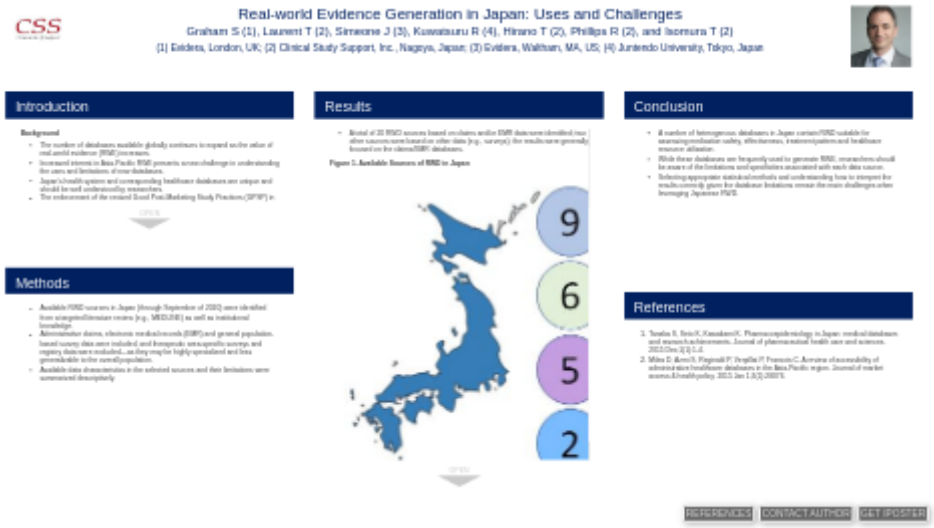
Real-world Evidence Generation in Japan: Uses and Challenges



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PRESENTED AT:

INTRODUCTION

Background

- The number of databases available globally continues to expand as the value of real-world evidence (RWE) increases.
- Increased interest in Asia-Pacific RWE presents a new challenge in understanding the uses and limitations of new databases.
- Japan’s health system and corresponding healthcare databases are unique and should be well understood by researchers.
- The enforcement of the revised Good Post-Marketing Study Practices (GPSP) in 2018 put a greater consideration on post-marketing database studies in Japanese regulatory.

Objective

- This research aims to compare the real-world data (RWD) sources that are available in Japan as RWD are increasingly used to generate RWE on medication safety and effectiveness.

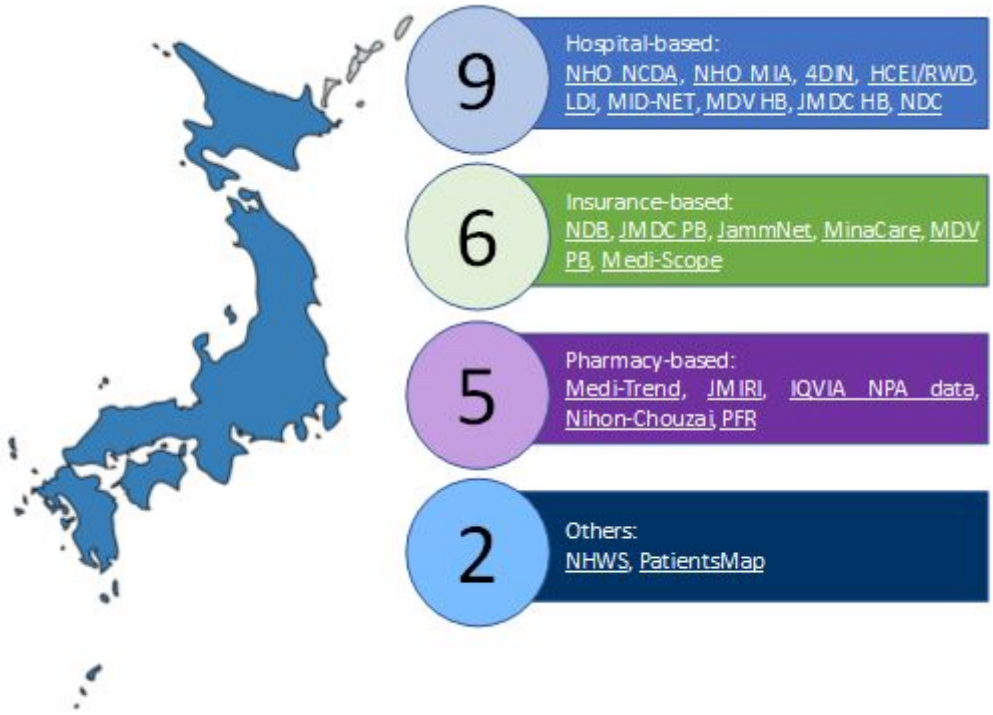
METHODS

- Available RWD sources in Japan (through September of 2020) were identified from a targeted literature review (e.g., MEDLINE) as well as institutional knowledge.
- Administrative claims, electronic medical records (EMR) and general population-based survey data were included, and therapeutic area-specific surveys and registry data were excluded—as they may be highly specialized and less generalizable to the overall population.
- Available data characteristics in the selected sources and their limitations were summarized descriptively.

RESULTS

- A total of 20 RWD sources based on claims and/or EMR data were identified; two other sources were based on other data (e.g., surveys); the results were generally focused on the claims/EMR databases.

Figure 1. Available Sources of RWD in Japan

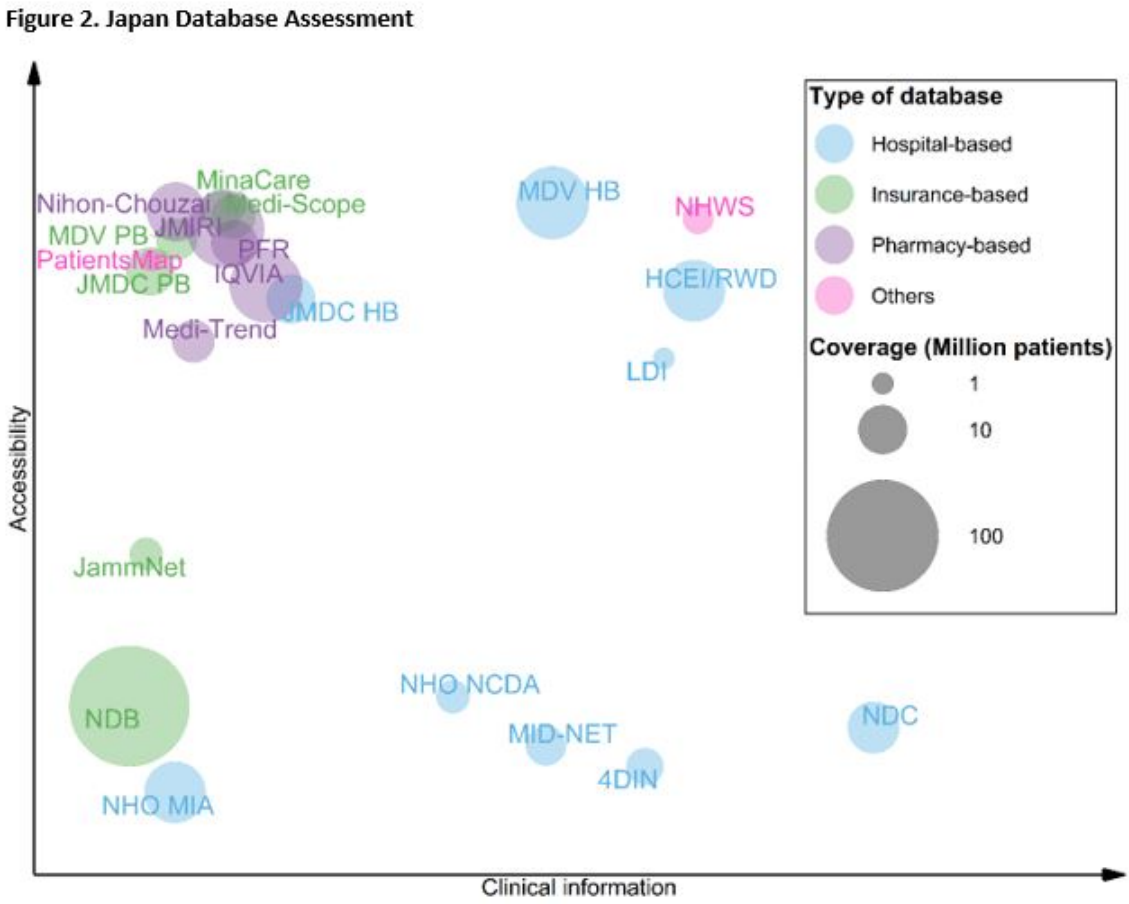


Abbreviations: NHO: National Hospital Organisation; NCDA: NHO Clinical Data Archives; MIA: Medical Information Analysis; 4DIN: a hospital based database owned by 4DIN; HCEI/RWD: Health, Clinic, and Education Information Evaluation Institute / Real-World Data; LDI: Life Data Initiative; MID-NET: Medical Information Database Network; MDV: Medical Data Vision; HB: Hospital Based; NCD: National Clinical Database; NDB: National Database of Health Insurance Claims and Specific Health Check-ups; PB: Payer-Based; JMIRI: Japan Medical Information Research Institute ; NPA: National Prescription Audit; PFR: a pharmacy-based database owned by 4DIN; NHWS: National Health and Wellness Survey Database.

- These RWD sources can be classified as either hospital-based (41%), insurance-based (27%), pharmacy-based (23%), or other sources, such as surveys (9%) (Figure 1). Eighty-two percent of these data include information on outpatient visits, with 64% including information on medications dispensed in the outpatient setting. Sixty-four percent of the databases include inpatient stay data, with 59%, including information on medication dispensed in-hospital. The Medical Data Vision (MDV) and JMDC databases have been widely used in the context of industry-sponsored studies, importantly for investigating treatment pattern and healthcare resource utilization.
- Pharmaceutical companies have access to most of the healthcare databases in Japan:
  - The most easily accessible sources include: Health, Clinic, and Education Information (HCEI)/RWD, Life Data Initiative (LDI), MDV (hospital and payer-based), JMDC (hospital and payer-based), Minacare, Medi-Scope, Medi-Trend, Japan Medical Information Research Institute, Inc. (JMIRI), IQVIA, Nihon-Chouzai, PFR (pharmacy-based database owned by 4DIN), National Health and Wellness Survey Database (NHWS), and PatientsMap.
- The size, type of data, degree of accessibility, and level of clinical information varies across databases (Figure 2).
- The limitations of the identified databases include:
  - Access restrictions
  - Potential for loss to follow-up when patients visit different healthcare facilities (Figure 3)
  - Under recording death data
  - Potential missing data in inpatient records
  - Restricted populations (e.g., only working population)

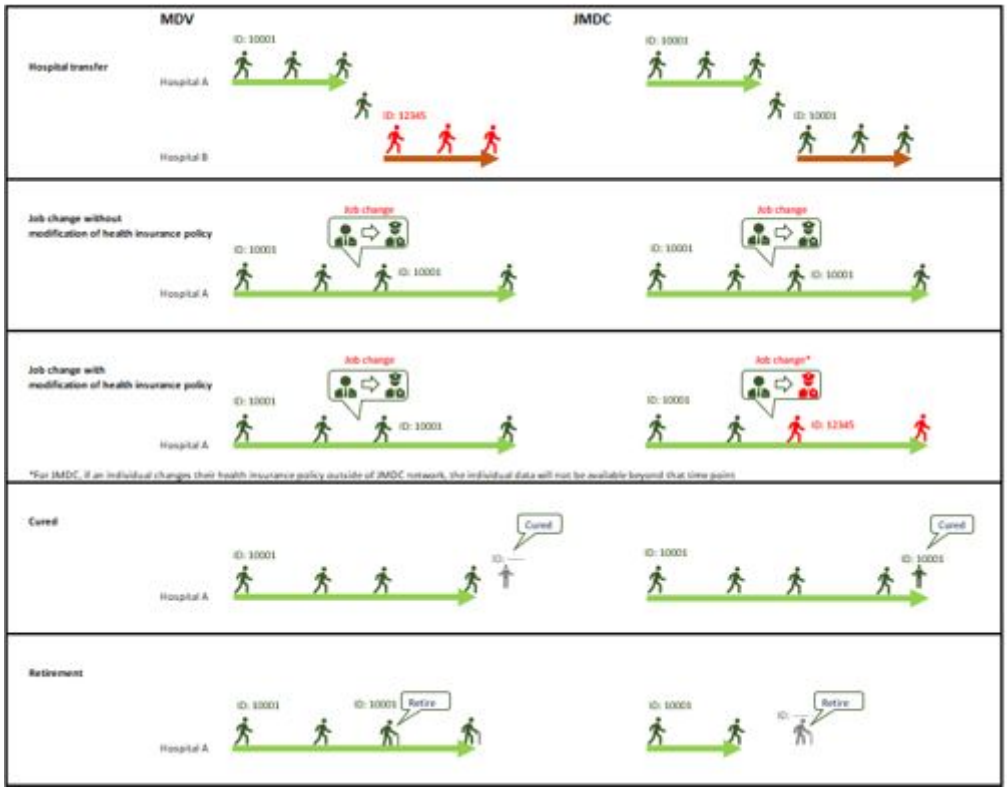
- Non-specific date information (i.e., month rather than day)
- Language barrier (i.e, documentation including data dictionaries)

Figure 2. Japan Database Assessment



Note: Size of each bubble depicts the relative size of each database

Figure 3. Considerations on Patient Follow-Up in MDV and JMDV



CONCLUSION

- A number of heterogenous databases in Japan contain RWD suitable for assessing medication safety, effectiveness, treatment pattern and healthcare resource utilization.
- While these databases are frequently used to generate RWE, researchers should be aware of the limitations and specificities associated with each data source.
- Selecting appropriate statistical methods and understanding how to interpret the results correctly given the database limitations remain the main challenges when leveraging Japanese RWD.

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