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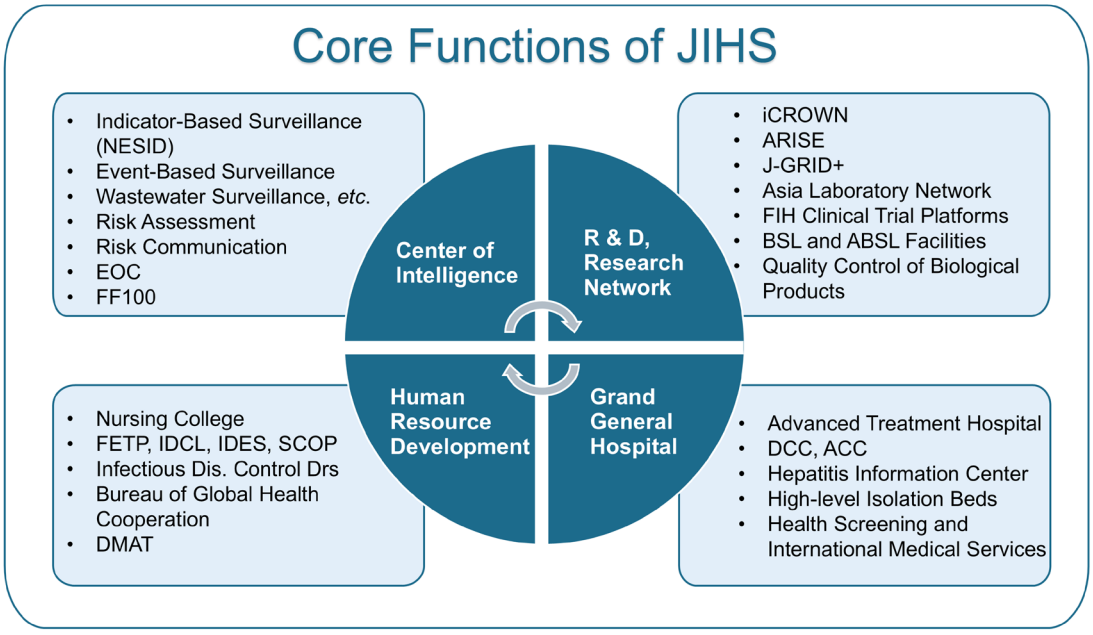

Core functional framework of the Japan Institute for Health Security (JIHS) (Page 73)

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Global Health & Medicine

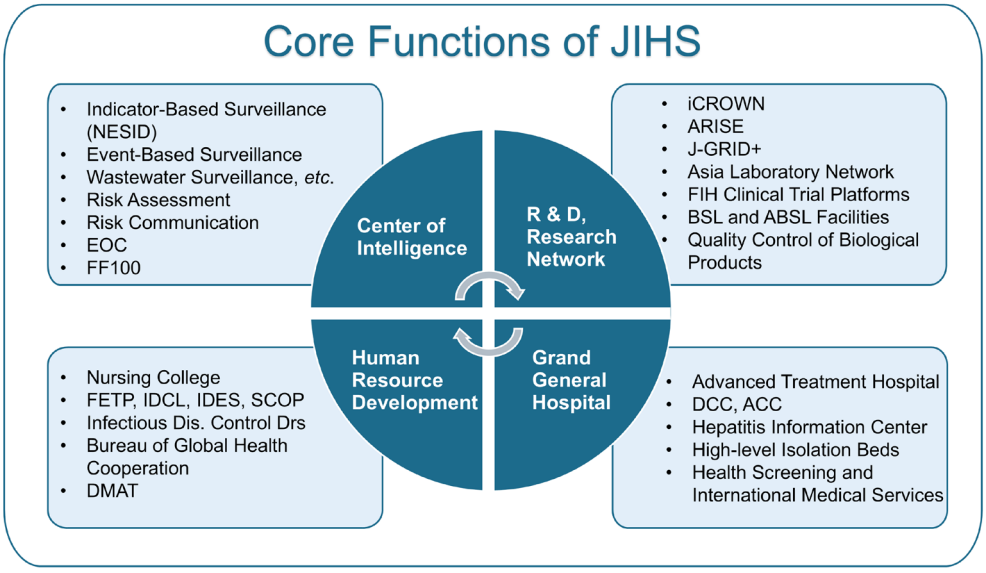
CONTENTS

Volume 8, Number 2, 2026

CORRESPONDENCE

COMMENTARY

COVER FIGURE



Core functional framework of the Japan Institute for Health Security (JIHS) (Page 73)

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EDITORIAL
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From fragmentation to integration: Can Japan's JIHS deliver a resilient system to deal with health emergencies?

Norihiro Kokudo*, Takaji Wakita

Japan Institute for Health Security, Tokyo, Japan.

Abstract: The establishment of the Japan Institute for Health Security (JIHS) in 2025 represents a major institutional reform aimed at enhancing Japan's preparedness for health emergencies in the aftermath of COVID-19. By integrating the National Institute of Infectious Diseases and the National Center for Global Health and Medicine, JIHS seeks to address the long-standing fragmentation of research, clinical practice, and public health responses. In its first year, the institute has made measurable progress in consolidating surveillance and clinical data systems and in expanding research and response networks. However, integration alone does not guarantee effectiveness. Critical challenges remain, including persistent workforce shortages, insufficient incentives for infectious disease research and development, and the complexity of aligning institutional cultures and operational frameworks. This editorial argues that the success of JIHS will depend not only on structural integration but also on sustained investment in human resources, governance reform, and cross-sector coordination. Japan's experience highlights both the promise and the limitations of centralized public health systems and provides important lessons for other countries seeking to build resilient systems to deal with health emergencies.

***Keywords*:** health security, JIHS, pandemic preparedness, system integration, public health governance, Japan

The establishment of the Japan Institute for Health Security (JIHS) in April 2025 marks a pivotal shift in Japan's approach to preparing for health emergencies. The integration of the National Institute of Infectious Diseases and the National Center for Global Health and Medicine reflects a strategic attempt to overcome the structural fragmentation that became evident during the COVID-19 pandemic (*1*). In principle, such institutional consolidation offers a pathway toward a more coordinated, data-driven, and operationally responsive system.

However, integration itself is not a guarantee of effectiveness. The central question is whether JIHS can translate structural reform into functional capacity. Early efforts have focused on building four core pillars: infectious disease intelligence, research and development (R&D) infrastructure, advanced clinical care, and workforce development (*2*). Notable progress includes the integration of epidemiological and clinical data platforms and the expansion of national research networks. These developments represent essential steps toward a unified national response system (Figure 1).

And yet, several structural constraints may limit the effects of those reforms.

First, workforce capacity remains a critical bottleneck. Japan continues to face shortages in field epidemiologists, infectious disease specialists, and trained public health professionals. Existing training programs, including field epidemiology and clinical workforce development initiatives, are not yet sufficient to meet the demands of a fully integrated emergency response system (*3,4*). Without sustained investment in human resource development and clear career pathways, the operational effectiveness of JIHS may be limited.

Second, the sustainability of infectious disease R&D is uncertain. Unlike other areas of biomedical innovation, infectious disease research is characterized by episodic demand driven by outbreaks. This creates weak and inconsistent incentives for long-term investment. Without policy mechanisms that ensure consistent funding and encourage public–private collaboration, Japan might fail to develop one of the core pillars of its health security strategy.

Third, institutional integration requires more than structural consolidation. Aligning organizational cultures, governance systems, and operational practices across previously independent institutions is inherently complex. Failure to achieve such alignment could result in persistent inefficiencies despite formal integration. In this context, governance reform and leadership will play a decisive role in determining whether JIHS can function

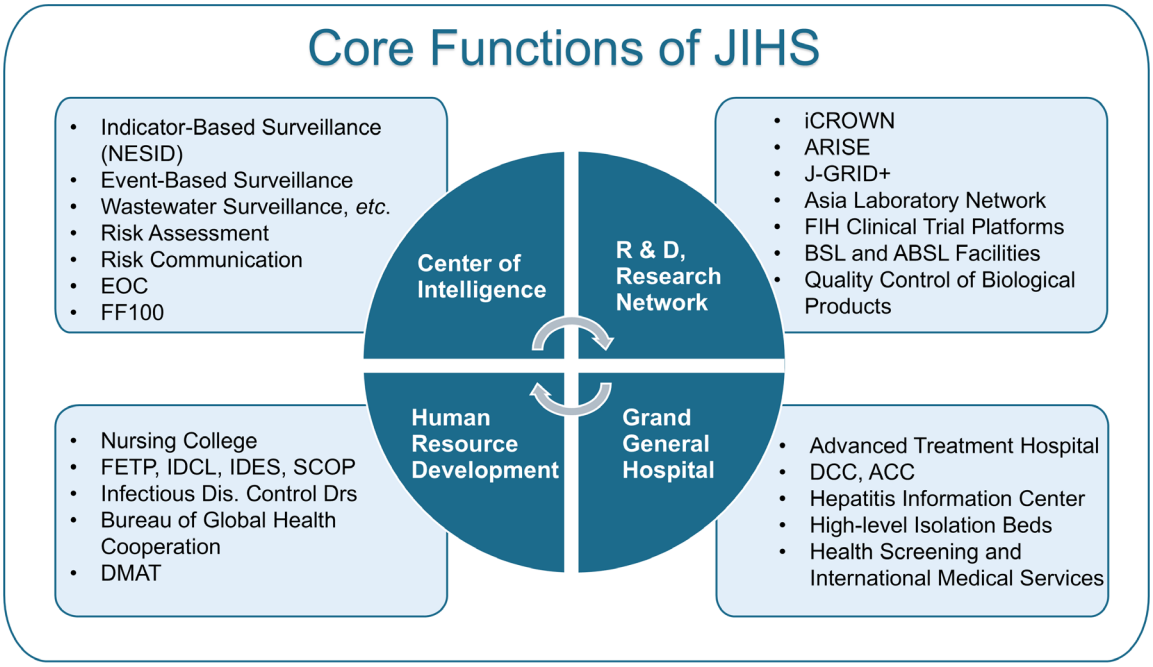

Figure 1. Core functional framework of the Japan Institute for Health Security (JIHS). The framework illustrates four integrated pillars: (1) intelligence and surveillance, including indicator-based surveillance (NESID), event-based surveillance, and wastewater surveillance, as well as risk assessment and risk communication, supported by the emergency operations center (EOC) and First Few Hundred (FF100) investigations; (2) research and development (R&D) and research networks, including iCROWN, ARISE, J-GRID+, and the Asia Laboratory Network, as well as first-in-human (FIH) clinical trial platforms, biosafety level (BSL) and animal biosafety level (ABSL) facilities, and quality control of biological products; (3) advanced clinical care, supported by specialized hospitals, disease control centers, and high-level isolation units; and (4) human resource development, including training programs and professional networks. Together, these components form the foundation of an integrated national system for infectious disease preparedness and response. *Abbreviations*: EOC, Emergency Operations Center; FF100, first few hundred cases and contacts investigation; R&D, research and development; iCROWN, Infectious Disease Clinical Research Network (Japan); ARISE, ARO Alliance for Southeast and East Asia; J-GRID+, Japan Initiative for Global Research Network on Infectious Diseases; FIH, first-in-human; BSL, biosafety level; ABSL, animal biosafety level; NESID, National Epidemiological Surveillance of Infectious Diseases; DCC, Disease Control and Prevention Center; ACC, AIDS Clinical Center; FETP, Field Epidemiology Training Program; IDCL, Infectious Disease Crisis Leadership Program; IDES, Infectious Disease Emergency Specialist; SCOP, Senior Clinical Operations Program; Dis, Diseases; Drs, Doctors; DMAT, Disaster Medical Assistance Team.

as a truly unified system.

From a global perspective, Japan's experience reflects a broader trend toward centralized public health institutions in a post-pandemic era. International analyses of pandemic prevention, preparedness, and response (PPPR) consistently emphasize the importance of integrating surveillance, data systems, and response capacity (*5*). However, global evidence also suggests that integration must be accompanied by sustained investment in workforce, governance, and cross-sector coordination to be effective.

JIHS's first year demonstrates both the potential for and limitations of institutional integration. While early achievements are encouraging, the long-term success of the Institute will depend on whether it can address underlying structural challenges. Integration should be viewed not as an endpoint, but as a foundation upon which a resilient and adaptive system to deal with health emergencies must be built.

Japan now stands at a critical juncture. If JIHS can successfully align its structural reforms with its functional capacity—particularly in workforce development, R&D sustainability, and governance—it has the potential to become a model for integrated health security systems. If not, the risk remains that integration will be largely symbolic, with a limited impact on Japan's real-world emergency response.

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Japan Pre-Entry Tuberculosis Screening (JPETS): A new phase in tuberculosis control following Japan's transition in a low-incidence era

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Abstract: In December 2024, Japan's Pre-Entry Tuberculosis Screening (JPETS) program was introduced in coordination with the Ministry of Health, Labour and Welfare (MHLW), the Ministry of Foreign Affairs, and the Immigration Services Agency to mandate tuberculosis (TB) screening for mid- to long-term visa applicants and Certificate of Eligibility applicants from selected countries with a large number of foreign-born TB cases in Japan. To date, the target countries are located in Asia, accounting for a large proportion of foreign-born TB cases in Japan. These countries also have strong labor-migration ties with Japan. Based on a quality-assured screening process at designated Panel Clinics, JPETS aims to prevent the importation of TB, reduce the risk of its domestic transmission, and ultimately contribute to global TB control. Through robust international collaboration, JPETS also incorporates safeguards to ensure fair and equitable opportunities for migrants' social participation and well-being. This article outlines the historical background of Japan's TB control, the rationale, design, and anticipated impact of JPETS.

***Keywords*:** Japan, tuberculosis, migration, pre-entry screening, public health policy

1. Introduction

Tuberculosis (TB) remains one of the most significant global infectious diseases. Globally, about a quarter of people with TB remain undiagnosed and untreated, causing more deaths annually than that of HIV/AIDS and malaria combined (*1-4*). In Japan, TB was also the leading cause of death with an annual death rate of more than 200 per 100,000 population before World War II (*5*), and was then often referred to as a "fatal disease" or "kokumin-byo" (a Japanese term meaning "national disease"). In 2024, more than 10,000 TB cases were newly notified under the Act on the Prevention of Infectious Diseases and Medical Care for Patients with Infectious Diseases (hereafter referred to as the Infectious Diseases Control Law) as one of the most frequently notified infectious diseases in Japan, causing more than 1,500 deaths (*5*). The burden persists among older adults. Individuals aged 80 years and above account for over 40% of new TB cases, primarily due to the reactivation of latent infections acquired during the pre-war or post-war high-incidence era (*6*). Simultaneously, a growing number of foreign-born TB cases are registered, accounting for approximately one-fifth of all newly notified TB cases in 2024. These trends highlight the need for a new phase of TB control in Japan, alongside continued strengthening of existing domestic control measures.

2. Policy context of tuberculosis control in Japan before achieving low-incidence status

Although TB still poses a nationwide public health threat, the number of TB patients has steadily declined since the postwar era through a comprehensive strategy. In 1951, Japan established the original legal framework of its comprehensive prevention strategy (*7*) (Figure 1). Under the Law, all patients with TB were subject to compulsory isolation until they became non-contagious. The amendment also introduced annual TB checkups for all individuals living in Japan, as well as full coverage of medical costs during isolation and continued coverage of 95% of outpatient treatment costs after discharge, nationwide. These countermeasures, as

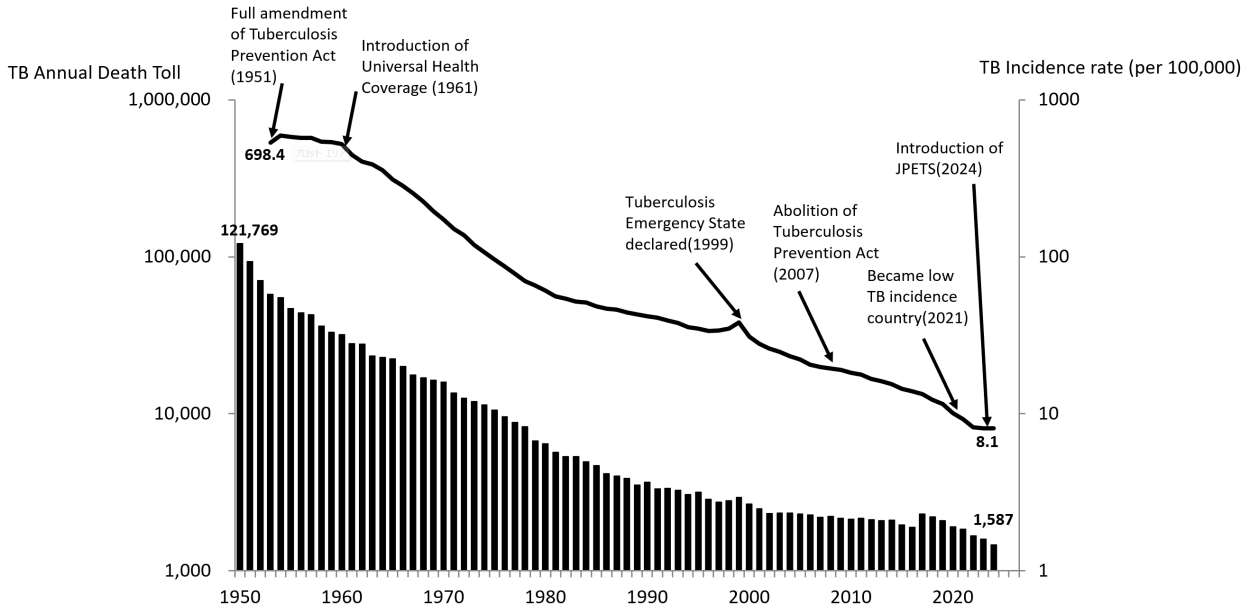

Figure 1. Trends in tuberculosis (TB) incidence and mortality rate in Japan. Since the postwar period, both the incidence and mortality rate of TB in Japan have steadily declined. Prior to the establishment of universal health coverage in 1961, patients with infectious TB were subjected to mandatory isolation, with the government covering all medical costs during hospitalization and most outpatient expenses thereafter. In 2007, the Tuberculosis Prevention Law was repealed and incorporated into the Act on the Prevention of Infectious Diseases and Medical Care for Patients with Infectious Diseases. Since 2021, Japan has maintained its status as a low-incidence country (fewer than 10 cases per 100,000 population).

well as the establishment of universal health coverage (UHC) by public health insurance in 1961, played a critical role in early detection and continue to serve as a safety net today. Consequently, annual TB cases began to decrease, which contributed to transition of Japan's countermeasures toward a more target-specific strategy.

Current annual TB checkups are primarily targeted at high-risk groups, such as inmates, individuals aged 80 years or older, and those deemed to have an elevated risk in local epidemiological contexts including healthcare workers, schoolteachers and residents in social welfare facilities. In addition, students entering upper secondary schools, specialized training colleges, or higher education institutions are required to undergo TB screening as part of the comprehensive medical examination upon school enrollment (*8*).

Japan has also maintained universal Bacillus Calmette–Guérin (BCG) vaccination as part of its regular immunization schedule since 1951 (*9*); however, its current target population is infants, mainly to protect them from severe forms of TB such as miliary TB and tuberculous meningitis.

In 2007, the Tuberculosis Prevention Law was repealed and integrated into the Infectious Diseases Control Law to reinforce comprehensive and multisectoral measures within a broader framework. Under the current legal framework, isolation of active TB patients follows a two-step process designed to protect their human rights. Newly notified active TB patients first receive an administrative recommendation for isolation, accompanied by an appropriate explanation from the public health center to ensure that their rights are respected. Isolation becomes a legal requirement only when a patient does not comply with the recommendation.

In the same period, Japanese Directly Observed Treatment, Short Course (DOTS) program, characterized by its comprehensive patient-centered approach, was introduced in the early 2000s. The Japanese DOTS model has played a critical role in ensuring coherent support for treatment adherence both in the community and in hospitals. Following the amendment of the Law in 2014, the Japanese DOTS evolved into a community-wide support model that incorporated not only multisectoral local healthcare providers, but also non-healthcare personnel trained as DOTS supporters under the initiative of public health centers.

3. The growing challenge of foreign-born TB in Japan

While domestic TB control has achieved remarkable progress, Japan now faces a growing challenge—the rising number of foreign-born TB cases. Approximately 2,000 foreign-born cases were newly notified in 2024, representing 19.7% of all newly notified TB cases, an increase of 361 cases (3.7 percentage points) from the previous year (*5*). Notably, this rise is concentrated among younger generations: those aged 20–39 accounted for around 60% of newly notified foreign-born TB cases. Among individuals aged 20–29, the number of foreign-born TB cases increased by 31.3% compared with the previous year, and the proportion of foreign-born TB

cases in that age group reached 90% (*5*).

This demographic pattern reflects broader migration trends in Japan. The number of migrant workers has been increasing steadily, having reached approximately 2.3 million as of October 2024 (*10*). Among residence status categories, the "Technical Intern Training Program" category ranks third after "Permanent Resident" and "Engineer/Specialist in Humanities/ International Services" (*11*). This program was designed to transfer skills and knowledge accumulated in Japan to developing regions by accepting trainees for a period of on-the-job training, which contributes to human resource development and international cooperation.

Two-thirds of technical interns were in their 20s in 2024 (*12*). In terms of nationality, Viet Nam had the largest number of workers (24.8% of the total in 2024), followed by the Philippines, Nepal, and Indonesia. Southeast Asian nationals together account for almost half of all migrant workers in Japan (*10*). In parallel, the number of international students has grown sharply—from 60,601 in 1990 to 294,198 in 2024 (*13*). These migration dynamics have substantially reshaped Japan's TB epidemiology.

Many migrants with TB infection may face challenges such as maintaining employment or continuing their studies during TB treatment (*14*). Ensuring their TB-free status upon entry to Japan is not only a public health measure but also supports their social and economic stability. In light of this, the MHLW has been encouraging employers to conduct regular health checkups for workers and technical interns who are at high risk of TB infection.

Thus, under Japan's national roadmap toward realization of a society of harmonious coexistence with foreign nationals, the proportion of TB cases among non-Japanese residents is expected to rise. Therefore, additional preventive measures targeting non-Japanese individuals have been anticipated.

4. What is JPETS?

Given these challenges, the Japan Pre-Entry Tuberculosis Screening (JPETS) program was introduced in December 2024, under the coordination of the MHLW, the Ministry of Foreign Affairs and the Immigration Services Agency. JPETS mandates TB screening for applicants from target countries who intend to stay in Japan for three months or longer as part of the visa or CoE application process.

Similar to Japan, in many low TB-incidence countries the health status of migrants influences TB epidemiology through the importation of cases. Several countries have implemented mandatory pre-migration TB screening and subsequently reported reductions in TB cases diagnosed after arrival (*15*). For example, in the United States, where approximately 77% of TB cases occurred among non-US-born persons in 2024 (*16*), implementation of a culture-based screening algorithm coincided with a decline in TB cases diagnosed among foreign-born persons within the first year after arrival (*17*). Notably, approximately 70% of TB cases among migrants were diagnosed within two years following entry into Japan (*18*), suggesting that many cases may have been present but undetected at the time of migration. Such screening programs therefore enable earlier detection and treatment of infectious cases prior to travel, thereby reducing the likelihood of transmission after arrival. These precedents suggest that TB screening programs targeting migrants may be warranted to address the rising number of foreign-born TB cases. Japan's adoption of JPETS represents both a continuation of these international trends and a tailored response to its unique migration and epidemiological context.

JPETS currently targets nationals of countries that account for a large proportion of TB cases reported in Japan. The program applies to those who intend to stay in Japan for longer than three months as mid-to-long-term residents (excluding re-entry permit holders). As of November 2025, the targeted nationalities are those of the Philippines, Viet Nam, and Nepal. According to the Statistics of TB in Japan 2024, by the Japanese Anti-Tuberculosis Association, the Philippines, Viet Nam, and Nepal together contributed to roughly half of foreign-born newly notified TB cases in Japan (*18*). If documentation from a government authority confirms that the applicant's current residence is outside these countries, they are exempt from screening.

Applicants who are already subject to medical examinations (including chest X-rays for TB testing) under existing official schemes are temporarily exempt from this screening. Examples include participants in specific programs sponsored by the Japanese Government, trainees and students under programs coordinated by Japan International Cooperation Agency (JICA), government-funded students, nurses and care workers who have been admitted under Economic Partnership Agreements, and individuals entering under the status of Specified Skilled Worker and related categories. Detailed information is provided on the MHLW website (*19*).

A TB Clearance Certificate is issued only by designated clinics (Panel Clinics, or PCs) in the target countries to applicants who are certified as free of active TB, following a standardized protocol including a clinical interview, physical examination, and chest X-ray. The certificate must be submitted at the time of application for a CoE (issued by the Immigration Services Agency) or for a visa (issued by Japanese embassies) (Figure 2).

One distinctive feature of JPETS is its structured quality assurance mechanism. Prior to designation by the Japanese government, PCs are subject to rigorous audits conducted by the Centre for JPETS Quality Assessment (CJPQA), which is commissioned to the Research Institute of Tuberculosis, Japan Anti-Tuberculosis Association. Beyond accreditation, CJPQA also plays

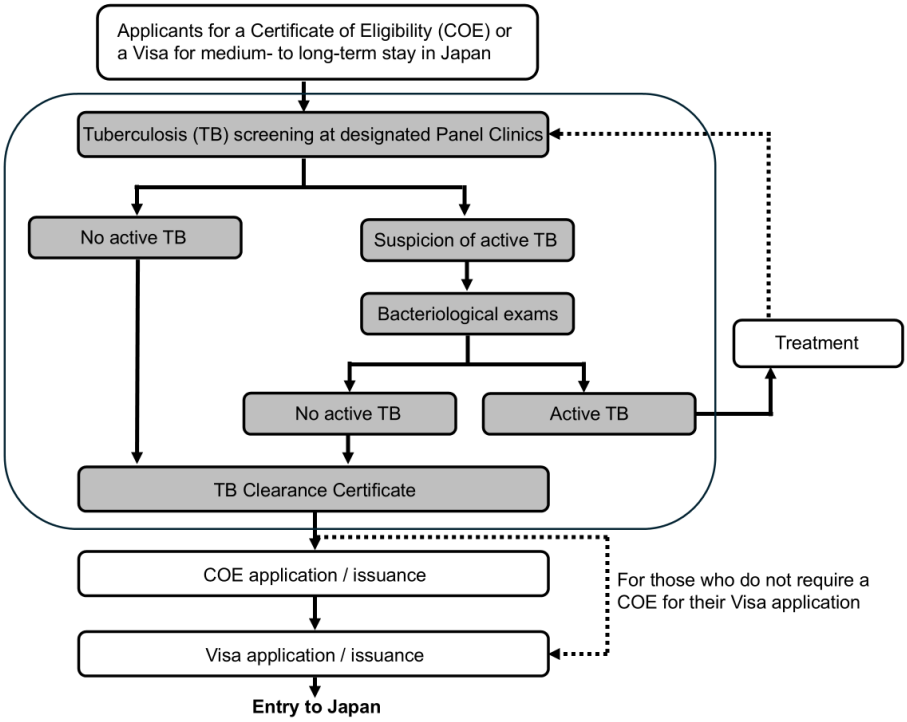

Figure 2. Screening flow of Pre-Entry Tuberculosis Screening (JPETS). Applicants will undergo a medical examination and chest X-ray (or sputum test at the doctor's discretion if there are concerns) at Panel Clinics located in the target countries for screening. A TB Clearance Certificate will be issued by the Panel Clinic when the applicant does not have active TB. Applicants are required to submit the TB Clearance Certificate when applying for a Certificate of Eligibility or, where applicable, when applying directly for a visa at a Japanese diplomatic mission abroad.

an active role in maintaining diagnostic quality and strengthening the capacity of PCs and PLs through training and technical guidance. This framework helps ensure standardized radiological interpretation and bacteriological testing, and contributes to improving the quality of TB care in the target countries. Such a technically supported quality assurance system represents a key advantage of JPETS compared with existing pre-entry screening programs implemented in other countries. These audits follow detailed technical instructions publicly available on the MHLW website, thereby ensuring transparency and uniformity. Adequate clinic capacity is estimated and maintained based on multiple factors, including geographical and demographic data, annual volume of migrants, and average processing time per applicant. As migration flows change, the overall capacity of PCs will be maintained accordingly.

If abnormalities are detected, additional tests such as sputum smear, culture, and/or World Health Organization (WHO)-recommended Nucleic Acid Amplification Tests will be performed. PCs are advised to take responsibility for specimen collection, which should be performed either outdoors or in a designated collection room with adequate negative air pressure to ensure safety. Staff are required to wear N95 respirators during specimen handling to minimize the risk of airborne transmission, and specimens are promptly transported to the laboratories (Panel Laboratories, or PLs). PCs are required to ensure access to these tests either in-house, through collaboration with affiliated PLs, or through outsourcing.

PLs are required to submit their standard operating procedures to the CJPQA and are advised to handle specimens in accordance with mycobacteriology laboratory manuals (*20*) and to regularly assess their quality in alignment with guidelines from the WHO (*21*). Individuals with active TB must complete standard treatment in accordance with the respective national TB guidelines before a TB Clearance Certificate can be issued.

The International Organization for Migration (IOM) manages the JPETS Information Management System (J-IMS), which ensures secure and standardized data collection. Documents including the TB Clearance Certificate and Chest X-ray Report will be directly issued through J-IMS. In terms of capacity building, CJPQA and IOM provide training programs for staff at PCs.

5. Monitoring and evaluation of JPETS

JPETS is expected to reduce importation of TB, strengthen domestic TB control and support the health of migrants by enabling proactive diagnosis and treatment before travel. Nevertheless, the impact of pre-entry screening programs may vary depending on migration patterns and domestic TB epidemiology, and continuous monitoring will therefore be essential.

One of the key anticipated outcomes is the number

of TB cases detected through this rigorous screening. Given the rising proportion of migrants among TB cases in Japan, this screening program will play a role in addressing this trend.

Another indicator will track newly notified active TB cases among migrants who arrived within the previous two years. As previously described, a substantial proportion of foreign-born TB cases are identified in Japan within two years of their arrival, supporting relevance of the timeframe to promote early detection (*18*).

Post-entry follow-up may present challenges because personal data collected through JPETS is not directly linked to national surveillance databases due to data security and privacy considerations. Instead, evaluation will rely on aggregated program data and national surveillance trends to assess population-level impact. Additionally, each applicant receives their screening records in electronic format, which can later assist healthcare providers if TB develops after entry. Migrants often encounter cultural and linguistic barriers, especially in the early phase after settlement, which potentially affect their health-seeking behavior. To mitigate such risks and promote awareness of TB, multilingual materials including videos are available for JPETS applicants, focusing on the significance of timely detection, infection control and TB care after migration. While Japan does not operate a follow-up program specifically within the JPETS framework, the national guidelines strongly encourage local authorities to take comprehensive countermeasures targeting populations at higher risk of TB such as TB-focused regular checkups (*22*) and to subsidize associated costs as much as possible. JPETS will also be periodically updated to improve diagnostic effectiveness in light of ongoing developments in tuberculosis diagnostic technologies, while maintaining operational feasibility and programmatic sustainability.

6. Way forward

Japan's comprehensive approach to TB control has served as a reference model for other countries. In this phase, JPETS represents a strategic convergence of public health, migration governance, and international collaboration. The program is aligned with global TB elimination frameworks, including the End TB Strategy and the UN Political Declaration on TB (*23,24*).

Japan's transition to a low TB-incidence setting underscores the necessity of maintaining seamless TB control strategies by integrating pre-entry screening with ongoing domestic strategies for individuals living in Japan such as rigorous surveillance and timely diagnosis, infection control and care (*25*). The introduction of JPETS will not justify any compromise on these countermeasures.

As part of its risk communication efforts, the MHLW conducts public awareness activities, notably during Tuberculosis and Respiratory Infection Prevention Week (September 24–30). During this period, multilingual posters and brochures are distributed through local authorities to a wide range of populations including migrant communities to promote comprehensive strategies.

The MHLW remains committed to ensuring continuity of care for migrants, while respecting their human rights, as stipulated in the Infectious Diseases Control Act. Recognizing the social determinants of health that affect migrants, the MHLW will continue to promote their well-being and safeguard fair and equitable opportunities for social participation, in line with principles of Sustainable Development Goals (*26*).

7. Conclusion

The JPETS program marks an advancement in Japan's tuberculosis control strategy, integrating domestic public health protection with equitable support for migrants who are at high risk of TB. Success will depend on continuous evaluation, maintenance of the quality of care and capacity at the PCs in line with migration trends, and sustained collaboration with partner organizations.

As an example of cross-border TB control in a high and a low incidence setting, JPETS illustrates how migration policy and infectious disease control can be harmonized to strengthen both national health security and global TB elimination efforts, while safeguarding fair and equitable opportunities for migrants. Thus, Japan's TB control will continue to evolve under the UHC framework, while adapting to changing epidemiological and migration trends.

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Integrating medical Mobility as a Service (MaaS) with the doctor-to-patient with nurse (D to P with N) telemedicine model and pharmacist-supported medication services: Towards mobility-integrated care for Japan's super-aged population

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Abstract: Japan has a super-aged society, where the population age 65 years or older accounted for 29.4% of the total population as of January 2026, and population aging, depopulation, and persistent physician shortages have increasingly constrained access to healthcare. These challenges are particularly evident in rural and remote areas, where mobility itself constitutes a major barrier to care. Although home medical care and telemedicine have been promoted as policy responses, each has inherent limitations when implemented independently. Against this backdrop, the practical integration of Mobility as a Service (MaaS) with the doctor-to-patient with nurse (D to P with N) telemedicine model has emerged as a policy-related approach to delivering multidisciplinary care under conditions of limited medical and transportation resources. In several municipalities in Japan, including early implementation sites such as the City of Ina, medical MaaS–based mobile healthcare initiatives have been implemented to reduce travel burdens while improving accessibility for patients with mobility challenges. From an implementation perspective, these initiatives demonstrate a growing convergence between medical MaaS and the D to P with N telemedicine model. Physicians provide remote consultations while nurses offer on-site clinical support, with telemedicine further linked to pharmacists' online medication counseling and medication delivery services. In practice, this integrated approach, which includes routine consultations, renewing prescriptions, and basic clinical monitoring, is primarily used for the stable management of chronic diseases and is mainly targeted at older patients receiving home-based care. By covering the care continuum from consultation to medication support, this approach aims to reduce patients' travel burden while ensuring the continuity of multidisciplinary care. Despite its potential, key challenges remain, including operational costs, data governance, and emergency response requirements. Overall, integrating medical MaaS with the D to P with N telemedicine model and pharmacist-supported medication delivery represents a significant step towards mobility-integrated care and may serve as a complementary component of community-based integrated care systems.

***Keywords*:** physician shortage, aging society, telemedicine, medical MaaS, health policy, Japan

1. Introduction

As of January 2026, individuals age 65 years or older accounted for 29.4% of Japan's total population, marking increased aging of the population (*1*). The extent and impact of this demographic shift vary substantially across regions (*2*). In remote islands and mountainous areas, depopulation has progressed rapidly: approximately 63.2% of the national land area and 51.5% of municipalities are classified as depopulated; these regions are home to only 9.3% of the national population, nearly 40% of whom are age 65 years or older (*2*). In such settings, declining public transportation services—driven by lower ridership and Labour shortages—have made private automobiles the primary means of accessing medical care (*3,4*). Recent traffic safety policies encouraging older adults to voluntarily surrender their driver's licenses have further intensified mobility constraints among older residents in depopulated areas (*5*).

At the same time, Japan faces chronic physician shortages, resulting in significant regional disparities in the distribution of medical care providers (*6*). According to OECD Health at a Glance 2025, Japan has 2.6

physicians per 1,000 population, well below the OECD average of 3.9 physicians (*7,8*). Despite policy efforts including government scholarships and programs of the Ministry of Health, Labour, and Welfare to increase physicians in certain regions, regional disparities in physicians remain acute (*6,8*). These challenges pose significant obstacles to the effective implementation of Japan's comprehensive community-based integrated care system, which seeks to enable older adults to continue living in familiar surroundings through the coordinated provision of medical, nursing, preventive, housing, and social services (*9*). Although community-based integrated care centers have been established nationwide (*9,10*), rural and depopulated regions continue to face structural barriers to healthcare access, and particularly where mobility limitations and medical resource constraints intersect (*4*).

In recent years, home healthcare and telemedicine guidelines have been revised to address these challenges. Moreover, in 2019, the Ministry of Economy, Trade and Industry (METI) and the Ministry of Land, Infrastructure, Transport, and Tourism (MLIT) jointly launched the Smart Mobility Challenge (*11*). Based on the Mobility as a Service (MaaS) concept, this initiative aims to solve mobility issues and revitalize local economies by integrating and utilizing multiple transportation services. As part of this effort, medical MaaS—designed to deliver healthcare to patients unable to be seen at hospitals—began pilot testing in select municipalities in 2020 and entered full operation in 2021 (*12*). As of October 2024, MONET Technologies' vehicles have been deployed in 25 municipalities, including those currently in the preparatory phase (*13*). Following MONET Technologies, TOYOTA AUTO BODY launched its service and had delivered vehicles to four municipalities by March 2024 (*14*). Growing attention has been directed toward the practical integration of medical MaaS with the doctor-to-patient with nurse (D to P with N) telemedicine model as a complementary approach to community-based integrated care.

Rather than proposing a new technology, this Policy Forum article focuses on how existing healthcare and mobility service components—specifically medical MaaS, the D to P with N telemedicine model, and pharmacist-supported medication services—are being operationally aligned in practice. Drawing on emerging medical MaaS initiatives in Japan, it examines the relevant policies, implementation challenges, and their potential role in overcoming barriers to healthcare access in super-aged societies.

2. Home healthcare and telemedicine, MaaS, and medical MaaS

2.1. Home healthcare and telemedicine

To address both patient transportation difficulties and physician shortages, the Ministry of Health, Labour, and Welfare (MHLW) has advanced legal frameworks and developed infrastructure for home healthcare such as home visits by physicians and telemedicine (*15-19*). Telemedicine in particular was promoted during the COVID-19 pandemic as an infection control measure (*17*). Home visits have long been a part of Japanese medical practice (*18*), but amendment of the Medical Service Act in 1992 officially recognized the home as a legitimate site of medical care (*18,19*). Telemedicine guidelines formulated in 2018 clarified the requirements for conducting online consultations and demonstrated telemedicine's potential as a complementary tool for home healthcare (*16*). However, home visits remain particularly vulnerable to physician shortages, primarily due to the significant travel time and burden on physicians. In contrast, telemedicine faces challenges due to dependence on patients' access to information and communication devices and their skill at operating those devices, as well as limitations in clinical information that physicians can obtain remotely (*16,20*).

2.2. MaaS

The "Smart Mobility Challenge", a project jointly launched by the METI and the MLIT in 2019, is founded on the concept of MaaS, an integrated mobility solution that encompasses route planning and payment systems. The initiative draws inspiration from Finland's successful implementation of MaaS in 2016 (*21*). However, Japan's Smart Mobility Challenge specifically aims to maintain and enhance local mobility services while simultaneously addressing transportation challenges and revitalizing regional economies (*11*). Examples include data-driven improvements to regional transport services based on ride histories and shared mobility services that coordinate vehicle dispatch based on appointments made by residents (*11*).

2.3. Medical MaaS

Medical MaaS was introduced in 2021 as a solution to address both the physician shortage in rural areas and the mobility challenges faced by patients, particularly those living in rural communities (*12*). The patients served are those with chronic illnesses who are unable to regularly be seen at hospitals and who are in stable condition, with implementation reports indicating that most are older patients (*12,22*).

For vehicle equipment and medical devices, all systems are designed to support remote consultations and basic clinical assessments. Depending on operational needs, vehicles can be equipped with examination beds, accessories for the disabled, digital communication devices, and various portable diagnostic equipment (*22-26*) (Table 1).

The system uses a D to P with N telemedicine model,

Table 1. Differences in vehicle equipment and installed medical devices by brand

Items	MONET Technologies	TOYOTA AUTO BODY
Standard equipment	Desk	Desk
	Examination bed	Examination bed
	Wheelchair lift	High-definition monitor
	Handrail	Handrail
	Step	Step
Optional equipment	Telemedicine system	Telemedicine system
	Personal computer	Personal computer
	Webcam	Zoom-capable camera
	Speakers	Speakers
	Microphone	Microphone
	Sink	Printer
		Wheelchair lift
Optional medical device	Portable ultrasound device	Portable ultrasound device
	Electronic stethoscope	Electronic stethoscope
	Upper arm blood pressure monitor	Upper arm blood pressure monitor
	Non-contact thermometer	Non-contact thermometer
	Pulse oximeter	Pulse oximeter
	Automated external defibrillator (AED)	Automated external defibrillator (AED)
	Portable blood glucose analyzer	Dermatoscope
	Centrifuge-based blood analyzer	Ultrasound bone density analyzer
	Portable ECG monitor	Portable ECG monitor
	ECG recording/analysis system	
	Spot-check monitor	
	Electronic auscultation device	
	Portable X-ray machine	

Note: This table presents examples of in-vehicle equipment used in medical MaaS services implemented across various regions in Japan. "Standard" and "optional" classifications reflect manufacturer-specific configurations. *Data source: Ref. (22-26)*

where nurses ride in the vehicle to see patients and to assist with examinations while physicians engage in telemedicine (*12*). Inside the vehicle, physicians engage in telemedicine while nurses perform delegated medical procedures such as intravenous infusions and injections under physician supervision. Additionally, when new symptoms that require additional testing develop, nurses can perform blood or urine tests (*27*). Notably, interpreting test results and making final treatment decisions must comply with relevant notification guidelines and requirements, with face-to-face consultations required as needed (*27*).

Since the initial deployment began, as of October 2024 MONET Technologies' vehicles had been deployed in 25 municipalities, including those currently in preparation (*13*), while TOYOTA AUTO BODY had delivered vehicles to four municipalities by March 2024 (*14*). Moreover, new body manufacturers have continued to enter the market (*28*), Some universities with medical schools are exploring operational models tailored to regional characteristics by implementing healthcare MaaS systems (*25,29,30*). Within this context, group-based online clinics are also being utilized as a mobile health screening unit or temporary medical facility in disaster-affected areas or other locations where hospital functions are limited (*23-25*).

Market research projected Japan's medical MaaS domestic market to be worth 1.76 billion yen as of 2025, with expected growth reaching 172 billion yen by 2035 (*31*).

In the next section, we will examine the benefits and challenges of this system within the regional care system in the City of Ina, the first municipality to adopt it.

3. An integrated approach to coordinating physician–nurse–pharmacist care based on medical MaaS

The City of Ina is a municipality where 32% of the population was age 65 or older in 2020, when the medical MaaS pilot program began (*32*). As of 2020, it had 151 physicians, corresponding to 228 per 100,000 population, which is below Japan's average (*33*). In addition, most hospitals are located in the city center, but many older people lived in mountainous outlying areas, making transportation costs for both patient visits and home healthcare increasingly problematic each year (*12,20,22*) (Figure 1).

The medical MaaS pilot program began when the City of Ina proposed the initiative to MONET Technologies, which had been operating a medical MaaS service (*12*). The pilot project began in 2020, with full-scale operations commencing in fiscal year 2021 (*12*). As of March 2026, 14 medical facilities in the City of Ina were using this service (*12*). Medical facilities apply

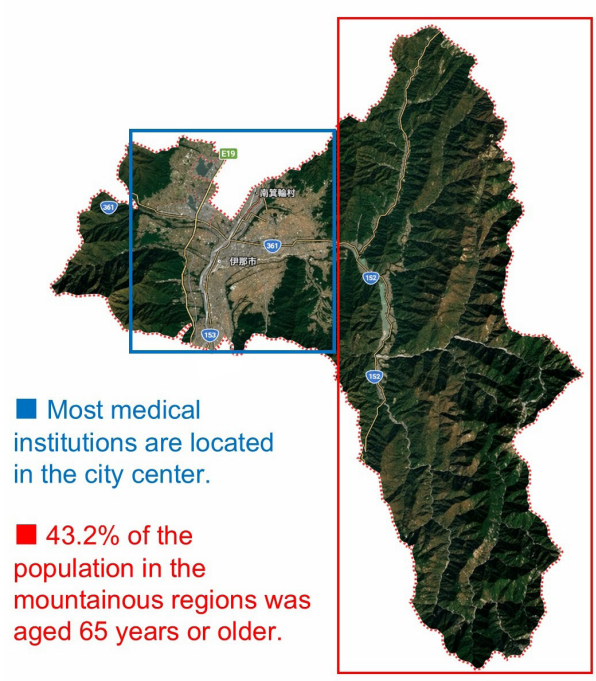

Figure 1. Satellite view of the City of Ina, Nagano Prefecture. The map shows the contrast between the central urban area and the surrounding mountainous regions. As of October 2024, 43.2% of the population in the mountainous regions was age 65 years or older, while most medical facilities are located in the city center. *Data source: Ref. (18) Map data ©2026 Google.*

to use the city-owned Medical MaaS vehicle, which is then dispatched to patients who have difficulty reaching healthcare facilities (*12*). By delivering medical care to patients' homes, this system supports the community-based integrated care system, which aims to enable older people to continue living in familiar surroundings (*12*).

The core practice of this model lies in the operational framework of the D to P with N telemedicine model, in which nurses perform examinations and provide medical assistance inside a vehicle on the patient's premises, while physicians deliver care through remote consultations. In rural healthcare settings and in recognition of the effectiveness of telemedicine with nurse support on site, the 2024 revision of medical fees introduced a new reimbursement item: a Nurse-assisted Telemedicine Add-on (50 points, equivalent to 500 yen) for telemedicine using D to P with N systems at remote clinics and core rural medical facilities (*34*). Further revisions in 2026 created a new evaluation category—a Nurse Support Fee for Visiting Telemedicine (265 points, equivalent to 2,650 yen)—along with newly defined rules for calculating fees for nurses performing tests, injections, and procedures (*35*). These expanded reimbursement measures provide institutional support for telemedicine incorporating on-site nursing assistance and could further support the expansion of multidisciplinary collaboration in future medical MaaS applications.

Moreover, the model includes multiple healthcare personnel to alleviate the burden on both healthcare personnel and patients. One key initiative involves the involvement of pharmacists. Following the 2019 amendment to the Pharmaceuticals and Medical Devices Act (implemented September 2020), online medication counseling became possible under certain conditions (*36,37*). And with the launch of electronic prescription management services in January 2023, pharmacies can now electronically verify prescription information under specified conditions, dispense medications, and combine this with online medication counseling to deliver drugs, including home delivery (*38*). Consequently, patients can receive telemedicine with nursing support, have prescribed medications delivered directly to their homes, and access online medication consultations with pharmacists—without being seen at hospitals, using digital devices installed in medical MaaS vehicles stationed on or near their premises. The City of Ina is also considering implementing a system for real-time delivery of prescription medications to medical MaaS vehicles by drones (*20*).

A distinctive feature of "the City of Ina's medical MaaS model" is its integration of telemedicine with pharmacists' online medication counseling and medication delivery services, thereby enabling the entire process of care, from consultation to medication support, to be designed with a minimal travel burden for patients (Figure 2).

Moreover, the City of Ina aims to establish an interprofessional collaboration platform for sharing information (*20*). By carefully managing patient data while respecting privacy—collecting information from physicians, pharmacists, and care workers—the City hopes to achieve both improved healthcare efficiency and service continuity for aging residents. The City of Ina has also promoted the use of this system for younger patients as well (*39*). As of 2025, the vehicles also began carrying fetal monitoring equipment for use in prenatal checkups (*40*).

4. A comparison of medical MaaS to home healthcare systems worldwide

While mobile healthcare services exist worldwide, Japan's medical MaaS differs in both its objectives and patients it serves (Table 2).

4.1. Japan's medical MaaS in comparison to mobile medical services worldwide

Although mobile clinics operated by international organizations such as the World Health Organization (WHO), universities, and Federally Qualified Health Centers (FQHCs) share the primary goal of providing primary care services, they differ from Japan's medical MaaS in their institutional focus and the populations served. Many mobile medical services around the world

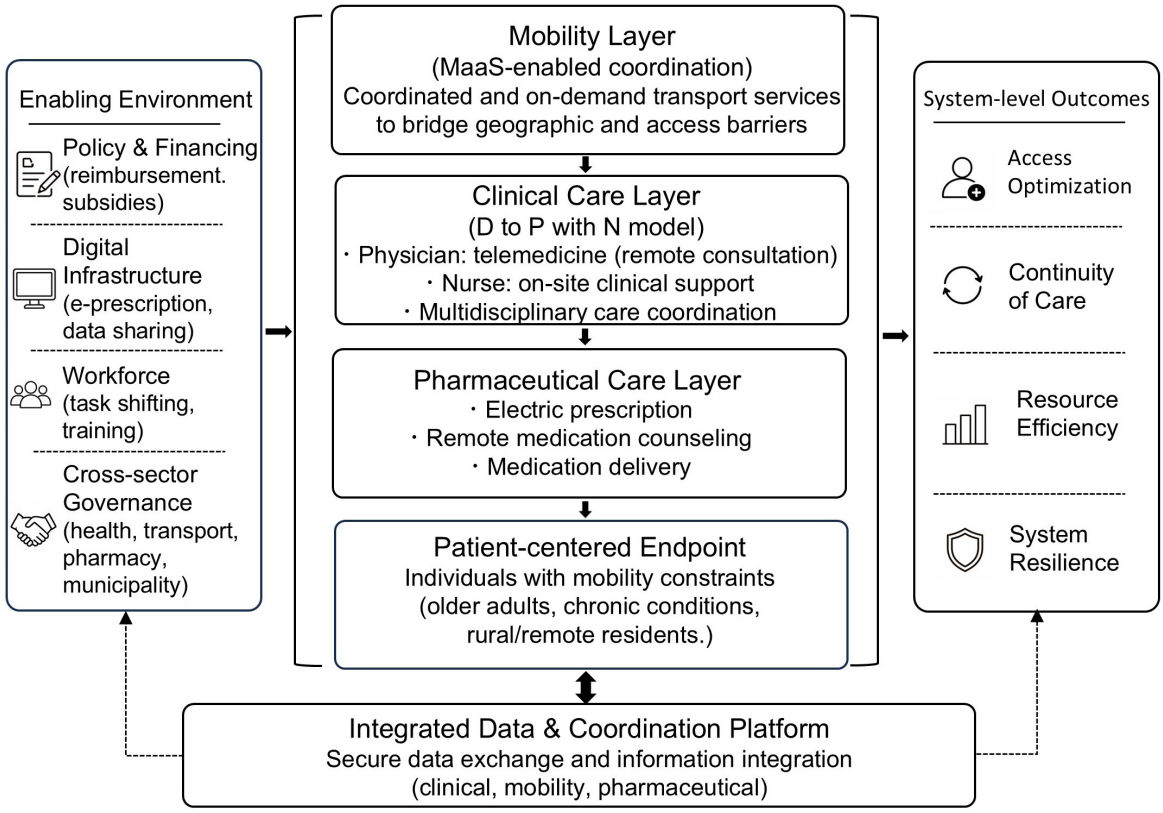

Figure 2. Conceptual approach to mobility-integrated care. Through this approach, patients can receive telemedicine services with in-person nursing support at home, obtain online medication guidance from pharmacists *via* computers installed in medical MaaS vehicles, and have prescribed medications delivered directly to their homes. *Abbreviations*: MaaS, Mobility as a Service (MaaS); D to P with N, Doctor-to-Patient with Nurse.

are designed primarily to improve healthcare equity by reaching populations with restricted access due to economic, geographic, or systemic barriers. In contrast, Japan's medical MaaS is more closely integrated with home medical care and community-based healthcare systems and is mainly intended to serve patients who have difficulty continuously accessing facility-based care (*41,42*).

A second important difference is the deployment context. Worldwide, mobile clinics are frequently utilized for outreach or response-based services in disaster-affected areas, humanitarian or conflict settings, and underserved communities. In contrast, Japan's medical MaaS is implemented predominantly as a routine, locally embedded healthcare delivery model, rather than as a temporary or emergency-focused intervention (*41,42*).

4.2. Japan's medical MaaS in comparison to home visiting medical care worldwide

In some developed countries, "Hospital at Home" models that rely heavily on visiting nurses have been implemented as alternatives to inpatient hospitalization. While both these models and Japan's medical MaaS involve the provision of medical care in the home setting with substantial involvement by nurses, their underlying objectives and populations served differ fundamentally.

"Hospital at Home" programs primarily focus on patients with acute conditions who would otherwise require hospital admission, aiming to substitute for inpatient care in order to reduce bed occupancy and healthcare costs. In contrast, Japan's medical MaaS is designed mainly for older adults in stable condition or with a chronic illness, so mobility-integrated services and telemedicine are routine components of ongoing community-based care rather than substitutes for acute hospitalization (*43*).

Accordingly, Japan's medical MaaS functions as a complementary implementation model that reinforces community-based integrated care systems rather than replacing hospital-based services. Its primary role lies in sustaining access to routine care for patients—particularly older adults with chronic illnesses—in familiar surroundings, particularly where mobility and medical resource constraints coexist.

5. Challenges and Perspectives

While medical MaaS is noteworthy for reducing the travel burdens for patients with mobility challenges and facilitating access to medical care for patients, and particularly older adults, several challenges remain.

First, like other telemedicine-based services, medical MaaS requires emergency ambulance services when

Table 2. Comparative analysis of medical transportation services

Items	Japan's Medical MaaS	International Mobile Clinics (Representative trends)	Hospital at Home (Representative model)
Purpose	Provision of home medical care for stable patients unable to be seen at a hospital. Chronic disease management and end-of-life care as part of community-based integrated care.	Provision of primary medical care and health education for low-income individuals, uninsured persons, and residents of disaster-affected or conflict zones who face difficulties accessing healthcare.	Alternative to acute-care hospitalization, providing hospital-level care at home to reduce bed occupancy and healthcare costs.
Targeted patients	Patients in stable condition or with a chronic illness, care recipients, pregnant women who cannot be seen at clinics.	Low-income populations, uninsured individuals, immigrants, homeless people, and disaster/conflict-affected communities.	Patients requiring hospitalization for acute conditions (such as pneumonia, heart failure, or infections) who are capable of managing their condition at home.
Type of medical care provided	Primarily focuses on stable management, prescription, and testing for chronic diseases.	Focus on primary care, emphasizing prevention, health education, maternal and child health, and chronic disease management.	Equivalent to secondary to tertiary medical care, with inpatient-level treatments including intravenous infusions, laboratory testing, and oxygen therapy at home.
Healthcare personnel involved	Physicians (telemedicine), nurses, pharmacists, laboratory technicians, *etc.*	Physicians (on-site medical treatment), nurses, pharmacists, laboratory technicians, *etc.*	Physicians (in-person or telemedicine), visiting nurses, laboratory technicians, *etc.*
Operating organization	Hospitals and clinics collaborate with local governments. university hospitals.	Diverse settings including hospitals, university hospitals, FQHCs, nonprofit organizations, and international NGOs.	Hospitals (public/private)
Source of funds	Public health insurance + subsidies provided by local or the national government.	Donations, federal grants, public insurance, private insurance, state grants, *etc.*	Payments through public insurance schemes (*e.g.,* Medicare/NHS), alternative payment models for inpatient care
Institutional position	A form of home medical care and telemedicine support.	Flexibly implemented as part of the public health and community medicine program.	Can be substituted for inpatient care and reimbursed by insurance (*e.g.,* U.S. Medicare Waiver).
Strengths	Suitable for continuous follow-up of older patients, family support, and community-based integrated care.	Improving equitable access to healthcare.	Reducing healthcare costs, preventing readmissions, and improving patient satisfaction.
Limitations	Inability to handle emergency situations, limitations when providing specialized medical care, and vehicle purchase/operation costs.	Funding, limitations in specialized care. Shortages in both rural and certain regions in the U.S.	Patient selection and safety management, attracting human resources, family burdens, and the fact that complete replacement with hospitals is impossible.
Representative cases	Representative case: Medical MaaS in the City of Ina, Nagano Prefecture and deployed across depopulated regions in Japan.	The Family Van (Harvard Univ), WHO Mobile Clinic.	Johns Hopkins Hospital at Home, NHS Virtual Ward.

Data Source: Ref. (12, 20, 22-27,30,31, 39-43)

patients experience a sudden deterioration in condition (*12*). The system operates under the assumption of a fully functional emergency medical system.

Second, vehicle-related operational challenges persist. These include the substantial costs of acquiring and maintaining vehicles, as well as the lack of nationally unified guidelines for vehicle specifications, which currently vary depending on local needs and operational models. At present, government subsidies and models in which municipalities own the vehicles and lease them to hospitals are commonly used to support implementation (*12,24,44*).

Third, medical MaaS is often implemented in mountainous or geographically remote areas, so service availability may be affected by adverse weather conditions such as heavy snowfall, posing region-specific operational constraints.

Fourth, the secure and appropriate management of personal health information across multiple institutions and sectors—including healthcare, transportation, and local government—remains a critical challenge, requiring robust governance frameworks and compliance with privacy protection regulations.

That said, the institutional and technical environment supporting the development of medical MaaS is gradually maturing. Revisions to medical fees in 2024 and 2026, which expanded the evaluation framework for the D to P with N telemedicine model, may serve as institutional foundations for sustaining telemedicine services that incorporate on-site clinical support by nurses and other healthcare personnel. Additionally, the introduction of electronic prescription management systems and the increased adoption of online medication counseling are creating an environment in which the entire care process—from prescription issuance to medication guidance and drug delivery—can be designed as an integrated service pathway.

Together, these developments suggest that medical MaaS may evolve beyond the role of a mobile clinic, functioning instead as a multidisciplinary collaboration platform capable of facilitating the continuous care required for chronic disease management. And by establishing secure mechanisms for sharing patient information in accordance with privacy protection standards, medical MaaS could provide a practical foundation for information-sharing systems within community-based integrated care frameworks, enabling collaboration among physicians, nurses, pharmacists, care workers, and local governments.

Moreover, case-based experiences in the City of Ina demonstrate that medical MaaS has already begun to be used beyond chronic disease management, including prenatal health checkups, indicating that its potential applications may extend to maternal and child health services, health screenings, and disaster response, depending on regional healthcare resources and transportation conditions.

6. Conclusions

This article examined medical MaaS as an emerging policy-related approach to addressing challenges to healthcare access in Japan's super-aged population, particularly in rural and depopulated areas where mobility limitations and medical resource constraints intersect. Rather than proposing a novel technology, this study highlighted how existing service components—including the D to P with N telemedicine model, on-site support provided by nurses, pharmacist-led online medication counseling, electronic prescriptions, and medication delivery—are being operationally integrated in practice.

While medical MaaS faces ongoing challenges related to operational costs, emergency preparedness, and information governance, this analysis suggests that it has substantial potential as a complementary implementation model within community-based integrated care systems. By facilitating continuous access to routine care for patients—and particularly older adults in stable condition or with a chronic illness—medical MaaS can overcome mobility-related barriers without replacing existing hospital-based or emergency services.

As institutional and technical environments continue to mature, including anticipated expansions in reimbursement frameworks and the wider adoption of electronic prescription systems, medical MaaS may evolve into a sustainable, multidisciplinary collaboration platform. In this context, medical MaaS represents not a standalone solution, but a pragmatic policy tool capable of enhancing coordination across healthcare, transportation, and caregiving systems in resource-constrained communities.

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Strengthening upper gastrointestinal endoscopy service in primary healthcare settings in low- and middle-income countries: Proposals from an implementation study in Vietnam

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Abstract: Vietnam has established favorable policies for upper gastrointestinal endoscopy, providing an opportunity to expand this technology to primary healthcare (PHC) settings. However, the policy dilemma between insurance coverage/supportive regulations and self-financing policy, and the one between intended and unintended outcomes of healthcare decentralization and administrative reform, posed constraints on expanding this technology at the PHC level. In response to these policy dilemmas, we conducted an implementation research study to identify subsequent policy bottlenecks and facilitating and hindering factors affecting the proper and sustainable implementation of this technology. The study was carried out in district hospitals (renamed regional general hospitals after 2025 administrative reform) in two southern provinces, using a qualitative research design based on interviews with hospital staff involved in upper gastrointestinal endoscopy. Data were analyzed deductively using the Consolidated Framework for Implementation Research (CFIR). Based on the identified policy dilemmas, bottlenecks and hindering factors, we propose five policy recommendations: *i*) mobilizing and redistributing financial resources for PHC-level hospitals; *ii*) facilitating participation in upper gastrointestinal endoscopy training; *iii*) establishing accessible professional networks; *iv*) raising awareness of upper gastrointestinal endoscopy services; and *v*) promoting adherence to national guidelines. After analyzing their potential constraints and trade-offs, we consider them to be relatively feasible to implement.

***Keywords*:** digestive endoscopy services, community-based healthcare, health system strengthening, Consolidated Framework for Implementation Research (CFIR), Southeast Asia

1. Introduction

Vietnam is classified as a lower-middle-income country, with a gross domestic product of USD 4,717.3 per capita in 2024 (*1*), and a disease burden dominated by noncommunicable diseases (NCDs) (*2*). Among NCDs, gastrointestinal diseases represent a significant burden, including gastric cancer (*3,4*) and other gastrointestinal diseases related to *Helicobacter pylori* infection, such as peptic ulcers or active gastritis (*5*).

Vietnam has a healthcare system that is accessible and affordable for most of the population by expanding universal health insurance coverage and establishing an administrative structure with three levels: primary (district and commune health facilities), secondary (provincial hospitals), and tertiary (national hospitals under the direct auspices of the central government) (*6,7*). Health services using upper gastrointestinal endoscopy technology have been incorporated into these policies. One is the social health insurance, listing basic endoscopy tests and interventions in the health insurance package (*8*). Another policy lists this technology on a national list of approved technologies, published in a Ministry of Health circular, to be provided at primary healthcare (PHC) settings for examination and treatment (*9*).

Despite these major enabling policies, two policy dilemmas influence the implementation of upper gastrointestinal endoscopy at the PHC level: *i*) the dilemma between insurance coverage/supportive

regulations and the self-financing policy; and *ii*) the dilemma between intended and unintended outcomes of healthcare decentralization and administrative reform. Regarding the first policy dilemma, although insurance coverage for upper gastrointestinal endoscopy facilitates its implementation, the concurrent self-financing policy applied to all public hospitals—including those at the PHC level—primarily through the introduction of user fees for patients outside the insurance scheme, undermines the financial sustainability of these hospitals (*10-12*). This is because most patients cannot afford such fees. Concerning the second policy dilemma, the Vietnamese government intended to streamline coordination across administrative levels (*13*) and clarify its respective roles through healthcare system decentralization and the 2025 administrative reform, which reorganized the three-tier provincial administration into a two-tier system (*14,15*). Despite these efforts by the Vietnamese government, the actual outcomes revealed coordination breakdowns and regulatory gaps across levels, primarily due to confusion among stakeholders.

To address these policy dilemmas hindering implementation of upper gastrointestinal endoscopy in PHC-level hospitals in Vietnam, we conducted an implementation research study to identify subsequent policy bottlenecks and facilitating and hindering factors affecting proper and sustainable implementation of this technology. The study was carried out in district hospitals (renamed regional general hospitals after the 2025 administrative reform) in two southern provinces, using a qualitative research design based on interviews with hospital staff involved in upper gastrointestinal endoscopy. Data were analyzed deductively using the Consolidated Framework for Implementation Research (CFIR) (*16*). Detailed data are shown in Supplementary Figure S1 and Tables S1–S2 (*https://www.globalhealthmedicine.com/site/supplementaldata.html?ID=118*).

2. Policy recommendations

We developed the following five policy recommendations to facilitate implementation of upper gastrointestinal endoscopy at district hospitals in Vietnam, drawing on the two identified policy dilemmas, four policy bottlenecks, and eight hindering factors (Table 1): *i*) mobilizing and redistributing financial resources for PHC-level hospitals; *ii*) facilitating participation in upper gastrointestinal endoscopy training; *iii*) establishing accessible professional networks; *iv*) raising awareness of upper gastrointestinal endoscopy services; and *v*) promoting adherence to national guidelines. Under each policy recommendation, we describe relationships among existing policy dilemmas, resulting policy bottlenecks, and hindering factors for upper gastrointestinal endoscopy derived from those bottlenecks.

Table 1. Policy recommendations to facilitate upper gastrointestinal endoscopy and underlying policy dilemmas, policy bottlenecks, and hindering factors

Policy recommendations	Policy dilemmas	Policy bottlenecks	Hindering factors of upper gastrointestinal endoscopy implementation
i) Mobilizing and redistributing financial resources for PHC-level hospitals	Dilemma between insurance coverage/ supportive regulations and self-financing policy	Inappropriate health financing policy	Constrained budgets Limited physical infrastructure
ii) Facilitating participation in upper gastrointestinal endoscopy training		Workforce allocation failures	Limited service delivery capacity Limited human resources in terms of number, skills, and training Non-standardized endoscope reprocessing
iii) Establishing accessible professional networks	Dilemma between the intended and unintended outcomes of healthcare decentralization and administrative reform	Coordination breakdowns	Lack of professional networks for seeking technical advice
iv) Raising awareness of upper gastrointestinal endoscopy services			Low awareness of upper gastrointestinal endoscopy services among local communities and clinicians
v) Promoting adherence to national guidelines		Regulatory gaps	Non-standardized endoscope reprocessing Low awareness of alignment between national guidelines and in-house guidelines among staff

Abbreviation: PHC, primary healthcare.

2.1. Mobilizing and redistributing financial resources for PHC-level hospitals

The first policy dilemma—between insurance coverage/supportive regulations and the self-financing policy—manifested as a policy bottleneck in the form of an inappropriate financing policy. This gave rise to the two hindering factors: *i*) budget constraints and *ii*) limited infrastructure, including insufficient service space within hospital buildings and an inadequate number of endoscopy units. We therefore recommend mobilizing and redistributing financial resources to PHC-level hospitals, rather than imposing unrealistic requirements for financial self-sufficiency.

Our study revealed that the district hospitals remain heavily dependent on provincial budgets, including the purchase and installation of new devices. In district hospitals with a low upper gastrointestinal endoscopy case volume, the responsible departments were operating at a financial deficit. Existing literature also suggests that insufficient equipment, inadequate maintenance, and weak device management frequently contribute to inefficiencies in healthcare systems, including endoscopy services in resource-limited settings (*17,18*).

2.2. Facilitating participation in upper gastrointestinal endoscopy training

The first policy dilemma between insurance coverage/supportive regulations and the self-financing policy also created a bottleneck in workforce allocation, as district hospitals cannot afford to hire additional staff despite management decentralization. This resulted in two hindering factors: *i*) limited service delivery capacity and *ii*) insufficient human resources in terms of number, skills, and training. We therefore recommend facilitating the participation of staff responsible for endoscopy in upper gastrointestinal endoscopy training programs for the purpose of improving service delivery capacity. At the same time, in order to increase the number of qualified professionals, hospitals could encourage non-qualified staff in hospitals to take training to obtain endoscopy certification. These newly trained staff members could then serve as substitutes during absence of regular personnel. This approach is considered more feasible than hiring additional staff, which is financially challenging under current financing policy.

Our study indicated that clinical preparedness remained suboptimal due to insufficient staff capacity. Furthermore, from a service delivery perspective, limited access to training opportunities—particularly for endoscopy nurses—resulted in non-standardized endoscope reprocessing practices across targeted hospitals, potentially increasing risk of compromised infection control. Ongoing training opportunities are essential not only to strengthen clinical capacity but also to enhance staff motivation. These findings underscore the urgency of developing staff capacity through expanded access to training opportunities.

2.3. Establishing accessible professional networks

The second policy dilemma—between intended and unintended outcomes of healthcare decentralization and administrative reform—manifested as a policy bottleneck characterized by coordination breakdowns across administrative levels. This resulted in a lack of professional networks that would allow district hospital staff to access upper-level hospital staff for seeking technical advice. We therefore recommend establishing accessible professional networks that can address the needs of endoscopists at district hospitals.

Our study revealed absence of professional networks through which PHC-level hospital staff could seek external technical advice in relation to endoscopy services. As confirmed in the study, PHC-level hospitals are staffed by only one or a limited number of professionals, who are required to manage multiple roles and responsibilities. District hospital staff were unsure of whom to approach when they needed to seek technical guidance outside their own facilities, due to insufficient internal resources. Given that one of Vietnam's strengths lies in the presence of experts at high-level hospitals and in domestic professional associations such as the Vietnamese Federation for Digestive Endoscopy (VFDE), multiple resources should be available beyond regional higher-level hospitals that lower-level staff can access.

2.4. Raising awareness of upper gastrointestinal endoscopy services

The second policy dilemma between intended and unintended outcomes of healthcare decentralization and administrative reform, again reflecting a bottleneck characterized by coordination breakdowns across administrative levels, contributed to a hindering factor of low awareness of upper gastrointestinal endoscopy services among local communities and clinicians. Frequent changes in mandates and role demarcations between hospitals at different levels (*7,14,15,19*) made it difficult for local communities and clinicians not directly involved in endoscopy services to recognize availability of these services at the district level (*13,20*).

We therefore recommend raising awareness of upper gastrointestinal endoscopy services at district hospitals among local communities and non-endoscopy clinicians through a targeted information, education, and communication (IEC) strategy.

Our study revealed that low utilization rates of upper gastrointestinal endoscopy in two of the four district hospitals studied were attributable to limited awareness among local residents about availability of these services. With regard to clinicians—who serve as the primary entry point for patient care in each hospital—limited

recognition of the effectiveness of upper gastrointestinal endoscopy contributed to a low volume of endoscopic examinations ordered.

2.5. Promoting adherence to national guidelines

The second policy dilemma between intended and unintended outcomes of healthcare decentralization and administrative reform manifested as another policy bottleneck characterized by regulatory gaps. This, in turn, resulted in two hindering factors: *i*) non-standardized endoscope reprocessing and *ii*) limited awareness among staff about alignment between national and in-house guidelines. The former primarily reflects a lack of supervision and monitoring of adherence to standard protocols, leading to varying levels of compliance across district hospitals. The latter reflects deficiencies in regulatory coherence and coordination across administrative levels. We therefore recommend promoting adherence to national guidelines within diagnostic imaging departments at PHC settings.

Our study revealed that although VFDE has established guidelines, including reprocessing procedures, in addition to the national policy ensuring access to basic examination and treatment using upper gastrointestinal endoscopy at the PHC level, these guidelines were not fully recognized by local staff nor applied in the form of in-house guidelines and protocols at PHC settings.

3. Responsible governance levels, policy instruments, and key implementation constraints of policy recommendations

For each of the five policy recommendations described above, we will elaborate on relevant governance levels, policy instruments or mechanisms required, and anticipated key implementation constraints or trade-offs (Table 2).

The first policy recommendation—to mobilize and redistribute financial resources for PHC-level hospitals—assumes governance responsibility at national and provincial levels for its implementation. The required policy instruments and mechanisms include health systems research focused on hospital financing to determine actual financial status of district hospitals. The establishment of a provincial committee under the Provincial Health Department to critically review and transform financial resource allocation and investment across hospitals at different administrative levels is also needed. Implementation of this policy recommendation may face constraints, as the principle of self-financing is firmly entrenched as a strategy to reduce national health expenditures, making it difficult to reform. In addition, reallocating financial resources to lower-level hospitals may encounter opposition from higher-level hospitals. However, mobilization and reallocation of funds at the provincial level may be feasible, provided that the provincial authority is the primary financier of capital investments in district hospitals.

The second policy recommendation—to facilitate participation in upper gastrointestinal endoscopy training—assumes governance responsibility at the national, provincial, and hospital levels for its implementation. The required policy instruments and mechanisms include establishment of a provincial committee under the Provincial Health Department to promote: *i*) on-site training opportunities in district hospitals, enabling staff to participate without leaving their workplaces; *ii*) a hospital-wide staff backup system to facilitate participation in external training; and *iii*) a Continuous Professional Development (CPD) system for endoscopists and endoscopy nurses. Implementation of this policy recommendation may compromise service continuity in the absence of adequate backup staff. In addition, expanding training opportunities will require mobilizing financial resources, which may pose further constraints.

The third policy recommendation—to establish accessible professional networks—assumes governance responsibility at the provincial and hospital levels for its implementation. The required policy instruments and mechanisms include formation of a task group comprising provincial health officers and hospital managers to establish: *i*) formal consultation networks with external experts and *ii*) systems to facilitate networking among hospitals at all levels within the region. Implementing this policy recommendation may require additional time and effort from the Provincial Health Department and hospital management.

The fourth policy recommendation—to raise awareness of upper gastrointestinal endoscopy services—assumes governance responsibility at the national, provincial, and hospital levels for its implementation. Required policy instruments and mechanisms include establishment of a task group comprising provincial health officers and district hospital staff responsible for community outreach to develop: *i*) IEC materials on upper gastrointestinal endoscopy for dissemination within local communities; *ii*) community-based health education modules to promote participation in upper gastrointestinal endoscopy screening; and *iii*) an educational module for district hospital clinicians on effectiveness of upper gastrointestinal endoscopy. Implementation of this policy recommendation may require additional financial resources, as well as increased time and effort from the Provincial Health Department and district hospital staff responsible for community outreach.

The fifth and the last policy recommendation—to promote adherence to national guidelines—assumes governance responsibility at the national and hospital levels for its implementation. Required policy instruments and mechanisms include developing in-house guidelines for district hospitals that align with

Table 2. Responsible level of governance, policy instruments or mechanisms required, and key implementation constraints or trade-offs of policy recommendations

Policy recommendations	Responsible level of governance	Policy instrument or mechanism required	Key implementation constraints or trade-offs
i) Mobilizing and redistributing financial resources for PHC-level hospitals	National and provincial levels	• Health systems research focusing on hospital financing to inform the actual financial status of district hospitals. • Provincial committee under the Provincial Health Department to consider financial resource allocation and investments across hospitals at different administrative levels.	• Self-financing discipline is firmly established in motivation to reduce national health expenditure, thus difficult to change. • Reallocation of financial resources to lower-level hospitals may face opposition from upper-level hospitals.
ii) Facilitating participation in upper gastrointestinal endoscopy training	National, provincial, and hospital levels	• Provincial committee under Provincial Health Department to promote: *i*) on-site training opportunities in district hospitals to enable staff to participate without leaving their workplaces; *ii*) a hospital-wide staff backup system to allow participation in external training; and *iii*) a CPD system for endoscopists and endoscopy nurses.	• Training participation may trade off with service continuity if there is no backup staff. • Additional training opportunities require financial resource mobilization, which may pose constraints.
iii) Establishing accessible professional networks	Provincial and hospital levels	• A task group comprised of provincial health officers and hospital managers, establishing: *i*) official consultation networks with external experts; and *ii*) systems to facilitate networking across hospitals at all levels within the region.	• Building networks and developing systems requires additional effort and time on the part of the Provincial Health Department and hospital management.
iv) Raising awareness of upper gastrointestinal endoscopy services	National, provincial, and hospital levels	• A task group comprised of provincial health officers and district hospital staff in charge of community outreach, developing: *i*) IEC materials on upper gastrointestinal endoscopy to be disseminated among local communities; *ii*) community-based health education modules to facilitate upper gastrointestinal endoscopy screening; and *iii*) an educational module for district hospital clinicians on the effectiveness of upper gastrointestinal endoscopy.	• Developing the IEC materials requires additional financial resources. • They also require additional effort and time on the part of the Provincial Health Department and district hospital staff in charge of community outreach.
v) Promoting adherence to national guidelines	National and hospital levels	• In-house guidelines for district hospitals that align with the national guidelines. • A national task group to publish a manual and conduct training to develop in-house guidelines in alignment with the national guidelines.	• Publication of the manual and conducting training require additional financial resources. • Limited motivation among district hospital staff to develop guidelines in alignment with the national ones may pose constraints.

Abbreviation: CPD, Continuous Professional Development; IEC, Information, Education and Communication; PHC, primary healthcare.

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national guidelines, and establishing a national task group to publish a manual and provide training to support development of in-house guidelines consistent with national standards. Implementation of this policy recommendation may require additional financial resources. In addition, limited motivation among district hospital staff to develop guidelines aligned with national standards may pose a constraint.

Despite the above mentioned anticipated constraints and/or trade-offs, our five policy recommendations are considered relatively feasible to implement compared with other policy alternatives, such as allocating additional staff specifically to endoscopic services at district hospitals or integrating an upper gastrointestinal endoscopy module into undergraduate medical education. The former may trigger debates over prioritization and justification - whether upper gastrointestinal endoscopy warrants a dedicated staff increase amid broader shortages of human resources and financing at the PHC level. The latter would likely require a joint agreement between Ministry of Health and Ministry of Education, necessitating interministerial coordination and negotiation, which may be time-consuming.

4. Conclusion

Vietnam has established favorable policies for upper gastrointestinal endoscopy, providing an opportunity to expand this technology to the grassroots level. However, the dilemma between insurance coverage/supportive regulations and self-financing policy as well as the one between intended and unintended outcomes of healthcare decentralization and administrative reform, together with the resulting four policy bottlenecks and eight hindering factors, have impeded implementation of upper gastrointestinal endoscopy services at district hospitals. We therefore propose five policy recommendations: *i*) mobilizing and redistributing financial resources for PHC-level hospitals; *ii*) facilitating participation in upper gastrointestinal endoscopy training; *iii*) establishing accessible professional networks; *iv*) raising awareness of upper gastrointestinal endoscopy services; and *v*) promoting adherence to national guidelines. In this article, we demonstrate that these recommendations are closely aligned with policy dilemmas, bottlenecks, and hindering factors identified. Furthermore, after analyzing their potential constraints and trade-offs, we consider them to be relatively feasible to implement.

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Pneumococcal vaccination and aspiration pneumonia in super-aged societies: A scoping review of the evidence landscape

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Abstract: Aspiration pneumonia is the leading cause of pneumonia-related death in Japan, where 29.3% of the population is aged ≥ 65 years, and it represents a growing challenge across rapidly aging Asian societies. Although pneumococcal vaccination is widely implemented for older adults, its effectiveness specifically against aspiration pneumonia remains unestablished. This scoping review systematically mapped the existing evidence on pneumococcal vaccination effectiveness for aspiration pneumonia prevention. Following Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) guidelines, PubMed, Cochrane Library, and Cumulative Index to Nursing and Allied Health Literature (CINAHL) were searched, identifying five studies (three primary studies and two reviews). None directly evaluated vaccine effectiveness with aspiration pneumonia as a defined outcome. Indirect evidence from studies including aspiration pneumonia within composite pneumonia outcomes suggests potential benefits; however, vaccine-specific effects could not be isolated. This review identifies a structural misalignment between the predominant pneumonia phenotype in super-aged societies and existing vaccine evaluation frameworks, and demonstrates that aspiration pneumonia has been systematically overlooked as a prespecified outcome in vaccine effectiveness research. Notably, the absence of direct evidence reflects limitations in study design and outcome definition, rather than evidence of vaccine ineffectiveness. Dedicated clinical studies are warranted to inform evidence-based immunization policies.

Keywords: aspiration pneumonia, pneumococcal vaccination, aged, *Streptococcus pneumoniae*, scoping review

1. Introduction

Aspiration pneumonia represents a significant and growing healthcare burden in aging societies. Japan, the world's most aged society with 29.3% of its population aged ≥ 65 years in 2024 (*1*), faces an urgent challenge in managing aspiration pneumonia. Other Asian countries are encountering similar demographic shifts. South Korea joined the ranks of super-aged societies in December 2024, with 20% of its population aged ≥ 65 years (*2*). In older adults, aspiration pneumonia is associated with high mortality, frequent recurrence, and prolonged hospitalization (*3,4*). Accordingly, developing effective prevention strategies has become a priority in geriatric medicine and public health across rapidly aging Asian societies.

Pneumococcal vaccination has demonstrated effectiveness in preventing invasive pneumococcal disease and pneumococcal pneumonia in adults (*5,6*). Many countries have implemented national immunization programs targeting older populations. South Korea and Japan introduced routine pneumococcal vaccination for adults aged ≥ 65 years in 2013 and 2014, respectively. More recently, a 21-valent pneumococcal conjugate vaccine designed for adults showed robust immunogenicity against serotypes responsible for approximately 83% of invasive pneumococcal disease in individuals aged ≥ 65 years (*7–9*). However, whether this protective effect extends to aspiration pneumonia, a condition with distinct pathophysiological mechanisms and potentially different microbial etiologies, remains unclear. *Streptococcus pneumoniae* is clinically relevant in aspiration pneumonia (*10,11*), providing a theoretical rationale for investigating pneumococcal vaccination as a potential preventive strategy.

To the best of our knowledge, no previous review has systematically examined the effectiveness of pneumococcal vaccination specifically for the prevention of aspiration pneumonia, despite its substantial clinical burden. This gap reflects a structural misalignment between the predominant pneumonia phenotype in super-aged societies and existing vaccine evaluation

frameworks, in which aspiration pneumonia has been systematically overlooked as a prespecified outcome. Therefore, this scoping review aims to map the existing evidence on the effectiveness of pneumococcal vaccination for aspiration pneumonia prevention, identify gaps in the current literature, and propose directions for future research.

2. Literature search strategy and process

2.1. Protocol

A scoping review is a methodology used to rapidly map key concepts within a research area, as well as the available sources of information and evidence (*12*). This scoping review adhered to the Joanna Briggs Institute methodology for scoping reviews (*13*) and was reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) guidelines (*14*).

2.2. Eligibility criteria

Studies were included if they: *i*) evaluated the effectiveness or efficacy of pneumococcal vaccines; *ii*) included populations with aspiration pneumonia, dysphagia, or swallowing disorders; *iii*) reported clinical outcomes related to pneumonia prevention, recurrence, hospitalization, or mortality; and *iv*) were published in English.

Studies were excluded if they: *i*) were animal studies; *ii*) involved pediatric populations (age < 18 years); *iii*) were published in languages other than English; or *iv*) did not report efficacy data.

2.3. Information sources and search strategy

A systematic search was conducted on November 30, 2025, across three electronic databases: PubMed, Cochrane Library, and Cumulative Index to Nursing and Allied Health Literature (CINAHL). The search strategy combined terms related to aspiration pneumonia and pneumococcal vaccination using the following search string:

("aspiration pneumonia" OR "deglutition disorders" OR "dysphagia") AND ("pneumococcal vaccine" OR "pneumococcal vaccination" OR "PPSV23" OR "PCV13" OR "PCV15" OR "PCV20" OR "PCV21" OR "pneumococcal polysaccharide vaccine" OR "pneumococcal conjugate vaccine")

No date restrictions were applied. Citation tracking of the included review articles was conducted to identify additional relevant studies. Notably, this search strategy intentionally required explicit aspiration-related terms to assess whether aspiration pneumonia has been recognized as a distinct and prespecified evaluative outcome in vaccine effectiveness research. This approach differs from searches targeting studies conducted in aspiration-prone populations (*e.g.*, nursing home residents or patients with dysphagia) without explicit aspiration-related outcome labeling. The rationale for this decision is discussed further in the Limitations section.

2.4. Selection of sources of evidence

Retrieved records were deduplicated and screened based on titles and abstracts. Title and abstract screening was initially conducted by one researcher and subsequently verified by a second researcher. Articles that met the inclusion criteria underwent full-text review, and ambiguous cases were resolved by consensus between two researchers. Full-text articles from potentially eligible studies were obtained and assessed according to the predefined inclusion and exclusion criteria. Although scoping reviews typically exclude review articles to prevent double-counting, we retained review articles in this study for two purposes: *i*) citation tracking to identify additional primary studies and *ii*) contextualizing the findings in the Synthesis and Implications section by referencing expert perspectives on aspiration pneumonia management. The evidence synthesis and identification of research gaps in the Evidence Overview section were based exclusively on primary studies.

2.5. Data charting process

The following data were extracted from the included studies: author, publication year, country, study design, population characteristics, sample size, vaccine type, and key findings related to aspiration pneumonia and pneumococcal vaccination.

3. Evidence overview

3.1. Study selection

The database search yielded 21 records (PubMed: 8, Cochrane Library: 2, CINAHL: 11). After removing 9 duplicates, 12 unique records underwent title and abstract screening. Six records were excluded during title and abstract screening: 4 animal studies, 1 pediatric study, and 1 article published in Chinese. Six records underwent full-text review, of which two were excluded: one cross-sectional survey without efficacy data (*15*) and one review article without specific discussion of aspiration pneumonia prevention (*16*). Ultimately, two primary studies (*17,18*) and two review articles (*3,4*) were included from the database search. Citation tracking of the included review articles identified one additional primary study (*19*), resulting in a total of five studies (three primary studies and two review articles) in the final synthesis (Figure 1).

3.2. Study characteristics

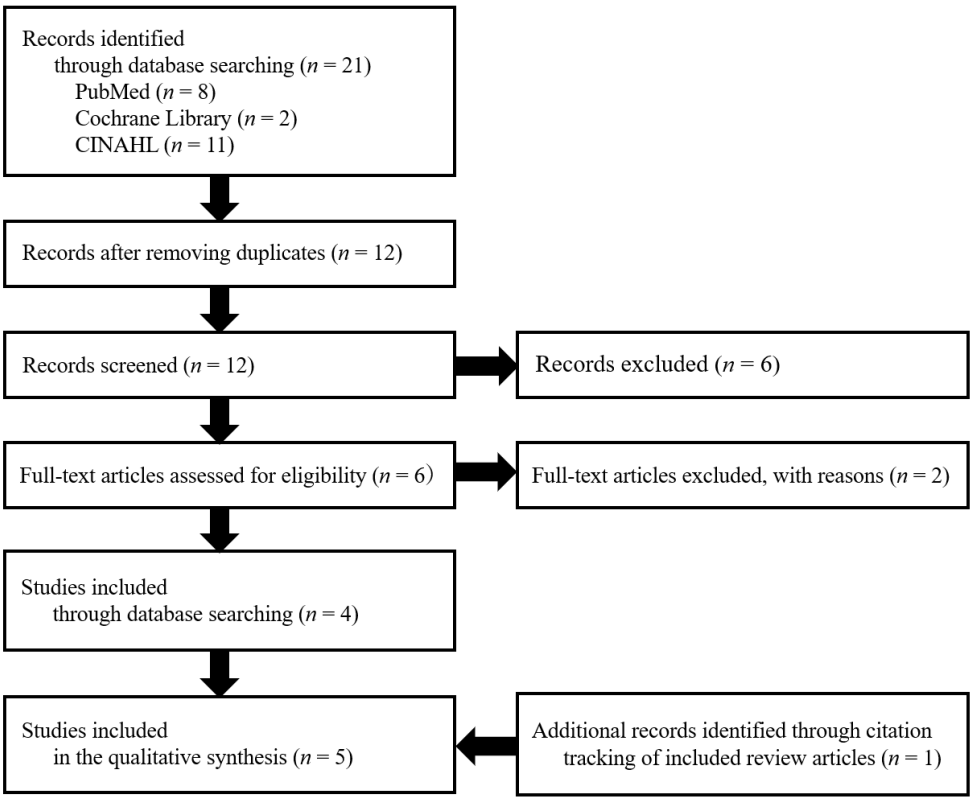

Figure 1. PRISMA-ScR flow diagram of study selection.

The five included studies comprised three primary studies and two review articles, published between 2003 and 2021. The primary studies were conducted in Singapore, Spain, and Sweden, and employed diverse methodological approaches, including a randomized controlled trial, a prospective cohort study, and a retrospective cohort study. Study populations ranged from 123 to more than 259,000 participants, all focusing on older individuals aged ≥ 65 years. The characteristics of the included studies are summarized in Table 1.

3.3. Synthesis of findings

A synthesis of the included studies revealed no direct evidence regarding the effectiveness of pneumococcal vaccination specifically for the prevention of aspiration pneumonia. The available evidence was derived from broader pneumonia populations or from theoretical considerations presented in review articles.

3.3.1. Direct evidence for aspiration pneumonia

None of the included studies directly evaluated the effectiveness of pneumococcal vaccination in preventing aspiration pneumonia as either a primary or secondary outcome.

3.3.2. Indirect evidence from related populations

Although no study directly evaluated aspiration pneumonia as a primary outcome, the available evidence suggests a potential vaccine benefit in aspiration-prone populations.

Hedlund *et al.* (*19*) conducted a large-scale retrospective cohort study evaluating influenza and pneumococcal vaccination in 259,627 older individuals. Notably, the outcome measure "pneumonia" explicitly included aspiration pneumonia (International Classification of Diseases, 10th Revision [ICD-10]: J69.0) alongside other pneumonia categories (ICD-10: J12–J18). Vaccinated individuals had significantly lower rates of hospital admission for pneumonia (relative risk [RR] = 0.78, 95% confidence interval [CI]: 0.71–0.86) and invasive pneumococcal disease (RR = 0.46, 95% CI: 0.25–0.87). The protective effect against pneumonia persisted during the non-influenza seasons (RR, 0.88), suggesting independent pneumococcal vaccine efficacy. Although these findings indicate a potential benefit in populations that include patients with aspiration pneumonia, the study did not report separate outcomes specifically for aspiration pneumonia.

Garcia-Vidal *et al.*(*17*) analyzed recurrent community-acquired pneumonia (CAP) episodes in 1,556 hospitalized patients and found that aspiration pneumonia was more prevalent among those with recurrent CAP episodes (10.3%) than among those without recurrence (5.7%). Lack of pneumococcal vaccination was identified

Table 1. Characteristics of the included studies

Authors, Year (*Ref.*)	Country	Study Design	Population	Sample Size	Vaccine Type	Key Findings
Primary Studies						
Hedlund *et al.*, 2003 (*19*)	Sweden	Retrospective cohort	Adults aged ≥ 65 years	259,627	PPSV23 + Influenza	Pneumonia outcome included aspiration pneumonia (ICD-10: J69.0). Vaccination reduced pneumonia hospitalization (RR = 0.78) and invasive pneumococcal disease (IPD) (RR = 0.46). This effect persisted in the non-influenza season.
Garcia-Vidal *et al*., 2009 (*17*)	Spain	Prospective cohort	Hospitalized patients with CAP	1,556	PPSV23	Aspiration pneumonia was more common in patients with recurrent CAP (10.3% *vs.* 5.7%). Lack of vaccination was associated with CAP recurrence (OR = 1.91). No direct analysis of the effect of the vaccine on aspiration pneumonia was performed.
Rosario *et al.*, 2021 (*18*)	Singapore	RCT	Geriatric inpatients aged ≥65 years	123	PCV13 + Influenza	Multi-component intervention including vaccination reduced respiratory rehospitalization (18.6% *vs.* 34.4%). Vaccine effect was not isolatable from other interventions.
Review Articles						
Teramoto *et al.*, 2015 (*3*)	Japan	Narrative review	Older patients with aspiration pneumonia	N/A	—	Vaccination was discussed as prevention strategy and cited Hedlund *et al.* (*19*) for vaccine effectiveness evidence.
Janssens, 2005 (*4*)	Switzerland	Narrative review	Older patients with pneumonia	N/A	—	Addressed pneumococcal vaccination in older patients and Referenced Hedlund *et al.* (*19*).

Abbreviations: CAP, community-acquired pneumonia; ICD-10, International Classification of Diseases 10th Revision; IPD, invasive pneumococcal disease; PCV13, 13-valent pneumococcal conjugate vaccine; PPSV23, 23-valent pneumococcal polysaccharide vaccine; RCT, randomized controlled trial; RR, relative risk; OR, odds ratio.

as an independent risk factor for CAP recurrence (odds ratio [OR] = 1.91, 95% CI: 1.30–2.80). However, this study did not examine whether pneumococcal vaccination specifically reduced recurrence of aspiration pneumonia, and no direct association was established between these findings.

Rosario *et al.* (*18*) implemented pneumococcal vaccination as part of a multicomponent intervention in older patients at high risk of aspiration and demonstrated reduced respiratory infection–related rehospitalization (18.6% *vs*. 34.4%). This finding is consistent with a potential benefit of vaccination as part of comprehensive prevention strategies; however, the study design precluded isolation of vaccine-specific effects from other intervention components.

3.3.3. Review article perspectives

Teramoto *et al.* (*3*) and Janssens (*4*) cited Hedlund *et al.* (*19*) in discussing the potential benefits of pneumococcal vaccination for preventing recurrent pneumonia in older patients, including those at risk of aspiration. These reviews suggest that vaccination may be beneficial based on evidence from the general older population; however, neither review provided additional primary data specific to aspiration pneumonia.

3.3.4. Summary of evidence landscape

This scoping review, based exclusively on primary studies, identified several critical evidence gaps: *i*) no studies evaluated pneumococcal vaccination effectiveness with aspiration pneumonia as a clearly defined outcome; *ii*) no data examined whether the association between pneumococcal vaccination and reduced CAP recurrence extends specifically to aspiration pneumonia; and *iii*) understanding of the contribution of pneumococci to aspiration pneumonia etiology in contemporary patient populations remains limited. In summary, none of the included primary studies provided direct evidence of pneumococcal vaccine effectiveness with aspiration pneumonia as a prespecified outcome; the available indirect evidence was derived from studies using composite pneumonia outcomes, multicomponent interventions in which vaccine-specific effects could not be isolated, and associative findings requiring additional inferential steps.

4. Synthesis and implications

4.1. Summary of main findings

This scoping review systematically examined the evidence on the effectiveness of pneumococcal vaccination for preventing aspiration pneumonia. The search identified three primary studies and two review articles that met the inclusion criteria; however, none directly evaluated pneumococcal vaccination effectiveness with aspiration pneumonia as a clearly defined outcome. Importantly, the absence of direct evidence reflects a structural gap in research design and outcome definition rather than demonstrated vaccine ineffectiveness. Hedlund *et al.* (*19*) reported reduced pneumonia-related hospitalizations in vaccinated older individuals, with aspiration pneumonia included within the composite pneumonia outcome; however, aspiration pneumonia was not reported separately. Garcia-Vidal *et al.* (*17*) identified aspiration pneumonia as a risk factor for recurrent CAP and lack of pneumococcal vaccination as an independent predictor of recurrence, findings that are consistent with a potential benefit of vaccination in aspiration-prone patients, although no direct association was established. Rosario *et al.* (*18*) demonstrated reduced respiratory infection–related rehospitalization with a multicomponent intervention that included pneumococcal vaccination, suggesting that vaccination may contribute to comprehensive prevention strategies; however, vaccine-specific effects could not be isolated. Collectively, these findings highlight the need for studies that directly examine the relationship between pneumococcal vaccination and aspiration pneumonia.

4.2. Clinical burden of aspiration pneumonia

The importance of addressing this evidence gap is underscored by the clinical significance of aspiration pneumonia. Among older adults, aspiration pneumonia is common and is associated with hospital mortality rates of approximately 10–15%, which increase with advancing age and the presence of swallowing abnormalities (*20,21*). This substantial burden provides a strong rationale for investigating vaccine effectiveness against aspiration pneumonia. The reported proportion of aspiration pneumonia among all pneumonia cases is notably high in Japan at 40–70% (*22-25*), substantially exceeding rates reported in Western countries at 5–15% (*20,21,26*). Comparable data from other Asian countries remain limited, although a single-center study in South Korea reported a proportion of 14.2% (*27*). A previous scoping review found that no uniform diagnostic criteria for aspiration pneumonia exist, indicating that direct comparisons across studies may not be feasible (*28*). Similarly, recent multidisciplinary consensus recommendations have emphasized the complexity of geriatric dysphagia management and the need for standardized approaches to screening, diagnosis, and rehabilitation in older adults (*29*).

4.3. Comparison with existing literature

The effectiveness of pneumococcal vaccination against CAP and invasive pneumococcal disease in older populations has been established through multiple systematic reviews and meta-analyses (*5,30*). However,

none of these reviews specifically addressed aspiration pneumonia as an outcome, making the present scoping review the first to systematically examine this issue. Although our search identified no direct evidence, noteworthy findings have been reported in populations with a high risk of aspiration. Maruyama *et al.* (*31*) conducted a randomized controlled trial demonstrating that PPSV23 reduced all-cause pneumonia by 44.8% and pneumococcal pneumonia by 63.8% among Japanese nursing home residents. Nursing home populations inherently carry an elevated aspiration risk due to advanced age, poor functional status, and a high prevalence of neurological comorbidities. Given the prevalence of swallowing dysfunction of approximately 60% (*32*) among nursing home residents, a proportion of the pneumonia cases prevented by Maruyama *et al.* (*31*) may have included aspiration pneumonia.

Collectively, these findings suggest a potential vaccine benefit in populations with inherently elevated aspiration risk. However, because the study did not distinguish between aspiration and non-aspiration pneumonia, whether the observed vaccine efficacy extended specifically to aspiration pneumonia remains unknown, representing a key evidence gap.

4.4. Microbiological considerations

The theoretical basis for pneumococcal vaccination in the prevention of aspiration pneumonia warrants careful consideration of contemporary microbiological evidence. Although anaerobic bacteria have traditionally been regarded as the predominant pathogens in aspiration pneumonia, contemporary molecular studies using 16S rRNA gene analysis have challenged this view by demonstrating that anaerobes account for only approximately 6% of cases, whereas oral streptococci are the most frequently detected pathogens in patients with aspiration risk factors. Notably, *S. pneumoniae* detection rates were similar regardless of the aspiration risk status (13.0% *vs.* 13.7%) (*10*). A cohort study in the UK using culture and urinary antigen testing reported that, although *S. pneumoniae* detection rates were lower in patients with aspiration risk factors than in those without such risk factors (20.5% *vs.* 32.5%), *S. pneumoniae* remained one of the predominant pathogens in this population (*11*). These findings indicate that *S. pneumoniae* remains clinically relevant in patients at risk of aspiration, thereby providing a microbiological rationale for investigating pneumococcal vaccination as a potential preventive strategy.

4.5. Implications for clinical practice

Given the absence of direct evidence, clinical recommendations regarding pneumococcal vaccination specifically for the prevention of aspiration pneumonia cannot be established definitively. However, several considerations suggest that vaccination may be beneficial for patients at risk of aspiration, and clinicians may reasonably consider vaccination for these patients. First, these patients frequently have additional risk factors for pneumococcal disease, including advanced age, chronic comorbidities, and institutional residence, all of which are established indications for vaccination. Second, the inclusion of aspiration pneumonia within composite pneumonia outcomes showing vaccine benefits (*19*), combined with demonstrated vaccine efficacy in nursing home populations at high aspiration risk (*31*), supports its potential effectiveness in this population. Clinicians should continue to recommend pneumococcal vaccination to patients with aspiration risk who meet established indications while recognizing that aspiration-specific benefits remain unproven.

Several factors underscore the importance of addressing this evidence gap. Aspiration pneumonia is associated with high mortality rates, frequent recurrence, and significant healthcare burden, particularly in aging societies (*3,4*). Among available preventive interventions, pneumococcal vaccination is relatively easy to integrate into routine clinical practice. The absence of dedicated research on vaccine effectiveness for this high-burden condition represents a significant missed opportunity for evidence-based prevention. This gap also carries direct policy implications: Japan has implemented a national immunization program providing PPSV23 to adults aged ≥ 65 years since 2014, yet the effectiveness of this program against aspiration pneumonia—the predominant pneumonia pathophysiology in this demographic—has not been evaluated. In this sense, current national immunization programs targeting older adults have been implemented without direct evidence regarding their effectiveness against aspiration pneumonia, which was the predominant pneumonia phenotype in this demographic. This creates an implicit assumption of benefit against the very condition that represents the majority of pneumonia cases in the target population, an assumption that has never been empirically tested. Identifying this evidence gap is itself a clinically and policy-relevant finding: aspiration pneumonia constitutes the majority of pneumonia cases among the target population of pneumococcal immunization programs, yet no study has examined whether these programs confer protection against this predominant pathophysiology. Other Asian super-aged societies, including South Korea, face similar challenges in optimizing their pneumococcal immunization strategies for aging populations. Addressing this evidence gap would contribute to informed immunization policies in super-aged societies.

4.6. Implications for future research

This scoping review identified several priorities for future research. Prospective studies evaluating pneumococcal vaccination with aspiration pneumonia as a prespecified

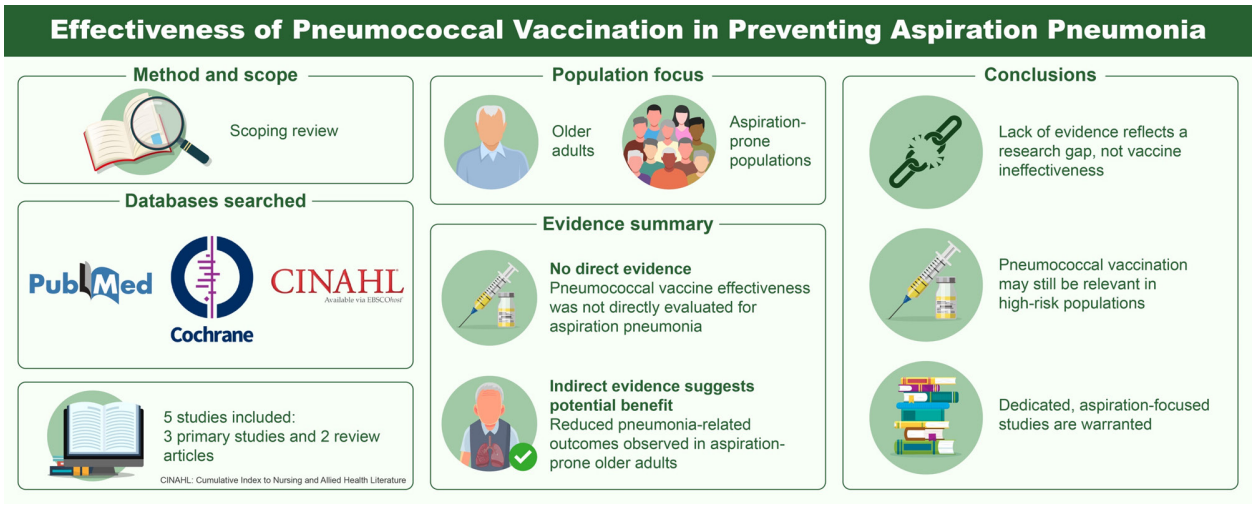

Figure 2. Graphical abstract summarizing the scope, methods, key findings, and conclusions of this scoping review on pneumococcal vaccination and aspiration pneumonia prevention in super-aged societies.

outcome are warranted. Microbiological studies determining the proportion of aspiration pneumonia cases caused by vaccine-covered serotypes may also help estimate the potential impact of vaccination. Additionally, secondary analyses of existing pneumonia vaccine trials stratifying outcomes according to aspiration risk factors may provide preliminary evidence.

4.7. Limitations

This scoping review has several limitations. First, the search strategy intentionally required explicit mention of aspiration pneumonia, dysphagia, or swallowing disorders to assess whether aspiration pneumonia has been recognized as a distinct evaluative outcome in vaccine research; however, this approach may have systematically excluded a substantial body of relevant literature from aspiration-prone populations without explicit outcome labeling. Studies conducted in populations inherently at high aspiration risk—such as nursing home residents, patients with stroke, or individuals with dementia—often do not explicitly label their populations or outcomes as "aspiration-related", even though these populations overlap significantly with those at risk for aspiration pneumonia. The trial by Maruyama *et al.* (*31*) exemplifies this limitation: despite enrolling nursing home residents with inherently elevated aspiration risk and demonstrating significant vaccine efficacy, our search did not capture this study because it did not include aspiration-related terms in its indexing. This suggests that indirect evidence regarding the effectiveness of pneumococcal vaccines in aspiration-prone populations may be considerably more extensive than that identified by our focused search. Second, the search was limited to English-language publications; searching regional databases such as Ichushi (Japan Medical Abstracts Society) may have identified additional relevant studies. Third, as a scoping review, a formal quality assessment of the included studies was not performed.

5. Conclusion

This scoping review revealed no direct evidence for pneumococcal vaccine effectiveness with aspiration pneumonia as a defined outcome, reflecting a lack of dedicated research rather than demonstrated ineffectiveness, as illustrated in Figure 2. Nevertheless, indirect evidence from related populations is consistent with the potential benefits for aspiration-prone patients. Given that Japan has invested substantial public health resources in pneumococcal vaccination programs for older adults, and other Asian super-aged societies are following suit, dedicated studies evaluating vaccine effectiveness against aspiration pneumonia are warranted to inform evidence-based immunization policies across the region. Secondary analyses of existing large-scale pneumonia vaccine trials, stratifying outcomes according to aspiration risk factors such as dysphagia, stroke history, or nursing home residence, represent a realistic and near-term approach to generating preliminary evidence while dedicated prospective studies are developed.

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Unlocking data elements potential for enhanced urban public health emergency governance: Configuration analysis based on 23 mega-cities in China

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Abstract: As the core production element of the digital era, data's multiplier effect is key to risk prevention and the modernization of emergency governance. This article combines the practical application of data elements in public health emergency management, based on the technology-organization-environment (TOE) theoretical framework, takes 23 mega-cities in China as research cases, and uses the fuzzy-set qualitative comparative analysis (fsQCA) method to explore the impact of technology, organization, environment, and other conditions on the effectiveness of urban public health emergency governance. The results show a significant conditional correlation between the effectiveness of urban public health emergency governance and the conditions for applying data elements. Based on the characteristics of multiple concurrent paths, the driving paths can be classified into three categories: "technology-based", "organization-environment dual core", and "organization-technology as the mainstay + environment as the supplement". Local governments should combine the regional digital resource endowment, promote phased and differentiated application of data elements, strengthen interconnection of data-sharing platforms, coordinate construction of institutional mechanisms, accelerate multi-scenario application of data elements, strengthen two-way empowerment of technology-driven and organizational coordination, and effectively transform linkage advantages of multidimensional elements into governance effectiveness.

***Keywords*:** data elements, emergency management, public health, mega-cities, configuration analysis

1. Introduction

As China's modernization advances, the connotation and extension of people's demand for security are more abundant. Effectively preventing and resolving sudden public health risks bears directly on national development and security, as well as overall social and political stability. Both the 15th Five-Year Plan and the Fourth Plenary Session of the 20th Central Committee of the Communist Party of China emphasized the need to strengthen the public health system, elevate public safety governance standards, and enhance effectiveness of coordinated emergency response and disease prevention and control. Cities, as hubs where diverse elements and economic activities converge most intensively, also serve as primary arenas bearing the brunt of disaster risks. In a realistic situation where the governance of risk complexity does not match the strip governance model, fragmentation of urban emergency governance functions further constrains governance efficiency. In recent years, rapid expansion of the digital economy has catalyzed an unprecedented transformation: human, spatial, material, and event-related elements in urban areas are progressively being digitized, fundamentally reshaping governance paradigms. Data resources, however, only unlock their full potential when applied to specific domains. As a new production factor, data can embed itself within traditional elements in informational form, generating multiplicative value through integration, amplification, and synergistic effects. Recognizing this, "Three-Year Action Plan for 'Data Element×'(2024–2026)" explicitly identifies "data element×emergency management" and "data element×urban governance" as core priorities, proposing to enhance emergency coordination and data-sharing capabilities, promote the integration of multi-dimensional urban data, and support the application of data elements in public health, public safety, and other fields.

Existing research mainly explains the enabling mechanism of big data technology in public health

governance from the aspects of monitoring and early warning, prevention and control strategies, and integrated risk management. Scholars argue that big data can break the information monopoly, promote comprehensive risk governance, and reshape the risk governance process (*1-4*). However, data is not a panacea—its introduction does not automatically eliminate deficiencies in existing emergency response systems and mechanisms (*5*). In practice, big data may fall short of expectations in governing urban public health emergencies. If used improperly or insufficiently, unexpected difficulties may be encountered (*6*). Moreover, the anticipated improvements in quality and efficiency from data element applications largely rest on theoretical deductions of technical logic. A potential mismatch between technical logic and actual organizational dynamics may hinder integration of big data technology and limit its effectiveness in public health emergency governance (*7*). So, what factors influence application of data elements in urban public health emergency governance? What configurational relationships exist among these factors, and how can they be leveraged to enhance governance effectiveness?

To address these questions, this article examines public health emergencies as a case study, selecting actual cases from 23 mega-cities in China, and uses the fuzzy-set qualitative comparative analysis (fsQCA) method to conduct configuration analysis. The marginal contribution of this article is that utilization of the fsQCA method to confirm multiple non-exclusive configuration paths for public health emergency governance effectiveness. This is conducive to deepening understanding of the mechanism of action in public health emergency governance, and promoting comprehensive modernization of digitally-enabled emergency governance.

2. Theoretical Analysis Framework

Government emergency governance aims to respond to sudden crises quickly and effectively, thereby minimizing casualties and property losses (*8*) and eliminating risks or potential risks in human activities (*9*). As a new type of production element, data can attach itself to traditional elements in information form, enhancing total factor productivity and generating multiplicative value through integration, amplification, and synergistic effects. Therefore, data elements can provide new technical support and strategic resources for urban public health emergency governance, reshape system architecture, and promote an intelligent emergency governance model (*10*).

Existing research has explored data elements' application process and role in public health emergency governance, preliminarily establishing a fuzzy correlation between data elements and governance effectiveness (*11,12*). However, few studies have explained the differentiated pathways to achieving effective governance. There is a lack of exploratory empirical analysis of combined linkage effects among various elements. In the digital age, all information elements, such as people, places, objects, events, and organizations, are highly correlated. The various elements within data-driven public health emergency governance processes are interdependent, and action paths for emergency governance effectiveness are also different. The key to effective governance lies in embedding big data throughout the entire emergency governance process, insuring accurate selection and design of data technology, and realizing the two-way empowerment of data elements and risk factors in the reconstruction of the entire process. Therefore, we attempt to introduce the fsQCA method and, based on the analysis ideas of the technology-organization-environment (TOE) framework proposed by Tornatzky and Fleischer (*13*), construct a theoretical explanatory framework for data elements to empower urban public health emergency governance effectiveness (Figure 1).

First, technical conditions. Specifically, two secondary conditions are introducing new technologies and establishing a data-sharing platform. Modernizing public health emergency governance systems and capabilities is inseparable from modern information technologies such as the Internet, big data, and cloud computing (*14*). By adopting new technical methods, a large amount of data can be analyzed and interpreted, breaking down "data barriers" and "data chimneys" (*15*), enabling information resource sharing and coordinated action within emergency systems (*16*), and improving risk perception and response capabilities. At the same time, with the advent of the risk society, risk factors in the public health field have increased significantly, and data openness and sharing also face various security risks. In response to major epidemic crises, building a data open-sharing and reuse platform based on emerging technologies such as privacy computing, secure multi-party computing, federated computing, and blockchain, can break down information islands across government departments. This not only provides data support for preventing viral spread, but also furnishes evidence sources for "evidence-based decision-making", thereby achieving sustainable long-term development of public health emergency governance.

Second, organizational conditions. Specifically, two secondary conditions exist: organizational system guarantee and government attention allocation. From the evolution of China's emergency management system, the focus of emergency management coordination has expanded from information and public opinion to plans, teams, and equipment and from emergency response to the entire prevention, preparation, response, and recovery process (*17*). It has gradually formed a strong institutional advantage and has become a prerequisite for effective coordination among all parties. Based on Simon's bounded rationality decision-making theory,

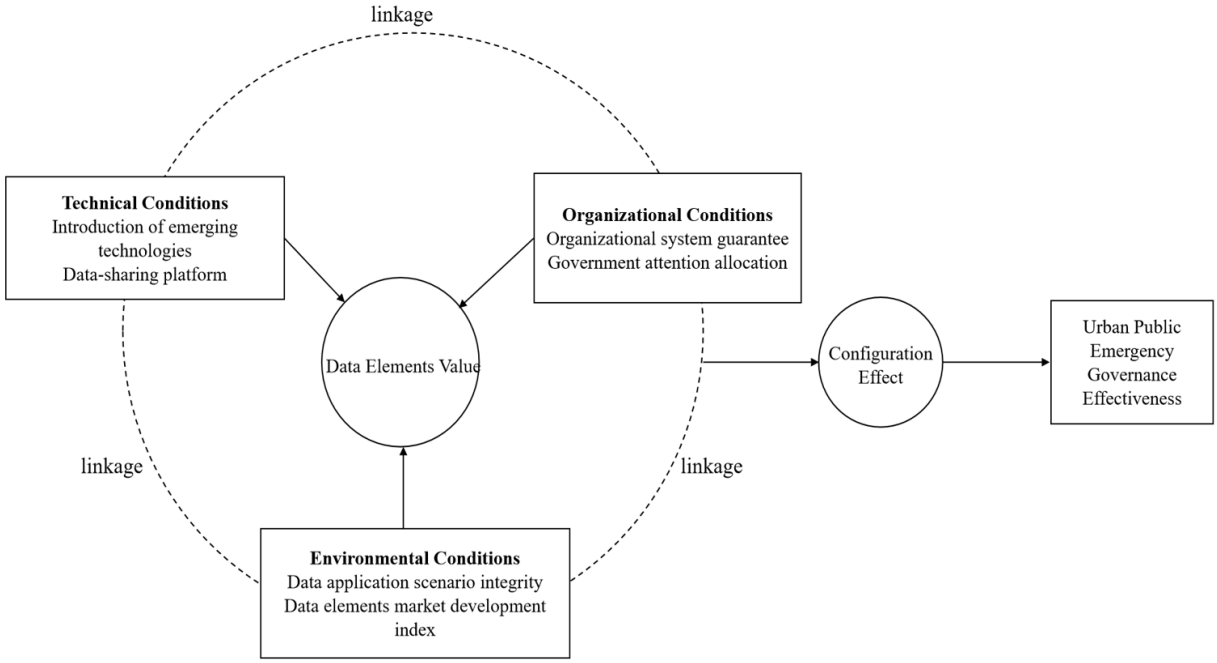

Figure 1. Theoretical analysis framework.

government attention is a scarce resource, and local decision-makers' behavioral choices depend on which issues and solutions they prioritize. Under conditions of agenda overload and limited governance resources, scarce government attention becomes key to effectively utilizing various data resources (*18*). In other words, when government decision-making agencies pay more attention to or prioritize data elements and their governance, this directly affects the realization process of data elements empowering public health emergency governance.

Third, environmental conditions. Specifically, they include two secondary conditions: data application scenario integrity and data elements market development index. Data only maximizes its value through application, and its value can only be fully explored when placed in specific application contexts. Based on the "risk governance chain" (*19*), big data applications in public health emergency governance are primarily reflected in multi-stage scenarios such as risk monitoring, risk warning, and risk response. The integrity of its application scenarios will affect release of the value multiplier effect of data elements. As the leading force in emergency management, the digital environment prompts the government to accelerate development and utilization of data resources and smooth the environment for data sharing and cooperation among departments. In 2020, the "Opinions on Further Improving the System and Mechanism of Element Market Allocation" proposed accelerating cultivation of the data elements market. Properly understanding and grasping the value creation mechanism of data elements enables optimal allocation of data across different stages of factorization through market-oriented means, thereby fully leveraging the role of data element markets in promoting digital construction of local governments.

3. Materials and Methods

3.1. Selection of research cases

QCA is a case-oriented research method, and selecting research cases is essential to applying this method. In our research, Mega-cities, serve as primary carriers of disaster risk shocks, given their complexity and dynamic nature. When public health incidents occur in large cities, transmission speed, control difficulty, and harm severity far exceed those in other areas. The public health security situation is more difficult, and urban emergency governance capabilities directly impact local public health services and risk control. To deeply explore which factors may drive or constrain application of data elements in urban public health emergency governance, this study is rooted in China's public health response practices and combined with the National Urban Construction Statistical Yearbook data to collect and organize the required research cases comprehensively. Among them, there are 8 super large-sized cities, including Shanghai, Beijing, Shenzhen, Chongqing, Guangzhou, Chengdu, Tianjin, and Wuhan, and 15 very large-sized cities, including Hangzhou, Dongguan, Xi'an, Zhengzhou, Nanjing, Jinan, Hefei, Shenyang, Qingdao, Changsha, Harbin, Kunming, and Shijiazhuang. Thus, a preliminary sample of 23 mega-cities was obtained, and case materials for each sample city were further collected. The selected case cities usually cover multiple regions, such as Central China, South China, North China, West China, and East China, and resource

endowments, crisis response measures, and effectiveness of each region are different. Overall, they conform to the principles of "maximum similarity" and "maximum difference", ensuring the scientific and accuracy of the research process.

3.2. Variable measurement and calibration

3.2.1. Outcome variable

We focus on the effectiveness of urban public health emergency governance. Government emergency governance aims to quickly respond to emergencies, thereby minimizing casualties and property damage to the greatest extent possible (*20*). "The Emergency Response Law of the People's Republic of China", "The National Emergency Plan for Public Health Emergencies", and other laws and regulations all emphasize the need to effectively prevent, control, and eliminate the hazards of public health emergencies, protect physical health and safety of the public, and maintain regular social order. Referring to the performance measurement standards of government public health governance of Tao *et al.* (*21*), combined with the complexity of risk prevention and control in mega-cities, three indicators were used to measure the urban public health emergency governance effectiveness: "the proportion of urban elderly in the total population at end of the year", "birth rate in various regions", and "incidence rate of Class A and B infectious diseases". These indicators are used as macro-level proxy measures reflecting long-term risk control capacity rather than short-term response performance, capturing the aggregate outcomes of public health emergency governance under sustained stress. Relevant data mainly come from the economic and social development bulletins and health development statistics bulletins issued by the Local Bureau of Statistics, Health Commission, and Centers for Disease Control and Prevention. Among them, the proportion of urban elderly in the total population at the end of the year and the birth rate in various regions will be based on the latest data released in 2024, while the incidence rate of Class A and B infectious diseases will be obtained by taking the average value from 2019 to 2023 to reflect the impact of the global epidemic crisis accurately.

3.2.2. Antecedent conditions

First, technical conditions. Introduction of new technologies is measured by the number of emerging technologies and methods, such as big data, cloud computing, blockchain, artificial intelligence, 5G, and the Internet of Things used in epidemic monitoring and analysis, virus tracking, prevention and control, and resource allocation. The data-sharing platform provides information support for public health risk assessment and coordinated response. By examining the number of public data-sharing platforms established by local governments, we can understand integration of data elements and public health risk response. Second, organizational conditions. Organizational system assurance is measured by the number of data governance policies issued by local governments. Specifically, we use keywords such as "data", "numbers", "data elements", and "digital technology" to collect and tally relevant policy texts. In December 2022, the Central Committee of the Communist Party of China and the State Council issued the "Opinions on Establishing a Data Infrastructure System to Better Leverage the Role of Data Elements" (referred to as "Data 20"), which is the first national remarkable policy document to systematically deploy value release of data elements from the perspective of production elements. Subsequently, Beijing, Shanghai, Shenzhen and other places successively issued a series of data element related policy documents. This article measures the government's attention allocation by the time difference between releasing "Data Element" policies and "Data 20" in sample cities. Third, environmental conditions. The integrity of data application scenarios is measured based on the number of big data applications in areas such as community prevention and control, emergency coordination, post-disaster recovery, resumption of work and production, *etc*., reflecting the scope of data application scenarios. The data elements market development index focuses on four dimensions: the development foundation of data elements, data governance and security, data elements supply, and data elements circulation. We combine the relevant indicator data from "China Urban Data Elements Development Index (2024)" and "China Digital Economy Development Index Report (2024)" for comprehensive measurement.

3.2.3. Variable calibration

In fsQCA, each condition and outcome is treated as an independent set, and each case has a membership score in these sets. The original cases must go through a calibration process. The data are converted into a fuzzy set of membership numbers. QCA calibration methods include direct and indirect methods. The results and conditional variables involved in this article lack empirical knowledge as a calibration basis. Therefore, following mainstream QCA research, objective quantile values are used to determine qualitative anchor points to reduce subjective bias and bias caused by outcome orientation. Specifically, 95%, 25%, and 5% of the sample data are used as the anchor points of the "completely affiliated", the "intersection point" and the "completely non-affiliated" attributes, respectively. Reasonable adjustments are made according to the actual situation (Table 1).

4. Configuration Analysis Results

4.1. Necessity analysis of a single condition

Before analyzing the sufficiency of condition type configuration, it is necessary to conduct necessity analysis for individual conditions individually to determine whether there is a specific condition that constitutes the necessary conditions of the resulting variable. Therefore, in this study, we adopt fsQCA version 3.0 to analyze the consistency and coverage of each condition variable. Table 2 shows the necessity analysis of a single condition. The results show that the consistency levels for all conditions are lower than 0.9. Therefore, a single condition variable cannot constitute a necessary condition for the result. It is necessary to further explore the combined linkage effect of the three dimensions of technology, organization, and environment throughout the application process of data elements.

4.2. Sufficient condition analysis

Concerning the results of existing studies, we set consistency threshold to 0.8 and case frequency threshold to 1, thereby constructing and analyzing the truth table to obtain complex solutions, intermediate solutions, and simple solutions. As the intermediate solution only incorporates logical residual terms that align with theoretical expectations and practical empirical evidence, complexity is moderate, and necessary conditions cannot be eliminated. Therefore, in this study, we mainly use the intermediate solution, supplemented by the parsimony solution, to determine the core edge conditions of different configurations. At the same time, keeping other conditions unchanged, the study also increases consistency level from 0.78 to 0.85, and configuration results produced are entirely consistent. The specific configuration paths and their explanatory case distributions are detailed in Table 3 and Figure 2. Based on the existence of configuration condition variables in technology, organization, and environment, we have identified three driving paths for effectiveness of high-level public health emergency governance. Each column in Table 3 represents a possible condition configuration path. In addition, consistency level of both the single solution and the overall solution is higher than that of the standard value, 0.75, and consistency of the three condition combinations is 1, indicating that the condition combination has high explanatory power for the outcome variable.

Configuration 1 indicates that existence of a data-sharing platform plays a central role. Compared with other conditions, data-sharing platforms are more important for effectiveness of high-level emergency governance and can independently constitute sufficient conditions for interpreting results. Under this condition configuration, when there is a data-sharing platform, other conditions are irrelevant to the effectiveness of

Table 1. Calibration of conditions and results

Conditions	Conditions and results	Calibration Anchor Point		
		Completely affiliated	Intersection point	Completely non-affiliated
Outcome Variable	Public health emergency governance effectiveness	15.199	13.15	9.536
Technical conditions	Introduction of emerging technologies	6.01	5.01	2.1
	Data-sharing platform	6.9	4.01	3.01
Organizational conditions	Organizational system guarantee	37	8.01	3.1
	Government attention allocation	138.4	361.01	729.09
Environmental conditions	Data application scenario integrity	4.01	3.01	2.01
	Data elements market development index	88.04	62.71	40.44

Table 2. Necessity analysis results

Condition variables	High public health emergency governance effectiveness		Low public health emergency governance effectiveness	
	Consistency	Coverage	Consistency	Coverage
Introduction of emerging technologies	0.6284	0.6730	0.6667	0.6125
~Introduction of emerging technologies	0.6381	0.6905	0.6441	0.5979
Data-sharing platform	0.7463	0.7446	0.614 9	0.5262
~Data-sharing platform	0.5250	0.6138	0.7015	0.7035
Organizational system guarantee	0.7609	0.8322	0.5603	0.5256
~Organizational system guarantee	0.5662	0.6002	0.8211	0.7466
Government attention allocation	0.5412	0.6788	0.6102	0.6565
~Government attention allocation	0.7262	0.6847	0.7015	0.5674
Data application scenario integrity	0.5767	0.7104	0.5951	0.6288
~Data application scenario integrity	0.6987	0.6680	0.7260	0.5954
Data elements market development index	0.7068	0.7682	0.4840	0.4513
~Data elements market development index	0.4952	0.5280	0.7514	0.6873

Table 3. Configuration paths for high-level public health emergency governance effectiveness

Conditional configuration	Technical-based	Organization-environment dual core	Organization-technology as the mainstay + environment as the supplement	Robustness test
	Configuration 1	Configuration 2	Configuration 3	Configuration 4
Introduction of emerging technologies	⊗	⊗	●	●
Data-sharing platform	●	⊗	●	●
Organizational system guarantee	⊗	●	●	●
Government attention allocation		●	●	●
Data application scenario integrity	⊗	●		
Data elements market development index	⊗	●	•	•
Consistency	0.8852	0.8854	0.8396	0.8306
Original coverage	0.2617	0.2746	0.4483	0.4830
Unique coverage	0.0840	0.0517	0.2189	0.4830
Consistency of the overall solution		0.8489		0.8306
Coverage of the overall solution		0.6082		0.4480

Note: ● or • means that the condition exists, ⊗ or ⊗ means that the condition does not exist. ● or ⊗ means the core condition, • or ⊗ means the edge condition, and blank means that the existence of the condition is irrelevant to the result.

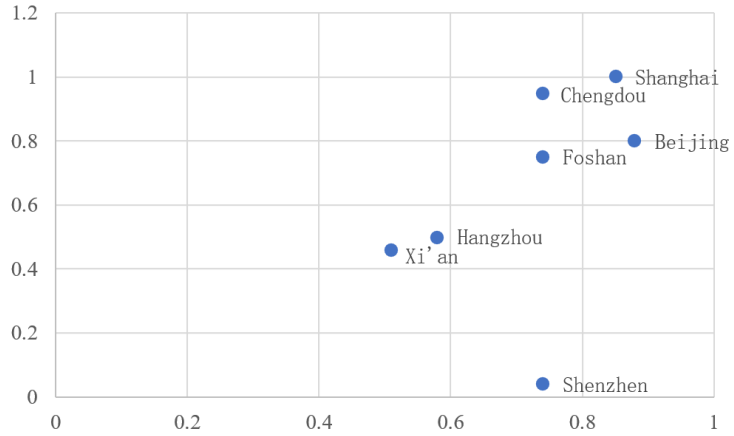

Figure 2. Distribution of explanation cases of configuration paths.

high-level emergency governance, so this path can be summarized as "technology-based". This means that establishing a data-sharing platform can systematically integrate information related to public health prevention and control, promote cross-departmental, cross-level, and cross-regional risk communication and collaborative efforts, address multiple bottlenecks in cross-border information, break through constraints of internal and external conditions such as organization and environment on local governments, and improve effectiveness of emergency governance of public health emergencies. The consistency of this configuration is 0.8852, and the original coverage rate is 0.2617, which can explain about 26.17% of emergency governance cases of urban public health emergencies. For example, in the face of public health emergencies, Foshan has built data-sharing platforms such as "Foshan Epidemic Prevention Information Live Broadcast System" and "Epidemic Special Module of Cooperative Office System" within six days, overcoming difficulties of incomplete systems, untimely government decisions, and limited scenario applications.

Configuration 2 indicates that organizational and environmental factors play a central role. In cities with rich data application scenarios and data element markets, when emerging technology methods are not introduced enough and data-sharing platforms are not perfect, with attention and support of government agencies at all levels, risk information scattered in multiple departments such as Emergency Management Agency, Health Commission, and Centers for Disease Control and Prevention should be coordinated to strengthen integration and utilization of cross-departmental data. Local governments can also quickly adjust their decision-making plans and improve their level of risk management. Considering that this driving path consists of four conditional elements: organizational system assurance, government attention allocation, application scenario integrity, and data element market development level, this path can be summarized as the "organization-environment dual core". Consistency of this configuration is 0.8854, with an original coverage rate of 0.2746, which can explain approximately 27.46% of urban public health emergency governance cases. For example, the "Implementation Opinions on Improving the System and Mechanism for Major Epidemic

Prevention and Control and Improving the Emergency Management System for Public Health Emergencies" in Chengdu City point out that it is necessary to rely on big data to establish a monitoring and early warning system and a linkage response and disposal mechanism between early warning departments, strengthen timely investigation and verification, and synchronously initiate early control measures.

Configuration 3 indicates that in the process of orderly promoting marketization of data elements, even if application scenarios of data elements are not diverse enough, high-level emergency governance efficiency can be achieved by fully introducing emerging technologies, building data-sharing platforms, providing organizational and institutional guarantees, and giving sufficient attention to the government. Among them, introducing emerging technologies, data-sharing platforms, organizational and institutional guarantees, and government attention allocation are all core conditions, with the development level of the data elements market playing a supporting role. Therefore, it can be summarized as "organization-technology as the mainstay + environment as the supplement". The consistency of this configuration is 0.8396, with an original coverage rate of 0.4483, which can explain approximately 44.83% of urban public health emergencies and emergency governance cases. For example, Beijing Emergency Command Center, as the only institution in China that undertakes the "three in one" work responsibilities, strengthens intelligent scheduling and big data analysis, and through the introduction of advanced information technology, collects and analyzes a large amount of urban operation data, predicts and evaluates potential risks, and achieves rapid response and efficient handling of various emergencies.

4.3. Robustness test

This article conducted a robustness test on the antecedent configuration of high-level emergency governance effectiveness. First, while keeping other conditions constant, the consistency level increased from 0.78 to 0.85, resulting in consistent configuration results. Then, drawing on the research methods of Zhang and Du (2019) (*22*), the case frequency threshold was adjusted from 1 to 2. The results indicate that when the number of cases is less than the threshold of 2, configurations 1 and 2 are removed as logical residues, but the resulting configuration 4 still belongs to a subset of the original configuration path set (see configuration 4 in Table 3). Therefore, the results of this study are generally robust.

5. Discussion

Drawing on the public health emergency governance practices of 23 mega-cities in China, this article examines the complex causal mechanisms through which various factors influence data elements empowerment and drive governance effectiveness, adopting a configurational perspective. The results show a significant conditional correlation between urban emergency governance effectiveness and data elements application conditions. The driving paths can be classified into three categories: "technology-based", "organization-environment dual core", and "organization-technology as the mainstay + environment as the supplement". To fully leverage the multiplier effect of data elements, unlock their latent value, and strengthen emergency governance capacity of urban public health, we propose the following suggestions based on our research findings.

First, following configuration 1, efforts should be made to promote interconnection of data-sharing platforms, and to streamline the entire process of technology adoption and output. As the core production element of the digital economy, data's value hinges on the cross-departmental sharing and utilization of information resources. Building an interconnected cross-departmental data-sharing platform is the core of achieving data empowerment. By establishing a comprehensive public health emergency governance platform that integrates cross-departmental data, governance objectives, and operational needs, and by embedding digital technology throughout the technology output process, fragmented data scattered across vertical and horizontal organizational units can be fully opened up—creating a new paradigm of networked circulation.

Second, following configuration 2, institutional coordination must be strengthened to accelerate multi-scenario applications of data elements. In the emergency governance of urban public health, this entails constructing integrated urban emergency command centers to coordinate cross-departmental operations, allocate emergency materials, equipment, and personnel, and effectively dismantle organizational barriers to data elements empowerment. Leveraging the "full-chain" attributes of data applications, data elements should be flexibly deployed across diverse scenarios, including epidemic risk screening, case early warning, and outbreak response coordination, to enhance scientific identification, precise assessment, professional evaluation, and efficient management of public health safety risks.

Third, following configuration 3, the dual drivers of technological advancement and organizational coordination must be reinforced to improve emergency response efficiency. Full realization of data element value depends jointly on technical sophistication and organizational synergy. We should leverage advantages of emerging data technologies in integration and clustering analysis to generate massive and dynamic urban public health and safety data, promote deep connections between different organizations through data streams, further facilitate effective integration of organizational information, and create favorable conditions for the

role of data elements in urban public health emergency governance.

In conclusion, research on data elements in urban public health emergency governance remains in its early stages. Given that public health emergency governance is a dynamically evolving process, we acknowledge certain limitations in assessing its effectiveness. Specifically, the selected indicators do not directly capture process-level performance, such as response speed and coordination efficiency. Future research will place greater emphasis on tracking temporal and regional variations in governance effectiveness. It will further explore applicability of data-driven approaches while balancing data privacy protection with open sharing, thereby advancing scientific and orderly integration of data elements into urban public health emergency governance and comprehensively enhancing overall effectiveness.

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The Japanese version of the European Moral Case Deliberation Outcomes Instrument (Euro-MCD 2.0): Validation and score distribution among nurses, doctors, and other healthcare providers—A cross-sectional study

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Abstract: The European Moral Case Deliberation Outcomes Instrument (Euro-MCD 2.0) is a widely used instrument for evaluating moral case deliberation (MCD); however, its psychometric properties have not been fully validated in Japan. Our goal is to assess the validity, reliability, and score patterns of the Japanese version of the Euro-MCD 2.0 among healthcare providers in six national hospitals. A cross-sectional web-based survey was conducted at six national centers for advanced and specialized medicine in Japan. Construct validity was assessed through exploratory and confirmatory factor analysis. Convergent and discriminant validity were examined using composite reliability and average variance extracted. Internal consistency was evaluated with Cronbach's alpha and McDonald's omega. The sample included 359 doctors, nurses, pharmacists, and other healthcare providers involved in clinical practice. Participants who were not in an employment relationship (*e.g.*, trainees) or directly involved with patients and their families in clinical practice were excluded. Items in the moral action domain had elevated 'I don't know' response rates, whereas Moral Competence items showed higher agreement. The three-factor model demonstrated acceptable fit, although discriminant validity between moral teamwork and moral action was limited. Healthcare providers with more years of experience scored higher across all subscales. The Japanese Euro-MCD 2.0 demonstrated acceptable validity and reliability, supporting its use in future evaluations in Japan.

***Keywords*:** ethically challenging situations, healthcare providers, moral competence, moral case deliberation, psychometric validation

1. Introduction

Health care providers often encounter ethically complex situations that demand interdisciplinary collaboration, mutual understanding, and the development of shared insights to guide both clinical decision-making and policy formulation (*1-3*). To support such processes, structured approaches such as moral case deliberation (MCD) have been developed (*4*). MCD is a dialogue-based, systematic method designed to facilitate reflection on ethical dilemmas (*5,6*). It enables participants to examine value-laden issues, collaboratively seek resolutions, and strengthen both individual ethical competence and teamwork skills.

Empirical studies in Europe and other regions have demonstrated MCD's effectiveness in improving moral reasoning, team communication, and shared decision-making (*7-9*). Although originally developed in the

Netherlands and widely adopted across Europe, MCD remains underexplored in the Japanese healthcare context (*10*). Despite recent efforts to establish clinical ethics consultation (CEC) in Japan, several structural issues continue to impede its development. Ambiguities regarding the definition and scope of CEC, unclear distinctions between ethics committees and consultation services, and a limited number of trained consultants remain major challenges. Preventive ethics activities are still underutilized, and quality-assurance practices are unevenly implemented. These limitations reflect the absence of nationally standardized competencies and the lack of structured training pathways in Japan (*11*).

To systematically assess MCD outcomes, the European Moral Case Deliberation Outcomes Instrument (Euro-MCD) was developed in 2014 through a literature review and the Delphi method, with initial studies confirming its content validity (*12*). The updated Euro-MCD 2.0, developed in 2020, incorporated insights from several field studies and expert consultations (*12,13*). A Japanese version of the Euro-MCD 2.0 was recently developed in 2023, but research to date has only examined its content validity (*10*). Given the cultural differences between Japan and Europe, psychometric validation of the Japanese version of the Euro-MCD 2.0 is essential before its widespread application. Accordingly, this study aims to evaluate the reliability and validity of the Japanese Euro-MCD 2.0 and to assess the moral competence of Japanese nurses, doctors, and other healthcare providers when confronted with ethically complex situations.

2. Materials and Methods

2.1. Study design and participants

We conducted a cross-sectional study at six national centers for advanced and specialized medicine in Japan. The eligible participants were medical professionals involved in clinical practice, including doctors, nurses, pharmacists, and other health care providers. Exclusion criteria were: *i*) Individuals not employed by the institution (*e.g.*, trainees), and *ii*) those not directly involved in patient and family care. These criteria were applied to ensure that participants could provide valid responses in their current clinical experience.

2.2. Data Collection

Research collaborators at each medical center received a study information sheet and a web link to the questionnaire, which they distributed to relevant staff through institutional mailing lists. The questionnaire was administered online using Google Forms (Google LLC, Mountain View, CA, USA). The participants were requested to complete the survey within two weeks, with a reminder sent after one week. Data collection occurred between July 1 and August 7, 2023. The questionnaire was anonymous to ensure confidentiality, and no identifying information was collected.

2.3. Measures

The survey collected demographic data, including gender, age, professional role, years of professional experience, and work schedule. MCD outcomes were assessed using the Japanese version, which contains 15 items across three factors—moral competence, moral teamwork, and moral action (*10*)—and has the same number of items and subscale structure as the original scale (*13*). Each item was rated on a 5-point Likert scale, consistent with the original instrument: 0 = "I do not know", 1 = "strongly disagree", 2 = "slightly disagree", 3 = "slightly agree", and 4 = "strongly agree". The response option "I do not know" was coded as 0 in the primary analysis in accordance with the scoring approach of the original Euro-MCD 2.0. This category reflects an inability to provide a directional rating rather than agreement with the item content; therefore, we examined its potential influence on psychometric findings through a sensitivity analysis in which "I do not know" responses were treated as missing values in both EFA and CFA, and results were compared with the primary analysis. Subscale scores were summed, with higher scores indicating greater moral competence.

The content validity of the Japanese version has already been examined in previous research (*10*). Following approval from the original authors, two native Japanese-speaking researchers independently translated the items. A panel of three researchers subsequently reviewed and refined the content. The Japanese version was then back-translated into English by a native English speaker, and the original authors evaluated the correspondence between the back-translation and the original items. Throughout the translation process, interpretations of wording and expressions were discussed as needed between the developers and the original authors. As a result, content validity was confirmed without introducing substantive deviations from the original instrument (*10*).

2.4. Data analysis

Descriptive statistics were calculated for participant characteristics and outcome variables. Construct validity was evaluated through a two-stage process involving exploratory factor analysis (EFA) and confirmatory factor analysis (CFA). To assess the stability of the factor structure, the total sample was randomly split into two approximately equal subsamples for the cross-validation process. Randomization was conducted in the Statistical Package for the Social Sciences (SPSS) by generating a random value for each case using the RV.UNIFORM (0,1) function. Cases with random

values < 0.5 were assigned to the EFA sample, and those with values > 0.5 were assigned to the CFA sample. EFA was conducted using maximum likelihood extraction with promax (oblique) rotation. The number of factors was decided based on the scree plot method and interpretability. When conducting CFA, model fit was assessed using the comparative fit index (CFI), Tucker–Lewis Index (TLI), standardized root mean square residual (SRMR), and root mean square error of approximation (RMSEA), with cut-off values of > 0.90, > 0.90, < 0.08, and < 0.08, respectively (*14,15*). Additionally, the Akaike information criterion (AIC) was used to compare the relative fit of competing models (*14,15*). Model modifications in CFA were guided by both statistical and theoretical considerations. Specifically, error covariances were added only when (a) the modification index exceeded 15 and (b) the items involved belonged to the same subscale or exhibited strong conceptual similarity. This approach ensured that modifications remained theoretically grounded rather than purely data-driven (*14*). To examine the potential influence of this response category on the psychometric results, we conducted a sensitivity analysis in which "I do not know" responses were treated as missing values. We then compared the overall factor structure and model fit with those from the primary analysis.

Convergent and discriminant validity were assessed based on the results of the CFA. Convergent validity was supported when factor loadings were ≥ 0.50, average variance extracted (AVE) was ≥ 0.50, and composite reliability (CR) was ≥ 0.70. Discriminant validity was confirmed when inter-factor correlations among subscales were below 0.85. In addition, following the Fornell–Larcker criterion, the square root of the AVE for each subscale was calculated, and discriminant validity was deemed adequate when this value exceeded the corresponding inter-factor correlations (*15*).

Independent-sample *t*-tests were conducted to compare groups based on professional experience (≤ 10 years *vs.* ≥ 11 years). Based on previous research, we hypothesized that ethical competence would be higher among those with more years of experience because they have more opportunities to encounter ethically challenging cases (*16*). In addition, drawing on Patricia Benner's theory of professional development, we used 10 years as a theoretically informed cutoff because it is commonly considered a reasonable timeframe for clinicians to progress towards a level of expertise (*17*).

Reliability was evaluated through item–total correlations (> 0.30 considered adequate) and internal consistency metrics, including Cronbach's alpha and McDonald's omega (> 0.70 considered acceptable) (*18*). All statistical analyses were conducted using SPSS Statistics version 28 and SPSS Amos version 29 (IBM Corp., Armonk, NY, USA).

2.5. Ethical considerations

This study was approved by the independent Ethics Review Committee of National Cancer Centre Hospital (approval number: 6000-076). Participation was voluntary, and all participants provided informed consent electronically *via* a checkbox on the web-based questionnaire. The study protocol adhered to the ethical standards of the institutional research committee and the Declaration of Helsinki.

3. Results

3.1. Participant Characteristics

Of the 12,994 health care provider members affiliated with the six national medical centers, those directly involved in patient and family care were targeted. A total of 579 individuals responded to the questionnaire, of whom 359 were included in the final analysis. Participants were excluded if they did not provide informed consent (n = 36), were not involved in clinical work (n = 158), or had missing or incomplete responses to the Euro-MCD 2.0 scale (n = 26). Response and valid response rates could not be calculated because the number of eligible staff actively engaged in clinical care was not known.

Table 1 presents participants' demographics. Among the 359 participants analyzed, 74.7% were women, and 49.0% identified as nurses. The mean age was

Table 1. Participants' characteristics (n = 359)

Characteristics	*n*	%	SD ± mean [range]
Age Responses (n = 357)			41.5 ± 10.9 [21–69]
21–29	58	16.2	
30–39	104	29.0	
40–49	104	29.0	
50 or above	91	25.3	
No response	2	0.5	
Gender			
Male	83	23.1	
Female	268	74.7	
No response	8	2.2	
Profession			
Doctor	98	27.3	
Nurse	176	49.0	
Pharmacist	12	3.3	
Social worker	10	2.8	
Nutritionist	9	2.5	
Clerical workers	9	2.5	
Rehabilitation specialist	8	2.2	
Other*	37	10.3	
Years of experience			16.2 ± 10.6 [1–47]
Responses (n = 348)			
≤ 10	122	34.0	
11–19	104	29.0	
≥ 20	122	34.0	
No response	11	3.1	

*Other professional roles included clinical research coordinators, medical concierges, genetic counselors, medical interpreters, nursing assistants, research assistants, dentists, dental hygienists, and childcare workers.

41.5 ± 10.9 years, with a mean of 16.2 ± 10.6 years of professional experience in the current occupation. Other professional roles included clinical research coordinators, medical concierges, genetic counselors, medical interpreters, nursing assistants, research assistants, dentists, dental hygienists, and childcare workers. These roles were grouped as 'other healthcare providers' because the number of respondents in each role was small, and all met the study eligibility criterion of direct involvement in patient and family care in clinical settings, even if their involvement occurred only in specific situations.

3.2. Descriptive statistics and score distribution

Table 2 presents the descriptive statistics for each item of the Euro-MCD 2.0. Mean item scores ranged from 2.3 to 2.9, with corresponding standard deviations reported in Table 2. More than 10% of respondents selected "I do not know" for Items 3, 12, and 14, and approximately 10% selected this option across all items in the Moral Action domain. Item 5 showed a relatively higher proportion of "slightly agree" and "strongly agree" responses compared with the other items.

3.3. Differences by occupation

Figure 1 illustrates subscale scores by occupation. No significant differences were observed between nurses and doctors across all subscales. However, nurses had significantly higher mean scores than other health care providers on all three subscales ($p < 0.05$).

3.4. Item analysis

Item–total correlation coefficients ranged from 0.49 to 0.75, indicating good internal consistency (Table 2).

3.5. Validity

Construct validity was assessed in two stages: exploratory factor analysis (EFA) to identify the underlying factor structure, followed by confirmatory factor analysis (CFA) to evaluate model fit. Sampling adequacy (KMO) and Bartlett's test of Sphericity were calculated using the EFA subsample prior to conducting the exploratory factor analysis. Prior to EFA, sampling adequacy was confirmed using the Kaiser–Meyer–Olkin (KMO) measure, which yielded a value of 0.90 ($p < 0.001$). The EFA yielded a two-factor structure, with Items 1–6 loading on the first factor and Items 7–15 loading on the second factor. Although the factor loading for Item 5 was 0.33—below the commonly accepted threshold of 0.40—the resulting structure reflected two dimensions: Moral competence (Factor 1) and a combined factor representing Moral Teamwork and Moral Action (Factor 2). In addition, in the sensitivity analysis in which "I don't know" responses were treated as missing values, the KMO value remained 0.90, and the factor structure did not change compared with the main analysis.

To examine the fit of the original three-factor structure of the Euro-MCD 2.0, CFA was conducted, despite the EFA suggesting a two-factor solution. The initial model without additional error covariances was designated Model 1. Modification indices for the item pairs 1–2 and 10–11 were > 15. Therefore, additional error covariances were specified to improve model fit, and this revised specification was designated Model 2 (Figure 2). Model fit indices for both models are reported in Table 3: CFI = 0.92, SRMR = 0.054, TLI = 0.90, and RMSEA = 0.085. While RMSEA slightly exceeded the recommended cutoff (< 0.08), the other fit indices met the established thresholds. In the sensitivity analysis (Model 3), CFI = 0.927, TLI = 0.897, and RMSEA = 0.082; SRMR was not calculated due to the handling of missing data. Overall, the model fit indices were highly similar to those obtained in the main analysis. Convergent validity was supported, with a composite reliability (CR) of 0.94 and an average variance extracted (AVE) of 0.50, both exceeding conventional thresholds. For discriminant validity, the inter-factor correlations were 0.79 between moral competence and moral teamwork, 0.89 between moral teamwork and moral action, and 0.75 between moral competence and moral action. According to the Fornell–Larcker criterion, the square roots of AVE values were 0.80 for Moral Competence, 0.86 for Moral Teamwork, and 0.87 for Moral Action. The criterion was not met for the pair of Moral Teamwork and Moral Action, indicating insufficient discriminant validity between these two subscales.

Independent-sample *t*-tests revealed significant differences between participants with ≤ 10 years and ≥ 11 years of experience in their current occupation across all three subscales (Table 4). In addition, the 11 participants with missing responses on years of experience were excluded from the analysis. Participants with greater professional experience had higher mean scores, consistent with the hypothesis that moral competence increases with years of practice ($p < 0.05$ for all subscales).

3.6. Reliability

Internal consistency was acceptable across all subscales. Cronbach's alpha values ranged from 0.80 to 0.85, and McDonald's omega values ranged from 0.81 to 0.85 (Table 2).

4. Discussion

This study found that the Japanese version of the Euro-MCD 2.0 demonstrated acceptable reliability; however, discriminant validity did not fully meet recommended

Table 2. Distribution of responses for each item (n = 359)

Domain	Item	Mean ± SD	Item-total correlation	Response per item (%)*				
				I do not know	Strongly disagree	Slightly disagree	Slightly agree	Strongly agree
Moral ability (range 0–24)	1. I recognize a situation as being ethically difficult	2.7 ± 0.86	0.49	5.3	1.4	20.9	63.2	9.2
	2. I am aware of others' perspectives in ethically difficult situations	2.6 ± 0.88	0.58	6.4	1.1	24.0	62.4	6.1
	3. I can identify the different values at stake in ethically difficult situations	2.4 ± 0.99	0.67	**10.6**	0.6	33.7	50.1	5.0
α = 0.804	4. I can formulate arguments in favor of and against different courses of action in ethically difficult situations	2.5 ± 0.87	0.62	5.6	3.6	27.6	58.2	5.0
ω = 0.806	5. I listen with an open mind to others when discussing an ethically difficult situation**	2.9 ± 0.80	0.52	4.2	1.1	10.6	71.0	13.1
	6. I speak up in ethically difficult situations	2.3 ± 0.86	0.62	4.7	6.4	44.0	40.1	4.7
	Total	15.4 ± 3.75	-	-	-	-	-	-
Moral teamwork (range 0–20)	7. We openly express our viewpoints in ethically difficult situations	2.4 ± 0.90	0.72	6.7	6.4	35.1	46.8	5.0
	8. We all have opportunities to express our viewpoint on ethically difficult situations	2.3 ± 0.91	0.69	6.1	6.4	43.7	37.6	6.1
	9. We respect different viewpoints when discussing ethically difficult situations	2.7 ± 0.89	0.69	5.3	2.8	23.1	59.1	9.7
α = 0.853	10. We feel secure to share emotions in ethically difficult situations	2.4 ± 0.96	0.71	6.4	9.2	32.9	45.1	6.4
ω = 0.851	11. We support each other when dealing with ethically difficult situations	2.5 ± 0.88	0.69	5.3	3.9	28.7	55.7	6.4
	Total	12.2 ± 3.64	-	-	-	-	-	-
Moral action (range 0–16)	12. We make decisions on how to act in ethically difficult situations	2.3 ± 1.01	0.75	**10.3**	5.6	31.5	49.0	3.6
	13. We base our decisions on moral considerations in ethically difficult situations	2.6 ± 0.97	0.69	8.4	2.5	15.9	65.7	7.5
	14. We are responsive to the values and needs of patients and their families in ethically difficult situations	2.5 ± 1.08	0.68	**11.7**	2.2	18.4	59.3	8.4
α = 0.822								
ω = 0.827	15. We are able to explain and justify our care towards patients and their families	2.6 ± 0.98	0.67	9.2	1.4	14.8	68.0	6.7
	Total	10.0 ± 3.26	-	-	-	-	-	-

α: Cronbach's alpha, ω: Macdonald's omega. *The scores for each response option are as follows: 0, "I do not know"; 1, "Strongly disagree"; 2, "Slightly disagree"; 3, "Slightly agree"; 4, "Strongly agree.". **In the exploratory factor analysis, the factor loading was 0.33.

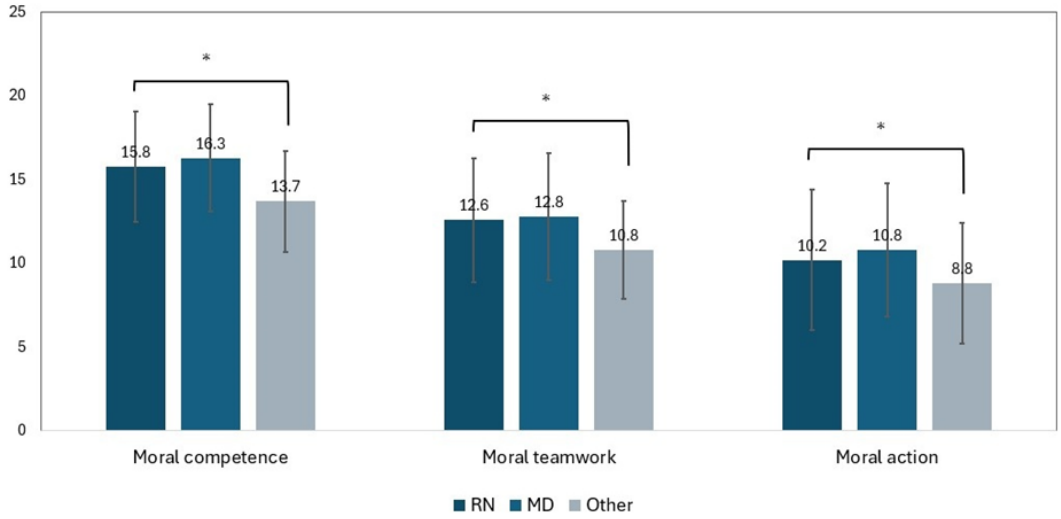

Figure 1. Differences in scores per subscale and reliability of scales by occupation (*n* = 359). *The nurses' score were considered as the reference; $p < 0.05$. *Abbreviations:* RN, registered nurse; MD, medical doctor; Other, other healthcare staff.

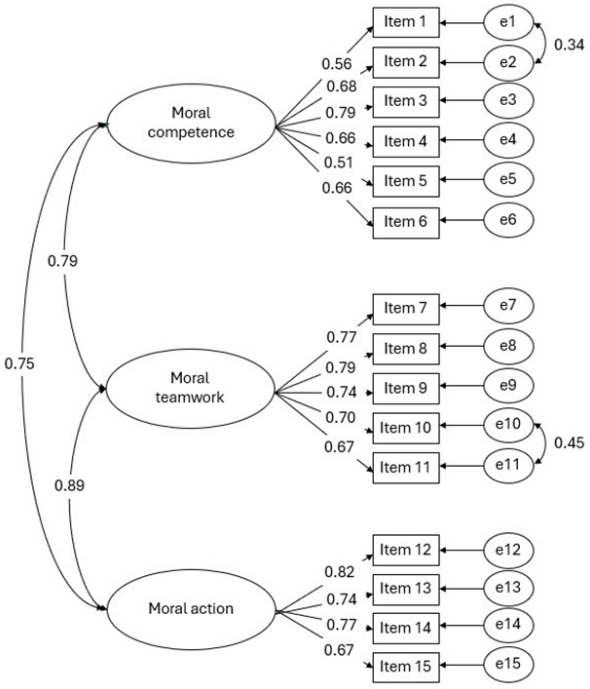

Figure 2. Confirmatory factor analysis: Model 2 (*n* = 188).

Table 3. Confirmatory Factor Analysis Models and Model Fit Indices (*n* = 188)

Models	CFI	SRMR	TLI	RMSEA	AIC
Model 1	0.885	0.062	0.861	0.101	317.325
Model 2	0.920	0.054	0.901	**0.085**	269.760
Model 3	0.927	NA*	0.897	**0.082**	291.167

CFI: Comparative Fit Index (> 0.90).SRMR: Standardized Root Mean Square Residual (< 0.08). TLI: Tucker-Lewis Index (> 0.90). RMSEA: Root Mean Square Error of Approximation (< 0.08). AIC: Akaike's Information Criterion. *Not calculated due to missing data handling.

thresholds. The study also provides insights into the moral competence of health care providers in ethically challenging situations in Japan and identifies potential areas for improving MCD discussions.

One of this study's strengths is the diversity of health care providers' backgrounds and roles. Participants were recruited from hospitals selected for convenience, each of which specialized in distinct clinical areas such as oncology, neuropsychiatry, cardiology, and pediatrics. This diversity allowed the inclusion of health care providers from multiple clinical backgrounds and with varied roles—doctors, nurses, pharmacists, and social workers—directly involved in patient care and familiar with ethically challenging situations. However, the response rate could not be calculated, limiting the ability to determine whether the sample was representative of the target population. Because the number of eligible staff directly involved in patient and family care could not be confirmed, we could not calculate a response rate. This limits confidence in how representative the sample is and raises the possibility of nonresponse bias, which may affect generalizability. Although the survey targeted all health care personnel, it was difficult to delineate the extent to which each staff member was involved in patient and family care in clinical settings. As this determination was left to the respondents themselves, calculating an accurate response rate was not feasible.

As MCD becomes more widely adopted in Japan, future research should employ more clearly defined eligibility criteria—such as including only individuals with prior MCD experience—to improve clarity in identifying the target population. In this survey, mean item scores were below 3, whereas previous research in the Netherlands employing the concentrate, unrush, reflect, and act (CURA) methodology (an MCD-based

Table 4. Differences in scores per subscale by years of occupational experience (*n* = 348)

Domain	Years of occupational experience	Mean ± SD	*p*
Moral competence	≤ 10 (*n* = 122)	14.3 ± 3.7	< 0.001
	≥ 11 (*n* = 226)	16.1 ± 3.4	
Moral teamwork	≤ 10 (*n* = 122)	11.6 ± 3.6	0.007
	≥ 11 (*n* = 226)	12.7 ± 3.6	
Moral action	≤ 10 (*n* = 122)	9.5 ± 3.4	0.010
	≥ 11 (*n* = 226)	10.4 ± 3.0	

approach) reported Euro-MCD 2.0 scores exceeding 3 across all subscales (*19*). While differences in participants and cultural context likely account for these discrepancies, familiarity with MCD may enhance ethical competence.

The Japanese version of the Euro-MCD 2.0 includes "I do not know" as a response option. High selection rates for this option may reflect respondents' uncertainty in understanding the questions or in self-assessing their moral competence. Low confidence in ethical competence may hinder healthcare providers' ability to manage moral distress, underscoring the need for interventions that strengthen healthcare providers' confidence in ethically challenging situations (*20*).

Item 3 ("I can identify the different values at stake in ethically difficult situations") suggests that the ability to recognize underlying values may be underdeveloped in Japanese clinical ethics discussions. Commonly used tools in Japan, such as Jonsen's Four-Box Method, emphasize clinical fact-finding over the exploration of participants' values and perspectives (*21*). MCD has been shown to reduce moral distress by encouraging awareness of what is important to each member, suggesting potential benefits for Japanese clinical ethics practice (*22*).

Items 12–15 from the Moral Action subscale had relatively high rates of "I do not know" responses, possibly reflecting participants' limited ability to act on moral judgments or unclear guidance on translating discussions into action. Variability in professional roles and clinical responsibilities may have contributed to these response patterns. Moral distress, defined as "knowing the right thing to do but being in a situation in which it is nearly impossible to do it" (*23*), can arise when individuals understand ethical issues but cannot act. Clinical ethics discussions should therefore include guidance on implementing individual actions based on deliberations.

While many participants endorsed Item 5 ("I listen with an open mind to others"), fewer agreed with Item 8 ("We all have opportunities to express our viewpoint"). This may reflect insufficient time for discussion in busy clinical settings or a lack of psychological safety, which can hinder open communication. Fostering a supportive, ethical climate is essential for encouraging all team members to share their perspectives during interprofessional ethics discussions (*24-26*).

The EFA indicated that the subscales of moral teamwork and moral action were extracted as a single factor, and the assessment of discriminant validity likewise suggested that these two factors lacked discriminant validity. The convergence between the EFA findings and the discriminant validity results suggests that these constructs are conceptually similar. Two possible explanations may account for this overlap. First, the Moral Teamwork and Moral Action subscale items consistently use "we" as the grammatical subject, in contrast to the Moral Competence items, which use "I". This distinction was preserved in the Japanese translation, and it is possible that respondents recalled similar situations or behaviors when responding to the moral teamwork and moral action items. Second, Japan's collectivist cultural orientation contrasts with the individualistic context in which the original scale was developed. Compared to Western populations, Japanese respondents may perceive weaker boundaries between individual and group roles, which could have led to similar interpretations of team-based behaviors and individual actions—contributing to the conceptual proximity between the two factors (*27*). Although individualism has been increasing in Japan, evidence suggests that collectivist orientations remain influential in contemporary society (*28*). In a collectivist context, ethical reflection and ethical action may be experienced as closely tied to group processes and shared responsibility, which may help explain the overlap observed between Moral Teamwork and Moral Action in this study. This interpretation aligns with cross-cultural ethics literature emphasizing that moral reasoning and action can be shaped by culturally patterned self-construal and relational norms, particularly in team-based clinical practice.

CFA result indicated that the RMSEA was the only fit index that did not meet the recommended threshold. This may have been partly influenced by the fact that some items within each factor had more than 10% of responses marked as 'I don't know', which could have lowered model fit (*29*). The response option "I don't know" may reflect an intent similar to "neither agree nor disagree", or it may indicate that the respondent cannot provide a clear answer. As a result, this option may have contributed to a departure from normality in the response distribution and may have influenced the RMSEA value. In the cultural context of Japan, "moral teamwork" and "moral action"

appeared to be closely related concepts. Consistent with this interpretation, EFA suggested a two-factor structure in which the moral teamwork and moral action items loaded on a single factor, and the discriminant validity assessment also indicated limited separation between these two subscales. Nevertheless, we retained the original three-factor model in CFA because Euro-MCD 2.0 was developed to distinguish individual moral competence from team-level processes (moral teamwork) and the translation of deliberation into practice (moral action), which remain conceptually distinct outcomes in clinical ethics support. In nursing and interprofessional ethics education, maintaining separate moral teamwork and moral action scores can be practically informative for identifying whether support is needed in inclusive participation and communication during deliberation versus follow-through and implementation after deliberation. At the same time, our findings suggest that the boundary between moral teamwork and moral action may be less distinct in Japan; therefore, future studies should further examine this relationship, including potential multicollinearity in multivariate analyses and evaluation of alternative models. However, because the fit indices other than RMSEA met recommended criteria and the main analysis results (Table 3, Model 2) were comparable to the sensitivity analysis results, the main findings were interpreted as robust. To preserve cross-cultural comparability, no modifications were made to the original factor structure, and results were interpreted as supporting the theoretical model of the original scale. Future research should further examine the correlation between "moral teamwork" and "moral action", and should use this scale with careful attention to multicollinearity in multivariate analyses. From an applied perspective, users should interpret moral teamwork and moral action subscale scores with caution in the Japanese context, as they may capture overlapping aspects of team-based ethical practice. When the goal is to evaluate intervention effects or model associations, reporting both subscales remains useful for comparability with international studies, but analyses should avoid treating them as fully independent outcomes. Depending on the analytic purpose, researchers may also consider conducting sensitivity analyses that use a combined teamwork-action score, while still reporting original subscales to maintain comparability.

Convergent validity met recommended thresholds for all constructs, indicating that it was adequately established. The known-groups validity analysis indicated that nurses and doctors scored comparably, while other healthcare providers demonstrated lower mean scores. This pattern may reflect underlying differences in professional roles and ethical values, with nurses often emphasizing patient-centered care and autonomy, and doctors prioritizing scientific reasoning and benefits (*30*). Interprofessional ethics education and improved communication may help bridge these differences (*31*). Ethical competence also increased with years of experience, regardless of occupation, suggesting that team competence may benefit from targeted training and inclusion of diverse professionals.

Cronbach's alpha and McDonald's omega values exceeded 0.8 for all subscales, indicating strong internal consistency. Test–retest reliability could not be assessed due to ethical and logistical constraints, including the requirement to maintain participant anonymity. Future studies should examine test–retest reliability by implementing follow-up measurements with participants who consent to repeated assessments.

5. Future directions and research limitations

This study provides evidence for the utility of the Japanese version of the Euro-MCD 2.0 across diverse health care professions. To address ethically complex situations effectively, healthcare teams should foster a supportive ethical climate, ensure psychological safety, and implement training programs aimed at enhancing interprofessional moral competence. Using the validated Japanese Euro-MCD 2.0, future studies and clinical programs can evaluate MCD implementation by measuring outcomes before and after MCD-based education or case deliberation initiatives, monitoring changes across three subscales, and comparing results across professions and clinical settings. This will also support international comparisons and inform the development of ethics education that is appropriate for Japan's cultural context.

This study has several limitations that should be acknowledged when interpreting the findings and designing future research. First, the response rate could not be calculated, which limits the ability to assess whether the sample accurately represents the target population. This limits confidence in how representative the sample is and raises the possibility of nonresponse bias, which may affect generalizability. Second, the CFA indicated suboptimal model fit, which may have been influenced by cultural differences and cross-cultural interpretation of questionnaire items. Third, the reliability assessment was limited to internal consistency; future research should incorporate additional reliability indicators, such as test–retest reliability, to confirm and strengthen these findings. Fourth, we did not collect information on participants' prior exposure to moral case deliberation (MCD) or ethics consultation; therefore, we could evaluate whether familiarity with these practices influenced Euro-MCD 2.0 scores, which should be considered when interpreting the findings. Fifth, as this study used a cross-sectional design, temporal sensitivity and responsiveness of the scale were not assessed; therefore, future longitudinal studies are warranted. Finally, inclusion of diverse professional roles beyond nurses and doctors may limit generalizability of findings, given variations in direct clinical involvement with

patients and families.

6. Conclusions

Although the Japanese version of the Euro-MCD 2.0 demonstrated acceptable internal consistency, discriminant validity was limited, and CFA model fit should be interpreted with caution because RMSEA exceeded the recommended cutoff. While the other fit indices were within acceptable ranges and the sensitivity analysis yielded comparable results, these findings suggest that further psychometric evaluation is warranted in larger samples and across diverse settings in Japan before drawing strong conclusions about stability of the factor structure. Therefore, the scale was retained in its original structure to facilitate future international comparative studies. These findings also underscore importance of implementing support systems and capacity-building strategies for healthcare providers, particularly in light of how cultural context in Japan may shape responses to ethically complex situations. Overall, this instrument offers a valuable tool for implementing MCD in clinical ethics in Japan, and its effectiveness should be further evaluated in future research.

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Cross-cultural adaptation and validation of the Internet Skills Scale in a Chinese older adult population

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Abstract: This study translated and back-translated the English version of the Internet Skills Scale (ISS) based on the Brislin translation model to develop a Chinese version of the scale. From June to December 2024, 260 older adults were recruited from the community to participate in the survey to evaluate the scale's reliability and validity. A total of 233 valid questionnaires were collected, yielding an effective response rate of 89.6%. Among the respondents, there were 121 males (52%) and 112 females (48%), with ages ranging from 60 to 90 years. The results showed that the Chinese version of the ISS consisted of four dimensions and 20 items. The Cronbach's α coefficient for the total scale was 0.862, and the Cronbach's α coefficients for the dimensions ranged from 0.705 to 0.912. Exploratory factor analysis (EFA) extracted four common factors, with a cumulative variance contribution rate of 68.533%. Confirmatory factor analysis (CFA) indicated a good model fit: $\chi^2/df = 2.26$, CFI = 0.978, IFI = 0.979, TLI = 0.974, GFI = 0.991, RMSEA = 0.074. For convergent validity, the composite reliability (CR) values were 0.932, 0.853, 0.795, and 0.88, respectively, and the average variance extracted (AVE) values were 0.734, 0.596, 0.511, and 0.616, respectively. These findings indicate that the scale demonstrates reliability and validity, making it an effective tool for assessing the digital competence of older adults.

***Keywords*:** digital competence, reliability, validity, older adults

1. Introduction

With the rapid advancement of the internet industry in China, the internet has become a vital platform for people to access information and healthcare services. In particular, younger generations have increasingly relied on online channels to obtain health-related data and professional medical support. However, China's large older adult population continues to experience a significant gap in internet adoption, which has led to a pronounced digital divide—a major social challenge—even as this group begins to benefit from digital convenience. This issue not only impacts older adults' physical and mental well-being but also considerably limits their social participation and overall quality of life (*1,2*). The persistent digital divide poses substantial barriers for older adults in accessing and using health information, medical services, and online communication tools (*3*). A lack of digital literacy also increases their vulnerability to online risks such as fraud and privacy breaches. During the COVID-19 pandemic, in particular, many older individuals struggled to access timely pandemic-related information and preventive measures due to low digital literacy and insufficient internet infrastructure. As a result, what began as a public health crisis further exposed and intensified the isolation of older adults in terms of information access (*4-6*). Studies indicate that a widening digital divide not only deepens disparities in information acquisition and usage among the older adults but also exerts long-term effects on their health and psychosocial well-being (*1,7,8*). Delayed or inadequate access to health information may undermine older adults' ability to manage their health effectively and respond to public health emergencies. Moreover, limited digital engagement reduces opportunities for social involvement and cultural participation, thereby diminishing life satisfaction (*9*).

China's aging process is characterized by unique developmental patterns and distinct transitional phases, highlighting the need to understand the relationship between digital exclusion and active aging. Building a digitally inclusive environment for older adults is not only a crucial social development goal but also a key strategy for addressing the challenges of population aging. To achieve this, it is essential to accurately and scientifically assess the digital capabilities of the older

adults, thereby providing an evidence base for policy and intervention.

Although the Chinese government has launched multiple initiatives—such as digital skill training programs and age-friendly adaptation of internet applications—to improve digital literacy among older adults (*10*), the evaluation of internet skills in this population remains underdeveloped. There is a notable absence of validated and reliable assessment tools, which hinders the effectiveness and monitoring of related interventions. Internationally, the ISS, developed by van Deursen and Helsper in 2016, is widely used to measure individuals' internet proficiency (*11*). However, its applicability to the sociocultural context and practical needs of Chinese older adults had not yet been established through rigorous translation and validation.

In response, this research team obtained official authorization to adapt the original English version of the ISS into Chinese. Through a systematic translation and cultural validation process, we developed a Chinese version of the scale and evaluated its psychometric properties. This study aims to fill the gap in validated assessment tools for digital literacy among older adults in China and to provide a robust instrument for future research and intervention in this field.

2. Materials and Methods

2.1. Questionnaire overview

The ISS is designed to measure an individual's ability to utilize the internet. Its development is based on an in-depth understanding and empirical research of internet skills, with the aim of providing a standardized tool to evaluate an individual's operational, information navigation, social, and creative skills in an online environment. The scale consists of 20 items divided into four dimensions: operational skills, information navigation skills, social skills, and creative skills. A 4-point Likert scale is used for scoring, where "does not describe me at all" is assigned 1 point and "describes me very well" is assigned 4 points.

2.2. Scale localization

To ensure the accuracy, cultural appropriateness, and psychometric properties of the translated scale, this study strictly followed the Brislin translation model. The localization of the ISS was carried out in three stages: forward translation, back translation, and cultural adaptation with consensus building.

2.2.1. Forward translation

In the forward translation stage, two bilingual translators with a medical background (both holding a master's degree or above, with over five years of experience in geriatric medicine and training in psychometrics) independently translated the original English scale into Chinese. Based on thorough discussion, they integrated their translations to form a preliminary Chinese version.

2.2.2. Back translation

In the back translation stage, two postgraduate students majoring in English who had no prior exposure to the original scale (both holding a TEM-8 certificate and possessing translation experience) independently back-translated the preliminary Chinese version into English. Subsequently, a review panel consisting of four interdisciplinary experts (covering the fields of geriatric medicine, clinical psychology, applied linguistics, and psychometrics) conducted an item-by-item comparison of the original scale, the forward-translated version, and the back-translated versions. The evaluation focused on semantic equivalence, linguistic expression, and cultural appropriateness. Items with discrepancies were revised following discussion among the expert panel and consultation with the original scale developer, ultimately resulting in a consensus version of the Chinese version of the ISS. This process ensured that the scale retained its original structure and meaning while aligning with the linguistic habits and cultural context of the Chinese older adult population.

2.2.3. Pilot survey

Using convenience sampling, 30 older adults who met the inclusion and exclusion criteria were selected. The Chinese version 2 of the ISS was distributed. The purpose of the survey and precautions were explained to the participants, and the questionnaires were collected immediately after completion. Participants were asked whether they fully understood the meaning of each item, whether each option was clear and unambiguous, and for any other questions or suggestions. After compiling, reviewing, and revising the feedback, the final Chinese version of the ISS was formed.

2.3. Reliability and validity testing of the Chinese version of the ISS

2.3.1. Study participants

A total of 260 older adult participants were recruited from the community for this survey. Inclusion criteria: aged 60 years or above, regardless of gender, and voluntarily participating in this study; able to complete the questionnaire independently or with assistance from the researcher. Exclusion criteria: individuals with severe physical illnesses or mental disorders; those who are illiterate or have a level of education too low to complete the questionnaire. After obtaining informed consent from all participants, the purpose and main

content of the study were explained using a standardized instruction script. Participants were also informed of considerations for completing the questionnaire and were provided with the Chinese version of the ISS. According to requirements for reliability and validity testing of questionnaires (*12*), a sample size of 5–10 times the number of items is necessary to achieve stable parameter estimates. The Chinese version of the ISS contains 20 items. Accounting for a 20% attrition rate, the minimum required sample size was 150. In accordance with factor analysis principles, a stable model requires a sample size of at least 200. Therefore, 233 participants were ultimately included.

2.3.2. Statistical methods

2.3.2.1. Item analysis

SPSS 26.0 was used for item analysis. The critical ratio method was applied to divide participants into high- and low-scoring groups: *i*) Discrimination analysis: All valid participants were ranked in descending order based on their total scale scores (after reverse scoring). The top 27% of participants were assigned to the high-scoring group, the bottom 27% to the low-scoring group, and the middle group was excluded. The Shapiro-Wilk test was used to assess the normality of item scores between the two groups. If the data were not normally distributed, the Mann-Whitney *U* rank sum test was performed; if the data were normally distributed, an independent samples *t*-test was conducted. An item was considered to have good discrimination if $p < 0.05$. *ii*) Homogeneity analysis: Using all valid samples, Spearman's rank correlation analysis was applied to calculate the correlation coefficient between each item score and the total scale score. An item was considered to have good homogeneity with the overall measurement objective of the scale if the correlation coefficient $r \geq 0.30$ and $p < 0.05$. Based on the results of discrimination and homogeneity analyses, items meeting the criteria were retained for subsequent factor analysis.

2.3.2.2. Reliability analysis

Internal consistency of the ISS was measured using Cronbach's α coefficient. The following criteria were applied: Cronbach's $\alpha < 0.65$ was considered poor, 0.65–0.7 as minimally acceptable, 0.7–0.8 as good, and 0.8–0.9 as excellent.

2.3.2.3. Validity analysis

i) EFA: EFA was performed on the questionnaire using SPSS 26.0. Common factors with eigenvalues > 1 were extracted using the principal component method. A cumulative variance contribution rate > 50% was considered acceptable. Orthogonal rotation (varimax) was applied to adjust the factor loadings of each item on the corresponding common factor. A factor loading ≥ 0.4 indicated good structural validity.

ii) CFA: CFA was conducted using AMOS 28.0 to evaluate the model fit. The following fit indices were used: the ratio of chi-square to degrees of freedom (χ^2/df) between 1 and 3, comparative fit index (CFI), incremental fit index (IFI), and Tucker-Lewis index (TLI) > 0.90, and root mean square error of approximation (RMSEA) < 0.08, indicating a good model fit.

Convergent validity was assessed using CR and AVE. A CR value > 0.7 and an AVE value > 0.5 for each dimension indicated good convergent validity (*13,14*). Discriminant validity refers to the distinctiveness between dimensions. Correlations between dimensions were compared using correlation coefficients, while the internal correlation of each dimension was calculated using the square root of the AVE. Discriminant validity was considered satisfactory when the internal correlation of items within a dimension was greater than the correlation between that dimension and other dimensions.

2.4. Ethics approval and consent to participate

This study was approved by the Ethics Committee of the Shanghai University of Medicine and Health Sciences (370683199710016823-SHUTCM). This trial was registered at *https://www.chictr.org.cn/* with registry number ChiCTR2500101978, registry date 2025-05-06. All participants were informed and volunteered to participate in the study and signed a written consent form.

3. Results

3.1. Demographic characteristics of participants

A total of 260 questionnaires were distributed, and 233 valid responses were collected, resulting in a valid response rate of 89.6%. Among the participants, 121 (52%) were male and 112 (48%) were female, with ages ranging from 60 to 90 years.

3.2. Item analysis results

Using the critical ratio method, participants were divided into a low-scoring group ($n = 65$) and a high-scoring group ($n = 70$). The Shapiro-Wilk test indicated that the total scores of the two groups were not normally distributed; therefore, the Mann-Whitney *U* rank sum test was used for between-group comparisons. The results showed that the rank mean of the total score in the high-scoring group (100.50) was significantly higher than that in the low-scoring group (33.00), with $Z = -10.026$, $p < 0.001$, indicating a highly statistically significant difference and confirming the validity of the grouping.

The correlation coefficients between each item score and the total score were used as indicators for item analysis. The results showed that the correlation coefficients for the 20 items ranged from 0.353 to 0.675, all reaching statistical significance ($p < 0.05$) (Table 1).

3.3. Reliability analysis

A Cronbach's α coefficient greater than 0.8 indicates good reliability of the scale. The overall Cronbach's α coefficient of the Chinese version of the ISS was 0.862, and the Cronbach's α coefficients for the four dimensions were 0.912, 0.705, 0.818, and 0.858, respectively, indicating good internal consistency of the questionnaire (Table 2).

Table 1. Rank sum test for differences between high- and low-scoring groups and correlation with total score for items of the Chinese version of the Internet Skills Scale (ISS)

Items	Contents	Rank Mean		*U*	*Z*	*p*	*r*
		Low-scoring group ($n = 65$)	High-scoring group ($n = 70$)				
Item 1	I know how to open downloaded files	44.02	90.27	716.00	-7.033	< 0.001	0.556
Item 2	I know how to download/save photos I find online	47.15	87.36	920	-6.157	< 0.001	0.513
Item 3	I know how to use keyboard shortcuts (*e.g.*, CTRL-C to copy, CTRL-S to save)	42.19	91.96	597.5	-7.551	< 0.001	0.568
Item 4	I know how to open a new tab in the browser	45.42	88.96	807.5	-6.627	< 0.001	0.508
Item 5	I know how to bookmark a website	42.95	91.26	646.5	-7.356	< 0.001	0.554
Item 6	I find it difficult to decide which keywords to use for online searches*	38.85	95.06	380.5	-8.529	< 0.001	0.657
Item 7	I find it difficult to find websites I have visited before*	54.93	80.14	1425.5	-3.823	< 0.001	0.398
Item 8	I feel tired when searching for information online*	51.51	83.31	1203	-4.835	< 0.001	0.369
Item 9	Sometimes I don't know how I ended up on a particular website*	52.45	82.44	1264	-4.562	< 0.001	0.353
Item 10	I find many websites confusing in their design*	57.17	78.06	1571	-3.170	< 0.005	0.384
Item 11	I know what information I should and should not share online	49.32	85.34	1061	-5.553	< 0.001	0.405
Item 12	I know when to share information and when not to	46.18	88.26	856.5	-6.476	< 0.001	0.465
Item 13	I am careful with my online comments and behavior to ensure they suit the context	45.46	88.93	810	-6.721	< 0.001	0.487
Item 14	I know how to change the audience for content I share (*e.g.*, friends, friends of friends, or the public)	38.98	94.95	388.5	-8.550	< 0.001	0.670
Item 15	I know how to delete a friend from my contact list	40.72	93.34	501.5	-8.090	< 0.001	0.670
Item 16	I know how to create something new using existing online images, music, or videos	40.08	93.93	460	-8.158	< 0.001	0.642
Item 17	I know how to make basic modifications to content created by others	38.32	95.56	346	-8.691	< 0.001	0.675
Item 18	I know how to design a website	50.19	84.84	1117.5	-5.558	< 0.001	0.414
Item 19	I know about different types of licenses applicable to online content	41.92	92.22	579.5	-7.858	< 0.001	0.586
Item 20	I am confident in putting video content I have created online	41.64	92.48	561.5	-7.812	< 0.001	0.564
Total score		33.00	100.50	< 0.001	10.026	< 0.001	1.000

*denotes a reverse scoring question.

3.4. Validity analysis

3.4.1. EFA

The suitability test for factor analysis indicated a KMO index of 0.83 and a Bartlett's test of sphericity with $p < 0.001$, suggesting that the data were appropriate for factor analysis. Using varimax orthogonal rotation, four common factors with eigenvalues greater than 1 were extracted. The cumulative variance contribution rates for Factors 1 to 4 were 29.520%, 47.137%, 59.616%, and 68.533%, respectively. The EFA results showed that the factor loadings of all items on the common factors ranged from 0.600 to 0.894, all exceeding the threshold of 0.4, indicating good structural validity of the questionnaire. The rotated factor loading matrix is presented in Table 3.

3.4.2. CFA

AMOS software was used to conduct CFA on the questionnaire, and model parameters were estimated using the maximum likelihood (ML) method. The CFA model of the Chinese version of the ISS is shown in Figure 1. The model fit indices are presented in Table 4.

Table 2. Overall Cronbach's α coefficient and Cronbach's α coefficients for each dimension of the Chinese version of the Internet Skills Scale (ISS)

Factors	Cronbach's α coefficients
Operational	0.912
Information Navigation	0.705
Social	0.818
Creative	0.858
Overall	0.862

The results showed a good model fit: $\chi^2/df = 2.26$, CFI = 0.978, IFI = 0.979, TLI = 0.974, GFI = 0.991, and RMSEA = 0.074. For convergent validity, the CR values were 0.932, 0.853, 0.795, and 0.880, respectively, and the AVE values were 0.734, 0.596, 0.511, and 0.616, respectively, indicating good convergence for each dimension of the questionnaire. The standardized factor loadings for each item are shown in Table 5.

4. Discussion

With the increasing aging of the population and rapid development of digital technology in China, the digital divide has become a critical issue affecting social participation and quality of life among older adults. Currently, internet usage is an important indicator reflecting the digital divide (*1,15*). A significant negative correlation exists between the digital divide among older adults and active aging in China—the wider the digital gap between older and younger generations, the lower the level of active aging among the older adult population, making it more difficult for them to fully benefit from the digital era (*16*). Research by Mariska *et al.* (*17*) demonstrated a close relationship between internet use and self-management abilities among older adults. Digital participation increases opportunities for meaningful engagement with friends and family, leading to higher life satisfaction, lower levels of depression, and reduced loneliness. Some scholars argue that older adults can acquire more health knowledge through the internet, thereby improving physical health (*18,19*). Internet use can also alleviate loneliness among older adults (*20*), thus promoting mental well-being, and supporting psychological health through continued learning (*21-*

Table 3. Factor loadings and communalities from principal component analysis of the Chinese version of the Internet Skills Scale (ISS)

Factors	Items	Factor Loading				Communality
		Operational	Information Navigation	Social	Creative	
Operational	1	0.831				0.725
	2	0.775				0.639
	3	0.853				0.748
	4	0.894				0.811
	5	0.878				0.789
Information Navigation	6		0.684			0.835
	7		0.709			0.525
	8		0.815			0.672
	9		0.836			0.735
	10		0.749			0.659
Social	11			0.821		0.731
	12			0.815		0.704
	13			0.766		0.609
	14			0.600		0.606
	15			0.581		0.600
Creative	16				0.683	0.610
	17				0.774	0.698
	18				0.774	0.654
	19				0.824	0.724
	20				0.781	0.635

23). Based on the aforementioned research background and practical needs, this study aims to conduct a cross-cultural validation of the ISS among the Chinese population and evaluate its psychometric properties. This not only provides a reliable tool for scientifically assessing the digital competence of older adults but also offers a solid empirical basis for the development of relevant interventions and policies.

This study conducted a systematic reliability and validity test of the Chinese version of the ISS, and the results indicated that the scale demonstrated good psychometric properties in the Chinese sample. Item analysis showed that the difference in total scores between the high- and low-scoring groups was highly statistically significant, and the correlation coefficients between each item and the total score were at a moderate level or above, suggesting that the items had good discrimination. This finding is consistent with previous studies reporting high discrimination of the ISS items, indicating that the scale can effectively capture differences in individuals' internet skill levels across different cultural contexts (*24*).

In terms of reliability, the overall Cronbach's α coefficient of the scale in this study was 0.862, and the coefficients for the dimensions ranged from 0.705 to 0.912, all reaching acceptable levels, indicating that the scale has good internal consistency. Previous studies have also shown that this type of ISS typically demonstrates reliability levels above 0.70 across samples from different countries (*24*), and the results of this study are generally consistent with those findings.

In terms of construct validity, this study extracted four common factors through EFA, with a cumulative variance contribution rate of 68.533%. The factor loadings for each item on its corresponding factor were above 0.6, indicating that the scale has a clear factor structure. This four-factor structure is highly consistent with the classic internet skills framework proposed by van Deursen *et al.* (*25*). Previous studies conducted in countries such as the Netherlands have also validated the stability of this four-dimensional structure and noted that the framework effectively captures the hierarchical nature of individuals' skills, ranging from basic operational skills to higher-order information utilization

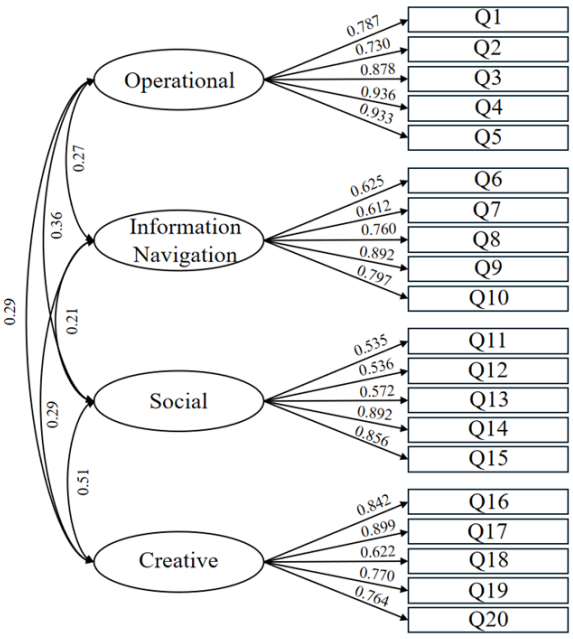

Figure 1. Confirmatory factor analysis model of the Chinese version of the Internet Skills Scale (ISS). This study constructed a confirmatory factor analysis model comprising four latent variables: "Operational", "Information Navigation", "Social", and "Creative". Each latent variable was measured by its corresponding observed variables (Q1–Q20). As shown in Figure 1, the standardized factor loadings of all observed variables on their respective latent variables were positive, ranging from 0.535 to 0.936. Specifically, the factor loadings for items in the "Operational" dimension ranged from 0.730 to 0.936; those in the "Information Navigation" dimension ranged from 0.612 to 0.892; those in the "Social" dimension ranged from 0.535 to 0.892; and those in the "Creative" dimension ranged from 0.622 to 0.899. All items met or exceeded the recommended threshold of 0.50, indicating that the scale overall demonstrated good construct validity. In addition, there were moderate correlations among the latent variables, suggesting that while the dimensions are distinct, they are also interrelated, which is consistent with theoretical expectations.

Table 5. Standardized factor loadings for each item of the Chinese version of the Internet Skills Scale (ISS)

Factors	Items	Standardized Factor Loadings
Operational	1	0.788
	2	0.729
	3	0.878
	4	0.935
	5	0.934
Information Navigation	6	0.971
	7	0.480
	8	0.634
	9	0.763
	10	0.648
Social	11	0.901
	12	0.955
	13	0.666
	14	0.838
	15	0.795
Creative	16	0.851
	17	0.893
	18	0.605
	19	0.770
	20	0.769

Table 4. Results of confirmatory factor analysis for the Chinese version of the Internet Skills Scale (ISS)

Fit Index	χ^2/df	RMSEA	CFI	IFI	TLI	GFI
Recommended Threshold	< 3.000	< 0.08	> 0.900	> 0.900	> 0.900	> 0.900
Model Result	2.26	0.074	0.978	0.979	0.974	0.991

(*24*). The results of this study replicated this structure within a Chinese sample, suggesting that the theoretical model has a certain degree of cross-cultural applicability.

It is noteworthy that subsequent developments of the ISS have proposed an expanded five-dimensional structure that additionally incorporates mobile skills (*11*). In the present study, this dimension was not included, which may be related to both the version of the scale adopted and the characteristics of the target population. Compared with younger populations, older adults may rely less on mobile-specific functions or exhibit different patterns of technology use. Therefore, future research could further examine whether incorporating mobile skills would improve the explanatory power of the scale in the context of rapidly evolving digital environments in China.

The results of CFA further supported the reasonableness of the scale's structure. The model fit indices in this study (χ^2/df = 2.26, CFI, TLI, *etc.* > 0.95, RMSEA = 0.074) met or approached the recommended thresholds, indicating that the four-factor model demonstrated good fit. Additionally, the CR values for all dimensions were above 0.7, and the AVE values exceeded 0.5, showing good convergent validity. These findings are consistent with previous studies that reported good structural stability of the ISS across samples from multiple countries, further confirming the applicability of this scale in the Chinese context.

It is worth noting that the measurement results of internet skills may be influenced by various factors across different cultural contexts. On the one hand, the Chinese internet environment is characterized by significant platform centralization, which may reduce the demands on "information navigation skills" to some extent while reinforcing the importance of "operational skills". On the other hand, Chinese users tend to rely more heavily on algorithmic recommendations and social dissemination during information retrieval, which may affect the performance of information skills and strategic skills. Moreover, factors such as generational differences, educational background, and the stage of digital development are also considered to influence the developmental levels of different skill dimensions. Previous research has pointed out that operational and formal skills rely more on experiential accumulation, whereas information and strategic skills depend more on cognitive ability and educational level (*25*), a conclusion that also holds explanatory power in the Chinese context.

This study has several limitations. In terms of sample acquisition, a convenience sampling method was employed. Although this approach is feasible in practice, it may introduce selection bias and thus affect the generalizability of the findings. Second, the study participants were primarily drawn from specific regions, resulting in certain geographical limitations in the sample distribution, which may not fully capture differences in internet usage environments and skill structures across populations from different areas. The data in this study relied mainly on self-reports from participants, which may have been influenced by social desirability bias and individual subjective perceptions, potentially introducing some degree of measurement interference. In addition, although the sample size met the requirements for statistical analysis, the overall representativeness remained relatively limited, particularly with respect to potential imbalances in age structure, educational level, and other demographic characteristics. Therefore, future research should adopt stratified random sampling methods across a broader scope, expand the geographical and population coverage of the sample, and incorporate objective behavioral data or situational assessment methods to further improve the stability and generalizability of the measurement results, thereby enabling a more comprehensive evaluation of the structural characteristics of internet skills across different populations.

5. Conclusions

In summary, this study validated the four-factor structure of the ISS and its reliability and validity within a Chinese sample, and found that this structure demonstrated good stability in cross-cultural comparisons. This not only provides a reliable measurement tool for digital divide research in China but also enhances the comparability of the ISS across different cultural contexts. Future research could further examine whether the scale exhibits the same structure and meaning across groups differing in gender, age, educational level, and urban–rural residency, thereby enabling a more precise analysis of digital inequality in the Chinese context.

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Barriers to advancing global oncology in an NCI-designated cancer center: A cross-sectional survey of faculty perspectives

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Abstract: Global oncology seeks to advance equitable cancer care across diverse populations worldwide. Recognizing its importance, the National Cancer Institute (NCI) has designated it as a strategic priority for its cancer centers. However, many struggle to integrate it into their clinical, scientific, and educational missions. We conducted an exploratory institutional needs assessment using a de-identified, cross-sectional survey at the University of Colorado Cancer Center (UCCC), an NCI-designated comprehensive cancer center. The survey, adapted from the NCI Global Oncology Assessment Survey, was distributed *via* email to UCCC members and assessed familiarity, prior involvement, motivations, and perceived barriers in global oncology work. Twenty-two members completed the survey. Over one-third (36%, 95% CI: 19.7%–57.0%) were unfamiliar with global oncology, and only 45% (95% CI: 26.9%–65.3%) had prior involvement in related initiatives. Motivators for engaging in global oncology included personal interest, opportunities for collaboration, and a commitment to addressing health disparities. Key barriers were limited funding, lack of time, and lack of institutional support. Among those with prior global oncology experience, most reported challenges securing funding, limited institutional support, administrative burdens, and a lack of academic recognition for global work. Despite strong personal interest and alignment with NCI priorities, global oncology remains under-recognized and under-supported at our institution, and may reflect similar challenges in other academic centers. Barriers impeding further engagement include limited funding, lack of institutional support, and administrative complexity. Targeted support, dedicated funding, and academic recognition could strengthen institutional capacity to advance cancer care locally and globally.

***Keywords*:** global health, global oncology, equity

1. Introduction

Global oncology has emerged as a branch of global health focused on addressing disparities in cancer care (*1*). In recent decades, there has been an increase in incidence and mortality in low- and middle-income countries (LMICs). According to the Global Cancer Observatory (GLOBOCAN), there were an estimated 20 million new cancer cases and 9.7 million cancer deaths worldwide in 2022, with disproportionately higher mortality rates in African and Asian regions (*2*). This growing burden highlights the urgency of strengthening global oncology efforts, prompting United States-based organizations such as the American Society of Clinical Oncology (ASCO) or the National Comprehensive Cancer Network (NCCN) to establish dedicated task forces and programs (*3*).

The National Cancer Institute (NCI) created the Center of Global Health (CGH) in 2011 to incorporate cancer control into global health programs, to coordinate NCI's engagement in global cancer control, and to encourage NCI-designated cancer centers to engage in global oncology projects. However, global oncology programs within NCI-designated cancer centers are still mostly underdeveloped, even with such initiatives (*4*). To better understand progress and persistent barriers, the NCI CGH developed and distributed a survey to assess the state of global oncology at all NCI-designated cancer centers. The most recent results, published in 2021, showed that 42% of cancer centers have formal global oncology programs, while an extra 49% engage in global oncology activities (*5*). Global oncology programs reported several challenges, such as a lack of funding and balancing global oncology projects with other professional demands (*5*). These findings are corroborated by reports from major academic institutions in the United States, noting that limited resources and institutional support are obstacles for

global collaboration (*6*).

The University of Colorado Cancer Center (UCCC) serves the entire state of Colorado as its catchment area, engaging more than 80 % of the state's population, including a significant immigrant population. Building on these domestic efforts, UCCC formally established a global oncology program in 2024 to foster global cancer research and equitable, bidirectional partnerships (*7-9*). In this research, we aimed to assess institutional engagement and identify barriers to global oncology advancement at UCCC before the initiation of the global oncology program, to better define strategies for successful implementation.

2. Study design

This exploratory, cross-sectional institutional needs assessment survey was conducted from February to March 2025, using an instrument adapted from the existing NCI Global Oncology Assessment Survey used in prior national assessments (*5*). No additional formal validation was performed for this adapted version. Eligible participants included UCCC members from both clinical and nonclinical divisions. The de-identified, voluntary survey was distributed *via* email to all UCCC members and collected in a secure Microsoft Smartsheet page, with five weekly reminders sent to maximize response rates. The main topics of the survey included: Familiarity and Definition of Global Oncology; Prior Experience and Engagement in Global Oncology; Barriers and Challenges; Motivations and Support Needs; and Future Directions (Supplementary File, *https://www.globalhealthmedicine.com/site/supplementaldata.html?ID=120*).

All survey responses were stored securely on institutional servers. Data analysis was performed using Stata V15.0, and descriptive statistics, including frequencies and percentages, were calculated. For key proportions, 95% confidence intervals (CIs) were calculated using the Wilson score method. The secondary analysis of de-identified survey data was reviewed and determined to be exempt by the University of Colorado Institutional Review Board under 45 CFR 46.104(d) (4).

3. Key research findings

3.1. Survey results

The survey was distributed to 622 UCCC members, of whom 22 (3.5%) completed it. Of the 22 respondents, 14 (64%, 95% CI: 43.0%–80.3%) were familiar with the concept of global oncology, and 10 (45%, 95% CI: 26.9% –65.3%) had participated in global oncology research in collaboration with international partners. Only 3 had collaborated with a global oncology department or team at UCCC.

Respondents represented a diverse range of disciplines within oncology, with the majority working in medical oncology (n = 6), followed by molecular oncology (n = 4), immunology (n = 3), and hematology oncology (n = 2). Smaller numbers identified their primary area of work as surgical oncology (n = 1), pediatric oncology (n = 2), palliative/supportive care (n = 2), or other disciplines (n = 2). Participation in UCCC programs was most reported in Developmental Therapeutics (45%), followed by Tumor–Host Interactions (23%), Molecular and Cellular Oncology (14%), and Cancer Prevention and Control (9%), with an additional 9% participating in other programs. With respect to research involvement, seven participants (32%) reported dedicating 76–100% of their professional time to research, six each (27%) reported dedicating 51–75% or 11–25%, and smaller proportions spent 26–50% (9%) or 0–10% (5%) of their time on research activities.

Motivations for involvement in global oncology initiatives were primarily driven by personal interest (n = 17, 77.3%, 95% CI: 56.6%–89.9%) and opportunities for collaboration (n = 17, 77.3%, 95% CI: 56.6%–89.9%). Addressing health disparities was also a major motivator, cited by 11 (50.0%, 95% CI: 30.7%–69.3%) respondents. Fewer participants identified institutional goals (n = 3) as a primary motivator. Regarding the focus of their global oncology projects, the most frequent responses were research collaboration with international institutions (n = 8) and clinical care or onsite cancer care delivery (n = 5). Other prominent areas included global cancer research networks (n = 4), capacity building and training in international settings (n = 4), and implementation of cancer control programs (n = 1). Research collaborators were identified in 57 countries across all continents, with most located in Europe and Latin America (Figure 1). When asked about the classification of their global research according to the Common Scientific Outline (CSO), projects were most often categorized as treatment (n = 4), followed by etiology (n = 2), biology (n = 1), and early detection, diagnosis, and prognosis (n = 1), while two projects remained uncoded.

Funding sources for global oncology projects were heterogeneous. The most frequently reported were charitable or philanthropic funds (n = 6), followed by international non-profit organizations (n = 4), investigator discretionary funds (n = 3), and NIH support (n = 3). Smaller numbers received U.S. government non-NIH funds (n = 2), administrative or U.S. non-profit support (n = 1 each), or were unfunded (n = 1).

Key challenges reported in conducting global oncology research included limited funding opportunities or timelines that do not align with real-world needs (n = 8) and limited institutional support for global initiatives (n = 6). Other commonly cited barriers were lack of recognition or credit for global oncology work (n = 5), bureaucratic hurdles (n = 5), and limited opportunities for academic advancement (n = 3). Reported barriers differed by level of engagement: participants more

Figure 1. Geographic distribution of global oncology research collaborators affiliated with the University of Colorado Cancer Center. Regions with reported collaborations are highlighted in red, most frequently in Europe and Latin America.

frequently cited structural challenges such as funding limitations and administrative burden, whereas non-participants more commonly reported lack of time and limited opportunities.

Our exploratory institutional needs assessment shows that a substantial proportion of respondents were unfamiliar with the concept of global oncology, indicating that awareness and understanding of this field remain limited within our institution. The low participation rate is also an important finding, showing that global oncology is either poorly known or not a priority for most oncology researchers. Although most participants expressed strong personal motivation and interest in international collaboration, significant barriers, particularly the lack of dedicated funding and institutional support, continue to hinder the development of global oncology initiatives.

3.2. Global oncology efforts

Over the past decade, increasing efforts have been made to address disparities in cancer care and strengthen global oncology in the United States (*1*). However, despite a push from the NCI CGH to encourage the creation of formal global oncology programs, faculty across many cancer centers, including UCCC, still report a high number of barriers and are mostly unaware of global oncology. Barriers identified in our study mirror the 2021 NCI Global Oncology Assessment findings, which identified limited institutional support and funding, and a lack of recognition of global oncology work as major obstacles across NCI-designated cancer centers (*5*). These findings highlight that barriers are not restricted to a single institution, and set the stage for collaborative work to tackle them.

The establishment of an ASCO Global Oncology Task Force and the creation of investigator awards have been successful at increasing awareness about the relevance of global oncology (*1*). However, as demonstrated, efforts are still necessary to increase awareness. The Task Force published recommendations encouraging the integration of global oncology principles, particularly cancer care delivery in low-resource settings, into Hematology/Oncology training programs (*10*). Some institutions are already including Global Health as a track in their training due to the increasing interest from the trainees (*11*). Our institution recently established a Global Oncology Department, with a small percentage of respondents already working with it.

3.3. Limitations of the study

Some notable limitations of our study include its small sample size, single-institution design, and potential for response bias given the low response rate. Familiarity with global oncology is likely even lower than reported, as those already interested or involved in the field were more likely to respond. With almost half of the respondents working in therapeutic development, this may contribute to response bias, as they are more frequently involved in global oncology, such as international clinical trials, than other groups. However, we were unable to compare respondents with non-respondents due to insufficient data. This possible

overestimation further highlights the need to raise awareness and increase engagement in global oncology across academic centers. Additionally, our analysis is descriptive and exploratory, not hypothesis-testing. Although our scope was limited, the overall patterns of engagement and barriers observed were consistent with previous reports, suggesting that our findings may still reflect broader institutional trends (*5*).

4. Conclusions

Despite growing interest and alignment with NCI priorities, global oncology remains under-recognized and insufficiently supported in our institution, and may reflect a reality within many academic institutions. Structural barriers, including limited funding mechanisms, lack of protected time, insufficient institutional infrastructure, and administrative complexity, continue to hinder meaningful participation. Addressing these challenges through targeted institutional investment, enhanced mentorship, and formal academic recognition could strengthen capacity and sustainability in this emerging field, ultimately advancing equitable cancer care on both local and global scales.

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COMMENTARY
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Reconsidering Japan's path to universal health insurance: Pre-war origins and the complementarity of occupational and community-based schemes

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Abstract: Japan's health security system began with the enactment of the Health Insurance Act in 1922, which was occupational health insurance intended for workers in large factories and mines. The scope of this social health insurance was subsequently expanded, but the issues of insurance coverage for agricultural workers and the self-employed remained. To address these issues, the Citizens' Health Insurance Act, a community-based health insurance system, was legislated in 1938. Japan's health security collapsed with the end of the Pacific War (World War II) in 1945, but during postwar reconstruction, legislation was conducted in 1958 and universal health insurance was achieved in 1961. Japan's universal health insurance system cannot be considered a purely postwar product. It began to be established before the war in response to the industrialization of society, and it was completed during the period of postwar economic growth, overcoming the interruption caused by the end of the war.

***Keywords*:** universal health insurance, occupational health insurance, community-based health insurance, solidarity

1. Introduction

Japan's healthcare system is highly regarded internationally (*1*). Its evolution is generally said to have been modeled on Germany's social health insurance system (*2*). Citizens' health insurance (community-based health insurance) is an important element (*2,3*), making it more than just a copy of Germany. Japan also experienced a major discontinuity with its defeat in the Pacific War (World War II). However, regarding the establishment of the system before the war, there is insufficient English literature. Several previous studies only briefly mention the legislation of the 1922 Health Insurance Act and the 1938 Citizens' Health Insurance Act.

This article aims to clarify how the pre-war Health Insurance Act expanded into occupational insurance, what functions the Citizens' Health Insurance Act played, and how the two were complementary. At the same time, it will demonstrate that these pre-war efforts formed the foundation for achieving post-war universal health coverage in Japan.

2. Enactment of the Health Insurance Act

The Health Insurance Act was enacted in 1922 and came into effect in 1927. The early 1920s was a time of growing mass movements known as Taisho Democracy and frequent labor disputes against the backdrop of rapid industrialization in Japanese society (*4*). It is worth noting that in the early stages of development of this social health insurance system, the government itself acted as insurer for companies that could not establish their own health insurance associations (government-managed health insurance). However, this law still limited compulsory insurance coverage to workers in large-scale factories covered by the Factory Act (that employed 10 or more people on a regular basis) and mines covered by the Mining Act. Small factories employees or workers in the primary and tertiary industries were not even subject to compulsory or voluntary coverage. Development of Japan's health security system began as a response to industrialization of society.

3. Revisions to the Health Insurance Act in 1934 and thereafter

The Great Depression is thought to have cast a dark shadow over Japanese society in the early 1930s. The fact that poverty in people's lives, especially in rural areas, was a real threat to social unrest can be seen from the establishment of the Ideological Countermeasures Council (ICC) based on a Cabinet decision (*5*). The Director-General of the Ministry of Home Affairs' Social

Affairs Bureau was appointed as a member of ICC. The Ministry of Home Affairs' Social Affairs Bureau was the predecessor of the Ministry of Health and Welfare (*6*). This is because social improvement measures were also a matter for deliberation at ICC, from the perspective of alleviating the anxiety in people's lives that led to ideological deterioration (*7*). This demonstrates the Japanese government's recognition that social solidarity is not only the foundation of social security but also its purpose. Social security cannot be established without social solidarity, and at the same time, the enhancement of social security is essential for social solidarity; there is a chicken-and-egg relationship, a mutual prerequisite. Amid this turbulent social situation in the early Showa period (the decade or so from the late 1920s onwards), the May 15 Incident (an attempted coup d'état by young naval officers, 1932) and the February 26 Incident (an attempted coup d'état by young army officers, 1936) occurred.

Around 1934, the Health Insurance Act limited coverage to approximately two million factory and mine workers (*8*). This represented only 3% of the population at the time. The government seemed to consider this limited health coverage inadequate. During deliberations on the amendment of the law in the Imperial Diet in 1934, a government committee member explained the purpose of the amendment by saying, "Ideally, we would like to extend health insurance coverage not only to factory and mine workers but also to workers employed in various businesses and other low-income earners" (*8*). As a result, the law's coverage was expanded to factories with five or more regular employees.

In 1939, the Employees' Health Insurance Act was enacted separately from the Health Insurance Act. This resulted in the establishment of health insurance coverage for employees in finance, retail, and other sectors. In essence, while the previous Health Insurance Act targeted factory or mine workers, the Employees' Health Insurance Act targeted some tertiary industry workers. However, there was no point in separating the laws governing health insurance according to detailed industry categories such as finance and mining. Therefore, in 1942, they were unified into the Health Insurance Act. This 1942 amendment to the Health Insurance Act marked the end of the legal expansion of the prewar occupational health insurance system. As the Pacific War worsened the government was unable to complete it even if it wanted to. This issue was carried over into the postwar period.

4. The old Citizens' Health Insurance

Japan's health insurance system began as a system for employed factory and mining workers and progressed by expanding coverage to include some tertiary industry workers. However, the issue of how to establish health coverage for agricultural and other primary industry workers, the self-employed, and the unemployed, including retired elderly people, remained unaddressed until the late 1930s. To solve this problem, a community-based health insurance system was established under the Citizens' Health Insurance Act in 1938. The Citizens' Health Insurance Act (Act No. 60 of 1938) was completely revised in 1958 after the war, and it is therefore generally referred to as the "old Citizens' Health Insurance Act" to distinguish it from the postwar Citizen's Health Insurance Act (Act No. 192 of 1958).

The old Citizens' Health Insurance Act stipulated creation of two distinct types of citizens' health insurance associations: ordinary citizens' health insurance associations (community-based insurance) and special citizens' health insurance associations (occupational insurance) (Article 9). While the previous health insurance system required employees to be insured, the citizens' health insurance associations were created to ensure health coverage for citizens not covered by the previous Health Insurance Act. Of these, special citizens' health insurance associations are defined as "organized to include individuals engaged in the same business or similar occupations" (Article 10, Paragraph 1). During the Imperial Diet deliberations on the legislation of the law, a government committee member stated, "We are planning to establish special citizens' health insurance associations in urban areas" (*9*). Therefore, the primary purpose of special citizens' health insurance is thought to improve health coverage in urban areas. The special citizens' health insurance associations for doctors and dentists practitioners and lawyers, which still exist today, were originally established in this legislation. The special citizens' health insurance could be considered a kind of occupational insurance for self-employed people in urban areas who worked in occupations with relatively high social status.

The more important form of citizens' health insurance than the special citizens' health insurance is the ordinary citizens' health insurance, a community-based insurance. When submitting the Citizens' Health Insurance Bill, minister of Health and Welfare Koichi Kido stated, "The primary problem with receiving medical care is the burden of medical expenses. The recent deterioration of rural residents and small and medium-sized urban merchants and industrialists is particularly severe, and medical expenses place a considerable financial burden on these people. We have recognized that the best solution to this medical expense problem is an insurance organization based on mutual aid and everyday preparations, and have drafted this bill" (*10*). He made it clear that the bill primarily targets rural residents and small business owners.

Shimazaki lists three characteristics of the old Citizens' Health Insurance system (*7*): *i*) Municipalities were not insurers: instead, they established insurance associations; *ii*) Municipalities were free to establish associations, and residents were also free to join

in principle; and *iii*) The associations themselves determined insurance premiums and benefit levels.

It is considered that there were two reasons why the establishment of citizens' health insurance associations was left to the discretion of local governments. One is that there were varying degrees of solidarity within local communities. The other is that even if citizens' health insurance associations were forcibly established, a large number of regions would end up with "insurance but no medical care" because many villages were without doctors.

5. Revision of the old Citizens' Health Insurance Act

In 1942, the law was amended to give prefectural governors the discretion to force the establishment of ordinary citizens' health insurance associations. As a result, the old Citizens' Health Insurance system had the character of compulsory insurance.

In accordance with this, ordinary citizens' health insurance associations were created in most regions. It was, however, common for these associations to not actually function at all. As the end of the war approached, medical services were not provided adequately due to shortages of doctors, nurses, and medicines. By the end of the war, more than half of the citizens' health insurance associations had effectively ceased operations (*6*). In this way, community-based health insurance under the old Citizens' Health Insurance Act was incomplete.

6. Universal Health Insurance

The development of Japan's health security system, both in terms of occupational insurance and community-based insurance, was never completed before the end of the war. Moreover, the war damage caused the collapse of the industry itself, which was the foundation of occupational health insurance. In addition, private practitioners, who provided medical services in the communities, were called away, and many medical institutions were forced to close, causing the health delivery system to collapse.

In 1956, the Economic White Paper loudly declared, "We are no longer in the post-war period" (*11*). However, the Health and Welfare White Paper of the same year stated, "11% of the population in the low-income bracket are left behind in the reconstruction, and are becoming entrenched and settling out at the bottom of the hierarchy," and asked, "Is the 'post-war' period really over?" (*12*). The period just over ten years after the end of the war was truly a time when economic recovery and poverty intersected (*7*). Furthermore, one-third of the population at the time were not enrolled in the social health insurances (*13*). In this way, during the transition from the end of the war to the period of high economic growth, the institutional guarantee of medical access, which had been a concern since before the war, was finally completed with the enactment of the (new) Citizens' Health Insurance Act and amendment of the Health Insurance Act. The public insurance program based on these two laws was fully implemented in 1961 (Figure 1). This meant that virtually all citizens were covered by either occupational or community-based insurance. However, the benefit levels of this fledgling universal health insurance system were "very basic" compared to current standards (*14*). Benefits were expanded to incorporate medical advances in the second half of the 20th century. Nevertheless, with the achievement of universal health insurance, it can be said that Japan had at least laid the foundation for universal health coverage (UHC), which the WHO defines as "all people have access to the full range of quality health services they need, when and where they need them, without financial hardship".

The UK achieved UHC in 1948 with the establishment of the tax-funded National Health Service (NHS), while Japan was more than a decade behind. France and Germany, which built their health security systems by social health insurance, achieved universal

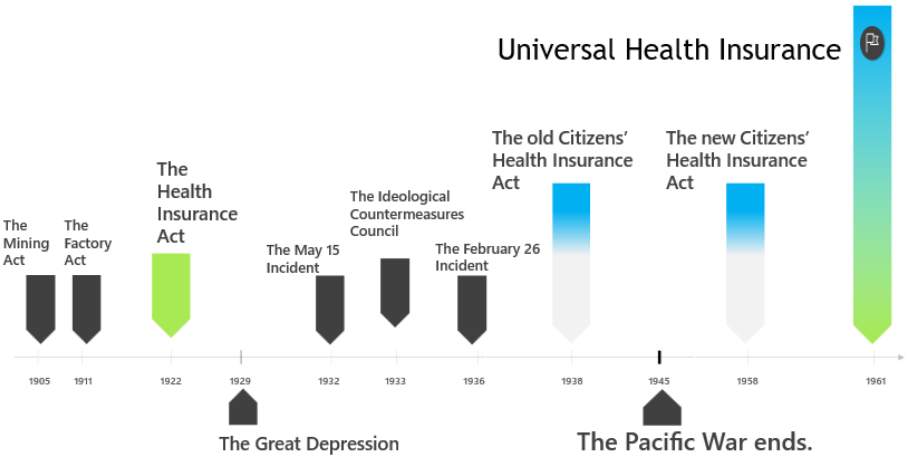

Figure 1. Chronological timeline of Japanese health security.

health insurance in 2000 (*15*) (legislation enacted in 1999 (*16*)) and 2009 (*17*) (legislation enacted in 2007 (*18*)), respectively. It can be said that Japan achieved universal health insurance relatively early. This is likely due to the flexible, trial-and-error approach to developing a system that is not tied to occupational insurance, which it had adopted since before the war.

In conclusion, Japan's universal health insurance system cannot be considered a purely postwar product. It began to be established before the war in response to industrialization of society, and it was completed during the period of postwar economic growth, overcoming the interruption caused by the end of the war. Pre-war efforts have led to achievement of universal health insurance after the war.

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