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# Bio-sampling alternative diagnostic imaging for telemedicine: a feasibility study of an AI-based throat camera for influenza

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**Introduction:** Telemedicine has progressed rapidly alongside advances in information and diagnostic technologies, providing benefits in accessibility, convenience, cost efficiency, and infection control. However, reliance on biological sample-based diagnostics, such as blood and urine tests, has limited the scope of fully remote diagnosis, confining many services to hybrid or in-clinic settings. Although home-based biological testing has partially addressed these constraints, fundamental barriers to complete remote diagnostic workflows remain.

**Methods:** This study evaluates the feasibility of bio-sampling alternative diagnostic imaging (BADI), an artificial intelligence-based diagnostic approach recently introduced in influenza testing. We developed a conceptual framework to compare conventional in-clinic testing, home-based biological testing, and BADI-based diagnostics across key dimensions relevant to remote medical implementation.

**Results:** The analysis identified four essential conditions for the transition of BADI-type diagnostics to remote healthcare delivery: (1) sufficient availability and accessibility for patients, (2) assurance of diagnostic accuracy and clinical reliability, (3) high usability and interpretive clarity for both patients and healthcare providers, and (4) seamless integration into medical systems with immediate linkage to appropriate treatment.

**Conclusion:** BADI demonstrates significant potential to overcome the limitations of biological sample-dependent diagnostics in telemedicine. Addressing the identified conditions is critical for enabling safe, scalable, and effective remote diagnosis and for advancing fully remote healthcare models.

## KEYWORDS

biological sampling, diagnostic imaging, medical equipment, remote diagnostics, telemedicine

## 1 Introduction

### 1.1 History of telemedicine: global and Japanese perspectives

Telemedicine initially emerged as an extension of medical practice that had once been confined to a single institution, evolving through the interconnection of hospitals that enabled the transmission of medical images and the remote utilization of specialist expertise. With the establishment of wireless communication during the First World War, the transmission of medical information became feasible, and by the 1930s such technology was already being deployed in geographically isolated regions such as Alaska and Australia. During the Korean and Vietnam Wars, wireless communication further matured into an operationally significant tool, endowing military medical systems with the capability to deliver telemedical services to specific groups. It was routinely employed for the coordination of medical teams and the dispatch of helicopters, thereby enhancing the responsiveness of battlefield medicine (Zundel, 1996). In parallel with advances in technology, the scope of telemedicine expanded from inter-physician consultation to include diagnostic interactions between physicians and patients. A seminal example occurred in the 1960s, when physicians at Massachusetts General Hospital employed a bidirectional audiovisual microwave circuit to deliver medical care to patients located at the Logan International Airport Medical Station, situated 2.7 miles away from the hospital (Zundel, 1996). In Japan, the earliest initiatives in telemedicine can be traced back to 1971, when an experimental transmission of medical images between physicians was conducted in a remote mountainous region of Wakayama Prefecture (Kaihara, 1998; Takashi, 2010). Subsequently, physician–patient telemedicine in Japan gained momentum from 1990 onward. By the mid-1990s, the development of devices robust enough for application in practical clinical settings had been achieved, marking the beginning of widespread adoption (Tofukuji, 2011). A decisive milestone was reached in 2015, when the advancement and dissemination of information and communication technologies facilitated the commencement of full-scale online medical consultations (Kawasaki, 2023).

### 1.2 Definitions of telemedicine and online consultation

Multiple definitions of *telemedicine* have been proposed in the literature and by international organizations. The World Health Organization (WHO) defines telemedicine as: “*Delivering of healthcare services, where distance is a critical factor, by all healthcare professionals using information and communication technologies for the exchange of valid information for the diagnosis, treatment and prevention of disease and injuries, research and evaluation, and for the continuing education of healthcare providers, all in the interests of advancing the health of individuals and their communities*” (WHO, 2025). Similarly, the American Telemedicine Association (ATA) characterizes it as “*the use of medical information exchanged from one site to another via electronic communications to improve patients’ health status*” (AMA

*Journal of Ethics*<sup>®</sup>, 2025). In the Japanese context, the Japan Telemedicine and Telecare Association defines telemedicine as “*actions contributing to health promotion, medical care, and nursing care through the use of communication technologies*” (Japanese Telemedicine and Telecare Association, 2025). Furthermore, one of the central technological domains of telemedicine, namely, teleradiology, has been defined by the Japan Radiological Society and the Subcommittee on Electronic Information of the Japan Radiological Specialist Association in the *Guidelines for Teleradiology 2018* as “*a diagnostic practice in which CT, MRI, and other medical images, together with associated information, are transmitted via networks to locations outside the facility where imaging was conducted, thereby enabling physicians at multiple facilities (e.g., attending physicians and specialists, or between specialists) to share and interpret such information*” (Radiology, 2025). The evolution of telemedicine has been closely intertwined with advances in information and communication technologies. The developmental trajectory of telemedicine can be broadly categorized into generational phases, beginning with the first generation, characterized by intra-hospital data sharing, and advancing to the fifth generation, defined by cloud-based platforms (Takagi and Kawamata, 2010). A pivotal turning point in this trajectory occurred in 2020 during the global COVID-19 pandemic. In response to the need for minimizing physical contact, governments across many nations implemented significant regulatory relaxations regarding telemedicine. These measures facilitated the rapid expansion of telemedicine, particularly in physician–patient interactions, capitalizing on its core advantage of reducing direct contact and thereby contributing to infection control (Kinoshita et al., 2020) (Nishimura et al., 2020).

### 1.3 Advantages and bottleneck of telemedicine

The benefits of telemedicine have been extensively documented, with accessibility, convenience, and cost-effectiveness ranking among the most frequently cited advantages (Kruse et al., 2021). Telemedicine has been reported to reduce time burdens and healthcare expenditures, thereby improving the efficiency of medical care delivery (OECD, 2023). From the patient’s perspective, telemedicine is especially valuable for those residing in remote regions or facing mobility challenges, as it improves access to healthcare services without necessitating physical travel. Patients benefit from the convenience of receiving timely medical care from their homes, alleviating the stress associated with commuting and long waiting times. For healthcare professionals, telemedicine enhances the ability to monitor patients’ health conditions, enabling more timely and effective interventions. Telehealth tools such as video consultations and automated reminders have been shown to strengthen communication between clinicians and patients, thereby improving clinical outcomes (Hwei and Octavius, 2021). During the COVID-19 pandemic, widespread adoption of remote monitoring through home pulse oximetry, often conceptualized as a “virtual ward,” was associated with reductions in emergency visits and mortality, contributing to the mitigation of hospital capacity strain during infection surges

(Mancilla-Tapia et al., 2022). In addition, digital contact-tracing systems—such as smartphone-based exposure notification frameworks (e.g., GAEN)—were suggested to exert greater infection control effects when implemented at larger population scales (Wittman et al., 2024).

In the field of telemedicine, particularly in the domain of diagnostics, the necessity of biological sampling tests has long been debated. As a major limitation of telemedicine, it has been noted that examinations requiring direct specimen collection—such as blood tests, body fluid analyses, and physical examinations—are difficult to perform remotely. This has been identified as a factor impeding adoption, with reports indicating that some patients prefer in-person visits over teleconsultations due to the need for laboratory results such as insulin levels (Wittman et al., 2024). In specialties such as surgery and ophthalmology, where specimen-based testing and physical examinations are indispensable, the demand for in-person consultations is considered particularly high (Ftouni et al., 2022).

When comparing in-person with remote care, several shortcomings of telemedicine have been highlighted. These include potential adverse effects on the physician–patient relationship, accessibility challenges for individuals with disabilities, concerns about the thoroughness of clinical examinations, technical barriers, privacy issues, hesitancy among healthcare providers, concerns regarding the quality of care, and the inability to effectively perform physical examinations (Hwei and Octavius, 2021). A qualitative study on “Internet hospitals” in China reported physicians’ concerns that the inability to conduct physical examinations or tests comparable to those performed in-person could compromise diagnostic accuracy and increase the risk of misdiagnosis (Wu X. et al., 2024). Historically, biological sampling has been a major factor reinforcing dependence on in-person care, particularly in specialties requiring precise diagnostics such as subspecialty practice, clinical trials, and ophthalmology (Ftouni et al., 2022). For these reasons, telemedicine has, until now, primarily been applied within the scope of conditions that can be managed without the need for laboratory-based biological testing, while leveraging the previously discussed advantages of remote care.

## 1.4 Technological advances for telemedicine applications

Conversely, advances in home-based testing devices and remote sensing technologies are beginning to address some of these challenges, and their effective integration is regarded as a key driver for the broader adoption of telemedicine. Substantial improvements in biophysical signal monitoring technologies have enabled the incorporation of mobile cardiac health information functions into telemedicine and remote diagnostics (NIH, 2025a). In addition, at the research stage, breath analysis using electronic noses and mass spectrometry has demonstrated promising diagnostic accuracy for conditions such as COVID-19 (Geenen et al., 2023). Other approaches include the measurement of physiological markers in sweat (e.g., cortisol, glucose) (Xu et al., 2021); indirect sensing of glycemic variability through near-infrared spectroscopy, millimeter/microwave radiation, and inductive coupling (Shi et al.,

2025); assessment of skin conductance or electrodermal activity (EDA), which allows estimation of autonomic nervous activity, sweating, stress responses, and peripheral nerve function (Smith et al., 2023); and minimally invasive monitoring of interstitial fluid (ISF) (Wu Z. et al., 2024). However, these techniques remain experimental and have yet to be fully integrated into routine telemedical practice.

Home-based diagnostic tests involving biological sampling have also become available. In the case of influenza diagnosis, rapid antigen detection kits for home use, including saliva- and nasal self-collection kits, are commercially distributed in the United States and Europe. Although the sensitivity of at-home tests is considered “moderate” (approximately 60%) compared with PCR, their diagnostic performance is comparable to that of rapid antigen tests performed in medical facilities, with particularly improved accuracy when used within 72 h of symptom onset (Periyaswamy et al., 2019). In the United States, over-the-counter (OTC) home test kits capable of simultaneously detecting influenza A/B and COVID-19 have also been approved and marketed (Health, 2025).

## 1.5 Utilization of emerging at-home testing in telemedicine and associated challenges

In response to the emergence of novel diagnostic modalities, pilot initiatives have already been undertaken in several healthcare systems. In the United States, the *Test-to-Treat* program, and in the United Kingdom, the NHS-led *COVID Oximetry @home (CO@h)* program, exemplify early efforts to address the limitations of traditional diagnostic testing based on biosampling. Within the Home Test to Treat model, exposure notifications, at-home testing, teleconsultations, and medication delivery are seamlessly integrated into a single continuum of care, while the risk of severe illness is monitored through pulse oximetry. This system represents a hybrid framework that combines remote triage with at-home monitoring (NIH, 2025a). While these diagnostic methods demonstrate the feasibility of enabling individuals to conduct their own biosample-based testing and device operation, unresolved challenges remain in relation to invasiveness, diagnostic accuracy, integration with healthcare institutions, and applicability to vulnerable populations such as children and the elderly (Smy et al., 2024).

## 1.6 Emergence of bio-sampling alternative diagnostic imaging (BADI)

In recent years, technological innovations have begun to transcend the aforementioned limitations through the development of diagnostic methods that substitute for biosampling. Among these is *bio-sampling alternative diagnostic imaging (BADI)*, which has reached the stage of practical application and presents new opportunities to extend the scope of telemedicine beyond its conventional boundaries (FDA, 2025a). Such innovations hold the potential to inaugurate a new generation of telemedicine, wherein diagnostic procedures that currently necessitate in-person visits may be conducted remotely. This transformation is anticipated to increase the rate of online consultations and decrease the

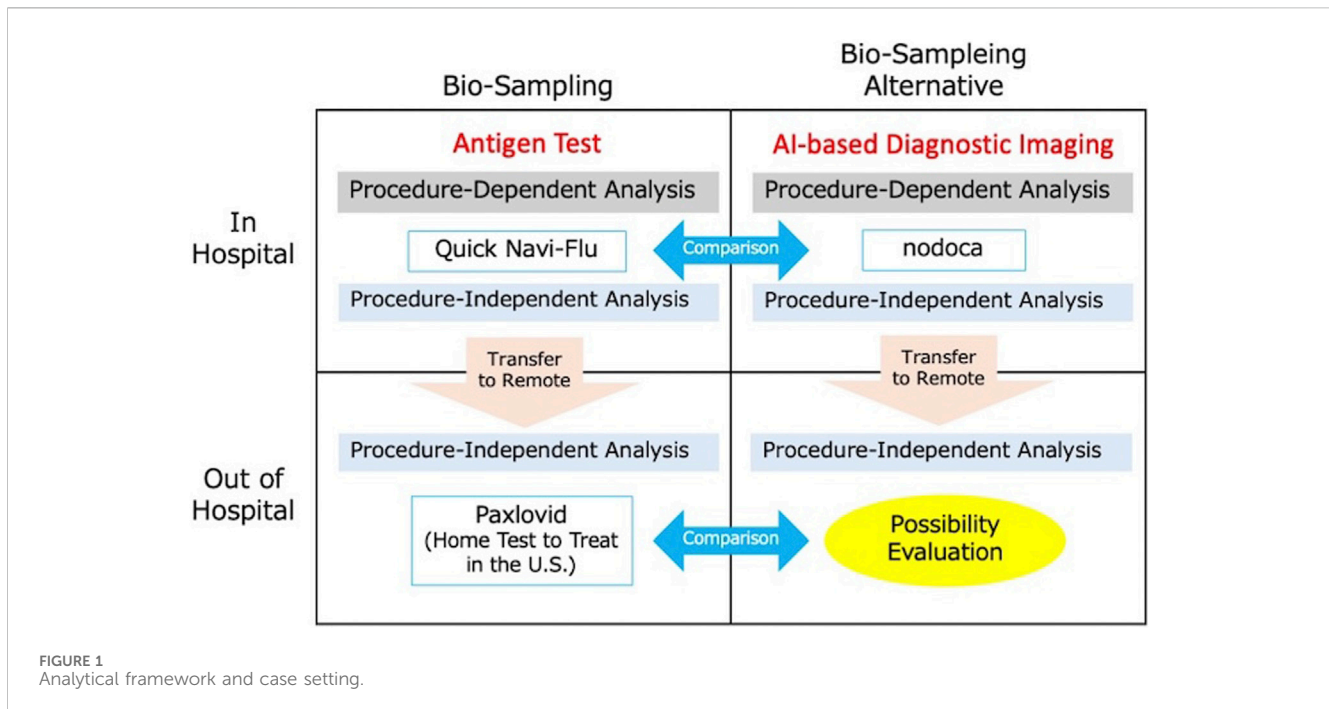


FIGURE 1 Analytical framework and case setting.

proportion of face-to-face visits. The development of BADI-type influenza diagnostic devices not only streamlines and accelerates the diagnostic process but also alleviates long-standing bottlenecks in remote diagnostics, thus expanding the feasibility of large-scale implementation.

Research into alternative diagnostic modalities has compared conventional biosample-based tests (e.g., nasopharyngeal swabs, saliva, blood, culture) with non- or minimally invasive methods, including breath analysis, smartphone-based imaging, wearable sensors, and self-acquired photographic data analyzed via artificial intelligence (AI). Examples include systematic analyses of the sensitivity and specificity of volatile organic compound (VOC) breath analysis for COVID-19 detection (Long et al., 2024), and comprehensive evaluations of the diagnostic accuracy of breath, saliva, oral swabs, and other non-invasive techniques (Althaus et al., 2025). In the field of imaging diagnostics, investigations have explored the use of AI to analyze throat images captured via smartphones to screen and triage for streptococcal infection and pharyngitis (Gomez et al., 2024), as well as the utilization of continuous biometric data (e.g., heart rate, skin temperature) obtained from smartwatches and other devices to detect early signs of infection (Mason et al., 2022). While none of these approaches independently provides definitive diagnosis, they have been identified as valuable for assisting physicians (Gomez et al., 2024), enabling early detection, and facilitating population-level surveillance (Mason et al., 2022). Nevertheless, no study to date has comprehensively evaluated the potential for these emerging alternatives to biosampling to be systematically integrated into remote healthcare.

Building upon the above background, the present study adopts a broad interpretation of telemedicine as encompassing “the entirety of medical activities conducted through information and communication technologies.” Within this frame, we undertake a comparative analysis of diagnostic methods that substitute for

conventional biosampling, and examine the extent to which such methods may be integrated into telemedicine. To this end, we develop an evaluative framework using the case of a BADI-type influenza diagnostic device, thereby analyzing the prospective contributions of alternative diagnostic strategies to the next-generation of telemedicine.

## 2 Methods

### 2.1 Analytical framework

In this study, we developed an analytical framework to evaluate the feasibility of using novel imaging-based diagnostic technologies for influenza testing in remote settings, as a potential substitute for conventional antigen tests requiring biological sampling (Figure 1). While prior studies have examined the accuracy and technical aspects of BDAI in comparison with established diagnostic methods (Long et al., 2024), our analysis extends this scope by specifically assessing the remote applicability of BDAI devices. To this end, we referred to the adoption criteria of *at-home rapid tests* within the Test-to-Treat model (Figure 1), where biological sampling-based diagnostics have already shifted to home testing (NIH, 2025b). Additional criteria were incorporated to evaluate whether such technologies could be used at home and whether integration with therapeutic pathways could be realized.

Two complementary analytical approaches were employed: (i) a procedure-dependent analysis and (ii) a procedure-independent analysis. The procedure-dependent analysis considered three sequential aspects: diagnostic steps, involvement of physicians or nurses, and required time. The procedure-independent analysis was organized into three major categories: clinical significance, cost, and feasibility of remote application. Within clinical significance, the subcategories included applicable age range, allowable time window

TABLE 1 Comparison between biological sample-based diagnostics (antigen test) and imaging diagnostics (procedure-dependent).

Diagnostic method	Item	Step 1: Patient data acquisition	Step 2: Examination and determination	Step 3: Notification of test results
Biological sample-based diagnostics (antigen test)	Procedure	Collection of nasal mucosal fluid	Antigen-antibody reaction test	Notification of test results
	Performer	Physician or nurse inserts a sterile swab into the nasal or pharyngeal cavity to collect mucosal sample	The collected specimen is mixed with reagents and dropped onto a test kit	Confirmation of results, explanation, and prescription
	Time required	A few seconds	Approximately 5–15 min	A few minutes
Imaging diagnostics	Procedure	Pharyngeal image capture	AI-based image analysis	Notification of test results
	Performer	Physician or nurse captures images of the patient's throat using a dedicated camera	Not applicable	Confirmation of results, explanation, and prescription
	Time required	A few seconds	A few seconds to several tens of seconds	A few minutes

after symptom onset, sensitivity (accuracy and strain-type discrimination), potential applicability to other diseases, and patient quality of life (QOL). Within cost, the categories included material cost, personnel cost, drug price per test, and insurance coverage. Feasibility of remote application was assessed based on home usability and potential integration with treatment pathways. Specifically, for antigen testing, comparisons were made between in-clinic testing and existing out-of-clinic tests, while for imaging-based diagnostics, where no out-of-clinic use currently exists, the feasibility of such an application was explored.

Data corresponding to each comparison item were collected from existing literature and company websites for the selected cases, and were categorized and analyzed according to the items of the two analytical frameworks.

## 2.2 Case selection

To compare conventional influenza antigen testing with emerging alternatives, the following cases were selected (Figure 1).

As the representative case of conventional influenza antigen testing, we selected *QuickNavi-Flu* (Otsuka Pharmaceutical), a product with the largest domestic market share in Japan, notable for its short turnaround time and high visual readability (Otsuka Pharmaceutical Co., Ltd., 2025). For the assessment of remote applicability, comparisons were also made with U.S. home-use antigen test products that serve as specific examples within the Test-to-Treat model (Nachc, 2025).

As the representative emerging product substituting for biological sampling, we selected *nodoca*, an AI-based influenza imaging diagnostic device launched in Japan by Aillis, Inc. in 2022 (Aillis Inc., 2025). Since December 1, 2022, influenza diagnosis using *nodoca* has been covered by national insurance, marking the first case in Japan of reimbursement under the “C2 category” for novel functions and technologies employing AI-based medical devices (Aillis Inc., 2025) (Primes, 2025). *Aillis Inc.* supports influenza diagnosis by integrating patient information with pharyngeal images captured during examination, which are analyzed through deep learning-based pattern recognition algorithms to detect influenza-specific findings and symptoms,

thereby providing diagnostic results indicating the presence or absence of influenza virus infection (Aillis Inc., 2025). However, at present, *nodoca* is used for screening purposes, and diagnoses are not made solely on the basis of the *nodoca* result. Physicians make comprehensive judgments by integrating *nodoca* outputs with clinical symptoms and other examination findings. *Aillis Inc.* is utilized to rapidly identify patients suspected of being positive during the initial screening stage through image-based assessment, enabling AI to flag patients as positive or high risk. Subsequently, only those deemed high risk by *nodoca* undergo confirmatory antigen.

## 3 Results

### 3.1 Comparison based on diagnostic procedures

Following the analytical framework, a comparative assessment was conducted between biological sampling-based diagnostics and imaging-based diagnostics. First, we compared the two approaches with respect to procedure-dependent aspects (Table 1).

- Step 1. Patient Data Acquisition: In biological sampling diagnostics, a physician or nurse collects saliva from the patient's pharynx using a specialized swab (Otsuka Pharmaceutical Co., Ltd., 2025). In imaging-based diagnostics, the physician or nurse similarly uses a dedicated examination camera to capture images of the patient's throat. In both approaches, the involvement of medical personnel is indispensable at this stage, and the procedure requires only a few seconds (Aillis Inc., 2025).
- Step 2. Examination and Determination: At this stage, the workflows of the two methods diverge significantly. In biological sampling diagnostics, the specimen collected by a physician or nurse is mixed with reagents, and an antigen test is performed using a test kit. This process generally requires between 5 and 15 min (Otsuka Pharmaceutical Co., Ltd.,

TABLE 2 Comparison between biological sample-based diagnostics (antigen test) and imaging diagnostics (procedure-independent).

Major category	Item	Biological sample-based diagnostics (antigen test)	Imaging diagnostics
Clinical significance	Applicable age	All age groups	6 years and older (condition: Ability to open mouth sufficiently wide)
	Eligible time window after onset	12–48 h after onset of fever	High detection rate expected even in the very early phase (within 6 h of onset)
	Sensitivity (accuracy, ability to distinguish subtypes)	Detection line appears after a waiting period (10–15 min), indicating presence of viral protein (antigen); sensitivity: 86.7% Capable of distinguishing influenza A and B	AI analyzes pharyngeal images for influenza-specific findings; sensitivity: >80% Can determine influenza infection, but cannot distinguish between influenza A and B
	Expandability to other diseases	Limited (some multiplex kits available, e.g., influenza and COVID-19 combined tests)	High (currently limited to influenza, but expected future applications include COVID-19, other respiratory infections, dermatological and other anatomical sites)
	Patient (QOL, incl. Waiting time)	May cause pain or discomfort; requires waiting time between sample collection and result	No pain or discomfort; minimal waiting time between image capture and result
Cost	Material cost	Cost of diagnostic kit	Device acquisition, disposable camera covers, system usage fees
	Personnel cost	Significant time and effort for specimen collection, result confirmation, explanation, and prescription	Minimal effort for image capture; allows more time for consultation and explanation
	Reimbursement per test	301 points (~¥903, with 30% patient copayment) (including test fee, interpretation fee, and collection fee)	305 points (~¥915, with 30% patient copayment) (including test fee, interpretation fee, and collection fee)
	Insurance coverage	Covered	Covered
Requirements for remote transition	Home use	Accessibility and availability Usability enabling non-experts to perform tests	Accessibility and availability Usability enabling non-experts to perform tests Accuracy equivalent to biological sample diagnostics Clear interpretability of results
	Integration with treatment	One-stop model (testing, consultation, prescription, dispensing/delivery) as the design premise Already incorporated into clinical guidelines in the U.S. Feasibility varies by national regulation	One-stop model (testing, consultation, prescription, dispensing/delivery) as the design premise Incorporation into clinical guidelines required Digital device availability and stable connectivity Integration with healthcare system and immediate treatment linkage

2025). In contrast, in imaging-based diagnostics, the acquired images are analyzed and interpreted by a pre-trained deep learning-based AI system. Physicians or nurses are not directly involved in this step, and AI analysis is completed within a few to several tens of seconds, detecting pharyngeal features and symptoms characteristic of influenza infection. Consequently, patients can complete the entire diagnostic process within the consultation room, without returning to the waiting area, resulting in a marked reduction in time compared with biological sampling diagnostics (Aillis Inc., 2025).

Step 3. Notification of Test Results: The final step, result notification, follows a similar process for both approaches. The test result is communicated to the patient by a physician or nurse. Simultaneously, prescriptions are issued as required, and the entire process takes several minutes in either case (Otsuka Pharmaceutical Co., Ltd., 2025; Aillis Inc., 2025). At present, irrespective of AI involvement, the ultimate responsibility for decision-making and explanation to the patient rests with healthcare professionals.

## 3.2 Comparison independent of diagnostic procedures

Subsequently, we compared biological sampling-based and imaging-based diagnostics according to procedure-independent items (Table 2).

### 3.2.1 Applicable age range

Biological sampling diagnostics are applicable across all age groups. In contrast, imaging-based diagnostics are restricted to patients aged 6 years and older, reflecting the exclusion of younger children from clinical trials due to the difficulty of maintaining an open and stable oral posture (Aillis Inc., 2025).

### 3.2.2 Permissible testing window and time to result

Biological sampling diagnostics can be performed 12–48 h after symptom onset, with results available in approximately 10–15 min (Otsuka Pharmaceutical Co., Ltd., 2025). In contrast, imaging-based diagnostics demonstrate a high detection rate even within 12 h after onset—a timeframe traditionally considered too early for reliable testing and prone to false negatives—with results available within seconds (Aillis Inc., 2025)]. Following influenza infection, distinct pharyngeal changes known as “influenza follicles” appear at an early

stage. Although these changes are not readily discernible to the human eye, *nodoca's* deep learning-based AI is capable of identifying them from accumulated datasets (Aillis Inc., 2025).

### 3.2.3 Sensitivity, accuracy, and strain differentiation

Biological sampling diagnostics, which directly detect viral proteins (antigens), are highly reliable and capable of distinguishing between influenza A and B strains (Otsuka Pharmaceutical Co., Ltd., 2025). By contrast, the accuracy of imaging-based diagnostics, based on AI analysis of influenza-specific features, exceeds 80%, but strain differentiation remains infeasible, representing a limitation (Aillis Inc., 2025)].

### 3.2.4 Potential for application to other diseases

Biological sampling diagnostics are available in kit formats capable of detecting multiple pathogens, including influenza and SARS-CoV-2. At present, imaging-based diagnostics are restricted to influenza. However, future extensions are anticipated, with AI-based image diagnostics expected to be applied to COVID-19 and other respiratory infections (Yoo et al., 2020), as well as dermatological diseases (Behara et al., 2024), thereby holding promise as a novel diagnostic platform.

### 3.2.5 Patient burden (quality of life, including waiting time)

Antigen testing involving biological sampling may cause pain or discomfort during specimen collection, particularly for pediatric patients (Aillis Inc., 2025). In contrast, *nodoca* achieves diagnosis without physical discomfort. Moreover, while biological sampling requires waiting time for test completion, *nodoca* delivers results within a few to several tens of seconds, enabling diagnosis at times previously unsuitable due to clinic hours, test turnaround, or waiting constraints. These features—painlessness, rapid results, and non-invasiveness—not only reduce burden but also potentially mitigate the spread of infectious diseases in clinical settings. Indeed, 90.6% of participants in clinical trials reported a preference for undergoing *nodoca* testing in the future (Aillis Inc., 2025)].

### 3.2.6 Cost (material and system)

The reimbursement fee per test under the national insurance scheme is comparable between the two approaches (Aillis Inc., 2025)]. However, while the main cost driver in biological sampling diagnostics is the test kit itself, *nodoca* requires device installation and system usage fees as operational costs.

### 3.2.7 Role and burden of healthcare professionals (human costs)

Biological sampling diagnostics require a series of time-consuming tasks, from specimen collection to testing and consultation (Otsuka Pharmaceutical Co., Ltd., 2025). By contrast, imaging-based diagnostics allow for rapid image acquisition and automated analysis, streamlining the consultation process. Furthermore, image capture can be delegated to nurses under physician supervision, suggesting the potential for more efficient task distribution and increased patient throughput for physicians (Aillis Inc., 2025).

### 3.2.8 Drug price per test (patient's out-of-pocket burden under 30% co-payment)

The drug price per test is approximately 903 yen for biological sampling diagnostics and 915 yen for imaging-based diagnostics, showing minimal difference (Aillis Inc., 2025).

### 3.2.9 Insurance coverage

Both biological sampling diagnostics and imaging-based diagnostics are covered by insurance reimbursement in Japan (Otsuka Pharmaceutical Co., Ltd., 2025) (Aillis Inc., 2025).

### 3.2.10 Home-based utilization

For out-of-clinic antigen testing, eligibility for home-based application has been conditioned upon the ability to readily obtain test kits through pharmacies or online platforms, as well as the feasibility of performing the test without professional medical training (NIH, 2025b; CDC, 2025a). By contrast, imaging-based diagnostics, while subject to the same prerequisites as out-of-clinic antigen testing in terms of home accessibility (NIH, 2025b), additionally require diagnostic accuracy equivalent to that of biological sample-based methods (Aillis Inc., 2025), user-friendly digital interfaces (NIH, 2025b), and applicability to individuals aged 6 years or older (Aillis Inc., 2025). Under these conditions, the potential for remote, home-based implementation of imaging diagnostics can be realized.

### 3.2.11 Integration with treatment

In the case of out-of-clinic antigen testing, healthcare provision is designed as a one-stop service—linking home testing, remote consultation, online prescription, and medication dispensing/delivery (NIH, 2025b). However, regulatory discrepancies create divergence: such integration is feasible in the United States but not currently in Japan (NIH, 2025b; Aillis Inc., 2025; CDC, 2025a). Even within the U.S., where out-of-clinic antigen testing is permitted, medical service provision remains predicated upon this one-stop design (NIH, 2025b). For the introduction of home-based remote imaging diagnostics, incorporation into clinical practice guidelines is a necessary prerequisite, yet such inclusion has not been achieved to date (Aillis Inc., 2025). Moreover, successful integration into existing telemedicine systems requires the establishment of robust infrastructures that enable rapid and reliable transmission of diagnostic results to healthcare providers, thereby ensuring timely clinical decision-making and coordinated care (CDC, 2025b).

## 4 Discussion

### 4.1 Findings

This study not only compared antigen testing, as a representative example of conventional biological sample-based diagnostics, with AI-driven imaging diagnostics capable of substituting biological sample-based methods across common evaluation domains, but also proposed a framework for assessing the feasibility of transition toward remote diagnostics from the perspective of integration into the healthcare service value chain. By employing this approach, it

was possible to evaluate both the healthcare services achievable within in-clinic testing and the potential for their migration toward remote diagnostics.

From the product-level comparison, the advantages and disadvantages of each modality were elucidated. The antigen test is already widely disseminated, implementable in many healthcare institutions, highly reliable, and capable of differentiating between influenza A and B. However, antigen testing also presents limitations. First, from the standpoint of quality of life (QOL), sample collection is invasive and often associated with discomfort or pain, particularly in pediatric populations. Second, regarding temporal constraints, false negatives may occur in the early stages of infection, when viral load is still low, thereby necessitating appropriate timing of testing.

By contrast, the most salient advantage of AI-based imaging diagnostics lies in the reduction of patient burden. Unlike antigen testing, no swab-based sampling is required; the examination is completed simply by photographing the throat, thereby eliminating pain or discomfort. This attribute is particularly advantageous for children reluctant to undergo invasive testing and for patients with nasal conditions that complicate swab collection. Furthermore, AI analysis captures pharyngeal findings that emerge in the early phase of influenza infection, enabling high detection accuracy even in the initial stages of onset, thereby mitigating the temporal limitations inherent to antigen testing. The disadvantages of AI-based imaging diagnostics include, first, one disadvantage of AI-based image diagnosis is that, given present accuracy levels, AI image analysis functions only as a screening tool. Patients who screen positive still require additional antigen testing. Thus, while remote screening can be offered in the home, the current system does not reduce the need for antigen testing and offers only limited incremental benefit. Second, applicability to children under 6 years of age due to the absence of clinical trial validation and the practical difficulty of obtaining sufficient cooperation. Third, the inability of AI to differentiate between influenza A and B, as its judgment is based solely on throat findings.

With respect to applicability to remote healthcare, antigen testing has already been implemented in the United States. Comparative analysis with this precedent clarified the conditions under which novel diagnostic technologies may be deployed remotely. While direct transition to remote use remains challenging due to the need for in-clinic sample collection and treatment, at-home antigen testing has become feasible through self-collection kits, enabled by easy accessibility, affordability, and usability by non-experts. Imaging diagnostics, by analogy, may also be transitioned to remote care provided that certain conditions are fulfilled. These conditions include (Zundel, 1996): the device is readily obtainable for household use, including affordability and distribution channels, as is the case for at-home antigen tests (Kaiharu, 1998); diagnostic accuracy is equivalent to that of antigen testing (Takashi, 2010); the procedure is simple, does not require complex equipment, and produces results that are unambiguous and interpretable even by non-experts; and (Tofukuji, 2011) a reliable system is established to ensure that diagnostic results are rapidly and securely shared with healthcare professionals, thereby enabling timely prescription of antiviral agents when positive results are detected.

## 4.2 Implications

The implications identified from the comparative analysis of technical and clinical challenges are outlined below.

### 4.2.1 Challenges as BADI products

The most critical challenge for BADI products lies in establishing robust scientific evidence to demonstrate diagnostic accuracy equivalent to that of biological sample-based methods. This requires the continuous implementation of large-scale comparative studies against existing antigen and PCR testing. Moreover, subgroup analyses across clinical segments—such as early-versus late-phase disease onset and different age groups—are necessary to delineate diagnostic limitations under specific conditions. Because test sensitivity varies depending on the time elapsed since symptom onset, further refinement is needed to maintain consistently high sensitivity across both early and late stages. Current research has reported concordance rates of only approximately 75% with antigen testing, indicating a pressing need for algorithmic enhancement and expansion of training datasets (Okuyama et al., 2022). Aillis Inc. is designed solely for rapid testing at the screening stage and is not intended to replace confirmatory diagnostic procedures. Therefore, if incorporated into remote diagnosis under current conditions, its role would be limited to providing a screening function. Patients who screen positive would still require antigen testing for definitive diagnosis, positioning nodoca as a complementary tool rather than a substitute. Conversely, if the complete replacement of antigen testing is to be pursued in the future, substantial improvements in accuracy will be indispensable. Potential enhancements include optimizing the quality of captured images, integrating multiview or multimodal inputs, and strengthening disease-specific data training.

In addition, BADI products must address AI-specific challenges. Ensuring the generalizability and robustness of AI models necessitates training on datasets encompassing a wide range of patient attributes. Variability in pharyngeal findings may arise from age (pediatric vs. elderly populations), comorbidities, or vaccination history, underscoring the need for inclusive clinical data that reflect these diverse factors. Clinical reliability of AI systems also depends on transparency regarding diagnostic reasoning. Strengthening visualization features and explanatory mechanisms—such as highlighting the anatomical regions or features flagged as abnormal—can provide physicians with interpretable feedback, thereby enhancing both clinical decision support and system-wide trust.

Currently, BADI devices cannot perform influenza strain typing; enabling such functionality would enhance their utility. To maximize clinical value, diagnostic functions should expand toward multiplex screening of multiple respiratory pathogens, including COVID-19. Improving device portability and usability, such as miniaturization of cameras for children under 6 years of age, would further increase clinical applicability.

### 4.2.2 Action plan for remote implementation

To enable the remote implementation of AI-based imaging diagnostics, assuming diagnostic accuracy comparable to antigen testing, three conditions must be addressed:

First, to facilitate adoption in home settings, regulatory approval should be swiftly followed by engagement with regulators regarding

OTC availability. Device and service pricing must remain affordable to minimize economic barriers. Distribution channels should be diversified to include community pharmacies, drugstores, and online medical platforms, ensuring broad accessibility. To reduce user costs, subscription-based models that combine device rental with AI analysis fees, as well as inclusion in public reimbursement schemes, should be considered. Furthermore, pilot programs in collaboration with medical associations and municipalities could establish operational models for deployment in elderly households and underserved rural regions.

Second, ease of use is essential to ensure reliable operation by lay users without medical expertise. Device design should avoid complex procedures and enable intuitive operation. Implementation of auxiliary features—such as voice guidance, auto-focus, and framing guides—can help ensure accurate image capture. Result displays must employ a simple, standardized UI (e.g., “positive/negative/indeterminate”) to eliminate interpretive ambiguity. Integration of QR-code or one-click result submission features can streamline healthcare coordination. Brief video tutorials may also accelerate user adoption and ensure correct operation.

Third, a reliable system for the rapid and secure transmission of diagnostic results to healthcare providers is indispensable. Interfaces should allow automated integration of results into electronic health records and telemedicine applications. Following a positive result, seamless linkage to online consultations must be ensured, including in-app video calls, electronic prescription transmission, and delivery or pharmacy pickup of antiviral medications. Such integration is vital to uphold care quality and continuity. System design must adhere to international standards such as HL7 FHIR and ISO/IEC 27001 to ensure interoperability, data security, and privacy protection. For large-scale implementation, alignment with national healthcare systems is indispensable. This includes formal integration into public insurance schemes as well as incorporation into clinical guidelines and diagnostic criteria.

#### 4.2.3 Potentialities and conditions for remote application of BADI devices

From a technical perspective, BADI devices may be broadly defined as “diagnostic devices that replace biological sampling through imaging of external or superficially accessible sites such as the throat, oral cavity, tongue, or iris.” Such devices expand diagnostic capabilities outside traditional clinical settings, thereby positioning associated medical interventions as future targets for telemedicine.

In anticipation of remote clinical trials, the U.S. FDA has highlighted *patient-performed digital photography* in dermatology as a relevant evaluative technology (FDA, 2025b). Advances in this technological category are expected to contribute significantly to the future of BADI devices. For remote implementation, however, four essential conditions must be consistently fulfilled: Availability and Accessibility, Diagnostic Accuracy Assurance, Usability and Interpretive Clarity, and Medical Integration with Immediate Treatment Linkage.

### 4.3 Limitation and future research

This study, based on a limited number of cases, entails several constraints regarding its validity.

First, the comparison was conducted within the context of the Japanese healthcare system, where the correspondence among products, services, and technologies may differ across countries. As a Japan-specific consideration, the universal health insurance system serves as a foundational premise for cost-related evaluations. In order to extend current in-clinic diagnostic devices into reimbursable home-based testing devices or over-the-counter (OTC) diagnostic tools, society must determine whether such tests should be covered by insurance even when conducted at home, or whether they should remain outside the insurance scheme as OTC devices—requiring out-of-pocket payment for the device and resulting in a form of mixed medical practice. Accordingly, the positioning of BADI could vary depending on national regulatory and healthcare frameworks. Second, the representative cases were restricted to Japan. Comparative analyses covering the United States and the United Kingdom have already been conducted (Teleradiology, 2025) (European Society of Radiology ESR communications@ myESR. org, 2014), leaving room for incorporating overseas products into the present framework. In identifying the conditions under which imaging-based diagnosis can transition to remote diagnosis, this study presents universal criteria. Nonetheless, because healthcare systems differ across countries—including the scope within which telemedicine is permitted, the range of services reimbursed under insurance schemes, and the policy-driven structure of costs from diagnosis to treatment—the specific conditions required for implementation will necessarily vary. Finally, with respect to imaging diagnostics, the present study generalizes from a single nascent case of BADI. The aim of this study is to present an analytical framework for evaluating the use of BADI in telemedicine, and the case study of *nodoca* was conducted as a pilot to assess the validity of this framework. Although the case study demonstrates a certain degree of validity, the generalizability and robustness of the analytical framework proposed in this study must be further examined through additional comparative studies and the accumulation of case analysis.

Future studies should expand the number of cases analyzed, enabling more granular comparisons across product generations, variations in embedded technologies, and differentiation among providers. Future research should therefore incorporate cross-national comparisons, as well as extend analysis to related technologies beyond AI. Furthermore, as telemedicine increasingly adopts alternatives to biological sampling, new devices are expected to emerge that apply to diseases other than influenza. For example, pharyngitis and streptococcal infections (throat images + AI-based assessment), otitis media (tympanic membrane images + AI), and dermatological infections (skin images + AI) may be considered. Demonstrating the effectiveness of evaluating the feasibility of integrating image-based assessment with AI into telemedicine for each of these conditions is expected to further strengthen the robustness of the proposed framework.

## 5 Conclusion

This study examined a case in which AI-driven diagnostic technology enabled the replacement of biological sampling in influenza care. By profiling its characteristics in comparison with existing sample-based diagnostics, the study identified both

opportunities and challenges associated with such technologies. In addition, the analysis highlighted the potential of biological sampling–substituting diagnostics to expand the scope of telemedicine, together with the conditions necessary for their successful implementation.

## Data availability statement

The original contributions presented in the study are included in the article/supplementary material, further inquiries can be directed to the corresponding author.

## Author contributions

MN: Writing – original draft, Writing – review and editing, Investigation, Methodology, Project administration, Visualization. SK: Writing – review and editing, Methodology, Conceptualization, Supervision, Validation.

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## Conflict of interest

The author(s) declared that this work was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

## Generative AI statement

The author(s) declared that generative AI was used in the creation of this manuscript. The use of generative AI technologies in the preparation of this manuscript. Gemini 3 (Google) and ChatGPT-5 (OpenAI) were utilized for language polishing, structural refinement, and translation assistance. The final content was reviewed and edited by the authors, who take full responsibility for the integrity of the work.

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