

# Real-world Evidence Generation in Japan: Uses and Challenges

**Real-world Evidence Generation in Japan: Uses and Challenges**  
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**Introduction**

**Background**

- The number of databases available globally continues to expand and value of real-world evidence (RWE) increases.
- Increased access to Real-World Data (RWD) presents some challenges in understanding the uses and limitations of these databases.
- Japan's health system and corresponding healthcare databases are unique and should be used judiciously by researchers.
- The advancement of the national Data Facilitating Study Platform (DFSP) in

**Methods**

- Available RWD sources in Japan (through September of 2020) were identified from grey/white literature sources (e.g., MEDLINE) as well as institutional knowledge.
- Administrative data, electronic medical records (EMR) and general population based survey data were included and categorized into specific source and registry database is included, as they may be high operational and less generalizable to the overall population.
- Available data characteristics in the selected sources and their limitations were summarized descriptively.

**Results**

- Based on 23 RWD sources based on studies within EMR database identified from other sources based on other data (e.g., survey) the real-world evidence generally based on the above RWD database.

**Figure 1. Available Sources of RWD in Japan**

**Conclusion**

- A number of heterogeneous databases in Japan various RWD suitable for generating evidence safety, effectiveness, real-world performance and healthcare resource utilization.
- While these databases can be generally used to generate RWE, researchers should be aware of the limitations and opportunities associated with each data source.
- Selecting appropriate data/subjects and understanding how to interpret the results accordingly given the database limitations remain the main challenges when leveraging Japanese RWD.

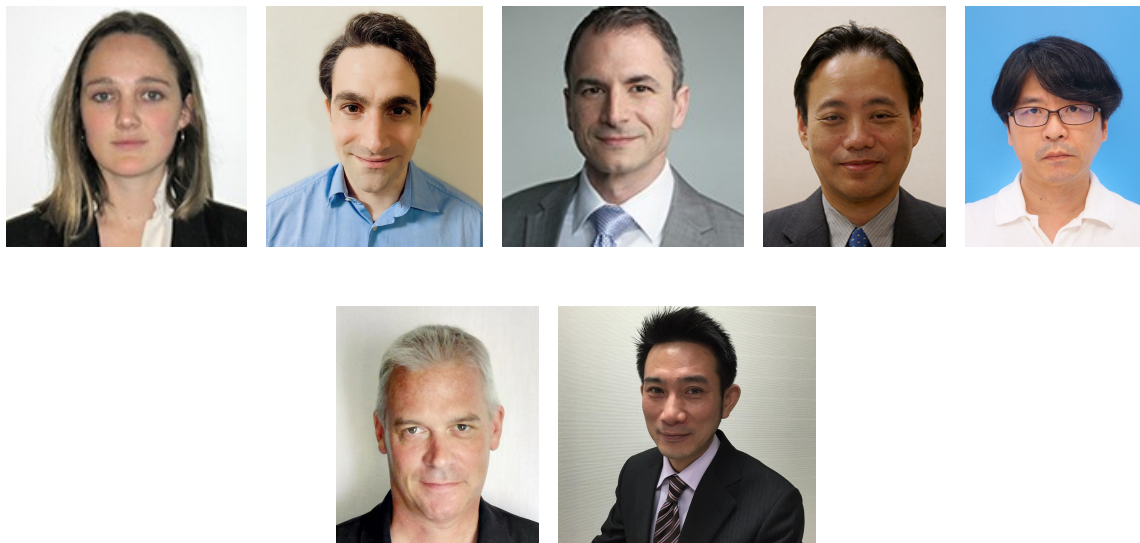
**References**

1. Tanihara H, Imai Y, Kawasumi K. Pharmacovigilance in Japan: real-world data and research challenges. *Journal of pharmaceutical health care and science*. 2020;16(2):1-6.
2. Mura S, Araki C, Kiyonishi T, Ueguchi T, Furusako C. Accuracy of recordability of adverse drug reaction database in the Real-World system. *Journal of real world evidence*. 2020;16(2):1-6.

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# 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.

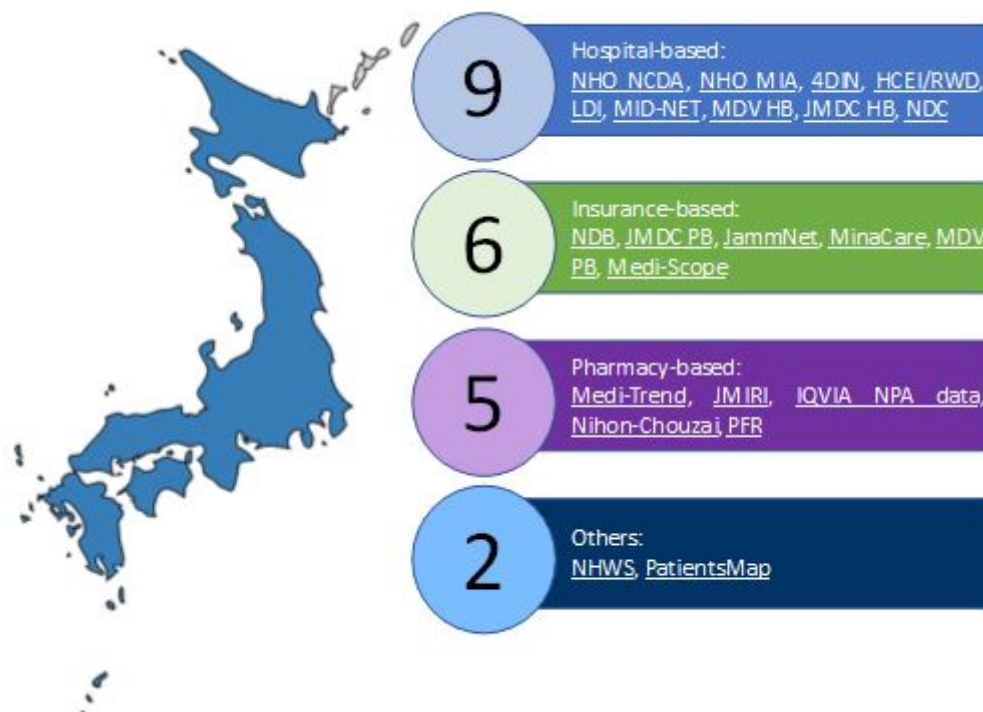
## METHODS

- 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**



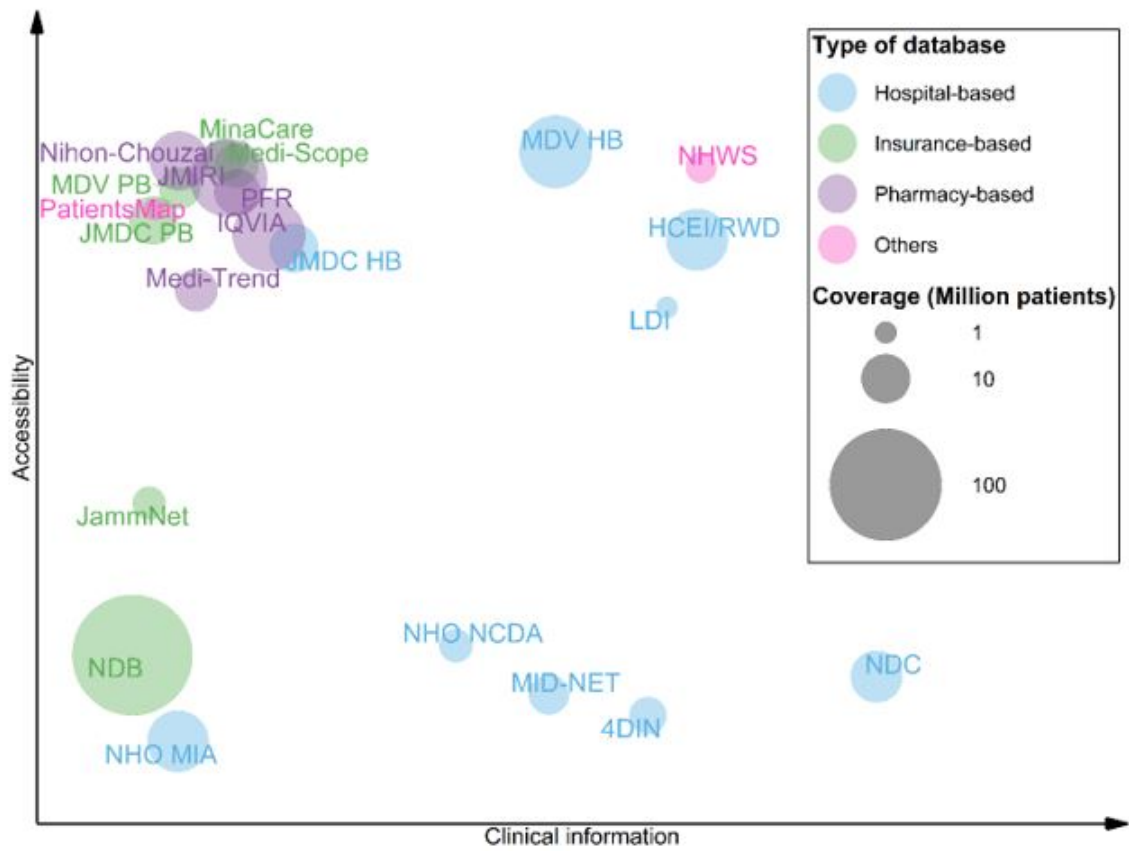
Abbreviations: NHO: National Hospital Organisation; NCDA: NHO Clinical Data Archives; MIA: Medical Information Analysis; 4DIN: a hospital based database owned by 4DIN; HCEI/RWD: Health, Clinic, and Education Information Evaluation Institute / Real-World Data; LDI: Life Data Initiative; MID-NET: Medical 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)

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

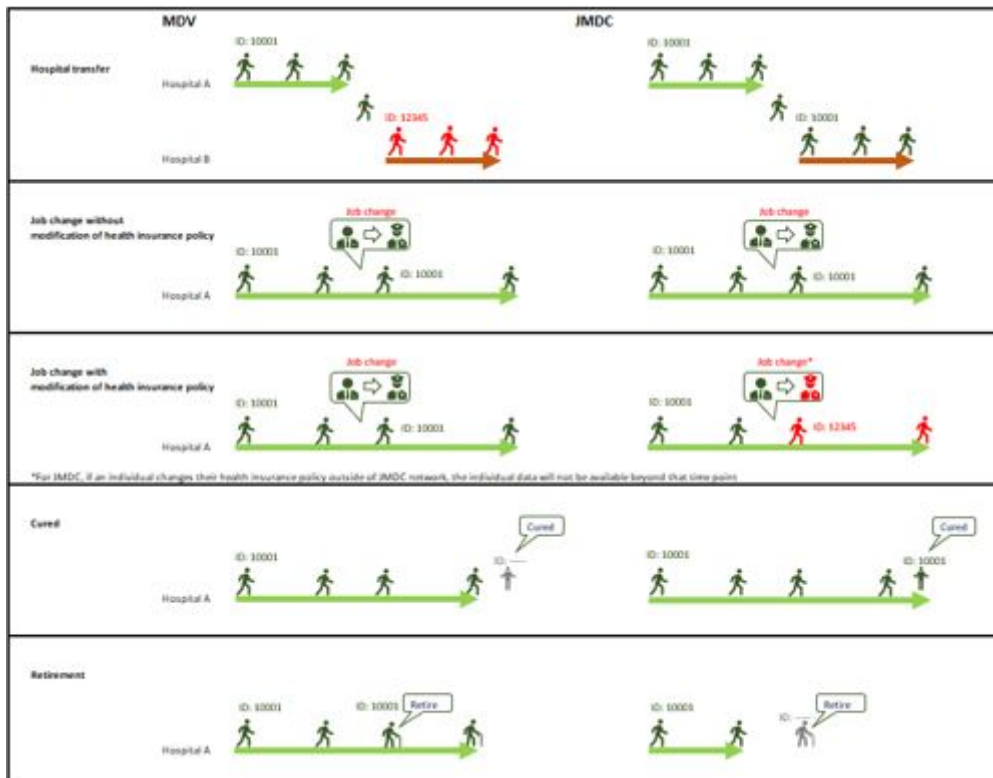
Figure 2. Japan Database Assessment

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.

## REFERENCES

1. Tanaka S, Seto K, Kawakami K. Pharmacoepidemiology in Japan: medical databases and research achievements. *Journal of pharmaceutical health care and sciences*. 2015 Dec;1(1):1-4.
2. Milea D, Azmi S, Reginald P, Verpillat P, Francois C. A review of accessibility of administrative healthcare databases in the Asia-Pacific region. *Journal of market access & health policy*. 2015 Jan 1;3(1):28076.

## REFERENCES

1. Tanaka S, Seto K, Kawakami K. Pharmacoepidemiology in Japan: medical databases and research achievements. *Journal of pharmaceutical health care and sciences*. 2015 Dec;1(1):1-4.
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