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Second Plenary Session: Monday, 10 September 2018, 8:30 AM - 10:00 AM
Real World Evidence in Asia-Pacific: Are We Ready? Is It Helpful for Decision Makers?

Database, research and regulation in Japan

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Real World Evidence in Japan

Are We Ready?
Is It Helpful for Decision Makers?

NO
(maybe in progress)

2

Topics Today

- Databases
- Researches
- Regulations/guidelines
- Future opportunities

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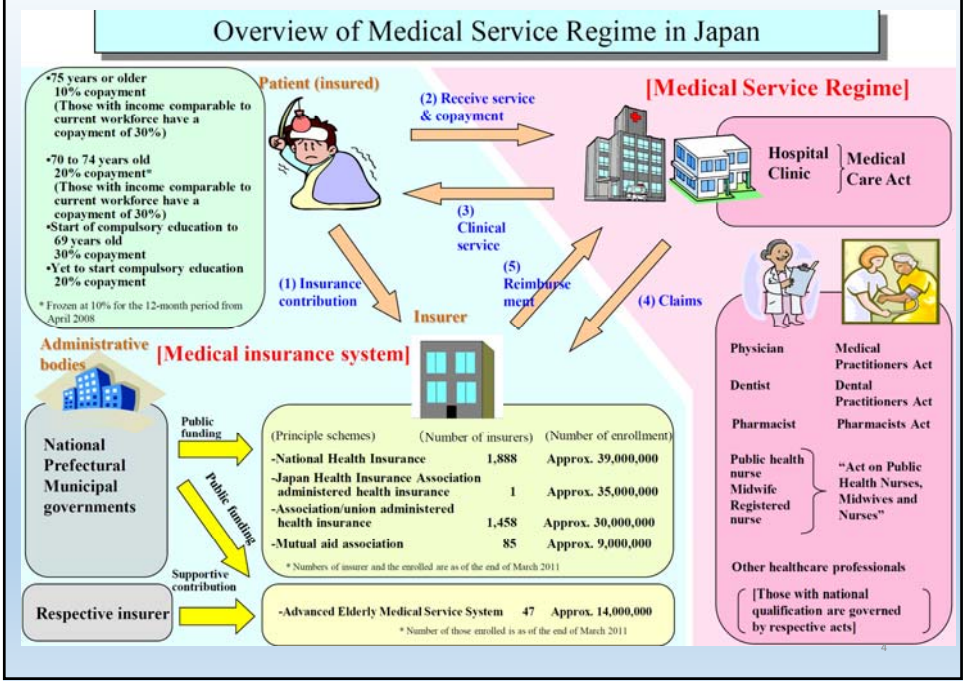

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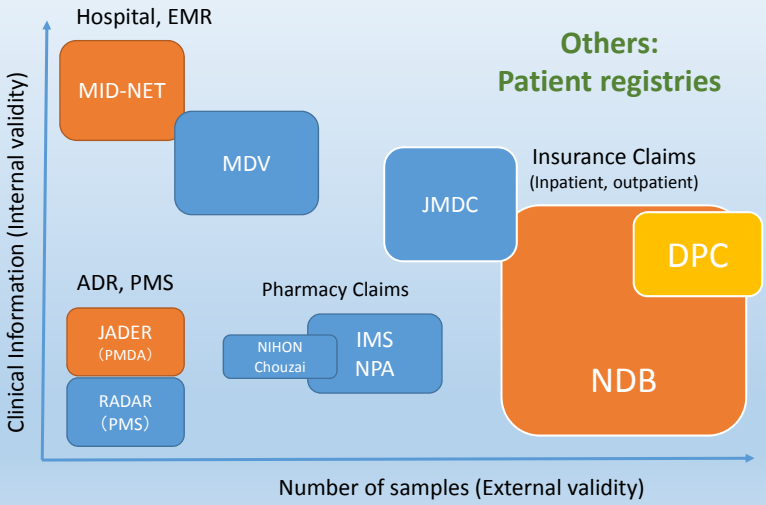
Available databases



Japanese Databases available at http://www.jspe.jp/mt-static/FileUpload/files/JSPE_DB_TF_E.pdf

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NDB

(national database of Health Insurance Claims and Specific health checkups of Japan)

- Health insurance claims data under Japan's National Health Insurance System (14.8 billion records from April 2009 to Dec 2017).
- Since FY2011, 229 research proposals submitted and 178 approved (50% from academic researchers).
- Web-based Open data available (statistical tables of top 30 most-frequently prescribed drugs in FY2014 and 100 drugs in FY2015 and FY2016).
- Onsite research centers at Tokyo and Kyoto Universities will open to support researchers.

Information for researchers (in Japanese) available at http://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryou/iryouhoken/reseputo/index.html

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NDB

Infection (2018) 46:207–214
https://doi.org/10.1007/s15010-017-1097-x

ORIGINAL PAPER

The first report of Japanese antimicrobial use measured by national database based on health insurance claims data (2011–2013): comparison with sales data, and trend analysis stratified by antimicrobial category and age group

Daisuke Yamasaki[1] · Masaki Tanabe[1] · Yuichi Muraki[2] · Genta Kato[3] · Norio Ohmagari[4] · Tetsuya Yagi[5]

Received: 27 July 2017 / Accepted: 27 October 2017 / Published online: 22 December 2017

Abstract
Purpose Our objective was to evaluate the utility of the national database (NDB) based on health insurance claims data for antimicrobial use (AMU) surveillance in medical institutions in Japan.
Methods The population-weighted total AMU expressed as defined daily doses (DDDs) per 1000 inhabitants per day (DID) was measured by the NDB. The data were compared with our previous study measured by the sales data. Trend analysis of DID from 2011 to 2013 and subgroup analysis stratified by antimicrobial category and age group were performed.

For developing National Action Plan on Antimicrobial Resistance

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NDB Open

Rheumatology International (2018) 38:663–668
https://doi.org/10.1007/s00296-017-3900-5

Rheumatology INTERNATIONAL

PUBLIC HEALTH

Wide difference in biologics usage and expenditure for the treatment of patients with rheumatoid arthritis in each prefecture in Japan analyzed using "National Database of Health Insurance Claims and Specific Health Checkups of Japan"

Yasuyuki Kamata[1] · Seiji Minota[1]

Received: 18 August 2017 / Accepted: 30 November 2017 / Published online: 5 December 2017

Abstract
To analyze the biologics usage and expenditure for the treatment of patients with rheumatoid arthritis (RA) in each prefecture throughout Japan using the national open database, the Ministry of Health, Labour and Welfare of Japan disclosed; in Oct 2016, the data of the top 30 most-frequently prescribed drugs during a 1-year period from April 2014 to March 2015 in each prefecture in Japan, along with the patients' age and sex. Seldom-used drugs were excluded. We picked up only biologics for the present study. The total expenditure on biologics used in each prefecture was correlated with the population thereof. However, there was a big difference, up to ~twofold, in the average expenditure used for an RA patient: highest in Toyama and lowest in Wakayama. There was also a big difference, ~4.5-fold, in the number of rheumatologists/1000 RA patients, highest in Kyoto and lowest in Aomori. The average expenditure used for an RA patient was correlated with the number of rheumatologists in the western part of Japan. Etanercept seemed to be used most frequently to Japanese RA patients followed closely by infliximab. Abatacept was used more frequently to the elderly than other biologics. There was a big difference in the number of rheumatologists and expenditure on biologics for the treatment of an RA patient among prefectures in fiscal 2014. Factors that brought this unevenness need to be scrutinized for universal implementation of good RA care throughout Japan, where there are uniform health insurance system and free access to rheumatologists.

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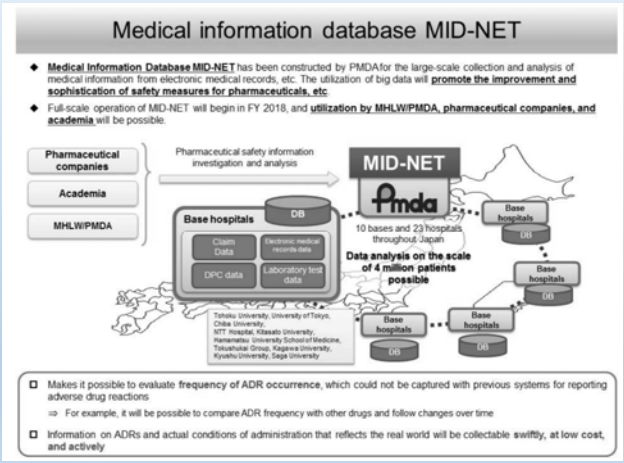
MID-NET
(Medical Information Database Network)



MHLW Pharmaceuticals and Medical Devices Safety Information No. 351 March 2018
available at http://www.pmda.go.jp/files/000223348.pdf

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JMDC

- Insurance provider database
  - Claims data (in-patient, out-patient, pharmacy) from 100 employee-based health insurance payers.
  - Approximately 5.6 million population accumulated since 2005 (4 million in 2015).
  - Data included basic patient characteristics (sex and age), recorded diagnoses, provided medical services, and fees.
  - Can track individuals' movement and treatment across medical facilities (hospitals, clinics and pharmacies).

But,
- No elderly patients over 75 years.
- Limited clinical information available.

Information about JMDC Claims Database
available at https://www.jmdc.co.jp/en/pharma/database.html

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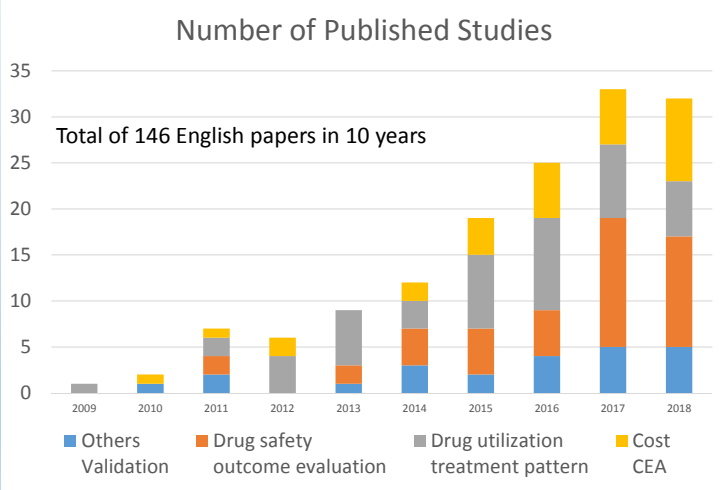
JMDC



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JMDC

PharmacoEconomics (2016) 34:1005–1014
DOI 10.1007/s40273-016-0402-3

CrossMark

ORIGINAL RESEARCH ARTICLE

The Effects of Diagnostic Definitions in Claims Data on Healthcare Cost Estimates: Evidence from a Large-Scale Panel Data Analysis of Diabetes Care in Japan

Haruhisa Fukuda[1] · Shunya Ikeda[2] · Takeru Shiroiwa[3] · Takashi Fukuda[3]

Published online: 25 March 2016

Abstract

Background Inaccurate estimates of diabetes-related healthcare costs can undermine the efficiency of resource allocation for diabetes care. The quantification of these costs using claims data may be affected by the method for defining diagnoses.

Objectives The aims were to use panel data analysis to estimate diabetes-related healthcare costs and to comparatively evaluate the effects of diagnostic definitions on cost estimates.

Research design Monthly panel data analysis of Japanese claims data.

Subjects The study included a maximum of 141,673 patients with type 2 diabetes who received treatment between 2005 and 2013.

Results The average follow-up period per patient ranged from 49.4 to 52.3 months. The number of patients identified as having type 2 diabetes varied widely among the diagnostic definition methods, ranging from 14,743 patients to 141,673 patients. The fixed-effects models showed that the additional costs per patient per month associated with diabetes ranged from US$180 [95 % confidence interval (CI) 178–181] to US$223 (95 % CI 221–224). When the diagnostic definition excluded rule-out diagnoses, the diabetes-related complications associated with higher additional healthcare costs were ischemic heart disease with surgery (US$13,595; 95 % CI 13,568–13,622), neuropathy/extremity disease with surgery (US$4594; 95 % CI 3979–5208), and diabetic nephropathy with dialysis (US$3689; 95 % CI 3667–3711).

Data are used for cost-effectiveness analysis of diabetes care

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MDV (medical data vision)

- Hospital-based database
  - Claims data (in-patient, out-patient) from 369 acute hospitals
  - Total of 9.22 million inpatient and outpatient records in 2016
  - Elderly population over 75 years old included
  - Lab result data available (blood tests)
  - Some clinical information (in DPC discharge summary since 2008)
- But,
  - Special population who use healthcare service at acute hospitals.
  - Limited information before and after hospitalization.
  - No information about location of hospitals.

Information about MDV Database
available at https://www.mdv.co.jp/

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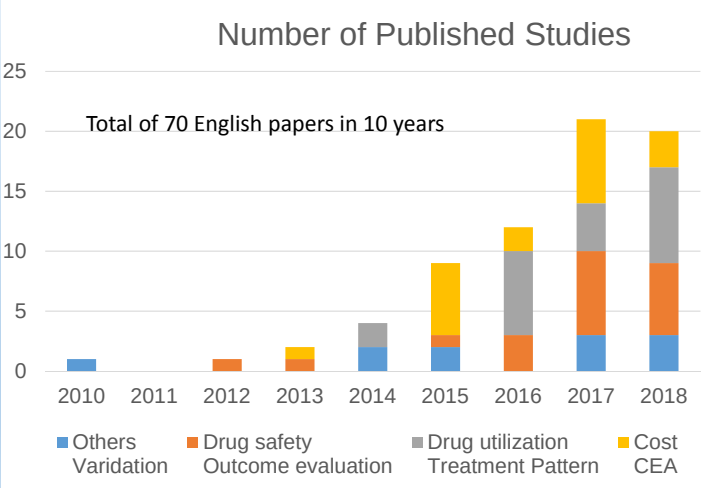
MDV (medical data vision)



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MDV

Konomura et al. Pneumonia (2017) 9:19
DOI 10.1186/s41479-017-0042-1

Pneumonia

RESEARCH Open Access

Economic burden of community-acquired pneumonia among elderly patients: a Japanese perspective

Keiko Konomura[1], Hideaki Nagai[2] and Manabu Akazawa[1*]

Abstract

Background: This study aimed to estimate the economic burden of community-acquired pneumonia (CAP) among elderly patients in Japan. In addition, the study evaluated the relationship between total treatment cost and CAP risk factors.

Methods: An administrative database was searched for elderly patients (≥ 65 years old) who had pneumonia (ICD-10 code: J12–J18) and an antibiotic prescription between 1 June 2014 and 31 May 2015. The all-cause total healthcare costs of outpatient and inpatient CAP episodes were calculated.

Results: This study evaluated data from 29,619 patients with CAP who experienced 14,450 outpatient CAP episodes and/or 20,314 inpatient CAP episodes. The mean ages were 77.5 ± 8.0 years and 81.5 ± 8.2 years among the outpatient and inpatient groups, respectively. The median treatment costs were US$346 (interquartile range: $195–551) per outpatient episode and US$4851 (interquartile range: $3313–7669) per inpatient episode. More severe cases had increased treatment costs at the treating hospitals. Male sex, diabetes, chronic obstructive pulmonary disease, and liver dysfunction were associated with increased total treatment costs, while dementia, dialysis, and rheumatism were associated with high costs of treating a CAP episode.

Conclusions: The economic burden of CAP might be decreased by reducing the number of hospitalizations for mild CAP and the incidence of severe CAP. Therefore, preventative care (e.g. oral hygiene or pneumococcus vaccination) is recommended for patients with related risk factors, such as male sex, older age, diabetes, chronic obstructive pulmonary disease, liver dysfunction, rheumatism, dementia, or dialysis.

Keywords: Community-acquired pneumonia, Economic burden of disease, Cost analysis, A-DROP system, Invasive pneumococcal disease, Pneumonia

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Data are used for cost-effectiveness analysis of adult pneumococcal vaccine

Need to know more

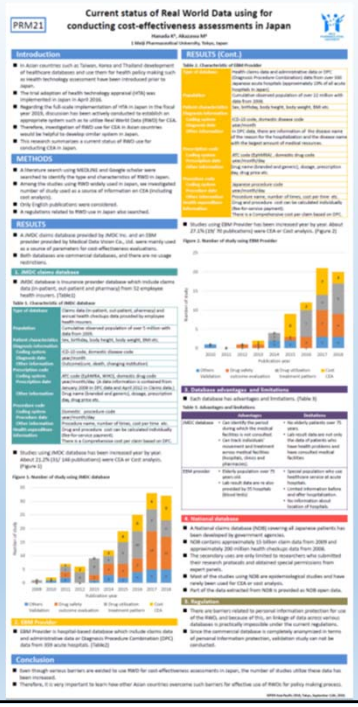
Poster Presentations Session IV
Tuesday, 11 September 2018

RESEARCH ON METHODS - Databases & Management Methods

PRM21

CURRENT STATUS OF REAL WORLD DATA USING FOR CONDUCTING COST-EFFECTIVENESS ASSESSMENTS IN JAPAN

Hanada K, Akazawa M
Meiji Pharmaceutical University, Tokyo, Japan


PRM21
Current status of Real World Data using for conducting cost-effectiveness assessments in Japan
Introduction
METHODS
RESULTS
RESULTS (Cont.)
Conclusion

Revised act on the Protection of Personal Information (個人情報保護法)

Outline of the amendment (effect on May 30, 2017)

- Clearer definition of "Personal Information"
- Rules for utilizing Personal Data
  - Sensitive personal information / de-identified information
- Establishment of Personal Information Protection Commission(PPC)
  - Monitor and supervise
- Globalization

Too much protection of personal medical information → Limit use (access) for medical research → Require new law to promote ICT for research

Ethical Guidelines for Medical and Health Research Involving Human Subjects also updated.

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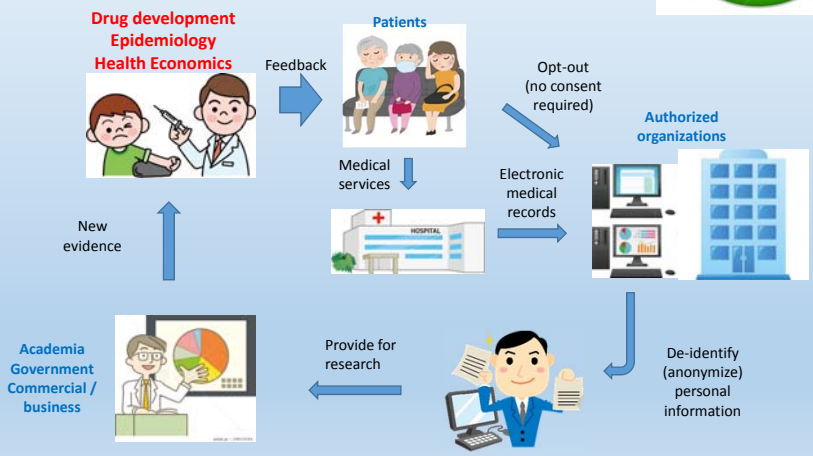
Next-Generation Medical Infrastructure Act (次世代医療基盤法)

Healthcare Big Data Law (effect on May 11, 2018)



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Guidelines

Official guideline for cost-effectiveness evaluation of drugs/medical devices in Japan

Approved by Central Social Insurance Medical Council (Chuikyo) in February 2016
Available as Shiroiwa et al. Value Health. 2017 Mar;20(3):372-378

Guideline on conduct of pharmacoepidemiological study utilizing medical record database for drug safety assessment

Published on March 2016 (Developed by PMDA)
Available at https://www.pmda.go.jp/files/000147250.pdf (in Japanese)

Task-force report for validation study of claims-based definitions for using clinical information

Published on May 2018 (by Japanese society of pharmacoepidemiology)
Available at http://www.jspe.jp/committee/pdf/validationtrr120180528.pdf (in Japanese)

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Future opportunities

- Increased access to clinical personal data
  - Getting better for researchers, still limited for business
  - Clinical Innovation Network (improving infrastructure for clinical study with disease registry @ core hospitals)
- Linkage across various healthcare database
  - Personal ID card (my number card) issued by government
  - Patient registry + insurance claims + death/birth records, etc.
- Education (human resource development)
  - Data Scientists (need both healthcare and IT knowledge)

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