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BRIEF REPORT

Validity of vaccination information in the COVID-19 surveillance system in Japan: Implications for developing efficient and highly valid data collection systems in future pandemics

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Abstract: Japan's government developed the Health Center Real-time Information-sharing System on COVID-19 (HER-SYS), the national COVID-19 surveillance system, which relies on manual data entry. Following the COVID-19 vaccination campaign, physicians were mandated to report COVID-19 cases with vaccination history *via* HER-SYS. However, concerns have arisen regarding the accuracy of this vaccination history. This study aimed to assess the validity of vaccination history recorded in HER-SYS. We used data from HER-SYS provided by three municipalities. The study cohort comprised COVID-19 cases registered in HER-SYS from February 2021 to March 2022. The validity of vaccination history in HER-SYS was assessed by cross-referencing with the Vaccination Record System (VRS) of these municipalities. We calculated sensitivity to gauge the extent of missing data in HER-SYS, and positive predictive value (PPV) to evaluate the accuracy of data entered into HER-SYS. Of the 19,260 COVID-19 cases included in the study cohort, HER-SYS and VRS identified 3,257 and 8,323 cases, respectively, as having the first-dose vaccination history. Cross-referencing identified 3,093 cases as true positives in HER-SYS. The sensitivity was 37.2% (95% confidence interval [CI]: 36.1–38.2) and the PPV was 95.0% (95% CI: 94.2–95.7). Collection of vaccination data by HER-SYS was found to be inadequate to obtain information on vaccination history of COVID-19 cases. This suggests that real-time data linkage across different systems such as HER-SYS and VRS would reduce the burden of manual data entry during the pandemic and lead to appropriate infection control measures based on more accurate information.

***Keywords*:** COVID-19, surveillance system, vaccine, validation, linkage

Introduction

Coronavirus disease (COVID-19) has become a global pandemic since the first reported case in Wuhan, China, in December 2019 (*1*). In Japan, COVID-19 monitoring commenced on February 1, 2020 in accordance with the Act on the Prevention of Infectious Diseases and Medical Care for Patients with Infectious Diseases (*2*). Under the act, reporting for *Designated Infectious Disease* cases typically involves the use of a handwritten *Report Form*, which must be completed by a physician diagnosing the infectious diseases. These reports are then sent to the Public Health Center in each municipality *via* fax, where Public Health Center officials enter this information into the National Epidemiological Surveillance of Infectious Disease (NESID) database to monitor trends in infectious disease outbreaks (*3*). COVID-19 monitoring was initiated utilizing this *Report Form,* along with other *Designated Infectious Diseases* (*4*). However, as the number of COVID-19 cases has increased, there was concern that entering information into the NESID would not keep pace. Therefore, the Health Center Real-time Information-sharing System on COVID-19 (HER-SYS) was developed in May 2020, as a system that allows each medical facility to report information on the online *Report Form* to the Public Health Center (*5*). HER-SYS data have been used to determine the number of COVID-19 cases in Japan, provide information to the advisory board of the Ministry of Health, Labour and Welfare (MHLW) against COVID-19, and perform epidemiological studies (*6-8*).

In the initial stage of its operation, the HER-SYS had approximately 120 entry items per COVID-19 case, including health status and medical information (*9*). However, as COVID-19 cases increased rapidly, extremely busy medical facilities could no longer cope with entering these items. In September 2020, a notification was issued to give top priority to the input of approximately 40 items, including items in the *Report Form* and the current health status of COVID-19 patients (*e.g.*, awaiting test results, recuperating at home, recuperating at a hotel, hospitalization, death, *etc.*) (*10*). Subsequently, in February 2021, when the COVID-19 vaccination campaign began, additional entry items for COVID-19 vaccination history were added to the *Report Form* (*11*). Consequently, physicians faced an increased burden of manually inputting these types of information. However, the quality of the information within HER-SYS had not previously been reported.

Conversely, the national COVID-19 vaccination registry, the Vaccination Record System (VRS) is a cloud-based system developed by the Digital Agency to record individuals' COVID-19 vaccination status for the smooth of the COVID-19 vaccination campaign in each municipality (*12*). In addition, the number of vaccinations based on VRS is utilized for COVID-19 vaccination policymaking and summarized on the MHLW website (*13*). In the VRS, the vaccination information is recorded at the COVID-19 vaccination facility using an electronic device to read the vaccination coupon. Although more accurate vaccination information is stored in the VRS than in the HER-SYS, these national systems were developed independently and are not linked. If VRS data were re-used as the vaccination status information in HER-SYS, it could not only facilitate efficient data collection to alleviate the burden on physicians during a pandemic but also enhance data accuracy. Therefore, the objective of this study was to quantitatively evaluate the validity of vaccination history information in the HER-SYS data by cross-referencing with VRS.

Materials and Methods

Data source

We used HER-SYS and VRS data from three municipalities (one in Chugoku- and two in Kanto-region) in Japan. These municipalities participated in the Vaccine Effectiveness, Networking, and Universal Safety (VENUS) Study (*14*), which links resident VRS and HER-SYS data to individuals using anonymous residential identifiers for secondary data use. The data period used in this study was from the date of the addition of the vaccination history section (February 10, 2021) in HER-SYS to the latest data provided (municipality A: February 10, 2021 to March 29, 2022; municipality B: February 10, 2021 to March 22, 2022; municipality C: February 10, 2021 to December 31, 2021). HER-SYS data included the following items related to each vaccination dose: vaccination status ("vaccinated", "unvaccinated", "not entered", or "unknown"), vaccination date, age at vaccination, vaccine manufacturer, and type (messenger ribonucleic acid, viral vector, *etc.*). On the other hand, the VRS data included the following items for each vaccination dose: vaccination history registration date, vaccination date, vaccination municipality code, vaccination site, vaccine manufacturer, and vaccine lot number. We utilized the VRS data as the gold standard for this validation study.

The Kyushu University Institutional Review Board for Clinical Research approved this study (No. 2021-399). The requirement for individual informed consent was waived based on the Japanese ethical guidelines, as this study secondary used routinely collected anonymized data by the municipalities.

Study cohort

The study cohort was defined as residents registered in HER-SYS, which consisted of patients with COVID-19, during the data period. The cohort entry date was defined by the registration date in HER-SYS was defined as a cohort entry date. Residents without an anonymized identifier that uniquely identified an individual within the municipality were excluded from the study. The data source profile was detailed in the previous article, with approximately 10% of COVID-19 patients excluded due to missing the unique identifier (*14*).

Comparing vaccination status in HER-SYS with that in VRS

To assess the validity of vaccination status information of the study cohort in HER-SYS, we extracted their VRS data. The vaccination status of the study cohort entered in HER-SYS was compared with their vaccination status recorded in the VRS prior to their cohort entry date. A flowchart of the study procedure is shown in Figure 1.

Statistical analysis

The sensitivity of the vaccination status for each vaccination dose in the HER-SYS data was calculated to evaluate the degree of omission of vaccination history in the HER-SYS data. The positive predictive value (PPV) of the vaccination status for each vaccination dose was calculated to evaluate the correctness of the information entered into HER-SYS. We also estimated the 95% confidence intervals (CIs) of sensitivity and PPV using Wilson's confidence intervals (*15*). Sensitivity was calculated as the proportion of the population with "vaccination status: vaccinated" entered in the HER-SYS data out of the vaccinated population in the VRS among the study cohort. PPV was calculated as the proportion of the vaccinated population in the VRS out of the population with "vaccination status: vaccinated" entered in HER-SYS. We also conducted subgroup analyses by municipality, fiscal quarter, and age for the primary outcome of each vaccination dose.

Additional analyses were conducted to assess the correctness of the vaccination date field in HER-SYS in addition to the vaccination status field. The PPV was

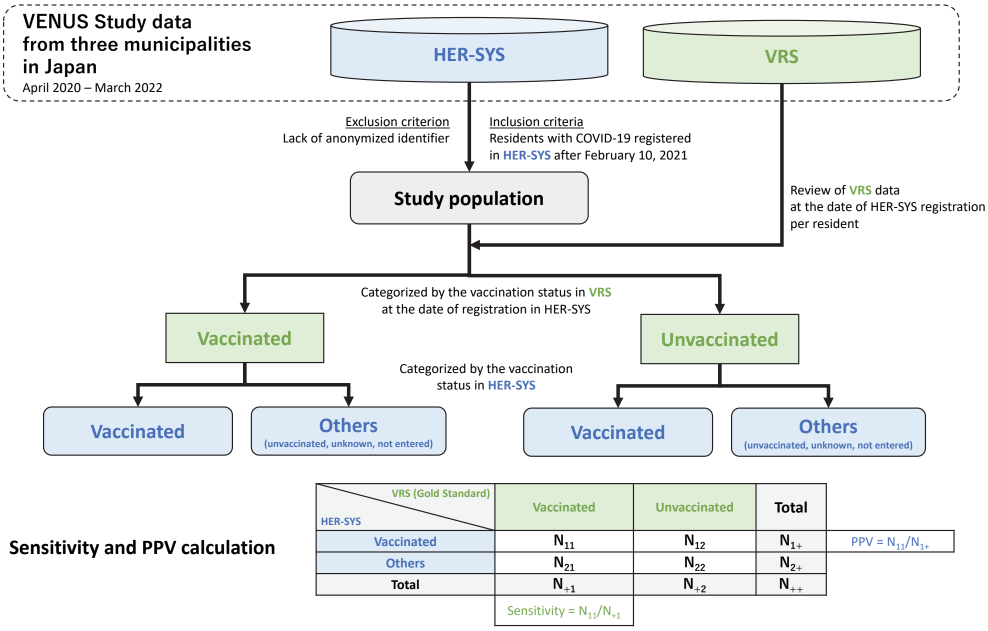

Figure 1. Study flow of assessment of the validity of vaccination status in the HER-SYS. HER-SYS, Health Center Real-time Information-sharing System on COVID-19; VRS, Vaccination Record System; PPV, positive predictive value.

calculated as the proportion of concordant HER-SYS vaccination status and date records with the VRS in the population where the HER-SYS fields "vaccination status: vaccinated" and "vaccination date" were entered. We also assessed the correctness of the vaccination date and vaccine manufacturer fields in HER-SYS, in addition to the vaccination status field. The PPV was calculated as the proportion of concordant HER-SYS and VRS vaccination status, vaccination date, and vaccine manufacturer data in the population in which the HER-SYS vaccination status, vaccination date, and vaccine manufacturer fields were entered.

The analysis was conducted using R Version 4.1.0. (R Foundation for Statistical Computing, Vienna, Austria).

Results and Discussion

A total of 19,260 residents were identified from HER-SYS as the study cohort. Table 1 shows the characteristics of the study cohort. Table 2 shows sensitivity and PPV of vaccination status for each vaccination dose including the main and subgroup analyses. The sensitivities of the main analysis were between 30% and 40%, but those of the subgroup analyses by municipality ranged from 18.0% to 72.1%. Most PPVs in the main and subgroup analyses were greater than 90%. Table 3 shows the PPVs of the combination of vaccination status, date, and manufacturer for each vaccination dose, which were lower than the PPV for vaccination status alone.

There are several possible reasons for the low sensitivity. First, the vaccination history information in the HER-SYS was based on patient self-reports. Patients have to remember their vaccination history if they do not have their vaccination certificate. As vaccination doses increase, it would be difficult to accurately recall the previous vaccination date. Second, there were many data entry items in HER-SYS that were entered by staff in medical facilities, and even when the number of entry items was reduced based on priority, there were still approximately 40 items per COVID-19 case, excluding vaccination history information (*9*). Third, it would have been challenging to collect information from patients with COVID-19 in a limited time when medical facilities and healthcare systems were overwhelmed by the increase in COVID-19 cases. These factors may have

Table 1. Demographics of the study cohort

Characteristics	Number of individuals	Proportion (%)
Total	19,260	100
Sex		
Male	9,932	51.6
Female	9,328	48.4
Age*		
< 15	3,533	18.3
15–65	13,257	68.8
≥ 65	2,343	12.2
Unknown	127	0.7
Municipality		
Municipality A	6,100	31.7
Municipality B	9,100	47.3
Municipality C	4,060	21.1
Quarter registered in HER-SYS		
2021-First	834	4.3
2021-Second	1,744	9.1
2021-Third	4,934	25.6
2021-Fourth	303	1.6
2022-First	11,445	59.4

HER-SYS, Health Center Real-time Information-sharing System on COVID-19. *Age at the date of HER-SYS registration.

Table 2. Sensitivity and PPV of vaccination status in the HER-SYS

	N_{11}	N_{+1}	N_{1+}	Sensitivity (95% CI)	PPV (95% CI)
All					
First dose	3,093	8,323	3,257	37.2 (36.1–38.2)	95.0 (94.2–95.7)
Second dose	2,821	7,797	2,934	36.2 (35.1–37.3)	96.1 (95.4–96.8)
Third dose	235	741	253	31.7 (28.5–35.2)	92.9 (89.0–95.5)
Subgroup					
Municipality					
A					
First dose	667	3,609	694	18.5 (17.2–19.8)	96.1 (94.4–97.3)
Second dose	650	3,528	665	18.4 (17.2–19.7)	97.7 (96.3–98.6)
Third dose	66	366	70	18.0 (14.4–22.3)	94.3 (86.2–97.8)
B					
First dose	2,119	4,270	2,205	49.6 (48.1–51.1)	96.1 (95.2–96.8)
Second dose	2,042	4,090	2,121	49.9 (48.4–51.5)	96.3 (95.4–97.0)
Third dose	169	375	183	45.1 (40.1–50.1)	92.3 (87.6–95.4)
C					
First dose	307	444	358	69.1 (64.7–73.3)	85.8 (81.8–89.0)
Second dose	129	179	148	72.1 (65.1–78.1)	87.2 (80.8–91.6)
Third dose	0	0	0	Null	Null
Quarter					
2021-First					
First dose	0	1	1	0.0 (0.0–79.3)	0.0 (0.0–79.3)
Second dose	0	1	1	0.0 (0.0–79.3)	0.0 (0.0–79.3)
2021-Second					
First dose	12	47	12	25.5 (15.3–39.5)	100 (75.8–100.0)
Second dose	0	0	0	Null	Null
2021-Third					
First dose	394	836	445	47.1 (43.8–50.5)	88.5 (85.2–91.2)
Second dose	157	424	186	39.4 (34.9–44.1)	89.8 (84.6–93.4)
2021-Fourth					
First dose	34	204	36	16.7 (12.2–22.4)	94.4 (81.9–98.5)
Second dose	26	181	29	14.4 (10.0–20.2)	89.7 (73.6–96.4)
Third dose*	0	0	0	Null	Null
2022-First					
First dose	2,653	7,235	2,763	36.7 (35.6–37.8)	96.0 (95.2–96.7)
Second dose	2,628	7,186	2,718	36.6 (35.5–37.7)	96.7 (95.9–97.3)
Third dose	235	741	253	31.7 (28.5–35.2)	92.9 (89.0–95.5)
Age					
< 65					
First dose	2,634	6,788	2,788	38.8 (37.7–40.0)	94.5 (93.6–95.3)
Second dose	2,410	6,361	2,515	37.9 (36.7–39.1)	95.8 (95.0–96.5)
Third dose	159	527	175	30.2 (26.4–34.2)	90.9 (85.7–94.3)
≥ 65					
First dose	459	1,535	469	29.9 (27.7–32.2)	97.9 (96.1–98.8)
Second dose	411	1,436	419	28.6 (26.3–31.0)	98.1 (96.3–99.0)
Third dose	76	214	78	35.5 (29.4–42.1)	97.4 (91.1–99.3)

N_{11}, numerator; N_{+1}, sensitivity denominator; N_{1+}, PPV denominator; PPV, positive predictive value; HER-SYS, Health Center Real-time Information-sharing System on COVID-19; CI, confidence interval. *The fields for third-dose vaccination history were added to a report form for COVID-19 cases in November 2021.

Table 3. PPV of the combinations of vaccination status, date, and vaccine manufacturer in the HER-SYS

	N_{11}	N_{1+}	PPV (95% CI)
Vaccination status and vaccination date			
First dose	1,166	1,438	81.1 (79.0–83.0)
Second dose	1,150	1,367	84.1 (82.1–86.0)
Third dose	169	200	84.5 (78.8–88.9)
Vaccination status, date, and vaccine manufacturer			
First dose	841	1,341	62.7 (60.1–65.3)
Second dose	830	1,323	62.7 (60.1–65.3)
Third dose	142	200	71.0 (64.4–76.8)

N_{11}, numerator; N_{1+}, PPV denominator; PPV, positive predictive value; HER-SYS, Health Center Real-time Information-sharing System on COVID-19; CI, confidence interval.

contributed to inaccurate or missing HER-SYS data.

The variation in sensitivity among municipalities (18.5%, 49.6%, and 69.1%) may have been influenced by differences in the number of COVID-19 cases, medical and human resources, and strategies against COVID-19 in each region and municipality (*16-18*). Approximately 500 Public Health Centers in municipalities played a major role in COVID-19 measures, and there were instances when staff entered information on COVID-19 cases instead of medical institutions. These centers have provided various services, such as health consultations, health status monitoring of COVID-19 patients, adjustment of hospital admission and recuperation at hotels, and active epidemiological investigation, which are important infection control measures in Japan. However, the role of Public Health Centers is not limited to COVID-19 measures but also includes other services, such as infectious disease control measures, mental health, food hygiene, environmental hygiene, and many other functions. Some COVID-19 measures have been strengthened and improved through outsourcing relative to their situation (*19*). However, when COVID-19 cases increased dramatically during the Delta variant wave in July 2021 (the fourth wave) and the Omicron variant wave in January 2022 (the fifth wave), it is considered that the burden significantly exceeded the prepared functions and resources in each municipality. These factors may have contributed to the differences in sensitivity results between municipalities.

One of Japan's neighboring countries, Taiwan, has established an excellent healthcare system that uses personal identification numbers as a common identifier for insurance cards (*20,21*). The development of such a system played an important role in COVID-19 measures, allowing for medical information to be easily shared across hospitals and clinics. A system that linked travel history and medical records was developed in the early stages of the pandemic; this system notified medical personnel of potential COVID-19 cases, thereby aiding the prevention of the spread of infection (*20*). Furthermore, introducing a mask distribution system based on personal identification numbers allowed all citizens to obtain masks fairly (*22*). In Japan, the linking and development of services based on personal identification numbers, known as "My number", is ongoing (*23*). Further, the VRS, which collects vaccination information on COVID-19, has been developed to link to personal identification numbers so that vaccination information can be shared among municipalities even if a resident moves to another municipality. In addition, each individual can obtain a vaccination certificate for the COVID-19 vaccine linked to their identification number (*24*). From October 20, 2021, an "Identification Number Card" can be used as a health insurance card (*23*). Using this card, medical facilities can share medical treatment and prescription drugs with each other, and patients can personally check previous medical history. The development of such infrastructure and the linking of various services using personal identification numbers could improve the quality of medical care and public health.

To prepare for the next pandemic, we recommend that it is necessary to go beyond the legal framework and develop national systems with real-time data linkage for primary data use. In the COVID-19 pandemic, HER-SYS and VRS were developed and operated independently of each other because HER-SYS is a system based on the Infectious Diseases Act and VRS is a system based on the Immunization Act. Therefore, COVID-19 vaccination history was registered in VRS by barcode scanning when individuals were vaccinated but it was manually entered in HER-SYS when COVID-19 occurred. If the vaccination history data in VRS had been linked and cross-referenced to HER-SYS, in real time, manual data entry would not have been required, thus more accurate data would have been obtained.

HER-SYS ceased operation in March 2024 (*5*), but individual patient-level data from HER-SYS for secondary use have been available since April 2024 and can be linked to three national healthcare claims databases: National Database (NDB), Diagnosis Procedure Combination Database, and Long-Term Care Claims Database (*25*). VRS was discontinued on April 2, 2024 (*26*). Currently, counts of vaccinations in VRS are available for download from the MHLW website (*13*). In addition, the National Vaccine Database (VDB), which contains all routine vaccination histories, is under construction, and linkage between the VDB and the NDB is also planned (*27*). Therefore, VDB and HER-SYS will be linked *via* NDB in the near future. However, the linkage between these national databases has been developed for secondary data use, not for primary data use. If these national systems are linked in real time, more specific information (*e.g.*, vaccination coverage by subgroup of specific diseases, quantitative analysis of the effectiveness and safety of each vaccine, *etc.*) can be evaluated in near real time. This real-time evidence will be of great benefit to frontline health care providers, health policy makers, researchers, and industry.

While this study provides valuable insights, there are some limitations that need to be acknowledged. Firstly, the generalizability of the results to the overall population of Japan is limited owing to the use of data from only three municipalities. Moreover, the sensitivity of the subgroup analysis tended to differ between municipalities. Secondly, the study cohort only included individuals who could be assigned an anonymized identifier, not all individuals registered in the HER-SYS. The HER-SYS and VRS in the VENUS Study data were linked using information such as name and age. If incorrect information was entered, the individual would not be included in the study cohort. However, because the number of such cases constituted less than 10% of the entire HER-SYS population, the impact on the results of this study was not expected to be significant. Thirdly, the period evaluated in this study was limited. We used data through to the end of March 2022, but after June 30, 2022, the content of the *Report Form* was simplified (*28*), and on August 4, 2022, the number of items was further reduced to seven (*29*). Furthermore, after September 26, 2022, the individuals for whom the report should be submitted were restricted to patients aged ≥ 65 years, those who need hospitalization, have a higher risk of developing severe COVID-19, and are pregnant, although the *Report Form* returned to that as of June 30, 2022 (*30*). Further research is required to determine the impact of changes in reporting methods after the study period on the validity of input information.

In conclusion, we quantitatively demonstrated the incomplete vaccination history information in the HER-SYS. This study highlights the critical importance of data linkage to access high-quality information during a pandemic. Moreover, linking data across national systems would reduce the burden of manual data entry and lead to appropriate infection control measures based on more accurate information. We hope that the results of this study will provide insight and help develop surveillance systems for future pandemics.

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