

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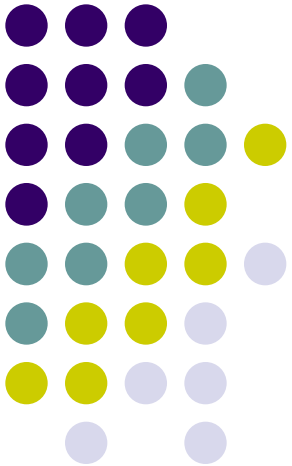
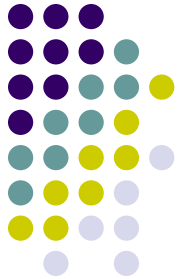




Small Databases

Databases in Japan

- Small databases (including commercially available databases)
  - posted in the web page of Japanese Society for Pharmacoepidemiology (JSPE)
    - http://www.jspe.jp/mt-static/FileUpload/files/JSPE_DB_TF_E.pdf

Electronic Health Record (EHR)-type DB

Claims data From Insurers

Claims data From Pharmacies

English	CCT	Medical Data Vision	Hamamatsu Med Univ	Osaka University	JMDC	JammNet	Medical Front	IMS NPA data	Nihon-chozai	JMIRI	RADAR
Database name	ConvergenceCT Global Research Network (CGRN)	Medical Data Vision EBM Provider®	D☆D: Analytical clinical information retrieval system, Hamamatsu University, School of Medicine	Osaka University	JMDC (Japan Medical Data Center) Claims Database	JammNet	Medi-Trend®	IMS NPA data	NIHON CHOUZAI Pharmacy Claims DB	JMIRI Pharmacy Claims DB	RADAR
General description of	Network to collect, de-identify and summarize	Administrative database for inpatient and	Clinical database based on hospital information system	Clinical database (EMR) based on hospital information system consists of	Claims database consistes of	Claims database using employee'	Pharmacy claims database based on extramural prescription from 650 pharmacies. It	Pharmacy claims database collecting extramural dispense claims	Claims database with extramural dispense claims and primary data (e.g. QoL) from patients visited one of the Nihon-chozai	Pharmacy claims database contains	Post marketing surveillance (AE reporting) for antihypertensive

~2million people

~1million

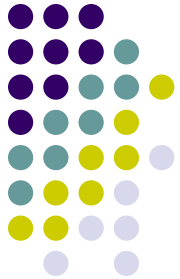
~0.6million

~7million

EHR-type DBs

- Merits
  - (Some) labo-data results are available
  - Patients covered by different-types of insurance are included
  - Almost complete data for inpatients
- Demerits
  - Source population cannot be well defined
    - Individual hospitals have no clear catchment area in Japan
  - not quite representative of the whole patients
  - Follow-up (particularly long follow-up) is difficult
    - All Japanese patients are allowed to make his/her own decision on the medical institution to visit.

Claims data from insurers

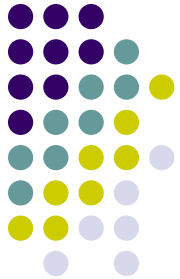


- Merits
  - Relatively long follow-up is possible
    - The insured can be followed unless he/she changes the insurance union (~ around job change).
  - The records of two or more clinics/hospitals he/she uses at the same time are available.
- Demerits
  - No labo-data are available
  - not representative of the whole nation
    - Age distribution is different from the whole population.
    - Data are those of workers and their family

Claims data from pharmacies

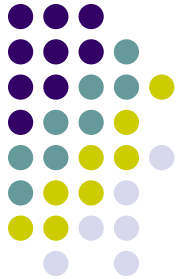
- Merits
  - Records for long period (more than 10 years)
  - Data come from many medical institutions
    - probably more representative as compared to other 2.
- Demerits
  - Source population cannot be defined
  - No data on diagnosis, labo results and procedures
  - Follow-up of individual patients is difficult

Problems common to all DBs



- Linkage to the data source outside the DB is currently very difficult
  - partly due to the lack of the Social Security Number or other identifier used in Health-Care

Two emerging large Databases

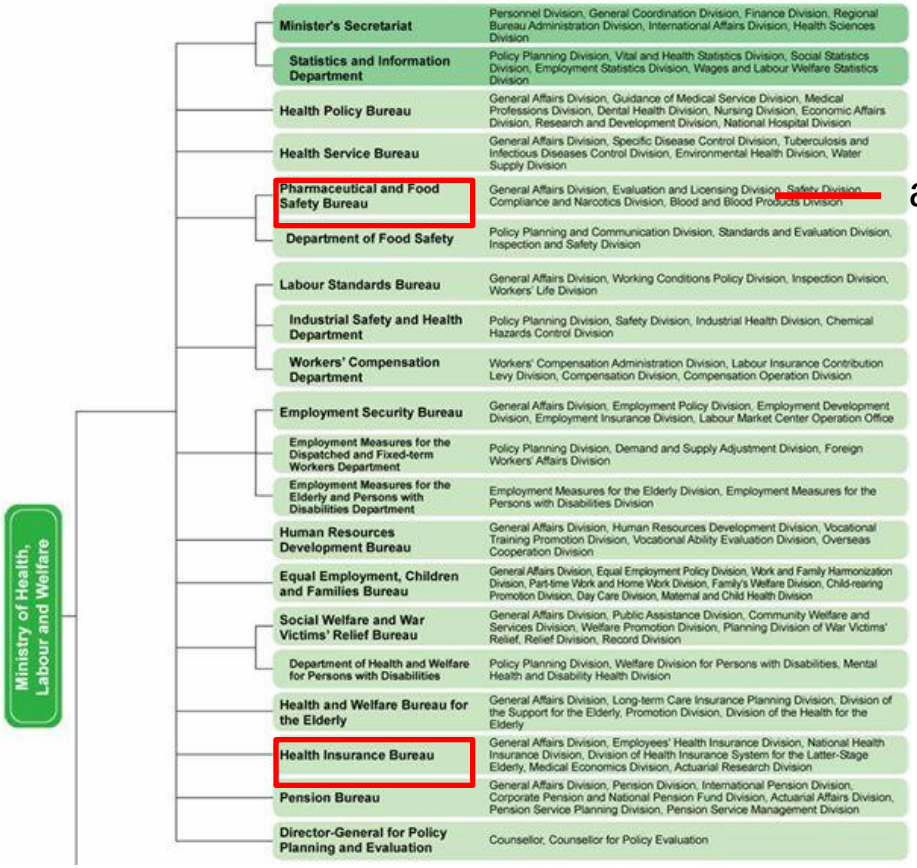


- [A] Medical Information Database*
  - mainly for Japanese Sentinel
    - * No formal English term is available
    - just beginning
  - EHR-type database
    - MHLW Pharmaceutical and Food Safety Bureau (Safety Division) + PMDA (Pharmaceuticals and Medical devices Agency)
- [B] National Database （NDB）
  - Claims database (plus some data from health screening)
    - Health Insurance Bureau
      - in the pilot phase for the secondary use

Two different bureaus for Two large DBs

厚生労働省
Ministry of Health, Labour and Welfare

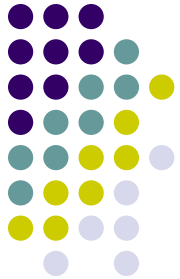
Organization of the Ministry of Health, Labour and Welfare



and Pharmaceuticals and Medical Devices Agency, Japan

[A] Medical Information Database (Japanese Sentinel)

[B] National Database (NDB)



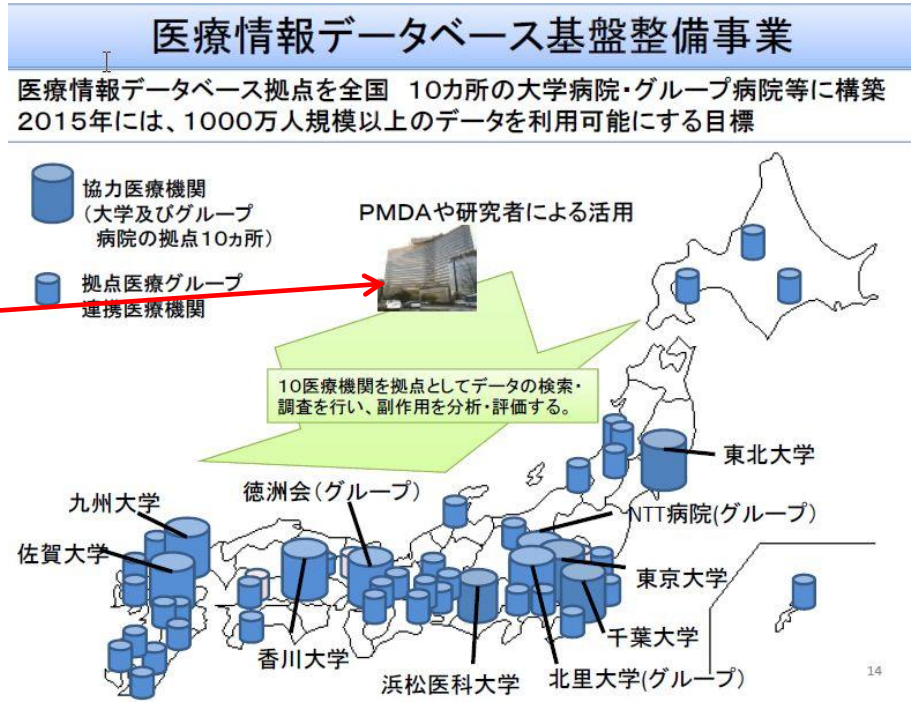
Medical Information Database

(for Japanese Sentinel)

Medical Information Database (for Japanese Sentinel)

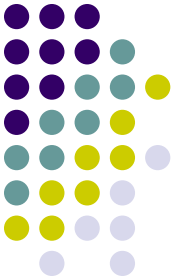
- By 2015, EHR-type data are collected from hospital groups in 5 area in Japan aiming database covering 10 million people

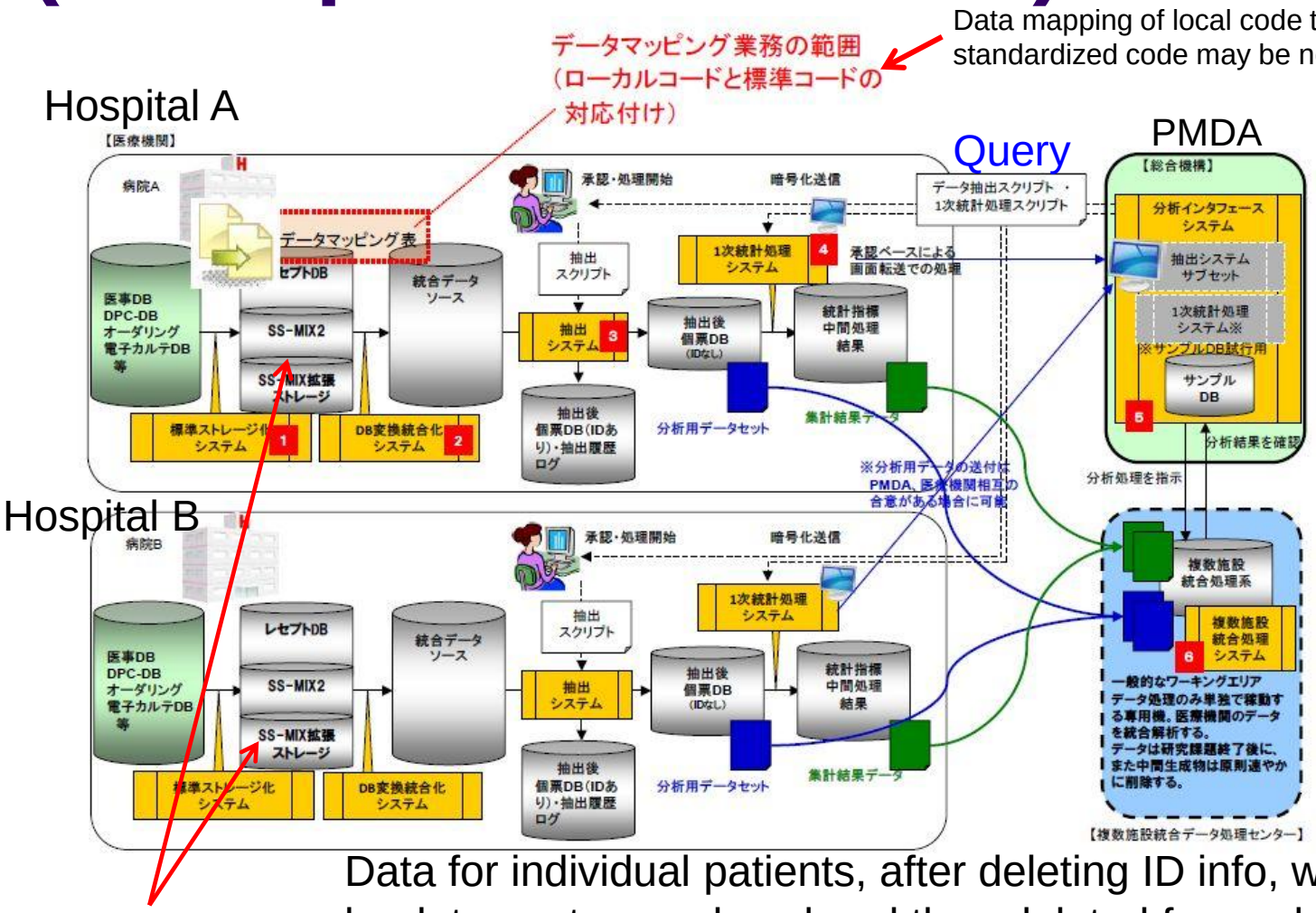
PMDA



http://square.umin.ac.jp/~helics/files/event_20111120/symposium_20111120-04.pdf

Medical Information Database (for Japanese Sentinel)



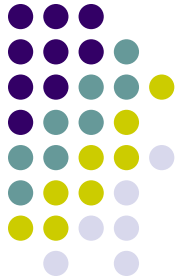


Data for individual patients, after deleting ID info, will be collected by data center, analyzed and then deleted for each query

- SS-MIX: storage of standardized information

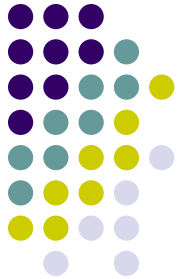
http://www.pmda.go.jp/chotatsu/bid/file/23/20111013_3nyusatsu_si.pdf

Medical Information Database (for Japanese Sentinel)

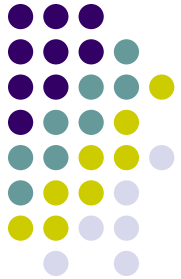


- Merits and Demerits: the same as that for HER-type data
- Merits
  - (Some) labo-data results are available
  - Almost complete data for inpatients
- Demerits
  - Source population cannot be well defined
    - not quite representative of the whole patients
    - Follow-up (particularly long follow-up) is difficult

Data in data center (Medical Information database)

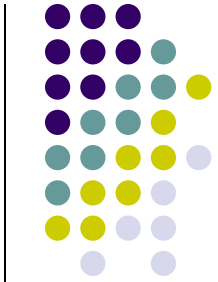


- Data in data center will be not allowed to be linked with other data source at least for the time being.
- For each query, data of individual patients, after deleting ID information, are collected from individual hospitals to the data center, analyzed and then deleted.
  - However, in the future, it may be not impossible to link the data with other data sources because
    - the original data in each hospital have the original ID information



National Database (NDB) in Japan

National Database (NDB)



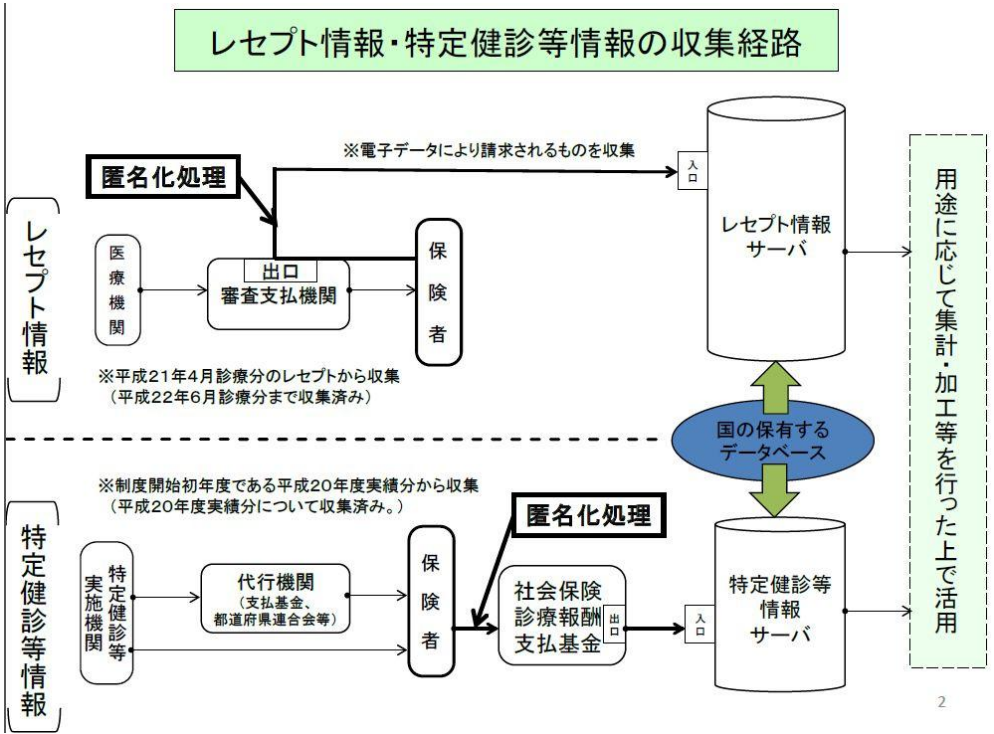
- 2010.10.5 First advisory committee for MHLW
- 2011.03.31 Guidelines for use of NDB during the pilot period (2011.04 to 2013.3) issued by the MHLW
- 2011.08 MHLW received 43 applications for the secondary use of NDB (first application)
  - Governmental bodies
  - Universities
  - National cancer centers and other centers with research activity
  - Drug companies are not allowed to make application (directly)
- 2011.11.10 The advisory committee approved 6 of 43 applications
- 2012.04 Second application will be received by the MHLW (only those who failed in the first application can make application)

NDB(1)

- Data of claims (from 2009.04) plus
- Data of the results of specific health screening
  - Data of about 20 million subjects, 38% (i.e., selective?) of 50-million target (by law) population of 40-74 of age (data on BP, serum lipid, FBS, HbA1c and smoking status)

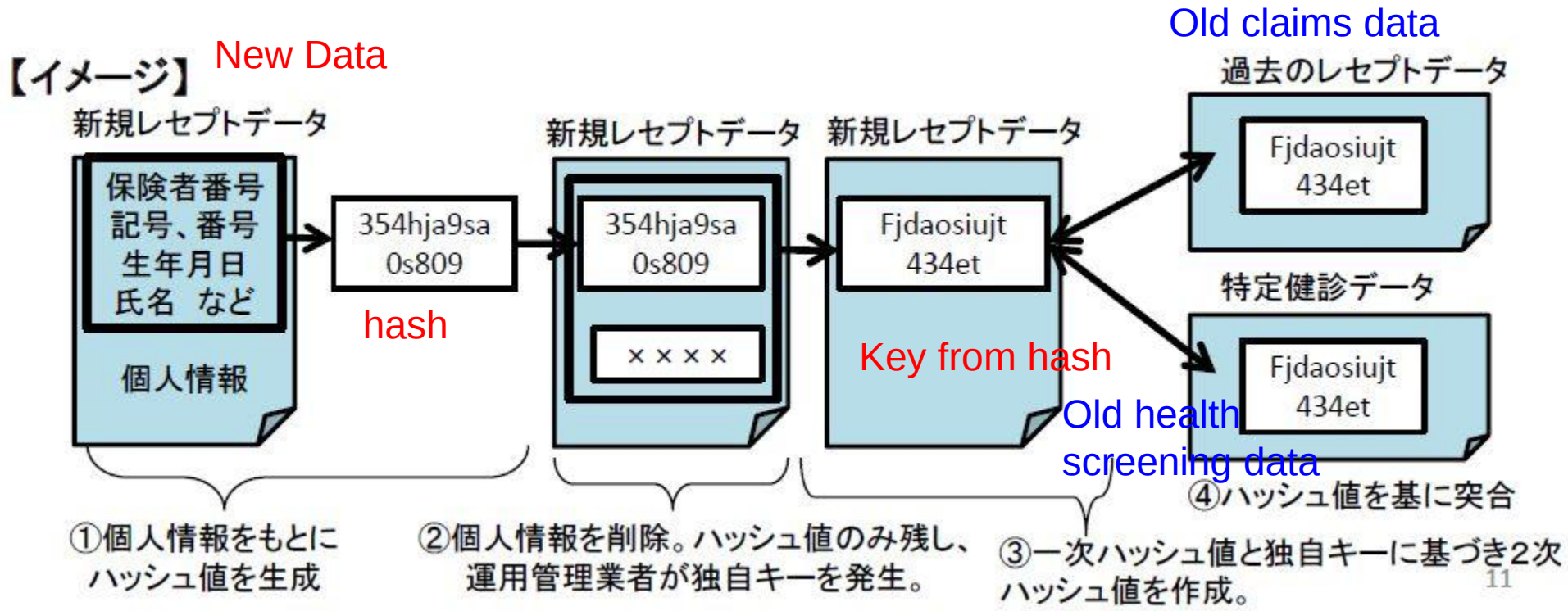
Claims data

Health screening data

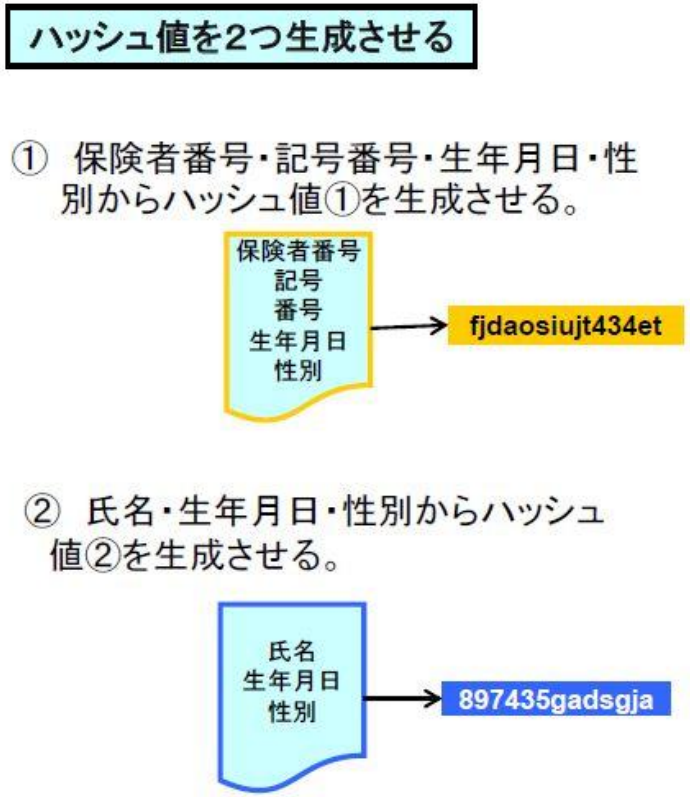


NDB(2)

- New data are added to the old data by using the ID which is undecodable “hash”



NDB(3)



[1] number for insured (two kinds)
DOB
Gender

[2] Name
DOB
Gender

- 2 kinds of “hash” will be made to match old and new data
  - [1] may work when family name is changed (e.g., marriage)
  - [2] may work when moving to different insurance union (e.g., job change)

NDB(4)

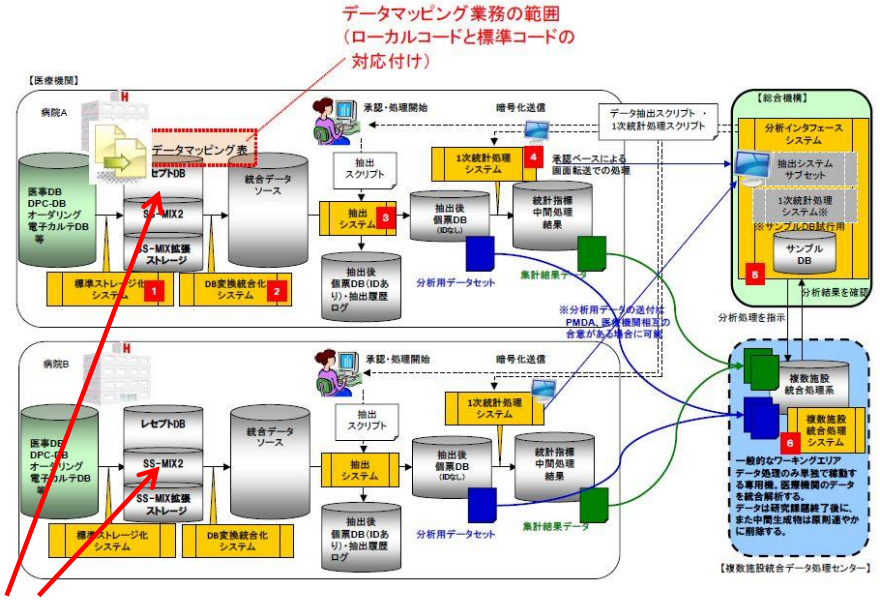
- It will be very difficult or actually impossible to link ID (hash) used in NDB with ID in the data source outside NDB: i.e.,
- Data in NDB
  - cannot be linked with demographic data
  - cannot be linked with disease registry
  - cannot be validated by the original medical record
    - as long as the current policy to use hash is maintained

- SS-MIX may provide a key function in the future Pharmacoepi study in Japan
  - Standard Structured Medical Information eXchange
    - Methods Inf Med. 2011;50:131-9.

Those in individual hospitals can use SS-MIX data in the own hospital

Hospital A

Hospital B

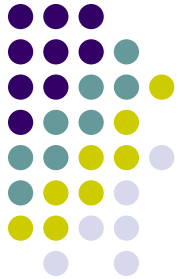


Data Center

- SS-Mix: storage of standardized information

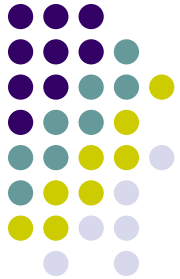
- The data in each hospital can be used with its original ID information inside the hospital.
- The data in SS-MIX is all standardized

Current status of SS-MIX storage



- SS-MIX storage can work when introduced to the hopital with the data in standardized format (HL7 and DICOM)
- About 700 large hospitals have now Hospital Information System with the data in standardized format but only a few hospitals have introduced SS-MIX storage so far.
- Cost is about 200 thousand USD for introducing SS-MIX storage to each hospital.
  - not very expensive but not very cheap
  - some incentive needed for more hospitals to introduce SS-MIX

SS-MIX, when introduced into hundreds of hospitals,



- can identify cohorts of new users of two drugs which may be compared with each other,
- can retrieve all drugs, labo data and diagnostic codes for those cohorts automatically,
- so that physicians who participate in the study in each hospital may just give information on the outcome to complete individual case report and
- may be an important tool in particular because the record linkage is difficult with NDB.