

Targeted Literature Review of the Hybrid Research Linking Real-World Databases and Questionnaire Surveys in Japan

Haruhiko Seki¹, Sooyeol Lim¹, Michael LoPresti¹
 1) INTAGE Healthcare Inc., Chiyoda-ku, Tokyo, Japan

Key points of this study

- ✓ Recent technological and operational advances in Japan now make it possible to conduct hybrid research linking surveys and claims databases.
- ✓ A literature search showed examples of custom-designed surveys as well as standard surveys of patient-reported outcomes (PRO) linked to claims databases in Japan.

INTRODUCTION

- The research designs utilizing (1) real-world databases and (2) questionnaire surveys are two major pillars of outcomes research.
- **Real-world database (DB) studies** allow for the analysis of a large amount of patient data accumulated longitudinally to investigate disease and treatment progression. However, they often do not permit post-hoc customization of the original data collection process, and they typically lack PRO.
- **Questionnaire surveys** can collect information from patients using validated instruments and custom surveys. They can deliver a wealth of information regarding patient experience, opinions, and emotions. However, it can be costly to recruit a large number of patients to respond to questionnaire surveys. Moreover, longitudinal traceability is challenging and resource-intensive.
- The shortcomings of each design can be addressed by implementing them separately. However, in that case, the data may not be from the same patients. Moreover, because the data collection processes are different, it may be difficult to align inclusion and exclusion criteria.
- The recent emergence of **personal health apps** in Japan allows deployment of surveys to app users whose claims data can be linked and analyzed together with survey responses.

OBJECTIVE

- We aimed to examine the evidence base for published cases of the hybrid research in Japan and to identify potential evidence gaps through a targeted literature review (TLR) using PubMed.

METHODS

- **Study Selection:** Literature published between 14 June 2014 to 13 June 2024 was identified using PubMed. The search strategy combined terms for database research with terms for questionnaire survey research, along with terms related to the real-world data landscape in Japan.
- **Evidence Synthesis:** The results of the TLR are presented descriptively. The studies were grouped into categories based on the nature of the questionnaire surveys (custom-survey, standardized QoL/WPAI survey, health check-up) and databases linked for the research. Studies within each category were assessed with respect to the purpose of the review.

RESULTS

1. Study Selection

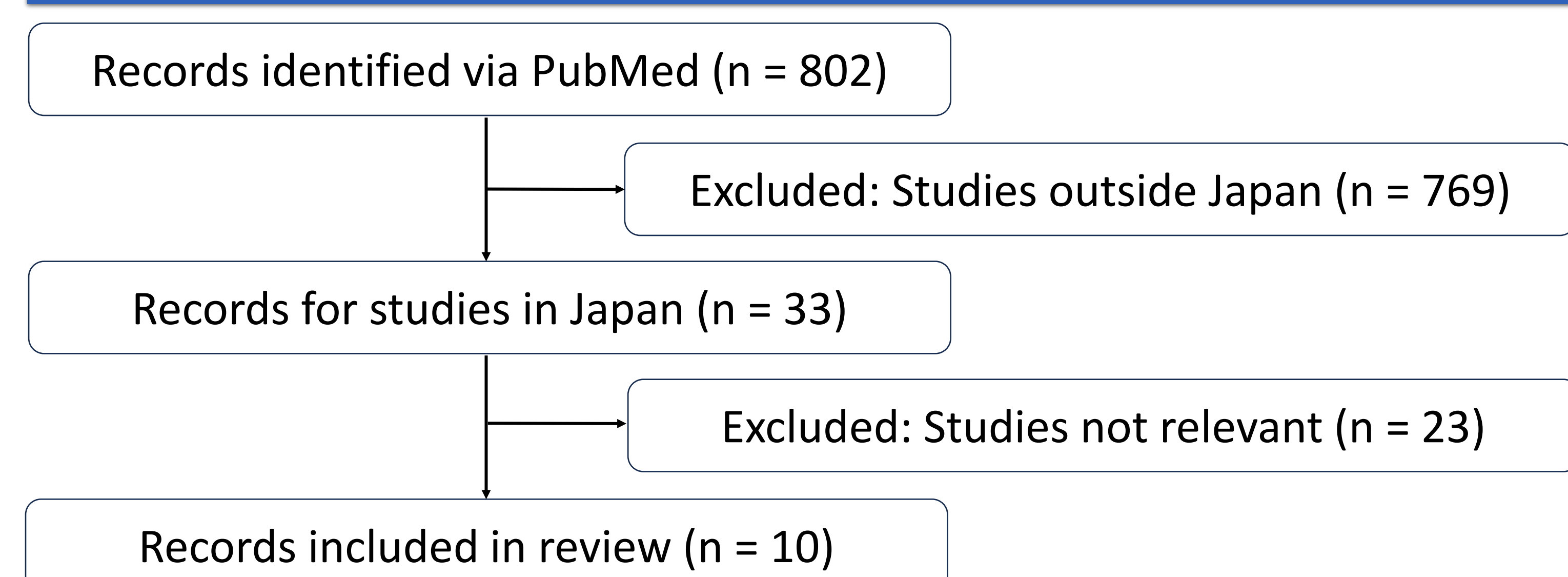


Figure 1 PRISMA Flow Diagram

2. Study Characteristics

Design	Number of studies
Claims DB studies linked to a survey that targeted <u>patients</u>	8 studies including: <ul style="list-style-type: none"> ✓ 4 publications used a custom-designed survey [1-4] ✓ 2 publications used data from standardized EQ-5D and WPAI questionnaires [5-6] ✓ 2 publications analyzed health check-up questionnaire data [7-8] ✓ Target diseases / areas included headaches, migraines, anemia, COVID-19, bone fractures, diabetes, etc.
Claims DB studies linked to a survey that targeted <u>nursing care facilities</u>	2 studies [9,10]

3. Merits of the hybrid research design

1. **Surveys supplementing claims database research:** Although responses may be subjective, surveys can enable identification of a target disease using a validated instrument in a therapeutic area with a low identification rate and estimate a prevalence rate [1], classification of subtypes of a target disease [2], and supply info not typically available in insurance claims databases, such as OTC drug usage or PROs such as symptoms, adherence, reasons for patient behaviors, quality of life, productivity loss, etc.
2. **Claims database research supplementing surveys:** Claims databases can supply objective information regarding treatment patterns as well as diagnosis rates of comorbidities [1,3], which could be too much info for a patient to accurately report during the limited amount of time typically allowed for most questionnaire surveys.
3. **Comparative validation of diagnostic methods:** Results from a validated standard diagnosis survey instrument can be compared with results from an alternative algorithm-based diagnosis method driven by analysis of claims data [4].

CONCLUSIONS

- A small number of publications showed how a hybrid research design can supplement the shortcomings of survey and database research designs. But evidence gaps still exist regarding the benefits and applications of the hybrid research design in Japan.
- Considering the opportunities to engage in more patient-centric evidence generation in Japan, more research is needed in the future to explore and realize the benefits of the hybrid approach.

REFERENCES

1. Sakai F, Hirata K, Igarashi H, Takeshima T, Nakayama T, Sano H, et al. A study to investigate the prevalence of headache disorders and migraine among people registered in a health insurance association in Japan. *J Headache Pain*. 2022 Jun 23;23(1):70.
2. Hirata K, Sano H, Kondo H, Shibasaki Y, Koga N. Clinical characteristics, medication use, and impact of primary headache on daily activities: an observational study using linked online survey and medical claims data in Japan. *BMC Neurol*. 2023 Feb 21;23(1):80.
3. Igarashi H, Sano H, Kondo H, Shibasaki Y, Koga N. Characteristics of patients who seek medical attention for headache and those who do not: cross-sectional survey and linked medical claims data analysis in Japan. *BMJ Open*. 2024 Apr 1;14(4):e077686.
4. Yamato K, Sano H, Hirata K, Nakayama T. Validation and comparison of the coding algorithms to identify people with migraine using Japanese claims data. *Front Neurol* [Internet]. 2023 Nov 27;14.
5. Miyaji C, Kobayashi T, Habu H, Hagiwara A, Horie Y, Takao S. Effect of COVID-19 Infection on Presenteeism: Cohort Study Using Large Health Insurance-Based Data in Japan. *JOEM*. 2024 Aug 66;8.
6. Takeshima T, Yamamoto Y, Iwasaki K, Ha C, Oishi M, Sato A, et al. Prevalence, treatment status, medical costs, quality of life, and productivity loss in Japanese adult patients with anemia: a real-world database study. *Journal of Medical Economics*. 2023 Oct 13; 26:1, 1386-1397.
7. Sato S, Sasabuchi Y, Aso S, Okada A, Yasunaga H. Association between subjective physical function and occurrence of new fractures in older adults: A retrospective cohort study. *Geriatr Gerontol Int*. 2024;24:337-343.
8. Okada A, Ono S, Yamaguchi S, Yamana H, Ikeda Kurakawa K, Michihata N, et al. Association between nutritional guidance or ophthalmological examination and discontinuation of physician visits in patients with newly diagnosed diabetes: A retrospective cohort study using a nationwide database. *J Diabetes Investig* 2021; 12: 1619-1631.
9. Jin X, Tamiya N, Jeon B, Kawamura A, Takahashi H, Noguchi H. Resident and facility characteristics associated with care-need level deterioration in long-term care welfare facilities in Japan. *Geriatr Gerontol Int* 2018; 18: 758-766.
10. Jin X, Tamiya N, Uda K, Yasunaga H. The impact of additional payments on functional decline among long-term care health facility residents in Japan. *Age and Ageing* 2021; 50: 2055-2062.